UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

X QUARTERLY REPORT PURSI	UANT TO SECTION	N 13 OR 15(d) OF THE SECUR	ITIES EXCHANGE ACT OF 1934	
	For t	he quarterly period ended March 31, 20)22	
		OR		
TRANSITION REPORT PURSI	UANT TO SECTION	N 13 OR 15(d) OF THE SECUR	ITIES EXCHANGE ACT OF 1934	
	FOR THE	TRANSITION PERIOD FROM	ТО	
	1	Commission File Number 001-37880		
		Noven Inc		
	(Evant w	Novan, Inc. ame of registrant as specified in its cha	outoul	
	(Exact II	ame of registrant as specified in its cha	arter)	
	Delaware		20-4427682	
(State or other jurisdiction of (I.R.S. Employer				
•	ation or organization)		Identification No.)	
	Creek Drive, Suite 110			
	rham, North Carolina orincipal executive offices)		27703 (Zip Code)	
(Address of p	inicipal executive offices)	(919) 485-8080	(Zip Code)	
	(Reg	istrant's telephone number, including area coo	de)	
Securities registered pursuant to Section 12(b)) of the Act:			
Title of E	ach Class	Trading Symbol(s)	Name of Each Exchange on Which Regis	tered
Common Stock, S		NOVN	The Nasdaq Stock Market LLC	
			d) of the Securities Exchange Act of 1934 during ct to such filing requirements for the past 90 da	
Indicate by check mark whether the registrant this chapter) during the preceding 12 months			to be submitted pursuant to Rule 405 of Regular such files). Yes X No \square	ntion S-T (§232.405 of
			filer, a smaller reporting company or an emergin growth company" in Rule 12b-2 of the Exchang	
Large accelerated filer			Accelerated filer	
Non-accelerated filer	X		Smaller reporting company	X
			Emerging growth company	
If an emerging growth company, indicate by caccounting standards provided pursuant to So			unsition period for complying with any new or r	evised financial

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

As of May 9, 2022, there were 19,172,585 shares of the registrant's Common Stock outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements

NOVAN, INC. Condensed Consolidated Balance Sheets (unaudited) (in thous ands, except share and per share amounts)

	March 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 35,492	\$ 47,085
Accounts receivable, net	16,013	4,473
Inventory, net	1,478	<u> </u>
Prepaid expenses and other current assets	5,699	2,572
Total current assets	58,682	54,130
Restricted cash	583	583
Property and equipment, net	13,441	12,201
Intangible assets, net	32,954	. 75
Other assets	295	278
Right-of-use lease assets	2,092	1,693
Goodwill	4,002	-
Total assets	\$ 112,049	\$ 68,960
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 4,753	\$ 2,170
Accrued expenses	34,619	4,988
Deferred revenue, current portion	5,823	2,586
Research and development service obligation liability, current portion	1,109	1,406
Contingent consideration liability, current portion	443	<u> </u>
Operating lease liabilities, current portion	228	_
Total current liabilities	46,975	11,150
Deferred revenue, net of current portion	10,019	10,665
Operating lease liabilities, net of current portion	3,904	3,613
Notes payable	16,500	_
Research and development service obligation liability, net of current portion	142	142
Research and development funding arrangement liability	25,000	25,000
Contingent consideration liability, net of current portion	3,330	_
Other long-term liabilities	297	71
Total liabilities	106,167	50,641
Commitments and contingencies (Note 10)		
Stockholders' equity		
Common stock \$0,0001 par value; 200,000,000 shares authorized as of March 31, 2022 and December 31, 2021; 18,981,072 and 18,816,842 shares issued as of March 31, 2022 and December 31, 2021, respectively; 18,980,122 and 18,815,892 shares outstanding as of March 31, 2022 and December 31, 2021, respectively	:	2
Additional paid-in capital	298,384	
Treasury stock at cost, 950 shares as of March 31, 2022 and December 31, 2021	(155	
Accumulated deficit	(292,349	
Total stockholders' equity	5,882	
Total liabilities and stockholders' equity	\$ 112,049	
- com monoton and stockmonths separate		

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

NOVAN, INC. Condensed Consolidated Statements of Operations and Comprehensive Loss (unaudited) (in thousands, except share and per share amounts)

	Three Months Ended March 31,			
		2022		2021
Net product revenues	\$	718	\$	_
License and collaboration revenues		1,174		747
Government research contracts and grants revenue		36		72
Total revenue	' <u></u>	1,928		819
Operating expenses:				
Product cost of goods sold		206		_
Research and development		4,833		6,418
Selling, general and administrative		9,994		2,686
Amortization of intangible assets		121		_
Total operating expenses		15,154		9,104
Operating loss		(13,226)		(8,285)
Other income (expense), net:				
Interest income		3		3
Interest expense		(132)		_
Other expense		(25)		(670)
Total other expense, net		(154)		(667)
Net loss and comprehensive loss	\$	(13,380)	\$	(8,952)
Net loss per share, basic and diluted	\$	(0.71)	\$	(0.60)
Weighted-average common shares outstanding, basic and diluted		18,829,534		15,002,886

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

NOVAN, INC. Condensed Consolidated Statements of Stockholders' Equity (unaudited) (in thousands, except share amounts)

Three Months Ended March 31, 2022

	Commo	n St	ock	Additional Paid-In	Treasury	Accumulated	
	Shares		Amount	Capital	Stock	Deficit	Total
Balance as of December 31, 2021	18,815,892	\$	2	\$ 297,441	\$ (155)	\$ (278,969)	\$ 18,319
Stock-based compensation	_		_	381	_	_	381
Common stock issued pursuant to equity distribution agreement (at-the-market facility)	164,230		_	562	_	_	562
Net loss	_		_	_	_	(13,380)	(13,380)
Balance as of March 31, 2022	18,980,122	\$	2	\$ 298,384	\$ (155)	\$ (292,349)	\$ 5,882

Three Months Ended March 31, 2021

	Commo	n St	ock	_	Additional Paid-In	Treasury	Accumulated	
	Shares		Amount		Capital	Stock	Deficit	Total
Balance as of December 31, 2020	14,570,009	\$	1	\$	252,408	\$ (155)	\$ (249,277)	\$ 2,977
Stock-based compensation	_		_		36	_	_	36
Exercise of common stock warrants	99,651		_		442	_	_	442
Exercise of stock options	2,492		_		13	_	_	13
Common stock issued pursuant to common stock purchase agreements	493,163		1		6,333	_	_	6,334
Net loss	_		_		_	_	(8,952)	(8,952)
Balance as of March 31, 2021	15,165,315	\$	2	\$	259,232	\$ (155)	\$ (258,229)	\$ 850

 $\label{thm:companying} \textit{The accompanying notes are an integral part of these condensed consolidated financial statements}$

NOVAN, INC. Condensed Consolidated Statements of Cash Flows (unaudited) (in thousands)

	Three Months	Ended March 31,
	2022	2021
Cash flow from operating activities:		
Net loss	\$ (13,380)	\$ (8,952)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of property and equipment	97	57
Amortization of intangible assets	121	_
Stock-based compensation	381	80
Foreign currency transaction loss	_	669
Changes in operating assets and liabilities:		
Accounts receivable	8,543	(43)
Inventory	232	_
Prepaid expenses and other current assets	565	948
Accounts payable	1,604	(226)
Accrued expenses	393	(431)
Deferred revenue	2,591	(747)
Research and development service obligation liabilities	(297)	(18)
Other long-term assets and liabilities	(84)	62
Net cash provided by (used in) operating activities	766	(8,601)
Cash flow from investing activities:		
Purchases of property and equipment	(928)	(934)
Payment for EPI Health Acquisition	(11,993)	_
Net cash used in investing activities	(12,921)	(934)
Cash flow from financing activities:		
Proceeds from exercise of common stock warrants	_	442
Proceeds from issuance of common stock under common stock purchase agreement	_	6,334
Proceeds from common stock issued pursuant to equity distribution agreement (at-the-market facility)	562	_
Proceeds from exercise of stock options	_	13
Net cash provided by financing activities	562	6,789
Net decrease in cash, cash equivalents and restricted cash	(11,593)	(2,746)
Cash, cash equivalents and restricted cash as of beginning of period	47,668	35,879
Cash, cash equivalents and restricted cash as of end of period	\$ 36,075	\$ 33,133
· •	- 20,072	ψ υυ,1υυ
Supplemental disclosure for cash flow information:		
Interest paid	\$ 45	\$ —
Supplemental disclosure of non-cash investing and financing activities:		
Purchases of property and equipment with accounts payable and accrued expenses	\$ 1,780	\$ 592
Contingent consideration related to EPI Health Acquisition	3,773	_
Note payable issued for EPI Health Acquisition	16,500	_
Reconciliation to condensed consolidated balance sheets:		
	ø 25.402	0 22.661
Cash and cash equivalents	\$ 35,492	\$ 32,661
Restricted cash included in noncurrent assets	583	472
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	\$ 36,075	\$ 33,133

 ${\it The accompanying notes are an integral part of these condensed consolidated financial statements}$

NOVAN, INC. NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (unaudited)

(dollar values in thousands, except per share data)

Note 1: Organization and Significant Accounting Policies

Business Description

Novan, Inc. ("Novan" and together with its subsidiaries, the "Company") is a medical dermatology company focused primarily on researching, developing and commercializing innovative therapeutic products for skin diseases. Its goal is to deliver safe and efficacious therapies to patients, including developing product candidates where there are unmet medical needs. The Company is developing SB206 (berdazimer gel, 10.3%) as a topical prescription gel for the treatment of viral skin infections, with a current focus on molluscum contagiosum. On March 11, 2022, the Company acquired EPI Health, LLC, a specialty pharmaceutical company focused on medical dermatology ("EPI Health"), from Evening Post Group, LLC, a South Carolina limited liability company ("EPG" or the "Seller"). The acquisition of EPI Health (the "EPI Health Acquisition") has provided the Company with a commercial infrastructure to sell a marketed portfolio of therapeutic products for skin diseases. Subsequent to the acquisition, the Company sells various medical dermatology products for the treatments of plaque psoriasis, rosacea, acne and dermatoses.

Novan was incorporated in January 2006 under the state laws of Delaware. In 2015, Novan Therapeutics, LLC, was organized as a wholly owned subsidiary under the state laws of North Carolina; in March 2019, the Company completed registration of a wholly owned Ireland-based subsidiary, Novan Therapeutics, Limited; and in March 2022, the Company acquired its wholly owned subsidiary, EPI Health, a South Carolina limited liability company.

See Note 2—"Acquisition of EPI Health" for further information regarding the EPI Health Acquisition. The post-acquisition operating results of EPI Health are reflected within the Company's condensed consolidated statement of operations and comprehensive loss for the three months ended March 31, 2022, specifically from March 11, 2022 through March 31, 2022.

Basis of Presentation

The accompanying condensed consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The December 31, 2021 year-end condensed consolidated balance sheet data was derived from audited financial statements but does not include all disclosures required by U.S. GAAP for annual financial statements. Additionally, the Company's independent registered public accounting firm's report on the December 31, 2021 financial statements included an explanatory paragraph indicating that there is substantial doubt about the Company's ability to continue as a going concern.

Basis of Consolidation

The accompanying condensed consolidated financial statements reflect the operations of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

Reverse Stock Split

On May 25, 2021, the Company amended its restated certificate of incorporation effecting a 1-for-10 reverse stock split of its outstanding shares of capital stock (the "Reverse Stock Split"). The Reverse Stock Split did not change the number of authorized shares of capital stock of the Company or cause an adjustment to the par value of the Company's capital stock. As a result of the Reverse Stock Split, the Company adjusted (i) the per share exercise price and the number of shares issuable upon the exercise of all outstanding stock options, warrants to purchase shares of common stock and stock appreciation rights, (ii) the share price targets of the Company's Tangible Stockholder Return Plan and (iii) the number of shares reserved for issuance pursuant to the Company's equity incentive compensation plans. No fractional shares were issued in connection with the Reverse Stock Split. Stockholders who would have otherwise held a fractional share of capital stock received a cash payment for any fractional share resulting from the Reverse Stock Split in an amount equal to such fraction multiplied by the closing sales price of the common stock as reported on the Nasdaq Stock Market on May 25, 2021, the last trading day immediately prior to the effectiveness of the Reverse Stock Split. See Note 11—"Stockholders' Equity" for further information regarding the Reverse Stock Split.

All disclosures of shares and per share data in the condensed consolidated financial statements and related notes have been retroactively adjusted to reflect the Reverse Stock Split for all periods presented, and certain amounts within the condensed consolidated balance sheets and condensed consolidated statements of stockholders' equity were reclassified between common stock and additional paid-in capital.

Liquidity and Ability to Continue as a Going Concern

The Company's condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The accompanying condensed consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from uncertainty related to the Company's ability to continue as a going concern.

The Company has evaluated principal conditions and events, in the aggregate, that may raise substantial doubt about its ability to continue as a going concern within one year from the date that these financial statements are issued. The Company identified the following conditions:

- The Company has reported a net loss in all fiscal periods since inception and, as of March 31, 2022, the Company had an accumulated deficit of \$292,349.
- As of March 31, 2022, the Company had a total cash and cash equivalents balance of \$35,492.
- The Company anticipates that it will continue to generate losses for the foreseeable future, and it expects the losses to increase as it continues the development of, and seeks regulatory approvals for, its product candidates and begins activities to prepare for potential commercialization of SB206, if approved.
- The Company has concluded that the prevailing conditions and ongoing liquidity risks faced by the Company, coupled with its current forecasts, including costs associated with implementing the SB206 prelaunch strategy and commercial preparation, raise substantial doubt about its ability to continue as a going concern.

This evaluation is also based on other relevant conditions that are known or reasonably knowable at the date that the financial statements are issued, including ongoing liquidity risks faced by the Company, the Company's conditional and unconditional obligations due or anticipated within one year, the funds necessary to maintain the Company's operations considering its current financial condition, obligations, and other expected cash flows, and other conditions and events that, when considered in conjunction with the above, may adversely affect the Company's ability to meet its obligations. The Company will continue to evaluate this going concern assessment in connection with the preparation of its quarterly and annual financial statements based upon relevant facts and circumstances, including, but not limited to, its cash and cash equivalents balance and its operating forecast and related cash projection.

Based on the Company's operating forecast, it believes that its existing cash and cash equivalents balance as of March 31, 2022, plus expected receipts associated with product sales from its commercial product portfolio, will provide it with adequate liquidity to fund its planned operating needs into the early fourth quarter of 2022, but not through the targeted submission of the SB206 new drug application ("NDA"), planned no later than the fourth quarter of 2022. This operating forecast and related cash projection includes (i) costs associated with preparing for and seeking U.S. regulatory approval of SB206 as a treatment for molluscum, including costs to prepare for pre-NDA meetings with the Food and Drug Administration (the "FDA") and NDA-enabling drug stability studies for SB206, (ii) costs associated with the readiness of its new corporate headquarters and manufacturing capability necessary to support small-scale drug substance and drug product manufacturing, (iii) conducting drug manufacturing activities with external third-party contract manufacturing organizations ("CMOs"), (iv) ongoing commercial operations, including sales, marketing, inventory procurement and distribution, and supportive activities, related to its portfolio of therapeutic products for skin diseases acquired with the EPI Health transaction, and (v) initial efforts to support potential commercialization of SB206, but excludes (a) progression of the SB019 program subsequent to the pre-investigational new drug submission, including the execution of a Phase 1 study, (b) any potential costs associated with other late-stage clinical programs, including executing the potentially registrational Phase 3 study of SB204 for acne, and (c) additional operating costs that could occur between a potential NDA submission for SB206 through NDA approval, including, but not limited to, marketing and commercialization efforts to achieve potential launch of SB206. The Company may decide to revise its development, commercial and operating plans or the related timing, depending on information it learns through its research and development activities, including regulatory submission efforts related to SB206, commercialization strategies, ongoing commercial operations, the impact of outside factors such as the COVID-19 pandemic, the Company's ability to enter into strategic arrangements or other transactions, its ability to access additional capital and its financial priorities. The Company does not currently have sufficient funds to complete commercialization of any of its product candidates that are under development, and its funding needs will largely be determined by its commercialization strategy for SB206, subject to the NDA submission timing and the regulatory approval process and outcome, and the operating performance of its commercial product portfolio.

The inability of the Company to obtain significant additional funding on acceptable terms, could have a material adverse effect on the Company's business and cause the Company to alter or reduce its planned operating activities, including, but not limited to, delaying, reducing, terminating or eliminating planned product candidate development activities, to conserve its cash and

cash equivalents. The Company may pursue additional capital through equity or debt financings or from non-dilutive sources, including partnerships, collaborations, licensing, grants or other strategic relationships. The Company's anticipated expenditure levels may change if it adjusts its current operating plan. Such actions could delay development timelines and have a material adverse effect on its business, results of operations, financial condition and market valuation.

The Company may also explore the potential for additional strategic transactions, such as strategic acquisitions or in-licenses, sales or divestitures of some of its assets, or other potential strategic transactions, which could include a sale of the Company. If the Company were to pursue such a transaction, it may not be able to complete the transaction on a timely basis or at all or on terms that are favorable to the Company. Alternatively, if the Company is unable to obtain significant additional funding on acceptable terms or progress with a strategic transaction, it could instead determine to dissolve and liquidate its assets or seek protection under the bankruptcy laws. If the Company decides to dissolve and liquidate its assets or to seek protection under the bankruptcy laws, it is unclear to what extent the Company would be able to pay its obligations, and, accordingly, it is further unclear whether and to what extent any resources would be available for distributions to stockholders.

Business Acquisitions

The Company accounts for business acquisitions using the acquisition method of accounting in accordance with Accounting Standards Codification ("ASC") 805, Business Combinations. ASC 805 requires, among other things, that assets acquired and liabilities assumed be recognized at their fair values, as determined in accordance with ASC 820, Fair Value Measurements, as of the acquisition date. For certain assets and liabilities, book value approximates fair value. In addition, ASC 805 establishes that consideration transferred be measured at the closing date of the acquisition at the then-current market price. Under ASC 805, acquisition-related costs (i.e., advisory, legal, valuation and other professional fees) are expensed in the period in which the costs are incurred. The application of the acquisition method of accounting requires the Company to make estimates and assumptions related to the estimated fair values of net assets acquired.

COVID-19

In December 2019, the novel strain of a virus named SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), which causes novel coronavirus disease ("COVID-19") was reported in China, and in March 2020, the World Health Organization declared it a pandemic. The extent to which COVID-19, and its variant strains, and domestic and global efforts to contain its spread will impact the Company's business including its operations, preclinical studies, clinical trials, and financial condition will depend on future developments, which are highly uncertain and cannot be predicted at this time, and include the duration, severity and scope of the pandemic, the availability and effectiveness of vaccines in preventing the spread of COVID-19 (and its variants), and the actions taken by other parties, such as governmental authorities, to contain and treat COVID-19 and its variants.

During the pandemic, the timetable for development of the Company's product candidates has been impacted and may face further disruption and the Company's business could be further adversely affected by the outbreak of COVID-19 and its variants. In particular, COVID-19 impacted the timing of trial initiation of the Company's B-SIMPLE4 Phase 3 study and is a factor influencing the Company's adjustment of its targeted SB206 submission timing, planned no later than the fourth quarter of 2022.

In addition, certain factors from the COVID-19 pandemic may delay or otherwise adversely affect the Company's generation of product revenues from its portfolio of therapeutic products for skin diseases, as well as adversely impact the Company's business generally, including (i) changes in buying patterns caused by lack of normal access by patients to the healthcare system and concern about the supply of medications, (ii) adverse impacts on the Company's manufacturing operations, supply chain and distribution processes, which may impact its ability to procure, produce and distribute its products or product candidates, (iii) the inability of third parties to fulfill their obligations to the Company due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems, (iv) the risk of shutdown in countries where the Company relies on CMOs to provide commercial manufacture of its products or clinical batch manufacturing of its product candidates, (v) the ability to procure raw materials needed for the production of the Company's active pharmaceutical ingredient ("API") and other manufacturing components for the Company's product candidates, (vi) the possibility that third parties on which the Company may rely for certain functions and services, including CMOs, suppliers, distributors, logistics providers, and external business partners, may be adversely impacted by restrictions resulting from the COVID-19 pandemic, which could cause the Company to experience delays or the incurrence of additional costs, and (vii) the risk that the COVID-19 pandemic may intensify other risks inherent in the Company's business.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. The Company reviews all significant estimates affecting the

condensed consolidated financial statements on a recurring basis and records the effects of any necessary adjustments prior to their issuance.

Significant estimates made by management include provisions for product returns, coupons, rebates, chargebacks, trade and cash discounts, allowances and distribution fees paid to certain wholesalers, inventory net realizable value, useful lives of amortizable intangible assets, stock-based compensation, accrued expenses, valuation of assets and liabilities in business combinations, developmental timelines related to licensed products, valuation of contingent consideration and contingencies. Actual results may differ materially and adversely from these estimates. To the extent there are material differences between the estimates and actual results, the Company's future results of operations will be affected.

Unaudited Interim Condensed Consolidated Financial Statements

The accompanying interim condensed consolidated financial statements and the related footnote disclosures are unaudited. These unaudited condensed consolidated financial statements have been prepared in accordance with U.S. GAAP and applicable rules and regulations of the Securities and Exchange Commission's ("SEC") Rule 10-01 of Regulation S-X for interim financial information. The condensed consolidated financial statements were prepared on the same basis as the audited consolidated financial statements and in the opinion of management, reflect all adjustments of a normal, recurring nature that are necessary for the fair statement of the Company's financial position and its results of operations and cash flows. The results of operations for interim periods are not necessarily indicative of the results expected for the full fiscal year or any future period. These interim financial statements should be read in conjunction with the consolidated financial statements and notes set forth in the Company's Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on February 18, 2022.

Reclassifications

Certain amounts in the Company's consolidated balance sheet as of December 31, 2021 have been reclassified to conform to the current presentation. Prepaid insurance in the amount of \$1,697 and other current assets related to leasing arrangement, net in the amount of \$109 has been reclassified to prepaid expenses and other current assets. In addition, certain current liabilities totaling \$2,164 have been reclassified to conform with the current presentation of accrued expenses. See Note 8—"Accrued Expenses" for additional detail regarding these amounts.

These reclassifications had no impact on the Company's consolidated current assets, current liabilities or on the consolidated statements of operations and comprehensive loss or cash flows as of and for the year ended December 31, 2021.

Comprehensive Loss

Comprehensive loss is defined as the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. For the three months ended March 31, 2022 and 2021, comprehensive loss was equal to net loss.

Net Loss Per Share

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net loss per share is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period. Diluted net loss per share is the same as basic net loss per share, since the effects of potentially dilutive securities are anti-dilutive for all periods presented.

The following securities, presented on a common stock equivalent basis, have been excluded from the calculation of weighted average common shares outstanding for the three months ended March 31, 2022 and March 31, 2021 because the effect is anti-dilutive due to the net loss reported in each of those periods. All share amounts presented in the table below represent the total number outstanding as of the end of each period.

	March 31,		
	2022	2021	
Warrants to purchase common stock (Note 11)	274,326	1,278,076	
Stock options outstanding under the 2008 and 2016 Plans (Note 16)	664,278	192,252	
Stock appreciation rights outstanding under the 2016 Plan (Note 16)	60,000	61,000	
Inducement stock options outstanding (Note 16)	1,250	6,250	

Segment and Geographic Information

Operating segments are identified as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker. The Company's chief operating decision maker reviews financial information on a disaggregated basis for purposes of allocating resources and evaluating financial performance. See Note 18—"Segment Information" for further information on reportable segments.

Revenue Recognition

The Company accounts for revenue in accordance with ASC 606, Revenue from Contracts with Customers. To determine revenue recognition for arrangements that are within the scope of Topic 606, the Company (i) identifies the contract with a customer, (ii) identifies the performance obligations within the contract, (iii) determines the transaction price, (iv) allocates the transaction price to the performance obligations in the contract, and (v) recognizes revenue when (or as) the Company satisfies a performance obligation. The Company only applies the five-step model to contracts when it is probable that it will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer.

At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within the contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Upon occurrence of a contract modification, the Company conducts an evaluation pursuant to the modification framework in Topic 606 to determine the appropriate revenue recognition. The framework centers around key questions, including (i) whether the modification adds additional goods and services, (ii) whether those goods and services are distinct, and (iii) whether the contract price increases by an amount that reflects the standalone selling price for the new goods or services. The resulting conclusions will determine whether the modification is treated as a separate, standalone contract or if it is combined with the original contract and accounted for in that manner. In addition, some modifications are accounted for on a prospective basis and others on a cumulative catch-up basis.

The Company currently has the following types of revenue generating arrangements:

Net Product Revenues

Net product revenues encompass sales recognized resulting from transferring control of products to the customer, excluding amounts collected on behalf of third parties and sales taxes. The amount of revenue recognized is the amount allocated to the satisfied performance obligation taking into account variable consideration. The estimated amount of variable consideration is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

Product sales are recognized at the point in time when legal transfer of title has occurred, based on shipping terms. For product sales for which the Company owns rights to the products, the Company records a reduction to the transaction price for estimated chargebacks, rebates, coupons, trade and cash discounts and sales returns. A liability is recognized for expected sales returns, rebates, coupons, trade and cash discounts, chargebacks or other reimbursements to customers in relation to sales made in the reporting period. Payment terms can differ from contract to contract, but no element of financing is deemed present as the typical payment terms are less than one year. Therefore, the transaction price is not adjusted for the effects of a significant financing component. A receivable is recognized as soon as control over the products is transferred to the customer as this is the point in time that the consideration is unconditional because only the passage of time is required before the payment is due.

Variable consideration relates to sales returns, rebates, coupons, trade and cash discounts, and chargebacks granted to various direct and indirect customers. The Company recognizes provisions at the time of sale and adjusts them if the actual amounts differ from the estimated provisions. The following describes the nature of each deduction and how provisions are estimated:

Chargebacks — The Company has arrangements with various third-party wholesalers that require the Company to issue a credit to the wholesaler for the difference between the invoice price to the wholesaler and the customer's contract price. Provisions for chargebacks involve estimates of the contract prices within multiple contracts with multiple wholesalers. The provisions for chargebacks vary in relation to changes in product mix, pricing and the level of inventory at the wholesalers and, in addition, fluctuate in proportion to an increase or decrease in sales. Provisions for estimated chargebacks are calculated using the historical chargeback experience and expected chargeback levels for new products and anticipated pricing changes. Chargeback provisions are compared to externally obtained distribution channel reports for reasonableness. The Company regularly monitors the provisions for chargebacks and makes adjustments when the Company believes that actual chargebacks may differ from estimated provisions.

Rebates – Rebates include managed care services, fee for service and Medicaid rebate programs. Rebates are primarily related to volume-based incentives and are offered to key customers to promote loyalty. Customers receive rebates upon the attainment of a pre-established volume or the attainment of revenue milestones for a specified period. Since rebates are contractually agreed upon, provisions are estimated based on the specific terms in each agreement based on historical trends and expected sales.

Returns – Returns primarily relate to customer returns of expired products that the customer has the right to return up to one year following the product's expiration date. Such returned products are destroyed and credits and/or refunds are issued to the customer for the value of the returns. Accordingly, no returned assets are recorded in connection with those products. The returns provision is estimated by applying a historical return rate to the amounts of revenue estimated to be subject to returns. Revenue subject to returns is estimated based on the lag time from time of sale to date of return. The estimated lag time is developed by analyzing historical experience. Additionally, the Company considers specific factors, such as levels of inventory in the distribution channel, product dating and expiration, size and maturity of launch, entrance of new competitors, changes in formularies or packaging and any changes to customer terms, in determining the overall expected levels of returns.

<u>Prompt pay discounts</u> – Prompt pay discounts are offered to most customers to encourage timely payment. Discounts are estimated at the time of invoice based on historical discounts in relation to sales. Prompt pay discounts are almost always utilized by customers. As a result, the actual discounts typically do not vary significantly from the estimated amount.

Coupons – The Company offers coupons to market participants in order to stimulate product sales. The redemption cost of consumer coupons is based on historical redemption experience by product and value.

Sales and other taxes the Company collects concurrent with revenue-producing activities are excluded from revenue. Shipping and handling costs are accounted for as a fulfillment cost and are recorded as cost of revenue. Incidental items that are immaterial in the context of the contract are recognized as expense. Costs incurred to obtain a contract will be expensed as incurred when the amortization period is less than a year.

There can be a lag between the Company's establishment of an estimate and the timing of the invoicing or claim. The Company believes it has made reasonable estimates for future rebates and claims, however, these estimates involve assumptions pertaining to contractual utilization and performance, and payor mix. If the performance or mix across third-party payors is different from the Company's estimates, the Company may be required to pay higher or lower total price adjustments and/or chargebacks than it had estimated.

License and Collaboration Revenues

The Company has entered into various types of agreements that license the Company's intellectual property. If the applicable license is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, the Company's management utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the estimated performance period and the appropriate method of measuring progress during the performance period for purposes of recognizing revenue. The Company re-evaluates the estimated performance period and measure of progress each reporting period and, if necessary, adjusts related revenue recognition accordingly.

The Company also enters into various types of collaborative arrangements to develop and commercialize products. The Company's collaborative activities may include marketing, selling and distribution of the developed drugs, which may be bundled with a license for the Company's intellectual property, as noted above. These arrangements often include milestone as well as royalty or profit-share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development, as well as expense reimbursements from or payments to the collaboration partner. Because of the risk that products in development will not receive regulatory approval, the Company does not recognize any contingent payments until after regulatory approval has been achieved.

Royalty revenue from licenses provided to the Company's collaboration partners, which is based on sales to third parties of licensed products and technology, is recorded when the third-party sale occurs and the performance obligation to which some or all of the royalty has been allocated has been satisfied. This royalty revenue is included in collaboration revenue in the accompanying condensed consolidated statements of operations and comprehensive loss.

Operating expenses for costs incurred pursuant to these arrangements are reported in their respective expense line item. Such contractually required reimbursements are recognized when amounts are known and determinable and are reported as a liability within the accompanying condensed consolidated balance sheets based upon the timing of cash receipt from the collaboration partner.

Government research contracts and grants revenue

Under the terms of the contracts and grants awarded, the Company is entitled to receive reimbursement of its allowable direct expenses, allocated overhead, general and administrative expenses and payment of other specified amounts. Revenues from development and support activities under government research contracts and grants are recorded in the period in which the related costs are incurred. Associated expenses are recognized when incurred as research and development expense. Revenue recognized in excess of amounts collected from funding sources is recorded as contracts and grants receivable. Any of the funding sources may, at their discretion, request reimbursement for expenses or return of funds, or both, as a result of noncompliance by the Company with the terms of the grants. No reimbursement of expenses or return of funds has been requested or made since inception of the contracts and grants.

Product Cost of Goods Sold

Product cost of goods sold includes the direct costs attributable to the Company's product revenue. It includes the cost of the purchased finished goods, as well as shipping costs related to the sales of these products.

Advertising Costs

Promotion, marketing and advertising costs are expensed as incurred. Promotion, marketing and advertising costs for the three months ended March 31, 2022 and 2021 were approximately \$113 and zero, respectively, and are included in selling, general and administrative expenses in the condensed consolidated statement of operations and comprehensive loss.

Income Taxes

Deferred tax assets and liabilities are determined based on the temporary differences between the financial statement carrying amounts and the tax bases of assets and liabilities using the enacted tax rates in effect in the years in which the differences are expected to reverse. In estimating future tax consequences, all expected future events are considered other than enactment of changes in the tax law or rates.

The Company did not record a federal or state income tax benefit for the three months ended March 31, 2022 or 2021 due to its conclusion that a full valuation allowance is required against the Company's deferred tax assets.

The determination of recording or releasing a tax valuation allowance is made, in part, pursuant to an assessment performed by management regarding the likelihood that the Company will generate future taxable income against which benefits of its deferred tax assets may or may not be realized. This assessment requires management to exercise judgment and make estimates with respect to its ability to generate taxable income in future periods.

Restricted Cash

Restricted cash as of March 31, 2022 and December 31, 2021 includes funds maintained in a deposit account to secure a letter of credit for the benefit of the lessor of the Company's headquarters. See Note 6—"Leases" for further information regarding the letter of credit.

Accounts Receivable, net

Accounts receivable are carried at original invoice amount less an estimate made for doubtful receivables. An account receivable is considered to be past due if any portion of the receivable balance is outstanding beyond the agreed-upon due date.

The Company records an allowance for credit losses, which includes a provision for expected losses based on historical write-offs, adjusted for current conditions as deemed necessary, reasonable and supportable based on forecasts about future conditions that affect the expected collectability of the reported amount of the financial asset, as well as a specific reserve for accounts deemed at risk. The allowance is the Company's estimate for accounts receivable as of the balance sheet date that ultimately will not be collected. Any changes in the allowance are reflected in the results of operations in the period in which the change occurs. The Company writes off accounts receivable and the related allowance recorded previously when it becomes probable, based upon customer facts and circumstances, that such amounts will not be collected. No allowance for credit losses was recorded as of March 31, 2022 or December 31, 2021 as all amounts included in accounts receivable are expected to be collected.

Account balances are written off against the allowance after all means of collection have been exhausted and the potential for recovery is considered remote. Recoveries of receivables previously written off are recorded when received. The Company does not charge interest on accounts receivable.

As part of the EPI Health Acquisition, accounts receivable, net, were marked to fair value as part of the Company's ASC 805 business combination accounting. See Note 2 —"Acquisition of EPI Health" for additional detail.

Inventory, net

The Company maintains inventory consisting of for-sale pharmaceuticals related to its marketed product portfolio. The Company measures inventory using the first-in, first-out method and values inventory at the lower of cost and net realizable value. Net realizable value represents the estimated selling price for inventories less all estimated costs to sell.

The Company performs an analysis and records a provision for potentially obsolete inventory. The reserve for obsolescence is generally an estimate of the amount of inventory held at period end that is expected to expire in the future based on projected sales volume and expected product expiration or sell-by dates. These assumptions require the Company to analyze the aging of and forecasted demand for its inventory and make estimates regarding future product sales.

Property and Equipment, net

Property and equipment are recorded at cost and depreciated using the straight-line method over their estimated useful lives. Leasehold improvements are amortized over the shorter of the life of the lease or the useful life of the improvements. Expenditures for maintenance and repairs are expensed as incurred. Improvements and betterments that add new functionality or extend the useful life of an asset are capitalized. Leases for real estate often include tenant improvement allowances, which the Company assesses according to applicable accounting guidance to determine the appropriate owner, and capitalizes such tenant improvement assets accordingly.

Intangible Assets, net and Goodwill

Intangible assets represent certain identifiable intangible assets, including pharmaceutical product licenses and patents. Amortization for pharmaceutical products licenses is computed using the straight-line method based on the lesser of the term of the agreement and the useful life of the license. Amortization for pharmaceutical patents is computed using the straight-line method based on the useful life of the patent.

Definite-lived intangible assets are reviewed for impairment whenever events or circumstances indicate that carrying amounts may not be recoverable. In the event impairment indicators are present or if other circumstances indicate that an impairment might exist, then management compares the future undiscounted cash flows directly associated with the asset or asset group to the carrying amount of the asset group being determined for impairment. If those estimated cash flows are less than the carrying amount of the asset group, an impairment loss is recognized. An impairment loss is recognized to the extent that the carrying amount exceeds the asset's fair value. Considerable judgment is necessary to estimate the fair value of these assets, accordingly, actual results may vary significantly from such estimates.

Indefinite-lived intangible assets, such as goodwill and the cost to obtain and register the Company's internet domain, are not amortized. The Company tests the carrying amounts of goodwill for recoverability on an annual basis at September 30 or when events or changes in circumstances indicate evidence that a potential impairment exists, using a fair value based test.

A significant amount of judgment is involved in determining if an indicator of goodwill impairment has occurred. Such indicators may include, among others: a significant decline in expected future cash flows, a sustained, significant decline in the Company's stock price and market capitalization, a significant adverse change in legal factors or in the business climate, adverse assessment or action by a regulator, and unanticipated competition. Key assumptions used in the annual goodwill impairment test are highly judgmental. Any change in these indicators or key assumptions could have a significant negative impact on the Company's financial condition, impact the goodwill impairment analysis or cause the Company to perform a goodwill impairment analysis more frequently than once per year.

Contingent Consideration

Contingent consideration is recorded as a liability and is the estimate of the fair value of potential milestone payments related to the EPI Health Acquisition. The estimated fair value of contingent consideration was determined based on a probability-weighted valuation model that measures the present value of the probable cash payments based upon the future milestone events of EPI Health at a discount rate that captures the risk associated with the liability and also based on a Monte Carlo simulation, whereby EPI Health's forecasted net sales from the EPI Health legacy products were simulated over the measurement period to calculate the contingent consideration. See Note 2—"Acquisition of EPI Health" for further information regarding purchase consideration.

Related Parties

Members of the Company's board of directors held 123,497 and 100,497 shares of the Company's common stock as of March 31, 2022 and December 31, 2021, respectively.

Recently Issued Accounting Standards

Accounting Pronouncements Adopted

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-13, Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, which is designed to provide financial statement users with more information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. When determining such expected credit losses, the guidance requires companies to apply a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. The adoption of this new accounting guidance, as of January 1, 2022, did not have a material impact on the Company's condensed consolidated financial statements.

Note 2: Acquisition of EPI Health

On March 11, 2022, the Company completed the EPI Health Acquisition, in which the Company acquired all of the issued and outstanding units of membership interest of EPI Health from EPG for estimated purchase consideration of \$36,335. EPI Health is an integrated medical dermatology company providing the Company with a commercial infrastructure to support the commercialization of products. Subsequent to the EPI Health Acquisition, the Company sells various dermatological products for the treatments of plaque psoriasis, rosacea, acne and dermatoses.

The portion of the estimated purchase consideration at closing was \$27,500, as adjusted for cash, indebtedness, net working capital estimates and other contractually defined adjustments (the "Closing Purchase Price"). The Closing Purchase Price consisted of (i) \$11,000 paid in cash, (ii) a secured promissory note issued to EPG in the principal amount of \$16,500 (the "Seller Note"), and (iii) a \$993 payment representing an adjustment for estimated net working capital. See Note 9—"Notes Payable" for additional detail regarding the Seller Note and its related terms.

The purchase agreement entered into in connection with the EPI Health Acquisition (the "EPI Health Purchase Agreement") included the potential payment of additional consideration totaling up to \$23,500 upon achievement of certain milestones, as follows:

- a. \$1,000, as a one-time cash payment, upon EPG's performance of transition services and the successful completion of the transition provided under the transition services agreement between the Company and EPG;
- b. \$3,000, as a one-time payment, payable in cash or the Company's common stock, at the discretion of the Company, upon net sales of certain of EPI Health's legacy products exceeding \$30,000 during the period from April 1, 2022 through March 31, 2023;
- c. up to \$2,500, paid in quarterly installments in cash or the Company's common stock at the discretion of the Company, upon net sales of Wynzora Cream ("Wynzora") exceeding certain quarterly thresholds or an annual threshold of \$12,500 during the period from April 1, 2022 through March 31, 2023;
- d. \$5,000, as a one-time payment, payable in cash or the Company's common stock at the discretion of the Company, upon the first occurrence of post-closing net sales of certain of EPI Health's legacy products exceeding \$35,000 during any twelve-month period from April 1, 2023 through March 31, 2026; and
- e. up to \$12,000 based on receipt by EPI Health of regulatory and net sales milestones related to Sitavig from EPI Health's OTC Switch License Agreement with Bayer.

Certain of the above milestone payments will accelerate and become immediately payable upon certain specified events during the applicable milestone periods, including a sale of all or substantially all of the assets with respect to certain of EPI Health's legacy products. The EPI Health Purchase Agreement provides that payment of any additional consideration may be made in cash or in shares of the Company's common stock, so long as the number of shares that may be issued pursuant to the EPI Health Purchase Agreement or otherwise in connection with the EPI Health Acquisition limited to no more than 19.99% of the Company's outstanding shares of common stock immediately prior to the closing, unless stockholder approval is obtained to issue more than 19.99%.

The EPI Health Acquisition is being accounted for as a business combination using the acquisition method in accordance with ASC 805, *Business Combinations*. Under this method of accounting the fair value of the consideration transferred is allocated to the assets acquired and liabilities assumed based upon their estimated fair values on the date of the EPI Health Acquisition. Any excess of the purchase price over the fair value of identified assets acquired and liabilities assumed is recognized as goodwill.

For the three months ended March 31, 2022, the Company incurred costs related to the EPI Health Acquisition of \$4,021 recognized in selling, general and administrative expenses within the condensed consolidated statements of operations and comprehensive loss.

From the EPI Health Acquisition date through March 31, 2022, \$1,246 of total net revenue and a net loss of \$726 associated with EPI Health's operations are included in the condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2022.

Purchase Consideration

The following table presents the allocation of the estimated purchase consideration to be allocated to the estimated fair values of the net assets acquired at the EPI Health Acquisition date.

	As of M	arch 11, 2022
Initial cash consideration to Seller	\$	11,000
Secured promissory note issued to Seller		16,500
Fair value of contingent consideration liability		3,773
Remaining working capital adjustment to be paid		4,069
Working capital adjustment paid at close		993
Total estimated purchase consideration	\$	36,335

The estimated fair value of the contingent consideration as of March 31, 2022 is \$3,773, of which \$443 and \$3,330 is recognized as a current liability and long-term liability, respectively, in the condensed consolidated balance sheets.

Significant increases or decreases in any of the probabilities of success or changes in expected achievement of any of the milestones underlying the contingent consideration would result in a significantly higher or lower fair value of the contingent consideration liability. The contingent consideration is revalued at each reporting period and changes in fair value are recognized in the condensed consolidated statements of operations and comprehensive loss until settlement. See Note 17—"Fair Value" for additional information.

Provisional Allocation of Purchase Consideration to Estimated Fair Values of Net Assets Acquired

ASC 805 requires, among other things, that the assets acquired and liabilities assumed in a business combination be recognized at their fair values as of the acquisition date. Further, ASC 805 requires any consideration transferred or paid in a business combination in excess of the fair value of the assets acquired and liabilities assumed should be recognized as goodwill.

The total estimated purchase consideration was allocated to the estimated fair values of the assets acquired and liabilities assumed as of March 11, 2022 as follows:

Assets acquired and liabilities assumed:	
Accounts receivable, net	\$ 20,083
Inventory, net	1,710
Prepaid expenses and other current assets	3,692
Property and equipment, net	100
Intangible assets, net	33,000
Other assets	27
Right-of-use lease assets	 400
Total assets	\$ 59,012
Accounts payable	\$ 947
Accrued expenses	24,892
Operating lease liabilities, current portion	208
Operating lease liabilities, net of current portion	342
Other long-term liabilities	290
Total liabilities	\$ 26,679
Total identifiable net assets acquired	\$ 32,333
Goodwill	 4,002
Total estimated purchase consideration	\$ 36,335

The Company determined the estimated fair value of the acquired intangible assets as of the closing date using the income approach. This is a valuation technique that is based on the market participant's expectations of the cash flows that the intangible assets are forecasted to generate. The projected cash flows from these intangible assets were based on various assumptions, including estimates of revenues, expenses, and operating profit, and risks related to the viability of and commercial potential for alternative treatments. The cash flows were discounted at a rate commensurate with the level of risk associated with the projected cash flows. The Company believes the assumptions are representative of those a market participant would use in estimating fair value.

Goodwill was determined on the basis of the provisional fair values of the assets and liabilities identified at the time of the EPI Health Acquisition. The estimated provisional allocation of purchase consideration will be adjusted, within a period of no more than 12 months from the EPI Health Acquisition date, if these fair values change as a result of circumstances existing at the acquisition date. These measurement period adjustments may arise with regard to amounts recorded as assets and liabilities upon verification of such amounts or upon finalization of the required valuations of intangible assets identified. The amounts of reserves and provisions may also be adjusted as a result of ongoing procedures to identify and measure liabilities, including tax, environmental risks and litigation. The purchase consideration may also be adjusted in connection with finalizing the valuation procedures for the contingent consideration liability and finalizing the amount of the working capital adjustment to the purchase price. Any adjustments to amounts may impact the valuation of the consideration or the amounts recorded as goodwill.

Goodwill was calculated as the excess of the consideration paid consequent to completing the acquisition, compared to the net assets recognized. Goodwill represents the future economic benefits arising from the other acquired assets, which could not be individually identified and separately valued. Goodwill is primarily attributable to the acquired commercial platform and infrastructure, including personnel, and expected synergies related to the commercialization of product candidates. Goodwill is not expected to be deductible for tax purposes.

Pro forma Information

The following pro forma information presents the combined results of operations for the three months ended March 31, 2022 and 2021, as if the Company had completed the EPI Health Acquisition at the beginning of the periods presented. The pro forma financial information is provided for comparative purposes only and is not indicative of what actual results would have been had the EPI Health Acquisition occurred at the beginning of the periods presented, nor does it give effect to synergies, cost savings, fair market value adjustments, and other changes expected to result from the EPI Health Acquisition. Accordingly, the pro forma financial results do not purport to be indicative of consolidated results of operations as of the date hereof, for any period ended on the date hereof, or for any other future date or period. The pro forma financial information has been calculated after applying the Company's accounting policies and includes adjustments for transaction-related costs.

	 Three Months Ended				
	 March 31, 2022		March 31, 2021		
Total revenue	\$ 5,947	\$	4,868		
Net loss and comprehensive loss	(14,434)		(12,300)		
Net loss per share, basic and diluted	\$ (0.77)	\$	(0.82)		

Note 3: Inventory, net

The major components of inventory, net, were as follows:

	March	31, 2022
Finished goods available for sale	\$	1,478
Reserve for obsolescence		_
Inventory, net	\$	1,478

As part of the EPI Health Acquisition, inventory, net, were marked to fair value as part of the Company's ASC 805 business combination accounting. See Note 2—"Acquisition of EPI Health" for additional detail.

Note 4: Prepaid Expenses and Other Current Assets

The following table represents the components of prepaid expenses and other current assets as of:

	March 31, 2022	December 31, 2021
Inventory and raw material deposits	\$ 1,228	<u> </u>
Prepaid service contracts	444	_
Prepaid insurance	1,148	1,697
Prepaid Prescription Drug User Fee Act (PDUFA) fees	923	_
Product samples	960	_
Other current assets related to leasing arrangement	51	109
Prepaid expenses and other current assets	945	766
Total prepaid expenses and other current assets	\$ 5,699	\$ 2,572

Note 5: Property and Equipment, net

Property and equipment consisted of the following:

	March 31, 2022	December 31, 2021
Computer equipment	\$ 101	\$ 58
Furniture and fixtures	79	23
Laboratory equipment	4,465	4,134
Office equipment	177	177
Leasehold improvements	10,298	9,391
Property and equipment, gross	15,120	13,783
Less: Accumulated depreciation and amortization	(1,679)	(1,582)
Total property and equipment, net	\$ 13,441	\$ 12,201

Depreciation and amortization expense was \$97 for the three months ended March 31, 2022, and \$57 for the three months ended March 31, 2021.

New Facility

As of March 31, 2022 and December 31, 2021, the Company had construction in progress amounts related to leasehold improvements of \$8,392 and \$7,485, respectively.

See Note 6—"Leases" for details regarding the new facility and related lease.

Note 6: Leases

The Company leases office space and certain equipment under non-cancelable lease agreements.

In accordance with ASC 842, *Leases*, arrangements meeting the definition of a lease are classified as operating or financing leases and are recorded on the balance sheet as both a right-of-use asset and lease liability, calculated by discounting fixed lease payments over the lease term at the rate implicit in the lease, if available, otherwise at the Company's incremental borrowing rate. For operating leases, interest on the lease liability and the amortization of the right-of-use asset result in straight-line rent expense over the lease term. Variable lease expenses, if any, are recorded when incurred.

In calculating the right-of-use asset and lease liability, the Company elected, and has in practice, historically combined lease and non-lease components. The Company excludes short-term leases having initial terms of 12 months or less from the guidance as an accounting policy election and recognizes rent expense on a straight-line basis over the lease term.

Office Lease at Triangle Business Center, Durham, North Carolina

On January 18, 2021, the Company entered into a lease with an initial term expiring in 2032, as amended for 19,265 rentable square feet, located in Durham, North Carolina. This lease dated as of January 18, 2021, as amended (the "TBC Lease"), is by and between the Company and Copper II 2020, LLC (the "TBC Landlord"), pursuant to which the Company is leasing space serving as its corporate headquarters and small-scale manufacturing site (the "Premises") located within the Triangle Business Center. The lease executed on January 18, 2021, as amended, was further amended on November 23, 2021 to expand the Premises by approximately 3,642 additional rentable square feet from 15,623 rentable square feet.

The Premises serves as the Company's corporate headquarters and has been and continues to be prepared to support various cGMP activities, including research and development and small-scale manufacturing capabilities. These capabilities include the infrastructure necessary to support small-scale drug substance manufacturing and the ability to act as a primary, or secondary backup, component of a potential future commercial supply chain.

The TBC Lease commenced on January 18, 2021 (the "Lease Commencement Date"). Rent under the TBC Lease commenced in October 2021 (the "Rent Commencement Date"). The term of the TBC Lease expires on the last day of the one hundred twenty-third calendar month after the Rent Commencement Date. The TBC Lease provides the Company with one option to extend the term of the TBC Lease for a period of five years, which would commence upon the expiration of the original term of the TBC Lease, with base rent of a market rate determined according to the TBC Lease; however, the renewal period was not included in the calculation of the lease obligation as the Company determined it was not reasonably certain to exercise the renewal option.

The monthly base rent for the Premises is approximately \$40 for months 1-10 and approximately \$49 for months 11-12, per the second amendment to the primary lease. Beginning with month 13 and annually thereafter, the monthly base rent will be increased by 3%. Subject to certain terms, the TBC Lease provides that base rent will be abated for three months following the Rent Commencement Date. The Company is obligated to pay its pro-rata portion of taxes and operating expenses for the building as well as maintenance and insurance for the Premises, all as provided for in the TBC Lease.

The TBC Landlord has agreed to provide the Company with a tenant improvement allowance in an amount not to exceed \$130 per rentable square foot, totaling approximately \$2,450, per the primary lease, inclusive of the first amendment, and \$115 per rentable square foot, totaling \$419, per the second amendment to the TBC Lease. The tenant improvement allowance will be paid over four equal installments corresponding with work performed by the Company. Pursuant to the terms of the TBC Lease, the Company delivered to the TBC Landlord a letter of credit in the amount of \$583, as amended, as collateral for the full performance by the Company of all of its obligations under the TBC Lease and for all losses and damages the TBC Landlord may suffer as a result of any default by the Company under the TBC Lease. Cash funds maintained in a separate deposit account at the Company's financial institution to fully secure the letter of credit are presented as restricted cash in non-current assets on the accompanying condensed consolidated balance sheets.

Office Lease at Meeting Street, Charleston, South Carolina

On March 3, 2022 EPI Health entered into a sublease agreement with EPG (the "Meeting Street Lease") for office space at 174 Meeting Street in Charleston, South Carolina for approximately 6,000 rentable square feet.

The term of the Meeting Street Lease is through September 30, 2024, and EPI Health has the right to terminate the Meeting Street Lease with 60 days' prior notice. The monthly base rent for the Meeting Street Lease is \$20 for months 1-12, inclusive of taxes and operating expenses such as maintenance and insurance. Beginning with month 13 and annually thereafter, the monthly base rent will be increased by 3%.

TBC Lease and Meeting Street Lease

Rent expense, including both short-term and variable lease components associated with the TBC Lease and the Meeting Street Lease, as applicable, was \$137 for the three months ended March 31, 2022 and \$145 for the three months ended March 31, 2021.

The remaining lease term for the TBC Lease and the Meeting Street Lease are 9.86 years and 2.42 years, respectively, as of March 31, 2022. The weighted average discount rate for both leases was 8.35% as of March 31, 2022.

Future net minimum lease payments, net of amounts expected to be received related to the tenant improvement allowance, as of March 31, 2022 were as follows:

Maturity of Lease Liabilities	Opera	iting Lease
2022	\$	(244)
2023		750
2024		816
2025		645
2026		665
2027 and beyond		3,700
Total future undiscounted lease payments	\$	6,332
Add: reclassification of discounted net cash inflows to other current assets		51
Less: imputed interest		(2,251)
Total reported lease liability	\$	4,132

The table above reflects payments for an operating lease with a remaining term of one year or more, but does not include obligations for short-term leases. In addition, the net cash inflow related to the 2022 fiscal year presented above relates to the expected timing of the remaining balance of the total tenant improvement allowance of \$2,450 being funded by the TBC Landlord, which the Company reasonably expects to receive within the next twelve months, partially offset by expected lease payments for the corresponding period.

Components of lease assets and liabilities as of March 31, 2022 were as follows:

	March 31, 2022
Assets	
Other current assets related to leasing arrangement	\$ 51
Right-of-use lease assets	2,092
Total lease assets	\$ 2,143
Liabilities	
Operating lease liabilities, current portion	\$ 228
Operating lease liabilities, net of current portion	3,904
Total lease liabilities	\$ 4,132

During the year ended December 31, 2021, the Company received \$1,523 related to payments as part of the total TBC Landlord funded tenant improvement allowance. The effective discounted value of the remaining tenant improvement allowance payments being funded by the TBC Landlord, of the total tenant improvement allowance of \$2,450, partially offset by the expected lease payments by the Company within the next twelve months, results in a net balance of \$51. This net amount is presented within the condensed consolidated balance sheets within prepaid expenses and other current assets as of March 31, 2022. Furthermore, this amount is also included in long-term lease liabilities within the condensed consolidated balance sheets as of March 31, 2022.

Note 7: Goodwill and Intangible Assets, net

Goodwill

The Company's goodwill balance as of March 31, 2022 was \$4,002. The entire goodwill balance relates to the EPI Health Acquisition during the three months ended March 31, 2022. None of the goodwill is expected to be deductible for income tax purposes.

Intangible Assets

The following table presents both definite and indefinite lived intangible assets as of March 31, 2022, comprised primarily of acquired product rights related to the EPI Health Acquisition:

	Initial Carrying Value	Accumulated Amortization	Net Book Value	Useful Life (Years)
Rhofade	\$ 15,500	\$ 57	\$ 15,443	15
Wynzora	3,000	11	2,989	15
Minolira	3,500	13	3,487	15
Cloderm	6,500	24	6,476	15
Nuvail	1,000	3	997	15
Sitavig	3,500	13	3,487	15
Website domain	75	_	75	_
Total intangible assets	\$ 33,075	\$ 121	\$ 32,954	15

The Company amortizes the product rights related to its commercial product portfolio over their estimated useful lives. As part of the EPI Health Acquisition, product rights were recorded at fair value as part of the Company's ASC 805 business combination accounting. See Note 2—"Acquisition of EPI Health" for additional detail.

The following table represents annual amortization of definite lived intangible assets for the next five fiscal years, and thereafter:

2022	\$ 1,657
2023	2,200
2024	2,206
2025	2,200
2026	2,200
Thereafter	22,416
Total amortization	\$ 32,879

Note 8: Accrued Expenses

The following table represents the components of accrued expenses as of March 31, 2022 and December 31, 2021:

	March 31, 2022	December 31, 2021
Accrued rebates, discounts and chargebacks	\$ 15,645	\$ _
Accrued returns	5,849	_
Accrued compensation	2,266	1,543
Accrued outside research and development services	172	194
Accrued royalties	1,040	_
Accrued working capital adjustment	4,069	_
Accrued construction in process	1,297	1,020
Accrued SB206 pre-commercial and marketing	420	_
Accrued collaboration reimbursement	493	_
Accrued other expenses	3,368	2,231
Total accrued expenses	\$ 34,619	\$ 4,988

Note 9: Notes Payable

Seller Note with Evening Post Group

On March 11, 2022, at the closing of the EPI Health Acquisition, the Company entered into a secured promissory note and security agreement with EPG. The Company entered into the Seller Note with EPG to finance a portion of the Closing Purchase Price related to the EPI Health Acquisition.

The Seller Note has a principal amount of \$16,500 with interest-only payments due over the course of the 24-month term of the Seller Note. The Seller Note will bear interest at the rate of 5.0% per annum for the first 90 days after the closing date, 15.0% per annum for the following 12 months, and 18.0% per annum for the remainder of the term. The non-amortizing principal of the Seller Note is to be paid in full at maturity and is secured by the membership interests of EPI Health held by the Company. EPI Health is a guarantor of the Seller Note. There is no penalty for repaying the Seller Note prior to the end of the term. Based on the escalating interest rate over the term of the Seller Note, the Company has recorded interest expense using the effective interest method.

During the three months ended March 31, 2022, the Company recorded interest expense of \$132 related to the Seller Note. As of March 31, 2022, the Company had \$87 of accrued interest included within accrued expenses on the condensed consolidated balance sheets.

The following table represents future maturities of the Seller Note obligation as of March 31, 2022:

2022	\$ _
2023	_
2024	16,500
Total notes payable	\$ 16,500

Note 10: Commitments and Contingencies

Contingencies

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of business activities. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated. See *Legal Proceedings* below for further discussion of pending legal claims

The Company has entered into, and expects to continue to enter into, contracts in the normal course of business with various third parties that support its clinical trials, preclinical research studies, development services, and commercial sales and marketing activities in addition to potential third-party manufactures for both the manufacture of the Company's product candidates and procurement of its commercial finished good products. The scope of the services under these agreements can generally be modified at any time, and these agreements can generally be terminated by either party after a period following written notice.

In connection with entering into the Equity Distribution Agreement with Oppenheimer discussed in Note 11—"Stockholders' Equity," the Company terminated its common stock purchase agreement with Aspire Capital on March 10, 2022. Other than such termination, there have been no material contract terminations as of March 31, 2022.

Also, see Note 11—"Stockholders' Equity" regarding outstanding common stock warrants.

Contingent Payment Obligations Related to the Purchase of EPI Health

See Note 2—"Acquisition of EPI Health" for certain contingent payments related to consideration due to EPG upon achievement of certain milestones by EPI Health.

Contingent Payment Obligations from Historical Acquisitions by EPI Health

EPI Health has in the past acquired certain rights to pharmaceutical products and such arrangements have typically included requirements that EPI Health make certain contingent payments to the applicable seller as discussed below.

Rhofade. On October 10, 2019, EPI Health entered into an agreement whereby it acquired certain assets related to Rhofade (the "Rhofade Acquisition Agreement"). In connection with the Rhofade Acquisition Agreement, EPI Health is required to make the following milestone payments to the seller upon reaching the following net sales thresholds during any calendar year following the closing date, as defined in the Rhofade Acquisition Agreement:

Calendar Year Net Sales Threshold	Milestone Payment
\$ 50,000	\$ 5,000
\$ 75,000	\$ 5,000
\$ 100,000	\$ 10,000

Under the terms of the Rhofade Acquisition Agreement, EPI Health assumed certain liabilities of the prior licensees of the Rhofade product. In particular, EPI Health would also be required to pay certain earnout payments pursuant to historic acquisition agreements for Rhofade upon the achievement of net sales thresholds higher than those set forth above. However, the Company has not recognized a liability for such Rhofade milestones based on current and historical sales figures and management's estimates of future sales.

Cloderm. On September 28, 2018, EPI Health entered into an agreement pursuant to which it acquired assets related to the product Cloderm. EPI Health is required to pay a low double-digit royalty once cumulative net sales of Cloderm reach \$20,833, until \$6,500 of royalty payments have been made by EPI Health.

Minolira. On August 20, 2018, EPI Health entered into an agreement pursuant to which it acquired assets related to the product Minolira. In connection with the agreement, EPI Health is required to make the following milestone payments to the seller upon reaching cumulative net sales thresholds as defined in the acquisition agreement:

Cumulative Net Sales Threshold			reshold	Mi	lestone Payment
\$	10,0	00		\$	1,000
\$	20,0	00		\$	1,000
Each addition	onal	\$	20,000	\$	1,500

See Note 12—"Licensing and Collaboration Arrangements" for certain obligations and contingent payments related to license agreements, including those related to the Company's commercial product portfolio.

Also see Note 15—"Research and Development Agreements" for certain obligations regarding the Company's research and development license agreements, including the Reedy Creek Purchase Agreement and the Ligand Funding Agreement.

For the three months ended March 31, 2022, the Company recorded \$98 of expense related to royalties on net sales and accruals of certain cumulative sales-based milestones related to its commercial product portfolio, described above. As of March 31, 2022 the Company had accrued royalties of \$1,040 and accrued milestones of \$297, presented within accrued expenses and other long-term liabilities, respectively, in its condensed consolidated balance sheets.

Development Services Agreement

In July 2021, the Company entered into a development services agreement with a third-party full-scale API manufacturer for certain manufacturing process feasibility services including process familiarization, safety assessments, preliminary engineering studies, and initial process and analytical methods determination. Following the successful completion of certain preliminary activities with this third-party API manufacturer and other preparatory activities, the Company would then proceed with the

third-party API manufacturer beyond the initial stages noted above, in which case the Company expects to incur substantial costs associated with technical transfer efforts, capital expenditures, manufacturing capabilities, and certain quantities of its drug substance.

Legal Proceedings

The Company is not currently a party to any material legal proceedings and is not aware of any claims or actions pending against the Company that the Company believes could have a material adverse effect on the Company's business, operating results, cash flows or financial statements. In the future, the Company might from time to time become involved in litigation relating to claims arising from its ordinary course of business.

Compensatory Obligations

The Company enters into employment agreements with certain officers and employees. These agreements are in the normal course of business and contain certain customary Company controlled termination provisions which, if triggered, could result in future severance payments.

See Note 16—"Stock-Based Compensation" regarding stock options, stock appreciation rights and the Tangible Stockholder Return Plan.

Note 11: Stockholders' Equity

Capital Structure

In conjunction with the completion of the Company's initial public offering in September 2016, the Company amended its restated certificate of incorporation and amended and restated its bylaws. The amendment provided for 210,000,000 authorized shares of capital stock, of which 200,000,000 shares are designated as \$0.0001 par value common stock and 10,000,000 shares are designated as \$0.0001 par value preferred stock.

At the Company's Annual Meeting of Stockholders held on July 28, 2020 (the "2020 Annual Meeting"), the Company's stockholders approved an amendment to the Company's restated certificate of incorporation of the Company to effect a reverse stock split of the Company's common stock at a ratio of not less than one-for-two and not more than one-for-fifteen, with such ratio and the implementation and timing of such reverse stock split to be determined by the Company's board of directors in its sole discretion. On May 18, 2021, the Company's board of directors approved a one-for-ten reverse stock split of the Company's issued and outstanding common stock. On May 24, 2021, the Company filed with the Secretary of State of the State of Delaware a Certificate of Amendment to the Restated Certification of Incorporation of the Company in order to effect the Reverse Stock Split. The Reverse Stock Split became effective as of 5:00 p.m. Eastern Time on May 25, 2021, and the Company's common stock began trading on a split-adjusted basis on May 26, 2021. As a result of the Reverse Stock Split, on the effective date thereof, each outstanding ten (10) shares of common stock combined into and became one (1) share of common stock, and the number of the Company's issued and outstanding shares of common stock was reduced to 15,170,678. The accompanying condensed consolidated financial statements and related notes give retroactive effect to the Reverse Stock Split.

Common Stock

The Company's common stock has a par value of \$0.0001 per share and consists of 200,000,000 authorized shares as of March 31, 2022 and December 31, 2021. There were 18,980,122 and 18,815,892 shares of voting common stock outstanding as of March 31, 2022 and December 31, 2021, respectively.

The Company had reserved shares of common stock for future issuance as follows:

	March 31, 2022	December 31, 2021
Outstanding warrants to purchase common stock	274,326	1,274,176
Outstanding stock options (Note 16)	665,528	518,553
Outstanding stock appreciation rights (Note 16)	60,000	60,000
For possible future issuance under the 2016 Stock Plan (Note 16)	1,066,249	1,213,224
	2,066,103	3,065,953

Preferred Stock

The Company's restated certificate of incorporation provides the Company's board of directors with the authority to issue \$0.0001 par value preferred stock from time to time in one or more series by adopting a resolution and filing a certificate of designations. Voting powers, designations, preferences, dividend rights, conversion rights and liquidation preferences shall be stated and expressed in such resolutions. There were 10,000,000 shares designated as preferred stock and no shares outstanding as of March 31, 2022 and December 31, 2021

March 2022 Equity Distribution Agreement – At-the-Market Facility

On March 11, 2022, the Company entered into an Equity Distribution Agreement (the "Equity Distribution Agreement") with Oppenheimer & Co. Inc. ("Oppenheimer"). Pursuant to the Equity Distribution Agreement, the Company may from time to time issue and sell to or through Oppenheimer, acting as the Company's sales agent, shares of the Company's common stock, par value \$0.0001 per share having an aggregate offering price of up to \$50,000. Sales of the shares, if any, will be made by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933 ("Securities Act"), or, if expressly authorized by the Company, in privately negotiated transactions. As sales agent, Oppenheimer will offer the shares at prevailing market prices and will use its commercially reasonable efforts, consistent with its sales and trading practices, to sell on the Company's behalfall of the shares requested to be sold by the Company, subject to the terms and conditions of the Equity Distribution Agreement. The Company or Oppenheimer may suspend the offering of the shares upon proper notice to the other party. The offering of the shares pursuant to the Equity Distribution Agreement will terminate upon the sale of shares in an aggregate offering amount equal to \$50,000, or sooner if either the Company or Oppenheimer terminates the Equity Distribution Agreement as permitted by its terms.

The Company will pay Oppenheimer a commission equal to 3.0% of the aggregate gross proceeds from the sale of the shares sold pursuant to the Equity Distribution Agreement and will reimburse Oppenheimer for certain expenses incurred in connection with its services under the Equity Distribution Agreement. The foregoing rate of compensation will not apply when Oppenheimer acts as principal, in which case the Company may sell the shares to Oppenheimer as principal at a price agreed upon among the parties.

During the three months ended March 31, 2022, the Company sold 164,230 shares of its common stock at an average price of \$3.53 per share for total net proceeds of \$562 under the Equity Distribution Agreement.

Outstanding Common Stock Warrants

The Company has historically entered into certain equity offerings with underwriters and placement agents, such as the March 2020 Public Offering, the March 2020 Registered Direct Offering and the January 2018 Offering, that included certain common stock warrant issuances.

The following table presents the Company's outstanding warrants to purchase common stock for the periods indicated.

	March 31, 2022	December 31, 2021	Exercise Price Per Share
Warrants to purchase common stock issued in the January 2018 Offering		999,850	\$ 46.60
Warrants to purchase common stock issued in the March 2020 Public Offering	252,417	252,417	3.00
Underwriter warrants to purchase common stock associated with the March 2020 Public Offering	11,304	11,304	3.75
Placement agent warrants to purchase common stock issued in the March 2020 Registered Direct Offering	10,605	10,605	5.375
	274,326	1,274,176	

The weighted average exercise price per share for warrants outstanding as of March 31, 2022 and December 31, 2021 was \$3.12 and \$37.24, respectively.

March 2020 Public Offering

On February 27, 2020, the Company entered into an underwriting agreement with H.C. Wainwright, as underwriter, relating to the offering, issuance and sale of common stock, prefunded warrants, and accompanying common warrants (the "CMPO Common Warrants"), in a public offering (the "March 2020 Public Offering"). The number of CMPO Common Warrants, excluding pre-funded warrants, issued in connection with the March 2020 Public Offering totaled 2,108,333. At closing, the Company also issued to designees of H.C. Wainwright, as underwriter, warrants to purchase an aggregate of up to 59,496

shares of common stock (the "CMPO UW Warrants") representing 3.0% of the aggregate number of shares of common stock sold and shares of common stock underlying the prefunded warrants sold in the March 2020 Public Offering.

The CMPO Common Warrants have an exercise price of \$3.00 per share and expire five years from the date of issuance. During the three months ended March 31, 2022, there were no exercises of CMPO Common Warrants. During the three months ended March 31, 2021, warrant holders exercised 6,250 of the CMPO Common Warrants for total proceeds of approximately \$18. There were 252,417 of the CMPO Common Warrants outstanding as of March 31, 2022.

The CMPO UW Warrants have an exercise price of \$3.75 per share and expire five years from the date of issuance. During the three months ended March 31, 2022, there were no exercises of CMPO UW Warrants. During the three months ended March 31, 2021, warrant holders exercised 48,192 of the CMPO UW Warrants for total proceeds of approximately \$181. There were 11,304 of the CMPO UW Warrants outstanding as of March 31, 2022.

March 2020 Registered Direct Offering

On March 24, 2020, the Company entered into a securities purchase agreement with several institutional and accredited investors, pursuant to which the Company agreed to sell and issue shares of the Company's common stock and pre-funded warrants in a registered direct offering priced at the market (the "March 2020 Registered Direct Offering"). The March 2020 Registered Direct Offering closed on March 26, 2020. At closing, the Company issued to designees of H.C. Wainwright, as placement agent, warrants to purchase an aggregate of up to 55,814 shares of common stock (the "RDO PA Warrants") representing 3.0% of the aggregate number of shares of common stock sold and shares of common stock underlying pre-funded warrants sold in the March 2020 Registered Direct Offering.

The RDO PA Warrants have an exercise price of \$5.375 per share and expire five years from the date of issuance. During the three months ended March 31, 2022, there were no exercises of RDO PA Warrants. During the three months ended March 31, 2021, warrant holders exercised 45,209 of the RDO PA Warrants for total proceeds of approximately \$243. There were 10,605 of the RDO PA Warrants outstanding as of March 31, 2022.

January 2018 Offering

There were no exercises of warrants issued in the Company's public offering that closed on January 9, 2018 (the "January 2018 Offering") during the three months ended March 31, 2022 and 2021, respectively. On January 9, 2022, the remaining 999,850 outstanding warrants related to the January 2018 Offering expired without being exercised.

July 2020 Aspire Common Stock Purchase Agreement

On July 21, 2020, the Company entered into the Common Stock Purchase Agreement (the "July 2020 CSPA") with Aspire Capital Fund, LLC ("Aspire"), which provided that, upon the terms and subject to the conditions and limitations set forth therein, Aspire was committed to purchase up to an aggregate of \$30,000 of shares of the Company's common stock at the Company's request from time to time during the 30-month term of the July 2020 Aspire CSPA. Upon execution of the July 2020 Aspire CSPA, the Company agreed to sell to Aspire 555,555 shares of its common stock at \$9.00 per share for proceeds of \$5,000. In consideration for entering into the July 2020 Aspire CSPA, upon satisfaction of certain conditions under the July 2020 Aspire CSPA, the Company issued to Aspire 100,000 shares of the Company's common stock (the "July 2020 Commitment Shares"). The July 2020 Commitment Shares, valued at approximately \$847, were recorded in July 2020 as non-cash costs of equity financing and included within general and administrative expenses. The July 2020 Aspire CSPA replaced the June 2020 Aspire Common Stock Purchase Agreement, which was terminated under the terms of the July 2020 Aspire CSPA.

On March 9, 2022, the Company provided notice to Aspire electing to terminate the July 2020 CSPA effective as of March 10, 2022. By its terms, the July 2020 CSPA could be terminated by the Company at any time, at its discretion, without any penalty or additional cost to the Company.

During the three months ended March 31, 2022, there were no sales of common stock under the July 2020 CSPA. During the three months ended March 31, 2021, the Company sold 493,163 shares of its common stock at an average price of \$1.28 for total proceeds of \$6,334.

Note 12: Licensing and Collaboration Arrangements

SB204 and SB206 Agreements

The Company has entered into a license agreement, as subsequently amended, with Sato Pharmaceutical Co., Ltd. ("Sato"), relating to SB204, its drug candidate for the treatment of acne vulgaris, and SB206, its drug candidate for the treatment of viral skin infections (the "Sato Agreement"). Pursuant to the Sato Agreement, the Company granted to Sato an exclusive, royalty-bearing, non-transferable license under certain of its intellectual property rights, with the right to sublicense with the Company's prior written consent, to develop, use and sell products in Japan that incorporate SB204 or SB206 in certain topical dosage forms for the treatment of acne vulgaris or viral skin infections, respectively, and to make the finished form of such products. The Company or its designated contract manufacturer will supply finished product to Sato for use in the development of SB204 and SB206 in the licensed territory. The rights granted to Sato do not include the right to manufacture the API of SB204 or SB206; rather, the parties agreed to negotiate a commercial supply agreement pursuant to which the Company or its designated contract manufacturer would be the exclusive supplier to Sato of the API for the commercial manufacture of licensed products in the licensed territory. Under the terms of the Sato Agreement, the Company also has exclusive rights to certain intellectual property that may be developed by Sato in the future, which the Company could choose to use for its own development and commercialization of SB204 or SB206 outside of Japan.

The term of the Sato Agreement (and the period during which Sato must pay royalties under the amended license agreement) expires on the twentieth anniversary of the first commercial sale of a licensed product in the licensed field in the licensed territory (adjusted from the tenth anniversary of the first commercial sale in the Sato Agreement). The term of the Sato Agreement may be renewed with respect to a licensed product by mutual written agreement of the parties for additional two-year periods following expiration of the initial term. All other material terms of the Sato Agreement remain unchanged by the Sato Amendment.

Sato is responsible for funding the development and commercial costs for the program that are specific to Japan. The Company is obligated to perform certain oversight, review and supporting activities for Sato, including (i) using commercially reasonable efforts to obtain marketing approval of SB204 and SB206 in the United States, (ii) sharing all future scientific information the Company may obtain during the term of the Sato Agreement pertaining to SB204 and SB206, (iii) performing certain additional preclinical studies if such studies are deemed necessary by the Japanese regulatory authority, up to and not to exceed a total cost of \$1,000, and (iv) participating in a joint committee that oversees, reviews and approves Sato's development and commercialization activities under the Sato Agreement. Additionally, the Company has granted Sato the option to use the Company's trademarks in connection with the commercialization of licensed products in the licensed territory for no additional consideration, subject to the Company's approval of such use.

The Sato Agreement may be terminated by (i) Sato without cause upon 120 days' advance written notice to the Company, (ii) either party in the event of the other party's uncured material breach upon 60 days' advance written notice, (iii) force majeure, (iv) either party in the event of the other party's dissolution, liquidation, bankruptcy or insolvency, and (v) the Company immediately upon written notice if Sato challenges the validity, patentability, or enforceability of any of the Company's patents or patent applications licensed to Sato under the Sato Agreement. In the event of a termination, no portion of the upfront fees received from Sato are refundable.

Wynzora Agreements

Effective as of January 1, 2022, EPI Health entered into an amended and restated promotion and collaboration agreement with MC2 Therapeutics Limited ("MC2"), relating to the commercialization of Wynzora for treatment of plaque psoriasis in adults in the United States (the "MC2 Agreement"). Pursuant to the MC2 Agreement, which set forth the collaborative efforts between EPI Health and MC2 to commercialize and promote Wynzora with MC2 in the United States, MC2 granted EPI Health an exclusive right and license under MC2's intellectual property rights to sell, or detail (as defined in the MC2 Agreement), and engage in certain commercialization activities with respect to Wynzora in the United States.

Under the terms of the MC2 Agreement, EPI Health is entitled to a commercialization fee equivalent to a percentage of net sales ranging from the mid-teens for net sales less than or equal to \$65,000 to the upper single digits for annual net sales greater than \$105,000. EPI Health collects this commercialization fee by retaining its portion of the Wynzora product net sales it collects, with the remainder of the net sales being remitted to MC2 periodically, pursuant to the MC2 Agreement. EPI Health is also entitled to an incentive fee, which will also be withheld from the royalty payment paid by EPI Health to MC2, equal to 5% of the first \$30,000 in net sales of Wynzora sold in the United States by EPI Health in each of the 2022 and 2023 calendar years; provided that such incentive fee shall not exceed \$1,500 each year and such incentive fee shall not be credited to EPI Health until the royalty payments paid to MC2 surpass the amount of certain commercialization payments made previously by MC2.

The term of the MC2 Agreement runs until the seventh anniversary of the first commercial sale of Wynzora (as defined in the MC2 Agreement) or June 30, 2028, whichever is earlier. Either party may terminate the MC2 Agreement for the other party's material uncured breach or the bankruptcy or insolvency of the other party. MC2 may terminate the MC2 Agreement under certain scenarios, including for convenience with twelve months' advance notice to EPI Health provided that the termination is not effective unless MC2 pays any unpaid historical liabilities related to commercialization of Wynzora owed by MC2. EPI Health may terminate the MC2 Agreement for convenience with twelve months' advance notice to MC2 provided that the termination is not effective unless the Company provides MC2 with a guarantee of the payment of any outstanding royalty payments, to the extent such royalty payments owed by EPI Health exceed any unpaid historical liabilities related to commercialization of Wynzora owed by MC2.

Rhofade Agreements

In connection with the Rhofade Acquisition Agreement that is described in Note 10—"Commitments and Contingencies," EPI Health acquired rights to that certain Assignment and License Agreement, whereby EPI Health licenses certain intellectual property from Aspect Pharmaceuticals, LLC ("Aspect" and such agreement, the "Aspect Agreement"). Under the terms of the Aspect Agreement, EPI Health, as successor-in-interest, has exclusive rights to, and is required to use commercially reasonable efforts to, commercialize the Rhofade product. EPI Health also has a duty to certain other parties to use commercially reasonable efforts to commercialize the Rhofade product based on historical acquisition agreements for Rhofade that were assumed by EPI Health.

The Aspect Agreement expires upon the last-to-expire of patent claims made under the assigned and licensed patents under the Aspect Agreement. Aspect may terminate the agreement upon a material breach by EPI Health after providing an opportunity to cure. Upon such termination by Aspect, EPI Health will cease all development and commercialization of Rhofade and EPI Health will assign and convey to Aspect its entire right, title and interest in and to the assigned intellectual property transferred under the Aspect Agreement.

Additionally, under the Aspect Agreement, the Rhofade Acquisition Agreement and the other historical acquisitions related to Rhofade, EPI Health is also required to pay a combined royalty on net sales of Rhofade and related products initially in the low double digits, which rate may increase based on the thresholds of net sales achieved by EPI Health. EPI Health is also required to pay 25% of any upfront, license, milestone or other related payments received by EPI Health related to any sublicenses of Rhofade and related products.

In connection with two abbreviated new drug application ("ANDA") settlement agreements that EPI Health entered into in connection with Rhofade in 2021, EPI Health granted two ANDA filers a license to launch their own generic product for the treatment of erythema in rosacea. The actual timing of the launch of such generic products is uncertain because the launch dates of such products under the settlement agreements are subject to acceleration under certain circumstances. In the absence of any circumstances triggering acceleration, the earliest launch of such a generic product would be in the third quarter of 2026.

Minolira Agreements

In connection with the Minolira acquisition that is described in Note 10—"Commitments and Contingencies," EPI Health assumed the royalty obligation related to an ANDA settlement in connection with Minolira. Accordingly, EPI Health is required to pay a royalty to an ANDA filer in the low double digits of any generic form of Minolira that is the pharmaceutical equivalent of the 105 mg or 135 mg strength Minolira product.

Cloderm Agreements

In connection with the Cloderm acquisition that is described in Note 10—"Commitments and Contingencies," on September 28, 2018, EPI Health entered into a distribution and supply agreement with Prasco, LLC ("Prasco"), whereby EPI Health has agreed to supply and Prasco has the right to purchase, distribute and sell an authorized generic ("AG") version of the Cloderm product in the United States. Prasco is required to pay EPI Health the supply price for the products, along with an amount equal to net sales of the product, minus an amount for certain fees and expenses of Prasco initially equal to the low double digits of net sales of such product, which is retained by Prasco. The agreement will continue, on a product-by-product basis, for an initial five-year term from the first commercial sale of such product, which will automatically renew for an additional one-year term unless either party elects not to renew. The agreement may be terminated for convenience by EPI Health upon nine months' written notice. Prasco may terminate with respect to a specific product based, among other factors, on a failure by EPI Health to deliver launch quantities. Either party may terminate immediately upon the occurrence of certain regulatory matters or based on a force majeure event.

Sitavig Agreements

On February 21, 2020, EPI Health entered into an agreement with Vectans Pharma ("Vectans") in which the parties terminated an existing license agreement dated March 17, 2014 which granted EPI Health the exclusive right to develop and commercialize

a prescription Sitavig product in the United States and Canada, and instead provided that EPI Health would purchase outright certain intellectual property (and license other intellectual property) related to the prescription Sitavig Rx product in the United States and Canada (the "Vectans Agreement").

At the time it entered into the Vectans Agreement, EPI Health also entered into an OTC Switch License Agreement (the "OTC License Agreement") with Bayer Healthcare LLC ("Bayer"). Under the OTC License Agreement, EPI Health granted to Bayer an exclusive and sublicensable license to develop and commercialize an OTC product in the United States and Canada.

Under the OTC License Agreement, Bayer has agreed to pay EPI Health various regulatory milestone payments upon the achievement of such regulatory milestones equaling a maximum aggregate amount of \$9,500, along with various commercial milestone payments upon the achievement of such commercial milestones equaling a maximum aggregate amount of \$20,000. Under the Vectans Agreement, EPI Health is required to pay Vectans various milestone and royalty payments in amounts ranging from 32% - 50% of the amounts paid by Bayer to EPI Health pursuant to the OTC License Agreement, and the Company will also be required to pay a portion of such milestone payments to EPG under the EPI Health Purchase Agreement.

Bayer has also agreed to pay to EPI Health a tiered royalty ranging from a mid-single digit to a low-double digit percentage of net sales of licensed products in the licensed territory, subject to a reduction in the royalty payments in certain circumstances.

Bayer is responsible for funding the development and commercial costs for the OTC product in the United States and Canada. The Company is obligated to perform certain oversight, review and supporting activities for Bayer, including (i) maintaining existing EPI Health patents related to the Sitavig product, and (ii) participating in a joint committee that oversees, reviews and approves development and commercialization activities under the OTC License Agreement.

The OTC License Agreement expires on the tenth anniversary of the first commercial sale of an OTC product on a country-by-country basis. The OTC License Agreement may be terminated by (i) Bayer without cause upon nine months' advance written notice to EPI Health, (ii) either party in the event of the other party's uncured material breach upon 60 days' advance written notice, (iii) either party, upon three months' notice, in the event Bayer provides EPI Health with notice that Bayer has elected to permanently discontinue development of the OTC product in the United States and Canada, and (iv) either party in the event of the other party's dissolution, liquidation, bankruptcy or insolvency. On the tenth anniversary of the first commercial sale of the OTC product on a country-by-country basis, assuming Bayer is not in breach and the OTC License Agreement has not been terminated, Bayer will have an irrevocable, royalty-free license to commercialize the OTC product without any further obligations to EPI Health.

Nuvail Agreements

On November 7, 2021, a predecessor of EPI Health entered into an exclusive license agreement with Chesson Laboratory Associates, Inc. ("Chesson"), as subsequently amended, for the sale of Nuvail, and pursuant to such agreement, EPI Health serves as an exclusive distributor of this product in the United States. Pursuant to the Nuvail license agreement, EPI Health is required to pay a tiered royalty up to a low double digit percentage of net sales of Nuvail, subject to a minimum annual royalty payment. The initial term of the license agreement expired in 2021 and was automatically extended for an additional five year renewal period. The license agreement may be terminated by either party for material breach. Chesson may terminate the license agreement early for convenience upon 12 months' notice but is required to pay a termination fee based on a multiple of trailing twelve months gross sales.

UNC Agreements

The Amended, Restated and Consolidated License Agreement dated June 27, 2012, as amended, with the University of North Carolina at Chapel Hill ("UNC," and such agreement, the "UNC License Agreement") provides the Company with an exclusive license to issued patents and pending applications directed to the Company's library of Nitricil compounds, including patents issued in the United States, Japan and Australia, with claims intended to cover NVN1000, the new chemical entity ("NCE") for the Company's current product candidates. The UNC License Agreement requires the Company to pay UNC up to \$425 in regulatory and commercial milestones on a licensed product by licensed product basis and a running royalty percentage in the low single digits on net sales of licensed products. Licensed products include any products being developed by the Company or by its sublicensees.

Unless earlier terminated by the Company at its election, or if the Company materially breaches the agreement or becomes bankrupt, the UNC License Agreement remains in effect on a country by country and licensed product by licensed product basis until the expiration of the last to expire issued patent covering such licensed product in the applicable country. The projected date of expiration of the last to expire of the patents issued under the UNC License Agreement is 2036.

Other Research and Development Agreements

The Company has entered into various licensing agreements with universities and other research institutions under which the Company receives the rights, and in some cases substantially all of the rights, of the inventors, assignees or co-assignees to produce and market technology protected by certain patents and patent applications. In addition to the UNC License Agreement, which is the Company's primary license agreement, the counterparties to the Company's various other licensing agreements are the University of Akron Research Foundation, Hospital for Special Surgery, Strakan International S.a.r.l., which is a licensee of the University of Aberdeen, KIPAX AB and KNOW Bio.

The Company is required to make payments based upon achievement of certain milestones and will be required to make royalty payments based on a percentage of future sales of covered products or a percentage of sublicensing revenue. As future royalty payments are directly related to future revenues (either sales or sublicensing), future commitments cannot be determined. No accrual for future payments under these agreements has been recorded, as the Company cannot estimate if, when or in what amount payments may become due.

KNOW Bio Agreements

On December 30, 2015, the Company completed the distribution of 100% of the outstanding membership interests of KNOW Bio, LLC ("KNOW Bio"), a former wholly owned subsidiary of the Company, to Novan's stockholders (the "Distribution"), pursuant to which KNOW Bio became an independent privately held company. In connection with the Distribution, the Company entered into exclusive license agreements and sublicense agreements with KNOW Bio, as described below. The agreements will continue for so long as there is a valid patent claim under the respective agreement, unless earlier terminated, and upon expiration, will continue as perpetual non-exclusive licenses. KNOW Bio has the right to terminate each such agreement, for any reason upon 90 days advance written notice to the Company.

License of existing and potential future intellectual property to KNOW Bio. The Company and KNOW Bio entered into an exclusive license agreement dated December 29, 2015 (the "KNOW Bio License Agreement"). Pursuant to the terms of the KNOW Bio License Agreement, the Company granted to KNOW Bio exclusive licenses, with the right to sublicense, under certain United States and foreign patents and patent applications that were controlled by the Company as of December 29, 2015 or that became controlled by the Company between that date and December 29, 2018, directed towards nitric-oxide releasing compositions and methods of manufacturing thereof, including methods of manufacturing Nitricil compounds and other nitric oxide-based therapeutics.

Sublicense of UNC and other third party intellectual property to KNOW Bio. The Company and KNOW Bio also entered into sublicense agreements dated December 29, 2015 (the "KNOW Bio Sublicense Agreements" and together with the KNOW Bio License Agreement, the "Original KNOW Bio Agreements"). Pursuant to the terms of the KNOW Bio Sublicense Agreements, the Company granted to KNOW Bio exclusive sublicenses, with the ability to further sublicense, under certain of the United States and foreign patents and patent applications exclusively licensed to the Company from UNC under the UNC License Agreement, and another third party directed towards nitric oxide-releasing compositions, to develop and commercialize products utilizing the licensed technology. Under the exclusive sublicense to the UNC patents and applications (the "UNC Sublicense Agreement"), KNOW Bio is subject to the terms and conditions under the UNC License Agreement, including milestone and diligence payment obligations. However, pursuant to the terms of the UNC License Agreement, the Company is directly obligated to pay UNC any future milestones or royalties, including those resulting from actions conducted by the Company's sublicensees, including KNOW Bio. Therefore, in the event of KNOW Bio non-performance with respect to its obligations under the UNC Sublicense Agreement, the Company would be obligated to make such payments to UNC. KNOW Bio would then become obligated to repay the Company pursuant to the UNC Sublicense Agreement, otherwise KNOW Bio would be in breach of its agreements with the Company and intellectual property rights would revert back to the Company. There were no milestone or royalty payments required during the three months ended March 31, 2022 and 2021.

On October 13, 2017, the Company and KNOW Bio entered into certain amendments to the Original KNOW Bio Agreements (the "KNOW Bio Amendments"). Pursuant to the terms of the KNOW Bio Amendments, the Company re-acquired from KNOW Bio exclusive, worldwide rights under certain United States and foreign patents and patent applications controlled by the Company as of December 29, 2015, and that became controlled by the Company between December 29, 2015 and December 29, 2018, directed towards nitric oxide-releasing compositions and methods of manufacturing thereof, including methods of manufacturing Nitricil compounds, and other nitric oxide-based therapeutics, to develop and commercialize products for all diagnostic, therapeutic, prophylactic and palliative uses for any disease, condition or disorder caused by certain oncoviruses (the "Oncovirus Field").

KNOW Bio also granted to the Company an exclusive license, with the right to sublicense, under any patents and patent applications which became controlled by KNOW Bio during the three-year period between December 29, 2015 and December 29, 2018 and directed towards nitric oxide-releasing compositions and methods of manufacturing thereof, including methods of manufacturing Nitricil compounds, and other nitric oxide-based therapeutics, but not towards medical devices, to develop and commercialize products for use in the Oncovirus Field.

Upon execution of the KNOW Bio Amendments, in exchange for the Oncovirus Field rights, the Company paid KNOW Bio a non-refundable upfront payment of \$250. Products the Company develops in the Oncovirus Field based on Nitricil will not be subject to any further milestones, royalties or sublicensing payment obligations to KNOW Bio under the KNOW Bio Amendments. However, if the Company develops products in the Oncovirus Field that incorporate a certain nitric oxide-releasing composition specified in the KNOW Bio Amendments and (i) are covered by KNOW Bio patents or (ii) materially use or incorporate know-how of KNOW Bio or the Company related to such composition that was created between December 29, 2015 and December 29, 2018, the Company would be obligated to make the certain contingent milestone and royalty payments to KNOW Bio under the KNOW Bio Amendments.

The rights granted to the Company in the Oncovirus Field in the KNOW Bio Amendments continue for so long as there is a valid patent claim under the Original KNOW Bio Agreements, and upon expiration continue on a perpetual non-exclusive basis, and are subject to the termination rights of KNOW Bio and the Company that are set forth in the Original KNOW Bio Agreements. In addition, under the KNOW Bio Amendments, KNOW Bio may terminate the rights granted to the Company in the Oncovirus Field without terminating the Original KNOW Bio Agreements.

The KNOW Bio Amendments also provide a mechanism whereby either party may cause a NCE covered by the Original KNOW Bio Agreements to become exclusive to such party by filing an investigational new drug application ("IND") on the NCE. An NCE that becomes exclusive to a party under this provision may not be commercialized by the other party until the later of expiration of patents covering the NCE or regulatory exclusivity covering the NCE. A party who obtains exclusivity for an NCE must advance development of the NCE pursuant to terms of the KNOW Bio Amendments in order to maintain such exclusivity; otherwise, such exclusivity will expire.

Note 13: Net Product Revenues

The Company has the following actively promoted products that generate net product revenues:

Rhofade (oxymetazoline hydrochloride cream, 1%), or Rhofade, is an alpha1A adrenoceptor agonist indicated for the topical treatment of persistent facial erythema associated with rosacea in adults.

Minolira (biphasic minocycline hydrochloride immediate release/extended release 105 mg and 135 mg tablets), or Minolira, is indicated to treat inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older.

Cloderm (clocortoline pivalate cream 0.1%), or Cloderm, is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

The post-acquisition operating results of EPI Health are reflected within the Company's condensed consolidated statement of operations and comprehensive loss for the three months ended March 31, 2022, specifically from March 11, 2022 through March 31, 2022. Net product revenues are summarized as follows:

	l Net Product Revenues	Percentage of Net Product Revenues		
Rhofade	\$ 838	117	%	
Minolira	78	11	%	
Cloderm	42	6	%	
Other	(240)	(34)	%	
Net product revenues	\$ 718	100	%	

For the period March 11, 2022 through March 31, 2022, the Company recorded adjustments for certain commercial products for accruals that were assumed as of the EPI Health Acquisition date. As such, the Other category presented in the table above is a net negative balance for the period presented.

As of March 31, 2022, two of the Company's customers accounted for more than 10% of its total accounts receivable balance at 23% and 14%, respectively.

For the three months ended March 31, 2022, one of the Company's customers accounted for more than 10% of its total gross product revenues, at 13%.

Note 14: License and Collaboration Revenues

The Company has the following actively promoted products that generate license and collaboration revenues:

Wynzora (calcipotriene and betamethasone dipropionate cream), or Wynzora, is a combination of calcipotriene, a vitamin D analog, and betamethasone dipropionate, a corticosteroid, indicated for the topical treatment of plaque psoriasis in patients 18 years of age or older.

Cloderm AG (clocortoline pivalate cream 0.1%), or Cloderm AG, is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

The post-acquisition operating results of EPI Health are reflected within the Company's condensed consolidated statement of operations for the three months ended March 31, 2022, specifically from March 11, 2022 through March 31, 2022. License and collaboration revenues are summarized as follows:

	Total Lice	nse and Collaboration Revenues	Percentage of License and Collaboration Revenues	
Sato Agreement - SB206 and SB204	\$	646	55	%
MC2 Agreement - Wynzora		413	35	%
Prasco Agreement - Cloderm AG		115	10	%
License and collaboration revenues	\$	1,174	100	%

Sato Agreement

The Company assessed the Sato Agreement in accordance with ASC 606, Revenue from Contracts with Customers, and concluded that the contract counterparty, Sato, is a customer within the scope of Topic 606. The Company identified the following promises under the Sato Agreement (i) the grant of the intellectual property license to Sato, (ii) the obligation to participate in a joint committee that oversees, reviews, and approves Sato's research and development activities and provides advisory support during Sato's development process, (iii) the obligation to manufacture and supply Sato with all quantities of licensed product required for development activities in Japan, and (iv) the stand-ready obligation to perform any necessary repeat preclinical studies, up to \$1,000 in cost. The Company determined that these promises were not individually distinct because Sato can only benefit from these licensed intellectual property rights and services when bundled together; they do not have individual benefit or utility to Sato. As a result, all promises have been combined into a single performance obligation.

The Sato Agreement also provides that the two parties agree to negotiate in good faith the terms of a commercial supply agreement pursuant to which the Company or a third-party manufacturer would be the exclusive supplier to Sato of the API for the commercial manufacture of licensed products in the licensed territory. The Company concluded this obligation to negotiate the terms of a commercial supply agreement does not create (i) a legally enforceable obligation under which the Company may have to perform and supply Sato with API for commercial manufacturing, or (ii) a material right because the incremental commercial supply fee consideration framework in the Sato Agreement is representative of a stand-alone selling price for the supply of API and does not represent a discount. Therefore, this contract provision is not considered to be a promise to deliver goods or services and is not a performance obligation or part of the combined single performance obligation described above.

Sato Amendment

On October 5, 2018, the Company and Sato entered into the second amendment to the Sato Agreement (the "Sato Amendment"). The Sato Amendment expanded the Sato Agreement to include SB206, the Company's drug candidate for the treatment of viral skin infections. The Company assessed the Sato Agreement in accordance with Topic 606 and concluded the contract modification should incorporate the additional goods and services provided for in the Sato Amendment into the existing, partially satisfied single bundled performance obligation that will continue to be delivered to Sato over the remaining development period. The Company determined that this contract modification accounting is appropriate as the additional goods and services conveyed under the Sato Amendment were determined to not be distinct from the single performance obligation,

and the additional consideration provided did not reflect the standalone selling price of those additional goods and services. As such, the Company recorded a cumulative adjustment as of the amendment execution date to reflect revenue that would have been recognized cumulatively for the partially completed bundled performance obligation.

The Company concluded that the following elements of consideration would be included in the transaction price as they were (i) received prior to March 31, 2022, or (ii) payable upon specified fixed dates and were not contingent upon clinical or regulatory success in Japan:

- The 1.25 billion JPY (approximately \$10,813 USD) original upfront payment received on January 19, 2017 following the execution of the Sato Agreement on January 12, 2017.
- A milestone payment of 0.25 billion JPY (approximately \$2,162 USD) received during the fourth quarter of 2018 following Sato's initiation of a Phase 1 trial in Japan.
- The Sato Amendment upfront payment of 1.25 billion JPY, payable in installments of 0.25 billion JPY, 0.5 billion JPY and 0.5 billion JPY on October 5, 2018, February 14, 2019 and September 13, 2019, respectively. On October 23, 2018, the Company received the first installment from the Sato Agreement of 0.25 billion JPY (approximately \$2,224 USD). On March 14, 2019, the Company received the second installment payment related to the Sato Agreement of 0.5 billion JPY (approximately \$4,460 USD). On November 7, 2019, the Company received the third installment payment related to the Sato Agreement of 0.5 billion JPY (approximately \$4,554 USD).
- An aggregate of 1.0 billion JPY in non-contingent milestone payments that become payable upon the earlier occurrence of specified fixed dates in the future or the achievement of specified milestone events. On May 20, 2021, the Company received one such non-contingent milestone payment in the form of a payment of 0.5 billion JPY (approximately \$4,572 USD) related to achievement of a time-based developmental milestone. On February 28, 2022, the Company received the remaining time-based milestone payment of 0.5 billion JPY (approximately \$4,323 USD).

The Company concluded that the following elements of consideration would not be included in the transaction price as they are contingent upon clinical or regulatory success in Japan:

- Up to an aggregate of 0.5 billion JPY upon the achievement of various development and regulatory milestones.
- Up to an aggregate of 3.9 billion JPY upon the achievement of various commercial milestones.
- A tiered royalty ranging from a mid-single digit to a low-double digit percentage (adjusted from a mid-single digit percentage in the Sato Agreement) of net sales of licensed products in the licensed territory, subject to a reduction in the royalty payments in certain circumstances.

The payment terms contained within the Sato Agreement related to upfront, developmental milestone and sales milestone payments are of a short-term nature and, therefore, do not represent a financing component requiring additional consideration.

The following tables present the Company's contract assets, contract liabilities and deferred revenue balances for the dates indicated.

	Contract Asset	t	Contract Liability		Net Deferred Revenue	
December 31, 2021	\$	_	\$ 13,25	1 \$	13,251	
March 31, 2022	\$	_	\$ 12,60	5 \$	12,605	
	Short-term Defer Revenue	red	Long-term Deferred Revenue		Net Deferred Revenue	
December 31, 2021	Revenue	2,586			Net Deferred Revenue 13,251	
December 31, 2021	Revenue		Revenue			

The Company has recorded the Sato Agreement (both the initial agreement and as amended by the Sato Amendment) transaction price, including the upfront payments received and the unconstrained variable consideration, as deferred revenue (comprised of (i) a contract liability, net of (ii) a contract asset).

The change in the net deferred revenue balance during the three months ended March 31, 2022 was associated with the recognition of license and collaboration revenue associated with the Company's performance during the period (continued amortization of deferred revenue).

During the three months ended March 31, 2022 and 2021, the Company recognized \$646 and \$747, respectively, in license and collaboration revenue under the Sato Agreement. The Company has concluded that the above consideration is probable of not resulting in a significant revenue reversal and therefore included in the transaction price and is allocated to the single performance obligation. No other variable consideration under the Sato Agreement is probable of not resulting in a significant revenue reversal as of March 31, 2022 and therefore, is currently fully constrained and excluded from the transaction price.

The Company evaluated the timing of delivery for its performance obligation and concluded that a time-based input method is most appropriate because Sato is accessing and benefiting from the intellectual property and technology (the predominant items of the combined performance obligation) ratably over the duration of Sato's estimated development period in Japan. Although the Company concluded that the intellectual property is functional rather than symbolic, the services provided under the performance obligation are provided over time. Therefore, the allocated transaction price will be recognized using a time-based input method that results in straight-line recognition over the Company's performance period.

The Company monitors and reassesses the estimated performance period for purposes of revenue recognition during each reporting period. The Company currently estimates a 10-year performance period, completing in the third quarter of 2024, based upon a Sato-prepared SB206 Japanese development program timeline. The SB204 Japanese development plan and program timeline has not been presented by Sato and remains under evaluation by the Company and Sato. Currently, the Company understands that the progression of the Japanese SB204 program could follow the same timeline as the Japanese SB206 program, subject to the nature of the results of Sato's comprehensive asset developmental program, including SB206.

The estimated timeline remains subject to prospective reassessment and adjustment based upon Sato's interaction with the Japanese regulatory authorities and other developmental and timing considerations. The combined SB204 and SB206 development program timeline in Japan is continuously reevaluated by Sato and the Company, and may potentially be further affected by various factors, including (i) the analyses, assessments and decisions made by the joint development committee and the applicable regulatory authorities, which will influence and establish the combined SB204 and SB206 Japan development programplan, (ii) the remaining timeline and progression of the SB206 NDA submission in the United States, which has been and may be further impacted by the COVID-19 pandemic, (iii) the API and drug product supply chain progression, including the Company's in-house drug manufacturing capabilities, (iv) the Company's manufacturing technology transfer projects with third-party CMOs, and (v) a drug delivery device technology enhancement project with a technology manufacturing vendor.

If the duration of the combined SB204 and SB206 development program timeline is further affected by the establishment of or subsequent adjustments to, as applicable, the mutually agreed upon SB204 and SB206 development plan in the Japan territory, the Company will adjust its estimated performance period for revenue recognition purposes accordingly, as needed.

In future periods, the Company would lift the variable consideration constraint from each contingent payment if there were no longer a probable likelihood of significant revenue reversal. When the constraint is lifted from a milestone payment, the Company will recognize the incremental transaction price using the same time-based input method that is being used to recognize the revenue, which results in straight-line recognition over the performance period. If the Company's performance is not yet completed at the time that the constraint is lifted, a cumulative catch-up adjustment will be recognized in the period. If no other performance is required by the Company at the time the constraint is lifted, the Company expects to recognize all revenue associated with such milestone payments at the time that the constraint is lifted.

Performance Obligations under the Sato Agreement

The net amount of existing performance obligations associated with the Sato Agreement unsatisfied as of March 31, 2022 was \$12,605. The Company expects to recognize approximately 21% of the remaining performance obligations as revenue over the next 12 months, and the balance thereafter. The Company applied the practical expedient and does not disclose information about variable consideration related to sales-based or usage-based royalties promised in exchange for a license of intellectual property.

MC2 Agreement

The Company assessed the MC2 Agreement in accordance with ASC 606, Revenue from Contracts with Customers. The Company identified the product distribution and commercialization services as the one single performance obligation under the MC2 Agreement. Per the MC2 agreement, the Company proposes a commercialization plan and incremental cost budget annually, which is developed in consultation with and subject to the approval of MC2. The Company is required to use commercially reasonable efforts to perform its commercialization activities in accordance with the commercialization plan, although the Company is not obligated to sell any minimum amount of Wynzora. MC2 then pays the Company on a quarterly basis prior to such calendar quarter for incremental costs to be incurred by the Company in the promotion and commercialization of Wynzora, including the supply price of Wynzora product inventory, in line with the budget.

The Company and MC2 work collaboratively in promoting and commercializing Wynzora. For instance, pursuant to the MC2 Agreement, MC2 is responsible for leading the overall strategy of messaging for the promotional materials for Wynzora and the Company is responsible for generating such promotional materials and executing all field promotional and sales activities via the Company's existing commercial sales force. MC2 is responsible for manufacturing Wynzora, and subject to MC2's obligation to supply product under the supply terms, the Company fills orders and distributes Wynzora. The parties share regulatory responsibilities, and except for the regulatory responsibilities assigned to the Company under the terms of the MC2 Agreement, MC2 is responsible for maintaining the NDA for Wynzora and all remaining regulatory activities. The MC2 Agreement also establishes a joint steering committee, which monitors and oversees the development, promotion, commercialization, and manufacturing of Wynzora, coordinates the collaborative activities of the parties and resolves disputes.

The transaction price will be allocated entirely to the single performance obligation. Further, the variable consideration is allocated to each distinct period of service, which is determined to be each year in which the pricing structure resets. During the year, the Company will estimate the variable consideration that will be earned and recognize that amount, updating its estimate of variable consideration each reporting period (quarterly). The Company determined that revenue will be recognized at a point in time, upon arranging for the delivery and distribution of Wynzora product on behalf of MC2.

During the three months ended March 31, 2022, the Company recognized \$413 in license and collaboration revenue under this agreement.

Performance Obligations under the MC2 Agreement

The net amount of existing performance obligations related to prepayments for future costs under the MC2 Agreement as of March 31, 2022 was \$3,237 and is reflected in the current portion of short-term deferred revenue within the condensed consolidated balance sheets. The Company expects to recognize these performance obligations as revenue over the next 3 months.

Note 15: Research and Development Agreements

Royalty and Milestone Payments Purchase Agreement with Reedy Creek Investments LLC

On April 29, 2019, the Company entered into a royalty and milestone payments purchase agreement (the "Reedy Creek Purchase Agreement") with Reedy Creek Investments LLC ("Reedy Creek"), pursuant to which Reedy Creek provided funding to the Company in an amount of \$25,000 for the Company to use primarily to pursue the development, regulatory approval and commercialization activities (including through out-license agreements and other third-party arrangements) for SB206, a topical gel with anti-viral properties being developed as a treatment for molluscum, and advancing programmatically such activities with respect to SB204, a once-daily, topical monotherapy being developed for the treatment of acne vulgaris, and SB414, a topical cream-based product candidate being developed for the treatment of atopic dermatitis. If the Company successfully commercializes any such product following regulatory approval, the Company will be obligated to pay Reedy Creek a low single digit royalty on net sales of such products in the United States, Mexico or Canada.

The Company determined that the Reedy Creek Purchase Agreement is within the scope of ASC 730-20, *Research and Development Arrangements*, and that there has not been a substantive and genuine transfer of risk related to the Reedy Creek Purchase Agreement. As such, the Company determined that the appropriate accounting treatment under ASC 730-20 was to record the proceeds of \$25,000 as cash and cash equivalents, as the Company had the ability to direct the usage of funds, and a long-term liability within its classified balance sheet.

Development Funding and Royalties Agreement with Ligand Pharmaceuticals Incorporated

On May 4, 2019, the Company entered into a development funding and royalties agreement (the "Ligand Funding Agreement") with Ligand Pharmaceuticals Incorporated ("Ligand"), pursuant to which Ligand provided funding to the Company of \$12,000, for the Company to use to pursue the development and regulatory approval of \$B206, a topical gel with anti-viral properties being developed as a treatment for molluscum.

Pursuant to the Ligand Funding Agreement, the Company will pay Ligand up to \$20,000 in milestone payments upon the achievement by the Company of certain regulatory and commercial milestones associated with SB206 or any product that incorporates or uses NVN1000, the API for the Company's clinical stage product candidates, as a treatment for molluscum. In addition to the milestone payments, the Company will pay Ligand tiered royalties ranging from 7% to 10% based on annual aggregate net sales of such products in the United States. Mexico or Canada.

The Company determined that the Ligand transaction is within the scope of ASC 730-20 as it represents an obligation to perform contractual services for the development of SB206 using commercially reasonable efforts. As such, the Company concluded that the appropriate accounting treatment under ASC 730-20 was to record the proceeds of \$12,000 as a liability and amortize the liability ratably during each reporting period, based on the Ligand funding as a percentage of the total direct costs incurred by the Company during the reporting period related to the estimated total cost to progress the SB206 program to a regulatory approval in the United States. The ratable Ligand funding is presented within the accompanying condensed consolidated statements of operations and comprehensive loss within research and development expenses associated with the SB206 program.

For the three months ended March 31, 2022 and 2021, the Company recorded contra-research and development expense related to the SB206 developmental program of \$297 and \$18, respectively, related to amortization of the Ligand Funding Agreement amount.

Note 16: Stock-Based Compensation

2016 Incentive Award Plan

During the three months ended March 31, 2022 and 2021, the Company continued to administer and grant awards under the 2016 Incentive Award Plan, as amended (the "2016 Plan"), the Company's only active equity incentive plan. Certain of the Company's stock options granted under the Company's 2008 Stock Plan (the "2008 Plan"), which is the predecessor to the 2016 Plan and became inactive upon adoption of the 2016 Plan effective September 20, 2016, remain outstanding and exercisable.

Stock Appreciation Rights

The Company has occasionally used stock appreciation rights ("SARs") as a component of executive compensation. As of December 17, 2019, the Company entered into an amended and restated employment agreement with Paula Brown Stafford which provided for a grant of 60,000 SARs with an exercise price of \$8.20 per share (the fair market value of the Company's common stock on the grant date) and with a ten year term. These SAR awards were vested in full as of December 31, 2021 and remain outstanding as of March 31, 2022

Tangible Stockholder Return Plan

On August 2, 2018, the Company's board of directors approved and established the Tangible Stockholder Return Plan, which was a performance-based long-term incentive plan (the "Performance Plan"). The Performance Plan was effective immediately upon approval and expired on March 1, 2022. The Performance Plan covered all employees, including the Company's executive officers, consultants and other persons deemed eligible by the Company's compensation committee. The core underlying metric of the Performance Plan was the potential achievement of two share price goals for the Company's common stock, which if achieved, could have represented measurable increases in stockholder value.

The Performance Plan expired on March 1, 2022. As the Company's stock price did not reach the minimum share price targets necessary to trigger a payment, no payments were made under the Performance Plan to any participants during the period the Performance Plan was effective.

Stock Compensation Expense

During the three months ended March 31, 2022 and 2021, the Company recorded stock-based compensation expense as follows:

	<u></u>	Three Months Ended March 31,			
	20	22		2021	
Stock options	\$	381	\$	7	
Stock appreciation rights		_		29	
Tangible Stockholder Return Plan		_		44	
Total	\$	381	\$	80	

Total stock-based compensation expense included in the accompanying condensed consolidated statements of operations and comprehensive loss is as follows:

	Th	Three Months Ended March 31,		
	20	22	2021	
Research and development	\$	73	\$	(52)
Selling, general and administrative		308		132
Total	\$	381	\$	80

Stock option activity for the three months ended March 31, 2022 is as follows:

	Shares Subject to Outstanding Options	Weighted- Average Exercise Price Per Share	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Options outstanding as of December 31, 2021	518,553	\$ 15.48		
Options granted	150,000	3.99		
Options forfeited	(3,025)	8.38		
Options exercised	_	_		
Options outstanding as of March 31, 2022	665,528	\$ 12.92	8.78	\$ 29

As of March 31, 2022, there were a total of 665,528 stock options outstanding and there were 1,066,249 shares available for future issuance under the 2016 Plan.

Note 17: Fair Value

The Company has contingent consideration associated with the EPI Health Acquisition that is required to be measured at fair value on a recurring basis, presented within the condensed consolidated balance sheets as both current and long-term liabilities, beginning as of March 11, 2022.

ASC 820-10, Fair Value Measurement Disclosure, requires use of a three-tiered hierarchy, which requires that fair value measurements be classified and disclosed in one of three tiers. These tiers are: Level 1, defined as quoted prices in active markets for identical assets or liabilities; Level 2, defined as valuations based on observable inputs other than those included in Level 1, such as quoted prices for similar assets and liabilities in active markets, or other inputs that are observable or can be corroborated by observable input data; and Level 3, defined as valuations based on unobservable inputs reflecting the Company's own assumptions, consistent with reasonably available assumptions made by other market participants.

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 and therefore, are based primarily upon estimates, are often calculated based on the economic and competitive environment, the characteristics of the asset or liability and other factors. Therefore, the results 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 uncertainties in any calculation technique, and changes in the underlying assumptions used, including discount rates and estimates of future cash flows, could significantly affect the results of current or future values. The Company utilizes fair value measurements to record fair value adjustments to certain assets and liabilities and to determine fair value disclosures.

The carrying values of accounts receivable, prepaid expenses and other current assets, accounts payable, and certain accrued expenses as of March 31, 2022 and December 31, 2021 approximate their fair values due to the short-term nature of these items. The Company's notes payable balance, which is comprised of the balance on the Seller Note, also approximates fair value as of March 31, 2022, as the effective interest rate on the notes payable approximates the rates available to the Company as of this date.

The Company's contingent consideration liability is measured on a recurring basis using level 3 inputs. The estimated fair value of the contingent consideration related to the EPI Health Acquisition requires significant management judgment and estimation, is calculated using a probability-weighted valuation model that measures the present value of the probable cash payments based upon the future milestone events of EPI Health at a discount rate that captures the risk associated with the liability, and is also based on a Monte Carlo simulation, whereby EPI Health's forecasted net sales from the EPI Health legacy products were simulated over the measurement period to calculate the contingent consideration.

For the three months ended March 31, 2022, there were no changes in fair value related to contingent consideration related to the EPI Health Acquisition based upon the closing date of March 11, 2022. See Note 2—"Acquisition of EPI Health" for additional detail regarding contingent consideration related to the transaction.

Note 18: Segment Information

The Company has determined that it operates in two segments, which represent (i) the promotion of commercial products for the treatment of medical dermatological conditions (the "Commercial Operations" segment), and (ii) research and development activities related to the Company's nitric oxide-based technology to develop product candidates (the "Research and Development Operations" segment).

- The Commercial Operations segment consists of the Company's portfolio of commercial products.
- · The Research and Development Operations segment consists of multiple drug product candidates under clinical development.

Costs associated with the development of SB206 are currently included in the Research and Development Operations segment. There are no significant inter-segment sales. The Company evaluates the performance of each segment based on operating profit or loss. There is no inter-segment allocation of non-operating expenses and income taxes. The Company's chief operating decision-maker ("CODM") is the Company's Chairman, President and Chief Executive Officer.

Three Months Ended

Segment revenue, net and comprehensive loss and total assets were as follows:

	March 31, 2022		
Revenue	<u>-</u>		
Commercial operations	\$	1,246	
Research and Development operations		682	
Total revenue	\$	1,928	
Net loss			
Commercial operations	\$	(726)	
Research and Development operations		(12,654)	
Net loss and comprehensive loss	\$	(13,380)	
	Mar	As of ech 31, 2022	
Assets			
Commercial operations	\$	59,050	
Research and Development operations		52,999	
Total assets	\$	112,049	

The net revenues attributed to the Commercial Operations segment are primarily derived from the sale of the Company's commercial products, and the net revenues attributed to the Research and Development Operations segment are primarily derived from the arrangement with the Company's licensing partner in Japan for SB206 and SB204. Drug development and potential commercialization costs are included in the Research and Development Operations segment. Total assets by reporting segment are not reviewed by the CODM when evaluating the reporting segments' performance, however, the Commercial Operations segment includes the acquired assets associated with the EPI Health Acquisition and changes in such assets, while the Research and Development Operations segment is comprised of the assets associated with the historical business of the Company related to the Company's product candidates that are in development.

Substantially all revenue was derived from product sales or from licensing agreements originating in the United States. All of the Company's long-lived assets are maintained in the United States.

Although all of the Company's operations are based in, and all net product revenue is generated from, sales in the United States, the revenue generated from its licensing partner in Japan was \$646, or 95% of total revenue during the three months ended March 31, 2022, which was attributed to the Research and Development Operations segment. During the three months ended March 31, 2021, the Company generated revenue from its licensing partner in Japan of \$747, or approximately 91% of total

revenue. Prior to the quarter ended March 31, 2022, the Company operated in only one segment, which was the Research and Development Operations segment.

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our condensed consolidated financial statements and notes thereto included in this Quarterly Report on Form 10-Q and our audited financial statements and notes thereto for the year ended December 31, 2021 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on February 18, 2022 (referred to herein as our Annual Report).

In addition to historical information, this discussion and analysis contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q are forward-looking statements. These statements are often identified by the use of words such as "believe," "contemplate," "continue," "due," "goal," "objective," "plan," "seek," "target," "expect," "believe," "anticipate," "intend," "may," "will," "would," "could," "should," "potential," "predict," "project," or "estimate," and similar expressions or variations. These statements are based on the beliefs and assumptions of management based on information currently available to management. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Except as may be required by law, we undertake no obligation to update any forward-looking statements.

These forward-looking statements are subject to numerous risks, including, without limitation, the following:

- We have incurred net losses since our incorporation and anticipate that we will continue to incur net losses for the foreseeable future.
- We have recently acquired EPI Health, LLC, or EPI Health, and such acquisition, the EPI Health Acquisition. EPI Health derives revenue from the sale of branded
 medical dermatology products. Achieving the anticipated benefits of the EPI Health Acquisition will depend in significant part upon us integrating the EPI Health
 businesses, operations, processes and systems in an efficient and effective manner, including potential synergies and the ability to successfully commercialize the
 product portfolio acquired.
- We will need significant additional funding to continue our commercial operating activities and for the advancement of our product development programs, including potential commercialization efforts for SB206, beyond what is currently included in our operating forecast and related cash projection. As of March 31, 2022, we had an accumulated deficit of \$292.3 million. If we are unable to raise capital when needed, we would be forced to delay, reduce, terminate or eliminate our product development programs, or our current and future commercialization efforts.
- Raising additional capital, including through the issuance of shares of our common stock through the March 11, 2022 Equity Distribution Agreement with Oppenheimer & Co. Inc., may reduce the trading price of our common stock. Any future additional issuances of equity, or debt convertible into equity, may result in significant dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies, product candidates or commercial products.
- The price of our common stock may be volatile and fluctuate significantly, which could result in substantial losses for our existing stockholders.
- Our revenue is dependent upon sales of our medical dermatology products, and any setbacks relating to the sale of such commercial products could impair our
 operating results, including if our competitors develop treatments for our commercial portfolio's target indications, which could limit our commercial opportunity and
 profitability.
- Our products and product candidates may pose safety issues, cause adverse events, have side effects or have other properties that could delay or prevent the regulatory approval for our product candidates, limit the commercial profile of an approved label or result in significant negative consequences.
- Our product candidates, if approved, and our commercial products may face significant competition, and our failure to effectively compete may prevent us from achieving significant market penetration or share. We face, and will continue to face, competition in the development and marketing of products from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies, including specialty and other large pharmaceutical companies, and OTC companies and generic manufacturers. The dermatology competitive landscape is highly fragmented, with many mid-size and smaller companies competing in the prescription sector. To successfully compete for business with managed care and pharmacy benefits management organizations, we must often

- demonstrate that our products offer not only medical benefits, but also cost advantages as compared with other forms of care.
- Our research and development activities relate solely to developing nitric oxide-based therapeutics to treat a range of diseases with significant unmet needs, and if we do not successfully achieve regulatory approval for any of our product candidates or successfully commercialize them, we may not be able to continue as a business.
- Clinical drug development involves a lengthy and expensive process with uncertain timelines and outcomes, and results of earlier studies and trials may not be predictive of future trial results. The results of any further development activities may not be sufficient to support a new drug application, or NDA, submission for or regulatory approval of any of our product candidates.
- Ongoing or future product development activities may not be successful, including in that our preclinical studies may not demonstrate proof-of concept or may show
 adverse toxicological findings, and our clinical trials may not show the requisite safety and efficacy of our product candidates. The regulatory approval processes of
 the Food and Drug Administration, or FDA, are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval
 for our product candidates on a timely basis or at all, our business will be substantially harmed.
- Delays or disruptions in the qualification of manufacturing facilities and processes or in the manufacture of our (i) active pharmaceutical ingredients, or APIs, including NVN1000 or any other NITRICIL new chemical entities, or NCEs, or (ii) clinical trial materials or commercial supplies of any approved product candidates, whether by us or any third-party manufacturer with whom we contract, including any delays in the commissioning of our new facility or in the transfer of technology to third-party manufacturers, could adversely affect our development timelines and result in increased costs of our development programs or in our breaching our obligations to others.
- We currently rely on third-party suppliers to provide the raw materials, finished goods and equipment that are used by us and our third-party manufacturers in the manufacture of our product candidates and commercial products. There are a limited number of suppliers for raw materials, including nitric oxide, and the equipment used to manufacture our product candidates. Any delay or disruption, especially in light of current global supply chain constraints, could adversely impact the timing or cost of our manufacturing activities or other associated development and commercialization activities.
- We currently rely on third-party logistics vendors to transport our raw materials, API, drug product and commercial products through our supply chain. Certain materials, including our API for our products in development, have designated hazard classifications that limit available transportation modes or quantities. Third-party logistics vendors may choose to delay or defer transportation of materials from time to time, which could adversely impact the timing or cost of our manufacturing activities or other associated development and commercialization activities.
- Many factors could cause production or distribution interruptions with the manufacture and distribution of any of our products and product candidates, including human error, natural disasters, pandemics, labor disputes, acts of terrorism or war, equipment malfunctions, or raw material shortages. If our commercial distribution partners are not able to satisfy our requirements within the expected timeframe, or are unable to provide us with accurate or timely information and data, including inventories and sales, serious adverse events, and/or product complaints, our business may be at risk. In addition, if specialty pharmacy services, including our third-party call center services, which provide patient support and financial services, prescription intake and distribution, reimbursement adjudication, and ongoing compliance support, is not effectively managed, the continuance of our sales of our commercial products or our product candidates, if approved, may be delayed or compromised. Finally, our third-party manufacturers may not be able to manufacture the materials required for our products or product candidates at a cost or in quantities necessary to make them commercially viable.
- We continue to assess global supply chain constraints, including any further impact of the COVID-19 pandemic and the military conflict between Ukraine and Russia, on our suppliers and vendors. Any delay could impact available inventories of our commercial products and our ability to meet demand. Furthermore, any further delay or disruption could adversely impact the timing for commissioning our new facility, which would cause us to rely solely on third parties for any small-scale manufacturing or other research and development and cGMP activities.
- We rely on third parties to conduct some of our preclinical studies, clinical trials, stability and analytical testing, and regulatory activities. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, or are adversely impacted by the COVID-19 pandemic, we may be unable to obtain regulatory approval for or commercialize any of our product candidates as planned or at all.

- We have entered into and rely on, and may enter into and rely on other, strategic relationships for the further development and commercialization of our products and product candidates. If we are unable to enter into such relationships on favorable terms or at all, or if such relationships are unsuccessful, if disputes arise between us and our strategic partners or if we fail to trigger contingent payments under such strategic relationships, we may be unable to realize the potential economic benefit of our products and product candidates.
- Changes to our leadership team or operational resources, including with the acquisition and integration of EPI Health, could prove disruptive to our operations and have adverse consequences for our business and operating results.
- If we are unable to obtain and maintain patent protection for our product candidates and commercial products, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology, product candidates and commercial products may be impaired.
- The ongoing military conflict between Russia and Ukraine has created additional volatile market conditions and uncertainties in the global economy, including increased cybersecurity risks.
- As a result of our operating losses and negative cash flows from operations, the report of our independent registered public accounting firm on our December 31, 2021 financial statements included an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern.
- We may not be able to achieve the objectives or successfully execute our strategy described in the sections entitled "Business Updates," "Commercial Portfolio," "Research and Development Portfolio," "Supply Chain" and "Manufacturing and Supplies" below.

For a further discussion of risks that could cause or contribute to differences between actual results and those implied by forward-looking statements, see the "Risk Factors" section in our Annual Report and in this Quarterly Report on Form 10-Q.

Novan is a registered trademark of our company in the United States. This Quarterly Report on Form 10-Q also includes trademarks, trade names and service marks that are the property of other organizations. Solely for convenience, our trademarks and trade names referred to in this Quarterly Report on Form 10-Q generally appear without any "TMP" or "®" symbol, but the absence of such symbols is not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of any applicable licensor, to these trademarks and trade names.

Overview

Novan, Inc. is a medical dermatology company primarily focused on researching, developing and commercializing innovative therapeutic products for skin diseases. Our goal is to deliver safe and efficacious therapies to patients, including developing product candidates where there are unmet medical needs. We are developing SB206 (berdazimer gel, 10.3%) as a topical prescription gel for the treatment of viral skin infections, with a current focus on molluscum contagiosum. We recently completed the EPI Health Acquisition. EPI Health equips us with a commercial infrastructure across sales, marketing, and communications, as well as a dedicated market access and pharmacy relation teams, and positions us as a fully integrated dermatology company with a pipeline of development candidates focused primarily on dermatological indications supported by a commercial platform to market and sell therapeutic products for skin diseases.

Following the acquisition, we employ approximately 100 staff, including sales personnel currently covering 42 territories. Through our acquisition of EPI Health, we promote products for plaque psoriasis, rosacea, acne and dermatoses, which we refer to as our Commercial Operations segment. We also have a pipeline of potential product candidates using our proprietary nitric oxide-based technology platform, NITRICIL, to generate new treatments for multiple indications, which we refer to as our Research and Development Operations segment. We disclose information about our reportable segments based on the way that we organize segments within the Company for making operating decisions and assessing financial performance. See "Note 18—Segment Information" to the accompanying condensed consolidated financial statements for certain financial information related to our reportable segments.

Business Updates

We continue to prepare for a regulatory submission and potential approval of SB206 as a treatment for molluscum. The timing of the targeted NDA submission is dependent upon (i) completion of our cGMP API registration batches, (ii) technical transfer and supportive manufacturing activities by our drug product CMO as it relates to the necessary registration batches of drug product, (iii) preparatory activities and data accumulation related to the NDA submission including conducting customary drug substance and drug product stability protocols, and (iv) regulatory and quality documentation compilation related to our preclinical CMC data related to the B-SIMPLE trials, and our drug manufacturing and related processes.

We are continuing to progress the prelaunch strategy and commercial preparations for SB206, if approved. We believe the addition of the EPI Health commercial infrastructure across the sales, marketing, and communications functions, in addition to the fully dedicated market access and pharmacy relation teams, will benefit the commercial launch of SB206, if approved. We continue to execute on the integration and combination of our companies.

Working Capital and Additional Capital Needs

We will continue to need additional funding to support our planned and future operating activities and make further advancements in our product development programs beyond what is currently included in our operating forecast and related cash projection. We believe that our existing cash and cash equivalents, plus expected receipts associated with product sales from our commercial portfolio, will provide us with adequate liquidity to fund our planned operating needs into the early fourth quarter of 2022. We do not currently have sufficient funds to complete the new drug application, or NDA, submission for SB206 (berdazimer gel, 10.3%) or commercialization of any of our product candidates that are under development, and our funding needs will largely be determined by our commercialization strategy for SB206 (berdazimer gel, 10.3%), subject to the NDA submission timing and the regulatory approval process and outcome.

Further advancement of our molluscum program, including through the potential NDA submission of SB206, or advancement of any other early-stage or late-stage clinical program across our platform, has been and may be further impacted by the COVID-19 pandemic and is subject to our ability to secure additional capital. Sources of additional capital may potentially include (i) equity or debt financings, including through sales of common stock or (ii) non-dilutive sources, such as partnerships, collaborations, licensing, grants or other strategic relationships. Any issuance of equity, or debt convertible into equity, would result in further significant dilution to our existing stockholders.

In addition to the regulatory progression of SB206, including implementing prelaunch strategy and commercial preparation, subject to obtaining additional financing or strategic partnering, our intention is to progress (a) SB204, a topical monotherapy for the treatment of acne, by commencing a pivotal Phase 3 study, and (b) SB019, as a potential intranasal treatment option for COVID-19, by submitting an investigational new drug application, or IND, and commencing Phase 1 activities.

As of March 31, 2022, we had total cash and cash equivalents of \$35.5 million and positive working capital of \$11.7 million. As of March 31, 2022, we had \$49.4 million in remaining availability for sales of our common stock under the Equity Distribution Agreement dated March 11, 2022, or the Equity Distribution Agreement, with Oppenheimer & Co., Inc., or Oppenheimer. Pursuant to the Equity Distribution Agreement, we may from time to time issue and sell our common stock to or through Oppenheimer, acting as our sales agent, in at-the-market transactions. See "Note 11—Stockholders' Equity" to the accompanying condensed consolidated financial statements for more information on the Equity Distribution Agreement.

We will need significant additional funding to continue our operating activities and make further advancements in our product development programs beyond what is currently included in our operating forecast and related cash projection. Please refer to "Liquidity and Capital Resources" for further discussion of our current liquidity and our future funding needs.

COVID-19 Overview

We have continued to closely monitor and rapidly respond to the ongoing impact of the COVID-19 pandemic on our employees, our community and our business operations. We have been able to resume normal operations in most areas of our business but have adopted a series of precautionary measures and plan to continue to adjust as the circumstances warrant.

The timetable for development of our product candidates has been impacted and may face further disruption and our business could be further adversely affected by the outbreak of COVID-19 and its variants. In particular, COVID-19 impacted the timing of trial initiation of our B-SIMPLE4 Phase 3 trial. In addition, certain factors from the COVID-19 pandemic may delay or otherwise adversely affect our generation of product revenues from our portfolio of therapeutic products for skin diseases, as well as adversely impact our business generally. Therefore, we continue to assess any potential further impact of COVID-19 on our operations.

Commercial Portfolio

On March 11, 2022, we completed the acquisition of EPI Health, a commercial-stage pharmaceutical company founded in 2017 that focuses on the commercialization of medical dermatology pharmaceutical products for the treatment of skin conditions. EPI Health's current portfolio includes six branded prescription drugs. EPI Health actively promotes four medical dermatological products in the U.S. and derives revenue from the sale of these branded products through pharmaceutical wholesalers as well as direct to pharmacies. These prescription dermatology therapies are targeted to patients with plaque psoriasis, rosacea, acne, and dermatoses. The branded and promoted product portfolio currently includes Wynzora, Rhofade, Minolira, and Cloderm.

The following summarizes the complete EPI Health product portfolio:

Wynzora Cream (calcipotriene and betamethasone dipropionate cream), or Wynzora, is a combination of calcipotriene, a vitamin D analog, and betamethasone dipropionate, a corticosteroid, indicated for the topical treatment of plaque psoriasis in patients 18 years of age or older. EPI Health entered into a collaboration agreement with MC2 Therapeutics, or MC2, in August 2020, as amended effective January 1, 2022, for the commercialization of Wynzora in the United States, or the MC2 Agreement. Under the MC2 Agreement, MC2 retains full ownership of Wynzora. In particular, EPI Health utilizes its commercial infrastructure to promote and sell Wynzora in return for retaining a share of net sales of Wynzora in the United States. The portion of net sales EPI Health retains varies depending on the aggregate annual net sales of the product, and ranges from a percentage in the mid-teens to a mid-single digit percentage as net sales reach certain thresholds. Additionally, MC2 also pays for certain incremental costs incurred by EPI Health in commercialization activities according to a budget to be agreed annually between EPI Health and MC2. The term of the MC2 Agreement expires in June 2028, unless earlier terminated by either party under certain conditions.

Rhofade (oxymetazoline hydrochloride cream, 1%), or Rhofade, is an alpha1A adrenoceptor agonist indicated for the topical treatment of persistent facial erythema associated with rosacea in adults. EPI Health acquired the rights to Rhofade in the United States in October 2019. In connection with that acquisition and other historical acquisitions related to Rhofade, EPI Health is required to make certain milestone payments based on future net sales of Rhofade along with paying a combined royalty on net sales of Rhofade and related products initially in the low double digits, which rate may increase based on the thresholds of net sales achieved by EPI Health.

Minolira (biphasic minocycline hydrochloride immediate release/extended release 105 mg and 135 mg tablets), or Minolira, is indicated to treat inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older. EPI Health acquired the rights to Minolira in the United States in August 2018. In connection with that acquisition, EPI Health is required to pay certain milestones based on future sales of Minolira.

Cloderm (clocortoline pivalate cream 0.1%), or Cloderm, is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. EPI Health acquired the rights to Cloderm in September 2018. In connection with that acquisition, EPI Health is required to pay minimum royalty payments on net sales of Cloderm, subject to meeting certain net sales milestones.

Sitavig (acyclovir 50mg buccal tablets), or Sitavig, is indicated for the treatment of recurrent herpes labialis (cold sores) in immunocompetent adults. EPI Health is party to a license agreement with Vectans Pharma, or Vectans, for the rights to commercialize Sitavig in the United States and Canada.

Nuvail (poly-ureaurethane 16% nail solution), or Nuvail, is indicated for managing signs and symptoms of nail dystrophy, i.e. nail splitting or nail fragility, for intact or damaged nails. EPI Health is party to a license agreement for the sale of Nuvail and serves as an exclusive distributor of this product in the United States.

Research and Development Portfolio

Our proprietary technology platform leverages nitric oxide's naturally occurring anti-viral, anti-bacterial, anti-fungal, and immunomodulatory mechanisms of action to treat a range of diseases with significant unmet needs. Nitric oxide plays a vital role in the natural immune system response against microbial pathogens and is a critical regulator of inflammation. Our ability to harness nitric oxide and its multiple mechanisms of action has enabled us to create a platform with the potential to generate differentiated product candidates. The two key components of our nitric oxide platform are our proprietary Nitricil technology, which drives the creation of macromolecular NCEs and our formulation science, both of which we use to tune our product candidates for specific indications. Our ability to deploy nitric oxide in a solid form, on demand and in localized formulations allows us the potential to improve patient outcomes in a variety of diseases.

We have clinical-stage dermatology and anti-infective drug candidates with multi-factorial (SB204), anti-viral (SB206), anti-fungal (SB208), and anti-inflammatory (SB414) mechanisms of action. We have also introduced a possible anti-viral product candidate for the treatment of external genital warts (SB207). We have conducted or are currently conducting preclinical work on NCEs, including berdazimer sodium, and formulations for the potential treatment of (i) SARS-CoV-2, the virus that causes COVID-19 (SB019), (ii) antimicrobial indications for the adjacent companion animal health market (NVN4100), (iii) cervical intraepithelial neoplasia caused by high-risk human papilloma virus in the men's and women's health field (WH504 and WH602), and (iv) inflammatory disorders.

Our primary programmatic focus is on our molluscum product candidate, SB206, and we intend to continue to focus our near term development efforts on this program. We are targeting a potential NDA submission of SB206 for molluscum no later than the fourth quarter of 2022.

Priority Development Pipeline

SB206, a Topical Anti-viral Treatment for Molluscum Contagiosum (a Viral Skin Infection)

We are developing SB206 (12% berdazimer sodium, 10.3% berdazimer) as a topical gel with anti-viral properties for the treatment of viral skin infections, with a current focus on molluscum contagiosum. Molluscum is a contagious skin infection caused by the molluscipoxvirus that affects up to six million people in the United States annually. The greatest incidence is in children aged one to 14 years. The average time to resolution is 13 months; however, 13% of children experience lesions that may not resolve in 24 months. There is no FDA-approved prescription drug treatment for molluscum. More than half of patients diagnosed with the infection are untreated. The majority of patients in the United States that receive treatment are treated with potentially painful procedures and the remaining are often prescribed products indicated for the treatment of external genital warts.

Following positive results of our phase 3 B-SIMPLE4 trial for SB206, in April 2022, we held a pre-NDA meeting with the FDA, and subsequently received written minutes related to this interaction. Based on the information provided and our consideration thereof, we are currently targeting a potential NDA submission of SB206 for molluscum no later than the fourth quarter of 2022 and are preparing for regulatory filing and potential approval of SB206 as a treatment for molluscum.

SB204, for the Treatment of Acne Vulgaris

SB204 is a product candidate designed as a once-daily, topical monotherapy for the treatment of acne vulgaris, a multi-factorial disease with multiple aspects of the disease pathology (immunomodulatory and anti-bacterial). Acne vulgaris is the most common skin condition in the United States. The disease ranges in severity from mild to severe cystic acne and causes both physical and psychological effects, including permanent scarring, anxiety, depression and poor self-esteem. Acne is a multi-factorial disease with several mechanistic contributors to the disease pathology, often requiring multiple treatments that address more than one of the major causes of acne pathogenesis. Localized nitric oxide delivery may provide immunomodulatory (anti-inflammatory) and anti-bacterial mechanisms of action from a single active ingredient. We believe that acne continues to be characterized as an unmet medical need due to the difficulty of balancing efficacy, systemic safety and cutaneous tolerability, as well as the growing concerns with anti-bacterial resistance with existing therapies. In our SB204 clinical development program, topical application of SB204 has been well-tolerated with no significant safety concerns identified. In maximal-use pharmacokinetic trials that we have conducted in adult and pediatric patients with acne vulgaris, we observed no detectable systemic exposure from SB204 following its topical application.

Based on the positive pivotal Phase 3 results in the SB206 molluscum development program, we believe we can optimize the trial design of a pivotal Phase 3 study for SB204 that has the potential to serve as a second pivotal trial to support an NDA submission. As such, our intention is to progress SB204 by commencing a pivotal Phase 3 study, subject to obtaining additional financing or strategic partnering.

Sato Agreement

In January 2017, we licensed rights to Sato Pharmaceutical Co., Ltd., or Sato, to develop, use, and sell SB204 in certain topical dosage forms in Japan for the treatment of acne vulgaris, and to manufacture the finished form of SB204 for sale in Japan. In 2018, we licensed rights to Sato to develop, use, and sell SB206 in certain topical dosage forms in Japan for the treatment of viral skin infections, and to manufacture the finished form of SB206 for sale in Japan. The significant terms and the related accounting considerations of our licensing arrangement with Sato are further described in "Note 14—License and Collaboration Revenues" to the accompanying condensed consolidated financial statements. For further information regarding the current status of the Japanese SB206 and SB204 programs see "Note 12—Licensing and Collaboration Arrangements" to the accompanying condensed consolidated financial statements.

SB019, an intranasal treatment option for Coronaviridae (COVID-19)

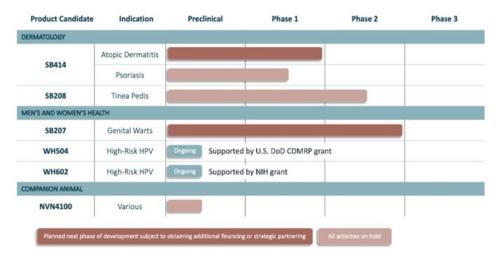
We continue to explore the use of our proprietary Nitricil technology to progress SB019, a potential intranasal treatment option for COVID-19, targeting the reduction of viral shedding and transmission. Nitric oxide has generally demonstrated the ability to inhibit viral replication of viruses within the *Coronaviridae* family, and we have an extensive body of *in vitro* and *in vivo* data demonstrating the efficacy of our proprietary technology for other anti-viral indications. Based on the scientific literature and data available to-date related to berdazimer sodium and SB206, we believe that nitric oxide may inhibit viral replication by disrupting protein function critical for viral replication and infection through generation of reactive intermediates.

Based on the positive preclinical and clinical data demonstrating anti-viral effect of berdazimer sodium against multiple viruses, as well as the public health need to reduce breakthrough infections and transmission, we have advanced our SB019 product candidate with the submission of a pre-IND in April 2022.

We currently await feedback and guidance from the FDA to inform next steps. As such, our intention is to progress SB019 by submitting an IND and commencing Phase 1 activities, subject to regulatory feedback and obtaining additional financing or strategic partnering.

Pipeline Expansion Opportunities

Our pipeline expansion opportunities are currently positioned as shown in the figure below:



SB414, for the Treatment of Inflammatory Skin Diseases, including Atopic Dermatitis and Psoriasis

SB414 is a product candidate designed as a topical cream for the treatment of inflammatory skin diseases, with a focus on the treatment of atopic dermatitis and psoriasis. The SB414 program is currently on hold with further advancement subject to obtaining additional financing or strategic partnering.

SB208, for the Treatment of Athlete's Foot (Tinea Pedis) and Fungal Nail Infections (Onychomycosis)

SB208 is a product candidate designed as a topical broad-spectrum anti-fungal gel for the potential treatment of fungal infections of the skin and nails, including athlete's foot (tinea pedis) and fungal nail infections (onychomycosis). The SB208 program is currently on hold with further advancement subject to obtaining additional financing or strategic partnering.

SB207, for the Treatment of External Genital Warts

Genital warts are among the world's most common sexually transmitted diseases. We have previously evaluated SB206's anti-viral activity against genital warts caused by HPV. In response to our identification of targeted viral opportunities of high unmet need where we believe our nitric oxide releasing technology could provide clinical benefit to patients, we developed SB207, a new anti-viral product candidate for the treatment of external genital warts. Further advancement of SB207 is subject to further evaluation of clinical plans and developmental timelines, as well as obtaining additional financing or strategic partnering.

Advancement in Men's and Women's Health

We have been awarded federal grants of approximately \$1.3 million from the National Institutes of Health, or NIH, and approximately \$1.1 million from the U.S. Department of Defense's, or DoD, Congressionally Directed Medical Research Programs, or CDMRP. These grants will enable the conduct of IND-enabling toxicology and pharmacology studies and other preclinical activity of a nitric oxide containing intravaginal gel (WH602) designed to treat high-risk HPV infections that can lead to cervical intraepithelial neoplasias, or CIN, and a non-gel formulation product candidate (WH504). Under the terms of these grants, we are entitled to receive the grant funds in the form of periodic reimbursements of our allowable direct expenses, allocated overhead, general and administrative expenses and payment of other specified amounts.

Companion Animal Health

We have initiated exploratory work to evaluate our new chemical entity, NVN4100, as a potential product candidate for antimicrobial indications in companion animal health. This program is currently on hold, pending the engagement of potential collaborators or strategic partners to progress this asset, including the conduct of additional studies and formulation work.

Supply Chain

We continue to assess the impact of COVID-19 on our supply chain and related vendors and global supply chain constraints across various industries, including interruption of, or delays in receiving, supplies of raw materials, API, drug product or finished goods from third-party manufacturers due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems. We are also continuing to evaluate the impacts of COVID-19 and global supply chain constraints on our new facility. We expect to complete the commissioning and validation of our new facility to support various research and development and cGMP activities, including small-scale manufacturing capabilities for API and drug product, by the end of the first half of 2022. We are in the process of, and proceeding with the related preparatory activities associated with qualifying, commissioning and validating the manufacturing equipment for use in API production.

We currently rely on third-party suppliers to provide the raw materials that are used by us and our third-party manufactures in the manufacture of our product candidates and commercial products. There are a limited number of suppliers for raw materials, including nitric oxide, that we use to manufacture our product candidates. We also rely on third-party logistics vendors to transport our raw materials, API, and drug products through our supply chain. Certain materials, including our API, have designated hazard classifications that limit available transportation modes or quantities. Third-party logistics vendors may choose to delay or defer transportation of materials from time to time, especially in light of the pandemic and related global supply chain constraints, which could adversely impact the timing or cost of our manufacturing supply chain activities or other associated development activities.

Manufacturing and Supplies

We have adopted a strategy of engaging with, utilizing and relying on third parties through partnerships, collaborations, licensing or other strategic relationships for the performance of activities, processes and services that (i) do not typically result in the generation of significant new intellectual property and (ii) can leverage their existing robust infrastructure, systems and facilities, as well as associated subject matter expertise. A parallel and inter-related strategic objective has been to manage our own internal resources, including our manufacturing capabilities.

Manufacturing and Supply of Commercial Products

We currently rely upon contract manufacturers to produce our commercialized products related to EPI Health's product portfolio and expect to continue to rely upon these contract manufacturers for any current and future EPI Health legacy product production. As with any supply agreement with contract manufacturers, obtaining finished goods of appropriate quality cannot be guaranteed. Our third-party manufacturers have other customers and may have other priorities that could affect their ability to perform their supply obligations to us satisfactorily and on a timely basis. Both of these occurrences would be beyond our control. We expect to similarly rely on contract manufacturing relationships for any products that we may acquire in the future.

Preparatory Work for Product Candidates in Development

For our product candidates that are currently in development, which generally use the drug substance berdazimer sodium as the API, we have adopted a dual approach of working with third parties and developing certain focused internal manufacturing capabilities. With third parties, we are conducting manufacturing process feasibility studies with a third party full-scale API manufacturer that, if successfully completed, could lead to full-scale production of our API, while also establishing a strategic alliance with Orion Corporation, or Orion, a Finnish full-scale pharmaceutical company with broad experience in drug manufacturing, to enable technology transfer and manufacturing of clinical trial materials for future clinical trials with our topical product candidates, and if any of our product candidates are approved, commercial supply of our nitric oxide-based drug products. Importantly, the Orion alliance is being structured to support major global markets in which we and our partners may pursue regulatory approvals for our product candidates. Within these arrangements with third parties, however, there are risks associated with these manufacturers that are similar to the manufacturing arrangements for our commercial products described above. Moreover, given the stage of these relationships, there are risks associated with the complexity, time and expense of technical transfer.

Internally, we have also worked to commission and validate our new facility, which we expect to complete by the end of the first half of 2022, to support various research and development and cGMP activities, including the production of cGMP API registration batches necessary to support the SB206 NDA submission as well as other small-scale manufacturing capabilities for API and drug product. While we have more control over our internal manufacturing capabilities as compared to our relationships with third parties, we do face risks associated with operating a manufacturing facility, including supply chain matters, which have impacted and may further impact the commissioning and validation of our new facility, and the inherent limitations that come from our internal capabilities being limited to small-scale manufacturing capabilities.

As we move forward with these initiatives, we will need significant additional funding to continue our operating activities, including these technical transfer projects, potential utilization and development of internal capabilities and cost structure

changes, and to make further advancements in our product development programs, as described in the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations —Liquidity and Capital Resources".

Financial Overview

Since our incorporation in 2006 through mid-March 2022, we have devoted substantially all of our efforts to developing our nitric oxide platform technology and resulting product candidates, including conducting preclinical and clinical trials and providing general and administrative support for these operations. With the acquisition of a commercial entity, EPI Health, we have expanded our operations into marketing and sales efforts with a portfolio of therapeutic products for skin diseases.

To date, we have focused our funding activities primarily on equity and strategic relationships. However, other historical forms of funding have included payments received from licensing and supply arrangements, as well as government research contracts.

We have incurred net losses in each year since inception. As of March 31, 2022, we had an accumulated deficit of \$292.3 million, and there is substantial doubt about our ability to continue as a going concern. We incurred net losses of \$13.4 million and \$9.0 million for the three months ended March 31, 2022 and 2021, respectively. We expect to continue to incur substantial losses in the future as we conduct our planned operating activities, including incurring significant expenses related to product candidate development, commercial product sales, marketing, manufacturing and distribution.

Please refer to the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources" for further discussion of our current liquidity and our future funding needs.

Components of our Results of Operations

Revenue

Net Product Revenues

The EPI Health Acquisition in March 2022 has provided our company with a commercial infrastructure to sell a marketed product portfolio of therapeutic products for skin diseases. Net product revenues represent the sales of medical dermatology products primarily for the treatment of rosacea, acne and dermatoses, including Rhofade, Minolira and Cloderm

For additional information regarding our accounting for net product revenues, see "Note 1—Organization and Significant Accounting Policies" and "Note 13—Net Product Revenues" to the accompanying condensed consolidated financial statements.

License and Collaboration Revenues

License and collaboration revenues consists of (i) the amortization of certain fixed and variable consideration under the Sato license agreement that was entered into during the first quarter of 2017, as amended in October 2018, or the Sato Agreement, that either has been received to date in the form of upfront and milestone payments or non-contingent milestone payments that become payable upon the earlier occurrence of specified fixed dates or are contingent milestone payments that become payable upon the achievement of specified milestone events, and (ii) promotional and distribution services revenue related to the MC2 Agreement, where we provide commercialization services with respect to Wynzora.

For additional information regarding our accounting for license and collaboration revenues, see "Note 1—Organization and Significant Accounting Policies" and "Note 14—License and Collaboration Revenues" to the accompanying condensed consolidated financial statements.

Government Research Contracts and Grants Revenue

Government research contracts and grant revenue relates to the research and development of our nitric oxide platform for preclinical advancement of NCEs and formulations related to potential treatments for illnesses in the women's health field. Revenue related to conditional government contracts and grants is recognized when qualifying expenses are incurred.

Product Cost of Goods Sold

Product cost of goods sold includes all costs directly incurred to produce net product revenues from our marketed portfolio of medical dermatology products. Product cost of goods sold primarily consist of (i) costs to procure, ship, handle and warehouse our marketed drug products, and (ii) royalty expenses incurred in connection with the various license and asset purchase agreements underlying our marketed portfolio of medical dermatology products.

Research and Development Expenses

Research and development activities include conducting preclinical studies and clinical trials, manufacturing development efforts and activities related to regulatory filings for our product candidates. Research and development expenses, including

those paid to third parties for which there is no alternative use, are expensed as they are incurred. Research and development expenses include:

- external research and development expenses incurred under agreements with clinical research organizations, or CROs, investigative sites and consultants to conduct our clinical trials and preclinical studies;
- · costs to acquire, develop and manufacture supplies for clinical trials and preclinical studies at our facilities;
- costs to establish drug substance and drug product manufacturing capabilities with external contract manufacturing organizations, or CMOs, and to enhance drug
 delivery device technologies through partnerships with technology manufacturing vendors;
- · legal and other professional fees related to compliance with FDA requirements;
- licensing fees and milestone payments incurred under license agreements;
- · salaries and related costs, including stock-based compensation, for personnel in our research and development functions; and
- · facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent, maintenance of facilities, equipment and other supplies

We expect that for the foreseeable future, the substantial majority of our research and development efforts will be focused on (i) completion of our cGMP API registration batches, (ii) technical transfer and supportive manufacturing activities by our drug product CMO as it relates to the necessary registration batches of drug product, (iii) preparatory activities and data accumulation related to the NDA submission including conducting customary drug substance and drug product stability protocols, and (iv) regulatory and quality documentation compilation related to our preclinical CMC data related to the B-SIMPLE trials, and our drug manufacturing and related processes.

We also expect to incur substantial costs in 2022 associated with our research and development personnel, and certain manufacturing capability costs related to the infrastructure necessary to support small-scale drug substance and drug product manufacturing operations at our new corporate headquarters, including capital costs subject to depreciation and various ongoing operating costs. We may decide to revise our development and operating plans or the related timing, depending on information we learn through our research and development activities, including regulatory submission efforts related to SB206, potential SB206 commercialization strategies, the impact of outside factors such as the COVID-19 pandemic, our ability to enter into strategic arrangements, our ability to access additional capital and our financial priorities.

The successful development and potential regulatory approval of our product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs required to complete the remaining development of our current product candidates or any future product candidates. This is due to the numerous risks and uncertainties associated with the development of product candidates. See the "Risk Factors" section in this Quarterly Report and also within our Annual Report for a discussion of the risks and uncertainties associated with our research and development projects.

Selling, General and Administrative Expenses

Our selling, general and administrative expenses consist primarily of salaries and related costs, including stock-based compensation expenses for personnel in our commercial, field sales, marketing, market access, medical affairs, regulatory, finance, corporate development and other functions. Other selling, general and administrative expenses include advertising, promotion, travel, consulting, market research costs, prelaunch strategy costs, medical affairs, and commercial costs, including preparation activities for our lead product candidate, SB206, allocated depreciation and facility-related costs, legal costs of pursuing patent protection of our intellectual property, insurance coverage and professional services fees for auditing, tax, general legal, business development, litigation defense and other corporate and administrative services.

We expect to continue to incur substantial selling, general and administrative expenses in 2022 in support of our commercial product portfolio acquired with the EPI Health Acquisition and the prelaunch strategy and commercial preparation activities for SB206. We may decide to revise our plans or the related timing associated with our commercial product portfolio, and prelaunch strategy and commercial preparation activities for SB206, depending on information we learn through our regulatory submission process and potential SB206 commercialization strategies.

We also expect to continue to incur substantial selling, general and administrative expenses in 2022 in support of our operating activities and as necessary to operate in a public company environment. Significant general and administrative expenses associated with operations in a public company environment include legal, accounting, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, directors' and officers' liability insurance premiums and investor relations activities

Amortization of Intangible Assets

Amortization of intangible assets is associated with the amortization of definite lived intangible assets acquired as part of the EPI Health Acquisition in March 2022.

For additional information regarding the recognition and amortization of our intangible assets, see "Note 7—Goodwill and Intangible Assets, net" to the accompanying condensed consolidated financial statements.

Other Income (Expense), net

Other income (expense), net consists primarily of (i) foreign currency adjustments related to the contract asset and contract receivables related to the Sato Agreement, (ii) interest expense on outstanding notes payable, (iii) interest income earned on cash and cash equivalents, and (iv) other miscellaneous income and expenses.

Financial Information About Segments

Management evaluates performance of the Company based on operating segments. Segment performance for our two operating segments is based on segment net revenue and net loss. Our reportable segments consist of (i) research and development activities related to our nitric oxide-based technology to develop product candidates, or the Research and Development Operations segment, and (ii) the promotion of commercial products for the treatment of medical dermatological conditions, or the Commercial Operations segment. We do not evaluate the following items at the segment level:

- Selling, general and administrative expenses that result from shared infrastructure, including certain expenses associated with litigation and other legal matters, public company costs (e.g. investor relations), board of directors and principal executive officers, and other like shared expenses.
- Operating expenses within selling, general and administrative expenses that result from the impact of corporate initiatives. Corporate initiatives primarily include integration, restructuring, acquisition and other shared costs.
- Other select revenues and operating expenses including research and development expenses, amortization, and asset sales and impairments, net, as not all such information has been accounted for at the segment level, or such information has not been used by all segments.

See "Note 18—Segment Information" in the accompanying condensed consolidated financial statements included in this Quarterly Report for more information about our reportable segments.

Results of Operations

Comparison of Three Months Ended March 31, 2022 and 2021

The following table sets forth our results of operations for the periods indicated, including information related to our Commercial Operations and Research and Development Operations segments:

	Three Months Ended March 31,			
	2022	2021	\$ Change	%Change
		(in thousand	s, except percentages)	
Net product revenues	\$ 7	18 \$ -	- \$ 718	*
License and collaboration revenues	1,1	74 74	7 427	57 %
Government research contracts and grants revenue		36 7.	2 (36)	(50) %
Total revenue	1,9	28 81	9 1,109	135 %
Operating expenses:				
Product cost of goods sold	2	06 –	- 206	— %
Research and development	4,8	6,41	8 (1,585)	(25) %
Selling, general and administrative	9,9	94 2,68	6 7,308	272 %
Amortization of intangible assets	1	21 –	- 121	*
Total operating expenses	15,1	54 9,10	4 6,050	66 %
Operating loss	(13,2	26) (8,28)	(4,941)	60 %
Other income (expense), net:				
Interest income		3	-	— %
Interest expense	(1	32) —	- (132)	*
Other expense	(25) (670	0) 645	(96) %
Total other expense, net	(1	54) (66'	7) 513	(77) %
Net loss	\$ (13,3	\$ (8,952	2) \$ (4,428)	49 %

^{*} Not meaningful

Net product revenues

The EPI Health Acquisition in March 2022 has provided the Company with a commercial infrastructure to sell a marketed product portfolio of therapeutic products for skin diseases. The post-acquisition net product revenues of EPI Health, specifically from March 11, 2022 through March 31, 2022, are reflected within our condensed consolidated statement of operations for the three months ended March 31, 2022. Net product revenues for the three months ended March 31, 2022 were \$0.7 million, which were all generated by our Commercial Operations segment.

Net product revenues represent the sales of medical dermatology products primarily for the treatment of rosacea, acne and dermatoses, including Rhofade, Minolira and Cloderm. There were no such net product revenues in the comparative period in 2021.

For additional information regarding our accounting for net product revenues, see "Note 1—Organization and Significant Accounting Policies" and "Note 13—Net Product Revenues" to the accompanying condensed consolidated financial statements.

License and collaboration revenues

License and collaboration revenues of \$1.2 million and \$0.7 million for the three months ended March 31, 2022 and 2021, respectively, were primarily associated with our Research and Development Operations segment and our performance during the periods and the related amortization of the non-refundable upfront and expected milestone payments under the Sato Agreement. For the three months ended March 31, 2022 and 2021, we recognized \$0.6 million and \$0.7 million, respectively under the Sato Agreement.

In addition, the post-acquisition licensing and collaboration revenues of EPI Health, specifically from March 11, 2022 through March 31, 2022, are reflected within our condensed consolidated statement of operations for the three months ended March 31, 2022. During the three months ended March 31, 2022, we recognized promotional and distribution services revenue of \$0.4 million associated with our performance under the MC2 Agreement, which is attributed to our Commercial Operations segment.

For additional information regarding our accounting for license and collaboration revenues, see "Note 1—Organization and Significant Accounting Policies" and "Note 14—License and Collaboration Revenues" to the accompanying condensed consolidated financial statements.

Product cost of goods sold

Product cost of goods sold of \$0.2 million for the three months ended March 31, 2022 is recorded by our Commercial Operations segment and includes all costs directly incurred to produce net product revenues from our marketed portfolio of medical dermatology products. Product cost of goods sold primarily consist of (i) costs to procure, ship, handle and warehouse our marketed drug products, and (ii) royalty expenses incurred in connection with the various license and asset purchase agreements underlying our marketed portfolio of medical dermatology products.

Research and development expenses

Our Research and Development Operations segment incurred the substantial majority of our research and development expenses, which were \$4.8 million for the three months ended March 31, 2022, compared to \$6.4 million for the three months ended March 31, 2021. The net decrease of \$1.6 million, or 25%, was primarily related to a \$2.4 million net decrease in the SB206 program, partially offset by a \$0.8 million increase in other research and development expenses.

The \$2.4 million net decrease in the SB206 program was primarily driven by (i) a \$3.7 million decrease in gross clinical trial costs primarily due to the conduct, active enrollment and treatment phase activities of the B-SIMPLE4 Phase 3 trial ongoing during the first quarter of 2021, (ii) a \$1.6 million increase in regulatory consulting services, stability and other analytical testing services, and CMC consulting services and materials in support of our planned SB206 NDA submission, and (iii) a \$0.3 million increase in contra-research and development expense from the ratable amortization of the development funding and royalties agreement with Ligand Pharmaceuticals, Inc., or the Ligand Funding Agreement, liability, which represents Ligand's contribution to specified clinical development and regulatory activities for SB206 as a treatment for molluscum.

The \$0.8 million increase in other research and development expenses was primarily driven by (i) a \$0.7 million net increase in research and development personnel costs, and (ii) a \$0.1 million increase related to our *in vitro* and *in vivo* studies to evaluate our SB019 product candidate as an intranasal treatment option for COVID-19.

The \$0.7 million net increase in research and development personnel costs is primarily due to (i) a \$0.1 million increase in non-cash compensation expense associated with stock based compensation, and (ii) a \$0.6 million increase in recurring salary and benefits costs due to an increased number of research and development personnel between the two comparative periods.

Selling, general and administrative expenses

Selling, general and administrative expenses were \$10.0 million for the three months ended March 31, 2022, compared to \$2.7 million for the three months ended March 31, 2021. The increase of approximately \$7.3 million, or 272%, was primarily due to (i) \$4.0 million of non-recurring transaction-related expenditures incurred in connection with the EPI Health Acquisition in March 2022, (ii) \$1.6 million of selling, general and administrative expenses incurred to support the conduct of EPI Health's commercial sales operations during the period ended March 31, 2022, (iii) a \$0.8 million increase in support costs related to the SB206 prelaunch strategy and commercial preparation, (iv) a \$0.1 million increase in human resources and recruiting costs, (v) a \$0.3 million increase in corporate tax and insurance costs, (vi) a \$0.2 million increase in consulting costs, and (vii) a \$0.3 million net increase in general and administrative personnel and related costs for the legacy Novan business.

The \$4.0 million of non-recurring transaction-related expenditures incurred in connection with the EPI Health Acquisition included fees paid to banking advisors, insurance brokers, due diligence costs, and legal, regulatory, intellectual property, information technology, valuation and accounting consultants and specialists.

The \$1.6 million of selling, general and administrative expenses incurred to support the conduct of EPI Health's commercial sales operations during the period ended March 31, 2022 included (i) \$0.8 million of recurring salary, incentive compensation and benefits costs, (ii) \$0.4 million of advertising and promotion costs, (iii) \$0.2 million of administrative costs related partially to third-party data providers which support the commercial sales team with market and analytical data, and (iv) \$0.2 million of travel and expense related costs

The \$0.3 million net increase in general and administrative personnel and related costs associated with the legacy Novan business includes (i) a \$0.2 million increase in non-cash compensation expense associated with stock based compensation, and (ii) a \$0.1 million increase in recurring salary and benefits costs between the two comparative periods.

Amortization of intangible assets

Amortization of intangible assets of \$0.1 million for the three months ended March 31, 2022 is associated with the amortization of definite lived intangible assets acquired as part of the EPI Health acquisition in March 2022.

For additional information regarding the recognition and amortization of our intangible assets, see "Note 7—Goodwill and Intangible Assets, net" to the accompanying condensed consolidated financial statements.

Other expense, net

Total other expense, net was \$0.2 million for the three months ended March 31, 2022, compared to \$0.7 million for the three months ended March 31, 2021. Total other expense, net in the current period is primarily comprised of \$0.1 million of interest expense related to the Seller Note issued in March 2022 in connection with the EPI Health Acquisition. Total other expense, net in the comparative 2021 period is primarily comprised of \$0.7 million of other expense related to the impact of foreign currency exchange rate fluctuations for certain time-based milestones related to the Sato Agreement.

For additional information regarding the Seller Note, see "Note 9—Notes Payable" to the accompanying condensed consolidated financial statements.

Liquidity and Capital Resources

As of March 31, 2022, we had an accumulated deficit of \$292.3 million. We incurred net losses of \$13.4 million and \$9.0 million during the three months ended March 31, 2022 and 2021, respectively, and there is substantial doubt about our ability to continue as a going concern. Despite revenues generated from the sales of commercial products acquired during the EPI Health Acquisition, we anticipate that we will continue to generate losses for the foreseeable future, and we expect the losses to increase as we further commercialize our existing commercial products and continue the development of, and seek regulatory approvals for, our product candidates and potentially begin commercialization activities for our product candidates that are currently under development. We are subject to all of the risks inherent in the commercialization of drug products, such as risks related to competition, supply issues or issues that may impact use of our commercial drug products, and in the development of new pharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The sales of our commercial products will decrease over time if and when they face generic competition or if other risks materialize, and we do not expect to generate revenue from product sales for our clinical-stage product candidates unless and until we obtain regulatory approval from the FDA for such product candidates. We will continue to incur significant expenses related to the commercial partners and commercial solutions providers would expect to incur significant expenses related to product sales, marketing, manufacturing and distribution.

As of March 31, 2022, we had total cash and cash equivalents of \$35.5 million and positive working capital of \$11.7 million.

From January 1, 2020 through March 31, 2022, we have raised total equity and debt proceeds of \$97.5 million to fund our operations, including (i) \$37.2 million in net proceeds from the sale of common stock in the June 2021 public offering, (ii) \$5.2 million in net proceeds from the sale of common stock (or pre-funded warrants in lieu thereof) and accompanying common warrants in the March 2020 public offering, (iii) \$7.2 million in net proceeds from the sale of common stock (or pre-funded warrants in lieu thereof) in the March 2020 registered direct offering, (iv) an additional \$6.0 million of proceeds associated with exercises of common stock warrants issued as part of the March 2020 public offering and March 2020 registered direct offering, (v) \$40.3 million in proceeds from the sale of common stock under our common stock purchase agreements with Aspire Capital, (vi) \$0.6 million from our Equity Distribution Agreement, and (vii) less than \$0.1 million of proceeds from the exercise of stock options. We also obtained a loan under the Paycheck Protection Program, or PPP, of approximately \$1.0 million in April 2020 to support certain qualified expenses, including payroll and rental expense. The PPP loan was forgiven in June 2021.

To date, we have focused our funding activities primarily on equity financings, while generating additional liquidity and capital through other sources, including (i) governmental research contracts and grants totaling \$12.9 million, (ii) our licensing and supply arrangements with Sato, totaling \$33.1 million, and (iii) \$25.0 million and \$12.0 million in proceeds from two funding transactions during the second quarter of 2019 with Reedy Creek Investments LLC, or Reedy Creek, and Ligand, respectively.

Going forward, we plan to finance our needs principally from the following:

- · equity and/or debt financing, including but not limited to sales under the Equity Distribution Agreement;
- · revenues from product sales;
- payments under existing out-license and distribution arrangements for our product candidates and commercial products; and
- · payments under current or future collaboration and licensing agreements with strategic partners.

We believe that our existing cash and cash equivalents as of March 31, 2022, plus expected receipts associated with product sales from our commercial product portfolio, will provide us with adequate liquidity to fund our planned operating needs into the early fourth quarter of 2022. This operating forecast and related cash projection includes (i) costs associated with preparing

for and seeking U.S. regulatory approval of SB206 as a treatment for molluscum, including costs to prepare for pre-NDA meetings with the FDA and NDA-enabling drug stability studies for SB206, (ii) costs associated with the readiness of our new corporate headquarters and manufacturing capability necessary to support small-scale drug substance and drug product manufacturing, (iii) conducting drug manufacturing activities with external third-party CMOs, (iv) ongoing commercial operations, including sales, marketing, inventory procurement and distribution and supportive activities, related to our portfolio of therapeutic products for skin diseases acquired with the EPI Health transaction, and (v) initial efforts to support potential commercialization of SB206. This forecast and projection excludes: (a) progression of the SB019 program subsequent to the pre-IND submission, including the execution of a Phase 1 study, (b) any potential costs associated with other late-stage clinical programs, including executing the potentially registrational Phase 3 study of SB204 for acne, and (c) additional operating costs that could occur between a potential NDA submission for SB206 through NDA approval, specifically including marketing and commercialization efforts to achieve potential launch of SB206. We may decide to revise our development and operating plans or the related timing, depending on information we learn through our research and development activities, including regulatory submission efforts related to SB206, potential commercialization strategies, the impact of outside factors such as the COVID-19 pandemic, our ability to enter into strategic arrangements, our ability to access additional capital and our financial priorities.

We will need significant additional funding to continue our operating activities, make further advancements in our product development programs and potentially commercialize any of our product candidates beyond those activities currently included in our operating forecast and related cash projection. Therefore, we will need to secure additional capital or financing and/or delay, defer or reduce our cash expenditures before the fourth quarter of 2022. There can be no assurance that we will be able to obtain additional capital or financing on terms acceptable to us, on a timely basis or at all.

Our inability to obtain significant additional funding on acceptable terms could have a material adverse effect on our business and cause us to alter or reduce our planned operating activities, including, but not limited to delaying, reducing, terminating or eliminating planned product candidate development activities, to conserve our cash and cash equivalents. We may pursue additional capital through equity or debt financings, including potential sales under the Equity Distribution Agreement, or from non-dilutive sources, including partnerships, collaborations, licensing, grants or other strategic relationships. Alternatively, we may seek to engage in one or more potential transactions, which could include the sale of our company, or the sale or divestiture of some of our assets, such as a sale of our dermatology platform assets, but there can be no assurance that we will be able to enter into such a transaction or transactions on a timely basis or at all on terms that are favorable to us.

Our cash and cash equivalents are held in a variety of interest-bearing instruments, including money market accounts. Cash in excess of immediate requirements is invested with a view toward liquidity and capital preservation, and we seek to minimize the potential effects of concentration and degrees of risk.

Cash Flows

The following table sets forth our cash flows for the periods indicated:

	Three Months Ended March 31,			
		2022		
		(in thousands)		
Net cash (used in) provided by:				
Operating activities	\$	766 \$	(8,601)	
Investing activities		(12,921)	(934)	
Financing activities		562	6,789	
Net decrease in cash, cash equivalents and restricted cash	\$	(11,593) \$	(2,746)	

Net Cash Used in Operating Activities

During the three months ended March 31, 2022, net cash provided by operating activities was \$0.8 million and consisted primarily of a net loss of \$13.4 million, with adjustments for non-cash amounts related primarily to (i) stock-based compensation expense of \$0.4 million, (ii) amortization of definite lived intangible assets acquired from EPI Health of \$0.1 million, (iii) \$0.1 million of depreciation and amortization of property and equipment expense, and (iv) a \$13.5 million change in cash related to changes in other operating assets and liabilities. The change in cash related to changes in assets and liabilities was primarily due to (i) \$8.5 million related to accounts receivable, including \$4.2 million received by EPI Health after March 11, 2022 and the receipt of a \$4.3 million time-based developmental milestone payment from Sato, (ii) a change in accounts payable of \$1.6 million, (iii) a change in deferred revenue of \$2.6 million, and (iv) a change in prepaid expenses and other current assets of \$0.6 million. See "Note 2—Acquisition of EPI Health" to the accompanying condensed consolidated financial

statements for additional detail regarding the purchase of EPI Health and the related impacts of the opening balances related to the EPI Health Acquisition.

During the three months ended March 31, 2021, net cash used in operating activities was \$8.6 million and consisted primarily of a net loss of \$9.0 million, with adjustments for non-cash amounts related primarily to (i) depreciation expense of \$0.1 million, (ii) stock-based compensation expense of \$0.1 million, (iii) a foreign currency transaction loss of \$0.7 million related to expected payments to be received under the Sato Agreement, and (iv) a \$0.5 million net decrease in cash related to changes in other operating assets and liabilities. The net decrease in cash related to changes in assets and liabilities was primarily due to (i) a \$0.9 million decrease in prepaid expenses and other current assets primarily related to the amortization of prepaid service contracts and directors and officers insurance premiums, and (ii) a \$0.1 million change in other long-termassets and liabilities. These increases in cash were more than offset by (i) a \$0.4 million decrease in accrued expenses primarily related to the payment of 2020 performance bonuses in March 2021, (ii) a \$0.7 million decrease in deferred revenue, and (iii) a \$0.2 million decrease in accounts payable.

Net Cash Used in Investing Activities

During the three months ended March 31, 2022, the \$12.9 million of net cash used in investing activities was primarily related to (i) cash used in connection with the EPI Health Acquisition of \$12.0 million, and (ii) \$0.9 million in cash used for purchases of property, equipment and services associated with the build-out of our corporate headquarters and small-scale manufacturing facility in Durham, North Carolina. See "Note 2—Acquisition of EPI Health" to the accompanying condensed consolidated financial statements for additional detail regarding the purchase of EPI Health.

During the three months ended March 31, 2021, the \$0.9 million of net cash used in investing activities was primarily related to investing activities including purchases of property, equipment and services associated with the planning, design and build-out of our new corporate headquarters and small-scale manufacturing facility in Durham, North Carolina.

Net Cash Provided by Financing Activities

During the three months ended March 31, 2022, net cash provided by financing activities was \$0.6 million and consisted of proceeds from the sale of our common stock pursuant to the Equity Distribution Agreement entered into in March 2022.

During the three months ended March 31, 2021, net cash provided by financing activities was \$6.8 million and consisted primarily of \$6.3 million of proceeds from the sale of our common stock pursuant to the July 2020 Aspire CSPA and \$0.4 million of proceeds from the exercise of common warrants associated with the March 2020 public offering and March 2020 registered direct offering.

Capital Requirements

As of March 31, 2022, we had a total cash and cash equivalents balance of \$35.5 million and positive working capital of \$11.7 million. While we currently generate revenue from our commercial portfolio of products acquired in the EPI Health acquisition that closed in March 2022, we do not believe that such revenues will be sufficient to fund operations of the business, specifically the development of our product candidates. To date, we have not generated any revenue from product sales of our product candidates, and we do not know when, or if, we will generate any such revenue. We do not expect to generate revenue from product sales of our product candidates unless, and until, we obtain regulatory approval of one of our current or future product candidates and achieve successful commercialization of such product candidate. As of March 31, 2022, we had an accumulated deficit of \$292.3 million.

We will need significant additional funding to support our planned and future operating activities and make further advancements in our product development programs beyond what is currently included in our operating forecast and related cash projection. We do not currently have sufficient funds to complete commercialization of any of our product candidates, and our funding needs will largely be determined by our commercialization strategy for SB206, subject to the NDA submission timing and the regulatory approval process and outcome.

Our ability to continue to operate our business, including our ability to advance development programs unrelated to SB206, as well as our ability to progress SB206 for molluscum subsequent to an NDA submission, is dependent upon future sales of our commercial products along with our ability to access additional sources of capital, including, but not limited to (i) equity or debt financings, including but not limited to potential sales using the remaining availability under the Equity Distribution Agreement, or (ii) non-dilutive sources, such as partnerships, collaborations, licensing, grants or other strategic relationships. There can be no assurance that we will be able to obtain new funding on terms acceptable to us, on a timely basis, or at all. Our inability to obtain significant additional funding on acceptable terms could have a material adverse effect on our business and cause us to alter or reduce our planned operating activities, including, but not limited to delaying, reducing, terminating or eliminating planned product candidate development activities, to conserve our cash and cash equivalents. Our anticipated expenditure levels may change if we adjust our current operating plan. Such actions could delay development timelines and

have a material adverse effect on our business, results of operations, financial condition and market valuation. We are also exploring the potential for alternative transactions, such as strategic acquisitions or in-licenses, sales or divestitures of some of our assets, or other potential strategic transactions, which could include a sale of the company. If we were to pursue such a transaction, we may not be able to complete the transaction on a timely basis or at all or on terms that are favorable to us.

Our equity issuances during the year ended December 31, 2021 and the three months ended March 31, 2022 have resulted in significant dilution to our existing stockholders. Any future additional issuances of equity, or debt that could be convertible into equity, would result in further significant dilution to our existing stockholders.

As of March 31, 2022, we had 18,980,122 shares of common stock outstanding. In addition, as of March 31, 2022, we had reserved 2,066,103 shares of common stock for future issuance related to (i) outstanding warrants to purchase common stock, (ii) outstanding stock options and stock appreciation rights, and (iii) future issuance under the 2016 Incentive Award Plan. Our common stock consists of 200,000,000 authorized shares as of March 31, 2022.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect, and we may use all of our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount or timing of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- market acceptance of approved products and successful commercialization of such products by either us or our partners;
- · our decision to expand our internal commercialization capabilities;
- the initiation, progress, timing, costs, results, and evaluation of results of trials for our clinical-stage product candidates, including trials conducted by us or potential future partners;
- the progress, timing, costs and results of development and preclinical study activities relating to other potential applications of our nitric oxide platform;
- the number and characteristics of product candidates that we pursue;
- the achievement of milestones that would require payment and whether such milestone payments are paid in cash or shares of our common stock, including those set forth in "Note 10—Commitments and Contingencies" to the accompanying condensed consolidated financial statements;
- our ability to enter into strategic relationships to support the continued development of certain product candidates and the success of those arrangements;
- · our success in optimizing the size and capability of our new manufacturing facility and related processes to meet our strategic objectives;
- our success in the technical transfer of methods and processes related to our drug substance and drug product manufacturing with our current and/or potential future contract manufacturing partners;
- · the outcome, timing and costs of seeking regulatory approvals;
- the occurrence and timing of potential development and regulatory milestones achieved by Sato, our licensee for SB204 and SB206 in Japan;
- the terms and timing of any future collaborations, licensing, consulting, financing or other arrangements that we may enter into;
- the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement
 of any patents or other intellectual property rights;
- · the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights;
- · defending against intellectual property related claims;
- · the costs associated with any potential future securities litigation, and the outcome of that litigation;
- the extent to which we in-license or acquire other products and technologies;
- · subject to receipt of marketing approval, revenue received from commercial sales or out licensing of our product candidates; and

revenue received from commercial sales of our existing medical dermatology products.

Contractual Obligations and Contingent Liabilities

During the three months ended March 31, 2022, there were no material changes to our commitments under contractual obligations, other than those related to the EPI Health Acquisition. The EPI Health Acquisition is described in "Note 2—Acquisition of EPI Health" to the condensed consolidated financial statements included in this Quarterly Report on Form 10-O.

Our significant accounting policies are more fully described in "Note 1—Organization and Significant Accounting Policies" to the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q, including those related to the EPI Health acquisition, and as described within the condensed consolidated financial statement footnotes within this Quarterly Report on Form 10-Q.

Except for items described in "Note 1—Organization and Significant Accounting Policies," "Note 2—Acquisition of EPI Health," "Note 10—Commitments and Contingencies" and "Note 12—Licensing and Collaboration Arrangements" to the accompanying condensed consolidated financial statements, there were no material changes during the three months ended March 31, 2022 in our commitments under contractual obligations, as disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations" contained in our Annual Report.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with United States generally accepted accounting principles. The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, as well as the reported revenue and expenses during the reporting periods. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources.

Significant estimates made by us include provisions for product returns, coupons, rebates, chargebacks, trade and cash discounts, allowances and distribution fees paid to certain wholesalers, inventory net realizable value, useful lives of amortizable intangible assets, stock-based compensation, accrued expenses, valuation of assets and liabilities in business combinations, developmental timelines related to licensed products, valuation of contingent consideration and contingencies. Actual results may differ materially and adversely from these estimates.

Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ materially from these estimates under different assumptions or conditions. To the extent there are material differences between the estimates and actual results, our future results of operations will be affected.

While our significant accounting policies are more fully described in the notes to our condensed consolidated financial statements included elsewhere in this Quarterly Report, we believe that the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our condensed consolidated financial statements and understanding and evaluating our reported financial results.

Business Acquisitions

Business acquisitions are accounted for using the acquisition method of accounting in accordance with Accounting Standards Codification, or ASC, 805, Business Combinations. ASC 805 requires, among other things, that assets acquired and liabilities assumed be recognized at their fair values, as determined in accordance with ASC 820, Fair Value Measurements, as of the acquisition date. For certain assets and liabilities, book value approximates fair value. In addition, ASC 805 establishes that consideration transferred be measured at the closing date of the acquisition at the then-current market price. Under ASC 805, acquisition-related costs (i.e., advisory, legal, valuation and other professional fees) are expensed in the period in which the costs are incurred. The application of the acquisition method of accounting requires us to make estimates and assumptions related to the estimated fair values of net assets acquired.

Significant judgments are used during this process, particularly with respect to intangible assets. Generally, intangible assets are amortized over their estimated useful lives. Goodwill and other indefinite-lived intangibles are not amortized, but are annually

assessed for impairment. Therefore, the purchase price allocation to intangible assets and goodwill has a significant impact on future operating results.

See "Note 2—Acquisition of EPI Health" to the accompanying condensed consolidated financial statements included in this Quarterly Report for additional discussion, in addition to "Note 17—Fair Value," related to the EPI Health acquisition.

Revenue Recognition

We account for revenue in accordance with ASC 606, Revenue from Contracts with Customers. To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we (i) identify the contract with a customer, (ii) identify the performance obligations within the contract, (iii) determine the transaction price (iv) allocate the transaction price to the performance obligations within the contract, and (v) recognize revenue when (or as) we satisfy a performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer.

Net Product Revenue:

Net product revenues encompass sales recognized resulting from transferring control of products to customers, excluding amounts collected on behalf of other third parties and sales taxes. The amount of revenue recognized is the amount allocated to the satisfied performance obligation taking into account variable consideration. The estimated amount of variable consideration is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

Product sales are recognized at the point in time when a product is delivered and legal transfer of title has occurred. For product sales for which we own rights to the products, we record a reduction of the transaction price for estimated chargebacks, rebates, coupons, discounts and returns. A liability is recognized for expected sales returns, rebates, coupons, trade and cash discounts, chargebacks or other reimbursements to customers in relation to sales made in the reporting period. Payment terms can differ from contract to contract, but no element of financing is deemed present based on the fact that typical payment terms are less than one year. Therefore, the transaction price is not adjusted for the effects of a significant financing component. A receivable is recognized as soon as control over the products is transferred to the customer as this is the point in time that the consideration is unconditional because only the passage of time is required before the payment is due.

Variable consideration relates to sales returns, rebates, coupons, trade and cash discounts, and chargebacks granted to various direct and indirect customers. We recognize provisions at the time of sale and adjust them if the actual amounts differ from the estimated provisions.

There can be a significant lag between our establishment of an estimate and the timing of the invoicing or claim. We believe we have made reasonable estimates for future rebates and claims, however, these estimates involve assumptions pertaining to contractual utilization and performance, and payor mix. If the performance or mix across third-party payors is different from our estimates, we may be required to pay higher or lower total price adjustments and/or chargebacks than we had estimated.

See "Note 1—Organization and Significant Accounting Policies" and "Note 13—Net Product Revenues" to the accompanying condensed consolidated financial statements included in this Quarterly Report for additional discussion.

License and Collaboration Revenues

We have entered into certain types of agreements to license our intellectual property. If this license is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenues from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the estimated performance period and the appropriate method of measuring progress during the performance period for purposes of recognizing revenue. We re-evaluate the estimated performance period and measure of progress each reporting period and, if necessary, adjust related revenue recognition accordingly.

We also enter into various types of collaboration arrangements to develop and commercialize products. Our collaborative activities may include licensing, marketing, selling and distribution of developed drugs. These arrangements often include milestone as well as royalty or profit-share payments, contingent upon the occurrence of certain future events linked to the success of the asset in development, as well as expense reimbursements from or payments to the collaboration partner. Because of the risk that products in development will not receive regulatory approval, we do not recognize any contingent payments until after regulatory approval has been achieved.

Royalty revenue from licenses provided to our collaboration partners, which is based on sales to third-parties of licensed products and technology, is recorded when the third-party sale occurs and the performance obligation to which some or all of

the royalty has been allocated has been satisfied. This royalty revenue is included in collaboration revenue in the accompanying condensed consolidated statements of operations and comprehensive loss.

Operating expenses for costs incurred pursuant to these arrangements are reported in their respective expense line item. Such contractually required reimbursements are recognized when amounts are known and determinable and are reported as a collaboration arrangement liability within the accompanying condensed consolidated balance sheets based upon the timing of cash receipt from the collaboration partner.

See "Note 14—License and Collaboration Revenues" to the accompanying condensed consolidated financial statements included in this Quarterly Report for additional discussion.

Accounts Receivable

Accounts receivable are carried at original invoice amount less an estimate made for doubtful receivables. An account receivable is considered to be past due if any portion of the receivable balance is outstanding beyond the agreed-upon due date.

We record an allowance for credit losses, which includes a provision for expected losses based on historical write-offs, adjusted for current conditions as deemed necessary, reasonable and supportable forecasts about future conditions that affect the expected collectability of the reported amount of the financial asset, and a specific reserve for accounts deemed at risk. The allowance is our estimate for accounts receivable as of the balance sheet date that ultimately will not be collected. Any changes in the allowance are reflected in the results of operations in the period in which the change occurs. We write off accounts receivable and the related allowance recorded previously when it becomes probable, based upon customer facts and circumstances, that such amounts will not be collected.

Account balances are written off against the allowance after all means of collection have been exhausted and the potential for recovery is considered remote. Recoveries of receivables previously written off are recorded when received. We do not charge interest on accounts receivable.

Inventory

We maintain inventory consisting of for-sale pharmaceuticals related to our marketed product portfolio. We measure inventory using the first-in, first out-method and value inventory at the lower of cost and net realizable value. Net realizable value represents the estimated selling price for inventories less all estimated costs to sell.

We perform an analysis and record a provision for potentially obsolete inventory. The reserve for obsolescence is generally an estimate of the amount of inventory held at period end that is expected to expire in the future based on projected sales volume and expected product expiration or sell-by dates. These assumptions require us to analyze the aging of and forecasted demand for our inventory and make estimates regarding future product sales.

Intangible Assets and Goodwill

Intangible assets represent identifiable intangible assets including pharmaceutical product licenses and patents. Amortization for pharmaceutical products licenses is computed using the straight-line method based on the lesser of the term of the agreement or the useful life of the license. Amortization for pharmaceutical patents is computed using the straight-line method based on the useful life of the patent.

Definite-lived intangible assets are reviewed for impairment whenever events or circumstances indicate that carrying amounts may not be recoverable. In the event impairment indicators are present or if other circumstances indicate that an impairment might exist, we compare the future undiscounted cash flows directly associated with the asset or asset group to the carrying amount of the asset group being determined for impairment. If those estimated cash flows are less than the carrying amount of the asset group, an impairment loss is recognized. An impairment loss is recognized to the extent that the carrying amount exceeds the asset's fair value. Considerable judgment is necessary to estimate the fair value of these assets, accordingly, actual results may vary significantly from such estimates.

Indefinite-lived intangible assets, such as goodwill, are not amortized. We test the carrying amounts of goodwill for recoverability on an annual basis at September 30 or when events or changes in circumstances indicate evidence that a potential impairment exists, using a fair value based test. A significant amount of judgment is involved in determining if an indicator of goodwill impairment has occurred. Such indicators may include, among others: a significant decline in expected future cash flows, a sustained, significant decline in our stock price and market capitalization, a significant adverse change in legal factors or in the business climate, adverse assessment or action by a regulator, and unanticipated competition. Key assumptions used in the annual goodwill impairment test are highly judgmental. Any change in these indicators or key assumptions could have a significant negative impact on our financial condition, impact the goodwill impairment analysis or cause us to perform a goodwill impairment analysis more frequently than once per year.

See "Note 7—Goodwill and Intangible Asset, net" to the accompanying condensed consolidated financial statements included in this Quarterly Report for additional discussion regarding intangible assets and goodwill related to the EPI Health acquisition.

Accrued Expenses

As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves reviewing open contracts and purchase orders, communicating with applicable vendor personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary.

See "Note 8—Accrued Expenses" to the accompanying condensed consolidated financial statements included in this Quarterly Report for additional detail.

Contingent Consideration

Contingent consideration is recorded as a liability and is the estimate of the fair value of potential milestone payments related to business acquisitions. The estimated fair value of contingent consideration is determined based on a probability-weighted valuation model that measures the present value of the probable cash payments based upon the future milestone events of EPI Health at a discount rate that captures the risk associated with the liability and also based on a Monte Carlo simulation, whereby EPI Health's forecasted net sales from the EPI Health legacy products is simulated over the measurement period to calculate the contingent consideration.

Significant increases or decreases in any of the probabilities of success or changes in expected achievement of any of these milestones would result in a significantly higher or lower fair value of these milestones, respectively, and commensurate changes to the associated liability.

The contingent consideration is revalued at each reporting period and changes in fair value are recognized in the condensed consolidated statements of operations and comprehensive loss until settlement.

See "Note 2—Acquisition of EPI Health" to the accompanying condensed consolidated financial statements included in this Quarterly Report for additional discussion regarding purchase consideration, including contingent consideration related to the EPI Health Acquisition.

Reedy Creek Purchase Agreement

We have previously determined that the Royalty and Milestone Payments Purchase Agreement with Reedy Creek, or the Reedy Creek Purchase Agreement, is within the scope of ASC 730-20, Research and Development Arrangements. We concluded that there has not been a substantive and genuine transfer of risk related to the Reedy Creek Purchase Agreement as (i) Reedy Creek has the opportunity to recover its investment regardless of the outcome of the research and development programs within the scope of the agreement (prior to commercialization of any in scope assets through potential out-licensing agreements and related potential future milestone payments), and (ii) there is a presumption that we are obligated to pay Reedy Creek amounts equal to its investment based on the related party relationship at the time the parties entered into the Reedy Creek Purchase Agreement. The Reedy Creek Purchase Agreement is a broad funding arrangement, due to (i) the multi-asset, or portfolio approach including three developmental assets that are within the scope of the arrangement, and (ii) Reedy Creek's approximate 5% ownership of our outstanding shares of common stock at the time of entry into the Reedy Creek Purchase Agreement.

As such, we have determined that the appropriate accounting treatment under ASC 730-20 was to record the initial proceeds of \$25.0 million as cash and cash equivalents, as we had the ability to direct the usage of funds, and a long-term liability within our classified balance sheet. The long-term liability will remain until we receive future milestones from other potential third parties, as defined within the Reedy Creek Purchase Agreement, of which 25% will be contractually owed to Reedy Creek. If potential future milestones are received by us, and become partly due to Reedy Creek, the corresponding partial repayment to Reedy Creek will result in a ratable reduction of the total long-term obligation to repay the initial purchase price.

See "Note 15—Research and Development Agreements" to the accompanying condensed consolidated financial statements included in this Quarterly Report for additional discussion regarding the applicable accounting treatment of the Reedy Creek Purchase Agreement.

Ligand Funding Agreement

We have previously determined that the Ligand transaction is within the scope of ASC 730-20 as it represents an obligation to perform contractual services for the development of SB206 using commercially reasonable efforts. In addition, the Ligand

Funding Agreement also states that if all development of SB206 is ceased prior to the first regulatory approval, we must pay to Ligand an amount equal to the purchase price less the amount spent in accordance with the development budget on development activities conducted prior to such cessation. As such, we concluded that the appropriate accounting treatment under ASC 730-20 was to record the initial proceeds of \$12.0 million, as a liability and as restricted cash on our consolidated balance sheet, as the funds could only be used for the progression of SB206.

We amortize the liability ratably during each reporting period, based on the Ligand funding as a percentage of the total direct costs we incur during the reporting period related to the estimated total cost to progress the SB206 program to a regulatory approval in the United States. The ratable Ligand funding has been presented within our accompanying consolidated statements of operations and comprehensive loss as an offset to research and development expenses associated with the SB206 program.

However, because the aggregate amount spent in accordance with the SB206 development budget on SB206 development activities had exceeded the \$12.0 million purchase price, we reported no restricted cash balance related to the Ligand Funding Agreement, as of December 31, 2021 in our consolidated balance sheet.

See "Note 15—Research and Development Agreements" to the accompanying condensed consolidated financial statements included in this Quarterly Report for additional discussion regarding the applicable accounting treatment of the Ligand Funding Agreement.

Determination of the Fair Value of Stock-based Compensation Grants

We record the fair value of stock options, and other stock-based compensation issued to employees and non-employees as of the grant date as stock-based compensation expense. We typically recognize compensation expense over the requisite service period, which is typically the vesting period.

We estimate the fair value of our stock-based awards to employees and non-employees using the Black-Scholes option-pricing model, which requires the input of assumptions, some of which are highly subjective, including (i) the fair value of our common stock on the date of grant, (ii) the expected volatility of our stock, (iii) the expected term of the award, (iv) the risk-free interest rate and (v) expected dividends. In applying these assumptions, we considered the following factors:

- We have based our estimate of expected volatility, in part, on the historical volatility of a group of similar companies that are publicly traded, in addition to our own historical volatility. We are transitioning to using our historical volatility as a sufficient amount of historical information regarding the volatility of our own stock price becomes available. We considered characteristics such as industry, stage of life cycle, financial leverage, enterprise value, risk profiles and position within the industry, along with historical share price information sufficient to meet the expected life of the stock-based awards in selecting the similar companies. We compute the historical volatility data using the daily closing prices during the equivalent period of the calculated expected term of our stock-based awards.
- We have estimated the expected term of our employee stock options using the "simplified" method, whereby, the expected life equals the average of the vesting term and the original contractual term of the option.
- The risk-free interest rate is based on the yields of United States Treasury securities with maturities similar to the expected term of granted stock-based awards.
- We have never declared or paid any cash dividends to common stockholders and do not presently plan to pay cash dividends in the foreseeable future. Consequently, we use an expected dividend yield of zero.

We estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from estimates. We use historical data to estimate prevesting option forfeitures and record stock-based compensation expense only for those awards that are expected to vest. To the extent that actual forfeitures differ from our estimates, the difference is recorded as a cumulative adjustment in the period the estimates were revised. Stock-based compensation expense recognized in the financial statements is based on awards that are ultimately expected to vest.

See "Note 16—Stock-Based Compensation" to the accompanying condensed consolidated financial statements included in this Quarterly Report for additional discussion regarding stock based compensation awards.

Recent Accounting Pronouncements

Recently issued accounting pronouncements that we have adopted or are currently evaluating are described in detail within "Note 1—Organization and Significant Accounting Policies" to the accompanying condensed consolidated financial statements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 4. Controls and Procedures

Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Securities Exchange Act of 1934 (the "Exchange Act") reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our chief executive officer and financial officers, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Rules 13a-15(e) and 15d-15(e) of the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our chief executive officer and financial officers, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on that evaluation, our chief executive and financial officers concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of March 31, 2022.

We closed the EPI Health Acquisition on March 11, 2022, and EPI Health's total assets and revenues constituted 52.7% and 64.6%, respectively, of our consolidated total assets (including goodwill and intangible assets, net) and revenues as shown on our condensed consolidated financial statements as of and for the three-months ended March 31, 2022. As the EPI Health Acquisition occurred in the first quarter of fiscal 2022, we excluded the internal control over financial reporting of EPI Health from the scope of our assessment of the effectiveness of our disclosure controls and procedures as of March 31, 2022. This exclusion is in accordance with the general guidance issued by the Staff of the Securities and Exchange Commission that an assessment of a recently-acquired business may be omitted from our scope in the year of acquisition, if specified conditions are satisfied.

Our disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives as specified above. Management does not expect, however, that our disclosure controls and procedures will prevent or detect all errors and fraud. Any control system, no matter how well designed and operated, is based upon certain assumptions and can provide only reasonable, not absolute, assurance that its objectives will be met. Further, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within the Company have been detected.

Changes in Internal Controls Over Financial Reporting

As noted above, on March 11, 2022, we completed the EPI Health Acquisition. We are in the process of integrating the operations of EPI Health into our overall internal control over financial reporting process. This process may result in additions or changes to our internal control over financial reporting.

There has been no other change in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Rules 13a-15 or 15d-15 under the Exchange Act that occurred during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings

We are not currently a party to any material legal proceedings and are not aware of any claims or actions pending against us that we believe could have a material adverse effect on our business, operating results, cash flows or financial statements. In the future, we may from time to time become involved in litigation relating to claims arising from our ordinary course of business.

Item 1A. Risk Factors

There have been no material changes to the risk factors disclosed in our Annual Report, except as follows:

Risks related to the EPI Health Acquisition

In connection with the EPI Health Acquisition, we have incurred additional indebtedness, which could adversely affect us, including our business flexibility and as a result we will incur significant interest expense.

We have incurred indebtedness following completion of the EPI Health Acquisition in the form of the Seller Note, which could have the effect, among other things, of reducing our flexibility to respond to changing business and economic conditions. Additionally, we will incur interest expense under the Seller Note. We will also incur various costs and expenses related to the financing of the EPI Health Acquisition. The indebtedness following completion of the EPI Health Acquisition could also reduce funds available for working capital, capital expenditures, and other general corporate purposes, and may create competitive disadvantages for us relative to other companies without debt. If we do not achieve the expected synergies and cost savings from the EPI Health Acquisition, or if our financial performance after the EPI Health Acquisition does not meet our current expectations, then our ability to service our indebtedness may be adversely impacted.

We may experience difficulties integrating the EPI Health businesses.

Achieving the anticipated benefits of the EPI Health Acquisition will depend in significant part upon us integrating the EPI Health businesses, operations, processes, and systems in an efficient and effective manner. The actual integration may result in additional and unforeseen expenses, and the anticipated benefits of the integration may not be realized. The companies may not be able to accomplish the integration process smoothly, successfully, or on a timely basis. The necessity of coordinating geographically separated organizations, systems of controls, and facilities and addressing possible differences in business backgrounds, corporate cultures, and management philosophies may increase the difficulties of integration. The integration of operations following the EPI Health Acquisition requires the dedication of significant management and external resources, which may temporarily distract management's attention from the day-to-day business of the combined company and be costly. Employee uncertainty and lack of focus during the integration process may also disrupt the business and results of the combined company. Any inability of management to successfully and timely integrate the companies could have a material adverse effect on the business and results of operations of the combined company.

EPI Health may have liabilities that are not known to us.

EPI Health may have liabilities that we failed, or were unable, to discover in the course of performing our due diligence investigations in connection with the EPI Health Acquisition. We may learn additional information about EPI Health that materially and adversely affects us and EPI Health, such as unknown or contingent liabilities related to compliance with applicable laws. Moreover, EPI Health may be subject to audits, reviews, inquiries, investigations, and claims of non-compliance and litigation by federal and state regulatory agencies which could result in liabilities or other sanctions. Any such liabilities or sanctions, individually or in the aggregate, could have an adverse effect on our business, financial condition, and results of operations.

We have made certain assumptions relating to the EPI Health Acquisition that may prove to be materially inaccurate.

We have made certain assumptions relating to the EPI Health Acquisition that may prove to be inaccurate, including as the result of the potential failure to realize the expected benefits of the EPI Health Acquisition, failure to realize expected revenue growth rates, higher than expected operating and transaction costs, as well as general economic and business conditions that could adversely affect the combined company.

The EPI Health Acquisition involves substantial costs.

We have incurred, and expect to continue to incur, a number of non-recurring costs associated with the EPI Health Acquisition. The substantial majority of the non-recurring expenses will consist of transaction costs related to the EPI Health Acquisition. We will also incur transaction fees and costs related to formulating and implementing integration plans, including system consolidation costs and employment-related costs. We continue to assess the magnitude of these costs, and additional unanticipated costs may be incurred relating to the EPI Health Acquisition and integration. Although we anticipate that the

elimination of duplicative costs and the realization of other efficiencies and synergies related to the integration should allow us to offset integration-related costs over time, this net benefit may not be achieved in the near term, or at all.

Risks Relating to our Common Stock

The market price and trading volume of our common stock has fluctuated substantially. The market price and trading volume of our common stock may fluctuate widely in the future and the value of an investment in our common stock may decline.

Our stock price has experienced extreme volatility and could vary significantly as a result of many factors. Between January 1, 2021 and April 30, 2022, the last reported sales price of our common stock fluctuated between a high of \$25.50 and a low of \$2.71. The market price and trading volume of our common stock may continue to fluctuate from time to time as a result of factors outside of our control. For example, the trading price of our common shares increased significantly in June 2021, which we believe was attributable to general market conditions and recognition of our announcement of top-line results of our B-SIMPLE4 study of SB206 as a potential treatment for molluscum contagiosum, and has since declined. There is a potential for rapid and substantial decreases in the price of our common stock, including decreases unrelated to our operating performance or prospects, which could result in substantial losses for our existing stockholders.

In addition, the stock market in general and smaller reporting companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. These broad market and industry fluctuations, including but not limited to those connected with the ongoing military conflict between Russia and Ukraine and trade and monetary sanctions in response to such developments, may negatively impact the price or liquidity of our common stock, regardless of our operating performance. Any actual or perceived negative operational developments or market or industry fluctuations may compound each other's negative impacts on the price of liquidity of our common stock.

Risks Relating to Technology

We may be subject to confidential information theft or misuse, which could harm our business and results of operations. Our internal computer systems, or those of any of our existing or potential future collaborators, CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs, expose the Company to liability, affect our reputation and otherwise harm our business.

We face attempts by others to gain unauthorized access to our information technology systems on which we maintain proprietary and other confidential information. Despite the implementation of security measures, our internal computer systems and those of our current and any future CROs, CMOs, and other contractors, consultants and collaborators are vulnerable to damage from cyberattacks, "phishing" attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. As a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our increased reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. We may also experience security breaches that may remain undetected for an extended period.

If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, the FDA and comparable foreign regulatory authorities regulate, among other things, the record keeping and storage of data pertaining to approved and potential pharmaceutical products, and we currently store most of our preclinical research data, our clinical data and our manufacturing data at our facilities. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to applicable data privacy and security law and regulations. We would also be exposed to a risk of loss, including financial assets or litigation and potential liability, which could materially adversely affect our business, financial condition, results of operations and prospects. We also rely on third parties to manufacture our product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could be subject to material legal claims and incur liability or other negative consequences.

including increased cybersecurity protection costs, damage to our reputation, disruption of our internal operations and delays in the further development of and potential commercialization of our product candidates.

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

Unregistered Sales of Equity Securities

None.

Issuer Purchases of Equity Securities

None

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

The compensation committee of our board of directors adopted a form of award agreement for our restricted stock units, or RSUs, for purposes of granting RSUs under our 2016 Incentive Award Plan to our employees, including potentially our named executive officers, and to directors. Below is a summary of certain terms related to such RSUs.

RSUs

Vesting Schedule RSUs generally vest one-third on each anniversary of the vesting start date, such that the RSUs vest in full on the third

anniversary of such date. Each RSU will convert into one share of Company common stock.

Dividend Equivalents Cash dividends will accrue and be paid in cash upon settlement.

Termination of Service In the event of a participant's Termination of Service (as defined in the 2016 Incentive Award Plan) for any reason, all

unvested RSUs will immediately and automatically be cancelled and forfeited, except as otherwise determined by the

compensation committee or provided in a binding written agreement with the participant.

The form of award agreement for the RSUs adopted by the compensation committee is filed as Exhibit 10.1 attached hereto. The descriptions of the material terms of the form of award agreement are qualified in their entirety by reference to such award agreement, which is incorporated herein by reference.

The Company has also amended its Non-Employee Director Compensation Policy, a copy of which is filed as Exhibit 10.3 attached hereto, to provide that directors' annual equity grants under the policy will vest in full on the first anniversary of such grants, rather than one fourth of each award vesting quarterly.

Item 6. Exhibits

The following exhibits are being filed herewith or are being incorporated by reference and are numbered in accordance with Item 601 of Regulation S-K:

					INCORPOR	ATED BY REFE	RENCE
EXHIBIT NO.		DESCRIPTION	Filed Herewith	FORM	File No.	Exhibit	Filing Date
2.1	†	Unit Purchase Agreement, dated as of March 11, 2022, by and among Novan, Inc., Evening Post Group, LLC and EPI Health, LLC.		8-K	001-37880	2.1	March 11, 2022
10.1		Form of Award Agreement Awarding Restricted Stock Units under the Novan, Inc. 2016 Incentive Award Plan.	X				
10.2		Employment Agreement, dated March 11, 2022, by and between Novan, Inc. and John Donofrio.	X				
10.3		Non-Employee Director Compensation Policy.	X				
10.4		Secured Promissory Note and Security Agreement, dated as of March 11, 2022, by and between Novan, Inc. and Evening Post Group. LLC.		8-K	001-37880	10.1	March 11, 2022
10.5		Equity Distribution Agreement, dated March 11, 2022, by and between Novan, Inc. and Oppenheimer & Co. Inc.		8-K	001-37880	10.1	March 11, 2022
10.6	Ť	Amended and Restated Promotion and Collaboration Agreement, effective as of January 1, 2022, by and between MC2 Therapeutics Limited and EPI Health, LLC.	X				
10.7	†	Assignment and License Agreement, effective as of August 3, 2009, by and between Aspect Pharmaceuticals, LLC and EPI Health, LLC (as successor-in-interest to Vicept Therapeutics, Inc.).	X				
10.8	†	Amended, Restated and Consolidated License Agreement between The University of North Carolina and Novan, Inc., dated as of June 27, 2012, and as amended on November 30, 2012.	X				
10.9	†	Second Amendment, dated April 12, 2016, to the Amended, Restated and Consolidated License Agreement between The University of North Carolina and Novan, Inc., dated as of June 27, 2012.	X				
10.10	†	UNC Sublicense Agreement, dated December 29, 2015, by and between Novan, Inc. and KNOW Bio, LLC.	X				
10.11	Ť	Novan Patent and Know-How License Agreement, dated December 29, 2015, by and between Novan, Inc. and KNOW Bio, LLC.	X				
			66				

				INCORPOR	RATED BY REFEREN	Œ
EXHIBIT NO.	DESCRIPTION	Filed Herewith	FORM	File No.	Exhibit	Filing Date
10.12	† Master Manufacturing and Supply Agreement, dated August 16, 2018, by and between DPT Laboratories, Ltd. and EPI Health, LLC (as successor-in-interest to Allergan Sales, LLC).	X				
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X				
31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.	X				
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X				
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	X				
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.					
101.SCH	Inline XBRL Taxonomy Extension Schema Document.	X				
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.	X				
101.DEF	Inline XBRL Taxonomy Extension Definition Document.	X				
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.	X				
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.	X				
104	Cover Page Interactive Data File - the cover page XBRL tags are embedded within the Inline XBRL Instance document included in Exhibit 101.					

[†] Certain confidential information contained in these exhibits were omitted by means of redacting a portion of the text and replacing it with [***], pursuant to Regulation S-K Item 601(b) of the Securities Act of 1933, as amended. Certain confidential information has been excluded from the respective exhibits because it is: (i) not material; and (ii) the Company treats such information as private or confidential.

SIGNATURES

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

Novan, Inc.

By: /s/ Paula Brown Stafford

Paula Brown Stafford

Chairman, President and Chief Executive Officer

(Principal Executive Officer)

/s/ John M. Gay

John M. Gay

Chief Financial Officer

(Principal Financial Officer)

/s/ Andrew J. Novak

Andrew J. Novak

Vice President, Accounting and Business Operations

(Principal Accounting Officer)

Date: May 16, 2022

NOVAN, INC. 2016 INCENTIVE AWARD PLAN

RESTRICTED STOCK UNIT GRANT NOTICE AND RESTRICTED STOCK UNIT AGREEMENT (Awarding Restricted Stock Units)

Novan, Inc., a Delaware corporation (the <u>Company</u>"), pursuant to the Novan, Inc. 2016 Incentive Award Plan, as amended from time to time (the <u>"Plan"</u>), hereby grants to the holder listed below (the <u>"Participant"</u>), an award of restricted stock units (<u>"Restricted Stock Units"</u> or <u>"RSUs"</u>). Each vested RSU represents the right to receive one share of the Company's Common Stock (<u>"Share"</u>). This award of RSUs is subject to all of the terms and conditions set in this Restricted Stock Unit Grant Notice (this <u>Grant Notice"</u>) and the Restricted Stock Unit Agreement attached hereto as <u>Exhibit A</u> (the <u>"Agreement"</u>) and the Plan, each of which is incorporated herein by reference, and the grant of RSUs is further conditioned upon Participant's compliance with any Confidentiality and Assignment of Inventions Agreement and/or Noncompete Agreement existing or entered into in connection herewith (the <u>"Restrictive Covenants Agreement[s]"</u>). Unless otherwise defined herein, the terms defined in the Plan shall have the same defined meanings in this Grant Notice and the Agreement.

[To be specified in individual award agreements]

If Participant experiences a Termination of Service [for any reason other than

Participant's death, Disability, or an involuntary termination without Cause], all RSUs that have not become vested on or prior to the date of such Termination of Service will thereupon be automatically forfeited by the Participant without payment of any consideration

Participant: Grant Date: Number of RSUs:

Vesting Schedule:

Termination:

Vesting Commencement Date:

the Restrictive Covenants Agreement[s]. Participant has reviewed Agreement[s] in their entirety, has had an opportunity to obtain the provisions of this Grant Notice, the Agreement, the Plan, and the Re	and by the terms and conditions of this Grant Notice, the Agreement, the Plan, and this Grant Notice, the Agreement, the Plan, and the Restrictive Covenant advice of counsel prior to executing this Grant Notice and fully understands all estrictive Covenants Agreement[s]. Participant hereby agrees to accept as binding, upon any questions arising under this Grant Notice, the Agreement, the Plan, or the
NOVAN, INC.	PARTICIPANT
By:	
Name:	[Participant Name]
Title:	

therefor.]

EXHIBIT A TO RESTRICTED STOCK UNIT GRANT NOTICE

RESTRICTED STOCK UNIT AGREEMENT

Pursuant to the Grant Notice to which this Agreement is attached, the Company has granted to Participant an RSU under the Plan on such terms an condition set forth in the Grant Notice.

Capitalized terms not specifically defined in this Agreement have the meanings specified in the Grant Notice or, if not defined in the Grant Notice, in the Plan.

Article I. GENERAL

1.1 Award of RSUs and Dividend Equivalents.

- (a) The Company has granted the RSUs to Participant effective as of the grant date set forth in the Grant Notice (the <u>Grant Date</u>'). Each RSU represents the right to receive one Share or, at the option of the Company, an amount of cash, in either case, as set forth in this Agreement Participant will have no right to the distribution of any Shares or payment of any cash until the time (if ever) the RSUs have vested.
- (b) The Company hereby grants to Participant, with respect to each RSU, a Dividend Equivalent for ordinary cash dividends paid t substantially all holders of outstanding Shares with a record date after the Grant Date and prior to the date the applicable RSU is settled, forfeited or otherwise expires. Each Dividend Equivalent entitles Participant to receive the equivalent value of any such ordinary cash dividends paid on a single Share. The Company will establish a separate Dividend Equivalent bookkeeping account (a 'Dividend Equivalent Account') for each Dividend Equivalent and credit the Dividend Equivalent Account (without interest) on the applicable dividend payment date with the amount of any such cash paid.
- 1.2 <u>Incorporation of Terms of Plan</u>. The RSUs are subject to the terms and conditions set forth in this Agreement and the Plan, which is incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan will control.
- 1.3 <u>Unsecured Promise</u>. The RSUs and Dividend Equivalents will at all times prior to settlement represent an unsecured Company obligation payable only from the Company's general assets.

Article II. VESTING; FORFEITURE AND SETTLEMENT

2.1 <u>Vesting: Forfeiture</u>. The RSUs will vest according to the vesting schedule in the Grant Notice except that any fraction of an RSU that woul otherwise be vested will be accumulated and will vest only when a whole RSU has accumulated. In the event of Participant's Termination of Service for any reason, all unvested RSUs will immediately and automatically be cancelled and forfeited, except as otherwise determined by the Administrator or provided in a binding written agreement between Participant and the Company. Dividend Equivalents (including any Dividend Equivalent Account balance) will vest or be forfeited, as applicable, upon the vesting or forfeiture of the RSU with respect to which the Dividend Equivalent (including the Dividend Equivalent Account relates.

2.2 Settlement.

(a) RSUs and Dividend Equivalents (including any Dividend Equivalent Account balance) will be paid in Shares or cash at the Company' option as soon as administratively practicable after the vesting of the applicable RSU, but in no event more than sixty (60) days after the RSU's vesting date Notwithstanding the foregoing, the Company may delay any payment under this Agreement that the

Company reasonably determines would violate Applicable Law until the earliest date the Company reasonably determines the making of the payment will not cause such a violation (in accordance with Treasury Regulation Section 1.409A-2(b)(7)(ii)), provided the Company reasonably believes the delay will not result in the imposition of excise taxes under Section 409A.

(b) If an RSU is paid in cash, the amount of cash paid with respect to the RSU will equal the Fair Market Value of a Share on the da immediately preceding the payment date. If a Dividend Equivalent is paid in Shares, the number of Shares paid with respect to the Dividend Equivalent will equa the quotient, rounded down to the nearest whole Share, of the Dividend Equivalent Account balance divided by the Fair Market Value of a Share on the day immediately preceding the payment date.

Article III. TAXATION AND TAX WITHHOLDING

3.1 Representation. Participant represents to the Company that Participant has reviewed with Participant's own tax advisors the tax consequences of this Award and the transactions contemplated by the Grant Notice and this Agreement. Participant is relying solely on such advisors and not on any statements or representations of the Company or any of its agents.

3.2 <u>Tax Withholding</u>.

- (a) Subject to Section 3.2(b) herein, payment of the applicable withholding tax obligations with respect to the RSUs may be by any of the following, or a combination thereof, as determined by [Participant or the Administrator / the Company in its sole discretion]:
 - (i) cash, wire transfer of immediately available funds or check;
 - (ii) by delivery of Shares, including Shares delivered by attestation, then-owned by Participant valued at their Fair Market Value on the date of delivery;
 - (iii) by the Company withholding of Shares otherwise issuable in respect of the RSUs in satisfaction of any applicable withholding tag obligations, valued at their Fair Market Value on the applicable date;
 - (iv) with the consent of the Administrator, by delivery of a promissory note or other property that the Administrator determines is good and valuable consideration; or
 - (v) by any combination of (i) (iv) above.
- (b) Unless [Participant or the Administrator / the Company] otherwise determines, payment of the withholding tax obligations with respect to the RSUs shall be by [delivery (including electronically or telephonically to the extent permitted by the Company) of an irrevocable and unconditional undertaking by a broker acceptable to the Company to deliver promptly to the Company sufficient funds to satisfy the applicable tax withholding obligations] / [delivery (including electronically or telephonically to the extent permitted by the Company) by Participant to the Company of a copy of irrevocable and unconditional instructions to a broker acceptable to the Company that Participant has placed a market sell order with such broker with respect to Shares then-issuable upon settlement of the RSUs, and that the broker has been directed to deliver promptly to the Company funds sufficient to satisfy the applicable tax withholding obligations; provided, that payment of such proceeds is then made to the Company at such time as may be required by the Administrator].
- (c) The number of Shares which may be so withheld or surrendered pursuant to Section 3.2(a) or (b) above shall be limited to the number of Shares which have a fair market value on the date of withholding no greater than the aggregate amount of such liabilities based on the minimum individual statutory withholding rates in Participant's applicable jurisdictions for federal, state, local and foreign income tax and payroll tax purposes that are applicable to such taxable income, in accordance with the Plan.

(d) Participant acknowledges that Participant is ultimately liable and responsible for all taxes owed in connection with the RSUs, regardless of any action the Company or any Subsidiary or affiliate takes with respect to any tax withholding obligations that arise in connection with the RSUs. Neither the Company nor any Subsidiary or affiliate makes any representation or undertaking regarding the treatment of any tax withholding in connection with the grant, vesting or payment of the RSUs or the subsequent sale of Shares. The Company and its Subsidiaries and affiliates do not commit and are under no obligation t structure the RSUs to reduce or eliminate Participant's tax liability.

Article IV. OTHER PROVISIONS

- 4.1 Adjustments. Participant acknowledges that the RSUs, the Shares subject to the RSUs and the Dividend Equivalents are subject to adjustment, modification and termination in certain events as provided in this Agreement and the Plan.
- 4.2 Notices. Any notice to be given under the terms of this Agreement to the Company must be in writing and addressed to the Company in care of the Company's Secretary at the Company's principal office or the Secretary's then-current email address or facsimile number. Any notice to be given under the terms of this Agreement to Participant must be in writing and addressed to Participant at Participant's last known mailing address, email address, or facsimile number in the Company's personnel files. By a notice given pursuant to this Section, either party may designate a different address for notices to be given to that party. Any notice will be deemed duly given when actually received, when sent by email, when sent by certified mail (return receipt requested) and deposited with postage prepaid in a post office or branch post office regularly maintained by the United States Postal Service, when delivered by a nationally recognized express shipping company or upon receipt of a facsimile transmission confirmation.
 - 4.3 <u>Titles</u>. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.
- 4.4 <u>Conformity to Securities Laws</u> Participant acknowledges that the Plan, the Grant Notice, and this Agreement are intended to conform to the extern necessary with all Applicable Laws and, to the extent Applicable Laws permit, will be deemed amended as necessary to conform to Applicable Laws.
- 4.5 <u>Successors and Assigns</u>. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement will inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer set forth in the Plan, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.
- 4.6 <u>Limitations Applicable to Section 16 Persons</u> Notwithstanding any other provision of the Plan or this Agreement, if Participant is subject to Section 16 of the Exchange Act, the Plan, the Grant Notice, this Agreement, the RSUs, and the Dividend Equivalents will be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3) that are requirements for the application of such exemptive rule. To the extent Applicable Laws permit, this Agreement will be deemed amended as necessary to conform to such applicable exemptive rule.
- 4.7 <u>Entire Agreement</u>. The Plan, the Grant Notice, and this Agreement (including any exhibit hereto) constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and Participant with respect to the subject matter hereof.
- 4.8 <u>Agreement Severable</u>. In the event that any provision of the Grant Notice or this Agreement is held illegal or invalid, the provision will be severable from, and the illegality or invalidity of the provision will not be construed to have any effect on, the remaining provisions of the Grant Notice or this Agreement.

- 4.9 <u>Limitation on Participant's Rights.</u> Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and may not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. Participant will have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the RSUs and Dividend Equivalents, and rights no greater than the right to receive cash or the Shares as a genera unsecured creditor with respect to the RSUs and Dividend Equivalents, as and when settled pursuant to the terms of this Agreement.
- 4.10 Not a Contract of Employment Nothing in the Plan, the Grant Notice, or this Agreement confers upon Participant any right to continue in the employ or service of the Company or any Subsidiary or interferes with or restricts in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of Participant at any time for any reason whatsoever, with or without Cause, except to the extent expressly provided otherwise in a written agreement between the Company or a Subsidiary and Participant.
- 4.11 <u>Counterparts</u>. The Grant Notice may be executed in one or more counterparts, including by way of any electronic signature, subject to Applicable Law, each of which will be deemed an original and all of which together will constitute one instrument.

* * * * *

EMPLOYMENT AGREEMENT

This Employment Agreement (the "Agreement") is entered into as of the Closing (as defined below) (the "Effective Date"), by and between Novan, Inc., a Delaware corporation with its principal place of business in Durham County, North Carolina (the Company"), and John Donofrio ("Executive"). Executive and the Company may be referred to individually as a "party" and collectively as the "parties."

WITNESSETH:

Pursuant to the Unit Purchase Agreement between the Company, the Evening Post Group, LLC, a South Carolina limited liability company, and El Health, LLC, a South Carolina limited liability company (EPI Health), made and entered into as of March 11, 2022 (the "Purchase Agreement"), the Company will purchase all of the outstanding units of EPI Health and EPI Health will become a wholly owned subsidiary of the Company as of the closing (the "Closing") of the transaction (the "Transaction").

WHEREAS, Executive has been employed as the President and Chief Executive Officer of EPI Health and, following the Closing, the Company wishes to employ Executive directly as its Executive Vice President and Chief Operating Officer, Novan and President, EPI Health, and Executive wishes to accept such employment on the terms and conditions set forth in this Agreement.

WHEREAS, this Agreement is a material agreement to be executed and delivered in connection with the Transaction, and is a condition of Closing c the Transaction under the Purchase Agreement.

WHEREAS, as a condition of the Company's willingness to enter into this Agreement, Executive is required to execute contemporaneously th Proprietary Information, Inventions, Non-Competition and Non-Solicitation Agreement (the "Restrictive Covenants Agreement").

WHEREAS, Executive acknowledges and agrees that Executive will personally receive significant benefits and compensation as the result of the Closing of the Transaction and, together with the additional compensation set forth in this Agreement, such benefits and compensation provide adequate consideration for Executive's agreement to the terms of this Agreement and the terms of the Restrictive Covenant Agreement.

NOW, THEREFORE, in consideration of the foregoing, the mutual promises herein contained, and other good and valuable consideration, includir the employment of Executive by the Company the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, hereby agree as follows.

1. <u>EMPLOYMENT</u>. As of the Effective Date, Executive shall serve as the Company's Executive Vice President and Chief Operating Officer Novan and President, EPI Health, reporting to the Company's President and Chief Executive Officer, upon the terms and conditions hereinafter set forth.

2. DUTIES; EXCLUSIVE SERVICE.

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- (a) Executive shall faithfully discharge his responsibilities and perform all duties prescribed to him by the Company's Chief Executive Officer (the 'CEO'), as well as any duties as are set forth in the Bylaws of the Company related to Executive's position. In addition, Executive expressly agrees that his services include but are not limited to attendance at scheduled meetings of the Company's Board of Directors (the 'Board') and all other normal duties associated with the responsibilities of the Executive Vice President and Chief Operating Officer, Novan and President, EPI Health. Executive agrees to comply with all Company policies, standards and regulations now existing or hereafter promulgated. Executive further agrees to devote all of his working time and attention to the performance of his duties and responsibilities on behalf of the Company and in furtherance of its best interests. Notwithstanding the foregoing, Executive may serve on boards or advisory committees without compensation of non-profit or charitable organizations and, with the prior written consent of the CEO, boards or advisory committees of for-profit organizations or companies, in each case, so long as such service and obligations do not interfere with Executive's duties at the Company. The Company consents to Executive's continued service as a director and committee chair of Aytu BioPharma, Inc. During the Term, Executive agrees to immediately resign from the board of any company that engages in any business that competes with or represents a conflict with the business of the Company as determined in the reasonable discretion of the Board.
- (b) Executive's primary work location will be EPI Health's offices in Charleston, South Carolina, subject to regular business trave including but not limited to regular travel to the Company's headquarters in Durham, North Carolina.

3. <u>COMPENSATION</u>. Executive's compensation shall be paid as follows:

- (a) <u>Base Salary</u>. Executive shall receive as compensation a base salary at an annual rate of Four Hundred Thousand Dollar (\$400,000.00) ("<u>Base Salary</u>"), less any federal, state and local payroll taxes and other withholdings legally required or properly requested by Executive. Base Salary shall be payable in accordance with the Company's regular payroll practices and procedures, which shall be no less frequently than once a month. Base Salary shall be subject to annual review by the Company and adjustment within the Company's discretion.
- (b) Annual Bonus. For each calendar year during the Term, Executive will be eligible to receive an annual performance-based cash bonus, upon achievement of the annual bonus objectives established by the Company ("Annual Bonus") pursuant to the Company's Executive Annual Incentive Plar or another bonus plan established by the Company, with a target Annual Bonus equal to fifty percent (50%) of Base Salary for achievement of the performance objectives established by the Company, with potential for seventy five percent (75%) of Base Salary for achievement of upside forecasts, as determined by the Board. Executive's eligibility for an Annual Bonus is contingent on Executive remaining employed through December 31 of the applicable calendar year. Each Annual Bonus will be paid to Executive no later than March 15 of the calendar year following the calendar year during which performance is measured. Executive's Annual Bonus for 2022 will be guaranteed to equal at least the target level.
- (c) <u>Equity Grant</u> Conditioned on approval by the Company's Board of Directors, the Company will grant to Executive 75,000 nonqualified stock options to purchase shares of the Company's Common Stock, with an exercise price to be determined in accordance with the terms of the Company's 2016 Incentive Award Plan, as amended or restated from time to time (collectively, the "2016 Plan"), which options will vest in three (3) equal annual installments on each annual anniversary of the grant until fully vested, subject to Executive's

continuous	service '	with the (Company	on each such	n vesting date	. Such options	will be	subject to	the terms	of the	2016 l	Plan and	the standard	l stock	option
award agre	ement.				_	-		-							•

- (d) <u>Equity Incentive Plan</u> Executive will be eligible to participate in Company's incentive award plans as may be approved by the Board from time-to-time, including the 2016 Plan, at such level and on such terms as shall be approved by the Compensation Committee of the Board, in its sok discretion.
- (e) Paid Time Off Executive is entitled to receive the maximum amount of paid-time-off ("PTO") allowed under the Company's policies, which PTO will be accrued and used in accordance with the Company's policies. Executive will also carry over up to 40 hours of Executive's accrued but unused PTO from EPI Health, which amount must be used before using any PTO under the Company's plan, and such carryover from EPI Health shall t forfeited if it has not been used as of December 31, 2022. All vacation or paid time off must be used by December 31 of each year, or it is forfeited, and is not paid upon termination of employment, except in either case where prohibited by law.
- (f) <u>Benefits</u>. Executive shall be entitled to participate in employee benefit plans, programs and arrangements of the Company as are provided generally from time to time to all other similarly situated employees of the Company. All such benefits are subject to the provisions of their respective plan documents in accordance with their terms and are subject to amendment or termination by the Company without Executive's consent.
- (g) <u>Business Expenses</u>. The Company will reimburse all reasonable expenses incurred by Executive in the performance of his duties to the Company, provided Executive complies with the Company's policies and procedures for reimbursement or advance of business expenses established by the Company.
- 4. <u>EMPLOYMENT AT WILL; TERMINATION</u>. The term of employment under this Agreement (the "<u>Term</u>") shall commence on the Effective Date and continue until termination as provided in this Section 4, and subject to the terms of Section 6. Subject to Section 6, Executive's employment with the Company is at will, and either party can terminate the employment relationship and/or this Agreement at any time, for any or no cause or reason, and with or without prior notice.
- 5. <u>EFFECT OF TERMINATION</u>. Upon termination of Executive's employment hereunder by either party regardless of the cause or reason, the Company shall pay Executive accrued, unpaid wages through the termination date and reimbursement for unreimbursed business expenses properly incurred by Executive, which shall be subject to and paid in accordance with the Company's expense reimbursement policy (the "<u>Accrued Amounts</u>"). The final payment of wages, less any withholdings required by law or properly requested by Executive, shall be made on the next regular payday of the Company following the termination, in accordance with the Company's normal payroll procedures. Except as otherwise provided in Section 6 of this Agreement, no other payments, benefits or other remuneration shall be due or payable to Executive.

6. SEVERANCE PROVISIONS.

- (a) <u>Definitions</u>. For the purposes of this Agreement, the following terms shall be defined as set out below:
 - i. "Cause" shall be determined in good faith by the Board (excluding Executive if then a director) and shall mean:

- a. Executive's conviction of, or plea of no contest to, any crime (whether or not involving the Company) that constitutes a felony in the jurisdiction in which Executive is charged, or that involves moral turpitude;
 - b. Any act of theft, fraud or embezzlement, or any other willful misconduct or materially dishonest behavior by Executive;
- c. Executive's failure to adequately perform his reasonably assigned duties, provided that such failure or refusal is not corrected as promptly as practicable, and in any event within thirty (30) calendar days after Executive shall have received written notice from the Company stating the nature of such failure or refusal and an opportunity to cure within such period;
- d. Executive's material violation of any of his obligations contained in any agreement between Executive and the Company, including but not limited to the Restrictive Covenants Agreement;
- e. Conduct by Executive that constitutes willful gross neglect or willful gross misconduct in carrying out his duties under this Agreement that results or that may result, as reasonably determined by the Company, in material harm to the Company, including harm to its reputation; and/or
- f. Any material failure by Executive to comply with the Company's written policies or rules, as they may be in effect from time to time, if such failure causes material/reputational or financial harm to the Company.
- ii. "Change in Control" shall have the same meaning given to such term in Section 2.9 of the Company's 2016 Plan. The Board shall have sole discretion to determine conclusively whether a Change in Control has occurred pursuant to the above definition, the date of the occurrence of such Change in Control and all incidental matters relating thereto; provided that any exercise of authority in conjunction with a determination of whether a Change ir Control is a "change in control event" as defined in Treasury Regulation Section 1.409A-3(i)(5) shall be consistent with such regulation.
- iii. "Disability" shall mean Executive's inability due to a physical or mental impairment to perform the essential functions of his job, with or without reasonable accommodation, for a period of at least ninety (90) consecutive or non-consecutive days in any twelve-month period.
- iv. "Effective Release" is defined as a general release of claims in favor of the Company substantially in the form of the release attached hereto as Exhibit A, that is executed after the Separation Date and within any consideration period required by applicable law and that is not revoked by Executive within any legallyprescribed revocation period. Failure to provide and have in effect an Effective Release within the sixty (60) day period following the Separation Date shall result in forfeiture of any benefits conditioned upon the existence of an Effective Release.
 - v. "Good Reason" shall mean the occurrence of any of the following, in each case during the Term without Executive's consent:

- a. a material diminution in Executive's Base Salary or Annual Bonus eligibility (other than in both cases a diminution that is ir connection with an across the board reduction in the base salaries or bonus eligibility of the management level employees of the Company);
- b. a material, adverse change in Executive's title, authority, duties, or responsibilities (other than temporarily while Executive is physically or mentally incapacitated or as required by applicable law), taking into account the Company's size, status as a public company, and capitalization as of the date of this Agreement; provided, however, that Good Reason shall not exist based on Executive's appointment to similar positions of a subsidiary or affiliate of the Company;
 - c. a relocation of Executive's principal place of employment by more than 50 miles, not to include regular business travel; or
 - d. any other action or inaction that constitutes a material breach of the terms of this Agreement by the Company.

Notwithstanding the forgoing, Good Reason shall not include an event or condition unless (A) Executive notifies the Company within thirty (30) days of the initial existence of one of the adverse events described above, (B) Executive provides the Company with at least thirty (30) days' written notice of his intent to resign for Good Reason, and (C) the Company fails to correct the adverse event within thirty (30) days of such notice.

- vi. "Separation Date" shall mean the date that Executive's employment is terminated.
- (b) Compensation upon Separation without Cause or for Good Reason Not in Connection with a Change in ControlUpon termination of employment by the Company without Cause or upon termination of employment by Executive for Good Reason, in each case, only if Executive is not entitled to benefits under Section 6(c) of this Agreement, conditioned upon the existence of an Effective Release and Executive's substantial and material compliance with the Restrictive Covenants Agreement and the terms thereunder, and subject to Section 7(c) and Section 8, Executive shall be entitled to, in lieu of any other separation payment or severance benefit available under any plan or otherwise:
- i. Payment of severance pay in an amount equal to (i) twelve (12) months of Executive's current Base Salary, plus (ii) a prorated Annual Bonus calculated at the target annual bonus level for the calendar year in which the Separation Date occurs based on the percentage of the calendar year actually worked by Executive as of the Separation Date (both (i) and (ii) referred to herein collectively as 'Regular Severance Pay'). All applicable withholdings required by law or authorized by Executive shall be withheld from Severance Pay. Severance Pay shall be paid in equal installments paid over the 12-month period (the "Regular Severance Period") following Executive's Separation Date pursuant to the Company's standard payroll practices and procedures applicable to Executive immediately prior to Executive's separation from service and such payments shall commence on the first such payroll date on or following the 10th day after the date on which the Effective Release becomes effective and non-revocable, as provided in Section 6(a)(iv); provided, however, that if the 60th day following Executive's termination from employment occurs in the year following the year of Executive's termination, then the payments shall commence no earlier than January 1 of such subsequent year, and the first such installment payment may include any payments missed due to any delay under this Section 6(b)(i);

- ii. Payment of the amount of any unpaid Annual Bonus for the prior calendar year, if any, to be paid when Annual Bonuses are paid to other executives at Executive's level or on the same date as the first installment of Regular Severance Pay is made, whichever date is later;
- iii. Vesting as of the Separation Date of any then unvested equity awards that would have otherwise vested through the end of the calendar year in which the Separation Date occurs; and
- iv. If Executive timely and properly elects health continuation coverage under the Consolidated Omnibus Budget Reconciliation Act o 1985 ("COBRA"), the Company shall reimburse Executive during the Regular Severance Period for the difference between the monthly COBRA premiur paid by Executive for himself and his dependents and the monthly premium amount paid by similarly situated active executives. Such reimbursement shall be paid to Executive on the $10^{\rm th}$ business day of the month immediately following the month in which the Executive timely remits the premium payment. Executive shall be eligible to receive such reimbursement until the earliest of: (a) the twelve-month anniversary of the Separation Date; (b) the date Executive is no longer eligible to receive COBRA continuation coverage; or (c) the date on which Executive becomes eligible to receives substantially similar coverage from anothe employer or other source. Notwithstanding the foregoing, if the Company's reimbursements under this Section 6(b)(iv) would violate the nondiscrimination rules applicable to non-grandfathered plans under the Affordable Care Act (the "ACA"), or result in the imposition of penalties under the ACA and the related regulations and guidance promulgated thereunder), the parties agree to reform this Section 6(b)(iv) in a manner as is necessary to comply with the ACA.
- (c) <u>Compensation upon Separation due to Change in Control</u> Upon termination of employment by the Company without Cause or upor termination of employment by Executive for Good Reason at the time of, or within twelve (12) months after a Change in Control, and conditioned upon the existence of an Effective Release and Executive's substantial and material compliance with the Restrictive Covenants Agreement and the terms thereunder, and subject to Section 7(c) and Section 8, Executive shall be entitled to, in lieu of any other separation payment or severance benefit available under any plan or otherwise (including but not limited to the severance benefits provided for in Section 6(b) hereof):
- i. Payment of severance pay in an amount equal to (i) twelve (12) months of Executive's current Base Salary, plus (ii) an amount equal to the Annual Bonus calculated at the minimum target level for the calendar year in which the Separation Date occurs (both (i) and (ii) referred to hereir collectively as "CIC Severance Pay"). All applicable withholdings required by law or authorized by Executive shall be withheld from Severance Pay. Severance Pay shall be paid in equal installments paid over the twelve-month period (the "CIC Severance Period") following Executive's Separation Date pursuant to the Company's standard payroll practices and procedures applicable to Executive immediately prior to Executive's separation from service and such payments shall commence on the first such payroll date on or following the 10th day after the date on which the Effective Release becomes effective and non-revocable, as provided in Section 6(a)(iv); provided, however, that if the 60th day following Executive's termination from employment occurs in the year following the year of Executive's termination, then the payments shall commence no earlier than January 1 of such subsequent year, and the first such installment payment may include any payments missed due to any delay under this Section 6(c)(i);
- ii. Payment of the amount of any unpaid Annual Bonus for the prior calendar year, if any, to be paid when Annual Bonuses are paid to other executives at

Executive's level or on the same date as the first installment of CIC Severance Pay is made, whichever date is later;

Date:

- iii. Accelerated vesting of the remaining unvested portion of any and all equity awards issued to Executive as of the Separation
- iv. The COBRA benefit described under Section 6(b)(iv).
- (d) Other Termination of Employment. Upon the termination of Executive's employment by Executive, other than for Good Reason, or due to Executive's death or Disability, or by the Company for Cause, Executive shall not be entitled to additional compensation under this Agreement beyond the Accrued Amounts and unpaid Annual Bonus for the prior calendar year, if any. For clarity and the avoidance of doubt, under no circumstances will Executive be entitled to benefits under both Section 6(b) and Section 6(c).

7. <u>SECTION 409A.</u>

- (a) Intent of the Parties The parties hereby acknowledge and agree that all benefits or payments provided by the Company to Executive pursuant to this Agreement are intended either to be exempt from Section 409A of the Internal Revenue Code of 1986, as amended (the <u>Code</u>"), or to be in compliance with Section 409A, and this Agreement shall be interpreted to the greatest extent possible to be so exempt or in compliance and to incorporate the terms and conditions required by Section 409A. If there is an ambiguity in the language of this Agreement, or if Section 409A guidance indicates that a change to this Agreement is required or desirable to achieve exemption or compliance with Section 409A, notwithstanding any provision of this Agreement to the contrary, the Company reserves the right (without any obligation to do so or to indemnify Executive for failure to do so) to (i) adopt such amendments to this Agreement and or adopt such other policies and procedures, including amendments, policies and procedures with retroactive effect, that the Company determines to be necessary or appropriate to preserve the intended tax treatment of the benefits provided by this Agreement, to preserve the economic benefits of this Agreement and to avoid less favorable accounting or tax consequences for the Company and/or (ii) take such other actions as the Company determines to be necessary or appropriate to exempt the amounts payable hereunder from Section 409A or to comply with the requirements of Section 409A and thereby avoid the application of penalty taxes thereunder. No provision of this Agreement shall be interpreted or construed to transfer any liability for failure to comply with the requirements of Section 409A from Executive or any other individual to the Company or any of its affiliates, employees or agents.
- (b) <u>Installments</u>. If any severance or other payments that are required by this Agreement are to be paid in a series of installment payments, each individual payment in the series shall be considered a separate payment for purposes of Section 409A. To the extent that any reimbursement of expenses or in-kind benefits constitutes "deferred compensation" under Section 409A, such reimbursement or benefit shall be provided no later than December 31 of the year following the year in which the expense was incurred. The amount of expenses reimbursed in one year shall not affect the amount of in-kind benefits provided in any other year.
- (c) <u>Delay.</u> If any severance compensation or other benefit provided to Executive pursuant to this Agreement that constitutes "nonqualified deferred compensation" within the meaning of Section 409A is considered to be paid on account of "separation from service" within the meaning of Section 409A, and Executive is a "specified employee" within the meaning of Section 409A, no payments of any such severance or other benefit shall be made for

six (6) months plus one (1) day after the Separation Date (the 'New Payment Date'). Amounts payable under this Agreement shall be deemed not to be 'nonqualified deferral of compensation' subject to Section 409A to the extent provided in the exceptions in Treasury Regulation § § 1.409A1(b)(4) ('short-term deferrals'') and (b)(9) ('separation pay plans,' including the exception under subparagraph (iii)) and other applicable provisions of Section 409A. The aggregate of any such payments that would have otherwise been paid during the period between the Separation Date and the New Payment Date shall be paid to Executive in a lump sum on the New Payment Date.

- 8. <u>EXCESS PARACHUTE PAYMENTS</u>In the event amounts payable under this Agreement or otherwise are contingent on a change in control for purposes of Section 280G of the Code, and it is determined by a public accounting firm or legal counsel authorized to practice before the Interna Revenue Service selected by the Company that any payment or benefit made or provided to Executive in connection with this Agreement or otherwise ("<u>Payment</u>" or collectively, the "<u>Payments</u>") would be subject to the excise tax imposed by Section 4999 of the Code (the "<u>Parachute Tax</u>"), the Payments under this Agreement shall be payable in full or, if applicable, in such lesser amount which would result in no portion of such Payments being subject to the Parachute Tax, whichever of the foregoing amounts, taking into account the applicable federal, state and local income taxes and the Parachute Tax, results in Executive's receipt, on an after-tax basis, of the greatest amount of Payments under this Agreement. If Payments are reduced pursuant to this paragraph, cash severance payments under Sections 6(b)(i), 6(b)(ii) and 6(b)(iv), Sections 6(c)(i),6(c)(ii) and 6(c)(iv) or Section 6(d)(i), 6(d)(ii) and 6(d)(iii), as applicable, shall first be reduced, and the other benefits under this Agreement shall thereafter be reduced, to the extent necessary so that no portion of the Payments is subject to the Parachute Tax.
- 9. <u>NOTICES</u>. Any notice required or permitted hereunder shall be made in writing (a) either by actual delivery of the notice into the hands of the party thereto entitled, by messenger, by fax or by over-night delivery service or (b) by the mailing of the notice in the United States mail, certified or registered mail, return receipt requested, all postage pre-paid and addressed to the party to whom the notice is to be given at the party's respective address set forth below, or such other address as the parties may from time to time designate by written notice as herein provided.

If to Executive: John Donofrio

If to the Company: Novan, Inc.

4020 Stirrup Creek Drive, Suite 110

Durham, NC 27703 (Fax) (919) 237–9212

Attn: President and Chief Executive Officer

The notice shall be deemed to be received, if sent per subsection (a), on the date of its actual receipt by the party entitled thereto and, if sent per subsection (b), on the third day after the date of its mailing.

10. EMPLOYEE REPRESENTATIONS.

(a) Executive represents that his performance of all of the terms of this Agreement does not and will not breach any arrangement to keep in confidence information acquired by Executive in confidence or in trust prior to Executive's employment by the

Company. Executive represents that he has not entered into, and agrees not to enter into, any agreement either oral or written in conflict herewith.

- (b) Executive understands as part of the consideration for this Agreement and for Executive's employment or continued employment by the Company, that Executive has not brought and will not bring with Executive to the Company, or use in the performance of Executive's duties and responsibilities for the Company or otherwise on its behalf, any materials or documents of a former employer or other owner which are generally not available to the public, unless Executive has obtained written authorization from the former employer or other owner for their possession and use and has provided the Company with a copy thereof.
- (c) Executive understands that during his employment for the Company he is not to breach any obligation of confidentiality that Executive has to a former employer or any other person or entity and agrees to comply with such understanding.

11. INDEMNIFICATION.

- (a) By Executive. Executive agrees to indemnify and hold harmless the Company, its directors, officers, agents and employees against any liabilities and expenses, including amounts paid in settlement, incurred by any of them in connection with any claim by any of Executive's prior employers that the termination of Executive's employment with such employer, Executive's employment by the Company, or use of any skills and knowledge by the Company is a violation of contract or law or otherwise violates the rights thereof.
- (b) By the Company. The Company will indemnify and hold harmless the Executive from any liabilities and expenses arising from Executive's actions as an officer, director or employee of the Company to the fullest extent permitted by law, excepting any unauthorized acts, intentional or illegal conduct which breaches the terms of this or any other agreement or Company policy, including but not limited to the Restrictive Covenants Agreement. Executive will be covered by the Company's D&O insurance to the same extent as other executive officers and directors. The indemnification described in this Section 12 is in addition to, and not in lieu of, any right to indemnification provided by the Company to Executive pursuant to any separate written agreement between them regarding indemnification.
- 12. <u>SEVERABILITY</u>. Executive hereby agrees that each provision herein shall be treated as a separate and independent clause, and the unenforceability of any one clause shall in no way impair the enforceability of any of the other clauses herein.
- 13. <u>WAIVER</u>. Any waiver by the Company of a breach of any provision of this Agreement shall not operate or be construed as a waiver of any subsequent breach of such provision or any other provision hereof.
- 14. <u>AFFILIATES; ASSIGNMENT; BINDING EFFECThe</u> term "Company" shall also include any of the Company's subsidiaries, subdivisions or affiliates. The Company shall have the right to assign this Agreement to its successors and assigns, and all covenants and agreements hereunder shall inure to the benefit of and be enforceable by said successors or assigns. Executive may not assign any of his rights or delegate any of his duties under this Agreement. This Agreement shall be binding upon and shall inure to the benefit of each of the parties hereto, and to their respective heirs, representatives, successors and permitted assigns.
- 15. <u>ENTIRE AGREEMENT</u>. The terms of this Agreement (together with any other agreements and instruments contemplated hereby or referred to herein) are intended by the parties hereto to be the final expression of their agreement with respect to the employment of

Executive by the Company and may not be contradicted by evidence of any prior or contemporaneous agreement (including, without limitation, any prior or contemporaneous employment agreement, term sheet or offer letter). The parties hereto further intend that this Agreement shall constitute the complete and exclusive statement of its terms and that no extrinsic evidence whatsoever may be introduced in any judicial, administrative or other legal proceeding to vary the terms of this Agreement. No modification of or amendment to this Agreement, nor any waiver of any rights under this Agreement, will be effective unless in writing and signed by each of the parties hereto.

- 16. GOVERNING LAW; VENUE. This Agreement shall be construed, interpreted, and governed in accordance with and by North Carolina law and the applicable provisions of federal law ("Applicable Federal Law"). Any and all claims, controversies, and causes of action arising out of or relating to this Agreement, whether sounding in contract, tort, or statute, shall be governed by the laws of the state of North Carolina, including its statutes of limitations, except for Applicable Federal Law, without giving effect to any North Carolina conflict-of-laws rule that would result in the application of the laws of a different jurisdiction. Both Executive and the Company acknowledge and agree that the state or federal courts located in North Carolina have persona jurisdiction over them and over any dispute arising under this Agreement, and both Executive and the Company irrevocably consent to the jurisdiction of such courts.
- 17. <u>COUNTERPARTS</u>. This Agreement may be executed in separate counterparts, each of which is deemed to be an original and all of which taken together constitute one agreement. Counterparts may be transmitted and/or signed by facsimile or electronic mail. The effectiveness of any such documents and signatures shall have the same force and effect as manually signed originals and shall be binding on the parties to the same extent as a manually signed original thereof.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties have executed this Employment Agreement effective as of the day and year first above written.
NOVAN, INC.
/s/ Paula Brown Stafford Paula Brown Stafford Chairman, President and Chief Executive Officer
JOHN DONOFRIO
/s/ John A. Donofrio
[Signature page for Employment Agreement]

Exhibit A

FORM OF GENERAL RELEASE AGREEMENT

the result of the termination of Executive's employment. Notwithstanding the foregoing, Executive remains entitled to any vested retirement or stock option benefits vested as of the Effective Date of the Agreement, pursuant to the terms of the applicable plans and agreements.

- 5. <u>COMPANY PROPERT</u>YBy signing this Agreement, Executive represents that: (i) Executive has delivered to the Company all records memoranda, data, documents and other property of any description which refer or relate in any way to trade secrets or confidential information, including all copies thereof, which are in Executive's possession, custody or control; (ii) Executive has delivered to the Company all Company property (including, but not limited to, keys, credit cards, computers, client files, contracts, proposals, work in process, manuals, forms, computer stored work in process and other computer data, research materials, other items of business information concerning any Company customer or client or potential prospect to purchase some or all of the Company's assets, or Company business or business methods, including all copies thereof) which is in Executive's possession, custody or control; and (iii) Executive will fully cooperate with the Company in winding up Executive's work and transferring that work to other individuals designated by the Company during the remainder of the employment with the Company.
- 6. <u>ADEQUACY OF CONSIDERATION</u> executive acknowledges that the benefits available to Executive under this Agreement are of greater value than the benefits to which Executive would be entitled to receive if Executive did not sign this Agreement, and constitute adequate consideration for the releases of claims, under Sections 7 and 8 of this Agreement.
- 7. RELEASE. IN CONSIDERATION OF THE BENEFITS CONFERRED BY THIS AGREEMENCUTIVE (ON BEHALF (EXECUTIVE, EXECUTIVE'S FAMILY MEMBERS, HEIRS, ASSIGNS, EXECUTORS AND OTHER REPRESENTATIVES) RELEATION COMPANY AND ITS AFFILIATES, INCLUDING BUT NOT LIMITED TO EPI HEALTH, LLC, AND ALL OF THEIR PAST, PRESE FUTURE PARENTS, SUBSIDIARIES, AFFILIATES, AND THEIR PREDECESSORS, SUCCESSORS, ASSIGNS, AND THEIR PAST, AND FUTURE OFFICERS, DIRECTORS, EXECUTIVES, OWNERS, INVESTORS, SHAREHOLDERS, ADMINISTRATORS, BUSINE EXECUTIVE BENEFIT PLANS (TOGETHER WITH ALL PLAN ADMINISTRATORS, TRUSTEES, FIDUCIARIES AND INSURI AGENTS (RELEASEES') FROM ALL CLAIMS AND WAIVES ALL RIGHTS KNOWN OR UNKNOWN, EXECUTIVE MAY HA'CLAIM TO HAVE IN EACH CASE RELATING TO EXECUTIVE'S EMPLOYMENT WITH THE COMPANY, OR EXECUTIVE'S SEPATHEREFROM, ARISING BEFORE THE EXECUTION OF THIS AGREEMENT BY EXECUTIVE, INCIDENTIFICATION
- (a) arising under laws prohibiting age (including but not limited to claims under the Age Discrimination in Employment Act of 1967 ("ADEA"), as amended, and the Older Worker Benefit Protection Act of 1990 ("OWBPA")), sex, national origin, race, religion, disability, veteran status or other protected class discrimination, the Family and Medical Leave Act, as amended, harassment or retaliation for protected activity;
- (b) for compensation, commission payments, bonus payments and/or benefits including but not limited to claims under the Fair Labor Standards Act of 1938, as amended, the Executive Retirement Income Security Act of 1974, as amended, the FMLA, and similar federal, state, and local laws, or the applicable laws of any foreign country;
 - (c) arising out of Executive's ownership of unvested stock or options in the Company or its affiliates;

- (d) under federal, state or local law, or the applicable laws of any foreign country, of any nature whatsoever, including but not limited to constitutional, statutory, contractual and common law, negligence, tort, alleged fraud, concealment, defamation, negligent misrepresentation, promissory estoppel, quantum meruit, intentional or negligent infliction of emotional distress, invasion of privacy, wrongful discharge, breach of the covenant of good faith and fair dealing, violation of public policy, constructive termination;
 - (e) under any employment agreement, including the Employment Agreement;
 - (f) for attorneys' fees;
 - (g) brought through the Executive's prosecution or participation in any class or collective action against the Company.

For the purpose of implementing a full and complete release and discharge, Executive expressly acknowledges that this Agreement is intended to include in its effect, without limitation, all claims which Executive does not know or suspect to exist in Executive's favor at the time of execution hereof, and that this Agreement contemplated the extinguishment of any such claims or claims.

- 8. <u>EXCLUDED CLAIM</u>SThis release in Section 7 does not apply to claims by Executive: (a) for workers' compensation benefits or unemployment benefits filed with the applicable state agencies; (b) for vested stock options or pension or retirement benefits including under the Company's 401(k) plan; (c) to continuation coverage under COBRA, or equivalent applicable law; (c) to rights that cannot lawfully be released by a private settlemen agreement; or (f) to enforce, or for a breach of, this Agreement (the "**Reserved Claims**").
- 9. <u>COVENANT NOT TO SUB</u>n consideration of the benefits offered to Executive, Executive will not sue Releasees on any of the releasee claims or on any matters relating to Executive's employment arising before the execution of this Agreement other than with respect to the Reserved Claims, including but not limited to claims under the ADEA, or join as a party with others who may sue Releasees on any such claims; provided, however, this paragraph will not bar a challenge under the OWBPA to the enforceability of the waiver and release of ADEA claims set forth in this Agreement, the Reserved Claims, or where otherwise prohibited by law. If Executive does not abide by this paragraph, then (i) Executive will return all monies received under this Agreement and indemnify Releasees for all expenses incurred in defending the action, and (ii) Releasees will be relieved of their obligations hereunder.
- 10. RIGHT TO REVIEWThe Company delivered this Agreement, containing the release language set forth in Sections 7, 8 and 9, to Executive on [______,] 20__ (the "Notification Date"), and informed Executive that it desires that Executive have adequate time and opportunity to review and understand the consequences of entering into it. The Company advises Executive as follows:
 - Executive should consult with Executive's attorney prior to executing this Agreement; and
 - Executive has 21 days from the Notification Date within which to consider this Agreement.

Executive must return an executed copy of this Agreement to the Company on or before the 22nd day following the Notification Date. Executive acknowledges and understands that Executive is not required to use the entire 21-day review period and may execute and return this Agreement at any time before the 22nd day following the Notification Date, *but not before the Separation Date*. If, however, Executive does not execute and return an executed copy of this Agreement on

or before the 22nd day following the Notification Date, this Agreement shall become null and void. This executed Agreement shall be returned to: *[insert address], with a copy sent to [insert email address]*

- 11. <u>REVOCATION</u>. Executive may revoke Executive's execution of this Agreement during the seven (7) day period immediately following Executive's execution of it. This Agreement will not become effective or enforceable until the revocation period has expired (the "Effective Date"). To revoke this Agreement, a written notice of revocation must be delivered to: [insert address], with a copy sent to [insert email address]
- 12. <u>AGENCY CHARGES/INVESTIGATIONS</u>. Executive understands that nothing contained in this Agreement limits Executive's ability to file a charge or complaint with the Equal Employment Opportunity Commission (although the Executive waives any right to monetary relief related to any filed charge or administrative complaint), the National Labor Relations Board, the Occupational Safety and Health Administration, the Securities and Exchang Commission or any other federal, state, or local governmental agency or commission ("Government Agencies"). Executive further understands that this Agreement does not limit Executive's ability to communicate with any Government Agencies or otherwise participate in any investigation or proceeding that may be conducted by any Government Agency, including providing documents or other information, without notice to the Company. This Agreement does not limit Executive's right to receive an award for information provided to any Government Agencies.
- 13. <u>NON-DISPARAGEMENT</u>. Executive agrees and covenants that Executive shall not at any time make, publish, or communicate to any person or entity or in any public forum any defamatory, maliciously false or disparaging remarks, comments, or statements concerning the Company, or its affiliates, or their businesses, or any of its employees, officers, or directors and their existing and prospective customers, suppliers, investors, and other associated third parties, now or in the future.
- 14. <u>DISCLAIMER OF LIABILI</u>TNothing in this Agreement is to be construed as either an admission of liability or admission of wrongdoing on the part of either party, each of which denies any liabilities or wrongdoing on their part.
- 15. GOVERNING LAW; VENUEThis Agreement will be construed, interpreted, and governed in accordance with and by North Carolina law and the applicable provisions of federal law ("Applicable Federal Law"). Any and all claims, controversies, and causes of action arising out of or relating to this Agreement, whether sounding in contract, tort, or statute, shall be governed by the laws of the state of North Carolina, including its statutes of limitations, except for Applicable Federal Law, without giving effect to any North Carolina conflict-of-laws rule that would result in the application of the laws of a different jurisdiction. Both Executive and the Company acknowledge and agree that the state or federal courts located in North Carolina have persona jurisdiction over them and over any dispute arising under this Agreement, and both Executive and the Company irrevocably consent to the jurisdiction of such courts.
- 16. <u>ENTIRE AGREEMEN</u> Texcept for the Proprietary Information and Non-Competition Agreement, the surviving terms of the Employmen Agreement, or as expressly provided herein, this Agreement: (i) supersedes and cancels all other understandings and agreements, oral or written, with respect to Executive's employment with the Company; (ii) supersedes all other understandings and agreements, oral or written, between the Parties with respect to the subject matter of this Agreement; and (iii) constitutes the sole agreement between the Parties with respect to this subject matter. Each party acknowledges that: (i) no representations, inducements, promises or agreements, oral or written, have been made by any party or by anyone acting on behalf of any party, which are not embodied in this Agreement; and

(ii) no agreement, statement or promise not contained in this Agreement shall be valid. No change or modification of this Agreement shall be valid or binding upon the Parties unless such change or modification is in writing and is signed by the Parties.

17. <u>SEVERABILITY</u>; <u>SEPARATE AND INDEPENDENT COVENANTS</u> any portion, provision, or part of this Agreement is held, determined, or adjudicated by any court of competent jurisdiction to be invalid, unenforceable, void, or voidable for any reason whatsoever, each such portion, provision, or part shall be severed from the remaining portions, provisions, or parts of this Agreement, and such determination or adjudication shall not affect the validity or enforceability of such remaining portions, provisions, or parts. The Company acknowledges and agrees that each of Executive's covenants in this Agreement or the Employment Agreement shall be construed for all purposes to be separate and independent from any other covenant, whether in this Agreement or otherwise, and the existence of any claim by the Company or any of its affiliates against Executive under this Agreement, the Employmen Agreement or otherwise, will not excuse the Company's breach of any covenant contained in this Agreement.

18. SECTION 409A OF THE INTERNAL REVENUE CODE.

- (a) Parties' Intent. The Parties intend that no payments or benefits hereunder shall constitute non-qualified deferred compensation within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended (the <u>Code</u>"), and the regulations thereunder (collectively, "<u>Section 409A</u>") and all provisions of this Agreement shall be construed in a manner consistent with such intention. If any provision of this Agreement (or of any award of compensation, including equity compensation or benefits) would cause Executive to incur any additional tax or interest under Section 409A, the Company shall, upon the specific request of Executive, use its reasonable business efforts to in good faith reform such provision to be exempt from, or comply with, Code Section 409A; provided, that to the maximum extent practicable, the original intent and economic benefit to Executive and the Company of the applicable provision shall be maintained, and the Company shall have no obligation to make any changes that could create any material additional economic cost or loss of material benefit to the Company. The Company shall timely use its reasonable business efforts to amend any plan or program in which Executive participates to bring it under an exemption from, or in compliance with, Section 409A. Notwithstanding the foregoing, the Company shall have no liability with regard to any failure to comply with Section 409A so long as it has acted in good faith with regard to compliance therewith.
- (b) <u>Separation from Service</u>. A termination of employment or separation from service shall not be deemed to have occurred for purposes of any provision of this Agreement providing for the payment of any amounts or benefits that constitute nonqualified deferred compensation within the meaning of Section 409A upon or following a termination of employment or separation from service unless such termination also constitutes a "<u>Separation from Service</u>" within the meaning of Section 409A and, for purposes of any such provision of this Agreement, references to a "termination," "termination of employment," "separation from service" or like terms shall mean Separation from Service.
- (c) <u>Installment Payments.</u> If any severance or other payments that are required by this Agreement are to be paid in a series of installment payments, each individual payment in the series shall be considered a separate payment for purposes of Section 409A. To the extent that any reimbursement of expenses or in-kind benefits constitutes "deferred compensation" under Section 409A, such reimbursement or benefit shall be provided no later than December 31 of the year following the year in which the expense was incurred. The amount of expenses reimbursed in one year shall not affect the amount eligible for reimbursement in any subsequent year. The amount of any in-kind benefits provided in one year shall not affect the amount of in-kind benefits provided in any other year.

(d) <u>Delay</u> . If any severance compensation or other benefit provided to Executive pursuant to this Agreement that constitutes "nonqualification".
deferred compensation" within the meaning of Section 409A is considered to be paid on account of "separation from service" within the meaning of Section 409A is considered to be paid on account of "separation from service" within the meaning of Section 409A is considered to be paid on account of "separation from service" within the meaning of Section 409A is considered to be paid on account of "separation from service" within the meaning of Section 409A is considered to be paid on account of "separation from service" within the meaning of Section 409A is considered to be paid on account of "separation from service" within the meaning of Section 409A is considered to be paid on account of "separation from service" within the meaning of Section 409A is considered to be paid on account of the service of the
409A, and Executive is a "specified employee" within the meaning of Section 409A, no payments of any such severance or other benefit shall be made for
(6) months plus one (1) day after the Separation Date (the 'New Payment Date'). Amounts payable under this Agreement shall be deemed not to be
"nonqualified deferral of compensation" subject to Section 409A to the extent provided in the exceptions in Treasury Regulation § § 1.409A1(b)(4) ("sho
term deferrals") and (b)(9) ("separation pay plans," including the exception under subparagraph (iii)) and other applicable provisions of Section 409A. T
aggregate of any such payments that would have otherwise been paid during the period between the Separation Date and the New Payment Date shall be paid
to Executive in a lump sum on the New Payment Date.
•

- 19. <u>COUNTERPARTS</u>. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, and all of which taken together shall constitute one and the same instrument. Any party hereto may execute this Agreement by signing any such counterpart.
- 20. WAIVER OF BREACHA waiver of any breach of this Agreement shall not constitute a waiver of any other provision of this Agreement or any subsequent breach of this Agreement.

[Signature Page Follows]

EXECUTIVE REPRESENTS THAT EXECUTIVE HAS CAREFULLY READ THIS ENTIRE GENERAL RELEASE AGREEMENT, UNDERSTANDS ITS CONSEQUENCES, AND VOLUNTARILY ENTERS INTO IT.

NOVAN, INC.	
JOHN DONOFRIO	
Date://	
[Signature page for Form of General Release Agreement]	

NOVAN, INC.

NON-EMPLOYEE DIRECTOR COMPENSATION POLICY

April 21, 2022

Non-employee members of the board of directors (the "Board") of Novan, Inc. (the "Company") shall be eligible to receive cash and equity compensation as set forth in this Non-Employee Director Compensation Policy (this "Policy"). The cash and equity compensation described in this Policy shall be paid or be made, as applicable, automatically and without further action of the Board, to each member of the Board who is not an employee of the Company or any parent or subsidiary of the Company (each, a "Non-Employee Director"), who may be eligible to receive such cash or equity compensation, unless such Non-Employee Director declines the receipt of such cash or equity compensation by written notice to the Company. This Policy shall become effective on the date hereof (the "Effective Date") and shall remain in effect until it is revised or rescinded by further action of the Board. This Policy may be amended, modified or terminated by the Board at any time in its sole discretion. The terms and conditions of this Policy shall supersede any prior cash and/or equity compensation arrangements for service as a member of the Board between the Company and any of its Non-Employee Directors and between any subsidiary of the Company and any of its non-employee directors. No Non-Employee Director shall have any rights hereunder, except with respect to equity awards granted pursuant to the Policy.

1. Cash Compensation.

- (a) <u>Annual Retainers</u>. Each Non-Employee Director shall receive an annual retainer of \$40,000 for service on the Board.
- (b) Additional Annual Retainers. In addition, a Non-Employee Director shall receive the following annual retainers:
- (i) <u>Chairman of the Board</u>. A Non-Employee Director serving as Chairman of the Board shall receive an additional annual retainer of \$32,500 for such service.
- (ii) <u>Lead Independent Director</u>. A Non-Employee Director serving as Lead Independent Director shall receive an additional annua retainer of \$22,500 for such service.
- (iii) <u>Audit Committee</u>. A Non-Employee Director serving as Chairperson of the Audit Committee shall receive an additional annua retainer of \$17,500 for such service. A Non-Employee Director serving as a member of the Audit Committee (other than the Chairperson) shal receive an additional annual retainer of \$8,750 for such service.
- (iv) <u>Compensation Committee</u>. A Non-Employee Director serving as Chairperson of the Compensation Committee shall receive at additional annual retainer of \$17,500 for such service. A Non-Employee Director serving as a member of the Compensation Committee (other than the Chairperson) shall receive an additional annual retainer of \$7,500 for such service.
- (v) Nominating and Corporate Governance Committee A Non-Employee Director serving as Chairperson of the Nominating and Corporate Governance Committee shall receive an additional annual retainer of \$10,000 for such service. A

Non-Employee Director serving as a member of the Nominating and Corporate Governance Committee (other than the Chairperson) shall receive a additional annual retainer of \$5,000 for such service.

- (vi) <u>Science and Technology Committee</u>. A Non-Employee Director serving as Chairperson of the Science and Technology Committee shall receive an additional annual retainer of \$20,000 for such service. A Non-Employee Director serving as a member of the Science and Technology Committee (other than the Chairperson) shall receive an additional annual retainer of \$6,000 for each service.
- (vii) Special Committee. In the event the Board creates a special committee, or designates the members of a standing committee to function with respect to a special purpose as members of a special committee, additional cash compensation in the form of a retainer or a per meeting fee, whether such meeting is attended in person or by telephone, shall be paid at the rate established by the Board at the time the Board establishes such committee or designates members of a standing committee to function with respect to a special purpose as members of a special committee. Only the members of the special committee (or members of a standing committee to function with respect to a special purpose as members of a special committee) are eligible for the payments described in this section with respect to meetings of such special committee.
- (c) <u>Payment of Retainers</u> The annual retainers described in Sections 1(a) and 1(b) shall be earned on a quarterly basis based on a calendar quarter and shall be paid by the Company in arrears not later than the fifteenth day following the end of each calendar quarter. In the event a Non-Employee Director does not serve as a Non-Employee Director, or in the applicable positions described in Section 1(b), for an entire calendar quarter, such Non-Employee Director shall receive a prorated portion of the retainer(s) otherwise payable to such Non-Employee Director for such calendar quarter pursuant to Section 1(b), with such prorated portion determined by multiplying such otherwise payable retainer(s) by a fraction, the numerator of which is the number of days during which the Non-Employee Director serves as a Non-Employee Director or in the applicable positions described in Section 1(b) during the applicable calendar quarter and the denominator of which is the number of days in the applicable calendar quarter.
- 2. <u>Equity Compensation</u> Non-Employee Directors shall be granted the equity awards described below. The awards described below shall be granted under and shall be subject to the terms and provisions of the Company's 2016 Incentive Award Plan or any other applicable Company equity incentive plan then-maintained by the Company (the "Equity Plan") and shall be granted subject to the execution and delivery of award agreements, including attached exhibits, in substantially the forms previously approved by the Board. All applicable terms of the Equity Plan apply to this Policy as if fully set forth herein, and all equity grants hereunder are subject in all respects to the terms of the Equity Plan.
- (a) Annual Awards. A Non-Employee Director who (i) serves on the Board as of the date of any annual meeting of the Company's stockholders (an "Annual Meeting") after the Effective Date and (ii) will continue to serve as a Non-Employee Director immediately following such Annual Meeting sha be automatically granted, on the date of such Annual Meeting, an option to purchase the number of shares of the Company's common stock (at a per-share exercise price equal to the closing price per share of the Company's common stock on the date of such annual meeting (or on the last preceding trading day if the date of the annual meeting is not a trading day)) that have an aggregate fair value on the date of grant of \$100,000 (as determined in accordance with ASC 718) (with the number of shares of Common Stock underlying each such award subject to adjustment as provided in the Equity Plan): provided that at the discretion of the Compensation Committee and pursuant to the exercise of its business judgment, taking into

account such factors, circumstances and considerations as it shall deem relevant from time to time, the Compensation Committee can impose a cap on the number of shares subject to such award (the "Cap"). The awards described in this Section 2(a) shall be referred to as the "Annual Awards." Notwithstanding the foregoing, the Board in its sole discretion may determine that the Annual Awards for any year be granted in the form of restricted stock units with equivalent value on the date of grant (with the number of shares of Common Stock underlying each such award not to exceed the Cap, if applicable, and subject to adjustment as provided in the Equity Plan). For the avoidance of doubt, a Non-Employee Director elected for the first tim to the Board at an Annual Meeting shall only receive an Annual Award in connection with such election, and shall not receive any Initial Award (as defined below) on the date of such Annual Meeting as well.

- (b) Initial Awards. Except as otherwise determined by the Board, each Non-Employee Director who is initially elected or appointed to the Board on any date other than the date of an Annual Meeting shall be automatically granted, on the date of such Non-Employee Director's initial election or appointment (such Non-Employee Director's "Start Date"), an option to purchase shares of the Company's common stock (at a per-share exercise price equal to the closing price per share of the Company's common stock on the date of such election or appointment (or on the last preceding trading day if such date is not a trading day)) equal to the lesser of the Cap, if applicable, or the number of shares that have an aggregate fair value on such Non-Employee Director's Start Date equal to the product of (i) \$100,000 (as determined in accordance with ASC 718), and (ii) a fraction, the numerator of which is (x) 36's minus (y) the number of days in the period beginning on the date of the Annual Meeting immediately preceding such Non-Employee Director's Start Date and ending on such Non-Employee Director's Start Date and the denominator of which is 365 (with the number of shares of Common Stock underlying each such awards." Notwithstanding the foregoing, the Board in its sole discretion may determine that the Initial Award for any Non-Employee Director be granted in the form of restricted stock units with equivalent value on the date of grant (with the number of shares of Common Stock underlying each such award not to exceed the Cap, if applicable, and subject to adjustment as provided in the Equity Plan). For the avoidance of doubt, no Non-Employee Director shall be granted more than one Initial Award.
- (c) <u>Termination of Service of Employee Directors</u> Members of the Board who are employees of the Company or any parent or subsidiary of the Company who subsequently terminate their service with the Company and any parent or subsidiary of the Company and remain on the Board will not receive an Initial Award pursuant to Section 2(b) above, but to the extent that they are otherwise eligible, will be eligible to receive, after termination from service with the Company and any parent or subsidiary of the Company, Annual Awards as described in Section 2(a) above.
- (d) <u>Vesting of Awards Granted to Non-Employee Directors</u>. Each Annual Award and Initial Award shall vest in full and become exercisable on the first anniversary of the date of grant, subject to the Non-Employee Director's continued service on the Board as a Non-Employee Director through th vesting date. No portion of an Annual Award or Initial Award that is unvested or unexercisable at the time of a Non-Employee Director's termination of service on the Board as a Non-Employee Director shall become vested and exercisable thereafter. All of a Non-Employee Director's Annual Awards and Initial Awards shall vest in full immediately prior to the occurrence of a Change in Control (as defined in the Equity Plan), to the extent outstanding at such time.

Certain confidential information contained in this exhibit have been omitted by means of redacting a portion of the text and replacing it with [***], pursuant to Regulation S-K Item 601(b) of the Securities Act of 1933, as amended. Certain confidential information has been excluded from this exhibit because it is: (i) not material; and (ii) the registrant treats such information as private or confidential.

AMENDED AND RESTATED PROMOTION AND COLLABORATION AGREEMENT

by and between

MC2 THERAPEUTICS LIMITED

and

EPI HEALTH, LLC

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Exhibit 1.77

Stage 1 Contracts
Product Descriptions
Product Labeling
[***]
[***]
Regulatory Activities
Pharmacovigilance Agreement
Commercialization Plan
Incremental Cost Budget

Licensed Marks

AMENDED AND RESTATED

PROMOTION AND COLLABORATION AGREEMENT

THIS AMENDED AND RESTATED PROMOTION AND COLLABORATION AGREEMENT Agreement") is entered into as of the date last written below (the "Execution Date") and deemed to be effective as of January 1, 2022 (the "Amendment Effective Date"), subject to satisfaction of the Condition Precedent (as defined below), by and between MC2 Therapeutics Limited, a limited company organized and existing under the laws of United Kingdom, having its principal place of business at James House, Emlyn Lane, Leatherhead KT22 7EP (MC2"), and EPI Health LLÇ a limited liability company having its principal place of business at 134 Columbus Street, Charleston, SC 29403, USA (EPI Health"). MC2 and EPI are sometimes referred to herein individually as a "Party" and collectively as the "Parties". Except as provided in Section 16.5, this Agreement, upon satisfaction of the Condition Precedent, will become amended and restated as of the Amendment Effective Date, and the Original Agreement (as defined below), upon satisfaction of the Condition Precedent, will be deemed terminated provided, however, that without limiting the rights and obligations under that certain Agreement and Release (as defined below), such termination shall not diminish or prejudice the rights and obligations of the Parties under the Original Agreement with respect to the period prior to the Amendment Effective Date.

Background

WHEREAS, MC2 and EPI Health are parties to the Promotion and Collaboration Agreement (the **Original Agreement**"), dated August 12, 2020 (the "Effective Date");

WHEREAS, [***]; and

WHEREAS, the Parties now desire to amend and restate the Original Agreement in its entirety, on the terms and conditions set forth herein.

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

Article 1

Definitions

As used in this Agreement, the following initially capitalized terms, whether used in the singular or plural form, shall have the meanings set forth in this Article 1.

1.1 "Added Sales Representatives" means the EPI Health Sales Representatives employed by EPI Health followin the Amendment Effective Date to, among other things, Detail and Promote the Product in the Territory, but not including the Base Sales Representatives.

1

- 1.2 "Affiliate" means, in relation to a Party, any person, firm, trust, corporation or other entity or combination thereof that directly or indirectly (a) controls said Party, (b) is controlled by said Party, or (c) is under common control with said Party; the terms "control" and "controlled," for purposes of this Section 1.1 only, meaning 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 or other entity or combination thereof or the power to direct the management of such person, firm, trust, corporation or other entity or combination thereof.
 - **1.3** "Agreement" has the meaning set forth in the preamble of this Agreement.
 - **1.4** "Agreed Budget Limitations" has the meaning set forth in Section 7.2.
 - 1.5 [***].
 - **1.6** "Alliance Manager" has the meaning set forth in Section 3.3.
 - 1.7 "Amendment Effective Date" has the meaning set forth in the preamble of this Agreement.
- 1.8 "Applicable Laws" means the applicable statutes, ordinances, other laws, rules, codes, orders, decrees of courts and regulations of any Governmental Authority in the Territory that may be in effect from time to time that apply to a Party's activities or obligations under or in connection with this Agreement, including the FD&C Act, the Prescription Drug Marketing Act of 1987, the Generic Drug Enforcement Act of 1992 (21 U.S.C. § 335a et seq.), the Anti-Kickback Statute (42 U.S.C. 1320a-7b et seq.), the Patient Protection and Affordable Care Act (42 U.S.C. § 18001 et seq.), the Antifraud and Abuse Amendment to the Social Security Act, FCPA, HIPAA, Debarment Laws, and all applicable implementing regulations for th foregoing, all as amended from time to time; and (b) the following guidelines: the Office of the Inspector General's ("OIG") Compliance Guidance Program issued in 2003, the American Medical Association (the "AMA") Guidelines on Gifts to Physicians, the Pharmaceutical Research and Manufacturers of America ("PhRMA") Code on Interactions with Healthcare Professionals, as hereafter amended from time to time (the "PhRMA Code"), and the PhRMA Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results, in each case to the extent applicable to the Parties' activities hereunder and as may be amended or supplemented from time to time (such guidelines in (b), the "Guidelines").
- **1.9** "Base Sales Representatives' means the EPI Health Sales Representatives employed by EPI Health as of th Amendment Effective Date [***] to, among other things, Detail and Promote the Product in the Territory.
- 1.10 "Business Day" means a day other than a Saturday, Sunday, and bank or other public holiday in Denmark or the U.S.
- **1.11** "Calendar Quarter" means for each Calendar Year, each of the three (3) month periods ending March 31, June 30, September 30 and December 31.

- **1.12** "Calendar Year" means the period commencing on the Effective Date and ending on December 31 of the calendar year during which the Effective Date occurs, and each successive period beginning on January 1 and ending twelve (12) consecutive calendar months later on December 31.
- 1.13 "cGMP" or "Good Manufacturing Practices" means current good manufacturing practices as set forth in 21 C.F.R. Parts 210 and 211, as established by the FDA or any similar set of laws, regulations, rules, or practices in the Territory or otherwise applicable to Development or Manufacturing of the Product pursuant to this Agreement, as may be amended from time-to-time.
- 1.14 "Change of Control" means, with respect to a Party: (a) the sale of all or substantially all of such Party's assets or business relating to this Agreement; (b) a merger, reorganization or consolidation involving such Party in which the voting securities of such Party outstanding immediately prior thereto cease to represent at least fifty percent (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation; or (c) a person or entity, or group of persons or entities, acting in concert acquire more than fifty percent (50%) of the voting equity securities or management control of such Party.
 - **1.15** "Claim" has the meaning set forth in Section 12.3(a).
 - 1.16 "Clinical Trial" means any human clinical trial of the Product.
 - **1.17** "CMS" has the meaning set forth in Section 7.7(b).
 - **1.18** "Commercial Agreements" has the meaning set forth in Section 7.8(c).
- 1.19 "Commercialization," with a correlative meaning for "Commercialize" and "Commercializing," means all activities undertaken before and after obtaining Regulatory Approvals relating specifically to the pre-launch, launch, Promotion, medical education and medical liaison activities, pricing, reimbursement, sale, and distribution of Products, including strategic marketing, sales force detailing, advertising, Product support, all customer support, Product distribution and invoicing and sales activities.
 - **1.20** "Commercialization Fee" has the meaning set forth in Section 9.1.
 - **1.21** "Commercialization Plan" has the meaning set forth in Section 7.2.
 - **1.22** "Commercialization Report" has the meaning set forth in Section 9.4.
 - **1.23** "Competing Product" has the meaning set forth in Section 2.5(a).
 - **1.24** "Commercial Trigger" has the meaning set forth in Section 6.9.
- 1.25 "Commercially Reasonable Efforts' means, with respect to the efforts to be expended by a Party with respect to such Party's obligations or tasks under this Agreement, the commercially reasonable, good faith efforts and resources to accomplish such objective

as such Party would normally use to accomplish a similar objective under similar circumstances exercising reasonable business judgement, it being understood and agreed that, in each case for manufacture, supply, regulatory matters, or Commercialization activities, as the case may be, such efforts shall be substantially equivalent to those efforts and resources used by such Party for a product owned by it or to which it has exclusive rights, which product is a similarly situated branded pharmaceutical product with similar commercial potential and product characteristics as the Product and at a similar stage of Regulatory Approval or Commercialization, taking into account efficacy, safety, proprietary position of the Product, including patent and regulatory exclusivity, regulatory requirements and FDA approval of the Product, availability of supply of Product, present and future market and commercial potential.

- **1.26** "Condition Precedent" has the meaning set forth in Section 16.5.
- 1.27 "Confidential Information" means, with respect to a Party, all Information that is disclosed by or on behalf of a Party to the other Party under this Agreement, which may include specifications, know-how, trade secrets, technical information, models, business information, inventions, discoveries, methods, procedures, formulae, protocols, techniques, data, and unpublished patent applications of the disclosing Party, its Affiliates or Third Parties, whether disclosed in oral, written, graphic, or electronic form. In addition, the terms of this Agreement will be deemed the Confidential Information of each Party. All Confidential Information (as defined in the Existing Confidentiality Agreement) disclosed by either Party or its Affiliates pursuant to the Existing Confidentiality Agreement shall be deemed to be the disclosing Party's Confidential Information hereunder.
- 1.28 "Control" means, with respect to any material, Information, or intellectual property right, that a Party (a) owns such material, Information, or intellectual property right, or (b) has a license or right to use such material, Information, or intellectual property right, in each case with the ability to grant to the other Party access, a right to use, a license, or a sublicense (as applicable) to such material, Information, or intellectual property right on the terms and conditions set forth herein, without violating the terms of any agreement or other arrangement with any Third Party.
- **1.29 "Cumulative MC2 IC"** means the aggregate amount actually paid by MC2 to EPI Health for Incremental Cost from the Amendment Effective Date until the end of the Term.
 - **1.30** "Debarment Laws" has the meaning set forth in Section 11.1(d)(iii).
 - **1.31** "**Detail**" or "**Detailing**" means, with respect to the Product, [***].
- **1.32** "Development" means non-clinical, pre-clinical and clinical drug development, research, regulatory, and/or development activities and activities related to obtaining and maintaining FDA approval of the NDA for the Product, including without limitation formulation, process and method development, quality assurance and quality control development, manufacturing, testing, and release of all clinical / registration and scale-up batches, Product validation, on-going stability testing (including post-launch

stability testing), and any other activities reasonably related to or leading to the development and submission of information to a Regulatory Authority and obtaining and maintaining approval of the NDA for the Product. When used as a verb, 'Develop' means to engage in Development.

- **1.33** "**Dispute**" has the meaning set forth in Section 15.2(a).
- **1.34** "**Dollar**" or "\$" means United States dollar.
- 1.35 [***].
- **1.36** "Effective Date" has the meaning set forth in the preamble of this Agreement.
- 1.37 "EPI Commercialization Activities' shall mean (a) Promotion, offering for sale, selling and distributing the Product in the Territory, (b) booking, processing, invoicing and collecting sales for the Product in the Territory (including handling all order-to-cash processing and related procedures), (c) handling of customer returns of the Product in the Territory, (d) handling of voluntary recalls and market withdrawals of the Product in the Territory, (e) negotiating and contracting with applicable payers and PBM's and Governmental Authorities regarding the price and reimbursement status of Products in the Territory, other than in connection with the Stage 1 Contracts, and (f) performing such other activities related to the commercial sale of the Product that are expressly designated to be performed by EPI Health pursuant to the terms of this Agreement, but excluding: (i) Development, and (ii) Manufacturing.
 - **1.38** "EPI Health" has the meaning set forth in the preamble of this Agreement.
 - **1.39** "EPI Health Claims" has the meaning set forth in Section 12.1.
 - **1.40** "EPI Health Commercial Know-How" has the meaning set forth in Section 14.6(a)(i).
 - **1.41** "EPI Health Damages" has the meaning set forth in 12.1.
 - **1.42** "EPI Health Indemnitees" has the meaning set forth in Section 12.1.
- 1.43 "EPI Health Sales Representatives" or "Sales Representatives" means pharmaceutical sales representatives, a national sales director, and regional sales managers, in each case, employed by EPI Health to, among other things, conduct Promotion, or otherwise manage such Promotion, of the Product in the Sales Territories in accordance with the terms of this Agreement.
- **1.44** "EPI Health Sales Territories" or "Sales Territories" means, as and to the extent set forth in a Commercialization Plan, sales territories within the Territory where EPI Health will hire and maintain EPI Health Sale Representatives to Detail the Product in accordance with this Agreement.

- 1.45 "EPI Health Target Quarterly Details" has the meaning set forth in Section 6.3(a).
- **1.46** "EPI Health Trademarks" has the meaning set forth in Section 6.7(a)(ii).
- **1.47** "Excused Interruption" has the meaning set forth in Section 6.3(c).
- **1.48** "Executive Officer" means, in the case of EPI Health, the President of EPI Health or his or her appointed designee, and in the case of MC2, the Chief Executive Officer of MC2 or another officer of MC2 designated by the Chie Executive Officer.
- **1.49** "Existing Confidentiality Agreement" means the Confidentiality Agreement between EPI Health and MC2, dated March 2, 2020, as may be amended.
- **1.50** "FCPA" means the U.S. Foreign Corrupt Practices Act of 1977, as amended, including the rules and regulations thereunder.
 - **1.51** "FDA" means the U.S. Food and Drug Administration or its successor entity.
 - **1.52** "FD&C Act" means the U.S. Federal Food, Drug and Cosmetic Act, as amended.
- 1.53 "Field" shall mean the treatment of any and all indications for which the Product is approved in humans in the Territory.
 - **1.54** "Field Force Detailing Plan" has the meaning set forth in Section 6.2.
- **1.55** "First Commercial Sale" means the first sale of the Product by or on behalf of EPI Health for monetary value to a Third Party for use or consumption in the Territory following receipt of Regulatory Approval.
 - **1.56** "First Measurement Period" has the meaning set forth in Section 6.9.
- 1.57 "Force Majeure Event' means an event impacting a Party due to causes beyond such Party's reasonable control, which may include actions of governmental authorities or agencies, war, hostilities between nations, civil commotions, riots, acts of terrorism, epidemics, pandemics, national industry strikes, lockouts, sabotage, fire, floods and acts of nature such as typhoons, hurricanes, earthquakes, or tsunamis, or any other event or circumstance beyond the reasonable control of such Party.
 - **1.58** "GAAP" means United States generally accepted accounting principles.
- **1.59** "Government Health Care Program' means the Medicare Part D Coverage Gap Discount Program (as defined in 42 U.S.C. 1395w-114A, as amended), the Medicaid program (Title XIX of the Social Security Act), the Department of Veterans Affairs Federal Supply Schedule Program, TRICARE, the Public Health Service 340B Program, and any simil federal, state, and local governmental health care plans and programs.

- **1.60** "Government Health Care Program Contract' means, with respect to the Product, any agreements that are necessary to give effect to any Government Health Care Program (whether or not such agreements constitute "government contracts" as such term is used in connection with government procurement).
- **1.61** "Governmental Authority" means any federal, state, local, municipal or other government authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, court or other tribunal).
- **1.62** "HIPAA" means the Health Insurance Portability and Accountability Act of 1996, as amended, and the regulations promulgated thereunder.
 - **1.63** "IC Prepayment Excess" has the meaning set forth in Section 9.3(a).
 - **1.64** "IC Prepayment Shortfall" has the meaning set forth in Section 9.3(a).
 - **1.65** "ICC" has the meaning set forth in Section 15.2(b).
 - **1.66** "Incentive Fee" has the meaning set forth in Section 9.2.
- 1.67 "Incremental Costs" means the reasonable and documented costs and expenses incurred by EPI Health beginning on the Amendment Effective Date in performing its obligations under this Agreement for Promotion and Commercialization wherein such costs and expenses would not have been incurred by EPI Health but for its obligations under this Agreement, in all cases, to the extent such costs are (i) consistent with (and do not exceed) the Incremental Cost Budget, as may be amended from time to time, (ii) reasonable by industry standards and substantially similar to those costs incurred by EPI Health in connection with products owned by it or to which it has exclusive commercial rights, (iii) incurred primarily for the benefit of the Product and not any other products owned by EPI Health or to which it has rights (provided that, in the event that any such costs are incurred for the benefit of the Product and other products of EPI Health, "Incremental Costs" shall only include the pro rata amount of such costs that are attributable to the Product (based, for example, on a determination of the relative volume of sales of the Product versus such other products or on the number of hours worked with respect to the Product versus other such products)), and (iv) incurred by EPI Health directly or by Third Party contractors already engaged by MC2 as of the Effective Date or otherwise reasonably acceptable to MC2 (such activities, the Incremental Cost **Activities**"). MC2 and EPI Health agree that a cost or expense that is included as an "Incremental Cost" in the Incremental Cost Budget is deemed to be an "Incremental Cost" for purposes of this definition. For clarity, Incremental Costs shall include payment of the Supply Price for supply of the Product. Notwithstanding anything to the contrary herein, (i) Incremental Costs with respect to the EPI Health Sales Representatives shall be defined as [***] of the costs incurred by EPI Health to employ u to [***] EPI Health Sales Representatives [***], and (ii) Incremental Costs will include all costs incurred by EPI Health t employ persons performing the operational positions identified in the Incremental Cost Budget so long as such positions are fully dedicated to the Promotion and Commercialization of the Product.

- **1.68** "Incremental Cost Budget" has the meaning set forth in Section 7.2.
- **1.69** "Indemnified Party" has the meaning set forth in Section 12.3(a).
- **1.70** "Indemnifying Party" has the meaning set forth in Section 12.3(a).
- 1.71 "Information" means any data, results and 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 materials, brochures, medical presentation materials, clinical and non-clinical study data and reports, regulatory submission summaries and regulatory submission documents, expertise, technology, test data including pharmacological, biological, chemical, biochemical, toxicological and clinical test data, analytical and quality control data, stability data, studies, procedures, territory analyses, customer lists and analyses, call point data, market research and other commercialization materials.
 - **1.72** "Infringement" has the meaning set forth in Section 10.3(a).
 - **1.73** "**Infringement Action**" has the meaning set forth in Section 10.5.
- **1.74** "**Inventions**" means any inventions and/or discoveries, including Information, processes, methods, assays, designs, protocols, and formulas, and improvements or modifications thereof, patentable or otherwise, that are generated, developed, conceived or reduced to practice by or on behalf of a Party or its Affiliate or their respective sublicensees pursuant to activities conducted under this Agreement, in each case including all rights, title and interest in and to the intellectual property rights therein and thereto.
- **1.75** "Joint Steering Committee" or "JSC" means the committee formed by the Parties as described in Section 3.1(a).
- **1.76** "Licensed Know-How" means all Information Controlled as of the Effective Date or thereafter during the Term by MC2 and/or its Affiliate(s) and reasonably necessary for the use, importation, marketing, Promotion or Commercialization of the Product in the Field in the Territory.
- **1.77** "**Licensed Marks**" means the U.S. trademarks and domain names for Wynzora™ Cream at any time during the Term and existing in the Territory for use with the Product. The Licensed Marks as of the Effective Date are listed on **Exhibit 1.77**.
- **1.78** "Licensed Patents" means all patents and patent applications in the Territory that are Controlled as of the Effective Date or thereafter during the Term by MC2 and/or its Affiliates and that are reasonably necessary for the use, importation, marketing, Promotion or Commercialization of the Product in the Field in the Territory.
 - **1.79** "Licensed Technology" means, collectively, the Licensed Patents and Licensed Know-How.

- **1.80** "Manufacture" or "Manufacturing" means (a) to make, produce, manufacture, process, fill, finish, package, label, perform quality assurance and testing (including stability testing) and release and (b) solely for the purpose of further Manufacturing (as defined in subsection (a)), to ship, supply, or store a compound or product or any intermediate or component thereof. When used as a noun or gerund, "Manufacture" or "Manufacturing" means activities involved in Manufacturing a compound or product or any intermediate or component thereof.
 - **1.81** "MC2" has the meaning set forth in the preamble of this Agreement.
 - **1.82** "MC2 Claims" has the meaning set forth in Section 12.2.
 - **1.83** "MC2 Damages" has the meaning set forth in Section 12.2.
- **1.84** "MC2 Commercialization Activities" shall mean (a) Non-Detailing Promotion of the Product in the Territory, (b) negotiating with applicable payers and PBM's and Governmental Authorities regarding the price and reimbursement status of Products in the Territory, in connection with the arrangements described in **Exhibit 1.84** (the "**Stage 1 Contracts**") and (c) performing such other activities related to the commercial sale of the Product that are expressly designated to be performed by MC2 pursuant to the terms of this Agreement, but excluding: (i) Development of the Product, (ii) Manufacturing of the Product and (iii) Detailing of the Product.
 - **1.85** "MC2 IC Prepayment" has the meaning set forth in Section 9.3(a).
 - **1.86** "MC2 Indemnitees" has the meaning set forth in Section 12.1.
 - **1.87** "MC2 Obligations" has the meaning set forth in Section 14.4.
- **1.88** "MC2 Pipeline Product' means a proprietary compound or product indicated for a dermatological indication owned and Controlled by MC2 that is in clinical Development or has received, or is in the process of receiving, Regulatory Approval in the Territory during the Term (but, for clarity, excluding any such product that came into MC2's Control as a result of a Change of Control of MC2 or any Affiliate of MC2 after the Effective Date).
 - **1.89** "Measurement Periods" has the meaning set forth in Section 6.9.
- 1.90 "Medical Affairs" means activities designed to facilitate appropriate medical use of, or conduct medical education or to support appropriate Third Party research regarding, the Product sold in the Territory, which may include: (a) activities of the Parties' respective medical science liaisons who (i) conduct medical activities including providing input and assistance with consultancy meetings, recommend medically appropriate investigators for Clinical Trials and provide input in the design of such trials and other research related activities, and (ii) deliver non-promotional scientific and medical communications and conduct non-promotional activities including responding to inquiries of healthcare professionals for off-label information and presenting new Clinical Trial and other scientific information; (b) assessing requests for grants to support continuing medical

education, symposia, or Third Party research related to the Product in the Territory; (c) development, publication and dissemination of publications relating to the Product in the Territory; (d) attendance at medical conferences and interaction with experts in the medical community, including Third Party organizations (e.g., health care professional societies and patient societies); (e) providing medical information services in response to inquiries communicated via EPI Health's Sales Representatives or received by letter, phone call or digital technologies; (f) preparation and maintenance of Academy of Managed Care Pharmacy dossiers and other medical communications appropriate for managed care and access; and (g) performing healthcare economics and healthcare outcomes research other than any Clinical Trials or to the extent such research does not include surveillance or biostatistical studies.

- **1.91** "Monthly IC Report" has the meaning set forth in Section 9.3(a).
- **1.92** "Minimum Detail Effort" has the meaning set forth in Section 6.2.
- **1.93** "NDA" means a New Drug Application, as defined in the FD&C Act and applicable regulations promulgated thereunder by the FDA.
- **1.94** "Net Sales" means the gross amount invoiced by EPI or its Affiliates, or its or their Sublicensees, for sales of the Product to Third Parties in the Territory (excluding any sales among EPI Health, its Affiliates and its or their Sublicensees) less the following deductions solely to the extent incurred, allowed, or accrued with respect to such sales, and solely to the extent such deductions are in accordance with GAAP: [***] (collectively, "Sales Deductions"). There will be no double-counting the foregoing Deductions.
 - **1.95** "New York Convention" has the meaning set forth in Section 15.2(b).
 - **1.96** "Novan" has the meaning set forth in Section 14.4.
 - **1.97** "Novan Transaction" has the meaning set forth in Section 16.5.
- **1.98** "**OPDP**" means the FDA's Office of Prescription Drug Promotion (formerly Division of Drug Marketing Advertising and Communications) or its successor entity
 - **1.99** "Original Agreement" has the meaning set forth in the preamble of this Agreement.
 - **1.100** "P1 Detail" means [***].
 - **1.101** "P1 Notice" has the meaning set forth in Section 6.9.
 - 1.102 [***].
 - **1.103** "Party" has the meaning set forth in the preamble of this Agreement.
 - **1.104** "Patent Challenge" has the meaning set forth in Section 11.4(a).

- **1.105** "PDF" has the meaning set forth in Section 16.15.
- **1.106** "**Person**" means any individual, partnership, limited liability company, firm, corporation, association, trust, unincorporated organization or other entity, including any Governmental Authority.
 - **1.107** "Pharmacovigilance Agreement" has the meaning set forth in Section 5.5.
 - **1.108** "Prepaid Quarter" has the meaning set forth in Section 9.3(a).
- **1.109** "**Product**" means the finished product form of the pharmaceutical product, referred to as Wynzora™ Cream in the then-current form and packaging supplied by or on behalf of MC2 pursuant to Section 8.1 (it being understood that, as of the Effective Date, the Product is supplied in the forms described in **Exhibit 1.109**).
 - **1.110** "Product Infringement" has the meaning set forth in Section 10.3(b).
 - **1.111** "**Product Inventions**" has the meaning set forth in Section 10.1(a).
- **1.112** "**Product Labeling**" means (a) the FDA full prescribing information for the Product, including any required patient information, and (b) all labels and other written, printed or graphic matter upon any container, wrapper or any package insert or outsert utilized with or for the Product, in all cases, as approved by the FDA As of the Effective Date, the Product Labeling is set forth in **Exhibit 1.112**.
- **1.113** "**Product Samples**" means Product packaged and distributed as a complimentary trial for use with patients in the Territory and in accordance with Applicable Laws and Guidelines and free goods provided for this purpose through coupons or other mechanisms.
- **1.114** "**Promotion**" means the conduct of (a) Detailing of the Product in the Territory and (b) other promotion, advertising, marketing, and/or offering for sale for purposes of a commercial sale of the Product in the Territory (such activities in subsection (b), collectively, "**Non-Detailing Promotion**").
- 1.115 "Promotional Materials" means all written, printed, graphic, electronic, audio or video matter, including journal advertisements, sales visual aids, reprints, direct mail, direct-to-consumer advertising, and digital technologies including internet and social media postings, internet sites, email and broadcast advertisements, in each case, intended for use or used by either Party or its Affiliates in connection with any Promotion of the Product.
 - **1.116** "Quality Agreement" has the meaning set forth in Section 8.2.
 - 1.117 "Quarterly IC Statement" has the meaning set forth in Section 9.3(a).
- **1.118** "Regulatory Approval" means all approvals necessary for the Manufacture, use, Promotion, importation, distribution, and sale of the Product in the Field in the Territory.

- **1.119** "Regulatory Authority" means any applicable Governmental Authority involved in granting Regulatory Approval in an applicable regulatory jurisdiction, including the FDA.
- **1.120** "Regulatory Materials" means regulatory applications, submissions, notifications, correspondences, registrations, Regulatory Approvals and/or other filings made to or with, or other approvals granted by, a Regulatory Authority that are necessary in order to Develop, Manufacture, market, sell or otherwise Commercialize, the Product in the Field in the Territory, including INDs and NDAs for the Product in the Field in the Territory.
 - **1.121** "Royalty Payment" has the meaning set forth in Section 9.1.
 - 1.122 [***].
 - **1.123** "SEC" means the U.S. Securities and Exchange Commission or its successor entity.
 - **1.124** "Second Measurement Period" has the meaning set forth in Section 6.9.
 - **1.125** "Subcommittee" has the meaning set forth in Section 3.4.
 - **1.126** "Sublicensee" has the meaning set forth in Section 2.4.
 - 1.127 "Sunset Payment" has the meaning set forth in Section 14.6(a).
 - **1.128** "Sunset Period" has the meaning set forth in Section 14.6(a).
 - **1.129** "Supply Terms" has the meaning set forth in Section 8.1.
 - 1.130 [***].
- 1.131 "Tax" means any tax (including any income tax, franchise tax, net worth tax, capital gains tax, gross receipts tax, value-added tax, surtax, excise tax, ad valorem tax, transfer tax, stamp tax, sales tax, use tax, property tax, business tax, withholding tax or payroll tax), levy, assessment, tariff, duty (including any customs duty), deficiency or fee, and any related charge or amount (including any fine, addition, penalty or interest), imposed, assessed or collected by any Governmental Authority in or with respect to the Territory.
 - **1.132** "Tax Withholding" has the meaning set forth in Section 9.9(c).
 - **1.133** "**Term**" has the meaning set forth in Section 14.1.
- **1.134** "Territory" means the United States of America (the "U.S."), including all possessions, territories and commonwealths thereof and all United States military bases.

- **1.135** "Third Party" means any Person other than MC2 or EPI Health or an Affiliate of either Party.
- **1.136** "True-up Adjustment" has the meaning set forth in Section 9.5.
- 1.137 "Uncured Late Payment" has the meaning set forth in Section 14.2.
- **1.138 "Unreimbursed Cumulative MC2 IC"** means the amount by which the Cumulative MC2 IC exceeds the tota Royalty Payments paid to MC2 hereunder from the Amendment Effective Date until the end of the Term.

Article 2

License Grants

- **2.1 Grant of Rights**. Subject to the terms and conditions of this Agreement, MC2 hereby:
- (a) grants to EPI Health an exclusive (even as to MC2 and its Affiliates) right and license under the Licensec Technology and the Product NDA to Detail the Product and conduct the EPI Commercialization Activities (other than Non Detailing Promotion) in the Field in the Territory, which license shall not be sublicensable except to EPI Health's Affiliates in accordance with Section 2.4 solely to perform EPI Commercialization Activities (other than Detailing) in accordance with the terms herein or with MC2's prior written consent;
- **(b)** grants to EPI Health a co-exclusive (with MC2 and its Affiliates) right and license under the Licensec Technology and the Product NDA to conduct Non-Detailing Promotion of the Product in the Field in the Territory, which license shall not be sublicensable except to EPI Health's Affiliates in accordance with Section 2.4 solely to perform Non-Detailing Promotion in accordance with the terms herein or with MC2's prior written consent; and
- (c) appoints EPI Health to serve as its exclusive (even as to MC2 and its Affiliates) distributor of the Product in the Field in the Territory, and accordingly grants EPI Health a right and license under the Licensed Technology and the Product NDA, which license shall not be sublicensable except to EPI Health's Affiliates in accordance with Section 2.4 to perform an other EPI Commercialization Activities (other than Detailing) not described in subsections (a) and (b) above with respect to the Product, in accordance with the terms herein, or with MC2's prior written consent.
- **2.2** Retained Rights. Notwithstanding the exclusive rights granted to EPI Health under Section 2.1, MC2 and it Affiliates shall retain the following rights:
 - (a) the co-exclusive right to conduct Non-Detailing Promotion of the Product in the Territory;

- **(b)** the exclusive right to perform any MC2 Commercialization Activities not described in subsection (a) above, with respect to the Product in the Territory;
 - (c) the exclusive right to Promote, Manufacture, and Commercialize the Products outside the Territory;
- (d) the exclusive right to Manufacture or have Manufactured the Products in the Territory for sale by EPI Health in the Territory, or for use by or on behalf of MC2 outside of the Territory; and
 - (e) the exclusive right to Develop or have Developed the Products.
- **2.3 Limited Trademark License to EPI Health** Subject to the terms and conditions of this Agreement, during the Term of this Agreement, MC2 grants to EPI Health a non-exclusive, non-sublicensable (except to a Sublicensee), non transferable (except as set forth in Section 16.4) right and license, to use the Licensed Marks in the Territory solely to the extent necessary for EPI Health to perform its obligations and exercise its rights under this Agreement.
- 2.4 No Sublicensing. EPI Health may not grant a sublicense under the licenses granted to EPI Health under Section 2.1 without MC2's prior written consent, except that EPI Health may grant a sublicense to an Affiliate of EPI Health for purposes of subcontracting certain obligations of EPI Health with respect to EPI Commercialization Activities (other than Detailing), Non-Detailing Promotion, and distribution pursuant to Section 2.1 to such Affiliate. For clarity, EPI Health may no grant a sublicense to or subcontract with an Affiliate of EPI Health or a Third Party for such Affiliate or Third Party to Detail th Product without MC2's prior written consent. For purposes of this Agreement, any permitted sublicensee of EPI's rights under Section 2.1 shall be deemed a "Sublicensee". EPI Health will include in each sublicense agreement an obligation of each of its Sublicensees to comply with all of the relevant provisions of this Agreement and EPI Health will remain responsible for its obligations under this Agreement and will be responsible for the performance of each of its Sublicensees and subcontractors. EPI Health 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 agreement.

2.5 Non-Compete.

(a) During the Term of this Agreement, neither EPI Health nor any of its Affiliates shall, directly or indirectly, market, detail, offer for sale, sell, have sold, promote or otherwise Commercialize any product that is approved as a drug for the same indication as a Product and directly competitive with such Product ("Competing Product") in the Territory; provided that, EPI Health shall have the right to continue to market, detail, offer for sale, sell, have sold, promote or otherwise Commercialize any product that it owns and Controls as of the Effective Date that would otherwise constitute a Competing Product.

- **(b)** During the Term of this Agreement, neither MC2 nor its Affiliates shall, directly or indirectly, market, detail, offer for sale, sell, have sold, promote, or otherwise Commercialize a Competing Product in the Territory; provided that, MC2 shall have the right to market, detail, offer for sale, sell, have sold, promote or otherwise Commercialize any product that it owns and Controls as of the Effective Date that would otherwise constitute a Competing Product [***].
- **2.6** MC2 Pipeline Product From time to time during the Term, but at least on an annual basis, MC2 shall present to EPI Health a summary of the material characteristics of any MC2 Pipeline Product(s) that MC2 intends to Promote an Commercialize in the Territory during the three year period following each such presentation; provided that, MC2 shall be required to disclose such information to EPI Health solely to the extent that MC2 has not notified EPI Health that EPI Health then in breach of any material term of this Agreement.
- **2.7 No Implied Rights.** Except for the limited rights expressly granted under Section 2.1 and the license to Licensed Marks granted under Section 2.3, no right, title or interest with respect to the Products or any Licensed Technology or other intellectual property right of MC2 or its Affiliates is granted by MC2 to EPI Health hereunder and MC2 retains all rights an interests other than expressly granted under this Agreement.

Article 3

Governance

3.1 Joint Steering Committee.

- (a) Purpose; Formation The Parties hereby establish a Joint Steering Committee (the "Joint Steering Committee" or "JSC") that will monitor and oversee the Development of the Product, the Promotion of the Product, the conduct of EPI Commercialization Activities, the conduct of the MC2 Commercialization Activities, the Manufacture of the Product and any collaborative activities of the Parties under this Agreement and that will facilitate communications between the Parties with respect to such activities and will otherwise have the responsibilities set forth in Section 3.1(c) below. EPI Health agrees that MC2 shall not be required to disclose to the JSC any CMC information regarding the Manufacture of the Product that is Confidential Information of MC2.
- (b) Composition. Each Party shall initially appoint three (3) representatives to the JSC, each of whom shall have sufficient seniority within the applicable Party to make decisions arising within the scope of the JSC's responsibilities and one (1) of which shall be the Party's Alliance Manager. Each Party shall designate their initial representatives to the JSC within ter (10) Business Days following the Effective Date. The JSC may change its size from time to time by mutual consent of its members; provided, however, that the JSC shall at all times consist of an equal number of representatives of each of MC2 and EPI Health. Each Party may replace its JSC representatives at any time upon written notice to the other Party. The JSC may invite non-members (including consultants and advisors of a Party who are under an obligation of confidentiality consistent with this Agreement) to

participate in the discussions and meetings of the JSC, <u>provided</u> that such participants shall have no voting authority at the JSC. The JSC shall have two (2) chairpersons, one from each of MC2 and EPI HealthThe role of the chairpersons shall be to convene and preside at meetings of the JSC.

- **(c) Specific Responsibilities.** In addition to its overall responsibility for monitoring and providing a forum to discuss and coordinate the Parties' activities and responsibilities under this Agreement, the JSC shall in particular:
 - (i) provide a forum to discuss and coordinate the Promotion of the Product;
 - (ii) discuss sales performance and metrics with respect to EPI Heath's Sales Representatives, including the identification of target prescribers and sales accounts, as applicable;
 - (iii) discuss and obtain MC2's approval of the Commercialization Plan (which shall include the Field Force Detailing Plan) and agree on the Incremental Cost Budget, and any amendments to either of the foregoing, and review and update from time to time, but no less than once per Calendar Year, the Commercialization Plan;
 - (iv) discuss the conduct of any post-Regulatory Approval Development of the Product to be conducted by MC2 in the Territory;
 - (v) review and discuss draft regulatory filings to be filed by MC2 and to discuss communications to be made by MC2 with Regulatory Authorities related to or required for the Product in the Territory, including in connection with the receipt of any regulatory notices;
 - (vi) establish Subcommittees as it deems necessary to achieve the objectives and intent of this Agreement, to which Subcommittees the JSC may delegate its responsibilities under this Section 3.1(c), and resolve disputes presented by such subcommittees;
 - (vii) provide compliance oversight with respect to EPI Health's activities under this Agreement; and
 - (viii) perform such other functions as appropriate to further the purposes of this Agreement as allocated to it in writing by the Parties or as specified in the Agreement.
- (d) Meetings. The Parties shall endeavor to have their first meeting of the JSC within [***]. The JSC shall meet at least [***] per Calendar Quarter during the Term spaced at regular intervals unless the Parties mutually agree in writing to a different frequency for such meetings. Either Party may also call a special meeting of the JSC (by videoconference of teleconference) by providing at least [***] prior written notice to the other Party in the event such Party reasonably believes that a significant matter must be

addressed prior to the next scheduled meeting, and such Party shall provide the JSC no later than [***] prior to the special meeting with materials reasonably adequate to enable an informed decision. No later than [***] prior to any regularly scheduled meeting of the JSC, the chairpersons of the JSC shall prepare and circulate an agenda for such meeting; provided, however, that either Party may propose additional topics to be included on such agenda, either prior to or in the course of such meeting. The JSC may meet in person, by videoconference or by teleconference. Notwithstanding the foregoing, at least [***] meetings per Calendar Year shall be in person. In-person JSC meetings will be held at locations in the U.S. alternately selected by MC2 and by EPI Health. Each Party will bear the expense of its respective JSC members' participation in JSC meetings. Meetings of the JSC shall be effective only if at least one (1) JSC representative of each Party is present or participating in such meeting Alliance Managers will be responsible for preparing reasonably detailed written minutes of all JSC meetings that reflect, withou limitation, decisions made at such meetings. The Alliance Managers shall send draft meeting minutes, including a description of all discussions and decisions, to each member of the JSC for review and approval within [***] after each JSC meeting. Such minutes will be deemed approved unless one (1) or more members of the JSC object to the accuracy of such minutes within [***] of receipt.

- (e) Decision-Making. In addition to resolving issues specifically delegated to it, the JSC shall have the authority to resolve any disputes not resolved by any Subcommittee or as designated in this Agreement. The representatives from each Party will have, collectively, one (1) vote on behalf of that Party on the JSC, and all decision-making shall be by consensus. If the JSC is unable to reach consensus on any issue for which it is responsible within [***] after good faith attempts to resolve the issue have failed, the JSC shall refer such dispute to the Alliance Managers of the Parties. If the Alliance Managers cannot resolve the dispute within [***] from the initiation of discussions of the Parties' Executive Officers. If the Executive Officers cannot resolve the dispute within [***] from the initiation of discussions, then, subject to Section 3.2, the decision of MC2's Executive Officer shall be final and binding on the Parties; provided that, any dispute regarding an issue that expressly requires the approval of both Parties shall be resolved by the Parties as set forth in Article 15 (Dispute Resolution).
- **3.2 JSC Authority**. The JSC shall have solely the powers expressly assigned to it in Section 3.1 and elsewhere in this Agreement, and shall not have any power to amend, modify, or waive compliance with this Agreement or to bind either Party to incur additional liability or expense not expressly provided for in this Agreement without such Party's consent. It is expressly understood and agreed that the control of decision-making authority by MC2, pursuant to Section 3.1(e), will not authorize MC2 to unilaterally modify or amend, or waive its own compliance with, the terms of this Agreement.
- **3.3** Alliance Managers. Within [***], each Party will appoint (and notify the other Party of the identity of) a representative of such Party having a general understanding in matters related to pharmaceutical development, commercialization, and promotion, 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. The Alliance Managers will serve as the primary contact point between the Parties for the

purpose of facilitating the flow of Information and otherwise promoting communication, coordination and collaboration between the Parties.

3.4 Subcommittees. From time to time, the JSC may establish joint subcommittees to oversee particular projects of activities (such as Licensed Product Development and Commercialization), as it deems necessary or advisable (each, a "Subcommittee").

Article 4

Development

- **4.1 Regulatory Approval for the Products**. MC2 shall use Commercially Reasonable Efforts to obtain approva from FDA of the Product NDA as soon as practicable after the Effective Date. Thereafter, MC2 shall be responsible for maintaining the Product NDA in full force and effect during the Term.
- **4.2 Post-Approval Development** Subject to Section 4.1, MC2 shall have the sole right to conduct Development of the Products, and may do so for any indication, and for purposes of Commercialization within or outside of the Territory, at its discretion and at its own cost. For clarity, MC2 shall be solely responsible for and shall bear all costs of conducting, any post-Regulatory Approval studies of the Product required by the FDA in the Field in the Territory. EPI Health shall not conduct any Development of the Products without MC2's prior written consent (which may be withheld in MC2's sole discretion).
- **4.3 Development Records and Reports** MC2 shall maintain complete and accurate records of all Development conducted by MC2 with respect to the Products in the Field in the Territory, including the conduct of any post-Regulatory Approval work conducted with respect to the Product. MC2 shall update the JSC on a [***] basis with the results and progress of any post-Regulatory Approval work conducted by MC2 with respect to the Product in the Field in the Territory.

Article 5

Regulatory Matters

5.1 Regulatory Filings and Approvals

(a) Except for the regulatory filings and responsibilities identified as being EPI Health's responsibility or Exhibit 5.1, MC2 shall be responsible for, and shall use Commercially Reasonable Efforts to prepare and file, all Regulatory Materials required by the FDA or other federal Regulatory Authority with respect to Product and shall be responsible for al regulatory and registration activities for the Product in the Territory at MC2's cost and expense, including, but not limited to being solely responsible for interacting with FDA and maintaining the Regulatory Approval for the Product. Subject to subsection 5.1(b) below, MC2 or its Affiliates shall be the holder of the Regulatory Approvals and the NDC code for the Product.

- **(b)** EPI Health shall maintain all licenses, permits, and approvals required to perform its obligations under this Agreement.
- Efforts to prepare and file, the Regulatory Materials that are indicated on **Exhibit 5.1** as being EPI Health's responsibility. EPI Health shall be responsible for preparing and filing Regulatory Materials associated with Promotional Materials, including al filings and interactions with the OPDP, and EPI Health shall use Commercially Reasonable Efforts to do so. EPI Health sha provide the JSC with a copy of each such filing before submission thereof to allow the JSC reasonable time to review and approve such filing, which the Parties will cause the JSC to review and respond within [***] of submission. EPI Health shal promptly, but in any case, within [***] of receipt, provide the JSC with complete copies of all correspondence relating to Promotional Materials with Regulatory Authorities, including OPDP.EPI Health shall not be permitted to use any such Promotional Materials in connection with its Promotion or Commercialization of the Product in the Territory until EPI Health has filed all required Regulatory Materials with the appropriate Regulatory Authorities. Subject to MC2's approval authority hereunder and subject to MC2's obligation to ensure that the Product Labeling complies with Applicable Laws, EPI Health sha ensure that all Promotional Materials used by or on behalf of EPI Health in connection with the Promotion or Commercialization of the Product in the Territory comply with all Applicable Laws and requirements of applicable Regulatory Authorities.
- 5.2 Regulatory Communications. MC2 will have primary operational responsibility for interactions and communications with the FDA or other federal Regulatory Authority regarding the Product, including attending related meetings. MC2 shall notify EPI Health in advance of any meetings with or communications to the FDA or other federal Regulator Authorities related to the Product, to the extent they may impact the Development or supply of the Product or otherwise relate to EPI Health's rights or obligations under this Agreement. Unless prohibited by FDA, EPI Health shall be permitted to have one EPI Health representative participate in any such meetings with FDA, that is relevant to the performance of the EP Commercialization Activities, as an observer. MC2 shall provide to EPI Health copies of such material correspondence with the FDA or any Regulatory Authority regarding the Product that is relevant to the performance of the EPI Commercialization Activities, except that MC2 may redact any CMC information with respect to the Product from such copies. MC2 sha consider in good faith any input timely provided by EPI Health regarding regulatory activities relating to the Product in the Territory and will promptly update EPI Health on the results of regulatory communications.
- **5.3 Regulatory Cooperation** In addition to any activities for which a Party is responsible pursuant to Sections 5.1 and 5.2, each Party shall use Commercially Reasonable Efforts to conduct the regulatory activities expressly assigned it to under **Exhibit 5.1**. Each Party shall reasonably assist the other Party in connection with activities for which such other Party is responsible under **Exhibit 5.1**. In addition, the Parties shall coordinate and discuss regulatory strategies, approaches and responses, as applicable, with respect to any areas that expressly require collaboration of the Parties pursuant to **Exhibit 5.1** (e.g., Product reimbursement).

- 5.4 Product Withdrawals and Recalls. If any Regulatory Authority (a) threatens, initiates or advises any action to remove the Product from the market in the Territory, or (b) requires or advises MC2, EPI Health or their respective Affiliates to distribute a "Dear Health Care Provider" letter or its equivalent regarding use of the Product in the Territory, then MC2 or EP Health, as applicable, shall notify the other Party of such event as soon as reasonably practicable, but in no event later than [***] (or sooner if required by Applicable Laws) after such Party becomes aware of the action, threat, advice or requirement (as applicable). Immediately thereafter, the JSC together with the Parties' respective heads of Quality or other designees, wil discuss and attempt to agree upon whether to recall or withdraw the Product in the Territory; provided, however, that the Parties will agree to any recall or withdrawal mandated by the applicable Regulatory Authority, and otherwise if the Parties fail to agree within an appropriate time period, MC2 shall have final decision-making authority and shall have the right to decide in its sole discretion whether to recall or withdraw the Product in the Territory. The Parties shall promptly implement any such recall, with EPI Health taking the lead role in implementing the recall. MC2 shall reimburse EPI Health for any expenses incurred by EF Health with respect to a recall or withdrawal of the Product in the Territory, except to the extent that the recall or withdrawal is attributable to a claim or damage for which EPI Health is responsible under Article 12, in which event EPI Health shall bear sucleosts.
- 5.5 Safety Reporting. The Parties' obligations with respect to exchanging and reporting adverse events and other safety Information relating to the Product are set forth in the pharmacovigilance agreement attached hereto as **Exhibit 5.5** (the "**Pharmacovigilance Agreement**'). The Pharmacovigilance Agreement shall require that EPI Health shall perform such pharmacovigilance activities (including the collection and reporting of quality complaints, adverse events and safety data related to the Products in the Territory to applicable Regulatory Authorities) performed by EPI Health for other products Promotec and/or Commercialized by EPI Health, in a manner that is consistent with the standards applied by EPI Health for such othe products (but in any event, applying no less than industry standards for the performance of such activities for products that are similar to the Product). Each Party hereby agrees to comply with its respective obligations under such Pharmacovigilance Agreement and to cause its Affiliates and Sublicensees to comply with such obligations.
- **5.6 Standards of Conduct**. Each Party shall make regulatory filings and conduct all other regulatory activities required to be performed by such Party under this Article 5 in compliance with all Applicable Laws.

Article 6

Promotion

6.1 Promotion Efforts. Subject to the terms and conditions of this Agreement, EPI Health shall deploy its Sales Representatives and use Commercially Reasonable Efforts to Promote the Product in the Field in the Territory in accordance with the Commercialization Plan (including the Field Force Detailing Plan) and the terms of this Agreement, and EPI Health sha be solely responsible for the operation, reporting and management of such

Promotional activities. Without limiting the generality of the foregoing, EPI Health shall be responsible for the following:

- (a) EPI Health shall supervise, train and maintain such competent and qualified Sales Representatives as may be required to Promote the Product as provided herein and in the Field Force Detailing Plan (such training to include a reasonable proficiency examination for all Sales Representatives who will be engaged in Detailing).
- **(b)** EPI Health shall use Commercially Reasonable Efforts to ensure that its Sales Representatives Promote th Product in the Field in the Territory as a P1 Detail [***] as set forth in the Commercialization Plan and Field Force Detailing Plan;
- (c) EPI Health shall, and shall ensure that its Sales Representatives shall, in all material respects conform its and their practices and procedures relating to the marketing and Promotion of the Product in the Field in the Territory to all Applicable Laws and shall promptly notify MC2 of and provide MC2 with a copy of any correspondence or other reports with respect to the marketing or Promotion of the Product submitted to or received from the applicable Governmental Authority relating to such Applicable Laws;
- (d) EPI Health shall, and shall ensure that its Sales Representatives shall, in all material respects conform its practices and procedures relating to educating the medical community in the Territory with respect to the Product to any applicable FDA regulations, as the same may be amended from time to time;
- (e) EPI Health shall in all material respects conform its practices and procedures relating to sampling in the Territory to sampling practices and procedures in compliance with the Prescription Drug Marketing Act of 1987, as the same may be amended from time to time;
- (f) At MC2's reasonable request, EPI Health shall provide MC2 with copies of any written materia communications disseminated by EPI Health generally to its Sales Representatives Promoting the Product in the Territor relating to the marketing strategy for the Product;
- (g) In connection with the Promotion of the Product hereunder, EPI Health shall not, and shall procure that its Sales Representatives shall not, make any statement, representation or warranty, oral or written, to Third Parties, concerning the Product that is inconsistent with, or contrary to, the Product Labeling or any Promotional Materials; and
- **(h)** Once a Calendar Quarterly basis, EPI Health shall furnish to MC2 a summary of information coming to EF Health's attention in the Territory concerning introductions and promotional activities of products competitive with the Product and of any serious complaints regarding the Product (other than those described in Section 5.5), it being understood that there is no obligation on EPI Health to solicit such information.
- **6.2** Field Force Detailing Plan EPI Health shall develop and propose for JSC approval for inclusion in the Commercialization Plan a Calendar Quarterly Detailing and

targeting plan for the Product ("Field Force Detailing Plan"), together with [***]. Such plan shall include [***] (collectively, the "Minimum Detail Effort"). Such Field Force Detailing Plan must be consistent with the then-current Incremental Cos Budget.

6.3 EPI Health's Minimum Detail Efforts.

- (a) The Field Force Detailing Plan shall set forth the target number of P1 Details expected to be conducted by EPI Health on a Calendar Quarter basis during the period covered by such plan (the "EPI Health Target Quarterly Details"), and EPI Health's performance against the EPI Health Target Quarterly Details shall be measured on a Calendar Quarter basis For the avoidance of doubt, only P1 Details shall constitute "Details" for purposes of meeting the EPI Health Target Quarterly Details. EPI Health shall use Commercially Reasonable Efforts to achieve the EPI Health Target Quarterly Details in eac Calendar Quarter during the Term. If the Parties cannot agree on increasing the EPI Health Target Quarterly Details when approving or amending the Commercialization Plan in accordance with Section 7.2 or 7.3, as applicable, the then-current EPI Health Target Quarterly Details will continue to apply, provided, however, that the number of EPI Health Target Quarterly Details will not be more than are covered by the then-current Incremental Cost Budget. In no event will EPI Health be able to decrease the EPI Health Target Quarterly Details without MC2's written approval, provided that the number of EPI Health Target Quarterly Details must not be more than the then-current Incremental Cost Budget.
- If, with respect to any Calendar Quarter during the Term, EPI Health fails to meet at least [***] of the EP Health Target Quarterly Details, as the case may be, for the Product as provided under Section 6.3(a), MC2 shall have the righ to undertake and/or cause a designated Third Party to assist MC2 in undertaking the Promotion of the Product upon providing notice to EPI Health. From and after such notice provided hereunder, EPI Health shall no longer have the exclusive right to Promote the Product and MC2 and such Third Parties as may be designated by MC2 from time to time shall have the right to undertake Promotion of the Product. Such remedy by MC2 may be exercised by MC2 in order to limit the damages it may otherwise suffer due to EPI Health's failure to perform under Section 6.3(a), but shall not limit any other right or remedy MC2 may have in connection with such failure, including termination of this Agreement due to material breach. During any Calendar Quarter in which MC2 exercises its right to assist (or have assisted by a Third Party) EPI Health in Promoting the Product, (the Commercialization Fee owed to EPI Health pursuant to Section 9.1 shall be reduced by [***] and (ii) MC2 shall not b responsible for paying the Incremental Costs for the Base Sales Representatives; provided that, (x) MC2 shall continue to fund the Incremental Costs for the operational positions fully dedicated to the Promotion and Commercialization of the Product and shall pay the fully loaded cost to employ any Additional Sales Representatives, as each is set forth in the Incremental Cost Budget, and (y) such Commercialization Fee shall be restored to its original percentage and MC2 shall resume payment of the Incremental Costs for the Base Sales Representatives after the first Calendar Quarter in which EPI Health meets at least [***] c the EPI Health Target Quarterly Details (it being understood that MC2 shall permit EPI Health to resume exclusive Promotion c the Product in the Territory upon EPI Health's reasonable demonstration to MC2 of its capabilities to do so).

- (c) Notwithstanding anything to the contrary herein, EPI Health's obligations hereunder in clause 6.1(b) to position the Product as a P1 Detail [***] to meet the Target Quarterly Details for the Product as set out in clause 6.3(a) shall be excused (and MC2's remedies under Section 6.3(b) to reduce Commercialization Fee or to terminate under Section 14.2 shal not apply) during any period of time during which: (i) the FDA approval for the Product has not been obtained or has been suspended or lapsed, (ii) there is insufficient supply of the Product to support P1 Detail positioning, or (iii) there is commercial sale of a generic equivalent product (as defined below) in the Territory by a non-Affiliated third party as evidenced by IMS data, in each case (i)-(iii) that such event is not due to a failure by EPI Health to comply with its obligations under this Agreement (each, an "Excused Interruption"). For the avoidance of doubt, a generic equivalent product is defined to be a product that must be approved by the FDA pursuant to the FDA's ANDA process and that must carry a generic equivalency rating of "AB' to the Product. If EPI Health's Detailing obligations hereunder are interrupted for any reason permitted under this Section 6.3(c), then those obligations shall be reinstated by EPI Health as soon as reasonably possible after such interruption.
- **6.4 Target Incentive Compensation**. Promptly after the Effective Date, EPI Health shall develop an incentive compensation package for each Sales Representative that [***], subject to MC2's review and comment prior to implementation of the incentive plan. On at least a Calendar Quarterly basis, the Parties shall meet, through the JSC, to review the targe incentive compensation and the actual incentive compensation paid out to the Sales Representatives to discuss, in good faith, any appropriate adjustments to the sales targets and goals related to the Product in the Field in the Territory.
- 6.5 Report. EPI Health shall keep reasonably complete and accurate records of all Details of the Product in the Territory carried out by it to Promote the Product in the Territory during each Year of the Term (and indicating which of such Details constitute P1 Details). Detailing performed by EPI Health hereunder shall be tracked using EPI Health's internal recording of such activity, which tracking shall be on substantially the same basis as EPI Health's measurement for the EPI Health Sales Representatives detailing of its other products, consistently applied throughout the Term. EPI Health shall submit to MC2, within [***] during the Term, a report containing the number of Details performed by the EPI Health Sales Representatives for each Product Detailed by such Sales Representatives in the Territory and an accounting of the number of the EPI Health Sales Representatives that performed such Detailing of the ProductEPI Health covenants that the records of all Details of the Products in the Territory shall be reported and kept in the same manner as done by EPI Health Sales Representatives and marketing personnel for all other products marketed by EPI Health's sales force or in a manner agreed to by MC2. The monthly report provided by EPI Health pursuant to this Section 6.5 shall include actual physician data, the number of Details made, the date or week in which made, and, if available, the location made. EPI Health shall provide the monthly reports required by this Section 6.5 by electronic means preferably compatible with MC2's systems, or otherwise in a form as the Parties may mutually agree upon; provided that EPI Health shall not be obligated to invest in any new electronic reporting system or software.

6.6 Activities of Sales Representatives.

- (a) EPI Health shall be responsible for hiring the EPI Health Sales Representatives. The number of EPI Sale Territories and the timing of hiring any EPI Health Sales Representatives shall be determined by mutual agreement of MC2 and EPI Health. Subject to MC2's obligation to reimburse EPI Health pursuant to Section 9.3 hereof, EPI Health shall, in the fir instance, have sole responsibility for paying all costs and expenses in connection with its Sales Representatives and related management, including salaries, travel expenses and other expenses, credentialing, licensing, providing benefits, deducting federal, state and local payroll taxes, Federal Insurance Contributions Act contributions, Federal Unemployment Insurance State Unemployment Insurance and any similar taxes and paying workers' compensation premiums, unemployment insurance contributions and any other payments required by Applicable Laws to be made on behalf of employees. Nothing in this Agreement shall be construed to conclude that any of EPI Health's Sales Representatives or any other agents or employees of EPI Health are agents or employees of MC2 or subject to MC2's direction and control.EPI Health shall have sole authority over the terms and conditions of employment of its Sales Representatives, including their selection, management, compensation (including incentive plans) and discharge.
- **(b)** EPI Health shall be responsible and liable for the compliance of its Sales Representatives with all relevan terms of this Agreement, the Field Force Detailing Plan and Applicable Law.
- (c) If EPI Health determines that any of its Sales Representatives that are engaged in Promotion of the Produc has violated any Applicable Laws in any material respect, or failed to comply with this Agreement in any material respect, then EPI Health shall notify MC2 of the violation and shall take the appropriate remedial action. Subject to the foregoing, EPI Healt shall be solely responsible for taking any disciplinary actions in connection with its Sales Representatives that are engaged in Promotion.

6.7 Promotional Materials; Training of Sales Representatives.

(a) Advertising and Promotional Materials.

- (i) MC2 shall be responsible for leading the overall strategy of the Product messaging for the Promotional Materials, and shall discuss and gain agreement with EPI Health, through the JSC, with respect to such strategy and messaging. EPI shall be responsible for generating Promotional Materials for the Product in the Territory, consistent with the Promotional strategy and Product messaging developed by MC2 and agreed to by EPI Health. The Parties shadiscuss any contemplated changes in strategy or brand messaging for the Product for consideration in an amended Commercialization Plan.
- (ii) The Parties agree that the Promotional Materials may include trademarks owned by EPI Health (collectively, "EPI Health Trademarks") to indicate that the Product is distributed by EPI Health. EPI Health shall ow all right,

title, and interest in any EPI Health Trademark. EPI Health hereby grants to MC2 during the Term a non-exclusive royalty-free, fully paid-up right and license under the EPI Health Trademarks, to use or otherwise exploit the Promotiona Materials in the Territory in the exercise of MC2's rights or performance of MC2's obligations under this Agreement.

- (iii) MC2 and EPI shall jointly own all right, title and interest in and to any and all Promotional Materials and any intellectual property rights therein, other than any trademarks owned by the other Party that are used in the Promotional Materials, which trademarks shall be owned in accordance with Sections 6.7(a)(ii) and Section 7.10(c), as applicable. Each Party shall be entitled to practice, license, assign and otherwise exploit the Promotional Materials and any intellectual property rights therein (other than the other Party's trademarks used in the Promotional Materials, which trademarks may be exploited solely in accordance with the licenses granted pursuant to Sections 6.7(a)(ii) and Section 2.3, as applicable), without the duty of accounting to or seeking consent from the other Party.
- **(b) Product Samples.** MC2 shall be responsible for Manufacturing or having Manufactured all Production Samples for Promotion in the Territory, pursuant to the Supply Terms. EPI Health shall distribute and manage the Production Samples in a manner consistent with the Commercialization Plan (including the budget therein), EPI's internal sampling practices for products owned by EPI and Applicable Laws relating to sample accountability, including reporting responsibilities and records pertaining to theft and loss.
- (c) Product Training. EPI shall be responsible, in consultation with MC2, for preparing the initial Product training programs and materials for the EPI Health Sales Representatives, and EPI Health shall conduct Product trainin programs for EPI Health Sales Representatives who will participate in Promoting the Product to ensure a consistent, focused promotional strategy.
- (d) Compliance Training. EPI Health shall provide its EPI Health Sales Representatives with appropriat training on proper marketing and sales techniques. EPI Health shall be responsible for training its Sales Representatives on, and will instruct its Sales Representatives to comply with, all Applicable Laws.
 - (e) [***].
- **6.8 MC2 Obligations** In connection with the Promotion of the Product hereunder, MC2 shall comply with al applicable Laws and not make any statement, representation or warranty, oral or written, to Third Parties, concerning the Product that is inconsistent with, or contrary to, the Product Labeling MC2 shall promptly notify EPI Health of and provide EPI Health with a copy of any correspondence or other reports with respect to the marketing or Promotion of the Product submitted to or received from any applicable Governmental Authority in the Territory. MC2 shall not use Promotional Materials for the Product other than those agreed upon by the Parties hereunder in the Territory.

P1 Detail Positioning. At any time following the twelve month anniversary of the Execution Date, EPI Health may cease Promoting the Product as a P1 Detail by providing written notice to MC2 (the **P1 Notice**") of its intent to no longer Promote the Product as a P1 Detail (including by Promoting the Product as anything other than a P1 Detail) ninety (90) day prior to the effective date of such change (which notice may be provided prior to the expiration of such twelve-month period, but in any event shall not be effective prior to the expiration of such twelve-month period). During such ninety-day period, the Parties may engage in good faith discussions to modify the Commercialization Plan consistent with EPI Health no longe Promoting the Product as a P1 Detail. From and after the effective date of such change (and, for clarity, regardless of whether or not EPI Health provides a P1 Notice), (i) MC2 shall not be responsible for paying or reimbursing EPI Health for th Incremental Costs for the Base Sales Representatives, (ii) MC2 otherwise shall continue to fund the Incremental Costs including for the operational positions fully dedicated to the Promotion and Commercialization of the Product and shall fund the fully loaded cost to employ any Additional Sales Representatives, as each is set forth in the Incremental Cost Budget, (iii) EP Health shall use Commercially Reasonable Efforts to Detail the Product but shall no longer be obligated to comply with any provisions herein that require P1 Detailing, comply with the Field Force Detailing Plan, to satisfy the Target Quarterly Details, o to pay incentive compensation to sales representatives in accordance with Section 6.4 hereof, (iv) MC2, in its sole discretion, subject to the Agreed Budget Limitations, may amend the then-current Incremental Cost Budget and approve all subsequen Incremental Cost Budgets consistent with EPI Health no longer Promoting the Product as a P1 Detail, provided that suc discretion shall not give MC2 the right to direct what position the Product will be detailed in by EPI Health, (v) the rights granted to EPI Health under Section 2.1 shall automatically become non-exclusive, and (vi) MC2 may terminate this Agreement upon sixty (60) days' written notice to EPI Health, such notice to be provided no later than one hundred twenty (120) days following receipt of the P1 Notice. In addition, MC2 may terminate this Agreement upon sixty (60) days' written notice to EPI Health (a if during the twelve month period following the Execution Date, EPI fails to Promote the Product as a P1 Detail (including b Promoting the Product as anything other than a P1 Detail), or (b) upon the occurrence of a Commercial Trigger, in each case (a) and (b), other than due to an Excused Interruption. For any period of time during the Term for which EPI Health fails to Promote the Product as a P1 Detail (including by Promoting the Product as anything other than a P1 Detail), MC2 shall not b responsible for paying or reimbursing EPI Health for the Incremental Costs for the Base Sales RepresentativesFor purposes of this Section 6.9, "Commercial Trigger" means, either (x) for the twelve-month period following the Execution Date (the "First Measurement Period'), (A) aggregate Net Sales of the Product in the Territory are less than Ten Million Dollars (\$10,000,000), and (B) aggregate prescriptions of the Product in the Territory are less than [***] or, at the end of such First Measurement Period, the Product is not selling at a gross-to-net of [***]; or (y) for the twelve-month period following the one year anniversary of the Execution Date (the "Second Measurement Period," and, together with the First Measurement Period, the "Measurement Periods"), (A) aggregate Net Sales of the Product in the Territory are less than Eighteen Million Dollars (\$18,000,000), and (B) aggregate prescriptions of the Product in the Territory are less than [***] or, at the end of the Second Measurement Period, the Product is not selling at a gross-to-net of [***], in each case (x) and (y), other than due to an

Excused Interruption; provided that MC2 may provide written notice of termination to EPI Health based on the occurrence of Commercial Trigger at the end of the applicable Measurement Period and shall provide such notice no later than the earlier of one hundred twenty (120) days following MC2's receipt of the Commercialization Report for the applicable Measurement Period to determine the gross-to-net or, if EPI Health fails to provide such Commercialization Report in the time period set forth in Section 9.4, one hundred twenty (120) days after such Commercialization Report is due pursuant to Section 9.4. Upor termination of this Agreement by MC2 pursuant to this Section 6.9 following a Commercial Trigger solely for the Second Measurement Period, EPI Health shall be entitled to receive from MC2, for the twelve month period immediately following the effective date of such termination, an aggregate payment equal to the amount of the Commercialization Fee earned by EPI Health pursuant to Section 9.1 during the twelve-month period immediately prior to the effective date of termination. Such payment shall be made in four (4) equal Calendar Quarterly installments during the duration of the twelve-month period following the effective date of the termination, each Calendar Quarterly installment to be paid within sixty (60) days after the end of each full or partial Calendar Quarter of such twelve (12) month period.

Article 7

Commercialization

- 7.1 Diligence. EPI Health shall use Commercially Reasonable Efforts to perform the EPI Commercialization Activitie with respect to the Product in the Field in the Territory, in accordance with the Commercialization Plan. Without limiting the foregoing or being limited thereby, EPI Health shall (a) subject to MC2's obligations under the Supply Terms, promptly take process and fulfill all orders that are placed for the Product in the Field in the Territory, and (b) utilize its distribution infrastructure to support the Commercialization of the Products, including through the provision of inventory support, third party logistics agreements, potential payer contract support and wholesaler access, and in each case of (a) and (b), EPI Health shall perform such activities in an efficient manner consistent with the commercially reasonable practices of the pharmaceutical industry, and as required by its respective contracts with such customers. In addition, EPI Health shall make available its employees and personnel to provide necessary operational support in connection with the conduct of EPI Commercialization Activities in order to fulfill EPI's obligations under this Agreement.
- **7.2** Commercialization Plan. The strategy and budget for the Commercialization of, the Product in the Territory will be described in a comprehensive plan (the "Commercialization Plan") and in a budget (the "Incremental Cost Budget"), each developed by EPI Health based on good faith assumptions regarding the then-current forecast for the Product in the Fiek in the Territory, in consultation with MC2, and each shall be subject to final approval by MC2, such approval not to be unreasonably withheld; provided that, notwithstanding the foregoing or anything to the contrary herein, (i) the Incremental Cost Budget as it pertains to the EPI Health Sales Representatives must be mutually agreed by MC2 and EPI Health; (ii) neither Par shall be permitted to decrease the number of EPI Health Sales Representatives to less than [***] or increase the number of

EPI Health Sales Representatives to more than [***], and (iii) MC2 may, in its sole discretion and acting in good faith, increase the Incremental Cost Budget relative to the then-current Incremental Cost Budget by no more than ten percent (10%) or decrease the Incremental Cost Budget relative to the then-current Incremental Cost Budget by no more than fifty percent (50%) solely with respect to increases or decreases in the Incremental Costs for non-inventory and non-personnel costs, provided that MC2 may not reduce the Incremental Cost Budget for noncancellable expenses so long as ÉPI Health uses Commerciall Reasonable Efforts to cancel or reduce such expenses (including in accordance with the terms of any contract therefor) as soon as practicable following a request to do so by MC2 ((i) through (iii), the "Agreed Budget Limitations"). The Commercialization Plan for Calendar Year 2022 is attached hereto as Exhibit 7.2 A, and the Incremental Cost Budget for Calendar Year 2022 (including the Incremental Costs actually incurred by EPI Health since the Amendment Effective Date until the date on which the Condition Precedent is satisfied) is attached hereto as Exhibit 7.2 B. The Commercialization Plan and Incremental Cost Budget shall be updated and may be amended during the Term in accordance with Section 7.3 and Section 9.3. The Commercialization Plan will be used as the basis for the Commercialization activities to be undertaken under this Agreement and shall specifically describe the (a) Commercialization activities for the Product in the Territory (including messaging, branding, list price and rebating strategy, pricing, advertising, education, planning, marketing, promotion, product sampling and sales force training and allocation), (b) key tactics for implementing those activities, (c) specific resource commitments required of the Parties, including number and location of EPI Sales Territories, number of EPI Health Sale Representatives, number of Details by position, and marketing spend, (d) the Field Force Detailing Plan, (e) a three (3)-yea sales forecast and (f) any other information necessary or useful for the successful Commercialization of the Product in the Field in the Territory. In the event of any inconsistency between either the Commercialization Plan or Incremental Cost Budget, on the one hand, and this Agreement, on the other hand, the terms of this Agreement shall govern and control. Notwithstanding anything to the contrary in this Agreement, the Commercialization Plan shall specify and account for the performance of EPI Commercialization Activities by EPI Health and MC2 Commercialization Activities by MC2In no event shall EPI Health be required to perform any function or activity or to purchase inventory set forth in the Commercialization Plan the cost of which is not covered by the then-current Incremental Cost Budget.

7.3 Amendments to the Commercialization Plan and Budget EPI Health shall prepare and propose on an annua basis, during the fourth (4th) Calendar Quarter of each Calendar Year, and provide to the JSC for discussion and approval, an updated Commercialization Plan covering the following Calendar Year (it being understood that the Commercialization Plan shall at all times be consistent with the then-current Incremental Cost Budget). If the Parties, through the JSC, do not approve Commercialization Plan prior to the start of Calendar Year 2023 or any Calendar Year thereafter, then EPI Health will continue to Promote the Product and perform the EPI Commercialization Activities with respect to the Product in the Field in the Territory consistent with the existing Commercialization Plan and using the same level of effort; provided that (i) the Parties will work in good faith to approve an updated Commercialization Plan for the applicable

Calendar Year as soon as practicable and (ii) EPI Health shall only be required to perform obligations under such Commercialization Plan to the extent the expenses therefor are included in the applicable Incremental Cost Budget. The Incremental Cost Budget as it pertains to the EPI Health Sales Representatives must be mutually agreed by MC2 and EI Health. The Incremental Cost Budget shall be updated quarterly in accordance with Section 9.3. In addition, subject to the Agreed Budget Limitations, either Party shall have the right, in consultation with and subject to written approval from the other Party (not to be unreasonably withheld) to update the Commercialization Plan and/or the Incremental Cost Budget from time to time during the Term in order to reflect material changes in the circumstances on which such plan or budget for such fiscal year is based, including in the event of an Excused Interruption. Notwithstanding anything to the contrary herein or in the Commercialization Plan or Incremental Cost Budget, EPI shall not be obligated to order or sell any minimum amount of Produc pursuant to the Commercialization Plan, including any forecast set forth therein.

7.4 Intentionally omitted.

- 7.5 Commercialization Reports. On a [***] basis during each Calendar Year, each Party shall keep the JSC informed regarding the progress of Commercialization activities for the Product in the Territory. In addition, each Party shall provide the JSC (a) annually, a detailed review of results versus plans for each of the items set forth in the Commercialization Plan for which such Party is designated as a responsible Party (or with respect to which the Parties share responsibility), (b) at each JSC meeting, a summary review of results versus plans, and (c) with respect to EPI Health, as soon as practicable after the end of each month, a report of the gross amount invoiced for sales of the Product in the Territory, Net Sales of the Product (including itemized gross to net deductions) in the Territory, number of new prescriptions for the Product in the Territory and number of total prescriptions for the Product in the Territory, as measured by IMS Health or comparable provider, in each case for such month.
- **7.6** Use of Commercial Data and Information MC2 shall have the right to use, in connection with its Commercialization of the Product outside the Field and/or the Territory, data, marketing materials and other Product-related communications developed by or on behalf of either Party or its Affiliates under this Agreement and which relate to the Product. EPI Health hereby grants MC2 the right to use and create derivative works of the Information provided under this Section 7.4 for Commercializing the Product outside Field and/or the Territory, and to grant such right to its Affiliates and to its Third Party collaborators or licensees to whom it has granted the right to develop, commercialize and/or otherwise exploit the Product outside the Field and/or the Territory.

7.7 Regulatory Compliance.

(a) Obligations. EPI Health shall conduct its Promotional activities, MC2 shall conduct its post-Regulator. Approval Development and manufacturing activities, and each of EPI Health and MC2 shall conduct their Commercialization activities or other activities assigned to one or both Parties under this Agreement in accordance with the requirements of this Agreement and Applicable Laws and shall cooperate with one another

in any efforts toward ensuring that government reporting (including price and honoraria reporting), sales, marketing and promotional practices in respect of the Product meet the standards required by Applicable Laws. In addition, each Party shall obtain and maintain all licenses, permits, approvals and other authorizations applicable to it in order to enable it to perform its respective obligations hereunder.

- **(b)** Reporting. Each Party shall be responsible for calculating, tracking and reporting transfers of value initiated and controlled by its employees and/or contractors pursuant to its respective obligations under the requirements of Section 6002 (Transparency Reports and Reporting of Physician Ownership and Investment Interest) of the Patient Protection and Affordable Care Act, commonly referred to as the "Sunshine Act", and applicable state marketing reporting laws. Subject to Applicable Laws and Guidelines, the value reported to the Centers for Medicare & Medicaid Services (**CMS**") shall be the amount expended by the controlling Party, irrespective of the division of or reconciliation of expenses between the Parties.
- (c) Information. Each of MC2 and EPI Health shall reasonably cooperate with the other Party to provide the other Party reasonable access to such Information and reports related to the Product reasonably required by the other in order to comply with the relevant provisions of the Medicare Modernization Act, as amended from time to time, and any other Applicable Laws, including reporting requirements, in a timely and appropriate manner. Each Party shall ensure that its reporting to CMS and other federal and state healthcare programs related to the Product is true, complete and correct in all respects; provided, however, that neither Party shall be held responsible for submitting erroneous reports if such deficiencies result from Information provided by the other Party which itself was not true, complete and correct. Each Party shall notify the other Party promptly upon becoming aware of any Product-related inquiries or document requests by any Governmental Authority or claims or threatened claims related to the Product.
- (d) Cooperation. The Parties agree that each Party will be solely responsible for conducting its own compliance program but likewise agree that from time to time the Party's compliance officers may convene for purposes of sharing their respective best practices in ethics and compliance operations. Notwithstanding the foregoing, if a Party becomes aware of a credible allegation of a significant violation of Applicable Laws related to such Party's performance hereunder, such Party's compliance officer and/or legal department has a duty to promptly investigate and timely notify the other Party's compliance officer and/or legal department of the commencement of the investigation. If the investigation is conducted in accordance with the attorney-client privilege, then such notification shall be made pursuant to a joint-defense agreement in order to maintain all attorney-client privilege protections. Without limiting the foregoing, each Party shall maintain an effective sales representative monitoring program.

7.8 Market Access Activities, Pricing and Reimbursement.

(a) The Parties shall cooperate in good faith for handling managed care and reimbursement matters for the Product in the Territory. As between the Parties, each Party shall have primary responsibility for the matters delegated to it under this Section 7.8.

- (b) MC2 shall be responsible for: (i) developing the initial managed care strategy; (ii) determining and negotiating pricing for the Product, as further described in Section 7.9; and (iii) negotiating and entering into all group purchasing, market access, managed care and similar agreements that constitute Stage 1 Contracts and government contracts for the Product; and (iv) obtaining, with EPI Health's assistance, reimbursement (including NDC) codes in MC2's name; provided that, EPI Health shall have the right to participate in any strategic meetings or negotiations described in (i)-(iii) above. EPI Health shall be responsible for submitting all government price reports for the Product bearing MC2's NDC number (subject to Section 7.7(c hereof) and EPI Health will pay all government rebates directly. MC2 will provide appropriate access to EPI Health in order for EPI health to report pricing data under MC2's NDC code.
- (c) EPI Health shall be responsible for: (i) execution (in the name of MC2 and subject to MC2's review and approval) of such list price and managed care rebating strategy; (ii) negotiating and using Commercially Reasonable Efforts to enter into (in the name of MC2 and subject to MC2's review and approval) all group purchasing, market access, managed care and similar agreements for the Product other than for Stage 1 Contracts (all such contracts, including the Stage 1 Contracts, the "Commercial Agreements"); (iii) handling (in the name of MC2) the operational aspects of managing and carrying out efforts related to obtaining reimbursement for the Product in the Territory, including assisting MC2 in obtaining reimbursement codes; (iv) maintaining and handling the day-to-day operational aspects of the Commercial Agreements and any government contracts for the Product, including provision of all relevant details (e.g., rebate, chargeback and/or discount levels, administrative fees and price protection provisions, each on a contract-by-contract basis); (iv) calculating and timely reporting accurate price metrics for the Product under contracts including any government contracts in accordance with Applicable Laws (subject to Section 7.7(c) hereof); (v) payment and processing of all co-pays, rebates, chargebacks, discounts, reimbursements or other fees payable with respect to the Product under (A) Commercial Agreements, and (B) the Government Health Care Progran Contract (it being understood that MC2 shall be responsible for such payments, and shall reimburse EPI Health for an payments made by EPI Health in connection therewith); and (vi) maintaining applicable records related thereto for a minimum of three (3) years or such longer period as may be required by Applicable Laws.
- 7.9 Medical Affairs. EPI shall be responsible for handling all aspects of Medical Affairs related to the Product in the Territory, including determining the overall strategy for responding to medical information requests, executing such strategy and handling the operational aspects of any Medical Affairs-related functions.

7.10 Labeling; Trademarks

(a) Use of Trademarks in Promotional Materials. EPI Health shall, with respect to the development of any Promotional Materials pursuant to Section 6.7: (i) ensure that all Promotional Materials feature the applicable Licensed Marks (ii) comply with MC2's requirements as to the form, manner, scale and context of the use of the Licensed Marks and the use of the statements to accompany the Licensed Marks, and (iii) adhere to any branding strategy policies (including, without limitation, logo design, product labeling,

messaging points, and visual branding elements) dictated by MC2 for the use of the Licensed Marks.

- (b) Commercialization. All quantities of Product supplied by MC2 to EPI Health pursuant to Article 8 will bear the Licensed Marks and the Product Labeling (and no other trademarks or content), and EPI Health shall Commercializ Products in the Field in the Territory under such Licensed Marks and with only such Product Labeling. The Product Labeling will include the MC2 corporate name and company trademark as provided and the designation that the Product is "manufactured in the U.S. for MC2 Therapeutics Ltd" and "distributed in the U.S. by EPI Health LLC for MC2 Therapeuti Ltd" or other similar designations as the Parties may agree. MC2 shall be responsible for ensuring that all Product Labeling complies with all Applicable Laws.
- **(c)** Ownership of Licensed Marks The ownership and use of the Licensed Marks shall be governed by the following provisions:
 - (i) MC2 or an Affiliate of MC2 shall retain the ownership of the entire right, title and interest in and to the MC2 Trademarks;
 - (ii) MC2 shall, at its cost and expense, file or register (to the extent necessary) in the Territory and thereafter maintain the Licensed Marks in the Territory. EPI Health agrees that in using Licensed Marks in its activities under this Agreement it will not represent in any way that it has any right or title to the ownership of the Licensed Marks or the registration thereof, and the registration will remain in the ownership of MC2. Such Licensed Marks will be used by EPI Health on behalf of, and in the interest of, MC2, and EPI Health will first obtain the written approval of MC2 of the form and manner in which the Licensed Marks will be used upon, in connection with, or in relation to materials other than Promotion Materials as may be permitted by this Agreement.
 - (iii) EPI Health recognizes MC2's title in and to the Licensed Marks and to the registration thereof, and will not, at any time, do or authorize any act or thing that will in any way impair the rights of MC2 in and to the Licensed Marks and the registration thereof. Wherever MC2's trademarks or tradenames are used (e.g., on any label, marketing material or advertisement), the first or most prominent use shall always be accompanied by a legend acceptable to MC2 indicating that the Product is a registered trademark of MC2 and the Licensed Marks are licensed to EPI Health by MC2. In the event that EPI Health, either directly or indirectly, challenges the title of MC2 to any Licensed Mark or the validit of such registration obtained by MC2 for the same, and EPI Health fails to withdraw such challenge within one (1) month of receipt of MC2's written request therefor, MC2 shall have the right to terminate this Agreement.
 - (iv) EPI Health shall, upon MC2's request, and at MC2's expense, reasonably assist MC2 in any action reasonably necessary or desirable to protect the Licensed Marks used or proposed to be used hereunder. EPI Health shall as soon as

practicable notify MC2 of any apparent infringement by a Third Party of any of the Licensed Marks.

- (v) After discussion and upon notice and demand from MC2, EPI Health shall immediately discontinuous the use of any of the Licensed Marks upon notice from a Third Party that such use is or is alleged to be an infringement of such Third Party's trademark rights
- 7.11 Cross-Territorial Restrictions. EPI Health hereby covenants and agrees that it shall not, and shall ensure that its Affiliates and Sublicensees will not intentionally, either directly or indirectly, promote, market, distribute, import, sell or have sold the Products, including via internet or mail order, into countries outside the Territory. As to such countries outside the Territory (which are exclusively reserved for MC2), EPI Health shall not, and shall ensure that its Affiliates and their respective Sublicensees will not: (a) establish or maintain any branch, warehouse or distribution facility for Products in such countries, (b) engage in any advertising or promotional activities relating to Products that are directed primarily to customers or other purchaser or users of Products located in such countries, (c) solicit orders for Products from any prospective purchaser primarily located in such countries, or (d) sell or distribute Products to any person in the Territory who EPI knows intends to sell or has in the past sold Products in such countries. If EPI Health receives any order for any Product from a prospective purchaser primarily located in a country outside the Territory, EPI Health shall immediately refer that order to MC2 and EP Health shall not accept any such orders. EPI Health shall not deliver or tender (or knowingly cause to be delivered or tendered) Products into a country outside of the Territory. EPI Health shall not, and shall ensure that its Affiliates and their respective Sublicensees will not, intentionally restrict or impede in any manner MC2's exercise of its retained exclusive rights outside the Territory.

Article 8

Manufacture and Supply

- **8.1 Manufacture and Supply**. EPI Health shall exclusively hold from MC2, and MC2 will manufacture and supply (either by itself or through a Third Party contract manufacturer) to EPI Health, all of the Product to be held by EPI Health, it Affiliates and Sublicensees' for Commercialization use in the Field in the Territory under this Agreement, in accordance with the Manufacturing and Supply Terms set forth on **Exhibit 8.1** (the "**Supply Terms**"). MC2 or its designee shall supply the Products, in fully finished (*i.e.*, labeled, packaged, and serialized) form, in accordance with written purchase orders placed by EPI Health in accordance with the Supply Terms and the Quality Agreement; provided however, that EPI shall be responsible for procuring and delivering to MC2 serialization codes/traceability for the Products (using Tracelink). EPI Health shall purchase, transport, import and store the Products. All Products shall be delivered by or on behalf of MC2 to EPI Health EXV MC2's facility (INCOTERMS 2020 ICC).
- **8.2 Quality Agreement.** As of the Effective Date, the Parties have entered into a certain quality agreement, attached hereto as **Exhibit 8.2** (the "**Quality Agreement**"),

relating to the supply of Products by MC2 to EPI Health for Commercialization of Products in the Field in the Territory.

Article 9

Financials

9.1 Commercialization Fee on Net Sales EPI Health shall retain from Net Sales, on a monthly basis, a commercialization fee that shall equal a percentage (as indicated in the table, below) of annual aggregate Net Sales of Product sold in the Field in the Territory by EPI Health, its Affiliates and their respective Sublicensees, as follows (the "**Commercialization Fee**") (as subsequently adjusted pursuant to Section 9.5):

Increments of Aggregate Annual Net Sales	Commercialization Fee
That portion of aggregate annual Net Sales of Products that is less or equal to \$[***]	[***]%
That portion of aggregate annual Net Sales of Products that is greater than \$[***] and less than or equal to \$[***]	[***]%
That portion of aggregate annual Net Sales of Products that is greater than \$[***]	[***]%

EPI Health shall pay MC2, on a calendar monthly basis within [***] following the end of the [***] period following the calendar month in which the sale of the Product is recorded by EPI Health (such recording to be done in accordance with GAAP), a royalty payment that shall equal one-hundred percent (100%) of the aggregate Net Sales of Product sold in the Field in the Territory by EPI Health, its Affiliates and their respective Sublicensees for which payment was received in the applicable calendar month, *minus* (i) the Commercialization Fee for such calendar month, *minus* (ii) any accrued but unpaid Incentive Fees (the remainder, the "**Royalty Payment**"); **provided**, however, that Incentive Fees owed to EPI Health will be deferred (and no be retained by EPI Health) in accordance with Section 9.2 below.

9.2 Incentive Fee. EPI Health shall be entitled to an incentive fee equal to [***] of the first [***] in Net Sales of Product sold in the Field in the Territory by EPI Health, its Affiliates and their respective Sublicensees in each Calendar Year beginning on the Amendment Effective Date and continuing until December 31, 2023 (the 'Incentive Fee'). For clarity, the Incentive Fee shall not exceed [***] each year. The Incentive Fee shall accrue on a monthly basis until December 31, 2023, and any Incentive Fee owed to EPI Health will be deferred (and not be retained by EPI Health) until MC2 has first received Royalt Payments that equal the amount of Unreimbursed Cumulative MC2 IC. Thereafter, the Incentive Fee for the applicable mont shall be retained by EPI Health from the Royalty

Payment, along with any accrued but unpaid Incentive Fees; provided that, the Incentive Fee shall accrue but shall only be retained by EPI Health to the extent that the amount of Unreimbursed Cumulative MC2 IC is less than the remainder of Ne Sales minus the Commercialization Fee in such month. If Net Sales are not sufficient to pay all accrued but unpaid Incentive Fees, the amount of remaining accrued but unpaid Incentive Fees each month will roll forward to the following calendar month. Upon expiration or termination of this Agreement, MC2 shall not be responsible for paying, and EPI Health may not retain, an accrued but unpaid Incentive Fees unless (i) MC2 has first received Royalty Payments that equal the amount of Unreimbursed Cumulative MC2 IC, and (ii) Net Sales are sufficient to pay such accrued but unpaid Incentive Fees.

9.3 Incremental Costs.

(a) Subject to Section 6.9 and Section 7.2, each of EPI Health and MC2 shall approve the Incremental Cost Budget at least [***] prior to the beginning of each Calendar Quarter. Such Incremental Cost Budget shall reflect a good faith estimate of the Incremental Costs to be incurred by EPI Health during the immediately following Calendar Quarter based on the Commercialization Plan and the forecast. Within [***] prior to the beginning of each Calendar Quarter, MC2 shall pay to EP Health an amount equal to the estimated Incremental Costs for the immediately following Calendar Quarter (the"Prepaid Quarter") based on the approved Incremental Cost Budget less the amount of any applicable IC Prepayment Excess (the "MC2 IC Prepayment"); provided, however, that, except for the first [***] MC2 IC Prepayments made after the Amendment Effective Date (which prepayments are made in the absence of a Quarterly IC Statement), in no event shall MC2 be required to pay the MC2 IC Prepayment within less than [***] following its receipt of a Quarterly IC Statement with respect to the last fur Calendar Quarter. If the Parties do not approve the Incremental Cost Budget at least [***] prior to the beginning of each Calendar Quarter, the Incremental Cost Budget for the prior Calendar Quarter shall remain in place (and the MC2 IC Calendar Quarter). Prepayment shall be based on such budget), provided that the Parties will work in good faith to approve an updated Incremental Cost Budget for such Calendar Quarter as soon as practicable (and to adjust the MC2 IC Prepayment as necessary based or such updated budget). EPI Health shall use Commercially Reasonable Efforts to manage the actual Incremental Costs so as no to exceed the Incremental Cost Budget. Within [***] following the end of each month during the Term, EPI Health will provide monthly statements to MC2 setting forth the Incremental Costs incurred by EPI Health in performing any Incremental Cost Activities in the applicable month (the "Monthly IC Report"). Upon request, EPI Health will promptly provide documentation reasonably requested by MC2 of any particular expense or cost included in the Incremental Costs, including a comparison of such expense against the amounts allocated therefor in the budget set forth in the Incremental Cost Budget. EPI Health shall promptly inform MC2, in writing, upon a determination that EPI Health is likely to overspend the respective budgeted costs it the Incremental Cost Budget in connection with any Incremental Cost Activities and the Parties shall thereafter promptly discuss in good faith any changes in the relevant activity or budget therefor; provided that, EPI Health shall not perform any Incrementa Cost Activity that would cause it to overspend the respective budgeted costs in the Commercialization Plan for such activity by more than [***] without MC2's prior written consent, which

consent shall not be withheld with respect to any increase in the Supply Price or increase in another noncancellable expense for items included in the Commercialization Plan, where such increases are outside EPI Health's reasonable control. Within [*** following the end of each Calendar Quarter following the Prepaid Quarter during the Term (the "True Up Quarter"), EPI Health shall deliver a statement and invoice (the "Quarterly IC Statement") showing the amount by which the actual Incremental Costs incurred by EPI Health during such Prepaid Quarter were less than or greater than the MC2 IC Prepaymen applicable to such Prepaid Quarter. Accordingly, where Q1 is the Prepaid Quarter, the True Up Quarter is the prior Q3. If the actual Incremental Costs incurred in the Prepaid Quarter were less than the MC2 IC Prepayment for such quarter (a IC Prepayment Excess"), then the difference shall be rolled forward by EPI Health and MC2 may reduce the amount of the MC. IC Prepayment for the True Up Quarter by such amount. If the actual Incremental Costs incurred in the Prepaid Quarter were greater than the MC2 IC Prepayment for such quarter (a "IC Prepayment Shortfall"), then MC2 shall pay to EPI Health the IC Prepayment Shortfall; provided, however, that the IC Prepayment Shortfall shall not exceed the Incremental Cost Budget for the applicable Prepaid Quarter by more than [***] unless the excess expenses were approved by MC2 in writing in accordance with this Section 9.3. The Quarterly IC Statement will include an invoice for the IC Prepayment Shortfall and MC2 shall pay suc invoice within [***] of receipt. [***].

(b) [***].

- 9.4 Commercialization Payments; Reports Commercialization Fees and Incentive Fees under Section 9.1 and 9.2 shall be calculated and reported for each calendar month during the Term. The Royalty Payment for a given calendar month shall be paid by EPI Health to MC2 within [***] after the end of the [***] period following the calendar month in which the sale of the Product is recorded by EPI Health (such recording to be done in accordance with GAAP), commencing with the calendar month in which the First Commercial Sale of a Product is recorded by EPI Health (such recording to be done in accordance with GAAP). Each Royalty Payment shall be accompanied by a report (the Commercialization Report") of Net Sales of Products by EPI Health, its Affiliates, and their respective Sublicensees in sufficient detail to permit confirmation of the accuracy of the Royalty Payment made, including: (a) the amount of gross sales and Net Sales of Products in the Territory on a Product-by- Product basis, (b) an itemized calculation showing the Sales Deductions from gross sales (by major category as set forth in the definition of Net Sales) to determine Net Sales, (c) a calculation of the amount of the Commercialization Fee retained by EPI Health in U.S. Dollars, (d) a calculation of the Unreimbursed Cumulative MC2 IC (including cumulative Royal Payments made to MC2 for purposes of determining whether MC2 has received Royalty Payments that equal the amount of Unreimbursed Cumulative MC2 IC), (e) a calculation of the Incentive Fee and a statement of any accrued and unpaid Incentive Fees, and (f) a calculation of the remaining amount to be paid to MC2 in the form of a Royalty Payment.
- 9.5 True Up. On a Calendar Quarterly basis, each of the Commercialization Fee, the Incentive Fee, and Royalt Payment will be subject to a true-up adjustment to take into account Sales Deductions either (a) allowed with respect to a Calendar Quarter that were not accrued during such Calendar Quarter, or (b) accrued during a Calendar Quarter but not

taken or later subject to a reversal following the end of such Calendar Quarter (each of (a) and (b), a "**True-up Adjustment**"). Each Commercialization Report provided by EPI Health with respect to a Calendar Quarter shall set forth the amount of an True-up Adjustment applicable to any prior Calendar Quarter.

- **9.6 Manner and Place of Payment.** All payments owed under this Agreement shall be made in United States Dollars (\$US) by wire transfer in immediately available funds to a bank and account in the United States designated in writing by the Party receiving payment.
- **9.7** Late Payments. If a Party does not receive payment of any sum due to it on or before the due date therefor, simple interest shall thereafter accrue on the sum due to such Party from the due date until the date of payment at a per-annum rate of prime plus two (2) percentage points or the maximum rate allowable by Applicable Laws, whichever is less.
- **9.8 Records; Audits**. EPI Health shall, and shall ensure that its Affiliates and its and their respective Sublicensees maintain complete and accurate records in sufficient detail to permit MC2 to confirm the accuracy of the calculation of Commercialization Fees, Incremental Costs, and Royalty Payments hereunder. All payments and other amounts under this Agreement shall be accounted for in accordance with GAAP. Upon reasonable prior notice, such records shall be available for examination during regular business hours for a period of five (5) years from the end of the EPI Health Fiscal Year to which they pertain, and not more often than once each Calendar Year, by an independent certified public accountant selected by MC2 and reasonably acceptable to EPI Health, for the sole purpose of verifying the accuracy of the financial reports furnished by EPI Health pursuant to this Agreement and any payments with respect thereto. Any such auditor shall not disclose EPI Health's Confidential Information, except to the extent such disclosure is necessary to verify the accuracy of the financial reports furnished by EPI Health or the amount of payments due under this Agreement. Any amounts shown to be owed but unpaid shall be paid within [***] from the accountant's report, plus interest (as set forth in Section 9.1) from the original due date. MC2 shall bear the full cost of such audit unless such audit discloses an underpayment by EPI Health of more than [***] of the amount due for the audited period, in which case EPI Health shall bear the full cost of such audit.

9.9 Taxes.

- (a) Taxes on Income. Each Party shall be solely responsible for the payment of all Taxes imposed on its share of income arising directly or indirectly from the efforts of, or the receipt of any payment by, the Parties under this Agreement.
- **(b)** 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 commercialization payments and any other payments made by EPI Health to MC2 under this Agreement. To the extent EPI Health is required to deduct and withhold Taxes from any payment to MC2, EPI Health shall pay the amounts of such Taxes to the proper Governmental Authority in a timely manner and promptly transmit to MC2 an official tax certificate or other evidence of such withholding sufficient to enable MC2 to

demonstrate such payment of Taxes to any applicable Government Authority. MC2 shall provide EPI Health any tax forms tha may be reasonably necessary in order for EPI Health not to withhold Tax or to withhold Tax at a reduced rate under an applicable bilateral income tax treaty. Each Party shall provide the other with reasonable assistance to enable the recovery, as permitted by Applicable Laws, of withholding 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.

(c) Withholding Taxes. If EPI Health is required by Applicable Laws to make any Tax deduction, Tax withholding or similar payment from any amount paid or payable by EPI Health to MC2 (a Tax Withholding") under this Agreement, then EPI Health will pay MC2 the actual stated amount set forth under this Agreement in full and shall also pay any such Tax Withholding (including any additional Tax Withholding required with respect to EPI Health's additional payments under this Section 9.4) directly to the proper Governmental Authority. For clarity, MC2 shall receive, without any deduction or offset with respect to Taxes and free of any Tax Withholding, a net amount equal to, after payment of any Tax Withholding, the amount to which MC2 was otherwise entitled under this Agreement and would have received had no Tax Withholding been required by Applicable Laws to be made.

Article 10

Intellectual property

10.1 Ownership of Inventions.

- (a) Ownership. Each Party shall own all Inventions generated by or on behalf of such Party in the course of conducting such Party's activities under this Agreement. EPI Health hereby assigns, and agrees to assign, to MC2 all right title and interest in all Inventions developed by EPI Health that are related to the Product, are generated, developed, conceived or reduced to practice pursuant to the performance of this Agreement, and are based on Confidential Information or trade secrets of MC2 (collectively, "Product Inventions"). EPI Health shall, and shall cause each of its Affiliates, and its and their Sublicensees, 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 Section 10.1.
- **(b) Disclosure of Inventions.** EPI Health shall promptly disclose to MC2 all Product Inventions arising in the course of conducting EPI Health's activities under this Agreement, including all invention disclosures or other similar documents submitted to EPI Health by its, or its Affiliates', employees, agents or independent contractors describing such inventions. EPI Health shall also respond promptly to reasonable requests from MC2 for more information relating to such Product Inventions.

10.2 Prosecution of Patents.

- (a) Licensed Patents. As between the Parties, MC2 shall have the sole right and authority to prepare, file prosecute (including any oppositions, interferences, reissue proceedings, reexaminations and post-grant proceedings) and maintain the Licensed Patents. MC2 shall be responsible for all costs incurred by it in the course of preparing, filing, prosecuting and maintaining the Licensed Patents.
- **(b)** Cooperation in Prosecution and Extensions EPI Health shall provide MC2 all reasonable assistance and cooperation in the patent prosecution efforts as provided in this Section 10.2, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution.

10.3 Infringement of Patents by Third Parties.

- (a) Notification and Cooperation If EPI Health becomes aware of any existing or threatened infringement of any Licensed Patent ("Infringement"), it shall promptly notify MC2 in writing to that effect, and shall provide evidence in EPI Health's possession demonstrating such Infringement.
- **(b)** Enforcement Rights. MC2 shall have the sole right, but not the obligation, to bring (and to control the prosecution and/or settlement of) an appropriate suit or other action against any Person or entity allegedly engaged in any Infringement of the Licensed Patents in the Territory (and to defend any related counterclaim) by a product containing betamethasone or ester thereof (such as betamethasone dipropionate) and calcipotriene (hereinafter "**Product Infringement**"). EPI Health shall provide at MC2's expense reasonable assistance to MC2 in any enforcement action under this Section 10.3 MC2 shall keep EPI Health regularly informed of the status and progress of any enforcement efforts with respect to a Produc Infringement.
- **(c) Settlement**. MC2 shall not, without EPI Health's prior written consent, settle any Product Infringemen action that is brought under this Section 10.3 that (i) admits the invalidity or unenforceability of any Licensed Patent, requires abandonment or limits the scope of any such Licensed Patent or would substantially limit or restrict EPI Heath's ability to sel the Product in the Territory or (ii) admits to any wrongdoing by EPI Health or any of its Affiliates.
- (d) Expenses. If MC2 recovers monetary damages in any Product Infringement action, such recovery shall be allocated first to the reimbursement of any documented expenses incurred by the Parties in such enforcement action, and any remaining amounts shall be treated as Net Sales and subject to the payment of the Commercialization Fee to EPI Health pursuant to Section 9.1.
- **(e)** Other Infringements. MC2 shall have the sole right to enforce Licensed Patents with respect to any Infringement that is not a Product Infringement, including in the Territory, and MC2 shall be entitled to retain all recoveries resulting from all such enforcements.

- 10.4 Third Party Intellectual Property Either Party shall notify the other Party upon becoming aware of any intellectual property owned by a Third Party that is necessary or useful to Develop, import, make (or have made), use, Promote or Commercialize the Product in the Field in the Territory. MC2 will have the sole right to acquire, at its sole cost and expense, any rights under any such Third Party intellectual property.
- 10.5 Third Party Infringement Claims If the manufacture, sale or use of the Products in the Field in the Territory pursuant to this Agreement results in a claim, suit or proceeding alleging patent infringement against either Party (or their respective Affiliates, licensees or sublicensees) (collectively, "Infringement Actions"), such Party shall promptly notify the other Party hereto in writing. MC2 shall have the sole right to direct and control the defense of such Infringement Action, at its own expense with counsel of its choice. In any event, MC2 agrees to keep EPI Health reasonably informed of all materia developments in connection with any such Infringement Action for which MC2 exercises its right to direct and control the defense. MC2 agrees not to settle such Infringement Action, or make any admissions or assert any position in such Infringement Action, in a manner that would substantially limit or restrict EPI Heath's ability to sell the Product in the Territory, without the prior written consent of EPI Health, which shall not be unreasonably withheld or delayed.

Article 11

Representations and Warranties

- 11.1 Mutual Representations and Warranties. Each Party hereby represents, warrants, and covenants (as applicable) to the other Party as follows, as of the Effective Date:
- (a) Corporate Existence and Power It is a corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is organized, and has full partnership, company or corporate power and authority, as the case may be, and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement, including the right to grant the rights purported to be granted by it hereunder.
- **(b)** Authority and Binding Agreement As of the Effective Date, (i) it has the corporate power and authority, as the case may be, and the legal right to enter into this Agreement and perform its obligations hereunder, (ii) it has taken all necessary corporate 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 such Party, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms, subject to enforcement of remedies under applicable bankruptcy, insolvency, reorganization, moratorium or similar Applicable Laws affecting generally the enforcement of creditors' rights and subject to a court's discretionary authority with respect to the granting of a decree ordering specific performance or other equitable remedies.

- (c) No Conflict. It is not a party to any agreement that would prevent it from granting the rights granted to the other Party under this Agreement or performing its obligations under this Agreement.
 - (d) No Debarment. None of such Party's employees, consultants or contractors:
 - (i) is debarred under Section 306(a) or 306(b) of the FD&C Act or by the analogous Applicable Laws of any Regulatory Authority;
 - (ii) has, to such Party'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 any analogous Applicable Laws, or is proposed for exclusion, or is the subject of exclusion or debarment proceedings by a Regulatory Authority; or
 - (iii) is excluded, suspended or debarred from participation, or is otherwise ineligible to participate, in any U.S. or non-U.S. healthcare programs, or is excluded, suspended or debarred by any Regulatory Authority from participation, or is otherwise ineligible to participate, in any procurement or nonprocurement programs, (the foregoing (i) through (iii), collectively, the "**Debarment Laws**").
- 11.2 Representations and Warranties by MC2. MC2 hereby represents and warrants to EPI Health as follows, as of the Effective Date:
- (a) Sufficient Rights. MC2 has sufficient title and/or rights to grant the licenses under Sections 2.1 and 2.3 for the purposes expressly contemplated in this Agreement for use in the Field in the Territory;
- **(b)** Notice of Infringement or Misappropriation To MC2's knowledge, no Third Party is infringing or has infringed the Licensed Technology or is misappropriating the Licensed Technology existing as of the Effective Date. In addition, as of the Effective Date, MC2 has not received any written notice from any Third Party asserting or alleging that any research, development or commercialization of the Product prior to the Effective Date infringed or misappropriated the intellectual property rights of such Third Party in the Territory;
- (c) Non-Infringement of Third Party Rights. To MC2's knowledge, the use, marketing, promotion or sale of the Product in the Territory in accordance with the terms of this Agreement after the Effective Date, and the manufacture of the Product after the Effective Date, in each case, can be carried out without infringing any patents, patent applications, trademarks, or other intellectual property rights owned or controlled by a Third Party; and
- (d) No Proceedings. MC2 has not received written notice of any pending or threatened investigations, actions, suits, proceedings arbitration, summons or subpoena (other than ordinary course patent prosecution proceedings) of any nature, civil, criminal,

regulatory or otherwise, in law or in equity, in the Territory against MC2 involving the Licensed Technology or the Product;

- (e) As of the Effective Date, MC2 has conducted Development of the Product in accordance with all Applicable Laws; and
- **(f)** MC2 has not granted, and will not grant during the Term, rights to any Third Party under the Licensed Technology that conflict with the licenses granted to EPI Health under this Agreement.
- 11.3 Representations and Warranties by EPI Health. EPI Health hereby represents and warrants to MC2 that, as of the Effective Date:
- (a) no enforcement action under any Debarment Laws prior the Effective Date relating to EPI Health or any o its Affiliates will have any effect on the right or ability of EPI Health and its Affiliates to fully perform their activities and obligations under this Agreement in compliance with all Applicable Laws and Guidelines; and
- **(b)** there is no action, claim, suit, proceeding, arbitration, summons or subpoena (other than ordinary course patent prosecution proceedings) of any nature, civil, criminal, regulatory or otherwise, in law or in equity, pending or, to EPI Health's knowledge, threatened in writing against EPI Health that would reasonably be expected to impact EPI Health's ability to perform its obligations under this Agreement.

11.4 Covenants by EPI Health.

- (a) Patent Challenge. If EPI Health or any of its Affiliates, either directly or indirectly through any Third Party commences any interference or opposition proceeding with respect to, or challenge the validity or enforceability of any Licensed Patent in the Territory ("Patent Challenge"), then in the event of any such Patent Challenge, MC2 shall have the right to terminate this Agreement in accordance with Section 14.5.
- **(b) EPI Health Activities**. EPI Health agrees and covenants, for itself and each of its Affiliates, that EPI Health shall use Commercially Reasonable Efforts to maximize Net Sales.

11.5 Covenants by Both Parties.

(a) Conduct of Activities.

(i) Each Party and its respective Affiliates, and its and their respective employees and contractors, in connection with the performance of its and their respective obligations under this Agreement, shall not violate any Applicable Laws, the federal civil false claims act (or any state equivalent), federal or state "sunshine"/aggregate spend reporting laws, government price reporting laws, consumer protection and unfair trade practices laws or export control laws.

- (ii) Each Party shall promptly (and in any event within three (3) Business Days) notify the other Party is such notifying Party has determined that there may be a violation of Applicable Laws or Guidelines in connection with the performance under this Agreement or the Commercialization of the Product by any Party or Person.
- **(b) No Debarment** Neither Party will use, during the Term, any employee, consultant or contractor who has been or is subject to debarment, exclusion, or suspension under any Debarment Laws.
- 11.6 No Other Representations or Warranties. EXCEPT AS EXPRESSLY STATED HEREIN, NEPRESENTATIONS OR WARRANTIES WHATSOEVER, WHETHER EXPRESS OR IMPLIED, INCLUMARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENTON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS, IS MADE OR GIVEN ON BEHALF OF A PARTY.

Article 12

Indemnification and Insurance

12.1 Indemnification by MC2 MC2 shall defend, indemnify, and hold EPI Health, its Affiliates, and each of their respective shareholders, owners, officers, directors, employees, and agents (the "EPI Health Indemnitees") harmless from and against any and all damages or other amounts payable to a Third Party claimant, as well as any reasonable attorneys' fees and expenses incurred by such EPI Health Indemnitees (collectively, 'EPI Health Damages'), all to the extent resulting from or arising out of any claims, suits, proceedings or causes of action brought by such Third Party (collectively, "EPI Health Claims") against such EPI Health Indemnitee that arise from or are based on: (a) the gross negligence, willful misconduct, or recklessness of any of MC2, its Affiliates, and each of their respective shareholders, owners, officers, directors, employees, and agents (the "MC2 Indemnitees"); (b) the Development and Manufacturing of the Product and performance of the MC2 Commercialization Activities by or on behalf of MC2; (c) any product liability claim involving a failure to warn claim, a Product manufacturing defect, or a Product design defect; (d) any actual or alleged infringement of intellectual property rights of a Third Party as a result of the Development or Manufacture of the Product by or on behalf of MC2 and Commercialization of the Product in the Territory conducted in accordance with the Terms of this Agreement and all Regulatory Approvals, including prescribing information, for the Product, except where the infringement is caused by acts or omissions of EPI Health which (i are not in accordance with the terms of this Agreement and all Regulatory Approvals, including prescribing information for the Product, or (ii) involve the misappropriation or violation of intellectual property rights in connection with the marketing, sale, offer for sale, or use of the Product by EPI Health without the approval of the JSC or the express written consent of MC2; c (e) a breach of any of MC2's representations, warranties, covenants or obligations under the Agreement; provided, however, except in each case to the extent that such EPI Health Claims or EPI Health Damages are attributable to any matter for which EPI

Health is obligated to indemnify a MC2 Indemnitee pursuant to Section 12.2. In the event of an infringement claim for which MC2 is responsible for indemnifying EPI Health as described in (d) above, MC2 has the right to immediately require that, or notice to EPI, EPI suspend or cease EPI's Commercialization of the Product in order to mitigate or eliminate such alleged Thir Party claims; provided that EPI Health may be permitted to terminate this Agreement with sixty (60) days prior written notice upon any cessation or suspension that lasts more than ninety (90) days.

12.2 Indemnification by EPI Health EPI Health shall defend, indemnify, and hold the MC2 Indemnitees harmless from and against any and all damages or other amounts payable to a Third Party claimant, as well as any reasonable attorneys' fees and expenses incurred by such MC2 Indemnitees (collectively, "MC2 Damages"), all to the extent resulting from any claims, suits, proceedings or causes of action brought by such Third Party (collectively, "MC2 Claims") against such MC2 Indemnitee that arise from or are based on: (a) the willful misconduct, recklessness or grossly negligent acts of any EPI Health Indemnitees; (b) the performance of the EPI Health Commercialization Activities by or on behalf of EPI Health; (c) any actual or alleged infringement of intellectual property rights of a Third Party as a result of the Commercialization of the Product in the Territory conducted by or on behalf of EPI Health which (i) is not in accordance with the terms of this Agreement and all Regulatory Approvals, including prescribing information for the Product, or (ii) involves the misappropriation or violation of intellectual property rights in connection with the marketing, sale, offer for sale, or use of the Product by EPI Health without the approval of the JSC or without the express written consent of MC2; or (d) a breach of any of EPI Health without the approval of the JSC or without the express written consent of MC2; or (d) a breach of any of EPI Health's representations warranties, covenants, or obligations under the Agreement; provided, however, except in each case to the extent that such MC2 Claims or MC2 Damages are attributable to any matter for which MC2 is obligated to indemnify a EPI Health Indemnite pursuant to Section 12.1.

12.3 Indemnification Procedures.

- (a) If any Party seeking indemnity under this Article 12 (the "Indemnified Party") receives written notice of the commencement of any claim, suit, proceeding or cause of action ("Claim") by a Third Party or the assertion of any Claim by a Third Party, and such Indemnified Party intends to seek indemnity pursuant to this Article 12 the Indemnified Party shal promptly provide the other Party (the "Indemnifying Party") with written notice of such Third Party Claim, stating the nature, basis for indemnification and the amount thereof, to the extent known, along with copies of any relevant documents evidencing such Third Party Claim. Failure of the Indemnified Party to give such notice, or provide such documentation, shall not relieve the Indemnifying Party from its indemnification obligations hereunder, except to the extent that the Indemnifying Party is actually prejudiced thereby.
- **(b)** Each Party shall, at its own expense, reasonably cooperate with the other Party in submitting insurance claims, securing insurance coverage and obtaining insurance proceeds for each Claim. Each Party agrees to, and shall cause its respective Affiliates and each of its and their respective shareholders, owners, officers, directors, employees, and agents to, promptly provide to the other Party upon request copies of such information,

documentation and correspondence relating to any Claim and/or factual or insurance matters relating to any Claim, which in the reasonable judgment of the requesting Party may be necessary or useful for perfecting insurance claims, or obtaining coverage or recoveries with respect to such Claim.

- (c) 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, that the Indemnifying Party may assume and conduct the defense of the Claim with counsel of its choice. The Indemnifying Party shall not be entitled without the Indemnified Party's written consent to (i) assume the defense, appeal or settlement of any Third Party Claim if (A) the Third Party Claim relates to or arises in connection with any criminal proceeding, action, indictment, allegation or investigation, or (B) the Third Party Claim seeks any injunction or equitable relief against the Indemnified Party, (ii) settle any Claim if such settlement contains a stipulation to or admission or acknowledgement of, any liability or wrongdoing (whether in contract, tort or otherwise) or the incurrence of any costs or expenses, on the part of any Indemnified Party, or (iii) maintain control of the defense, appeal or settlement of any Third Party Claim if the Indemnifying Party has failed or is failing to defence in good faith the Third Party Claim.
- (d) So long as the Indemnifying Party is entitled to do so and has assumed the defense, appeal or settlement proceedings of the Third Party Claim in accordance herewith, (i) the Indemnified Party may retain separate co-counsel at its sole cost and expense and participate in the defense, appeal or settlement proceedings of the Third Party Claim (provided, that the Indemnifying Party shall pay the fees and expenses of such separate counsel incurred by the Indemnified Party prior to the date the Indemnifying Party assumes control of the defense of the Third Party Claim or if representation of both the Indemnifying Party and the Indemnified Party by the same counsel would create a conflict of interest (due to one or more legal defenses or counterclaims which are different from or additional to those available to the Indemnifying Party or other such conflicts)), (ii) the Indemnified Party shall not file any papers or consent to the entry of any judgment or enter into any settlement with respect to the Third Party Claim without the prior written consent of the Indemnifying Party, and (iii) the Indemnifying Party shall not (A admit to any wrongdoing by the Indemnified Party or any of its Affiliates, or (B) consent to the entry of any judgment or enter into any settlement with respect to the Third Party Claim to the extent such judgment or settlement provides for equitable relief against the Indemnified Party or any of its Affiliates or if such judgment or such settlement does not expressly and unconditionally release the Indemnified Party and its Affiliates from all liabilities and impose no ongoing constraint on the Indemnified Party, in each case, without the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld or delayed).
- **(e)** The Parties shall act in good faith in responding to, defending against, settling or otherwise dealing with all Third Party Claims. The Parties shall also cooperate in any such defense, appeal or settlement proceedings, and give each other reasonable access, upon reasonable prior notice during normal business hours, to all information relevant

thereto. Whether or not the Indemnifying Party has assumed the defense, appeal or settlement proceedings, such Indemnifying Party shall not be obligated to indemnify the Indemnified Party hereunder for any settlement entered into or any judgment that was consented to without the Indemnifying Party's prior written consent (which consent shall not be unreasonably withheld or delayed).

12.4 Insurance. Each Party shall procure and maintain insurance, at its sole cost and expense and at all times during the Term of this Agreement, with respect to its activities hereunder that is consistent with normal business practices of prudent companies similarly situated, including general liability and workers' compensation insurance. All required insurance will be purchased from insurance companies authorized to do business within the state(s) where the services are being performed, and rated A.M. Best A-VIII or better. Any deductibles associated with the required insurance coverage of either Party will be assumed by the respective Party at its sole cost and expense. 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 12 or as otherwise required by law. Neither Party represents that coverage and limits required will be adequate to fund all losses for which either Party may be liable. Upon execution of this Agreement, each Party shall provide the other Party with written evidence of such insurance. Each Party shall further provide written notice to the other Party at least thirty (30) days prior to cancellation or non-renewal of such insurance of self-insurance which materially adversely affects the rights of the other Party hereunder.

Article 13

Confidentiality and Non-Use

- 13.1 Confidentiality. Except to the extent expressly authorized by this Agreement or otherwise agreed in writing by the Parties, each Party agrees that, during the Term and for ten (10) years thereafter, it shall keep confidential and shall not publish or otherwise disclose and shall 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) any Confidential Information furnished by or on behalf of a Party to the other Party pursuant to this Agreement, except for that portion of such information or materials 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 hereunder;
- **(b)** was generally available to the public or otherwise part of the public domain at the time of its disclosure or becomes so after its disclosure other than through any act or omission of the receiving Party or its Affiliates in breach of this Agreement;
- (c) was previously disclosed to the receiving Party or its Affiliate by a Third Party without obligations of confidentiality with respect thereto and who did not obtain such information directly or indirectly from the other Party or its Affiliate; or

- (d) was previously independently discovered or developed by the receiving Party or its Affiliate without access to or use of Confidential Information.
- **13.2 Authorized Disclosure**. Each Party or its Affiliate may disclose Confidential Information of the other Party without violation of Section 13.1 to the extent such disclosure is reasonably necessary in the following situations:
 - (a) filing or prosecuting patent applications in accordance with Article 10;
- **(b)** regulatory filings and other filings with Governmental Authorities (including Regulatory Authorities), including filings with the SEC or FDA, all with respect to the Product;
 - (c) prosecuting or defending litigation;
- (d) complying with Applicable Laws or Guidelines, including regulations promulgated by securities exchanges, court order, administrative subpoena or other order; and
- (e) disclosure to its Affiliates, officers, directors, employees, agents, consultants, independent contractors, licensees, sublicensees, attorneys, accountants, financial advisors, actual or potential acquirers, lenders, and investors, insurers and/or licensors in each case only on a need-to-know basis and, except for disclosures to lenders, solely in connection with the performance of this Agreement, <u>provided</u>, that each disclosee must be bound by obligations of confidentiality and non-use at least as restrictive in scope as those set forth in this Article 13 prior to any such disclosure.

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Sections 13.2(a), 13.2(b), 13.2(c) or 13.2(d), it will, unless otherwise prohibited by Applicable Laws or Guidelines, give reasonable advance notice to the other Party of such disclosure and use reasonable efforts to secure confidential treatment of such information at the other Party's sole cost and expense. In any event, the Parties agree to take all reasonable action to avoid disclosure of Confidential Information hereunder.

13.3 Publicity.

- (a) The Parties agree that the terms of this Agreement are the Confidential Information of both Parties, subject to disclosure permitted by Section 13.2. The Parties have agreed to each make an individual public announcement of the execution of this Agreement in form and substance to be mutually agreed by the Parties.
- **(b)** After release of such press release, if either Party desires to make a public announcement concerning the activities under this Agreement (not including Promotion of the Products as contemplated by this Agreement), such Party shall 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 herein), such approval not to be unreasonably withheld, except that in the case of a press release or governmental

filing required by law, the disclosing Party shall provide the other Party with such advance notice as it reasonably can, shall use reasonable efforts to obtain approval therefor, and shall consider in good faith any comments timely received from the other Party. A Party commenting on such a proposed press release shall provide its comments, if any, within seven (7) Business Days after receiving the press release for review. Neither Party shall be required to seek the permission of the other Party to repeat any information regarding the terms of this Agreement that have already been publicly disclosed by such Party, or by the other Party, in accordance with this Section 13.3.

- (c) The Parties acknowledge that a Party may be obligated to describe in a periodic report filed with the SEC of other Governmental Authorities the material terms of this Agreement and file a copy of this Agreement with the SEC or other Governmental Authorities. Such Party shall be entitled to describe such material terms and to make such a required filing, provided, that it requests confidential treatment of at least the commercial terms and sensitive technical terms hereof and thereof to the extent such confidential treatment is reasonably available to such Party. In the event of any such filing, such Party will provide the other Party with a copy of the Agreement marked to show provisions for which such Party intends to seek confidential treatment before such intended filing, and shall reasonably consider and incorporate the other Party's comments thereon to the extent consistent with the legal requirements governing redaction of information from material agreements that must be publicly filed.
- 13.4 Return of Confidential Information Except as otherwise set forth in this Agreement, upon termination of this Agreement and at the disclosing Party's written request, the receiving Party will promptly return or, at the disclosing Party's election, destroy all of the disclosing Party's Confidential Information, including all reproductions and copies thereof in any medium, except that the receiving Party may retain one (1) copy for its legal files. The receiving Party shall confirm in writing that all of the disclosing Party's Confidential Information has been returned or destroyed and that not more than one (1) copy has been kept.
- 13.5 Exclusive Property. Except as otherwise set forth in this Agreement, as between the Parties, all Confidential Information of a disclosing Party is the sole and exclusive property of such 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.
- 13.6 Restrictions on Use. Each Party shall not, and shall ensure that its Affiliates shall not, use any Confidential Information of the other Party in development, regulatory, manufacturing or commercialization activities with respect to any pharmaceutical product other than the Product.

Article 14

Term and Termination

- **14.1 Term.** This Agreement shall become effective on the Effective Date and shall continue until the earlier of seventh (7th) anniversary of the First Commercial Sale of the Product or end of June 2028, unless the Agreement is terminated earlier pursuant to the other provisions of this Article 14 (the "**Term**").
- 14.2 Material Breach Each Party shall have the right to terminate this Agreement upon written notice to the other Party if such other Party has materially breached this Agreement and, after receiving written notice from the non-breaching Party identifying such material breach in reasonable detail, the other Party has (a) failed to cure such material breach within sixty (60) calendar days from the date of such notice, or (b) failed to pay an Uncured Late Payment within the twenty (20) calendar day time period provided for below. Any failure to pay any undisputed amount shall be deemed, and is hereby agreed by the Parties to be, a material breach of this Agreement if it remains unpaid for a period longer than twenty (20) calendar days after notice of non-payment has been provided (an "Uncured Late Payment"). For clarity, EPI Health's failure to meet the EPI Health Targe Quarterly Details for two (2) consecutive Calendar Quarters, other than (i) due to an Excused Interruption or (ii) if such failure occurs after the effective date of a change from P1 Detailing following a P1 Notice, shall be deemed a material breach.
- **14.3 Bankruptcy**. Each Party shall have the right to terminate this Agreement upon the filing or institution of any bankruptcy, reorganization, liquidation or receivership proceedings by the other Party, or upon the failure by such Party for more than ninety (90) days to discharge or obtain the dismissal of any such actions filed against it. Such termination shall be effective upon receipt of notice from the Party not involved in such event.
- 14.4 Termination for Convenience. MC2 shall have the right to terminate this Agreement at any time, for any reason or no reason, upon twelve (12) months' written notice to EPI Health; provided however, that no such termination shall be effective unless and until MC2 has either (i) paid in full to EPI Health the Incremental Costs, EPI Commercialization Fees, an the Sunset Payments owed by MC2 to EPI Health as of and following termination as calculated in accordance with the term hereof (the "MC2 Obligations"), or (ii) provided EPI Health with a letter of credit from a U.S. bank or a guarantee of similar security duly executed by the two controlling shareholders (holding companies of Clausen and Schroder families) of MC2 Therapeutics A/S (the 100% parent company of MC2) that is reasonably satisfactory to EPI Health in an amount sufficient to satisfy the MC2 Obligations in full for as long as any portion of the MC2 Obligations remain outstanding and which permits EP Health to draw on such letter of credit in the event that MC2 fails to pay in full any MC2 Obligation to EPI Health when due is accordance with the terms hereof. EPI Health shall have the right to terminate this Agreement at any time, for any reason or no reason, upon twelve (12) months' written notice to MC2; provided however, that no such termination shall be effective unless and until EPI Health has either (i) provided MC2 with a letter of credit from a U.S. bank or (ii)

has provided MC2 with a guarantee duly executed by Novan, Inc. ('Novan') (as the parent company of EPI Health), or the parent company of EPI Health at the time such guarantee is provided, in each case providing for the punctual and complete payment to MC2 when due of (x) the amount by which the outstanding Royalty Payments owed by EPI Health to MC2 excee the accrued Sales Deductions and unreimbursed Incremental Cost that have not been paid by MC2 or assumed in writing by MC2 and (y) the payment to the applicable third party by EPI Health of the accrued rebates to the extent such accrued rebates have been deducted from the Royalty Payments paid to MC2; provided further, that once nine (9) months have passed following EPI Health's delivery of a termination notice to MC2 under this Section 14.4, EPI Health shall have no furthe obligation under Section 2.5 (non-competition) of this Agreement and Section 2.5 shall no longer apply to EPI Health.

14.5 Termination by MC2 for Patent Challenge MC2 shall have the right to immediately terminate this Agreement upon written notice to EPI Health in the event of a Patent Challenge, brought either directly by EPI Health or any of its Affiliate or indirectly through any Third Party, pursuant to Section 11.4(a). In the event of termination by MC2 pursuant to this Section 14.5, beginning from the date of such written notice of termination by MC2, all amounts received in connection with Net Sales of the Product shall be solely and exclusively for MC2's benefit.

14.6 Effects of Termination of the Agreement.

- (a) Upon termination of this Agreement by MC2 pursuant to Section 14.4 or Section 16.4, or by EPI Healt pursuant to Section 12.1, 14.2, or Section 14.3, EPI Health shall be entitled to receive from MC2, for the twenty-four (24 month period immediately following the effective date of such termination (the "Sunset Period"), a payment (the "Sunset Payment") calculated as follows:
 - (i) if the effective date of termination occurs prior to the thirty-three (33) month anniversary of the First Commercial Sale, the greater of (A) the difference between [***] and the aggregate Commercialization Fee and Incentive Fee retained by EPI Health pursuant to Section 9.1 and Section 9.2 as of the effective date of termination, or (B) a aggregate payment equal to [***] the amount of the Commercialization Fee by EPI Health pursuant to Section 9.1 ove the twelve (12) month period preceding the effective date of termination;
 - (ii) If the effective date of termination occurs on or after the thirty-three (33) month anniversary of the First Commercial Sale, an aggregate payment equal to [***] the amount of the Commercialization Fee by EPI Healt pursuant to Section 9.1 over the twelve (12) month period preceding the effective date of termination.

Such Sunset Payments shall be made in [***] equal Calendar Quarterly installments during the duration of the Sunse Period, each Calendar Quarterly installment to be paid within [***] days after the end of each full or partial Calendar Quarter of such twelve (12) month period.

- (b) Upon termination of this Agreement by MC2 pursuant to Section 6.9, Section 14.4, or Section 16.4, or by EPI Health pursuant to Section 12.1, Section 14.2, or Section 14.3, EPI Health shall be entitled to receive from MC reimbursement for reasonable and documented costs incurred to terminate EPI Health's sales force that is no longer necessary to meet its obligations under the Commercialization Plan, solely to the extent such sales force cannot be terminated within the notice period (it being understood that EPI Health shall use Commercially Reasonable Efforts to terminate such sales force promptly after giving or receiving, as applicable, notice of termination). Upon termination of this Agreement for any reason, MC2 shall pay to EPI Health the amount of any unreimbursed Incremental Costs owed by MC2 to EPI pursuant to Sectic 9.3(a) hereof as of the effective date of such termination, or, if the actual Incremental Costs are less than the MC2 IC Prepayment, EPI Health shall pay MC2 the difference within [***] days following the effective date of such termination provided that, (i) if MC2 terminates this Agreement pursuant to Section 6.9, Section 14.2, Section 14.3, or Section 14.5 or i EPI Health terminates this Agreement pursuant to Section 14.4, MC2 shall not be responsible for payment of any Incrementa Costs incurred by EPI Health to employ the Base Sales Representatives during the period following the notice of termination, then, during such period, EPI Health shall not be required to Promote the Product in the Field in the Territory as a P1 Detail and shall be required to reasonably promote the Product.
- (c) A final Commercialization Report shall be delivered, and a final True-Up Adjustment shall occur, no later than twenty-four (24) months following the expiration or termination of this Agreement. The Parties will use Commercially Reasonable Efforts to transition customer contracts to MC2 or its designee following termination or expiration of this Agreement, pursuant to which MC2 or its designee shall assume any remaining obligations under such contracts for Sales Deductions applicable to Product sales during the Term. To the extent there are any Sales Deductions that are not assumed by MC2 or its designee, the amount of such remaining Sales Deductions shall reduce any amounts owed by EPI Health to MC2 i Royalty Payments, and any excess will be paid by MC2 to EPI Health within [***] days following delivery of the final Commercialization Report delivered hereunder.
- (d) Except as expressly set forth in this Agreement, upon expiration or termination of this Agreement for any reason, neither Party shall have any obligation to make any payments to the other, except for amounts accrued or incurred prior to expiration or termination.
- (e) Upon termination of this Agreement for any reason, the following shall apply (in addition to any other rights and obligations under this Agreement with respect to such termination); provided that, notwithstanding anything to the contrary herein, with respect to any termination by EPI Health pursuant to Section 12.1, Section 14.2, or Section 14.3, or any termination by MC2 pursuant to Section 6.9, Section 14.4 or Section 16.4, or where the Agreement terminates at the end of the curren Term, MC2 shall promptly reimburse EPI Health for EPI Health's reasonable, documented, internal and external costs incurred in performing the following:

- (i) Information Transfer. Within thirty (30) days after termination, EPI Health shall transfer to MC2 al material Information related to its Promotion and Commercialization of the Product and conduct of EPI Additiona Activities under this Agreement, including sales data, marketing materials, analytics and studies (including relevant contact information), advertising, promotional and marketing materials, payer information and medical affairs information, in each case relating to the Product in the Field in the Territory (collectively, the "EPI Health Commercial Know-How). MC2 shall not use any EPI Health Trademark following termination of the Agreement.
- (ii) Rights and Licenses. EPI Health's exclusive Detailing rights, exclusive right to conduct EP Commercialization Activities with respect to the Product in the Territory and all other rights granted under Section 2.1 and the license granted in Section 2.3 shall terminate. EPI Health hereby grants MC2, effective upon such termination, a non exclusive, worldwide, fully-paid, perpetual, irrevocable, royalty-free license, with the right to grant multiple tiers of sublicenses, to use the EPI Health Commercial Know-How for all purposes in connection with the Product in th Territory.
- (iii) Transition Assistance. Upon MC2's reasonable request, EPI Health shall provide reasonable consultation and assistance following termination for the purpose of enabling MC2 to continue the Development, Manufacture, Commercialization and other exploitation of the Products, in the form that such Products exist as of the effective date of termination, in the Field in the Territory. For clarity, EPI Health shall not be required to perform any activities as a result of this Section 14.7(b)(iv) that are unrelated to the activities that EPI Health performed prior to the effective date of termination. Each Party shall undertake not to actively and personally solicit or hire any employee of the other Party for a period of six (6) months from effective date of termination.
- (iv) Remaining Inventories. Upon payment to EPI Health of the Supply Price as part of the reimbursement of EPI's Incremental Costs hereunder, EPI Health shall deliver all remaining inventory of Product to MC2.
- (v) Access to Information EPI Health shall reasonably cooperate with MC2 to provide MC2 with reasonable access to such Information and reports related to the Product reasonably required by MC2 in order to comply with the relevant provisions of the Medicare Modernization Act, as amended from time to time, and any other Applicable Laws and Guidelines, including reporting requirements, in a timely and appropriate manner.
- **14.7 Survival**. Termination or expiration of this Agreement shall not affect rights or obligations of the Parties under this Agreement that have accrued prior to the date of termination or expiration of this Agreement. Notwithstanding anything to the contrary, the following provisions shall survive and apply after expiration or termination of this Agreement: Sections 2.7 (No Implied Rights), 6.5 (Report (solely for the period specified therein)), 6.7(a)(iii) (Advertising and Promotional Materials), 7.5 (Commercialization

Reports (solely for the period specified therein)), 7.6 (Use of Commercial Data and Information), 7.10(c)(i) (Ownership o Licensed Marks), 9.3 (Commercialization Payments; Reports (solely for the period specified therein)), 9.7 (Records; Audits) 9.8 (Taxes), 10.1 (Ownership of Inventions), 11.6 (No Other Representations or Warranties), 12.1 (Indemnification by MC2) 12.2 (Indemnification by EPI Health), 12.3 (Indemnification Procedures), 14.7 (Effects of Termination of the Agreement) and 14.8 (Survival), and Articles 1 (as applicable), 13 (Confidentiality and Non-Use), 15 (Dispute Resolution) and 16 (Miscellaneous). All provisions not surviving in accordance with the foregoing shall terminate upon expiration or termination of this Agreement and be of no further force and effect.

14.8 Non-Exclusive Remedy. Termination of this Agreement shall be in addition to, and shall not prejudice, the Parties' remedies at law or in equity, including, without limitation, the Parties' ability to receive legal damages and/or equitable relief with respect to any breach of this Agreement, regardless of whether or not such breach was the reason for the termination.

Article 15

Dispute Resolution

15.1 Governing Law. This Agreement will be governed by and construed in accordance with the laws of the State of New York, without regard to the conflict of law principles thereof. Each Party hereto agrees that any such proceeding will be conducted solely in the English language.

15.2 JSC Jurisdiction; Executive Escalation for Other Disputes.

- (a) If a dispute, other than a dispute that is subject to and to be resolved pursuant to Article 3 (Governance), arises between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection herewith (a "Dispute"), then either Party shall have the right to refer such dispute to Executive Officers who shall confer within [***] after such dispute was first referred to them to attempt to resolve the Dispute by good faith negotiations. If such Executive Officers cannot resolve the dispute within [***] days from the initiation of discussions, then the Parties hereby agree to submit the matter to arbitration in accordance with Section 15.2(b) and (c).
- **(b)** Any and all disputes, controversies, or claims arising out of or relating to this Agreement which have not been resolved by negotiation between the Parties as provided herein, will be finally resolved by arbitration as set forth in this Section 15.2. All disputes submitted to arbitration shall be finally, exclusively and conclusively settled by binding arbitration under the Rules of Conciliation and Arbitration of the International Chamber of Commerce (**TCC**"), as modified by Section 15.2(c) below. The place of arbitration shall be New York, New York. The language of the arbitrators shall be English and all documents not in English submitted by any Party shall be accompanied by a certified English translation thereof. Unless otherwise agreed by the Parties, the tribunal shall be comprised of three (3) arbitrators; each Party shall nominate one arbitrator and the two

Party-nominated arbitrators shall nominate the third arbitrator, who shall serve as the presiding arbitrator, within fifteen (15) days after the second arbitrator's appointment. The arbitrator shall have knowledge of and experience in the pharmaceutical industry. An arbitrator shall be deemed to meet these qualifications unless a Party objects within ten (10) days after the arbitrator is nominated. The arbitral award must be consistent with the provisions of the Agreement and shall be exclusive, final, and binding upon both Parties and the Parties undertake to carry out any award without delay. The Parties acknowledge that the 1958 United Nations Convention on the Recognition and Enforcement of Foreign Arbitral Awards (the 'New York Convention') applies to this Agreement and to any arbitral award or order resulting from any arbitration concluded hereunder. The award may be made a judgment of a court of competent jurisdiction.

- (c) Notwithstanding any provision to the contrary in the ICC Rules, the Parties hereby stipulate that any arbitration hereunder shall be subject to the following special rules:
 - (i) Each Party shall have the right to request from the arbitrators, and the arbitrators shall order upon good cause shown, reasonable and limited pre hearing discovery, including (I) exchange of witness lists, (II) depositions under oath of named witnesses, (III) written interrogatories, and (IV) document requests;
 - (ii) Upon conclusion of the pre-hearing discovery, the arbitrators shall promptly hold a hearing upon the evidence to be presented by the parties and shall promptly render a written opinion and award;
 - (iii) NOTWITHSTANDING OTHER PROVISIONS OF THE AGREEMENT WHICH MA' INTERPRETED TO THE CONTRARY, THE ARBITRATOR(S) APPOINTED IN ACCORDANCE WITH TE RULES SHALL NOT HAVE THE AUTHORITY TO GRANT DAMAGES TO ANY PARTY HERETO THAT DISCLAIMED OR LIMITED (TO THE EXTENT OF SUCH LIMITATION) UNDER THE TERMS OF AGREEMENT; and
 - (iv) Each party shall bear its own costs and expenses of the arbitration and one half (1/2) of the fees and costs of the arbitrators, subject to the power of the arbitrators, in their sole discretion, to award all such reasonable costs, expenses and fees to the prevailing party, including its reasonable attorneys' fees.
- 15.3 Interim Relief Nothing in this Article 16 will preclude either Party from seeking equitable relief or interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a Dispute if necessary to protect the interests of such Party or to preserve the status quo.
- 15.4 Specific Performance. Notwithstanding anything to the contrary in this Agreement, the Parties understand and agree that monetary damages may not be sufficient remedy for breach of this Agreement and that the injured Party will be entitled to seek equitable relief, including injunction and specific performance of the terms of this

Agreement, for any such breach. The arbitrators shall not have the authority to amend or modify the terms of this Agreement.

Article 16

Miscellaneous

- 16.1 Entire Agreement; Amendment. This Agreement, including the Exhibits attached hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior agreements and understandings between the Parties with respect to the subject matter hereof, including the Existing Confidentiality Agreement. The foregoing shall not be interpreted as a waiver of any remedies available to either Party as a result of any breach, prior to the Effective Date, by the other Party of its obligations pursuant to the Existing Confidentiality Agreement. In the event of any inconsistency between any plan hereunder (including the Commercialization Plan or Field Force Detailing Plan) and this Agreement, the terms of this Agreement will govern and control. There are no covenants, promises, agreements, warranties, representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.
- **16.2 Notices**. Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement, and shall 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 17.2, and shall be (a) delivered personally, (b) sent by registered or certified mail, return receipt requested, postage prepaid, (c) sent via a reputable national or international overnight courier service, or (d) sent by e-mail to at least two persons designated as representatives of the receiving party below and receipt acknowledged by at least one such representative, provided that in each case (a) (c) an email copy shall be sent to the receiving Party, as well. Any such notice, instruction or communication will be deemed to have been given for all purposes (i) when received, if hand-delivered, (ii) one (1) Business Day after it is sent by a reputable international or national overnight delivery service, (iii) five (5) Business Days after mailing, if mailed by first class certified or registered mail, postage prepaid, return receipt requested or (iv) upon acknowledgement of receipt by at least one representative, if sent by e-mail.

If to MC2: MC2 Therapeutics A/S

Agern Alle 24-26 2970 Hoersholm

Denmark Attn: [***] Email: [***] [***]

With a copy to: Cooley LLP

Reston Town Center

11951 Freedom Drive, 14th Floor

Reston, VA 20190 Attention: [***] Email: [***]

If to EPI Health: EPI Health, LLC

174 Meeting Street

Suite 200

Charleston SC 29401

Attn: [***] Email: [***]

With a copy to: Blank Rome LLP

501 Grant Street, Suite 850 Pittsburgh, PA 15219

Attention: [***]
Email: [***]

16.3 No Strict Construction; Headings; Construction This Agreement has been prepared jointly and shall not be strictly construed against either Party. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision. The word "or" is used in the disjunctive sense and the word "and" is used in the conjunctive sense. Unless the context requires otherwise, (a) 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), (b) any reference to any Applicable Laws will be construed as referring to such Applicable Laws as from time to time enacted, repealed or amended, (c) any reference to any Person will be construed to include the Person's successors and permitted assigns, (d) 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, (e) 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, (f) all references to Sections or Exhibits will be construed to refer to Sections and Exhibits to this Agreement, (g) the word "days" means calendar days unless otherwise specified, (h) except as otherwise expressly provided herein all references to "\$" or "dollars" refer to the lawful money of the U.S., (i) 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, (j) wherever used, the singular includes the plural, the plural the singular, the use of any gender applies to all genders, and (k) the word "shall" means "will". 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. The terms "includes," "including," "include" and derivative forms of them shall be deemed followed by the phrase "without limitation", regardless of whether it is actually written there, and drawing no implication from the actual inclusion of such phrase in some instances after such terms but not others.

- **16.4 Assignment**. Except as set forth in Section 16.4(a), neither Party may assign or transfer, by operation of law or otherwise, this Agreement or any rights or obligations hereunder without the prior written consent of the other. If such assignment results from a Change of Control of EPI Health, except as provided in Section 16.4(c), MC2 shall have the right to terminate this Agreement immediately in its sole discretion, and the provisions of Section 14.6 shall apply in the event of such termination by MC2 under this Section 16.4.
- (a) **Permitted Assignments**. Notwithstanding the foregoing, upon ten (10) Business Days' advance notice provided to EPI Health, MC2 may assign any of its obligations to any of its Affiliates or in connection with a Change of Contro of MC2.
- **(b)** Assigning Party Remains Responsible Any permitted successor or assignee of rights and/or obligations hereunder shall, in a writing to the other Party, expressly assume performance of such rights and/or obligations (and in any event, any Party assigning this Agreement to an Affiliate shall remain bound by the terms and conditions hereof and shall provide written notice upon such assignment). Any permitted assignment shall 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 16.4 shall be null, void and of no legal effect.
- (c) Change of Control of EPI Health EPI Health shall provide to MC2 at least [***] prior written notice o its intent to undergo a Change of Control, including identifying for MC2 the proposed Third-Party successor to EPI Healt resulting from such Change of Control transaction. During such [***] notice period, and prior to EPI Health closing on a definitive agreement with the Third Party identified by EPI Health to give effect to such Change of Control, MC2 shall have the opportunity to determine whether it wishes to continue with such Third Party in place of EPI Health in accordance with the existing terms of this Agreement. If (i) at any time during such [***] notice period and prior to EPI Health completing the Change of Control transaction with such identified Third Party, MC2 consents in writing to continue with such identified Third Party, or (ii) an additional [***] notice period expires after written reminder notice from EPI Health without

MC2 notifying EPI Health of its intent to terminate, then thereafter MC2 shall not have the right to terminate this Agreemen under Section 16.4 in the event of such Change of Control of EPI Health provided, however, that if at any point during the full [***] notice period MC2 provides EPI Health with prior written notice of its intent not to continue with such identified Third Party, then MC2 retains the right to terminate this Agreement immediately under Section 16.4 in the event of such Change of Control of EPI Health.

- 16.5 Condition Precedent. The effectiveness of this Agreement (except as provided in this Section 16.5) is expressly conditioned on the closing of that certain Unit Purchase Agreement pursuant to which Novan will acquire the business as currently conducted by EPI Health, including the rights under this Agreement, by the acquisition of all of the outstanding equity interests of EPI Health (the 'Condition Precedent'). Once the Condition Precedent is satisfied, this entire Agreement will be fully in effect and each of the Parties will be bound by its terms and conditions without any further action by the Parties. Until such time as the Condition Precedent is satisfied, only Article 13 (Confidentiality) and this Section 16.5 (Condition Precedent of this Agreement are in effect, and the Original Agreement will remain in full force and effect. If the Condition Precedent is not satisfied within [***] after the Execution Date, this Agreement (including Section Article 13 (Confidentiality) and Section 16.5 (Condition Precedent)) shall automatically terminate in its entirety and have no effect, and the Original Agreement will continue to remain in full force and effect.
- 16.6 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 a Force Majeure Event 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 the Force Majeure Event continues and the non-performing Party takes reasonable efforts to remove the condition. Notwithstanding the foregoing, a Party will not be excused from making payments owed hereunder because of a Force Majeure Event affecting such Party. If a Force Majeure Event persists for more than [***], then the Parties will discuss in good faith the modification of the Parties rights and obligations under this Agreement to mitigate the delays caused by such Force Majeure Event.
- **16.7 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.
- 16.8 Limitation of Liability. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY LOUNG PROFITS OR SPECIAL, CONSEQUENTIAL, INCIDENTAL, PUNITIVE, OR INDIRECT DAMAGES ARISING OR RELATING TO ANY BREACH OF THIS AGREEMENT OR ANY OTHER CLAIMS ARISING HEREUNDISTHEREUNDER, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAM NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS SECTION 16.8 IS INTENDED TO OR SHALL OR RESTRICT THE INDEMNIFICATION RIGHTS OR OBLIGATIONS OF ANY PARTY UNDER SECTION 112.2, OR DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS ULARTICLE 13.

- 16.9 Severability. If any one or more of the provisions of this Agreement is held to be invalid or unenforceable in any respect for any reason, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable one such that the objectives contemplated by the Parties when entering this Agreement may be realized; 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 Applicable Law.
- **16.10 No Waiver**. Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written and signed waiver relating to a particular matter for a particular period of time.
- 16.11 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. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, each Party shall act solely as an independent contractor, and nothing in this Agreement shall be construed to give either Party, or representative or employee thereof, the power or authority to act for, bind, or commit the other Party in any way without such Party's approval. Nothing herein shall be construed to create the relationship of partners, principal and agent, or joint-venture partners 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 Code or the regulations thereunder and any foreign equivalents thereto. Except as provided for in this Agreement, neither EPI Health nor MC2 shall 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.
- **16.12 Third Party Beneficiary**. None of the provisions of this Agreement shall be for the benefit of or enforceable by any Third Party, including any creditor of either Party hereto. No such Third Party shall obtain any right under any provision of this Agreement or shall by reasons of any such provision make any Claim in respect of any debt, liability or obligation (or otherwise) against either Party hereto.
- **16.13 Expenses**. Each Party will pay all of its own fees and expenses (including all legal, accounting and other advisory fees) incurred in connection with the negotiation and execution of this Agreement and the arrangements contemplated hereby, except as specifically provided herein.
- **16.14 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.

16.15 Counterparts. This Agreement may be executed in one (1) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Each Party may execute this Agreement by facsimile transmission or in AdobeTM Portable Document Format ('**PDF**") sent by electronic mail, which 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.

(Signature Page Follows)

IN WITNESS WHEREO, Fthe Parties have executed this Promotion and Collaboration Agreement by their duly authorized officers as of the Amendment Effective Date.

MC2 Therapeutics Limited EPI Health, LLC

/s/ Jesper J. Lange	By:	/s/ John Donofrio
Jesper J. Lange	Name:	John Donofrio
CEO	Title:	President
2/28/2022	Date:	2/27/2022
	Jesper J. Lange CEO	Jesper J. Lange Name: CEO Title:

(Signature Page to Amended and Restated Promotion and Collaboration Agreement)

Certain confidential information contained in this exhibit have been omitted by means of redacting a portion of the text and replacing it with [***], pursuant to Regulation S-K Item 601(b) of the Securities Act of 1933, as amended. Certain confidential information has been excluded from this exhibit because it is: (i) not material; and (ii) the registrant treats such information as private or confidential.

CONFIDENTIAL EXECUTION VERSION

ASSIGNMENT AND LICENSE AGREEMENT

THIS ASSIGNMENT AND LICENSE AGREEME(Nife "Agreement") is made effective as of August 3, 2009 (the "Effective Date"), by and between VICEPT THERAPEUTICS, INC., a Delaware corporation, having an address of 585 E. Swedesford Road, Suite 200 Wayne, PA 19087 ("Vicept"), and ASPECT PHARMACEUTICALS, LLC, a Delaware limited liability company, having an address of 4351 East Lohman Ave., Suite 208, Las Cruces, NM 8 ("Aspect").

BACKGROUND

- 1. Aspect has developed and tested certain formulations of compounds that act [***], that it believes are useful to treat rosacea and other dermatological conditions, as well as certain related intellectual property, data and know-how;
- 2. Vicept is interested in acquiring such intellectual property, data and know-how, and in developing a product for a dermatological condition based on such a compound; and
- 3. Aspect is willing to assign to Vicept, and Vicept is willing to purchase from Aspect, such intellectual property, data and know-how, all of the terms and editions more particularly set forth below;

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing premises and the covenants and obligations set forth in this Agreement, the Parties (defined below hereby agree as follows:

ARTICLE 1

DEFINITIONS

As used herein, the following terms have the following meanings (with derivative forms being interpreted accordingly) and the words "include," "including" and derivative forms of them shall be deemed followed by the phrase "without limitation":

- 1.1 "\$" and "Dollars" means United States dollars.
- 1.2 "[***] **Compounds**" means [***].
- 1.3 "Affiliate" means, with respect to a given legal entity, any other entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such first legal entity. For this purpose, "control" shall mean the ownership of fifty percent (50%) or more of the voting securities entitled to elect the directors or management of the entity, or the actual power to elect or direct the management or policies of the entity by law, contract, or otherwise.
- 1.4 "Aspect Group" means (a) Aspect and its Affiliates; (b) the Aspect People; and (c) any entity under the "control" (as defined in the definition of Affiliate and in the last sentence of this definition of Aspect Group) of any Aspect Person, or of any entity controlled (as so defined above) by one (1) or more of the Aspect People (or any combination of the foregoing non-natural legal entities referred to in (a) and (c) and any of the Aspect People). In addition, if any of the legal entities (including the natural people) listed in the first sentence of this Section own (either alone or in combination) more than twenty percent (20%) of the voting securities entitled to elect the directors or management of an entity, or of any class of shares of an entity, then that entity is a member of the Aspect Group.

- 1.5 "Aspect People" means [***].
- 1.6 "Assigned Current Families" means [***].
- 1.7 "Assigned Know-How" means all Know-How related to or constituting Technology and known to Aspect or any member of Aspect Group on or before three (3) years after the Effective Date, including: (a) all preclinical and clinical data generated relating to Technology before the Effective Date by or on behalf of Aspect or any member of Aspect Group; (b) all manufacturing information regarding the processes for Technology and/or Formulations that Aspect or any member of Aspect Group has made or tested on or before the Effective Date (including the formula and master batch records for each one); (c) such Formulations; and (d) all information as to clinical investigators Aspect or any member of Aspect Group knows to be currently (as of the Effective Date) exploring Technology or to have done so in the three (3) years prior to the Effective Date.
- 1.8 "Assigned Patents" means (a) the Assigned Current Families; (b) all Patents that meet all of the following criteria: (i) they claim inventions conceived on or before five (5) years after the Effective Date; (ii) they name as an inventor any of the inventor(s) named in any of the Assigned Current Families (iii) they Claim Technology; and (iv) they were not invented under any separate (outside of this Agreement) duty to assign to Vicept; (c) all other Patents owned by Aspect or any member of the Aspect Group during the term of this Agreement that are necessary or useful for the manufacture, sale, use, import or commercialization of Product(s); and (d) all Patents claiming Assigned Know-How (and explicitly excluding those that disclose but do not claim Assigned Know-How)
 - 1.9 "Business Day" means any Monday, Tuesday, Wednesday, Thursday or Friday that is not a national, statutory holiday in the United States.
- 1.10 "Claims" means, with respect to a particular item or product and a particular patent, that such patent claims (whether directly or via the doctrine of equivalents) the composition of such item or product or any of its ingredients or formulations; a method of making or using it or them; or an item used or present in the manufacture of such item or product (including chemical intermediates).
- 1.11 "Confidential Information" means, subject to the limitations set forth in Section 8.1, all information received by Aspect or any of the Aspect People pursuant to the Prior CDA or pursuant to this Agreement from Vicept or any of its investors or prospective investors; the Assigned Know-How; and the existence and terms of this Agreement and nature of the Products and of intellectual property assigned and licensed under this Agreement.
- 1.12 "Control" means, with respect to a particular item of know-how, patent application or patent, that the applicable Party has a license to and has the ability to grant to the other Party access to and a sublicense under such item or rights as provided for in this Agreement.
 - 1.13 "Dermatology Indication" means any dermatologic disease or condition, including erythema, rosacea, and purpura.
 - 1.14 "FDA" means the United States Food and Drug Administration, and any successor thereto.
 - 1.15 "Fair Market Value" means the fair market value of Vicept capital stock, which shall be determined as follows:
- (a) if the Vicept capital stock to be issued is traded on a public securities exchange or through the Nasdaq National Market, the fair market value thereof shall be deemed to be the average of the closing prices of such security on such exchange over the 30-day period ending three (3) business days prior to the date the liability that Vicept capital stock is being disgorged to cover was found;

- (b) if the Vicept capital stock to be issued is actively traded over-the-counter, the fair market value thereof shall be deemed to be the average of the closing bid or sale prices (whichever is applicable) over the 30-day period ending three (3) business days prior to the date the liability that Vicept capital stock is being disgorged to cover was found; or
- (c) If there is no active public market for any Vicept capital stock, the fair market value thereof shall be as determined in good faith by Vicept's Board of Directors based on a reasonable consideration of all relevant factors.
 - 1.16 "Formulation" means any formulation (including topical and non-topical formulations) of any [***] Compound.
- 1.17 "IND" means an Investigational New Drug Application as defined in the United States Food, Drug and Cosmetic Act and applicable regulation promulgated thereunder by the FDA or the equivalent application to the equivalent agency in any other country or group of countries, the filing of which is necessary to commence clinical testing of Product in humans in a particular jurisdiction.
- 1.18 "Know-How" means any and all data, instructions, processes, methods, formulae, materials, expert opinions, inventions (whether or not patentable), biological materials (including cell lines, vectors and their progeny and derivatives), know-how, and information (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical, analytical, clinical, safety, manufacturing and quality control data). Know-How does not include what is set forth in any published and/or issued Patents.
- 1.19 "Licensed Patents" means all Patents Controlled by Aspect or any member of the Aspect Group is Agreement that claim an invention that is necessary or useful to for the manufacture, sale, use, import or commercialization of the Products, but excluding the Assigned Patents.
- 1.20 "Licensee" means any entity to which Vicept or an Affiliate of Vicept grants a license under the Assigned Patent and/or Assigned Know-How and/or Licensed Patents to make, have made, use, sell, offer for sale, import and/or export Product. The term "Licensee" also include the sublicensees of those whom Vicept or its Affiliate has directly licensed under the Assigned Patents or Licensed Patents. The term "Licensee" also includes assignees of the Assigned Patents (or any subset thereof) and their licensees and sublicensees of the Assigned Patents (or any subset thereof).
 - 1.21 "NDA" means a New Drug Application, which is an application for Regulatory Approval in the United States.
 - 1.22 "**Net Sales**" means [***].
 - 1.23 "Party" means Vicept or Aspect.
- 1.24 "Patent" means any patent application or patent, including all of the following kinds and their equivalents outside the United States (as applicable): provisional, converted provisional (or regular), divisional, continuation, continuation-in-part, and substitution applications; and regular utility, re-issue, re-examination, renewal and extended patents (including Supplementary Protection Certificates).
- 1.25 "Phase III Trial' means a clinical trial in humans that is denominated a phase III trial in accordance with Federal Regulation 21 C.F.R §312.21(c).
 - 1.26 "Prior CDA" means that certain Mutual Confidential Disclosure Agreement between Aspect and Vivo Ventures dated March 28, 2008.

- 1.27 "Products" means all compositions that constitute or the use of which constitutes Technology or whose manufacture, sale or use is covered by a Valid Claim in the Assigned Patents (other, to avoid definitional circularity, than solely such a Valid Claim contained solely in a Patent mentioned in clause (c) of the definition of Assigned Patents.
- 1.28 "Regulatory Agency" means a supranational, regional, federal, state, provincial or other local regulatory agency, department, bureau or other governmental authority with jurisdiction over Regulatory Approvals, including the FDA.
- 1.29 "Regulatory Approval" means, collectively with respect to a particular jurisdiction, all governmental approvals, product and/or establishment licenses, registrations or authorizations necessary for the manufacture, use, storage, import, export, transport, marketing and sale of a composition as a prescription or over-the-counter pharmaceutical product in such jurisdiction.
- 1.30 "Regulatory Exclusivity" means, with respect to a Product and a given time period, that the Regulatory Agency with responsibility for Regulatory Approvals of such Product, during such time period, either (a) is not legally entitled to grant Regulatory Approval of another product containing the same active ingredient(s) as such Product for any (i.e. can legally provide Regulatory Approval for none) of the same indication(s) (with each including its subindications) for which Product is Regulatorily Approved (and thus can only legally grant Regulatory Approval of such other product for other indications not overlapping any for which the Product is approved); or (b) is not legally entitled to grant Regulatory Approval of another product that shows bioequivalence to such Product, in reliance on the safety and efficacy data on the Product submitted by or on behalf of Vicept, its Affiliate or Licensee. For the avoidance of doubt Regulatory Exclusivity shall include new chemical entity (NCE), clinical investigation (CI) exclusivity, orphan drug exclusivity (ODE), pediatric exclusivity and 18 day generic product exclusivity by the FDA, each of the foregoing in the U.S. as currently defined in U.S. federal regulations, or any equivalent exclusivities in an other jurisdiction. To avoid doubt, the "clinical investigation (CI) exclusivity" referred to in the foregoing sentence refers to the 3-year exclusivity that is provided under 21 C.F.R. §314.108 for an applicant who has conducted new clinical investigations as described in such C.F.R. section; as used in such sentence, "clinical investigation (CI) exclusivity" does not have other definition than that, and in particular no colloquial meaning shall be imported.
- 1.31 "Technology" means (a) [***] Compounds having utility to treat any Dermatology Indication(s) (including all [***] Compounds mentioned of covered in the Assigned Current Family); (b) all Formulations of the foregoing Compounds; (c) all methods of use and delivery (and devices used in such use of delivery) of the [***] Compounds of clause (a) and/or Formulations to treat Dermatology Indication(s); and (c) all methods of making any of the foregoing. To avoid doubt, the Technology includes the Formulations described in the Assigned Current Family Patents on file as of the Effective Date of the Agreement, which Formulations have previously been tested by or for Aspect.
 - 1.32 "Third Party" means any entity or person other than Vicept, Aspect, an Affiliate of either of them or any other member of the Aspect Group.
- 1.33 "Trademarks" means all Technology-related trademarks and tradenames owned, use or conceived of by Aspect or any member of Aspect Group on our before the Effective Date, including the trademark identified in Exhibit B.
- 1.34 "Valid Claim" means with respect to any country, (i) a claim of any pending patent application within the Assigned Patents that is being prosecuted in good faith and has not lapsed or been disclaimed, abandoned or finally disallowed (or finally rejected) without the possibility of appeal or refiling and has not been pending more than three (3) years from the Effective Date or (ii) a claim of any issued, unexpired patent within the Assigned Patents that has not been held permanently revoked, unenforceable or invalid by a decision of a court or governmental authority of competent jurisdiction, which decision is unappealable or unappealed or will not be appealed within the time allowed for appeal,

and has not lapsed or been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise.

1.35 "Vicept Original Entity" means Vicept Therapeutics, Inc., a Delaware corporation, regardless of any assignment of this Agreement that may occur and result in another entity being a party to this Agreement.

ARTICLE 2

GRANTS OF RIGHTS

- 2.1 **Assignment**. Subject to Section 9.4, Aspect hereby irrevocably, perpetually and forever assigns and conveys to Vicept the entire right, title and interest in and to the Assigned Patents, and Assigned Know-How, together with all powers, privileges, benefits, causes of action, remedies, and other rights relating, appertaining to and/or associated with the Assigned Patents and Assigned Know-How. Such assignment is effective as of the Effective Date. Vicep hereby accepts such assignment.
- 2.2 **Specific Rights and Privileges**. Without limiting the generality of the assignment in Section 2.1, but subject to Article 4, as owner of the Assigned Patents, Vicept shall have, and the assignment and conveyance pursuant to Section 2.1 includes, the following specific rights and privileges:
- (a) Vicept shall have the sole' and exclusive right, but not the duty, to file and prosecute pending and future applications within the Assigned Patents worldwide, except as and to the extent explicitly provided in Article 5;
- (b) Vicept shall have the sole and exclusive right, but not the duty, to maintain and enforce the Assigned Patents worldwide, except as and to the extent explicitly provided in Article 5;
- (c) Vicept shall have the sole and exclusive right, but not the duty, to grant license (which licenses may include the right to grant sublicenses) under the Assigned Patents and to collect and retain royalty and/or other payment for such licenses; provided, however, that such license shall require the licensee to comply with the applicable terms and conditions of this Agreement (it being understood and agreed that this refers to respecting the back-up prosecution and enforcement rights of Article 5, and that as regards payments due under this Agreement it shall suffice for Vicept to make the payments required under this Agreement (Vicept shall not be required to contract for the licensee to pay directly));
- (d) Vicept shall have the sole and exclusive right, but not the duty, to sue on the Assigned Patents, and to collect all damages and profits for any past, present and/or future infringements thereof, except as and to the extent explicitly provided in Article 5; and
- (e) Vicept shall have the sole and exclusive right to sell, assign or otherwise transfer to any other entity or entities any or all of the rights assigned and transferred to Vicept under this Agreement; provided, however, that (1) such entity or entities must comply with the applicable terms and conditions of this Agreement (it being understood and agreed that this refers to respecting the back-up prosecution and enforcement rights of Article 5, and that as regards payments due under this. Agreement it shall suffice for Vicept to obtain such information from the licensee as is needed to enable Vicept to make the payments required under this Agreement (Vicept shall not be required, for purposes of this clause (1), to contract for the licensee to pay directly)) and (2) Vicept must either make such payments as are required under this Agreement based on the assignee's practice of Assigned Patent or require the assignee to do so.

Except as expressly provided in Article 4, Vicept shall not currently or in the future owe any further consideration to Aspect for or in respect of Vicept's exercise of the rights assigned to Vicept hereunder, including any amounts Vicept may collect on licenses it grants under the Assigned Patents;

recover by enforcing the Assigned Patents against infringement; and/or receive for the sale or transfer of any of the rights assigned Vicept hereunder.

- 2.3 Further Documentation to Perfect and Record. Aspect shall sign the short-form patent assignment document attached hereto as Exhibit A upon execution of this Agreement. Aspect shall further execute and deliver to Vicept and/or its representatives all other documents and instruments, to be prepared by Vicept, as Vicept reasonably requests, in order for Vicept to prosecute, perfect, record and/or enforce any of the rights that are granted to it under this Agreement, promptly after requested by Vicept. If Vicept is unable, after making reasonable inquiry, to obtain Aspect's signature on any such documents, then if and only if such documents are reasonably necessary due to Aspect having previously been the assignee of record on the Assigned Patents, Aspect hereby appoints Vicept as Aspect's attorney-in-fact for the sole purpose of executing and delivering such documents, which appointment is coupled with an interest. Aspect shall also cause employees, ex-employees and consultants who are named inventors on any of the Assigned Patents to do the same and to make the same appointment (and each inventor who signs an acknowledgement of this Agreement by so signing is hereby specifically agreeing to this Section and making such appointment).
- 2.4 **Further Assurances**. Aspect and such inventors shall take reasonable further actions to execute and deliver all further documents that Vicept may reasonably require to further documents that Vicept may reasonable require to further the purpose and intent of this Agreement.
- 2.5 **License Grant**. Aspect hereby grants to Vicept and its Affiliates a worldwide, exclusive (even as to Aspect, its Affiliates and the other members of the Aspect Group) license under the Licensed Patents to use, research, develop, make, have made, use, offer to sell, sell, import, export and otherwise commercialize [***] Compounds and Products throughout the world. Such license shall be freely sublicenseable, through one (1) or more tiers or layers of sublicensees, without the need to obtain consent from Aspect. Vicept shall be responsible for all payments due to Aspect based on the Product milestone achievements and Net Sales by the sublicensees, as if those activities were performed by Vicept.
- 2.6 **Assigned Know-How Confidentiality Protection** Aspect acknowledges that the Assigned Know-How is, as a result of the assignment of this Agreement, the commercially valuable confidential information of Vicept. Accordingly, Aspect and the other members of the Aspect Group shall treat such Know-How as the Confidential Information of Vicept. Aspect acknowledges that as between Aspect and Vicept, Vicept shall have the sole right to file, prosecute maintain and enforce Patents Claiming Assigned Know-How.
- 2.7 **Disclosure of Know-How**. Commencing within fifteen (15) days after the Effective Date, (a) Aspect shall begin providing to Vicept true, complete and correct copies and/or originals of all Assigned Know-How in existence as of the Effective Date (including all relevant clinical data, to the extent not already provided to Vicept prior to the Effective Date), and (b) make appropriate personnel reasonably available to Vicept to transfer and discuss such Assigned Know-How. Aspect shall complete the disclosure required in clause (a) of the foregoing sentence within thirty (30) days after the Effective Date.
- Assignment of Trademarks. Subject to Section 9.4, Aspect hereby irrevocably, perpetually and forever assigns and conveys to Vicept all of Aspect's right, title and interest throughout the world in and to: (a) the Trademarks; (b) all renewals and extensions for registrations included in the Trademarks; and (c) all benefits, privileges, causes of action and remedies relating to or conferred by any of the foregoing, whether accrued before or after the Effective Date. Such benefits, privileges, causes of action and remedies include the exclusive rights to apply for and maintain all such registrations, renewals and/or extensions; to sue for all past, present or future infringements or other violations of any rights in the Trademark; and to settle and retain proceeds from any such actions. Neither Aspect nor any other member of the Aspect Group retains any rights to use or to display the Trademarks. Aspect and the other members of the Aspect Group shall not challenge the validity of Vicept's ownership in the Trademarks. Aspect and all members of the Aspect Group each hereby further agrees to execute and deliver all

documents and instruments required to evidence or record such assignment or to enforce the assigned rights (and hereby appoints Vicept as Aspect's attorney-infact to execute and deliver such documents if unable after making reasonable inquiry to obtain Aspect's signatures on any of them).

2.9 **Rights of Reference.** To the extent relevant, necessary or useful to support Vicept's (and its Affiliates' and the Licensees') Product activities, Vicept (and its Affiliates and Licensees) shall have the right to reference and the right to access all INDs of Aspect relating to Technology and in existence as of the Effective Date.

ARTICLE 3

DEVELOPMENT/COMMERCIALIZATION

- 3.1 Allocation of Rights for Development and Commercialization As between the Parties, Vicept shall have the right to conduct all additional preclinical and clinical studies of Products, in order to be able to seek Regulatory Approval of and commercialize Products. As between the Parties, Vicept will be responsible for the costs of these activities. Vicept shall also have the exclusive right to commercialize Products. Vicept shall be fully and freely entitled to engage Licensees, contractors and distributors in Product development and commercialization. Subject to the provisos of Sections 2.2(c) and 2.2(e), Vicept shall have ful and sole discretion over licensing, intellectual property transactions and use of contractors and distributors. Vicept will still owe the milestones and royalties set forth in this Agreement, even if it is a Vicept Affiliate or a Licensee who achieves the relevant milestone events or sold the relevant Net Sales. As between the Parties, Vicept shall have the sole right and sole discretion to select (and use and own) the trademarks and tradenames for Products.
- 3.2 Vicept Responsibilities in Further Development and Commercialization; Diligence Vicept shall devote Commercially Reasonable Efforts (defined below in this Section) to develop and commercialize at least one (1) Product for at least one (1) Dermatology Indication for the United States market. To avoid doubt, the foregoing sentence shall not be read to require Commercially Reasonable Efforts towards development and commercialization of more than one (1) Product, nor towards development and commercialization of that Product for more than one (1) Dermatology Indication, nor development and commercialization for any market other than the U.S. market. All development and commercialization activities performed by any Vicept Affiliate(s) and any Licensee(s), contractors and distributors shall inure to the benefit of Vicept for purposes of determining Vicept's compliance with such obligation. [***]. No diligence obligations other than the ones set forth in this Section 3.2 shall be implied under or in connection with this Agreement or at law, and Vicept's diligence obligations in relation to its rights under this Agreement shall be solely as set forth in this Section 3.2.

"Commercially Reasonable Efforts" means a reasonable level of efforts, commensurate with the efforts that a company similarly situated to the Vicept Original Entity would devote to a product of similar potential and having similar commercial advantages and disadvantages as the Product, taking into account al relevant commercial factors, such as, but not limited to: (1) the intellectual property landscape and level of intellectual property exclusivity available for the product, (2) technical, scientific and clinical results and developments, (3) the competitive landscape and maturity of the marketplace, (4) the regulatory framework and hurdles, (5) pricing, (6) cost of goods, and (7) all other similarly relevant commercial factors.

If Vicept Original Entity is acquired (whether through merger, reverse merger, sale of assets or other form of transaction) ('M&A Transaction'), or any successor entity under this Agreement undergoes such an event, this Section 3.2 shall survive such acquisition. However, under no circumstances shall the surviving entity or Vicept Original Entity's successor under this Agreement be required, in order to be in compliance with this Agreement, to put forth a greater level of effort or conduct more activities or conduct activities on any faster timeline than set forth in Vicept Original Entity's development plan for the lead Product as such plan is in effect and approved by Vicept Original Entity's Board of Directors immediately prior to the closing of the M&A Transaction.

- 3.3 **Authorization of and Non-Interference with Consulting and/or Advisory Relationships** It is understood and agreed that Vicept may wish to engage one (1) or more of the inventors on the Assigned Patents in a consulting, advisory, or other contract relationship. Both Parties recognize this may be beneficial for Product progress. A spect -- to the extent its permission, waiver or other act would be required -- hereby agrees that Vicept and any of the inventors may enter into such a relationship, and hereby provides all permissions and waivers and agrees to perform such other acts as may be required to permit this.
- 3.4 Non-Competition for Protection of Licensed Trade Secrets and Confidential Information. Recognizing that such activities would necessarily entail use of the Assigned Know-How and/or Confidential Information of Vicept reported to Aspect in connection with this Agreement, Aspect hereby covenants that it shall not during the term of this Agreement research, develop, make, have made, offer to sell, sell, import or export any Products. Aspect hereby acknowledges on behalf of itself that the foregoing covenant is legally enforceable and is reasonable, necessary and appropriate to protect Vicept's Confidential Information.
- 3.5 Assistance With Patent Activities. In accordance with Article 2, Vicept has the sole right to file, prosecute, conduct interferences of and enforce the Assigned Patents and all Patents on Assigned Know-How. Aspect shall assist, and shall cause the inventors named in the Assigned Patents to reasonably assist, Vicept in all of the foregoing, standard patent activities, promptly upon each reasonable request by Vicept, and at Vicept's expense. As regards this assistance being at Vicept's expense, to avoid doubt, Vicept is entitled to elect to require the inventors on the Assigned Patents, to the extent that either personally has a direct relationship with Vicept (such as an employment or consulting relationship), to include the patent support activities referred to in this Section within the scope of and fully compensated by the compensation provided for in such separate, direct relationship with the particular individual.
- 3.6 **Improvements**. Vicept shall as between the Parties have the right to own all improvements, modifications, derivatives and amendments (including Know-How and published patentable or patented inventions to that Technology that is in existence as of the Effective Date, which improvements, modifications derivatives and amendment are made, conceived, developed, reduced to practice or acquired by or for Vicept (including under any consulting or employment agreement between Vicept or its Affiliate and any inventor on any Assigned Current Family) (**'Improvements**') and all Patents on the Improvements. Such Patents, to avoid doubt, are not considered Assigned Patents.

ARTICLE 4

FINANCIAL TERMS

- 4.1 **Signing Fee**. Vicept shall pay Aspect a signing fee equal to [***], within [***] days after the Effective Date.
- 4.2 Milestone Payments.
 - (a) Development Milestones.

(i)	Dermatology Indication	Other Than Purpura.Su	bject to Sections 4.2(a))(iii) and (iv), Vicept sha	all pay to Aspect the	following
one-time milestones, each wi	thin [***] after achievement	of the corresponding even	t in the following table, t	for the first time, with the	e first Product being of	developed
for any Dermatology Indication	on other than the treatmen	nt or prevention of purpura	that achieves such ev	ent through activities by	or on behalf of Vicer	ot:

Non-Purpura Milestone Event	Milestone Payment
1. [***]	1. [***]
2. [***]	2. [***]
3. [***]	3. [***]
4. [***]	4. [***]

(ii) **Purpura**. Subject to Section 4.2(a)(iii), Vicept shall pay to Aspect the following one-time milestones, each within [***] after first achievement of the corresponding event in the following table, for the first time, with the first Product for the treatment or prevention of purpura to achieve such event by activities by or on behalf of Vicept:

Purpura Milestone Event	Milestone Payment
1. [***]	1. [***]
2. [***]	2. [***]

- (iii) [***].
- (iv) [***].

(b) Sales Milestone. Vicept shall pay to Aspect the following sales milestone within [***] after first achievement of the following sales event with any Product:

Calendar Year Net Sales in countries with issued Valid Claim or Regulatory Exclusivity coverage	Royalty Rate
 Achievement of [***] in Net Sales in a calendar year, all of which Net Sales occur in country(ies) in which the Product sold is Claimed at the time of sale by a Valid Claim (whether pending or issued) of the Assigned Patents, or is Covered by Regulatory Exclusivity at the time of sale. 	

(c) **One-Time Only Milestones**. Each milestone payment specified above in Sections 4.2(a) and 4.2(b) shall be payable a maximum of one (1) time only, over the life of this Agreement, regardless of how many additional times (more than once) the particular milestone may be achieved with one (1) or more Products. Accordingly, the total maximum amount of milestones potentially payable under this Agreement equals [***].

4.3 Royalty Payments.

(a) **Base Rates**. Vicept stall pay Aspect royalties on annual Net Sales of Products sold to Third Parties in countries where the Product sold is (1) Claimed by an issued Valid Claim, or (2) covered by Regulatory Exclusivity, at the following tiered (or incremental) rates:

Calendar Year Net Sales in countries with Issued Valid Claim or Regulatory Exclusivity coverage	Royalty Rate
Portion from \$0 - \$[***]	[***]
Portion from \$[***] - \$[***]	[***]
Portion greater than \$[***]	[***]

These tiers apply on a worldwide and Product-by-Product basis; provided that for the purpose of determining the applicable royalty rate tier under this Section 4.3, (X) the Net Sales of any Products will be aggregated if such Products were subject to the same Regulatory Approval or one was approved through supplement to the other's existing Regulatory Approval, and (Y) the Net Sales of any Products will not be aggregated if such Products were not subject to the same Regulatory Approval and one was not approved as a supplement to an existing Regulatory Approval of the other (as non-limiting examples, (Y) applies where the second Product was approved through a stand-alone NDA, an abbreviated New Drug Application or 505(b)(2) application, or like separate application) It is also understood that the worldwide Net Sales of a given Product will be aggregated even though the Regulatory Approval for such Product in another country). Where the approval route is different in different countries, the decision as to whether or not to aggregate 2 Products' Net Sales (the choice between (X) and (Y) of the proviso above in this paragraph) shall be made based on the approval route in the U.S.

Example 1: [***].

Example 2: [***].

(b) Adjustments Based on Nature of Protection for the Product The full royalty rates of subsection (a) shall apply to sales in any country in which the Product is Claimed by an issued Valid Claim. The royalty rates shall be decreased by [***] for sales in any country in which the Product is no Claimed by an issued Valid Claim but is covered by Regulatory Exclusivity. No royalties shall be due

on Net Sales neither Claimed in the country of sale by a Valid Claim nor covered by Regulatory Exclusivity. Without limiting the generality of the foregoing, no royalties are due on the basis solely of the Product being Claimed in the country of sale by a pending Valid Claim.

(c) Offset for Third-Party Patent Royalties If Vicept or its Affiliate or a Licensee were to make payments to a Third Party under a Paten license encompassing a Product that is royalty-bearing to Aspect, then Vicept would be entitled to deduct up to [***] of the Third-Party payments from the royalty owed by Vicept to Aspect, but could not reduce the royalty owed to Aspect to below [***] of the royalties that would otherwise have been due to Aspect in any calendar quarter. Any amounts that Vicept is unable to credit due to the foregoing [***] limitation on the reduction in Aspect's royalties as applied in any calendar quarter shall carry forward to future calendar quarters, subject always to such [***] limitation on the reduction in Aspect's royalties as applied in such future calendar quarters; provided, however, that under no circumstances shall Aspect be responsible for more than [***] of the total Third-Party payments made by Vicept or its Affiliate or a Licensee to a Third Party under such Patent license.

(d) Generic Competition Adjustment.

- (i) **Prior to Launch by or on behalf of Vicept** If a Formulation other than the one marketed by or on behalf of Vicept -- but containing the same active ingredient as Vicept's Product, and labeled for a Dermatology Indication that is described or disclosed in the Assigned Patents as of the Effective Date (or a Dermatology Indication that is encompassed within such a described or disclosed indication) (to avoid doubt, unaffected by whether claims issue on the particular such indication) (all of the foregoing Dermatology Indications, '**Disclosed Dermatology Indications**') -- were approved and launched in the particular country prior to the first commercial sale (after Product Regulatory Approval is obtained in the country) of Product by or on behalf of Vicept in that country, then going forward from the time that such Formulation other than the one marketed by or on behalf of Vicept is first approved, no royalties would be due on Net Sales sold thereafter in that country.
- (ii) Adjustment. If a Formulation other than the one marketed by or on behalf of Vicept -- but containing the same active ingredient as Vicept's Product, and labeled for any Disclosed Dermatology Indications were approved and marketed in the particular country only after (and none were approved before) first commercial sale (after Product Regulatory Approval is obtained in that country, and captured at least [***] of the market share (based on units) in that country in any calendar quarter, then going forward the royalties to Aspect would be reduced to [***] of the royalties that would otherwise have been due in that country.
- (iii) Reinstatement. The royalty reduction of Sections 4.3(d)(i) and (ii) shall cease to apply in a given country if and with respect to Net Sales after both of the following occur: (1) as the result of settlement (including agreements to refrain from patent assertion or settling a patent assertion) or judgment on an infringement suit under the Assigned Patents the seller of the competing Formulation ceases all sales of such product or seller continues sales of such product pursuant to a binding legal agreement with Vicept with a royalty or other consideration due to Vicept, and (2) in the case solely of Section 4.3(d)(ii), Vicept achieves in four consecutive calendar quarters a level of Net Sales covered by an issued Valid Claim or Regulatory Exclusivity in such country equal to a least fifty percent (50%) of the level of Net Sales covered by an issued Valid Claim or Regulatory Exclusivity in such country in the 12 months leading up to the time the competing product was first sold in such country (or such lesser period as the Product by or on behalf of Vicept was being sold).
- (iv) **Clarification**. To avoid doubt, the competing Formulation may be either a prescription or an over-the-counter product, as long as it contains the same active ingredient as Vicept's Product and is labeled for a Disclosed Dermatology Indication. To avoid doubt, the adjustments of this Section 4.3(d) apply on a country-by-country basis. To avoid doubt, in each country, all Third-Party Formulations other than the one marketed by or on behalf of Vicept --but containing the same active ingredient as Vicept's Product, and labeled for a Disclosed Dermatology Indication -- that were approved

and launched in the country shall be taken into account in determining whether at least [***] of the market share (based on units) has been taken and in determining whether the sales level of Section 4.3(d)(iii)(B) has been reached. To avoid doubt, "Product marketed by or on behalf of Vicept" and "Vicept's Product" as used in this Section 4.3(d) each encompasses Products marketed by Vicept Affiliates and Licensees.

- (e) **Royalty Floor**. Notwithstanding anything to the contrary other than the royalty reduction of Section 4.3(d)(i) (which shall apply, fully, in the circumstances it describes, and be unaffected by this Section 4.3(e)), in no other event shall the royalties due under this Section 4.3 with respect to any Product for any calendar quarter be less than [***] of the Net Sales of such Product for such calendar quarter [***].
- 4.4. **Recoveries on Infringement of Assigned Patents.** In accordance with Section 2.1 and 2.2, Vicept has the sole right to enforce the Assigned Patents against infringement. Any recoveries on such infringement suits in excess of Vicept's (or its Affiliate's or Licensee's) costs in connection with such infringement suits (including all outside counsel costs and a reasonable allocation of the costs of internal counsel) shall be deemed Net Sales under this Agreement, and shall be deemed sold in a country in which the Product's active ingredient is Claimed by an issued Valid Claim, in the calendar quarter in which the recovery over costs is actually received, and shall bear a royalty under Section 4.3.
- 4.5 **Quarterly Payment Timings**. All royalties due under Section 4.3 shall be paid quarterly, on a country-by-country basis, within [***] after the end of the relevant calendar quarter for which royalties are due. The same applies to payments due under Section 4.4.
- 4.6 **Royalty Payment Reports.** With respect to each calendar quarter, within [***] after the end of the calendar quarter, Vicept shall provide to Aspect a written report stating the number and description of all Products sold during the relevant calendar quarter; the gross sales associated with such sales; and the calculation of Net Sales on such sales, including the amount of any deduction provided for in the definition of Net Sales in Article 1. The report shall provide al such information on a country-by-country and Product-by-Product basis.
- 4.7 **Payment Method** All payments due under this Agreement to Aspect shall be made by bank wire transfer in immediately available funds to an account designated by Aspect. All payments hereunder shall be made in the legal currency of the United States of America.
- 4.8 **Taxes**. Vicept shall be responsible to withhold from payments otherwise to be made to Aspect under this Agreement any taxes required to be withheld by Vicept under applicable law. If any such taxes are levied on such payments due hereunder ("**Withholding Taxes**"), Vicept shall (i) deduct the Withholding Taxes from the payment amount, (ii) pay all applicable Withholding Taxes to the proper taxing authority, and (iii) send evidence of the obligation together with proof of tax payment to Aspect with the next royalty report under Section 4.6.
- 4.9 **Foreign Exchange**. If any currency conversion shall be required in connection with the calculation of amounts payable hereunder, such conversion shall be made using the average of the exchange rates for the purchase and sale of U.S. dollars, as reported by Bank of America in San Francisco, California (o its successor entity) on the last business day of the calendar quarter to which such payment pertains. With any payment in relation to which a currency conversion is performed to calculate the amount of payment due, Vicept shall provide to Aspect a true, accurate and complete copy of the exchange rates used in the calculation.
- 4.10 **Late Payments**. Any payment due under this Article 4 that is not paid on or before the date such payment is due shall bear interest at a rate equal to the lesser of: the Prime Rate during the period of late payment plus two percent (2%) interest compounded annually; or the maximum rate permitted by law, calculated based on the number of days that payment is delinquent until full payment has been made. "Prime Rate" means the prime or equivalent rate quoted by The Wall Street Journal (or

similarly reputable source, if The Wall Street Journal no longer exists) with respect to the time period in which payment was delinquent.

4.11 **Records and Audit.** Vicept shall keep (or cause to be kept) complete and accurate records pertaining to Net Sales of Products and the payments due under this Agreement, in sufficient detail to permit Aspect to confirm the accuracy of all payments due under this Agreement. Aspect shall have the right, at its expense, to cause an independent, certified public accountant to audit such records as necessary to confirm Vicept's payments for the preceding year. Such independent, certified public accountant shall be legally bound by written confidentiality and non-use obligations running directly to Vicept. It shall be nationally recognized in the United States. Such audit rights may be exercised no more often than [***], upon reasonable advance notice to Vicept and during norma business hours. The terms of this Section shall survive any termination or expiration or termination of this Agreement for a period of [***].

In the case of records held by Vicept's Licensees, Vicept will request a direct audit right for Aspect, but it shall suffice if Vicept obtains a similar audit right for itself and the right to share the results of its own audits with Aspect.

ARTICLE 5

PATENT PROSECUTION, MAINTENANCE AND ENFORCEMENT

5.1 Patent Prosecution and Maintenance. Vicept shall have the right to prosecute (including, but not limited to, by conducting interferences, oppositions and reexaminations or other similar proceedings) and maintain (including, but not limited to, the timely payment of all maintenance fees, renewal fees and other applicable fees) and extensions of the Assigned Patents. If Vicept elects not to prosecute or maintain or extend any such Assigned Patents, Vicept shall provide written notice thereof to Aspect at least [***] prior to abandonment of any such Assigned Patents. In response to such a notice, Aspect may, in its sole discretion and, at its sole expense, request to assume responsibility for prosecuting and maintaining such Assigned Patent. Vicept shall reasonably consider and shall not unreasonably withhold its consent to any such request by Aspect. If Vicept (on such standard) approves for Aspect to assume such responsibility, then Aspect shall prosecute in Vicept's name, and Vicept's other rights with respect to the Assigned Patent(s) concerned shall continue, as shall the requirement to pay royalties based on such Assigned Patent(s). Vicept may exercise its rights under this Section 5.1 via an Affiliate or Licensee or extend its rights under this Section 5.1 via an Affiliate or Licensee.

5.2 Patent Enforcement.

- (a) **Right to Bring Suit**. Vicept shall have the first right to enforce or otherwise sue on the Assigned Patents against a Third Party. Each Party shall provide the other Party with written notice of any alleged infringement of the Assigned Patents. If Vicept elects not to enforce or otherwise sue on any such Assigned Patents within [***] after such a notice between the Parties, Vicept shall provide written notice thereof to Aspect, and Aspect may, in its sole discretion and at its sole expense, elect to enforce or sue on such Assigned Patent in Aspect's name.
- (b) **Cooperation**. Each Party will reasonably cooperate in the other's suits under this Section 5.2, at the expense of such other Party (on ε pass-through basis at reasonable rates).
- (c) **Recoveries**. All recoveries shall go first to reimburse litigation expenses (including internal and external costs and including reimbursing the prosecuting Party for expenses it has previously reimbursed to the other Party). For remaining recoveries where it was Vicept who brought suit, then Vicept shal be entitled to retain [***]% of the remaining recovery, and shall pay over to Aspect [***]% of the remaining recovery. For remaining recoveries where it was Aspect who brought suit, Aspect shall be entitled to retain [***]% of the remaining recovery, and shall pay over to Vicept [***]% of the remaining recovery.

- (d) **No Licenses by Aspect** Aspect shall not be entitled to grant licenses or any forward-looking rights under the Assigned Patents (or any subset thereof), including in connection with infringement suits that Aspect has the right to bring in accordance with this Section. Nothing in this Article 5 shall be construed so as to imply any right to grant licenses or any forward-looking rights under the Assigned Patents (or any subset thereof).
- (e) Extension of Rights to Vicept Affiliates and Licensees. To avoid doubt, Vicept may exercise its rights under this Article 5, or extend its rights under this Article 5, to its Affiliates and to Licensees.

ARTICLE 6

REPRESENTATIONS AND WARRANTIES

- 6.1 **Reciprocal Representations and Warranties**. Each Party hereby represents and warrants to the other Party that as of the Effective Date the representing and warranting Party has the full legal right, power and authority to enter into and perform this Agreement; that this Agreement has been authorized by all requisite action within such representing and warranting Party (in the case of a corporate entity); and that this Agreement is legally binding upon such representing and warranting Party.
 - 6.2 Aspect Representations and Warranties. Aspect represents and warrants to Vicept as follows:
- (a) **Sole Owner**. Immediately prior to the assignment hereunder becoming effective, Aspect was the sole and lawful owner of the entire right, title, and interest in and to the Assigned Current Families and Assigned Know-How.
- (b) No Liens. There are as of the Effective Date no outstanding liens, security interests, pledges, charges, mortgages, restrictions, interests and/or encumbrances burdening any of the Assigned Patents nor the Assigned Know-How.
- (c) **No Licenses or Encumbrances.** Aspect has not granted, expressly or otherwise, any assignment, license or other extension of rights, covenant not to sue or other similar interest or benefit, exclusive or otherwise, to, under or in the Assigned Patents or the Assigned Know-How.
- (d) **No Inconsistent Agreements.** Aspect and the Aspect Group have not executed, and Aspect further covenants that it and they shall not execute, any agreements inconsistent with this Agreement or to the detriment of the Assigned Patents or the Assigned Know-How.
- (e) Non-infringement of Third Party Rights As of the Effective Date and to Aspect's and the other members of the Aspect Group's actual knowledge, after making a reasonable inquiry, no published Patents or trade secret rights owned or controlled by a Third Party, dominate or would be infringed or misappropriated by the manufacture, use, sale, offer for sale or importation of any Products in topical applications for Dermatology Indications, and Aspect and the other members of the Aspect Group have received no written claims relating to any claims of such domination, infringement or misappropriation.
- (f) Claims. There are no claims, actions, suits or proceedings commenced or pending, or to Aspect's knowledge threatened, against it or any other member of the Aspect Group as of the Effective Date that could affect the rights and benefits granted to Vicept under this Agreement. As of the Effective Date, Aspect has not received verbal or written notice that any third party is challenging or intends to challenge the patentability, validity or ownership of the Assigned Current Families. As of the Effective Date, Aspect and the other members of the Aspect Group have no knowledge of prior art

(g) Aspect Group Bound. Aspect has the legal right to bind the other members of the Aspect Group in the manner required to require Aspec
to comply with and perform its obligations under this Agreement. Aspect and the other members of the Aspect Group that are not natural people (i.e., excluding
the people who are the inventors of the Assigned Patents) are the "Responsible Aspect Group Members." The Responsible Aspect Group Members shall I
jointly and severally liable for performance hereunder. Vicept, in case of breach of this Agreement by Aspect or any other member of the Aspect Group, shall be
entitled to proceed against any of the Responsible Aspect Group Members or any combination of them that it chooses to enforce Vicept's rights hereunder
without any obligation to first exhaust remedies with respect to any other(s) of them. To avoid doubt or concern, this Section explicitly does not make the Aspec
People jointly and severally liable for Aspect's performance under this Agreement.

relevant to the Assigned Patents not cited in the file wrappers of the Assigned Current Families [***] and believes claims covering the use of oxymetazoline to

treat rosacea will issue in the United States.

- (h) **Third-Party Activities; Grounds**. As of the Effective Date and to Aspect's actual knowledge without any special enquiry, there are no (i) activities by Third Parties that would constitute infringement or misappropriation of the Assigned Current Families (in the case of pending claims, evaluating then as if issued), nor (ii) grounds currently existing on which any claims, actions, suits or proceedings might be commenced against Aspect or Vicept with respect to the practice of the Assigned Current Families within the scope of the license set forth in Section 2.5.
- (i) Patents. The Assigned Current Families are the only Patents that Aspect or any other member of the Aspect Group owns or Controls, as o the Effective Date, that Claim Technology.
- (j) **Trade marks**. Exhibit B contains a complete list of all trademarks that Aspect or any other member of the Aspect Group owns or Controls as of the Effective Date, that are associated with Technology or have been registered for use with Technology.
- (k) **Data**. Aspect has disclosed to Vicept all data and information (including preclinical and clinical data and information) disclosed in regulatory filings (including adverse event and serious adverse event reports to Regulatory Agencies and all other safety-related data and information) prior to the Effective Date (including toxicology, carcinogenicity and mutagenicity data and information) generated by, disclosed to and/or known to Aspect or any other member of the Aspect Group regarding Technology and any information required to fairly and accurately interpret such data and information and make Aspect's disclosures thereof to Vicept complete, accurate and not misleading.
- (1) **No Debarment**. In the course of developing Technology and any products based on it, Aspect has not engaged any person who has been debarred by the FDA or to Aspect's knowledge is the subject of debarment proceedings by the FDA.
- (m) Affiliates of Aspect. As of the Effective Date, Aspect has no Affiliates and there are not members of the Aspect Group other than Aspect and the Aspect People.
- 6.3 **Aspect Covenants**. Aspect hereby covenants that, without limiting Vicept's right set forth elsewhere in this Agreement (including in Section 6.2(d)), Aspect and the other members of the Aspect Group shall not purpose to convey to any Third Party any Assigned Patent.
- 6.4 **Disclaimer of Warranties**. EXCEPT FOR THE REPRESENTATIONS AND WARRANTIES EXPLICITLY SET FORTH IN SECTION 6.2 EACH OF VICEPT AND ASPECT HEREBY EXPRESSLY DISCLAIMS ALL REPRESENTATIONS AND WARRANTIES, I STATUTORY OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT OR FITNESS FOR A PAR PURPOSE.

ARTICLE 7

INDEMNIFICATION

- 7.1 **Indemnification by Vicept**. Vicept shall indemnify, hold harmless and defend Aspect, the other members of the Aspect Group, and their respective officers, directors, members, employees and agents (the "**Aspect Indemnitees**") from and against any and all losses, damages, liabilities, judgments, fines, amounts paid in settlement, expenses and costs of defense (including reasonable attorneys' fees and witness fees) (collectively "**Losses**") resulting from any demand, claim, action or proceeding brought or initiated by a Third Party (each a "**Third-Party Claim**") against any Aspect Indemnitees(s) to the extent that such Third-Party Claim arises out of (i) the breach or alleged by Vicept in this Agreement; (ii) the negligence or willful misconduct of any Vicept Indemnitee (defined ir Section 7.2); or (iii) the development, manufacture, storage, handling, use, sale, offer, import, export or distribution of Products by or for Vicept and its Affiliates and Licensees; *provided* that (a) the Aspect Indemnitees comply with the procedure set forth in Section 7.3; and (b) such indemnity shall not apply to the extent Aspect has an indemnification obligation pursuant to Section 7.2 for such Loss.
- 7.2 **Indemnification by Aspect**. Aspect shall indemnify, hold harmless and defend Vicept, its Affiliates, the Licensees, the investors in Vicept and the respective officers, directors, employees and agents of each of the foregoing (the "Vicept Indemnitees") from and against any and all Losses resulting from any Third-Party Claim(s) arises out of (i) the breach of alleged breach of any representation, warranty or covenant by Aspect in this Agreement; or (ii) the negligence or willful misconduct of any Aspect Indemnitee; *provided* that (a) the Vicept Indemnitees comply with the procedure set forth in Section 7.3; and (b) such indemnity shall not apply to the extent Vicept has an indemnification obligation pursuant to Section 7.1 for such Loss.
- Party") and the Indemnifying Party shall defend against such Third Party Claim with the reasonable cooperation of the Indemnified Party; provided that the Indemnifying Party shall not settle any such Third-Party Claim for anything other than money damages without the prior written consent of the Indemnified Party which consent shall not be unreasonably withheld, conditioned or delayed. The Indemnified Party's Indemnitees must tender defense of the applicable Third-Party Claim and provide all reasonable cooperation and assistance in such defense, in order to remain eligible to be indemnified and held harmless; provided, however, that where Vicept is the Indemnified Party, unless Aspect has adequate insurance to cover the alleged potential Losses and is tendering defense to such insurer who has indicated in writing that they will fully assume the defense and cover any resulting Losses, the Vicept Indemnitees shall not be required to tender defense in order to remain eligible to be indemnified and held harmless and instead notwithstanding anything express or implied in this Section 7.3 Vicept and/or the Vicept Indemnitees may do so and be indemnified under this Agreement. The Indemnified Party shall have the right to be present in person or through counsel a substantive legal proceedings relating to the Third-Party Claim giving rise to the Indemnified Party's right to indemnification hereunder. If the Parties cannot agree as to the application of Sections 7.1 and 7.2 to any Loss or Third-Party Claim, the Parties may conduct separate defenses of such Third-Party Claim. In such case, each Party further reserves the right to claim indemnity from the other upon resolution of such underlying Third-Party Claim.
- 7.4 Limitation of Aspect's Liability. IN NO EVENT SHALL ASPECT BE REQUIRED TO PAY COMPENSATION (I.E., DISGORGE I OR RETURN EQUITY) TO COVER DAMAGES FOR ITS BREACH OF THIS AGREEMENT OR IN SATISFACTION OF ITS INDEMNOBLIGATIONS UNDER THIS AGREEMENT IN AN AMOUNT THAT EXCEEDS THE TOTAL AMOUNT (INCLUDING BOTH CAEQUITY) RECEIVE VICEPT AS OF THE DATE THE LIABILITY WAS INCURRED. IN THE EVENT ASPECT IS LIABLE TO VICEITHIS AGREEMENT, ASPECT SHALL TENDER FIRST IN CASH OR FIRST IN RETURN OF VICEPT EQUITY PURPOSES OF THIS SETHE VALUE OF THE VICEPT EQUITY IS ITS FAIR MARKET VALUE. IF ASPECT'S LIABILITY OR INDEMNIFICATION

OBLIGATION TO VICEPT EXCEEDS THE AMOUNT ASPECT CAN BE REQUIRED TO PAY PER THE FOREGOING IN THIS SECTION VICEPT SHALL BE ENTITLED TO A CREDIT FOR ALL ADDITIONAL, CREDITABLE AGAINST ALL FUTURE PAYMENTS DUE UNI AGREEMENT UNTIL FULLY SATISFIED.

THE FOREGOING PARAGRAPH SHALL NOT APPLY TO LIMIT COMPENSATION WITH RESPECT TO DAMAC INDEMNIFICATION LIABILITIES ARISING FROM FRAUD.

NOTHING IN THIS SECTION 7.4 SHALL PRECLUDE NON-MONETARY REMEDIES THAT MAY BE AVAILABLE WITH RESI ANY BREACH BY ASPECT OF THIS AGREEMENT, INCLUDING PROPER ASSIGNMENT OF INTELLECTUAL PROPERTY TO REM BREACH OF THE INTELLECTUAL PROPERTY ASSIGNMENT PROVISIONS OF THIS AGREEMENT.

7.5 **Limitation of Liability.** IN NO EVENT SHALL EITHER PARTY OR ITS RESPECTIVE AFFILIATES (OR IN THE CASE OF A ANY RESPONSIBLE ASPECT GROUP MEMBERS) BE LIABLE FOR SPECIAL, EXEMPLARY, CONSEQUENTIAL OR PUNITIVE I WHETHER IN CONTRACT, WARRANTY, TORT, STRICT LIABILITY OR OTHERWISE, EXCEPT TO THE EXTENT SUCH PARTY REQUIRED TO INDEMNIFY THE OTHER PARTY FROM SUCH DAMAGES CLAIMED BY THIRD PARTIES UNDER THIS ARTICLE EXCEPT TO THE EXTENT THAT SUCH DAMAGES ARISE FROM BREACH OF THE OBLIGATIONS SET FORTH IN ARTICLE 8 (RE CONFIDENTIALITY).

ARTICLE 8

CONFIDENTIALITY

8.1 **Confidential Information; Exceptions**. The Parties shall maintain all Confidential Information in trust and confidence and shall not disclose any Confidential Information to any Third Party (except as expressly provided below) or use any Confidential Information for any purposes other than for performance under or determining compliance with and administering this Agreement. The Parties shall not disclose Confidential Information to any employee, agent, consultant or Affiliate who does not have a reasonable need for such information for the foregoing purposes. Disclosures to such persons with a reasonable need for the information are only permitted to the extent the person is subject to binding obligations of confidentiality and limited use at least as restrictive in scope and as long in duration as those of this Article 8. The Parties shall use at least the same standard of care as it uses to protect its own confidential information of a similar nature to prevent unauthorized disclosures or uses of the Confidential Information, but no less than reasonable care. Each Party shall promptly notify the other Party upon discovery of any unauthorized use or disclosure of the Confidential Information. Confidential Information of Aspect does not include the Assigned Know-How, rather, Assigned Know-How is the Confidential Information of Vicept.

Confidential Information shall not include any information which, as shown by competent proof:

- (a) is now, or hereafter becomes, through no act or failure to act on the part of the receiving Party in breach hereof, generally known or available;
 - (b) is known by the receiving Party at the time of receiving such information, as shown by contemporaneous written records;
- (c) is independently developed by the Receiving Party without the aid, application or use of Confidential Information, as shown by writter records:

- (d) is hereafter furnished to the receiving Party by a Third Party, as a matter of right, without breach of any confidentiality agreement, and without restriction on disclosure; or
 - (e) is the subject of a prior, express, written permission to disclose provided by the disclosing Party.
- 8.2 **Authorized Disclosure**. Notwithstanding any other provision of this Agreement, either Party may disclose Confidential Information to the exten and to the persons and entities required by an applicable governmental law, rule, regulation or order; provided, however, that a Party shall first have given prompt notice to the other Party to enable the first Party to seek any available exemptions from or limitations on such disclosure requirement and shall reasonably cooperate in any such efforts by the first Party.
- 8.3 **Return of Confidential Information** If this Agreement is terminated for breach according to the provisions of Section 9.2, the Parties shall use diligent efforts to return all Confidential Information. Each Party will be allowed to keep one archival copy of any Confidential Information for record-keeping purposes only.
- 8.4 **Use of Names.** A Party shall not use any of the other Party's names, trademarks, logos, employee names, investor names or symbols in any publicity, promotion or similar public disclosure, without the advance written withholdable consent of such other Party, except as may be required by law or stock exchange requirement.

ARTICLE 9

TERM AND TERMINATION

9.1 **Term.** The term of this Agreement shall commence upon the Effective Date and, unless sooner terminated as provided in this Article 9, shall expire upon the expiration of the last-to-expire Valid Claim, but in any event no sooner than ten (10) years after the Effective Date.

9.2 Termination for Breach.

- (a) Terminable Breaches.
- (i) **Termination by Aspect**. Aspect may terminate this Agreement if Vicept materially breaches Section 3.2 of this Agreement, by ninety (90) days written notice to Vicept specifying in detail what the material breach of Section 3.2 is an stating explicitly that the notice is a breach and potential termination notice under this Section 9.2(a), *provided* that Vicept fails to cure such material breach that is incapable that is incapable of cure within ninety (90) days, but is capable of cure in a longer reasonable period, fails to provide within such ninety (90) day notice period a reasonable written plan to cure the breach as soon as practicable.
- (ii) **Termination by Vicept**. Vicept may terminate this Agreement if Aspect materially breaches this Agreement in a way that (x) results in Vicept (or its Affiliate or Licensee) owning less than all of the Assigned Patents and Assigned Know-How, (y) detracts from the strength or value of the Assigned Patents or Assigned Know-How, or (z) is a breach of Section 3.4 (**TP Breaches**"), by ninety (90) days written notice to Aspect specifying in detail what the IP Breach is and stating explicitly that the notice is a breach and potential termination notice under this Section 9.2(a), provided that Aspect fails to cure such material breach within such ninety (90) day notice period, or in the case of such a material breach that is incapable of cure within ninety (90) days, but is capable of cure in a longer reasonable period, fails to provide within such ninety (90) day notice period a reasonable written plan to cure the breach as soon as practicable

- (b) **Mechanics**. If a Party gives notice of termination under Section 9.2(a)(i) or (ii) and the other Party disputes whether such notice was proper (i.e., whether the Party having received such notice had actually materially breached this Agreement through the type of breach specified in the applicable such Section), then the issue of whether this Agreement has been terminated shall be resolved in accordance with Section 10.1. If as a result of such dispute resolution process it is finally determined that the notice of termination was proper, then such termination shall become effective as of the date of such final determination; provided, however, that the breaching Party fails thereafter to cure the underlying breach in accordance with the determination made in the resolution process under Section 10.1 within the time period set forth in this Section 9.2 for the applicable breach following such determination (meaning it must either cure within ninety (90) days after such final determination or provide within such time period a reasonable written plan for cure). If, however, as a result of such dispute resolution process it is determined that the notice of termination was improper, then no termination shall have occurred and this Agreement shall remain in effect.
- 9.3 **Elective Termination by Vicept**. Vicept shall have the right to terminate this Agreement at any time, with or without cause, upon written notice to Aspect.

9.4 Effects of Termination.

- (a) After Aspect Terminates for Vicept Breach. If Aspect terminates this Agreement pursuant to Section 9.2(a) following Vicept's uncured material breach of Section 3.2, then all licenses to Vicept under this Agreement shall terminate, Vicept and its Affiliates shall cease all development and commercialization of any Products and Vicept shall assign and convey to Aspect its entire right, title and interest in and to the Assigned Patents, the Assigned Know-How and the Assigned Trademarks, together with all powers, privileges, benefits, causes of action, remedies, and other rights relating, appertaining to and/or associated with the Assigned Patents, the Assigned Know-How and the Assigned Trademarks. Notwithstanding any provision to the contrary, not termination of this Agreement by either Party shall be construed as a termination of any valid grant of rights to a Licensee with respect to the rights granted under this Agreement. Upon termination of this Agreement by Aspect, each grant of rights to a Licensee shall, to the extent not imposing obligations on Aspect in excess of those contained herein, be assigned to Aspect if requested in writing by the Licensee or be automatically assigned to Aspect if requested in writing by the Licensee or be automatically assigned to Aspect if requested in writing by the Licensee.
- (b) After Vicept Effectively Terminates. If Vicept terminates this Agreement under Section 9.3, then the foregoing effects in Section 9.4(a) shall apply.
- (c) After Vicept Terminates for Aspect's Breach. If Vicept terminates this Agreement pursuant to Section 9.2 following Aspect's uncured material breach of this Agreement, then Vicept shall as between the Parties be entitled to retain full ownership of the Assigned Patents and the Assigned Know-How; the license granted Vicept pursuant to Section 2.5 (and such Section) shall survive such termination; and, in addition to those provisions that survive any expiration or termination of this Agreement as set forth in Section 9.4(d), the following shall survive and apply: Articles 2; Sections 4.1-4.4 shall survive but all payment obligations thereunder shall be reduced by fifty percent (50%) of the payment that would otherwise be due for all payments becoming due after the termination; and Sections 3.4, 3.5 and 3.6. Article 5 shall not survive such a termination. Section 3.2 shall not survive such a termination (nor shall Vicept have any diligence obligation under this Agreement, express or implied, after such a termination).
- (d) General. Expiration or termination of this Agreement for any reason shall not affect any accrued rights or obligations of the Parties, and the following Articles shall survive any expiration or termination of this Agreement: Articles 1 and 7-10. Also, Article 2 shall survive expiration of this Agreement (but shall not survive termination except as described above in sub-section (c)).

ARTICLE 10

MISCELLANEOUS

10.1 **Dispute Resolution**.

(a) Initial Dispute Resolution The Parties recognize that disputes may from time to time arise between the Parties during the term of this Agreement. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Section 10.1 to resolve any dispute arising under this Agreement. If such a dispute between the Parties arises, then either Party, by written notice to the other Party, may have such dispute referred to the Parties' respective executive officers designated below or their successors, for attempted resolution by good faith negotiations within [***] after such notice is received. Said designated officers are as follows:

Vicept: President and CEO Aspect: President and CEO

- (b) **Preliminary Relief** A Party is entitled to seek interlocutory relief and/or a preliminary injunction without first following the procedure of this Section 10.1; *provided* that it also invokes the procedure of this Section 10.1 in parallel. Each Party hereby irrevocably waives its right to jury trial of any and all disputes arising under this Agreement, and consents to have such disputes decided instead by a judge or justice.
- (c) Arbitration. Except as otherwise set out in this Section 10.1, any dispute that cannot be settled amicably by agreement of the Parties pursuant to Section 10.1(a) shall be finally settled by an arbitration administered by JAMS applying its most applicable procedural rules (and the substantive laws of the State of California) provided that the appointed arbitrator(s) shall have appropriate experience in the pharmaceutical industry (or if no such person is available then in the biopharmaceutical industry or the closest industry possible). The place of arbitration shall be Delaware, U.S.A. The language to be used in the arbitration proceedings shall be English. The award rendered in any arbitration shall be final and binding upon both Parties. The judgment rendered by the arbitrator(s) may include costs of arbitration, reasonable legal fees and reasonable costs for any expert and other witnesses. Nothing in this Agreement shall be deemed as preventing either Party from seeking injunctive relief (or any other provisional remedy) from any court having jurisdiction over the Parties and the subject matter of the dispute as necessary to protect either Party's name, Confidential Information (in the case of Vicept) or intellectual property. Judgment upon the award may be entered in any court having jurisdiction, or application may be made to such court for judicial acceptance of the award and/or an order of enforcement as the case may be. Notwithstanding the foregoing, either Party shall be free to submit any dispute relating to the scope, validity, enforceability or other like matter regarding intellectual property to any court having jurisdiction over the Parties and the subject matter of the dispute and to seek such relief and remedies as are available in that court.
- Juris diction. Both Parties consent to the exclusive personal jurisdiction of all courts sitting within Delaware, U.S.A., for resolving all dispute arising out of or in connection with this Agreement. Each Party hereby waives any and all defenses it may have to the jurisdiction and venue of such courts, including a defense that such a court may not assert personal jurisdiction over such Party, or of *forum non conveniens*.
- 10.3 **Governing Law**. This Agreement is made in accordance with and shall be governed and construed under the laws of the State of California excluding its choice of law principles.
- 10.4 **No Agency, Joint Venture or Partnership.** Neither Party is, nor will be deemed to be an employee, agent or legal representative of the other Party for any purpose. Neither Party will be entitled

to enter into any contracts in the name of, or on behalf of the other Party, nor will a Party be entitled to pledge the credit of the other Party in any way or hold itself out as having authority to do so. The parties are independent contractors, this Agreement is for an arm's-length transaction, and the relationship that it governs shall not be construed to be or create any agency, joint venture or partnership.

- 10.5 **Assignment.** Except as explicitly provided for in this Agreement, neither Party shall have the right or power to assign any rights or obligations under this Agreement without the consent of the other Party, except that Vicept may assign one or more times to an Affiliate or to a successor to substantially all of the business or assets of Vicept to which this Agreement relates (whether through merger, sale of stock, sale of assets or other transaction). This Agreement shall be binding upon and inure to the benefit of the successors and explicitly permitted assigns of the Parties. Any assignment of this Agreement not made in accordance with this Agreement is prohibited hereunder and shall be null and void. Any assignee must certify in writing to the non-assigning Party, within [***] after the requested in writing by the non-assigning Party, that such assignee agrees to the terms and conditions of this Agreement going forward from the date of assignment.
- 10.6 Amendment. No amendment or modification hereof shall be valid or binding upon the Parties unless made in writing and signed by authorized officers of both Parties.
- 10.7 **Notices**. Any notice or other communication required or permitted to be given to either Party hereto shall be in writing unless otherwise specified and shall be deemed to have been properly given and to be effective (a) on the date of delivery if delivered in person; (b) the date of electronically confirmed facsimile transmission if during the recipient's normal business hours, or otherwise on the next Business Day; and (c) two (2) Business Days after sending for next Business Day delivery by internationally recognized expedited courier service for no later than next-possible-business-day delivery:

In the case of Vicept: [***]

With a required copy to: [***]

In the case of Aspect Pharmaceuticals: [***]

With a required copy to: [***]

In the case of (c) (expedited courier service), the Party providing the notice shall as a courtesy additionally provide the notice by a facsimile in accordance with (b). Either Party may change its address for communications by a notice to the other Party in accordance with this Section 10.7.

- Bankruptcy; Intellectual Property. All rights and licenses granted under or pursuant to this Agreement by a bankrupt Party to the other Party are, and shall be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code and any similar law or regulation in any other country, licenses of rights to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code. The Parties agree that all intellectual property rights licensed hereunder, are part of the "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code subject to the protections afforded the non-terminating Party under Section 365(n) of the Bankruptcy Code, and any similar law or regulation in any other country. Aspect and Vicept shall be entitled to all similar protections as licensee under bankruptcy laws of other countries.
- 10.9 **No Implied Licenses**. Except as otherwise expressly set forth in this Agreement, nothing in this Agreement shall give either Party any right, title or interest in or to any Patents or other intellectual property owned by or licensed to the other Party.
- 10.10 **Force Majeure.** Any delay in or failure of performance by any Party under this Agreement shall not be considered a breach of this Agreement if and to the extent caused by occurrences beyond the reasonable control of the Party affected, including acts of God, embargoes, governmental

restrictions, strikes or other acts of workers, fire, flood, earthquake, explosion, riots, wars, acts of terrorism, civil disorder, rebellion or sabotage; provided, however, the payment of any value due and owing hereunder shall not be delayed by the payor because of a force majeure affecting the payer, unless such force majeure specifically precludes the payment process. The Party suffering such occurrence shall notify the other Party and any time for performance hereunder shall be extended by the actual time of delay caused by the occurrence.

- 10.11 **Counterparts.** This Agreement may be executed in any number of counterparts, each of which shall be deemed an original but all of which together shall constitute a single instrument.
- 10.12 **Captions.** All section titles or captions contained in this Agreement, in any Exhibit referred to herein and the table of contents, if any, to this Agreement are for convenience only, shall not be deemed a part of this Agreement and shall not affect the meaning or interpretation of this Agreement.
- 10.13 **Drafts mans hip.** Each Party acknowledges that it has participated in, and has been represented by counsel in the drafting of this Agreement. Any applicable rule of construction to the effect that ambiguities are to be resolved against the drafting party will not be applied in connection with the construction or interpretation of this Agreement.
- 10.14 **No Third Party Rights or Obligations.** Except as expressly provided in Article 9, no provision of this Agreement shall be deemed or construed in any way to result in the creation of any rights or obligation in any Third Party.
- 10.15 **Severability.** If any term, condition or provision of this Agreement is held to be invalid or unenforceable for any reason by any court of competent jurisdiction form which no appeal can be or is taken, or in arbitration proceedings between the Parties as set forth in Article 10 of this Agreement, it shall, if possible, be narrowed, shortened, or interpreted to achieve the intent of the Parties to this Agreement to the extent legally possible rather than voided or if not to any extent legally possible be deemed severed from this Agreement. In any event, all other terms, conditions and provision of this Agreement shall be deemed valid and enforceable to the full extent.
- 10.16 **Compliance with Laws.** Each Party shall carry out its activities pursuant to this Agreement in compliance with all applicable supranational, national, state, provincial and other local laws, rules, regulations and guidelines.
- 10.17 **Cumulative Rights.** The rights, powers and remedies hereunder shall be in addition to, and not in limitation of, all rights, powers and remedies provided at law or in equity, or under any other agreement between the Parties. All of such rights, powers and remedies shall be cumulative, and may be exercised successively or cumulatively.
- Right of Offset; Recoupment. Notwithstanding any other provision of this Agreement, every liability of Vicept to Aspect is subject to and conditioned upon the recoupment of any and all liabilities owing from Aspect to Vicept, so as to establish a net liability. Vicept is entitled to credit against or net out against amounts due under this Agreement, any and all liabilities of Aspects to Vicept, including any damages for breach of contract if applicable.
- 10.19 **Waiver.** No failure or delay on the part of either Party to exercise any power, right, privilege or remedy under this Agreement will operate as a waiver thereof. No single or partial exercise of any such power, right, privilege or remedy will preclude any other or further exercise thereof or of any other power; right, privilege or remedy. Waivers of powers, rights, privileges and remedies under this Agreement may only be waived in a writing executed by a duly authorized officer of the waiving Party.
 - 10.20 **Costs**. Each Party shall bear its own legal costs of and incidental to the preparation, negotiation and execution of this Agreement.

10.21 Entire Agreement. This Agreement embodies the entire understanding of the Parties with respect to the subject matter hereof and shall upersede all provious communications, representations or understandings, either oral or written, between the Parties relating to the subject matter of this greement. To be clear, this Agreement supersedes the Prior CDA with respect to Confidential Information and the Parties' rights and obligations with respect hereto. [remainder of page intentionally blank]					
[remainder of page intentionally blank]	10.21 Entire Agreement. supersede all previous communications, Agreement. To be clear, this Agreement hereto.	This Agreement embodies the entire representations or understandings, er t supersedes the Prior CDA with response	understanding of the Parties with ther oral or written, between the ect to Confidential Information and	respect to the subject matter here Parties relating to the subject ma d the Parties' rights and obligations	of and shall atter of this with respect
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IN WITNESS WHEREOF, both Vicept and Aspect Pharmaceuticals have executed this Agreement by their respective officers hereunder duly authorized.

1717	CEDT	THED	ADDITT	ICC INC

ASPECT PHARMACEUTICALS, LLC

By:	/s/ Neal Walker	By:	/s/ Stuart Daniel Shandler
Name:	Neal Walker	Name:	Stuart Daniel Shandler
Title:	CEO	Title:	President & CEO Aspect Pharmaceuticals
Date:	8/3/09	Date:	8/3/09

Certain confidential information contained in this exhibit have been omitted by means of redacting a portion of the text and replacing it with [***], pursuant to Regulation S-K Item 601(b) of the Securities Act of 1933, as amended. Certain confidential information has been excluded from this exhibit because it is: (i) not material; and (ii) the registrant treats such information as private or confidential.

AMENDED, RESTATED AND CONSOLIDATED LICENSE AGREEMENT

This AMENDED, RESTATED AND CONSOLIDATED LICENSE AGREEMENT (this "LICENSE AGREEMENT") is entered into this 27th day of June, 2012 (the "EFFECTIVE DATE") between The University of North Carolina at Chapel Hill having an address at Campus Box 4105, 308 Bynum Hall, Chapel Hill, North Carolina, 27599-4105 ("UNIVERSITY") and Novan, Inc., a corporation organized and existing under the laws of the State of Delaware ("LICENSEE").

WITNESSETH

WHEREAS, UNIVERSITY entered into a first license agreement with LICENSEE effective July 18, 2007, a FIRST AMENDMENT thereto effective September 30, 2008 and a SECOND AMENDMENT thereto effective October 29, 2010 (such license agreement, as amended by the FIRST AMENDMENT and the SECOND AMENDMENT thereto, the "FIRST AGREEMENT"); and

WHEREAS, UNIVERSITY entered into a second license agreement with LICENSEE effective October 1, 2009 and a FIRST AMENDMENT thereto effective October 29, 2010 (such license agreement, as amended by the FIRST AMENDMENT thereto, the "SECOND AGREEMENT"); and

WHEREAS, UNIVERSITY and LICENSEE wish to amend, restate and consolidate the FIRST AGREEMENT and the SECOND AGREEMENT into a single agreement as provided herein.

NOW, THEREFORE, in consideration of the premises and mutual promises and covenants contained in this LICENSE AGREEMENT and for good and valuable consideration, it is agreed by and between UNIVERSITY and LICENSEE as follows:

ARTICLE 1: DEFINITIONS

In addition to such terms defined elsewhere in this LICENSE AGREEMENT, the following terms shall have the meanings described below.

- 1.1 "AFFILIATE" means (a) any person or entity which owns or controls at least fifty percent (50%) of the equity or voting stock of the LICENSEE, or (b) any person or entity fifty percent (50%) of whose equity or voting stock is owned or controlled by LICENSEE or (c) any person or entity of which at least fifty percent (50%) of the equity or voting stock is owned or controlled by the same person or entity owning or controlling at least fifty percent (50%) of LICENSEE.
 - 1.2 "EXISTING PATENT RIGHTS" means all PATENT RIGHTS claiming INVENTIONS or otherwise existing as of the EFFECTIVE DATE.
- 1.3 "FIRST COMMERCIAL SALE' means the first sale of commercial quantities of any LICENSED PRODUCT (as defined below) for human therapeutic use under an approved NDA or BLA (or foreign equivalent thereof) by LICENSEE, an AFFILIATE, or any SUBLICENSEE of either of the foregoing for which the proceeds of such sale qualify as NET SALES (as defined below).
- 1.4 "IMPROVEMENT" means any (i) modification, enhancement, or improvement of an INVENTION or any other invention described in the EXISTING PATENT RIGHTS or (ii) other invention, the manufacture, use, or sale of which modification, enhancement, or improvement would, but for the licenses granted hereunder, infringe one or more claims of the EXISTING PATENT RIGHTS.
- 1.5 "INVENTIONS" means the subject matter of any invention disclosures, patent applications or patents identified in <u>Appendix A</u>. "UNIVERSITY INVENTIONS" refers to INVENTIONS that have only inventors, as determined under the Patent Laws of the United States of America, that are obligated to assign their rights in any INVENTIONS to the UNIVERSITY. "JOINT INVENTIONS" refers to INVENTIONS that have inventors, as

determined under the Patent Laws of the United States of America, that are obligated to assign their rights in any INVENTIONS to the UNIVERSITY and inventors that are obligated to assign their rights in any INVENTIONS to LICENSEE or an AFFILIATE.

- 1.6 "LICENSED FIELD" means all uses and applications.
- 1.7 "LICENSED PRODUCTS" means any method or process, composition, product, or component part thereof claimed in whole or in part by an issued, unexpired, or pending claim contained in the PATENT RICHTS whose manufacture, intended use, or sale would, but for the license(s) granted in this LICENSE AGREEMENT, infringe on the PATENT RICHTS in the country of sale.
 - 1.8 "LICENSED TERRITORY" means the entire world.
- 1.9 "NET SALES" means the total invoiced sales price received for LICENSED PRODUCTS sold by LICENSEE, its AFFILIATES, and their SUBLICENSEES less (a) sales taxes or other taxes, (b) shipping and insurance charges, (c) actual allowances, rebates, credits, or refunds for returned or defective LICENSED PRODUCTS, (d) trade discounts and quantity discounts, retroactive price reductions, or other allowances actually allowed or granted from the billed amount and taken, (e) rebates, credits, and chargeback payments (or the equivalent thereof) granted to managed health care organizations, wholesalers, or to federal, state/provincial, local and other governments, including their agencies, purchasers, and/or reimbursers, or to trade customers, and (f) any import or export duties, tariffs, or similar charges incurred with respect to the import or export of LICENSED PRODUCTS into or out of any country in the LICENSED TERRITORY. LICENSED PRODUCTS will be considered sold when paid for. Notwithstanding the foregoing, NET SALES shall not include, and shall be deemed zero with respect to, (1) the distribution of reasonable quantities of promotional samples of LICENSED PRODUCTS, (2) LICENSED PRODUCTS provided for clinical trials or research purposes, or charitable or compassionate use purposes, or (3) LICENSED PRODUCTS provided to any AFFILIATE, SUBLICENSEE or other strategic partner under an agreement in which NET SALES by such AFFILIATE, SUBLICENSEE or other strategic partner shall be subject to royalties under Section 3.5 or 3.6.

Notwithstanding the foregoing, in the event that LICENSED PRODUCTS are sold by LICENSEE, an AFFILIATE, or a SUBLICENSEE as part of a combination product or bundled product, or in conjunction with a delivery system, the NET SALES of such product, for the purposes of determining royalty payments due under this LICENSE AGREEMENT, shall be determined by multiplying the NET SALES (as originally defined above) of the combination product by the fraction A/(A+B), where A is the average sale price of the LICENSED PRODUCT when sold separately in finished form and B is the average sale price of the other product(s) or system sold separately in finished form, so that A+B is the average sale price of all of the product(s) and, if applicable, the delivery system together, as the case may be. In the event that such average sale price cannot be determined for both the LICENSED PRODUCT and such other product(s) or system(s) in combination, NET SALES for the purposes of determining royalty payments with respect to such combination or bundled product shall be commercially reasonable and determined by good faith negotiation between UNIVERSITY and LICENSEE.

- 1.10 "PATENT RIGHTS" means any United States, foreign or international patents and/or patent applications claiming the INVENTIONS or any IMPROVEMENTS owned or controlled by UNIVERSITY prior to or during the term of this LICENSE AGREEMENT, which shall include but not be limited to those patents and patent applications listed on <u>Appendix A</u>, attached hereto, as well as any continuations, continuations-in-part (to the extent they are directed to subject matter described in, claimed by, or enabled by the patents or patent applications set forth on <u>Appendix A</u>, any INVENTIONS, or any IMPROVEMENT), divisionals, provisionals, continued prosecution applications, reexaminations, renewals, extensions, request for continued examinations, or reissues thereof, and any foreign counterpart of any of the foregoing.
- 1.11 "PHASE I CLINICAL TRIAL" means any human clinical trial, conducted by or on behalf of LICENSEE, an AFFILIATE, or a SUBLICENSEE with respect to a LICENSED PRODUCT, including typically the first phase of clinical trials conducted in relatively small numbers of healthy volunteers or patients with the targeted condition to obtain information on a LICENSED PRODUCT's safety, tolerability, pharmacological activity, pharmacokinetics, drug metabolism and mechanism of action, as more fully defined in 21 C.F.R. § 312.21(a), as may be amended, and, with respect to any other country or jurisdiction, the equivalent of such a clinical trial in such other country or jurisdiction.
- 1.12 "PHASE II CLINICAL TRIAL" means any well-controlled clinical trial, conducted by or on behalf of LICENSEE, an AFFILIATE, or a SUBLICENSEE with respect to a LICENSED PRODUCT, in human subjects, including clinical trials conducted in patients with the targeted condition, and designed to evaluate clinical activity (including but not limited to, pertinent pharmacodynamic effects or biomarker responses) and safety for a LICENSED PRODUCT for one or more indications, as well as to obtain an indication of the dosage regimen

required, as more fully defined in 21 C.F.R. § 312.21(b), as may be amended, and, with respect to any other country or jurisdiction, the material equivalent of such a clinical trial in such other country or jurisdiction.

- 1.13 "SUBLICENSEE" means any third party to whom LICENSEE or any AFFILIATE licenses any of the rights granted under this LICENSE AGREEMENT pursuant to Article 6.
- 1.14 "SUBLICENSING REVENUE" means sublicense payments to the extent received by LICENSEE directly and solely, as reasonably determined by LICENSEE, as consideration for the grant of rights to PATENT RICHTS, including upfront fees or milestone payments but excluding sales-based royalties, sales-based milestone fees, or other payments calculated on the basis of SUBLICENSEES' sales of LICENSED PRODUCTS, purchases of equity or debt of LICENSEE, payments made in connection with research and development agreements or collaborations, or other payments made by a SUBLICENSEE where LICENSEE is obligated to performservices or to provide goods in connection with such payment shall not be considered sublicense payments for purposes of this LICENSE AGREEMENT.
- 1.15 "UNIVERSITY TECHNOLOGY" means any unpublished research and development information, know-how, and technical data in the possession of UNIVERSITY prior to or following the EFFECTIVE DATE of this LICENSE AGREEMENT which relates to and is necessary for the practice of the INVENTIONS or IMPROVEMENTS and which UNIVERSITY has the right to provide to LICENSEE.

ARTICLE 2: GRANT OF LICENSE

- 2.1 UNIVERSITY hereby grants to LICENSEE and its AFFILIATES to the extent of the LICENSED TERRITORY a non-exclusive right and license to use UNIVERSITY TECHNOLOGY in the LICENSED FIELD, with the right to sublicense, subject to all the terms and conditions of this LICENSE AGREEMENT. Nothing herein shall constitute a sale of the UNIVERSITY TECHNOLOGY.
- 2.2 UNIVERSITY hereby grants to LICENSEE and its AFFILIATES to the extent of the LICENSED TERRITORY an exclusive right and license under the PATENT RIGHTS to make, have made, use, offer for sale, sell and import LICENSED PRODUCTS in the LICENSED FIELD, with the right to sublicense, subject to all the terms and conditions of this LICENSE AGREEMENT.
- 2.3 UNIVERSITY reserves the right to practice under the PATENT RIGHTS, to use UNIVERSITY TECHNOLOGY, and to make, use and provide LICENSED PRODUCTS for, in each and every case, its own internal, not-for-profit research, public service, teaching and educational purposes, without payment of royalties, provided that the exercise of such reserved rights by UNIVERSITY shall not (i) be on behalf of, sponsored with funding received from, or subject to any intellectual property rights granted to any commercial third party nor (ii) include any human use or clinical administration without prior written approval from LICENSEE. Furthermore, UNIVERSITY shall be free to publish UNIVERSITY TECHNOLOGY as it sees fit, provided that (i) UNIVERSITY shall provide LICENSEE with a manuscript of any proposed paper or an abstract of any proposed presentation describing any INVENTIONS, IMPROVEMENTS, or technology claimed or described in the patents and patent applications included in the PATENT RIGHTS at least [***] ([***]) days prior to its submission for publication or presentation and (ii) as reasonably requested by LICENSEE, UNIVERSITY shall instruct its patent counsel to make such patent filings or conduct the prosecution of the patents and patent applications included in the PATENT RIGHTS as appropriate prior to publication or presentation of such material to prevent the loss of any rights granted under this LICENSE AGREEMENT.
- 2.4 UNIVERSITY may transfer (i) any materials incorporating UNIVERSITY TECHNOLOGY or any of the INVENTIONS or (ii) any materials whose manufacture, use, or practice would infringe any of the PATENT RIGHTS to nonprofit, academic research institutions for their own internal, not-for-profit, research, teaching, and educational purposes upon such institution's execution of a Material Transfer Agreement with UNIVERSITY in a form substantially similar to that attached hereto as Appendix B (any such material transfer agreement entered into, a "Material Transfer Agreement"), provided that (1) any such third party's use of, or research concerning, such materials shall not (a) be on behalf of, sponsored with funding received from, or subject to any intellectual property rights granted to any commercial third party nor (b) include any human use or clinical administration without prior written approval of UNIVERSITY and LICENSEE and (2) the UNIVERSITY shall provide written notification to LICENSEE of any such transfer of materials identifying the party to whom such materials were transferred and the materials transferred.

UNIVERSITY shall promptly notify LICENSEE in writing in the event they receive (i) disclosure of any INVENTION (as defined in the Material Transfer Agreement) or (ii) a copy of any proposed manuscript describing, referencing, or including the results of any use of materials transferred under any Material Transfer Agreement from

any third party research institution pursuant to any Material Transfer Agreement, and shall include with such notice to LICENSEE a copy of such disclosure or manuscript.

- 2.5 Notwithstanding the foregoing, any and all licenses and other rights granted hereunder are limited by and subject to the rights and requirements of the United States Government which arise out of its sponsorship (if any) of the research which led to the conception or reduction to practice' of the INVENTIONS covered by PATENT RIGHTS. To the extent applicable due to any such sponsorship, the United States Government is entitled, as a right, under the provisions of 35 U.S.C. §§ 200-212 and applicable regulations of Title 37 of the Code of Federal Regulations, to a non-exclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on the behalf of the United States Government any of the PATENT RIGHTS throughout the world and LICENSEE agrees to comply and require compliance therewith.
- 2.6 Nothing herein grants to UNIVERSITY from LICENSEE any right or interest in any JOINT INVENTIONS or any related patent rights owned by LICENSEE, or in any other intellectual property conceived or made by or on behalf of LICENSEE unless set forth in a separate agreement between the Parties. To the extent that a JOINT INVENTION no longer includes any inventors with an obligation to assign their rights to the UNIVERSITY, such JOINT INVENTION and any related PATENT RIGHTS shall no longer be considered owned by the UNIVERSITY but shall be and hereby are automatically and without further action on the part of any inventors, the UNIVERSITY or LICENSEE assigned to and owned exclusively by LICENSEE and no longer shall be subject to the terms of this AGREEMENT. The Parties agree to amend the Patent Rights to reflect such change in ownership.

ARTICLE3: CONSIDERATION

- 3.1 As partial consideration for the licenses granted LICENSEE under the FIRST AGREEMENT, LICENSEE has issued directly to The University of North Carolina at Chapel Hill Foundation, Inc. ("the Foundation") on behalf of UNIVERSITY two-hundred twenty nine thousand two hundred and sixty three shares (229,263) of common stock of LICENSEE. LICENSEE'S common stock was issued pursuant to a Stock Purchase Agreement in a form acceptable to UNIVERSITY.
- 3.2 As partial consideration for the licenses granted LICENSEE under the SECOND AGREEMENT, LICENSEE has paid UNIVERSITY a license issue fee of five thousand dollars (\$5,000).
- 3.3 At all times, the LICENSEE common stock held by Foundation shall be subject to a shareholders agreement in the form set forth in <u>Appendix C</u>. The Foundation agrees to enter into reasonable or customary agreements required by any future equity investors regarding subjecting their shares of LICENSEE common stock to rights of first refusal and co-sale, such rights to terminate on an initial public offering of Company stock pursuant to a registration statement filed pursuant to the Securities Act of 1933, as amended.
- 3.4 LICENSEE shall reimburse UNIVERSITY for reasonable, documented costs ([***]) arising out of the patenting of the UNIVERSITY INVENTIONS pursuant to Article 8 of this LICENSE AGREEMENT ("PATENT COSTS") as described in this Section 3.4. The reimbursement of patenting costs shall be non-refundable and shall not be a credit against any other amounts due hereunder except as may be provided for elsewhere in this LICENSE AGREEMENT. Reimbursement of patenting costs under this LICENSE AGREEMENT shall commence and be due within [***] ([***]) days of billing.
- 3.5 Beginning on the EFFECTIVE DATE and continuing for the term of this LICENSE AGREEMENT, on a country-by-country and LICENSED PRODUCT-by-LICENSED PRODUCT basis, LICENSEE will pay UNIVERSITY a running royalty of [***] percent ([***]%) of all NET SALES of LICENSED PRODUCTS sold by LICENSEE, its AFFILIATES and SUBLICENSEES of the foregoing. For clarity, the obligation to pay royalties under this Section 3.5 shall be imposed only once (i) with respect to any sale of any LICENSED PRODUCT, and (ii) with respect to any LICENSED PRODUCT, in each case regardless of whether such LICENSED PRODUCT, or the manufacture, use or sale thereof, is covered by more than one claim contained in the PATENT RIGHTS. LICENSEE shall pay to UNIVERSITY said royalties on the NET SALES of LICENSED PRODUCTS concurrently with the making of [***] written reports as provided in Section 4.2 below.
- 3.6 In respect to sublicenses granted by LICENSEE under Article 6 below, LICENSEE shall pay to UNIVERSITY an amount equal to [***] percent ([***]%) of SUBLICENSING REVENUE received by LICENSEE as consideration for the grant of rights to PATENT RIGHTS. All payments based on SUBLICENSING REVENUE shall be made within [***] days of receipt of the SUBLICENSING REVENUE.
- 3.7 Should a compulsory license be granted, or be the subject of a possible grant, to a third party under the applicable laws of any country in the LICENSED TERRITORY under the PATENT RICHTS licensed hereunder,

LICENSEE shall notify UNIVERSITY, including any material information concerning such compulsory license, and the running royalty rates payable under Section 3.5 for sales of LICENSED PRODUCTS in such country will be adjusted to equal any lower royalty rate granted to such third party for such country with respect to the sales of such LICENSED PRODUCTS therein (the "COMPULSORY ROYALTY"), provided that during such periods such third parties sell or offer for sale under the compulsory license articles that compete with the LICENSED PRODUCTS then marketed and sold by LICENSEE or its AFFILIATES or SUBLICENSEES in that country.

3.8 LICENSEE shall pay UNIVERSITY the following payments within [***] ([***]) days of LICENSEE, an AFFILIATE, or any SUBLICENSEE of either of the foregoing achieving the indicated milestone for each LICENSED PRODUCT covered by PATENT RIGHTS corresponding to UNIVERSITY INVENTIONS:

Milestone Payment Due

[***]

Notwithstanding the conduct of clinical trials, submission of applications for regulatory approval, regulatory approval, sale, or marketing of a particular LICENSED PRODUCT for multiple indications, in multiple dosage or delivery forms, or in multiple bundled or combination products, the milestone fees described above shall only be due and paid once with respect to each LICENSED PRODUCT. Amounts paid UNIVERSITY under Section 3.6 with respect to SUBLICENSE REVENUE paid to LICENSEE by a SUBLICENSEE for the achievement of a milestone substantially similar to any of those established above shall be creditable against, and deducted from, the corresponding payment due UNIVERSITY under this Section 3.8.

- 3.9 All fees, royalties, and other payments due to UNIVERSITY under this LICENSE AGREEMENT shall be made in United States Dollars. All royalties owing with respect to NET SALES or sublicensing revenue stated in currencies other than U.S. dollars shall be converted at an exchange rate which is the arithmetic mean of the opening telegraphic transfer selling and buying rate published by the American East Coast edition of the Wall Street Journal on the day preceding the payment.
- 3.10 In the event royalty payments or fees are not received by UNIVERSITY when due, LICENSEE shall pay to UNIVERSITY interest and charges at the lower of (a) the thencurrent prime lending rate as published by the American East Coast edition of the Wall Street Journal or (b) the maximum rate of interest allowed by law on the total royalties or fees overdue.

ARTICLE 4: REPORTS AND RECORDS

- 4.1 UNIVERSITY shall promptly notify LICENSEE in writing of any IMPROVEMENT.
- 4.2 Following the FIRST COMMERCIAL SALE of a LICENSED PRODUCT or receipt of SUBLICENSE REVENUE, LICENSEE agrees to make [***] written reports to UNIVERSITY within [***] ([***]) days following the end of each [***] during the term of this LICENSE AGREEMENT, stating in each such report, if and as applicable, (i) the number, description, and aggregate selling prices of LICENSED PRODUCTS sold or otherwise disposed of and deductions taken during the such [***] and upon which royalty is payable as provided in Section 3.5 hereof and (ii) the amount of SUBLICENSE REVENUE received. The first such report shall include all such LICENSED PRODUCTS so sold or otherwise disposed of, and all such sublicensing revenue received, prior to the date of such report. Until the FIRST COMMERCIAL SALE of a LICENSED PRODUCT, a report shall be submitted by LICENSEE at the end of each July after the EFFECTIVE DATE of this LICENSE AGREEMENT and will include a written report summarizing LICENSEE'S technical and other efforts made towards such first commercial sale for all LICENSED PRODUCTS under development.
- 4.3 LICENSEE will keep complete, true and accurate books of account and records, and require AFFILIATES and SUBLICENSEES to do the same, for the purpose of showing the derivation of all amounts payable to UNIVERSITY under this LICENSE AGREMENT. Such books and records will be kept at LICENSEE's, AFFILIATE's or SUBLICENSEE's principal place(s) of business for at least [***] ([***]) years following the end of the [***] to which they pertain, and will be open at all reasonable times for inspection by an independent certified public accountant reasonably acceptable to LICENSEE, AFFILIATE or SUBLICENSEE acting on behalf of UNIVERSITY for the purpose of verifying LICENSEE's, AFFILIATES' or SUBLICENSEE's royalty statements or LICENSEE's compliance in other respects with this LICENSE AGREEMENT. The representative will be obliged to treat as confidential all relevant matters but shall be free to disclose all conclusions of any such inspection(s) to UNIVERSITY and support such conclusions with underlying confidential information if challenged by LICENSEE, provided that all such disclosures shall be maintained as confidential by such representative and UNIVERSITY with respect to third parties.

4.4 Inspections made under Section 4.3 shall be at the expense of UNIVERSITY, unless an underpayment to UNIVERSITY exceeding [***]% of the amount properly due UNIVERSITY with respect to the audited period is discovered in the course of any such inspection, whereupon all [***] costs of such inspection shall be paid by LICENSEE. LICENSEE will promptly pay to UNIVERSITY the full amount of any underpayment, together with interest thereon at the lower of (a) the then-current prime lending rate as published by the American East Coast edition of the Wall Street Journal or (b) the maximum rate of interest allowed by law.

ARTICLE 5: DUE DILIGENCE

- 5.1 LICENSEE shall use its commercially reasonable efforts and due diligence to proceed with the research, development, and commercial exploitation of LICENSED PRODUCTS during the term of this LICENSE AGREEMENT. In making any determination regarding such efforts and diligence, UNIVERSITY shall take into account the normal course of such programs conducted with sound and reasonable business practices and judgment, the [***], and shall take into account [***].
- 5.2 In particular, LICENSEE will achieve the performance milestones set forth in Appendix D, which is attached hereto, on the time frames indicated. Notwithstanding the foregoing, the dates or timelines outlined or established for the achievement of such milestones assume that (i) LICENSEE obtains reasonably sufficient funding to achieve such milestones consistent with such dates or timelines and (ii) LICENSEE's product candidates do not cause adverse events in clinical trials or encounter regulatory delays for reasons outside of LICENSEE's reasonable control. LICENSEE and UNIVERSITY shall negotiate in good faith the extension of these dates in the event any matters adversely affect achievement of any stated milestones by the dates or timelines outlined or established therefor. UNIVERSITY'S sole and exclusive remedy with respect to LICENSEE's breach of this Article 5 or failure to achieve the above-referenced milestones shall be its right to terminate this Agreement in accordance with Section 7.2.

ARTICLE 6: SUBLICENSING

- 6.1 LICENSEE may sublicense any or all of the rights licensed hereunder, provided that LICENSEE notifies UNIVERSITY in writing and provides UNIVERSITY with a copy of each sublicense agreement and each amendment thereto within [***] ([***]) days after their execution, provided that LICENSEE may redact any portions of such agreements disclosing SUBLICENSEES' proprietary information, technology, or research and development plans as reasonably necessary to comply with any confidentiality provisions of such sublicense.
- 6.2 LICENSEE shall require that all sublicenses be materially consistent with the terms, conditions and limitations of this LICENSE AGREEMENT. UNIVERSITY agrees that all such sublicenses shall survive termination of this LICENSE AGREEMENT and will automatically be assigned to UNIVERSITY upon such termination in the event this LICENSE AGREEMENT is terminated, to the extent (i) provided for in each such sublicense and (ii) such agreement does not impose any obligations on UNIVERSITY in excess of those imposed on UNIVERSITY herein.
- 6.3 Upon execution of each sublicense agreement, LICENSEE agrees to be fully responsible for the performance of its SUBLICENSEES hereunder, provided that the activities of any SUBLICENSEE of LICENSEE shall be deemed the acts of LICENSEE for purposes of satisfying LICENSEE's obligations under Article 5 above.

ARTICLE 7: TERM AND TERMINATION

- 7.1 The term of this LICENSE AGREEMENT shall begin on the EFFECTIVE DATE and continue until (i) this LICENSE AGREEMENT is terminated as provided herein or (ii) on a country-by-country and LICENSED PRODUCT-by-LICENSED PRODUCT basis, the expiration of the last to expire of the PATENT RIGHTS covering a particular LICENSED PRODUCT in each country in which a patent included in the PATENT RIGHTS and covering such LICENSED PRODUCT may have issued. Upon expiration of this LICENSE AGREEMENT due to the expiration of the last-to-expire of all patents included in the PATENT RIGHTS with respect to a particular country and LICENSED PRODUCT, LICENSEE shall have the perpetual, unrestricted, fully-paid, royalty-free right, with rights of sublicense, to make, use, and sell, lease, or otherwise dispose of such LICENSED PRODUCT in such country.
- 7.2 It is expressly agreed that, notwithstanding the provisions of any other paragraph of this LICENSE AGREEMENT, if LICENSE should materially breach a material provision of this LICENSE AGREEMENT and fail to (i) cure any such breach within ninety (90) days of receipt of written notice from UNIVERSITY describing such breach ("BREACH NOTICE") or (ii) provide written notification to UNIVERSITY that such breach is not curable within such ninety (90) day period, accompanied by a plan to cure such breach, and initiate commercially reasonable efforts to cure such breach consistent with such plan within ninety (90) days of receipt of BREACH

NOTICE, then UNIVERSITY will have the right to terminate this LICENSE AGREEMENT or render it nonexclusive immediately upon further written notice to LICENSEE, provided that such further written notice must be given by UNIVERSITY within ten (10) days of the expiration of the ninety (90) period established above. A material breach is a violation of or failure to keep or perform any material covenant, condition, or undertaking of this LICENSE AGREEMENT, including, but not limited to, the failure to deliver to UNIVERSITY any royalty or other payment at the time or times that the same should be due to UNIVERSITY under this LICENSE AGREEMENT, failure to provide reports as specified in Section 4.2, failure to meet or achieve performance milestones in accordance with Section 5.2, and failure to possess and maintain insurance as set forth in Section 11.3. Notwithstanding the foregoing, UNIVERSITY's right to terminate this LICENSE AGREEMENT or render it nonexclusive for failure to meet or achieve performance milestones in accordance with Section 5.2 shall apply only with respect to the particular PATENT RIGHTS to which such failure relates, and in such case this LICENSE AGREEMENT and the exclusivity of the license set forth herein will remain in full force and effect with respect to all other PATENT RIGHTS.

- 7.3 If LICENSEE becomes bankrupt, files a petition for or is the subject of a petition for bankruptcy, or is placed in the hands of a receiver, assignee, or trustee for the benefit of creditors, whether by the voluntary act of LICENSEE or otherwise, then this LICENSE AGREEMENT may be terminated or rendered non-exclusive by UNIVERSITY upon written notice to LICENSEE within thirty (30) days of the occurrence of such events.
- 7.4 LICENSEE may terminate this LICENSE AGREEMENT at any time upon giving written notice of not less than thirty (30) days to UNIVERSITY. In addition, LICENSEE may terminate this LICENSE AGREEMENT solely with respect to any particular PATENT RIGHTS upon similar written notice, and in such case this LICENSE AGREEMENT will remain in full force and effect with respect to all other PATENT RIGHTS.
- 7.5 Upon termination of this LICENSE AGREEMENT in whole or in part, LICENSEE shall provide UNIVERSITY with a written inventory of all LICENSED PRODUCTS subject to such termination that are in the process of manufacture by or on behalf of LICENSEE, in use by LICENSEE, or under LICENSEE'S exclusive control. LICENSEE shall have the privilege of completing the manufacture and disposing of any such LICENSED PRODUCTS within a period of [***] following such termination [***]. LICENSEE will also have the right to complete performance of all contracts (i) for the marketing, sale, or manufacture of such LICENSED PRODUCTS, (ii) requiring use of UNIVERSITY TECHNOLOGY, any technology claimed in any terminated PATENT RIGHTS, or such LICENSED PRODUCTS within such [***] period. All such LICENSED PRODUCTS which are not disposed of as provided above shall be delivered to UNIVERSITY or otherwise disposed of in a reasonable manner determined by UNIVERSITY in its sole reasonable discretion at LICENSEE's sole expense.
- 7.6 Any termination or cancellation under any provision of this LICENSE AGREEMENT shall not relieve LICENSEE of its obligation to pay any royalty or other fees (including attorney's fees pursuant to Section 3.4 hereof) due or owing at the time of such termination or cancellation.

ARTICLE 8: PATENT PROSECUTION AND MAINTENANCE

8.1 Subject to the remaining Sections of this Article 8, LICENSEE shall bear the cost of all reasonable, documented patent expenses, [***], associated with the preparation, filing, prosecuting, issuance and maintenance of U.S. Patent applications and U.S. Patents included within the PATENT RIGHTS. Such filings and prosecution corresponding to UNIVERSITY INVENTIONS shall be by counsel of UNIVERSITY's choosing and shall be in the name of UNIVERSITY. UNIVERSITY shall keep LICENSEE advised as to the prosecution of such applications by forwarding, and directing UNIVERSITY's patent counsel to forward, to LICENSEE copies of all official correspondence, (including, but not limited to, Applications, Office Actions, responses, etc.) relating thereto. LICENSEE shall have the right to comment and advise UNIVERSITY and its counsel as to the conduct of such prosecution and maintenance, provided, however, that UNIVERSITY shall have the right to make the final decisions for all matters associated with such prosecution and maintenance of any issued patent without first, to the extent reasonably possible, giving LICENSEE notice at least [***] ([***]) days prior to the date on which such patent application or patent will become abandoned, and shall allow LICENSEE to assume prosecution of any such patent application, or maintenance of any such patent, at LICENSEE's own expense and with counsel of its choosing and with LICENSEE having the final decision for all matters associated with prosecution and maintenance. If LICENSEE assumes prosecution of any such patent application or maintenance of any such patent, LICENSEE's obligations for payment under Article 3 based upon such patent application or patent shall terminate at the time that LICENSEE assumes prosecution or maintenance of such patent.

8.2 UNIVERSITY shall, [***], keep LICENSEE apprised in writing and in advance of incurring any costs with respect to the filing, prosecution, and or maintenance of any PATENT RIGHTS. By concurrent written notification to UNIVERSITY, LICENSEE may elect not to pay expenses associated with prosecuting or maintaining

any U.S. PATENT RIGHTS corresponding to UNIVERSITY INVENTIONS, provided that LICENSEE pays for all reasonable, documented costs incurred up to UNIVERSITY's receipt of such notification, to the extent LICENSEE was provided reasonable advance notice of such costs (or a reasonably detailed estimate of such costs). Upon such notice with respect to any such PATENT RIGHTS, UNIVERSITY may file, prosecute, and/or maintain such PATENT RIGHTS at its own expense and for its own benefit and any rights or license granted hereunder with respect to such PATENT RIGHTS shall terminate.

8.3 As regards prosecution and maintenance of foreign patent applications corresponding to the U.S. Patent applications corresponding to UNIVERSITY INVENTIONS, LICENSEE shall designate in writing that country or those countries, if any, in which LICENSEE desires such corresponding patent application(s) to be filed. LICENSEE shall pay all reasonable, documented costs [***] associated with the preparation, filing, prosecuting, issuance and maintenance of such designated foreign patent applications and foreign patents pursuant to Section 3.4. All such applications shall be in the UNIVERSITY's name. UNIVERSITY shall keep LICENSEE advised as to the prosecution of such applications by forwarding, and directing UNIVERSITY's patent counsel to forward, to LICENSEE copies of all official correspondence, (including, but not limited to, Applications, Office Actions, responses, etc.) relating thereto. LICENSEE shall have the right to comment and advise UNIVERSITY and its counsel as to the conduct of such prosecution and maintenance, provided, however, that UNIVERSITY shall have the right to make the final decisions for all matters associated with such prosecution and maintenance. Notwithstanding the foregoing, UNIVERSITY shall not abandon prosecution of any foreign patent application or maintenance of any issued foreign patent without first, to the extent reasonably possible, giving LICENSEE notice at least [***] ([***]) days prior to the date on which such patent application or patent will become abandoned, and shall allow LICENSEE to assume prosecution of any such patent application, or maintenance of any such patent application or patent will become abandoned, and with LICENSEE having the final decision for all matters associated with prosecution and maintenance. If LICENSEE assumes prosecution of any such foreign patent application or maintenance of such patent, LICENSEE's obligations for payment under Article 3 based upon such patent application or patent shall terminate at the time that LICENSEE assumes prosecution or

8.4 By concurrent written notification to UNIVERSITY at least [***] ([***]) days in advance of any filing or response deadline, or fee due date, LICENSEE may elect not to have a patent application filed in any particular foreign country or not to pay expenses associated with prosecuting or maintaining any patent application or patent in any particular foreign country, in each case corresponding to UNIVERSITY INVENTIONS, provided that LICENSEE pays for all reasonable, documented costs incurred up to UNIVERSITY's receipt of such notification, to the extent LICENSEE was provided reasonable advance notice of such costs (or a reasonably detailed estimate of such costs). Failure to provide written confirmation of LICENSEE's desire to file such a patent application in any particular country or to pay expenses associated with prosecuting or maintaining any such patent application or patent to UNIVERSITY at least [***] ([***]) days in advance of any filing or response deadline, or fee due date shall be considered by UNIVERSITY to be LICENSEE's notice that it no longer wishes to support such particular patent(s) or patent application(s). Upon such notice (or failure to provide such confirmation) with respect to such PATENT RIGHTS in any foreign country, UNIVERSITY may file, prosecute, and/or maintain such patent applications or patents at its own expense and for its own benefit, and any rights or license granted hereunder with respect to such PATENT RIGHTS, shall terminate.

8.5 Filings and prosecution corresponding to JOINT INVENTIONS shall be by counsel of LICENSEE's choosing and shall be in the name of UNIVERSITY and LICENSEE. LICENSEE shall keep UNIVERSITY advised as to the prosecution of such applications by forwarding, and directing LICENSEE's patent counsel to forward, to UNIVERSITY copies of all official correspondence, (including, but not limited to, Applications, Office Actions, responses, etc.) relating thereto. UNIVERSITY shall provide reasonable assistance to LICENSEE related to the preparation, filing, prosecuting, issuance and maintenance of patent applications and patents corresponding to JOINT INVENTIONS, including, without limitation, providing necessary assignment documents, declarations, power of attorney documents, copies of any supporting data, analysis or reports, and reasonable access to the INVENTORS during normal working hours. UNIVERSITY shall have the right to comment and advise LICENSEE and its counsel as to the conduct of such prosecution and maintenance, provided, however, that LICENSEE shall have the right to make the final decisions for all matters associated with such prosecution and maintenance. Notwithstanding the foregoing, LICENSEE shall not abandon prosecution of any patent application or maintenance of any issued patent corresponding to JOINT INVENTIONS without first, to the extent reasonably possible, giving UNIVERSITY notice at least [***] ([***]) days prior to the date on which such patent application or patent will become abandoned, and shall allow UNIVERSITY to assume prosecution of any such patent application, or maintenance of any such patent, at UNIVERSITY's own expense and with counsel of its choosing and with UNIVERSITY having the final decision for all matters associated with prosecution and maintenance.

ARTICLE 9: INFRINGEMENT

- 9.1 If the production, sale, import or use of LICENSED PRODUCTS under this LICENSE AGREEMENT results in any claim for patent infringement against LICENSEE, AFFILIATES, SUBLICENSEEs, or any customer(s) or sublicensee(s) of the foregoing, LICENSEE shall, upon becoming aware of such claim and subject to any applicable confidentiality obligations, promptly notify the UNIVERSITY thereof in writing, setting forth the facts of such claim in reasonable detail. As between the parties to this LICENSE AGREEMENT, LICENSEE shall have the first and primary right [***] at its own expense to defend and control the defense of any such claim, by counsel of its own choice. LICENSEE shall be free to enter into a settlement, consent judgment, or other voluntary disposition of any such actions, provided that any settlement, consent judgment or other voluntary disposition of such actions which (i) [***], (ii) [***], (ii) [***], unsus be approved by UNIVERSITY, such approval not being unreasonably withheld. UNIVERSITY shall provide LICENSEE notice of such approval or denial of such approval within [***] ([***]) business days of any request for such approval by LICENSEE, provided that (i) in the event UNIVERSITY wishes to deny such approval, such notice shall include a detailed written description of UNIVERSITY's reasonable objections to the proposed settlement, consent judgment, or other voluntary disposition, and (ii) UNIVERSITY shall be deemed to have approved of such proposed settlement, consent judgment, or other voluntary disposition in the event it fails to provide such notice within such [***] ([***]) day period in accordance herewith. UNIVERSITY agrees to cooperate with LICENSEE in any reasonable manner deemed by LICENSEE to be necessary in defending any such action. LICENSEE shall reimburse UNIVERSITY for [***] out of pocket expenses incurred in providing such assistance.
- 9.2 In the event that any PATENT RIGHTS licensed to LICENSEE are infringed by a third party, LICENSEE shall have the first, primary right, but not the obligation, to institute, prosecute and control any action or proceeding with respect to such infringement, by counsel of its choice, including any declaratory judgment action arising from such infringement. Subject to Section 9.5, UNIVERSITY shall reasonably cooperate in any such action or proceeding at LICENSEE's sole expense, including joining in such action or proceeding. LICENSEE shall be free to enter into a settlement, consent judgment, or other voluntary disposition of such action, provided that any settlement, consent judgment or other voluntary disposition of such actions which (i) [***], (ii) [***], or (iii) [***] must be approved by UNIVERSITY, such approval not to be unreasonably withheld. UNIVERSITY shall provide LICENSEE notice of its approval or denial of such approval within [***] ([***]) business days of any request for such approval by LICENSEE, provided that (i) in the event UNIVERSITY wishes to deny such approval, such notice shall include a detailed written description of UNIVERSITY's reasonable objections to the proposed settlement, consent judgment, or other voluntary disposition, and (ii) UNIVERSITY shall be deemed to have approved of such proposed settlement, consent judgment, or other voluntary disposition in the event it fails to provide such notice within such [***] ([***]) day period in accordance herewith. If LICENSEE recovers monetary damages in the form of lost profits from a third party infringer as a remedy for the infringement of PATENT RIGHTS licensed hereunder, then LICENSEE shall first apply such recovery to the costs and expenses incurred in obtaining or negotiating for such recovery (including but not limited to attorneys' fees), and pay to UNIVERSITY the [***]. If LICENSEE recovers monetary damages in the form of an ongoing reasonable royalty as a remedy for the infringement of PATENT RIGHTS and/or consideration for an on
- 9.3 If, within [***] ([***]) months after receiving notice of any alleged infringement of the PATENT RICHTS by a third party, LICENSEE (i) shall have been unsuccessful in persuading the alleged infringer to desist, (ii) shall not have brought and shall not be diligently prosecuting an infringement action, and (iii) has not entered into settlement discussions with respect to such infringement, or if LICENSEE shall notify UNIVERSITY in writing, at any time prior thereto, of its intention not to undertake any of the foregoing actions with respect to the alleged infringer, then UNIVERSITY shall have the right, but not the obligation, to prosecute, at its own expense and utilizing counsel of its choice, any infringement of the PATENT RIGHTS, and UNIVERSITY may, at its own expense and control, take steps to defend or enforce any patent within the PATENT RIGHTS and recover, for its own account, any damages, awards or settlements resulting therefrom LICENSEE and/or its AFFILIATES shall cooperate as reasonably requested by UNIVERSITY, including joining in such actions, at the expense of UNIVERSITY.
- 9.4 In any challenge to the PATENT RIGHTS brought or declaratory judgment action defended not already addressed by the provisions of this Section 9, LICENSEE shall have the first right, exercisable upon written notice to UNIVERSITY within [***] ([***]) days of receipt of notice of such action, but not the obligation, to defend such action at the sole expense of LICENSEE. UNIVERSITY shall reasonably cooperate in any such defense at LICENSEE's sole expense, including joining in such actions. If LICENSEE does not so elect, UNIVERSITY may defend but has no obligation to do so.
- 9.5 Notwithstanding the foregoing, and without limiting LICENSEE's rights under Section 9.1 or 9.2 above to enter into any settlement, consent judgment, or other voluntary disposition of any legal or equitable action, UNIVERSITY shall be entitled, in its sole discretion and at its own expense, to participate through counsel of its

own choosing in any legal action involving INVENTIONS and PATENT RIGHTS. LICENSEE acknowledges that UNIVERSITY may not join in any litigation without the approval of authorized agencies of North Carolina, including the Board of Governors of the University of North Carolina. UNIVERSITY agrees to use its best efforts to obtain such approval promptly in the event that UNIVERSITY is required to be joined in any litigation under this Article 9 to establish standing. Nothing in the foregoing Sections shall be construed in any way which would limit the authority of the Attorney General of North Carolina.

ARTICLE 10: REPRESENTATIONS

10.1 UNIVERSITY makes no warranties that any patent will issue on UNIVERSITY TECHNOLOGY or INVENTIONS. UNIVERSITY does not warrant the validity or enforceability of any patent included in the PATENT RIGHTS or that practice under such patents shall be free of infringement.

10.2 UNIVERSITY represents and warrants that, to its actual knowledge and belief, as of EFFECTIVE DATE, (i) the entire right, title, and interest in the patent applications or patents comprising UNIVERSITY INVENTIONS included in the PATENT RIGHTS and the entire right, title, and interest of inventors with an obligation to assign to the UNIVERSITY the patent applications or patents comprising JOINT INVENTIONS included in the PATENT RIGHTS have been assigned to it free and clear of all liens, claims and encumbrances of any inventor or any nongovernmental third party, (ii) that UNIVERSITY has all requisite power and authority to grant the licenses contained in this LICENSE AGREEMENT under said PATENT RIGHTS and UNIVERSITY TECHNOLOGY, (iii) UNIVERSITY has not entered into any agreements other than grants from the U.S. Government which provide for the rights described in Section 2.5, with any third party with respect to the PATENT RIGHTS, the technology claimed therein, nor INVENTIONS, (iv) its execution and performance of this LICENSE AGREEMENT will not result in a breach of any other contract to which it is, or will become, a party, and (v) it has not received any notification that the PATENT RIGHTS are invalid or that the exercise by LICENSEE of the rights granted hereunder will infringe on any patent or other proprietary right of any third party.

10.3 EXCEPT AS PROVIDED IN SECTION 10.2, UNIVERSITY DISCLAIMS ALL WARRANTIES WITH REGARD TO INVENTIONS, PATENT RIGHTS, PRODUCT(S), AND SERVICE(S) LICENSED UNDER THIS AGREEMENT, INCLUDING, BUT NOT LIMITED TO, ALL WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY AND FITNESS FOR ANY PARTICULAR PURPOSE.

10.4 EXCEPT WITH RESPECT TO BREACHES OF SECTIONS [***], AND 12.1, THE INDEMNIFICATION PROVIDED UNDER SECTION 11, AND CLAIMS FOR PATENT INFRINGEMENT, NEITHER PARTY SHALL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY INDIRECT, CONSEQUENTIAL, SPECIAL, EXEMPLARY, OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT.

ARTICLE 11: INDEMNIFICATION

- 11.1 In exercising its rights under this LICENSE AGREEMENT, LICENSEE shall materially comply with the requirements of any and all applicable laws, regulations, rules and orders of any governmental body having jurisdiction over the exercise of rights under this LICENSE AGREEMENT. LICENSEE further agrees to indemnify and hold UNIVERSITY harmless from and against any costs, expenses, attorney's fees, citation, fine, penalty and liability of every kind and nature which might be imposed directly against UNIVERSITY by reason of any asserted or established violation of any such laws, order, rules and/or regulations by LICENSEE.
- 11.2 LICENSEE agrees to indemnify, hold harmless and defend UNIVERSITY, its officers, employees, and agents against any and all claims, suits, losses, damage, costs, fees, and expenses ("LOSSES") asserted by third parties, both government and private, resulting from or arising out of the exercise of LICENSEE's rights under this LICENSE AGREEMENT, provided such LOSSES do not result from the UNIVERSITY'S or its employees', faculty's, students', or other agents or representatives' gross negligence, intentional misconduct, breach of this Agreement, or failure to comply with any applicable laws, rules, or regulations.
- 11.3 LICENSEE is required to maintain in force at its sole cost and expense, with reputable insurance companies, insurance coverage in amounts and of types reasonably sufficient to protect against liability under Sections 11.1 and 11.2 above. The UNIVERSITY shall have the right to ascertain [***] that such coverage exists, such right to be exercised in a reasonable manner.

ARTICLE 12: MISCELLANEOUS

12.1 Confidentiality.

(a) LICENSEE shall keep confidential and not disclose any unpublished UNIVERSITY TECHNOLOGY or any patent applications furnished by UNIVERSITY pursuant to Sections 2.1 and 2.2 to third parties during the term of this LICENSE AGREEMENT or any time thereafter, provided that LICENSEE shall have the right to disclose such information under conditions of confidentiality to prospective investors, acquirors, sublicensees, strategic partners, and investment bankers in connection with its financing, acquisition, licensing, development, commercialization, and stockholder relations activities. Notwithstanding the foregoing, disclosure may be made to third parties of any such UNIVERSITY TECHNOLOGY or document related to or embodying PATENT RIGHTS at any time (a) with the prior written consent of UNIVERSITY, (b) after the same shall have become public through no unauthorized act or omission of LICENSEE, or (c) as required by governmental authority or applicable law or regulation.

(b) UNIVERSITY shall keep confidential and not disclose to any third party any information provided to it by LICENSEE (i) as a result of LICENSEE's performance under this LICENSE AGREEMENT or (ii) that may relate to the LICENSEE's research, development, technology(ies), or business. Notwithstanding the foregoing, disclosure may be made to third parties of any such research, development, or technology(ies) at any time (a) with the prior written consent of LICENSEE, (b) after the same shall have become public through no unauthorized act or

omission of UNIVERSITY, or (c) as required by governmental authority or applicable law or regulation, provided that UNIVERSITY (1) provides LICENSEE, to the extent practicable, advance written notice of any such disclosure, (2) reasonably assists LICENSEE, as reasonably requested by LICENSEE, in obtaining protective or confidential treatment of such information, and (3) minimizes the extent of any such disclosure.

- 12.2 Assignability. This LICENSE AGREEMENT is binding upon and shall inure to the benefit of the parties hereto, their successors and assigns. However, this LICENSE AGREEMENT shall be personal to LICENSEE, and it is not assignable by LICENSEE to any other person or entity without the written consent of UNIVERSITY, which consent shall not be unreasonably withheld. Notwithstanding the foregoing, (1) LICENSEE shall be free to assign this LICENSE AGREEMENT without such consent (i) to any AFFILIATE of LICENSEE or (ii) in connection with any sale of substantially all of its assets or business (or portion of its assets or business related to the subject matter hereof), merger, acquisition, consolidation, reorganization, or other similar transaction and (2) in the event lenders to the LICENSEE require a security interest in the LICENSE AGREEMENT as a term of any loans to LICENSEE, UNIVERSITY shall (a) consent to the assignment of this LICENSE AGREEMENT to such lenders or any assignee thereof in conjunction with the exercise of their rights under such security interest and (b) enter into any reasonable form of collateral assignment agreement requested by such lenders in conjunction with their exercise of such rights.
- 12.3 Waiver. It is agreed that no waiver by either party hereto of any breach or default of any of the covenants or agreements herein set forth shall be deemed a waiver as to any subsequent and/or similar breach or default.
- 12.4 Use of UNIVERSITY's Name. The use of the name of UNIVERSITY, or any contraction thereof, in any manner in connection with the exercise of rights under this LICENSE AGREEMENT is expressly prohibited without the prior written consent of UNIVERSITY, provided that, notwithstanding the foregoing, LICENSE shall have the right to identify UNIVERSITY as the licensor and, under conditions of confidentiality, to disclose the terms of this LICENSE AGREEMENT to prospective investors, acquirors, sublicensees, strategic partners, investment bankers, and regulatory authorities, in connection with its financing, regulatory, licensing, development, and stockholder relations activities or that it may deem to be required in any prospectus, offering memorandum, or other document or filing prepared in connection with its compliance obligations under applicable securities law or other applicable law or regulation.
- 12.5 **Independent Contractor Status.** Neither party hereto is an agent, joint venture or representative of the other for any purpose. Neither party shall have the right to obligate or bind the other in any manner.

12.6 **Notice.** Any notice required or permitted to be given to the parties hereto shall be in writing and deemed to have been properly given if delivered in person or mailed by first-class mail to the other party at the appropriate address as set forth below. Other addresses may be designated in writing by the parties during the term of this LICENSE AGREEMENT.

UNIVERSITY LICENSEE
Cathy Innes President
Director Novan, Inc.

Office of Technology Development 4222 Emperor Boulevard

[***]

- 12.7 **Governing Law and Venue**. This LICENSE AGREEMENT shall be interpreted and construed in accordance with the laws of the State of North Carolina. The State and Federal Courts of North Carolina shall have exclusive jurisdiction to hear any legal action arising out of this LICENSE AGREEMENT.
- 12.8 Complete Agreement. It is understood and agreed between UNIVERSITY and LICENSEE that, from and after the EFFECTIVE DATE, this LICENSE AGREEMENT constitutes the entire agreement, both written and oral, between the parties with respect to the subject matter hereof and supersedes the FIRST AGREEMENT and the SECOND AGREEMENT and any amendments thereto. For clarity, all patent rights, inventions, modifications, enhancements, improvements, information, know-how and technical data that were subject to the FIRST AGREEMENT or the SECOND AGREEMENT prior to the EFFECTIVE DATE are subject to this LICENSE AGREEMENT. This LICENSE AGREEMENT shall not be amended or modified except by a written agreement signed by all parties.
- 12.9 **Severability.** In the event that a court of competent jurisdiction holds any provision of this LICENSE AGREEMENT to be invalid, such holding shall have no effect on the remaining provisions of this LICENSE AGREEMENT, and they shall continue in full force and effect.
- 12.10 **Survival of Terms.** The provisions of Sections 2.3, 2.4, 2.6, 3.3, 6.2, 7.1, 7.5, 7.6, 8.5, 12.1, 12.2, 12.3, 12.4, 12.5, 12.6, 12.7, 12.8, 12.9, and 12.10 and Articles 1, 4, 9, 10 and 11 shall survive the expiration or termination of this LICENSE AGREEMENT.
- 12. 11 Export Controls. It is understood that UNIVERSITY is subject to United States laws and regulations controlling the export of technical data, computer software, laboratory prototypes, and other commodities that may require a license from the applicable agency of the United States Government and/or may require written assurances by LICENSEE that it will not export data or commodities to certain foreign countries without prior approval of such agency. UNIVERSITY neither represents that a license is required, nor that, if required, it will be issued.

[Signature page to follow.]

IN WITNESS WHEREOF, UNIVERSITY and LICENSEE have executed this LICENSE AGREEMENT on the EFFECTIVE DATE, in duplicate originals, by the duly authorized respective officers. INVENTORS have likewise indicated their acceptance of the terms hereof by signing below.

THE UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL		4	NOVAN, INC.			
Signature: (SEAL)	/s/ Catherine Innes		Signature: (SEAL)	<u>/</u>	/s/ Nathan Stasko	
Catherine Innes Director			Nathan Stasko President			
Date:	6/29/12		Date:	7/9/12		
Acknowledged and A	agreed by:					
/s/ Mark Schoenfisch Mark Schoenfisch						

APPENDIX A PATENT RIGHTS

UNIVERSITY INVENTIONS [***]

JOINT INVENTIONS
[***]



APPENDIX R FORM OF MATERIAL TRANSFER AGREEMENT

Office of Technology Development CB# 4105, 308 Bynum Hall
The University of North Carolina at Chapel Hill
Chapel Hill, NC 27599-4105

<< Recipient Scientist>> << Recip_Scientist_Address>>

RE: MATERIALS TRANSFER AGREEMENT; OUR FILE NO. << MTA_ID>>>

Dear << Recipient_Scientist>>:

The University of North Carolina at Chapel Hill ("UNC") is engages in research relating to the Material (as defined below) which is considered proprietary to UNC. Furthermore, UNC has granted an exclusive license to commercial rights related to the Material to Novan, Inc. (The "Exclusive Commercial Licensee"), having an address at ______. UNC agrees to provide your Institution with the Material for the purpose of a scientific collaboration and for Institution's internal research purposes subject to the following conditions:

- 1. The parties to this Agreement are: UNC and <<<u>Univ>></u> (hereinafter "Institution"). You are also requested to countersign this Agreement signifying your acceptance of its terms. You will be referred to herein as "Scientist."
- 2. The Material covered by this Agreement includes:
- a. <<material description>>;
- b. any related biological material or associated know-how and data received by Institution form UNC; and
- c. any progeny or unmodified derivatives produced from any of the foregoing by Institution, its employees and/or agents.

 3. Institution and Scientists acknowledge that UNC has informed Institution and Scientist that UNC owns certain rights in patent applications relating to the Material, which are licensed exclusively to the Exclusive Commercial Licensee.
- 4. The Material shall be used solely for research in Scientist's laboratory at Institution, such research to be limited to the studies described in Attachment A hereto. UNC shall be free, in its sole discretion, to distribute the Material to others and to use it for its own purposes.
- 5. In return for the provision of the Material, Institution shall reimburse <u>UNC \$</Fee Requested>></u> upon execution of this Agreement to cover costs of preparing the sample of the Material which is to be sent to Institution. Said reimbursement will be made payable to The University of North Carolina at Chapel Hill and will be sent to <u><<Pre>revider Scientist> at</u> the address specified by said person.
- 6. Institution shall not distribute or release the Material to any person other than Institution laboratory personnel under Scientist's direct supervision. Institution shall ensure that no one will be allowed to take or send the Material to any other location, unless written permission is obtained from <a href="mailto:reverliest) at UNC. This Material is made available for investigational use only in laboratory animals or *in vitro* experiments. Institution and Scientist agree that the Material will not be used for any other purpose. Neither the Material nor any biological materials treated therewith will be used in human beings.
- 7. This Agreement and the resulting transfer of Material constitute a license to use the Material solely for its internal not-for-profit academic research purposes. Institution agrees that nothing herein shall be deemed a grant under any UNC patents (either existing or future) or any rights to use the Material for any products or processes for profit-making or commercial purposes. The Material will not be used in research that is on behalf of, sponsored with funding received from or subject to consulting, licensing, or option obligations or other intellectual property rights granted to any other institution, corporation or business entity unless written permission is obtained from UNC.

- 8. Institution shall have no rights in the Material other than as provided in this Agreement, and at the request of UNC, Institution and/or Scientist will return all unused Material.
- 9. Scientist will inform Serientist of research results related to the Material by personal written communication. UNC and/or Serientist shall be free to use such data and information for any purpose, but will make proper acknowledgment of the work done by Scientist. Institution and Scientist shall provide Serientist with a manuscript of any proposed paper or an abstract of any proposed presentation describing any research results at least thirty (30) days prior to submission for publication. At the request of UNC, Institution and Scientist agree to delay the proposed disclosure for an additional ninety (90) days to allow for the filing of a patent application.
- 10. If the research involving the Material or any other use of the Material by Scientist or Institution results in an invention, discovery, or improvement (whether or not patentable) (an "INVENTION"), Scientist or Institution will promptly disclose the INVENTION, prior to any submission for publication thereof, to Institution's patent administrator, technology transfer, technology commercialization, licensing, or technology development officer or reasonable equivalent thereof ("Technology Transfer Officer") and notify the Technology Transfer Officer of UNC's role as a supplier of Material used. Institution, in cooperation with Scientist, will promptly supply UNC with a copy of the disclosure, in confidence, for evaluation purposes only. Institution, to the extent it is legally able to do so, hereby grants UNC or, if Institution is willing to negotiate directly therewith, the Exclusive Commercial Licensee an option to obtain an exclusive license to INVENTIONS, under reasonable commercial terms, pursuant to good faith negotiations between the parties fairly reflecting the relative contributions of the parties, to commercially make, use, or sell the INVENTION. UNC or the Exclusive Commercial Licensee, as applicables hall have a period of ninety (90) days form the receipt of the disclosure above within which to exercise such option in writing with respect to each INVENTION (the "Option Period"). If the applicable party exercises its option with respect to a particular INVENTION, the applicable party and Institution shall have an additional twelve (12) month period following Institution's and/or Scientist's receipt of the applicable party's exercise notice within which to negotiate in good faith the terms of the license (the "Negotiation Period"). The terms of every such license shall be reasonable and fairly reflect the relative contributions of each party. During the Option Period and Negotiation Period, neither Institution nor Scientist shall offer a license to any other party. If the part to which such option wa
- 11. If Institution desires to use or license the Material for commercial purposes, Institution agrees, in advance of such use, to negotiation in good faith with the Exclusive Commercial Licensee to establish the terms of a commercial license. It is understood by Institution that the Exclusive Commercial Licensee shall have no obligation to grant such a license to Institution or any other third party.
- 12. THE MATERIAL IS EXPERIMENTAL IN NATURE AND IT IS PROVIDED WITHOUT WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER WARRANTY, EXPRESS OR IMPLIED. UNC MAKES NO REPRESENTATION OR WARRANTY THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT OR OTHER PROPRIETARY RIGHT.
- 13. In no event shall UNC be liable for any use by institution, its employees and/or agents of the Material or any loss, claim, damage or liability, of whatsoever kind or nature, which may
- arise from or in connection with this Agreement or the use, handling or storage of the Material. Furthermore, to the extent provided by applicable law, Institution agrees to indemnify UNC and any of its employees and hold it and them harmless from any action, claim, or liability for death, personal injury, or property damage, arising directly or indirectly from Institution's possession, testing, screening, distribution or other use of the Material provided under the Agreement, and/or from Institution's publication or distribution of the test reports, data, and other information relating to said Material.
- 14. Institution will use the Material in compliance with all law and governmental regulations and guidelines applicable to the Material, and when the Material is used in the United States, Institution and Scientist will comply with current NIH guidelines.
- 15. This Agreement is not assignable or otherwise transferable, whether by operation of law or otherwise, without the prior written consent of UNC.
- 16. This Agreement shall be interpreted and construed in accordance with the laws of the State of North Carolina.

After the Original of this Agreement has been signed, in duplicate, by yourself and an authorized representative of Institution, please return them to me; the copy is for your records. The Material will be shipped as soon as possible upon receipt of this signed Agreement.
Sincerely,
Catherine Innes Director Office of Technology Development cathy_inness@unc.edu
ACCEPTED AND AGREED TO:
SCIENTIST
By:
<< r style="text-align: center;"> r style="text-align: center;" r style="tex</td
INSTITUTION
(to be signed only by an authorized signatory of the Institution)
Title:
Date:

APPENDIX C SHAREHOLDER AGREEMENT

[Intentionally omitted as superseded by the Seventh Amended and Restated Stockholders Agreement dated December 1, 2015]



FIRST AMENDMENT TO AMENDED, RESTATED AND CONSOLIDATED LICENSE AGREEMENT

This FIRST AMENDMENT to the AMENDED, RESTATED AND CONSOLIDATED LICENSE AGREEMENT (this "FIRST AMENDMENT") is entered into this 30th day of November, 2012 (the "EFFECTIVE DATE") between The University of North Carolina at Chapel Hill having an address at Campus Box 4105, 308 Bynum Hall, Chapel Hill, North Carolina, 27599-4105 ("UNIVERSITY") and Novan, Inc., a corporation organized and existing under the laws of the State of Delaware and having an address at 4222 Emperor Blvd, Suite 470, Durham, NC 27703 ("LICENSEE").

WITNESSETH

WHEREAS, UNIVERSITY entered into a first license agreement with LICENSEE effective July 18, 2007, a FIRST AMENDMENT thereto effective September 30, 2008 and a SECOND AMENDMENT thereto effective October 29, 2010 (such license agreement, as amended by the FIRST AMENDMENT and the SECOND AMENDMENT thereto, the "FIRST AGREEMENT"); and

WHEREAS, UNIVERSITY entered into a second license agreement with LICENSEE effective October 1, 2009 and a FIRST AMENDMENT thereto effective October 29, 2010 (such license agreement, as amended by the FIRST AMENDMENT thereto, the "SECOND AGREEMENT"); and

WHEREAS, UNIVERSITY entered into an AMENDED, RESTATED AND CONSOLIDATED LICENSE AGREEMENT effective June 27, 2012 ("THIRD AGREEMENT") thereby amending, restating and consolidating the FIRST AGREEMENT and the SECOND AGREEMENT into a single agreement; and

WHEREAS, UNIVERSITY and LICENSEE wish to amend the INVENTIONS and PATENT RIGHTS covered by the THIRD AGREEMENT to include inventions owned by UNIVERSITY and closely related to the INVENTIONS currently included under the THIRD AGREEMENT, titled "[***]" UNIVERSITY File: [***] and "[***]", UNIVERSITY File: [***] (the "ADDED INVENTIONS"); and

WHEREAS, the ADDED INVENTIONS were conceived of by Yuan Lu and Mark Schoenfisch. .

- NOW, THEREFORE, in consideration of the premises and mutual promises and covenants contained in this FIRST AMENDMENT and for good and valuable consideration, it is agreed by and between UNIVERSITY and LICENSEE as follows:
- 2. The term "INVENTIONS" is deemed to include the ADDED INVENTIONS and the items set forth in the attached Appendix A.
- 3. The term "PATENT RIGHTS" is deemed to include the patent rights set forth in the attached Appendix A.
- 4. In consideration for amending the INVENTIONS and PATENT RIGHTS to include UNC files: [***] and [***], LICENSEE shall pay UNIVERSITY [***] dollars ([***]) within [***] ([***]) days of the EFFECTIVE DATE of this FIRST AMENDMENT.
- 5. Except as expressly amended in this FIRST AMENDMENT, the THIRD AGREEMENT shall continue in full force and effect in accordance with the provisions thereof prior to the effectiveness of this FIRST AMENDMENT.
- 6. Capitalized terms used herein but not otherwise defined have the meanings assigned to them in the THIRD AGREEMENT.
- 7. This FIRST AMENDMENT shall be interpreted and construed in accordance with the laws of the State of North Carolina. The State and Federal Courts of North Carolina shall have exclusive jurisdiction to hear any legal action arising out of this FIRST AMENDMENT.
- 8. This FIRST AMENDMENT may be executed by one or more of the parties to this FIRST AMENDMENT on any number of separate counterparts (including by facsimile transmission or PDF signature), and all of said counterparts taken together shall be deemed to constitute one and the same instrument.

Signature Page to Follow

IN WITNESS WHEREOF, UNIVERSITY and LICENSEE have executed this FIRST AMENDMENT in duplicate originals, by their respective officers hereunto duly authorized, the day and year first above written. The inventors of the ADDED INVENTION have likewise indicated their acceptance of the terms hereof by signing below.

THE UNIVER	SITY OF NORTH CAROLINA AT CHAPEL HILL	NOVAN, IN	С.	
By:	/s/ Jacqueline Quay	By:	/s/ Jeff Hunter	
Name:	Jacqueline Quay		Jeff Hunter	
Title:	Interim Director, OTD	Title:	VP of Operations	
Date:	12/14/12	Date:	12/28/12	
Acknowledge	d and agreed:			
INVENTORS				
/s/ Yuan Lu				
Yuan Lu				
/s/ Mark Scho	penfisch			
Mark Schoen	fisch			

APPENDIX A PATENT RIGHTS

UNIVERSITY INVENTIONS

[***]

JOINT INVENTIONS

[***]

Certain confidential information contained in this exhibit have been omitted by means of redacting a portion of the text and replacing it with [***], pursuant to Regulation S-K Item 601(b) of the Securities Act of 1933, as amended. Certain confidential information has been excluded from this exhibit because it is: (i) not material; and (ii) the registrant treats such information as private or confidential.

SECOND AMENDMENT TO AMENDED, RESTATED AND CONSOLIDATED LICENSE AGREEMENT

This second amendment (the "Second Amendment") to the Amended, Restated and Consolidated License Agreement dated June 27th, 2012 by and between The University of North Carolina at Chapel Hill ("University") and Novan, Inc. ("Licensee"), as amended by the First Amendment to Amended, Restated and Consolidated License Agreement dated November 30, 2012 (hereinafter referred to as the "Agreement"), is effective as of April 12, 2016.

WHEREAS, the parties now wish to amend the Agreement to update Appendix A of the Agreement to include the Improvement known as [***] as a University Invention and;

WHEREAS, the parties agree to be bound by the terms and conditions of the Agreement, as amended herein;

NOW THEREFORE, the parties agree as follows:

The following Improvement is deemed to be included in the University Inventions, and all patents and/or patent applications claiming such Improvement are deemed to be included in the Patent Rights for all purposes under the Agreement, including but not limited to the license granted to Licensee and Its Affiliates pursuant to Section 2.2 of the Agreement:

[***]

- 2. Appendix A of the Agreement is hereby deleted in the entirety and replaced with the attached Appendix A.
- 3. Capitalized terms used herein have the same meaning as was given them in the Agreement.
- 4. Other than as amended herein, the Agreement remains in full force and effect.
- 5. This Second Amendment may be executed by one or more of the parties to this Second Amendment on any number of separate counterparts (including by facsimile transmission or PDF signature), and all of said counterparts taken together shall be deemed to constitute one and the same instrument.

[Signatures appear on following page]

IN WITNESS WHEREOF, the parties have executed this Second Amendment to the Agreement, as indicated below.

THE UNIVERSITY OF NORTH CAROLINA AT CHAPEL HILL	NOVAN INC.
/s/ Jacqueline Quay Jacqueline Quay Director of Licensing, Office of Commercialization and Economic Development	/s/ Emily K. Hales Name: Emily K. Hales Title: Corporate Counsel
4/22/2016 Date	5/6/2016 Date
Acknowledged and Agreed:	
INVENTORS	
/s/ Mark Schoenfisch Mark Schoenfisch	
/s/ Robert Soto Robert Soto	
ROUGH SOLO	

APPENDIX A Patent Rights

University Invention

[***]

Certain confidential information contained in this exhibit have been omitted by means of redacting a portion of the text and replacing it with [***], pursuant to Regulation S-K Item 601(b) of the Securities Act of 1933, as amended. Certain confidential information has been excluded from this exhibit because it is: (i) not material; and (ii) the registrant treats such information as private or confidential.

Execution Copy

UNC SUBLICENSE AGREEMENT

THIS UNC SUBLICENSE AGREEMENT (this "Agreement") is made as of December 29, 2015 (the "Effective Date") by and between Novan, Inc., a Delaware corporation with a principal place of business at 4222 Emperor Boulevard, Suite 200, Durham, NC 27703 ("Novan"), and KNOW Bio, LLC, a North Carolina limited liability company with a principal place of business at 627 Davis Drive, Suite 400, Morrisville, NC 27560 ("Licensee"). Novan and Licensee may each be referred to as a "Party," and together as the "Parties."

RECITALS

WHEREAS, as of the Effective Date, Licensee is a wholly-owned subsidiary of Novan;

WHEREAS, following the Effective Date, Novan is transferring all of the ownership interests in Licensee to the stockholders of Novan on a pro rata basis, and Novan will no longer have any ownership interest in Licensee;

WHEREAS, Novan has licensed certain Patents related to pharmaceutical and medical device applications of nitric oxide pursuant to an Amended, Restated and Consolidated License Agreement, dated June 27, 2012, between The University of North Carolina at Chapel Hill ("UNC") and Novan, as amended (the "UNC Agreement"), and Licensee is interested in developing and commercializing such Patents in the Licensee Field (each as defined below); and

WHEREAS, subject to the terms and conditions set forth in this Agreement, Novan is willing to grant to Licensee a sublicense under the UNC Patents to develop and commercialize, on a worldwide basis, Licensed Products (each as defined below) in the Licensee Field.

NOW, THEREFORE, for good and valuable consideration, receipt of which is hereby acknowledged, the Parties agree as follows:

AGREEMENT

- 1. DEFINITIONS. Capitalized terms shall have the meanings ascribed to them below or in this Agreement.
- 1.1 "Affiliate" means: (a) any person or entity which owns or controls at least fifty percent (50%) of the equity or voting stock of a Party; or (b) any person or entity fifty percent (50%) of whose equity or voting stock is owned or controlled by a Party; or (c) any person or entity of which at least fifty percent (50%) of the equity or voting stock is owned or controlled by the same person or entity owning or controlling at least fifty percent (50%) of such Party. For clarity, Novan and Licensee shall not be deemed Affiliates.
- 1.2 "Confidential Information" means information disclosed (whether in writing, electronically, orally or by observation) by one Party (the "Disclosing Party") to the other Party (the "Receiving Party") unless in each case such information, as shown by competent evidence:
 - (a) was known to the Receiving Party or to the general public prior to the Disclosing Party's disclosure, as demonstrated by contemporaneous written records;
 - (b) became known to the general public, after the Disclosing Party's disclosure hereunder, other than through a breach of the confidentiality provisions of this Agreement by the Receiving Party or any Person to whom such Receiving Party disclosed such information;

- (c) was subsequently disclosed to the Receiving Party by a Person having a legal right to disclose, without any restrictions, such information; or
- (d) was developed by the Receiving Party independent of the Disclosing Party's Confidential Information.

For clarity, the UNC Technology constitutes Confidential Information of Novan.

- 1.3 "Control" means, with respect to any Patents, information, know-how or technical data, that a Party or any of its Affiliates has the ability to grant to the other Party access and a license to the foregoing, including on the terms and conditions set forth in this Agreement, as applicable, without violating the terms of any agreement or other arrangement with any Third Party. The term "Controlled" shall be construed accordingly.
- 1.4 "Covered Product" means any Licensed Product comprising a method or process, composition, product, or component part thereof claimed in whole or in part by an issued, unexpired, or pending claim contained in the UNC Patents whose manufacture, intended use, or sale would, but for the sublicense(s) granted in this Agreement, infringe on the UNC Patents in the country of sale.
- 1.5 "First Commercial Sale" means the first sale of commercial quantities of any Covered Product for human therapeutic use under an approved NDA or BLA (or foreign equivalent thereof) by Licensee, any of its Affiliates, or any Sublicensee of either of the foregoing for which the proceeds of such sale qualify as Net Sales (as defined below).
- 1.6 "Licensed Product" means any pharmaceutical products and medical devices covered by any claim of the UNC Patents, other than any products or devices that incorporate or utilize Novan Particles. For clarity, the products existing as of the Effective Date with the internal Novan designations NVN1000 and NVN4000 are not Licensed Products.
- 1.7 "Licensee Field" means all diagnostic, therapeutic, prophylactic and palliative uses for any disease, condition or indication in humans or animals that is outside of the Novan Retained Field
- 1.8 "Net Sales" means the total invoiced sales price received for Covered Products sold by Licensee, its Affiliates, and their Sublicensees less (a) sales taxes or other taxes, (b) shipping and insurance charges, (c) actual allowances, rebates, credits, or refunds for returned or defective Covered Products, (d) trade discounts and quantity discounts, retroactive price reductions, or other allowances actually allowed or granted from the billed amount and taken, (e) rebates, credits, and chargeback payments (or the equivalent thereof) granted to managed health care organizations, wholesalers, or to federal, state/provincial, local and other governments, including their agencies, purchasers, and/or reimbursers, or to trade customers, and (f) any import or export duties, tariffs, or similar charges incurred with respect to the import or export of Covered Products into or out of any country in the Territory. Covered Products will be considered sold when paid for. Notwithstanding the foregoing, Net Sales shall not include, and shall be deemed zero with respect to, (1) the distribution of reasonable quantities of promotional samples of Covered Products, (2) Covered Products provided for clinical trials or research purposes, or charitable or compassionate use purposes, or (3) Covered Products provided to any of Licensee's Affiliates, Sublicensees or other strategic partner under an agreement in which Net Sales by such Affiliate, Sublicensee or other strategic partner shall be subject to royalties under Section 2.6(b)(ii). Notwithstanding the foregoing, in the event that Covered Products are sold by Licensee, or any of its Affiliates or Sublicensees as part of a combination product or bundled product, or in conjunction with a delivery system, the Net Sales of such product, for the purposes of determining royalty payments due under this Agreement, shall be determined by multiplying the Net Sales (as originally defined above) of the combination product by the fraction A/(A+B), where A is the average sale price of the Cove
 - 1.9 "Novan Particles" means any particles that include: (a) [***]; (b) [***]; (c) [***]; or (d) [***].
- 1.10 "Novan Retained Field" means: (a) all diagnostic, therapeutic, prophylactic and palliative uses for any disease, condition or disorder of the skin, nails, hair or scalp in humans or animals, including [***], as well as any other dermatological diseases, conditions or disorders (including [***]); and (b) all cosmetic uses for the skin, nails, hair or scalp. Notwithstanding the foregoing, the Novan Retained Field does not include: (i) wound (i.e., [***]) care by use of pharmaceutical products formulated specifically to treat chronic wounds, thermal burns, radiation injury,

accidental injury, surgical sites or scars; or (ii) therapeutic uses for any form of cancer, excluding basal cell carcinoma, squamous cell carcinoma and any forms of precancerous skin lesions or precancerous skin conditions, including actinic keratosis, actinic cheilitis, cutaneous hom, Bowen disease, radiation dermatosis, and dysplastic nevi.

- 1.11 "Patents" means any of the following, whether existing now or in the future anywhere in the world: (a) patents and patent applications; (b) continuations, continuations-in-part, provisionals, divisionals and substitute applications with respect to any such patent application; (c) any patents issued based on or claiming priority to any such patent applications; (d) any reissue, reexamination, renewal, patents of addition, or extension (including any supplemental patent certificate) of any such patents; and (e) any confirmation patent or registration patent or patent of addition based on any such patents.
- 1.12 "Person" means a natural person, a corporation, a partnership, a trust, a joint venture, a limited liability company, any governmental authority, or any other entity or organization.
- 1.13 "Phase I Clinical Trial" means any human clinical trial, conducted by or on behalf of Licensee, any of its Affiliates, or a Sublicensee with respect to a Covered Product, including typically the first phase of clinical trials conducted in relatively small numbers of healthy volunteers or patients with the targeted condition to obtain information on a Covered Product's safety, tolerability, pharmacological activity, pharmacokinetics, drug metabolism and mechanism of action, as more fully defined in 21 C.F.R. § 312.21(a), as may be amended, and, with respect to any other country or jurisdiction, the equivalent of such a clinical trial in such other country or jurisdiction.
- 1.14 "Post Grant Proceeding" means any and all proceedings before any patent office in the Territory that involves the review, examination, analysis or any combination thereof of any issued Patent, including without limitation post grant review proceedings, inter partes review proceedings, supplemental examinations, patent interference proceedings, opposition proceedings, and reexaminations.
- 1.15 "Prosecute" and "Prosecution" means the preparation, filing, prosecution and maintenance of Patents, including seeking patent extensions and supplementary protection certificate applications pursuant to 35 U.S.C. § 156 or similar statutes, but excluding Post Grant Proceedings.
- 1.16 "PTO" means, as applicable, the United States Patent and Trademark Office or any other relevant patent office in any country of the Territory other than the United States.
 - 1.17 "Sublicensee" means any Third Party to whom Licensee or any of its Affiliates sublicenses any of the rights granted under this Agreement.
- 1.18 "Sublicensing Revenue" means sublicense payments to the extent received by Licensee directly and solely, as reasonably determined by Licensee, as consideration for the grant of rights to UNC Patents, including upfront fees or milestone payments but excluding sales-based royalties, sales-based milestone fees, or other payments calculated on the basis of Sublicensees' sales of Covered Products, purchases of equity or debt of Licensee, payments made in connection with research and development agreements or collaborations, or other payments made by a Sublicensee where Licensee is obligated to perform services or to provide goods in connection with such payment shall not be considered sublicensee payments for purposes of this Agreement.
 - 1.19 "Territory" means the entire world.
 - 1.20 "Third Party" means any entity other than Licensee or Novan or an Affiliate of Novan or Licensee.
- 1.21 "UNC Inventions" means Inventions that have only inventors, as determined under the Patent Laws of the United States of America, that are obligated to assign their rights in any Inventions to UNC. "Inventions", for purposes of this definition, means the subject matter of UNC Patents.
- 1.22 "UNC Patents" means, to the extent Controlled by Novan: (a) the Patents in <u>Appendix A</u>; (b) any other Patents licensed by UNC to Novan under the UNC Agreement after the Effective Date, including in accordance with Section 2.5 of this Agreement ("Additional UNC Patents"); and (c) any Patents claiming priority from the foregoing Patents. The Parties will promptly update <u>Appendix B</u> in writing to reflect any additional Patents that become licensed by UNC to Novan under the UNC Agreement after the Effective Date.

1.23 "UNC Technology" means, to the extent Controlled by Novan, any unpublished research and development information, know-how, and technical data in the possession of UNC which relates to and is necessary for the practice of the inventions claimed in the UNC Patents.

2. LICENSE GRANT

- 2.1 Exclusive Sublicense under UNC Patents. Subject to the terms and conditions of this Agreement, Novan hereby grants to Licensee an exclusive (even as to Novan and its Affiliates), sublicensable (through multiple tiers), sublicense in the Territory, under the UNC Patents, to develop, make, have made, use, sell, offer for sale, import and export Covered Products in the Licensee Field.
- 2.2 Non-Exclusive Sublicense to UNC Technology. Subject to the terms and conditions of this Agreement, Novan hereby grants to Licensee a non-exclusive, sublicensable (through multiple tiers), sublicense in the Territory, to use the UNC Technology to develop, make, have made, use, sell, offer for sale, import and export Licensed Products in the Licensee Field.
- 2.3 Sublicenses. All sublicenses granted under Section 2.1 and Section 2.2 of this Agreement must be in writing and must be materially consistent with the terms, conditions and limitations of this Agreement. Licensee promptly shall provide a copy to Novan of any sublicense entered into hereunder. Licensee shall be directly and primarily responsible and liable for any acts or omissions of its sublicensees in relation to any subject matter of this Agreement.
- 2.4 Retained Rights; No Implied Licenses. Only the licenses expressly granted under this Agreement shall be of legal force and effect. No other licenses shall be created under this Agreement by implication, estoppel or otherwise. For clarity, Novan retains the exclusive rights under the UNC Patents and UNC Technology in the Territory to develop, make, have made, use, sell, offer to sell and import any and all products and services in the Novan Retained Field. In addition, Novan retains the right under the UNC Patents and UNC Technology to conduct research and development related to any of the subject matter claimed in the UNC Patents; provided that such research and development is not conducted for the purpose of commercialization of Licensed Products in the Licensee Field. Licensee acknowledges that the sublicenses granted to Licensee under this Article 2 are subject to the retained rights of UNC under the UNC Agreement, including Section 2.3 and Section 2.4 thereof. In addition, notwithstanding the foregoing, any and all licenses and other rights granted hereunder are limited by and subject to the rights and requirements of the United States Government which arise out of its sponsorship (if any) of the research which led to the conception or reduction to practice of the inventions covered by UNC Patents. To the extent applicable due to any such sponsorship, the United States Government is entitled, as a right, under the provisions of 35 U.S.C. §§ 200-212 and applicable regulations of Title 37 of the Code of Federal Regulations, to a non-exclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on the behalf of the United States Government any of the UNC Patents throughout the world and Licensee agrees to comply and require compliance therewith.
- 2.5 Additional UNC Patents. In the event that UNC notifies Novan of an Improvement (as defined in the UNC Agreement) that becomes available for license to Novan under the UNC Agreement, Novan will notify Licensee of such Improvement. If Novan includes such Improvement in the license granted to Novan in the UNC Agreement, then the Patents of UNC claiming such Improvement shall be included in the UNC Patents under this Agreement. In the event that Novan does not desire to include such Improvement in the license granted to Novan in the UNC Agreement, Novan shall inform Licensee of such fact together with notification of the existence of such Improvement, and Licensee may, by providing written notice to Novan within [***] ([***]) days of receiving notice from Novan of such Improvement, require that such Improvement be included in the license granted to Novan in the UNC Agreement and the sublicense granted to Licensee under the UNC Patents under Section 2.1, in which case, [***] will be responsible for any and all costs arising from the addition of such Patents of UNC to the UNC Agreement and from the Prosecution of such Patents.

2.6 UNC Agreement.

(a) Licensee acknowledges and agrees that Novan obtained the rights to the UNC Patents and UNC Technology through the UNC Agreement and that Licensee has received a copy thereof. Licensee's rights and obligations under this Agreement as they relate to the license of the UNC Patents and UNC Technology shall be subject to terms and conditions of the UNC Agreement. Licensee acknowledges that if UNC renders the license granted under the UNC Agreement non-exclusive in accordance with the UNC Agreement with respect to any or all UNC Patents, the statement that the license granted by Novan under Section 2.1 is "exclusive" shall not include exclusivity as to any non-exclusive rights of UNC under such UNC Patents.

- (b) For so long as Novan is required to make payments under the UNC Agreement, Licensee shall pay the following payments directly to UNC, and shall copy Novan on all remittances:
 - (i) During the term of this Agreement, on a country-by-country and Covered Product-by-Covered Product basis, Licensee will pay UNC a running royalty of [***] percent ([***]%) of all Net Sales of Covered Products sold by Licensee, any of its Affiliates and Sublicensees. For clarity, the obligation to pay royalties under this Section 2.6(b)(i) shall be imposed only once (i) with respect to any sale of any Covered Product, and (ii) with respect to any Covered Product, in each case regardless of whether such Covered Product, or the manufacture, use or sale thereof, is covered by more than one claim contained in the UNC Patents. Licensee shall pay to UNC said royalties on the Net Sales of Covered Products concurrently with the making of [***] written reports as provided in Section 2.6(f) below;
 - (ii) In respect to sublicenses granted by Licensee under this Agreement, Licensee shall pay to UNC an amount equal to [***] percent ([***]%) of Sublicensing Revenue received by Licensee as consideration for the grant of rights to UNC Patents. All payments based on Sublicensing Revenue shall be made within [***] ([***]) days of receipt of the Sublicensing Revenue;
 - (iii) Should a compulsory license be granted, or be the subject of a possible grant, to a Third Party under the applicable laws of any country in the Territory under the UNC Patents licensed hereunder, Licensee shall notify UNC and Novan, including any material information concerning such compulsory license, and the running royalty rates payable under Section 2.6(b)(i) for sales of Covered Products in such country will be adjusted to equal any lower royalty rate granted to such Third Party for such country with respect to the sales of such Covered Products therein (the "Compulsory Royalty"), provided that during such periods such Third Parties sell or offer for sale under the compulsory license articles that compete with the Covered Products then marketed and sold by Licensee or its Affiliates or Sublicensees in that country; and
 - (iv) Licensee shall pay UNC the following payments within [***] ([***]) days of Licensee, any of its Affiliates, or any Sublicensee achieving the indicated milestone for each Covered Product covered by UNC Patents corresponding to UNC Inventions:

Milestone Payment Due

[***]

Notwithstanding the conduct of clinical trials, submission of applications for regulatory approval, regulatory approval, sale, or marketing of a particular Covered Product for multiple indications, in multiple dosage or delivery forms, or in multiple bundled or combination products, the milestone fees described above shall only be due and paid once with respect to each Covered Product. Amounts paid UNC under Section 2.6(b)(ii) with respect to Sublicensing Revenue paid to Licensee by a Sublicensee for the achievement of a milestone substantially similar to any of those established above shall be creditable against, and deducted from, the corresponding payment due UNC under this Section 2.6(b)(iv).

- (c) All fees, royalties, and other payments due to UNC under this Agreement shall be made in United States Dollars. All royalties owing with respect to Net Sales or Sublicensing Revenue stated in currencies other than U.S. dollars shall be converted at an exchange rate which is the arithmetic mean of the opening telegraphic transfer selling and buying rate published by the American East Coast edition of the Wall Street Journal on the day preceding the payment.
- (d) In the event royalty payments or fees are not received by UNC when due, Licensee shall pay to UNC interest and charges at the lower of (a) the then-current prime lending rate as published by the American East Coast edition of the Wall Street Journal or (b) the maximum rate of interest allowed by law on the total royalties or fees overdue.
- (e) Licensee acknowledges and agrees that its payment obligations under this Section 2.6 are subject to the terms and conditions of the UNC Agreement. Without limiting any other provision of this Section 2.6, in the event that Novan is required to make any payment to UNC based on any activity of Licensee or any of its Affiliates or any sublicensees under this Agreement in order to comply with the UNC Agreement, Licensee shall promptly reimburse Novan for such payment made by Novan to UNC upon request by Novan.
- (f) Following the First Commercial Sale of a Covered Product or receipt of Sublicensing Revenue, Licensee agrees to make [***] written reports to UNC, and copy Novan on such reports, within [***]

([***]) days following the end of each [***] during the term of this Agreement, stating in each such report, if and as applicable, (i) the number, description, and aggregate selling prices of Covered Products sold or otherwise disposed of and deductions taken during the such [***] and upon which royalty is payable as provided in Section 2.6(b)(i) hereof and (ii) the amount of Sublicensing Revenue received. The first such report shall include all such Covered Product so sold or otherwise disposed of, and all such Sublicensing Revenue received, prior to the date of such report. Until the First Commercial Sale of a Covered Product, a report shall be submitted by Licensee, and a copy thereof delivered to Novan, at the end of each July after the Effective Date and will include a written report summarizing Licensee's technical and other efforts made towards such first commercial sale for all Covered Products under development.

- (g) Licensee will keep complete, true and accurate books of account and records, and require its Affiliates and Sublicensees to do the same, for the purpose of showing the derivation of all amounts payable to UNC under this Agreement. Such books and records will be kept at Licensee's, its Affiliate's or Sublicensee's principal place(s) of business for at least [***] ([***]) years following the end of the [***] to which they pertain, and will be open at all reasonable times for inspection by an independent certified public accountant reasonably acceptable to Licensee, its Affiliate's or Sublicensee's royalty statements or Licensee's compliance in other respects with the terms of this Agreement. The representative will be obliged to treat as confidential all relevant matters but shall be free to disclose all conclusions of any such inspection(s) to UNC and Novan and support such conclusions with underlying confidential information if challenged by Licensee, provided that all such disclosures shall be maintained as confidential by such representative and UNC and Novan with respect to Third Parties.
- (h) Inspections made under Section 2.6(g) shall be at the expense of UNC or Novan, as applicable, unless an underpayment to UNC exceeding [***]% of the amount properly due UNC with respect to the audited period is discovered in the course of any such inspection, whereupon all [***] costs of such inspection shall be paid by Licensee. Licensee will promptly pay to UNC the full amount of any underpayment, together with interest thereon at the lower of (a) the then-current prime lending rate as published by the American East Coast edition of the Wall Street Journal or (b) the maximum rate of interest allowed by law.
- (i) Licensee shall use its commercially reasonable efforts and due diligence to proceed with the research, development, and commercial exploitation of Covered Products during the term of this Agreement. In making any determination regarding such efforts and diligence, Novan shall take into account the normal course of such programs conducted with sound and reasonable business practices and judgment, the [***], and shall take into account [***].
- (j) Licensee and Novan acknowledge that Section 6.2 of the UNC Agreement provides that sublicenses thereunder shall survive termination of the UNC Agreement and will be automatically assigned to UNC upon such termination in the event that the UNC Agreement is terminated, to the extent (i) provided for in such sublicense and (ii) such agreement does not impose any obligations on UNC in excess of those imposed on UNC in the UNC Agreement. It is the intent of the Parties that this Agreement survive termination of the UNC Agreement and be assigned to UNC upon such termination in accordance with Section 6.2 of the UNC Agreement.
- (k) The use of the name of UNC, or any contraction thereof, by Licensee or any of its Affiliates or sublicensees in any manner in connection with the exercise of rights under this Agreement is expressly prohibited without the prior written consent of UNC, provided that, notwithstanding the foregoing, Licensee shall have the right to identify UNC as the prime licensor of the UNC Patents and, under conditions of confidentiality, to disclose the terms of this Agreement in accordance with Section 6.3.
- (1) It is understood that Novan and UNC are subject to United States laws and regulations controlling the export of technical data, computer software, laboratory prototypes, and other commodities that may require a license from the applicable agency of the United States Government and/or may require written assurances by Licensee that it will not export data or commodities to certain foreign countries without prior approval of such agency. Novan and UNC neither represent that a license is not required, nor that, if required, it will be issued.

3. PATENT PROSECUTION AND ENFORCEMENT

3.1 Prosecution of UNC Patents.

(a) Prosecution by UNC. The Parties acknowledge that UNC has the right to Prosecute UNC Patents under the UNC Agreement. During such time as UNC is Prosecuting UNC Patents, Novan will keep Licensee reasonably apprised of information it receives from UNC regarding such Prosecution,

and will convey comments from Licensee to UNC regarding such Prosecution. In the event that Novan desires not to continue to pay Prosecution costs to UNC with respect to any UNC Patent, Novan shall notify Licensee in advance of ceasing to pay such costs to UNC, and if Licensee requests in writing that Novan continue to pay such costs to UNC, then Novan will continue to do so in accordance with the UNC Agreement, [***].

- (b) Prosecution by Novan. In the event that Novan is Prosecuting any UNC Patents pursuant to the UNC Agreement, except as provided for in Section 3.1(c), Novan shall have the exclusive right to Prosecute such UNC Patents, as Novan determines in good faith, [***]. In the event that Novan desires not to continue to Prosecute any of such UNC Patents, Novan shall notify Licensee sufficiently in advance of any deadlines to afford Licensee an opportunity to request that Novan continue the Prosecution of such Patent prior to such Patent lapsing or becoming abandoned. If Licensee requests in writing that Novan continue to Prosecute such UNC Patent, then Novan will continue to do so in accordance with this Section 3.1(b), [***].
- (c) Filing of Continuations, Divisionals and National Applications. If Licensee desires to file a continuation, divisional or national Patent application to any of the UNC Patents that UNC and Novan have not filed, Licensee will notify Novan of such desire. If UNC is Prosecuting the applicable UNC Patent at such time, Novan will inform UNC of such desire, and Licensee will reimburse Novan for Prosecution costs paid to UNC in relation to such continuation, divisional or national Patent application. If Novan is Prosecuting the applicable UNC Patent at such time, Novan may elect to Prosecute such Patent requested by Licensee [***]. Novan will notify Licensee of its election whether or not to Prosecute such Patent within [***] ([***]) days of such notice from Licensee. If Novan does not elect to Prosecute such Patent within such [***] ([***]) day period, then Licensee may Prosecute such Patent [***]. Licensee shall control the Prosecution of such Patent (whether Prosecuted by Novan or by Licensee) in consultation with Novan; provided, however, that all Prosecution decisions will be subject to Novan's prior written approval (not to be unreasonably withheld). In no event will Licensee be permitted to undertake any act in the Prosecution of such Patent that may adversely affect the scope, enforceability or patentability of any other UNC Patent, as determined by Novan in good faith. For clarity, any Patent Prosecuted by either Party pursuant to this Section 3.1(c) shall be a UNC Patent and owned solely by UNC and sublicensed under Section 2.1 of this Agreement to Licensee.
- (d) Cooperation in Prosecution. The Party exercising the right to Prosecute UNC Patents pursuant to this Section 3.1 will (i) use reasonable efforts to apprise the other Party of any significant developments in the Prosecution of such UNC Patent, and (ii) copy the other Party, or have the other Party copied, on all official correspondence relating to the relevant UNC Patents received from or to be filed with the PTO, within [***] ([***]) days of receipt from the PTO and present a draft of any material proposed response to such correspondence at least [***] ([***]) days prior to filing with the PTO, respectively, including without limitation copies of each patent application, official action, response to official action, declaration, information disclosure statement, terminal disclaimer filing, and request for reexamination. The Party that is not Prosecuting any particular UNC Patent shall cooperate reasonably with the Party that is conducting Prosecution of such UNC Patent. [***] shall satisfy its obligations under this Section 3.1 to fund Prosecution costs incurred by [***] by reimbursing [***] on a [***] basis within [***] ([***]) days of receipt of reasonable documentation of such Prosecution costs incurred by Novan in the prior [***].
- (e) Rights of UNC. All rights of Novan and Licensee under this Section 3.1 are expressly subject to the terms of the UNC Agreement. The Parties agree to cooperate reasonably with UNC with respect to matters described in this Section 3.1 to the extent required by the UNC Agreement.

3.2 Post Grant Proceedings.

(a) Third Party Defense. In the event that Novan becomes aware that a Third Party has filed a Post Grant Proceeding with respect to any UNC Patent, Novan will notify Licensee in writing to that effect within [***] ([***]) days of becoming aware of such filing. Once such a Post Grant Proceeding has commenced, as between the Parties, Novan shall have the first right to respond to and/or contest such proceeding; provided, however, that if Novan does not take action to respond to and/or contest such proceeding by [***] ([***]) days before the expiration of the time limit, if any, set forth in the applicable laws and regulations for such response or contest, then Licensee shall have the right to respond to and/or contest such proceeding. The Party that responds to and/or contests such Post Grant Proceeding shall provide the other Party: (i) with a copy of any action, communication, letter or other correspondence issued by the PTO or the Third Party within [***] ([***]) days of receipt thereof; (ii) with a copy of any proposed response, amendment, paper or other correspondence to be filed with the PTO no less than [***] ([***]) days prior to filing the same in the PTO, unless otherwise agreed by patent counsel for both Parties; provided that the other Party shall have the right to provide suggestions and recommendations regarding the content of the response, amendment, paper or other correspondence

by no later than [***] ([***]) days prior to its filing; and (iii) with a copy of any response, amendment, paper or other correspondence as filed with the PTO no more than [***] ([***]) days after the responding/contesting Party receives confirmation from the PTO that the response, amendment, paper or other correspondence has been filed.

- (b) Commencement of Post Grant Proceedings. If either Party desires that Novan commence a Post Grant Proceeding with respect to a UNC Patent, the Party shall notify the other Party of such desire. The Parties shall then consult with each other and consider each other's input with respect to whether such a Post Grant Proceeding should be commenced. Novan shall have the sole right to commence a Post Grant Proceeding with respect to a UNC Patent. Should such a proceeding be commenced: (i) Novan shall provide Licensee with a copy of any action, communication, letter or other correspondence issued by the PTO within at least [***] ([***]) days of receipt thereof; (ii) Novan shall provide Licensee with a copy of any proposed response, amendment, paper, or other correspondence to be filed with the PTO no less than [***] ([***]) days prior to filing the same in the PTO, unless otherwise agreed by patent counsel for both Parties; provided that Licensee shall have the right to provide suggestions and recommendations regarding the content for the response, amendment, paper or other correspondence by no later than [***] ([***]) days prior to its filing; (iii) Novan shall provide Licensee with a copy of any response, amendment, paper, or other correspondence as filed with the PTO no more than [***] ([***]) days after Novan receives confirmation from the PTO that the response, amendment, paper, or other correspondence has been filed.
- (c) Decision-Making Authority; Costs. Novan shall have final decision-making authority with respect to all aspects of Post Grant Proceedings related to the UNC Patents. Each Party shall bear its own costs incurred in connection with any Post Grant Proceeding under this Section 3.2.
- (d) Rights of UNC. All rights of Novan and Licensee under this Section 3.2 are expressly subject to the terms of the UNC Agreement. The Parties agree to cooperate reasonably with UNC with respect to matters described in this Section 3.2 to the extent required by the UNC Agreement.

3.3 Enforcement and Defense of UNC Patents.

- (a) Notice of Infringement. Each Party shall (i) notify the other Party promptly of any conduct on the part of a Third Party that it deems to be a potential infringement of any UNC Patent or receipt of any notice of a certification filed pursuant to 21 U.S.C. § 355(b)(2)(A) or 355(j)(2)(A)(vii)(IV) or its successor provisions or any similar provision in a country in the Territory other than the United States ("Paragraph IV Notice") claiming that any UNC Patents are invalid or otherwise unenforceable, or that infringement of UNC Patents will not arise from the manufacture, use, import or sale of a product by a Third Party (collectively, "Infringement"), and (ii) provide the other Party with such information in its possession regarding the potential Infringement and/or a copy of any Paragraph IV Notices within [***] ([***]) days of receipt thereof.
- (b) Enforcement by Novan. Novan will have the right (but not the obligation), at its sole discretion, to take any and all action it deems necessary to stop any Infringement (or respond to any Paragraph IV Notice), including the bringing of an action based on the UNC Patents in the Territory. Novan will exclusively control the prosecution or settlement of any such action; provided that if such Infringement is in the Licensee Field and does not involve Novan Particles, Novan agrees not to settle such action without the prior written approval of Licensee, not to be unreasonably withheld or delayed. Novan will be permitted to bring any such action in the name of Novan only or in the name of both Novan and Licensee. If such Infringement is in the Licensee Field and does not involve Novan Particles, Licensee shall have the right (but not obligation, other than use of its name as set forth in the immediately preceding sentence) to participate in such action in a consultative capacity through its own counsel at its cost. Licensee will provide [***] cooperation and assistance requested by Novan in connection with any action taken by Novan with respect to an Infringement, including by making relevant employees, inventors, documents, materials and information available to Novan.
- (c) Enforcement by Licensee in the Licensee Field. In the event of a material Infringement (including a Paragraph IV Notice) in the Licensee Field that does not involve Novan Particles, if Novan does not commence an action based on the UNC Patents within (i) [***] ([***]) days after notice of the Infringement or (ii) [***] ([***]) days before the expiration of the time limit, if any, set forth by applicable law for the filing of such action in response to a Paragraph IV Notice, whichever comes first, and in the case of an Infringement other than one arising by reason of a Paragraph IV Notice, such Infringement otherwise has not been abated, Licensee will have the right (but not the obligation), at its sole discretion and expense, to take any and all action it deems necessary to stop such Infringement (or respond to such Paragraph IV Notice), including the bringing of an action based on the UNC Patents. Licensee will control the prosecution or settlement of any such action in consultation with Novan;

provided that Licensee agrees not to settle any such action without the prior written approval of Novan, not to be unreasonably withheld or delayed, and the prior written approval of UNC. Licensee will be permitted to bring such action in the name of Licensee only or in the name of both Licensee and Novan. Novan shall have the right (but not obligation, other than use of its name as set forth in the immediately preceding sentence) to participate in such action in a consultative capacity through its own counsel at its cost. Novan will provide [***] cooperation and assistance requested by Licensee in connection with any action taken by Licensee with respect to an Infringement pursuant to this Section 3.3(c), including by making relevant employees, inventors, documents, materials and information available to Licensee.

- (d) Invalidity Claims. In the event that an action or claim alleging invalidity, unenforceability or non-infringement of any of the UNC Patents shall be brought or made against Novan or Licensee, Novan, at its sole discretion, shall have the right, but not be obligated, within [***] ([***]) days after the commencement of such action or claim, to take or regain control of the action or defend such claim at its own expense. If Novan shall determine not to exercise this right, then Licensee may take over or remain in control of the action or defense in consultation with Novan; provided that Licensee agrees not to settle any such action or defense without the prior written approval of Novan.
- (e) Infringement Costs and Proceeds. Each Party shall bear its own costs incurred in connection with any action initiated or defended under this Section 3.3. Any monetary proceeds, damages and other relief obtained by a Party in connection with such an action ("Proceeds") shall be applied in the following order of priority: (i) first, to reimburse each Party for such costs paid by that Party in connection with such action, and (ii) second, after application of the foregoing clause (i), the Party that initiated or defended the action [***]. Notwithstanding the foregoing, any such amounts retained by Licensee in the form of lost profits shall be subject to the royalty payment obligation set forth in Section 2.6(b)(i), and any such amounts retained by Licensee in the form of an ongoing reasonable royalty, and/or consideration for an ongoing sublicense with respect to UNC Patents, shall be treated as Sublicensing Revenue subject to Section 2.6(b)(ii).
- (f) Novan Retained Rights. Except as expressly set forth in Section 3.3(c) and Section 3.3(d), Novan retains all rights with respect to enforcement and defense of the UNC Patents.
- (g) Rights of UNC. All rights of Novan and Licensee under this Section 3.3 are expressly subject to the terms of the UNC Agreement. Novan will use reasonable efforts to cause UNC to comply with its obligations under Article 9 of the UNC Agreement in connection with any Infringement. The Parties agree to cooperate reasonably with UNC with respect to matters described in this Section 3.3 to the extent required by the UNC Agreement.
- 3.4 Infringement Actions by Third Parties. If the production, sale, import or use of Licensed Products under this Agreement results in any claim for patent infringement against Licensee, any of its Affiliates, Sublicensees, or any customer(s) or sublicensee(s) of the foregoing, Licensee shall, upon becoming aware of such claim and subject to any applicable confidentiality obligations, promptly notify Novan and UNC thereof in writing, setting forth the facts of such claim in reasonable detail. As between the parties to this Agreement, Licensee shall have the first and primary right [***] at its own expense to defend and control the defense of any such claim, by counsel of its own choice. Licensee shall be free to enter into a settlement, consent judgment or other voluntary disposition of such actions which (i) [***], (ii) [***], or (iii) [***] must be approved by Novan and UNC, as applicable, such approval not being unreasonably withheld. Novan agrees to cooperate with Licensee in [***] defending any such action, and Novan will use reasonable efforts to cause UNC to cooperate in a similar manner. Licensee shall reimburse Novan and UNC for [***] out of pocket expenses incurred in providing such assistance. All rights of Novan and Licensee under this Section 3.4 are expressly subject to the terms of the UNC Agreement.

4. REPRESENTATIONS AND WARRANTIES

4.1 Power and Authority. Each Party represents and warrants to the other Party that: (a) it has the right, power, and authority to enter into and perform this Agreement, and to grant the licenses set forth herein, and that the person signing this Agreement on such Party's behalf has been duly authorized and empowered to enter into this Agreement; (b) the execution and delivery by such Party of this Agreement and the consummation by such Party of the transactions contemplated hereby have been duly authorized by all necessary corporate action on the part of such Party and no other corporate proceedings on the part of such Party are necessary to authorize this Agreement or to consummate the transactions contemplated hereby; (c) this Agreement has been duly executed and delivered by such Party and, assuming the due authorization, execution and delivery of this Agreement by the other Party, constitutes a legal, valid and binding obligation of such Party, enforceable against such Party in accordance with its terms; (d) the execution, delivery, and performance of and compliance with this Agreement will not, with or without the passage of time or giving of notice, (i) conflict with, or result in any violation of or default or loss of any benefit under, any provision of the certificate of incorporation or bylaws (or other company governing instruments) of such Party;

(ii) conflict with, or result in any violation of or default or loss of any benefit under, any permit, concession, grant, franchise, law, rule or regulation, or any order to which such Party is a party or to which any of its property is subject; (iii) conflict with, or result in a breach or violation of or default or loss of any benefit under, or accelerate the performance required by, the terms of any agreement, contract, indenture or other instrument to which such Party is a party or to which any of its property is subject; or (iv) result in the suspension, revocation, impairment, forfeiture or nonrenewal of any material permit, license, authorization or approval applicable to such Party, its business or operations or any of its assets or properties; and (e) no consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any governmental authority or any other person or entity is required to be obtained or filed by such Party in connection with the consummation of the transactions contemplated by this Agreement.

- 4.2 Disclaimers. EXCEPT AS SET FORTH IN SECTION 4.1 ABOVE, THE UNC PATENTS ARE PROVIDED "AS IS", AND NOVAN DISCLAIMS ALL REPRESENTATIONS AND WARRANTIES WITH RESPECT TO THE UNC PATENTS, WHETHER EXPRESS, IMPLIED OR STATUTORY, INCLUDING, BUT NOT LIMITED TO, ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE, VALIDITY, NON-INFRINGEMENT, NON-INTERFERENCE AND/OR QUIET ENJOYMENT, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES. WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, NOVAN EXPRESSLY DOES NOT REPRESENT OR WARRANT: (A) THE SAFETY OR USEFULNESS FOR ANY PURPOSE OF THE SUBJECT MATTER IT PROVIDES HEREUNDER; (B) THAT ANY PATENT WILL ISSUE ON ANY UNC PATENT; OR (C) THE VALIDITY OF ANY PATENT INCLUDED IN THE UNC PATENTS.
- **4.3 UNC Disclaimers.** Licensee hereby expressly acknowledges, for the benefit of Novan and UNC, the disclaimers and limitations of liability of UNC set forth in Article 10 of the UNC Agreement.

5. INDEMNITY: INSURANCE: LIMITATION OF LIABILITY.

- (a) In exercising its rights under this Agreement, Licensee shall materially comply with the requirements of any and all applicable laws, regulations, rules and orders of any governmental body having jurisdiction over the exercise of rights under this Agreement. Licensee further agrees to indemnify and hold UNC harmless from and against any costs, expenses, attorney's fees, citation, fine, penalty and liability of every kind and nature which might be imposed directly against UNC by reason of any asserted or established violation of any such laws, order, rules and/or regulations by Licensee.
- (b) Licensee agrees to indemnify, hold harmless and defend UNC, its and their respective officers, employees, and agents against any and all claims, suits, losses, damage, costs, fees, and expenses ("Losses") asserted by Third Parties, both government and private, resulting from or arising out of the exercise of Licensee's rights under this Agreement, provided such Losses do not result from UNC's or its employees', faculty's, students', or other agents or representatives' gross negligence, intentional misconduct, breach of this Agreement, or failure to comply with any applicable laws, rules, or regulations.
- (c) Licensee is required to maintain in force at its sole cost and expense, with reputable insurance companies, insurance coverage in amounts and of types reasonably sufficient to protect against liability under Sections 5(a) and 5(b) above. Novan and UNC shall have the right to ascertain [***] that such coverage exists, such right to be exercised in a reasonable manner.
- (d) NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, INCIDENTAL, PUNITIVE OR INDIRECT DAMAGES OR LOSS OF PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS ARTICLE 5 IS INTENDED TO OR SHALL LIMIT OR RESTRICT LICENSEE'S OBLIGATIONS UNDER THIS ARTICLE 5 OR THE DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE 6 OR [***].

6. CONFIDENTIALITY.

- **6.1 Confidential Information.** The Parties agree that, unless the Receiving Party obtains the prior written consent of the Disclosing Party, at all times during the term of this Agreement and for a [***] ([***]) year period following its expiration or earlier termination, the Receiving Party will keep completely confidential, will not publish or otherwise disclose and will not use directly or indirectly for any purpose other than as contemplated by this Agreement any Confidential Information of the Disclosing Party.
 - 6.2 Limited Disclosure Permitted. Each Party may disclose Confidential Information of the Disclosing Party to the extent that such disclosure is:

- (a) required by applicable laws, in the opinion of legal counsel to the Receiving Party; provided, however, that the Receiving Party will first have given reasonable notice to the Disclosing Party (if practicable) and given the Disclosing Party a reasonable opportunity to obtain a protective order or confidential treatment requiring that the Confidential Information and documents that are the subject thereof be held in confidence by the recipient or, if disclosed, be used only for purposes required by such law; provided further, however, that if a protective order is not obtained, the Confidential Information so disclosed will be limited to that information that is legally required to be disclosed by applicable laws;
- (b) made by Receiving Party to a governmental or regulatory authority as required to conduct clinical trials or obtain or maintain regulatory approval for products or services that are the subject of licenses granted to the Receiving Party under this Agreement;
- (c) made by Receiving Party to a Third Party as may be necessary or useful in connection with the manufacture, development and commercialization of any products or services that are the subject of licenses granted to the Receiving Party under this Agreement, in connection with financing activities of the Receiving Party, or in connection with the transfer or sale of all or substantially all of the business of the Receiving Party to which this Agreement relates to a Third Party, whether by merger, sale of stock, sale or transfer of assets or otherwise; provided, however, that: (i) each such Third Party has, in the reasonable determination of the Receiving Party, a need to know such Confidential Information and is bound by an agreement containing confidentiality and non-use obligations no less protective than those set forth in this Agreement in any material respect; (ii) the Receiving Party informs each Third Party receiving Confidential Information of its confidential nature; and (iii) the Receiving Party will be responsible for any breach of this Article 6 by any such Third Parties to the same extent as if the breach were by the Receiving Party;
- (d) made by a Receiving Party in order to comply with applicable securities law disclosure requirement or any disclosure requirements of any applicable stock market or securities exchange; or
 - (e) made by Novan pursuant to the UNC Agreement.
- **6.3 Terms of Agreement.** The Parties agree that the material terms of this Agreement shall be considered Confidential Information of both Parties, subject to the special authorized disclosure provisions set forth below in this Section 6.3 (in lieu of the authorized disclosure provisions set forth in Section 6.2, to the extent of any conflict) and without limiting the generality of the definition of Confidential Information set forth in Article 1. If either Party desires to make a public announcement concerning the terms of this Agreement, such Party shall give reasonable prior advance notice of the proposed text of such announcement to the other Party for its prior review and approval, such approval not to be unreasonably withheld. A Party shall not be required to seek the permission of the other Party to repeat or disclose any information as to the terms of this Agreement that has already been publicly disclosed by such Party in accordance with the foregoing or by the other Party, or any similar or comparable information. Either Party may disclose the terms of this Agreement to such Party's existing investors, lenders, directors and professional advisors and to potential investors, lenders, acquirors or merger partners and their professional advisors who are bound by written or professional obligations of non-disclosure and non-use that are at least as stringent as those contained in this Article 6 or are customary for such purpose. Each Party also may disclose the relevant terms of this Agreement to potential sublicensees who agree to be bound by obligations of non-disclosure and non-use at least as stringent as those contained in this Article 6 in all material respects. Novan may disclose this Agreement to UNC.
- **6.4 Publications.** Novan shall have the right to review and comment on any material proposed for disclosure or publication by Licensee, such as by oral presentation, manuscript or abstract, which includes data generated from the use of the UNC Patents or any Confidential Information of Novan. Before any such material is submitted for publication, Licensee shall deliver a complete copy to Novan at least [***] ([***]) days prior to submitting the material to a publisher or initiating any other disclosure. Novan shall review any such material and give its comments to Licensee within [***] ([***]) days of the delivery of such material to Novan. Licensee shall comply with Novan's request to delete references to Novan'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 [***] ([***]) days for the purpose of preparing and filing appropriate Patent applications.

7. TERM AND TERMINATION

7.1 Term. The term of this Agreement shall commence on the Effective Date and, unless earlier terminated in accordance with the provisions of this Article 7, shall expire upon the expiration of the last-to-expire of the UNC Patents. Upon such expiration (but not the earlier termination of this Agreement), the license granted under Section 2.2 shall continue in perpetuity on a non-exclusive basis in accordance with the terms of this Agreement.

- 7.2 Termination for Breach. Each Party may terminate this Agreement by written notice to the other Party at any time, if the other Party breaches any provision of this Agreement and fails to cure such breach within thirty (30) days of receipt of a written notice thereof from the non-breaching Party.
- 7.3 Termination for Patent Challenge. Novan may terminate this Agreement by written notice if Licensee or its Affiliate or sublicensee directly, or through assistance granted to a Third Party, commences or participates (except as such participation may be required by applicable law) in any interference, pre- or post-grant opposition or other pre- or post-grant proceeding related to the validity, enforceability and/or patentability of, or challenges the validity or enforceability of, any UNC Patent before any tribunal or patent office.
- 7.4 Additional Termination by Licensee. Licensee may terminate this Agreement for any reason or no reason without penalty on ninety (90) days written notice to Novan. Such termination shall become effective at the end of such ninety (90) day period.
- 7.5 Effect of Termination. Upon termination of this Agreement all licenses granted to Licensee and any sublicenses thereunder will cease to be in effect. In addition, upon termination of this Agreement, each Party shall return to the other Party, or destroy, all Confidential Information belonging to the other Party, in each case except as necessary for such Party's continued enjoyment of any license or right that survives termination of this Agreement.
- **7.6 Survival.** Expiration or termination of this Agreement for any reason will not relieve either Party of any obligation or liability accruing prior thereto and will be without prejudice to the rights and remedies of either Party with respect to any antecedent breach of the provisions of this Agreement. The provisions of Sections 2.2 (but only in connection with expiration of this Agreement and not its earlier termination), 2.4, 2.6 (to the extent required for Novan to comply with the UNC Agreement), 4.2, 4.3, 7.5, 7.6, 7.7 and 7.8, and Articles 1 (to the extent required to enforce other surviving rights and obligations), 5, 6 and 8, are intended to and shall survive termination or expiration of this Agreement in accordance with the terms of such Articles or Sections.
- 7.7 Bankruptcy Code. All licenses granted under this Agreement will be deemed licenses of rights to intellectual property for purposes of Section 365(n) of the United States Bankruptcy Code and a licensee under this Agreement will retain and may fully exercise all of its rights and elections under the United States Bankruptcy Code.
- 7.8 Additional Remedies. The remedies set forth in this Article 7 or elsewhere in this Agreement will be in addition to, and will not be to the exclusion of, any other remedies available to the Parties at law, in equity or under this Agreement.

8. GENERAL

- **8.1 Independent Contractors.** The Parties are and at all times will be and remain independent contractors as to each other, and at no time will either Party be deemed to be the agent or employee of the other. No joint venture, partnership, agency, or other relationship will be created or implied as a result of this Agreement.
- **8.2 Governing Law.** Any questions, claims, disputes, or litigation concerning or arising from this Agreement shall be governed by the laws of the State of North Carolina without giving effect to the conflicts of laws principles of that state or other country. Subject to Section 8.3, all disputes with respect to this Agreement shall be brought and heard exclusively either in the North Carolina state courts located in Durham County, North Carolina, or the federal district court for the Middle District of North Carolina located in Wake County, North Carolina. The Parties each consent to the *in personam* jurisdiction and venue of such courts exclusively.

8.3 Dispute Resolution.

(a) Organization Resolution. The Parties will try to settle their differences amicably between themselves. In the event of any controversy or claim arising out of or relating to any provision of this Agreement or the performance or alleged non-performance of a Party of its obligations under this Agreement ("Dispute"), a Party may notify the other Party in writing of such Dispute. Upon a Party's receipt of written notice of a Dispute, the Dispute will be referred to the respective representatives of the Parties with authority to resolve the Dispute. If the designated representatives of the Parties are unable to resolve the Dispute within [***] ([***]) days of receipt of the written notice by the other Party, the Dispute will be referred to the Chief Executive Officers of each of the Parties (or any other representative) designated by the board of directors of the applicable Party) who will use their good faith efforts to resolve the Dispute within [***] ([***]) days after it was referred to the Chief Executive Officers (or other such representative).

- (b) Arbitration. Any Dispute that is not resolved as provided in Section 8.3(a), whether before or after termination of this Agreement, will be resolved by final and binding arbitration. Each Party may refer such Dispute for arbitration by written notice to the other Party. Such Disputes will be finally settled by the American Arbitration Association ("AAA") under its Commercial Arbitration Rules and Mediation Procedures (the "Rules"), or by such other arbitration tribunal or arbitration rules as the Parties may agree upon. Arbitration proceedings will be held in Raleigh, North Carolina, U.S.A, or in another place which is mutually agreeable to the Parties. The arbitration shall be conducted and the award shall be rendered in English. The arbitration will be conducted by three (3) arbitrators agreed to by the Parties within [***] ([****]) days of receipt by respondents of the request for arbitration or, in default of such agreement, according to the Rules' Expedited Procedures for the Appointment and Qualifications of Arbitrators. [***] selected shall be a lawyer with pharmaceutical and medical device industry legal experience. During the period beginning with the selection of the arbitrators and ending upon the conclusion of the arbitration proceedings, the Parties may conduct such discovery as is permitted under the Rules; provided, however, that the Parties shall be entitled, without any further showing of good cause to the arbitrators, to [***]. In conducting the arbitration, the arbitrators will apply the Rules as they apply to matters of evidence. The decision by the arbitrators shall be final and binding upon the Parties, their successors and permitted assigns and the Parties will comply with such decision in good faith. The award may be entered and enforced in any court having jurisdiction. Without limitation of the foregoing, each Party hereby submits itself to the jurisdiction of the courts of the place where the arbitration is held, but only for the entry of judgment with respect to the decision of t
- (c) [***] Arbitration for Certain Matters. Notwithstanding the foregoing provisions of Section 8.3(b), any Disputes related to [***] of this Agreement shall be resolved through binding arbitration administered by the AAA as follows:
 - (i) Within [***] ([***]) days of receipt by respondent of the request for arbitration, the Parties shall designate in writing a single arbitrator to resolve the dispute. If the Parties cannot agree on an arbitrator within such [***]-day period, or if the arbitrator agreed to by the Parties declines to serve, an arbitrator shall be selected, within [***] ([***]) days after notice from either Party of such inability to agree on an arbitrator willing to serve, by the AAA. The arbitrator shall be a lawyer with pharmaceutical and medical device industry legal experience who is available to serve on the timetable established in this Section 8.3(c), and shall not be an Affiliate, or an employee, consultant, legal advisor, officer, director or stockholder of, or have any conflict of interest with respect to, any Party. Arbitration proceedings will be held in Raleigh, North Carolina, U.S.A, or in another place which is mutually agreeable to the
 - (ii) The Party submitting a dispute to arbitration shall include with its notice pursuant to Section 8.3(b) a written summary of the disputed issues, not to exceed [***] ([***]) pages per disputed issue, and a proposed ruling on the merits of each such issue. Within [***] ([***]) days thereafter, the other Party shall provide a written response, not to exceed [***] ([***]) pages per disputed issue, as well as such other Party's proposed ruling on the merits of each disputed issue, to the Party initiating such arbitration and to the arbitrator.
 - (iii) Within [***] ([***]) days after the selection of the arbitrator and in any event within [***] ([***]) days after the notice initiating the arbitration, the arbitrator and the Parties shall meet. During such meeting, the arbitrator shall establish a schedule for discovery. Unless the Parties otherwise agree, the arbitrator shall limit discovery by each Party to [***]. The Parties shall have [***] ([***]) days to respond to written discovery. Depositions shall be scheduled at the mutual convenience of the Parties and the witnesses; provided that all discovery shall be conducted so as to be completed within [***] ([***]) days after the initiation of arbitration.
 - (iv) The arbitrator shall set a date for a hearing, which shall be no later than [***] ([***]) days after the notice initiating the arbitration pursuant to Section 8.3(b). At the hearing, in accordance with a schedule established by the arbitrator, the Parties shall present evidence with respect to each of the disputed issues.
 - (v) Within [***] ([***]) days following the close of the hearing, the Parties shall submit post-hearing briefs to the arbitrator. The post-hearing briefing shall not exceed twenty double-spaced pages. Within [***] ([***]) days after the timely submission of post-hearing briefs, the arbitrator shall enter a written award that rules on each disputed issue and that sets forth the grounds for the decision, applying the law of the State of North Carolina. The determination of the arbitrator as to the resolution of any dispute shall be binding and conclusive on all Parties. Either Party may bring an action in any court of competent

jurisdiction to enforce a final award entered by the arbitrator. The Parties expressly agree that the state and federal courts located in the State of North Carolina have jurisdiction to confirm the arbitration award and enter judgment thereon. The Parties hereby waive any and all objections and defenses to such jurisdiction regardless of the nature of such objection or defense.

- (vi) The (i) [***], (ii) [***] and (iii) [***], shall be borne by the non-prevailing Party or, if neither Party is the prevailing Party as to all disputed issues, by the Parties in inverse proportion to the proportion of the dispute on which they prevailed, respectively, as determined by the arbitrator. Prior to such determination, each Party shall bear its own [***] and [***]; provided that the arbitrator shall, in his or her final award, require the non-prevailing Party (or the Party that prevails on [***]) to reimburse the other Party for the excess share of such costs and expenses borne by such other Party prior to such determination.
 - (vii) Except as modified by this Section 8.3(c), Disputes subject to arbitration hereunder shall be governed by the Rules.
- (d) Confidentiality. Except as may be required by applicable law, neither a Party nor the arbitrator(s) may disclose the existence, content or results of any arbitration award without the prior written consent of both Parties, unless to protect or pursue a legal right.

(e) Disputes Not Subject to Arbitration.

- (i) IP Disputes. Notwithstanding the Parties' agreement to arbitrate, unless the Parties agree in writing in any particular case, claims and disputes between the Parties relating to or arising out of, or for which resolution depends in whole or in part on a determination of the interpretation, validity, enforceability or infringement of, Patents or the misappropriation of trade secrets, shall not be subject to arbitration under this Agreement, and the Parties may pursue whatever rights and remedies may be available to them under law or equity, including litigation in a court of competent jurisdiction, with respect to such claims and disputes.
- (ii) Emergency Relief. Notwithstanding the Parties' agreement to arbitrate, the Parties hereby agree that either Party may apply to any court of law or equity of competent jurisdiction for specific performance or injunctive relief to enforce or prevent any violation of this Agreement. Without prejudice to such provisional remedies as may be available under the jurisdiction of a court, the arbitral tribunal under this Section 8.3 shall have full authority to grant provisional remedies and to direct the Parties to request that any court modify or vacate any temporary or preliminary relief issued by such court, and to award damages for the failure of any Party to respect the arbitral tribunal's orders to that effect.
- 8.4 No Assignment. Neither Party may assign, delegate or otherwise transfer, in whole or in part, any rights or obligations under this Agreement, by operation of law or otherwise, without the other Party's express prior written consent, which shall not be unreasonably withheld; provided, however, that a Party may assign or transfer its rights and delegate its obligations under this Agreement without such consent: (a) to the transferee or successor entity to such Party upon the transfer or sale of all or substantially all of the business of such Party to which this Agreement relates to a Third Party, whether by merger, sale of stock, sale or transfer of assets or otherwise; or (b) to an Affiliate, provided that the assigning Party shall remain liable and responsible to the other Party for the performance and observance of all such duties and obligations by such Affiliate for so long as such entity remains an Affiliate of the assigning Party. In the case of any permitted assignment or transfer of or under this Agreement, this Agreement shall be binding upon, and inure to the benefit of, the transferees, successors and assigns of the Parties hereto. Any attempted assignment, delegation, or transfer in violation of the foregoing will be null and void.
- **8.5 Compliance with Laws.** Each Party will comply with all applicable federal, state, provincial and local laws, rules, and regulations in performance of its obligations under this Agreement.
- **8.6 Notices.** All notices or reports permitted or required under this Agreement will be in writing and will be delivered by personal delivery, telecopier, facsimile transmission, or by certified or registered mail, return receipt requested, and shall be deemed given upon personal delivery, five days after deposit in the mail, or upon acknowledgment of receipt of electronic transmission. Notices shall be sent to the addresses set forth below. Either party may amend its address upon written notice to the other.

If to Novan:	If to Licensee:
Novan, Inc.	KNOW Bio, LLC
4222 Emperor Boulevard, Suite 200	627 Davis Drive, Suite 400
Durham, NC 27703	Morrisville, NC 27560
Attn:	Attn:
Fax	Fax

- 8.7 Waivers; Amendment. No waiver of any terms or conditions of this Agreement will be valid or binding on a Party unless such Party makes the waiver in writing. Any such waiver shall constitute a waiver only with respect to the specific matter described therein and shall in no way impair the rights of the Party granting such waiver in any other respect or at any other time. The failure of one Party to enforce any of the provisions of this Agreement, or the failure to require at any time the performance of the other Party of any of the provision of this Agreement, will in no way be construed to be a present or future waiver of such provisions, nor in any way affect the ability of a Party to enforce each and every provision thereafter. This Agreement may not be altered, amended, modified, or otherwise changed in any way except by a written instrument signed by the authorized representatives of each Party.
- **8.8 Severability.** If any provision of this Agreement is found or held to be invalid or unenforceable by any tribunal of competent jurisdiction, then the meaning of such provision will be construed, to the extent feasible, so as to render the provision enforceable, and if no feasible interpretation would save such provision, it will be severed from the remainder of this Agreement, which will remain in full force and effect.
- 8.9 Construction. The headings of sections of this Agreement are included solely for convenience of reference and are not to be used to interpret, construe, define, or describe the scope of any aspect of this Agreement. As used in this Agreement, the word "including" means "including but not limited to". Each Party represents that it has had the opportunity to participate in the preparation of this Agreement, and any rule of construction to the effect that ambiguities are to be resolved against the drafting Party will not be followed in connection with the construction or interpretation of this Agreement. For purposes of this Agreement, the word "will" shall be equivalent in meaning to the word "shall," both of which describe an act or forbearance which is mandatory under this Agreement. The word "may" describes an act or forbearance which is optional under this Agreement. Unless otherwise expressly stated to the contrary herein, all remedies are cumulative, and the exercise of any express remedy by either Party does not by itself waive such Party's right to exercise its other rights and remedies available at law or in equity.
- **8.10 Entire Agreement.** This Agreement, including its attached exhibit, constitutes the entire agreement and final understanding of the Parties with respect to the subject matter hereof, and supersedes any other and all prior or contemporaneous negotiations, representations, understandings, discussions, offers, and agreements between the Parties, whether written or oral, express or implied, relating in any way to the subject matter hereof. This Agreement is intended by the Parties to be a complete and wholly integrated expression of their understanding and agreement.
- 8.11 Counterparts. This Agreement may be executed in counterparts (by facsimile transmission or in Adobe Portable Document Format (PDF) sent by electronic mail), each of which will be considered an original, but all of which together will constitute one and the same instrument.

Signature Page to Follow

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives.

Novan, Inc.		KNOW Bio, LL	KNOW Bio, LLC		
:	/s/ Nathan Stasko	By:	/s/ Neal Hunter		
me:	Nathan Stasko, PhD	Name:	Neal Hunter		
le:	President	Title:	Managing Director		

Appendix A
UNC Patents
[***]



Appendix B

Additional UNC Patents

[***]

Certain confidential information contained in this exhibit have been omitted by means of redacting a portion of the text and replacing it with [***], pursuant to Regulation S-K Item 601(b) of the Securities Act of 1933, as amended. Certain confidential information has been excluded from this exhibit because it is: (i) not material; and (ii) the registrant treats such information as private or confidential.

Execution Copy

NOVAN PATENT AND KNOW-HOW LICENSE AGREEMENT

THIS NOVAN PATENT AND KNOW-HOW LICENSE AGREEMENT (this "Agreement") is made as of December 29, 2015 (the "Effective Date") by and between Novan, Inc., a Delaware corporation with a principal place of business at 4222 Emperor Boulevard, Suite 200, Durham, NC 27703 ("Novan"), and KNOW Bio, LLC, a North Carolina limited liability company with a principal place of business at 627 Davis Drive, Suite 400, Morrisville, NC 27560 ("Licensee"). Novan and Licensee may each be referred to as a "Party," and together as the "Parties."

RECITALS

WHEREAS, as of the Effective Date. Licensee is a wholly-owned subsidiary of Novan:

WHEREAS, following the Effective Date, Novan is transferring all of the ownership interests in Licensee to the stockholders of Novan on a pro rata basis, and Novan will no longer have any ownership interest in Licensee;

WHEREAS, Novan owns certain Patents and Know-How related to pharmaceutical and medical device applications of nitric oxide, and Licensee is interested in further developing and commercializing such Patents and Know-How in the Licensee Field (each as defined below);

WHFREAS, contemporaneously with this Agreement, Novan and Licensee are, among other things, entering into three separate license agreements, under which Novan is granting to Licensee a license under certain other Patents owned by Novan and sublicenses under certain Patents licensed by Novan from third parties, in each case in the Licensee Field; and

WHEREAS, subject to the terms and conditions set forth in this Agreement, Novan is willing to grant to Licensee a license under the Novan Patents and to Novan Know-How to further develop and commercialize, on a worldwide basis, Licensed Products (each as defined below) in the Licensee Field.

NOW, THEREFORE, for good and valuable consideration, receipt of which is hereby acknowledged, the Parties agree as follows:

AGREEMENT

- 1. DEFINITIONS. Capitalized terms shall have the meanings ascribed to them below or in this Agreement.
- 1.1 "Affiliate" means, with respect to a Party, any Person directly or indirectly controlling, controlled by, or under common control with, such Party. For purposes of this definition only, the term "controlled" (including the terms "controlled by" and "under common control with") as used in this context, means the direct or indirect ability or power to direct or cause the direction of management policies of a Person or otherwise direct the affairs of such Person, whether through ownership of equity, voting securities, beneficial interest, by contract or otherwise. For clarity, Novan and Licensee shall not be deemed Affiliates. In addition, Affiliate shall not include any Acquirer of a Party or of any of its Affiliates, where "Acquirer" means, with respect to a Party or its Affiliate, any Third Party that, directly or indirectly, comes to control such Party or such Affiliate, or any Third Party which acquires such Party or such Affiliate, whether by merger or otherwise.
- 1.2 "Confidential Information" means information disclosed (whether in writing, electronically, orally or by observation) by one Party (the "Disclosing Party") to the other Party (the "Receiving Party") unless in each case such information, as shown by competent evidence:

- (a) was known to the Receiving Party or to the general public prior to the Disclosing Party's disclosure, as demonstrated by contemporaneous written records;
- (b) became known to the general public, after the Disclosing Party's disclosure hereunder, other than through a breach of the confidentiality provisions of this Agreement by the Receiving Party or any Person to whom such Receiving Party disclosed such information;
 - (c) was subsequently disclosed to the Receiving Party by a Person having a legal right to disclose, without any restrictions, such information; or
 - (d) was developed by the Receiving Party independent of the Disclosing Party's Confidential Information.

For clarity, the Novan Know-How constitutes Confidential Information of Novan, and the Licensee New Nitric Oxide Know-How and New Device IP constitutes Confidential Information of Licensee.

- 1.3 "Control" means, with respect to any Know-How or Patents, that a Party or any of its Affiliates owns such Know-How or Patents and has the ability to grant to the other Party access and a license to the foregoing, including on the terms and conditions set forth in this Agreement, as applicable, without violating the terms of any agreement or other arrangement with any Third Party. The term "Controlled" shall be construed accordingly.
- 1.4 "Know-How" means any data, results, technology, business information, technical information and other information of any type whatsoever, in any tangible or intangible form, including, without limitation, know-how, intellectual property, practices, techniques, analytical methods and other methods, processes, inventions, developments, development reports, 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, toxicological, preclinical and clinical test data), analytical and quality control data, stability data, other study data and procedures, case report forms, data analyses, and information contained in submissions to and information from ethical committees and regulatory authorities. Know-How includes any rights, including trade secrets, copyright, database rights or design rights, protecting such Know-How.
- 1.5 "Licensed Product" means any pharmaceutical products and medical devices covered by any claim of the Novan Patents or developed utilizing any Novan Know-How, other than any products or devices that incorporate or utilize Novan Particles. For clarity, the products existing as of the Effective Date with the internal Novan designations NVN1000 and NVN4000 are not Licensed Products.
- 1.6 "Licensee Field" means all diagnostic, therapeutic, prophylactic and palliative uses for any disease, condition or indication in humans or animals that is outside of the Novan Retained Field.
 - 1.7 "Licensee New Nitric Oxide Know-How" means, to the extent Controlled by Licensee or any of its Affiliates, any New Nitric Oxide Know-How that is not New Device IP.
 - 1.8 "Licensee New Nitric Oxide Patents" means, to the extent Controlled by Licensee or any of its Affiliates, any New Nitric Oxide Patents that are not New Device IP.
- 1.9 "New Device IP" means, to the extent Controlled by Licensee or any of its Affiliates: (a) any Patents that disclose an invention comprising a medical device, and/or a combination of a pharmaceutical product and a medical device, conceived by Licensee or any of its Affiliates during the New Nitric Oxide Period; and (b) any Know-How that (i) comes to be Controlled by Licensee or any of its Affiliates during the New Nitric Oxide Period and (ii) is necessary for the practice of such Patents or otherwise directly relates to a medical device, and/or a combination of a pharmaceutical product and a medical device; but [***].
- 1.10 "New Nitric Oxide Know-How" means any Know-How that (i) comes to be Controlled by a Party or any of its Affiliates during the New Nitric Oxide Period and (ii) is necessary or useful for the practice of New Nitric Oxide Patents Controlled by such Party or otherwise relates to any nitric oxide-releasing chemistries, materials, formulations, products or devices, or any method of manufacture or use thereof; but [***].
- 1.11 "New Nitric Oxide Patents" means any Patents Controlled by a Party or any of its Affiliates that (i) disclose an invention conceived by such Party or any of its Affiliates during the New Nitric Oxide Period and (ii) include claims to any nitric oxide-releasing chemistries, materials, formulations, products or devices, or any method of manufacture or use thereof; but [***].

- 1.12 "New Nitric Oxide Period" means the period beginning on the Effective Date and ending on the third anniversary of the Effective Date.
- 1.13 "Novan Know-How" means, to the extent Controlled by Novan or any of its Affiliates: (a) all Know-How existing as of the Effective Date that is related to the Novan Patents or the Separately-Licensed Patents; and (b) any New Nitric Oxide Know-How. For clarity, Novan Know-How as of the Effective Date includes all such Know-How generated as part of Novan's wound care development program, and includes all data from all Novan development and testing utilizing a wound model or relevant to the Licensee Field, in each case prior to the Effective Date. Notwithstanding the foregoing, Novan Know-How does not include the Wound Care Device Data or any Know-How that specifically relates to any products or devices that incorporate or utilize Novan Particles (including the products existing as of the Effective Date with the internal Novan designations NVN1000 and NVN4000) or any method of manufacture or use thereof.
 - **1.14** "Novan Particles" means any particles that include: (a) [***]; (b) [***]; (c) [***]; or (d) [***].
- 1.15 "Novan Patents" means, to the extent Controlled by Novan or any of its Affiliates: (a) the Patents set forth in <u>Appendix A</u>, and any Patents claiming priority from those Patents; and (b) any New Nitric Oxide Patents. Notwithstanding the foregoing, the Novan Patents do not include any claims within such Patents that are directed to any products or devices that incorporate or utilize Novan Particles (including the products existing as of the Effective Date with the internal Novan designations NVN1000 and NVN4000) or any method of manufacture or use thereof.
- 1.16 "Novan Retained Field" means: (a) all diagnostic, therapeutic, prophylactic and palliative uses for any disease, condition or disorder of the skin, nails, hair or scalp in humans or animals, including [***], as well as any other dermatological diseases, conditions or disorders (including [***]); and (b) all cosmetic uses for the skin, nails, hair or scalp. Notwithstanding the foregoing, the Novan Retained Field does not include: (i) wound (i.e., [***]) care by use of pharmaceutical products formulated specifically to treat chronic wounds, thermal burns, radiation injury, accidental injury, surgical sites or scars; or (ii) therapeutic uses for any form of cancer, excluding basal cell carcinoma, squamous cell carcinoma and any forms of precancerous skin lesions or precancerous skin conditions, including actinic keratosis, actinic cheilitis, cutaneous hom, Bowen disease, radiation dermatosis, and dysplastic nevi.
- 1.17 "Patents" means any of the following, whether existing now or in the future anywhere in the world: (a) patents and patent applications; (b) continuations, continuations-in-part, provisionals, divisionals and substitute applications with respect to any such patent application; (c) any patents issued based on or claiming priority to any such patent applications; (d) any reissue, reexamination, renewal, patents of addition, or extension (including any supplemental patent certificate) of any such patents; and (e) any confirmation patent or registration patent or patent of addition based on any such patents.
- 1.18 "Person" means a natural person, a corporation, a partnership, a trust, a joint venture, a limited liability company, any governmental authority, or any other entity or organization.
- 1.19 "Post Grant Proceeding" means any and all proceedings before any patent office in the Territory that involves the review, examination, analysis or any combination thereof of any issued Patent, including without limitation post grant review proceedings, inter partes review proceedings, supplemental examinations, patent interference proceedings, opposition proceedings, and reexaminations.
- 1.20 "Prosecute" and "Prosecution" means the preparation, filing, prosecution and maintenance of Patents, including seeking patent extensions and supplementary protection certificate applications pursuant to 35 U.S.C. § 156 or similar statutes, but excluding Post Grant Proceedings.
- 1.21 "PTO" means, as applicable, the United States Patent and Trademark Office or any other relevant patent office in any country of the Territory other than the United States.
- 1.22 "Separately-Licensed Patents" means, to the extent Controlled by Novan: (a) the Patents in <u>Appendix B</u>; (b) any other Patents licensed by UNC to Novan under the UNC Agreement after the Effective Date ("Additional UNC Patents"); and (c) any Patents claiming priority from the foregoing Patents. The Parties will promptly update <u>Appendix C</u> in writing to reflect any additional Patents that become licensed by UNC to Novan under the UNC Agreement after the Effective Date.
 - 1.23 "Territory" means all countries of the world, or worldwide.
 - 1.24 "Third Party" means any entity other than Licensee or Novan or an Affiliate of Novan or Licensee.

- 1.25 "UNC Agreement" means the Amended, Restated and Consolidated License Agreement dated June 27, 2012 between Novan and The University of North Carolina at Chapel Hill ("UNC"), as in effect from time to time.
- 1.26 "Wound Care Device Data" means all data assigned by Novan to Licensee pursuant to that certain assignment and assumption agreement of even date herewith, under which Novan assigned to Licensee certain data solely related to the medical device that was under development by Novan for wound care prior to the Effective Date.

2. LICENSE GRANTS

- 2.1 Exclusive License under Novan Patents. Subject to the terms and conditions of this Agreement, Novan agrees to grant and hereby grants to Licensee a fully-paid, royalty-free, exclusive (even as to Novan and its Affiliates), sublicensable (through multiple tiers), license in the Territory, under the Novan Patents, to develop, make, have made, use, sell, offer for sale, import and export Licensed Products in the Licensee Field.
- 2.2 Non-Exclusive License to Novan Know-How. Subject to the terms and conditions of this Agreement, Novan agrees to grant and hereby grants to Licensee a fully-paid, royalty-free, non-exclusive, sublicensable (through multiple tiers), license in the Territory, to the Novan Know-How, to develop, make, have made, use, sell, offer for sale, import and export Licensee Products in the Licensee Field.
- 2.3 Exclusive Licensee under Licensee New Nitric Oxide Patents. Subject to the terms and conditions of this Agreement, Licensee agrees to grant and hereby grants to Novan a fully-paid, royalty-free, exclusive (even as to Licensee and its Affiliates), sublicensable (through multiple tiers), license in the Territory, under the Licensee New Nitric Oxide Patents, to develop, make, have made, use, sell, offer for sale, import and export products and services in the Novan Retained Field.
- 2.4 Non-Exclusive License to License New Nitric Oxide Know-How. Subject to the terms and conditions of this Agreement, Licensee agrees to grant and hereby grants to Novan a fully-paid, royalty-free, non-exclusive, sublicensable (through multiple tiers), license in the Territory, to the Licensee New Nitric Oxide Know-How, to develop, make, have made, use, sell, offer for sale, import and export products and services in the Novan Retained Field.
- 2.5 Sublicenses. All sublicenses granted under Section 2.1 or Section 2.2 of this Agreement must be in writing and must contain provisions that are not inconsistent with the terms and conditions of this Agreement. Licensee promptly shall provide a copy to Novan of any sublicense entered into hereunder. Licensee shall be directly and primarily responsible and liable for any acts or omissions of its sublicensees in relation to any subject matter of this Agreement.
- 2.6 Retained Rights; No Implied Licenses. Only the licenses expressly granted under this Agreement shall be of legal force and effect. No other licenses shall be created under this Agreement by implication, estoppel or otherwise. For clarity, (i) Novan retains the exclusive rights under the Novan Patents and Novan Know-How in the Territory to develop, make, have made, use, sell, offer to sell and import any and all products and services in the Novan Retained Field, and (ii) Licensee retains the exclusive rights under the Licensee New Nitric Oxide Patents and Licensee New Nitric Oxide Know-How in the Territory to develop, make, have made, use, sell, offer to sell and import any and all products and services in the Licensee Field. Novan retains the right under the Novan Patents and Novan Know-How to conduct research and development related to any of the subject matter claimed in the Novan Patents; provided that such research and development is not conducted for the purpose of commercialization of Licensee Products in the Licensee Field. Licensee New Nitric Oxide Patents and Licensee New Nitric Oxide Know-How to conduct research and development related to any of the subject matter claimed in the Licensee New Nitric Oxide Patents; provided that such research and development is not conducted for the purpose of commercialization of products and services in the Novan Retained Field. In addition, notwithstanding the foregoing, any and all licenses and other rights granted hereunder are limited by and subject to the rights and requirements of the United States Government which arise out of its sponsorship (if any) of the research which led to the conception or reduction to practice of the inventions covered by Novan Patents or Licensee New Nitric Oxide Patents. To the extent applicable due to any such sponsorship, the United States Government is entitled, as a right, under the provisions of 35 U.S.C. §§ 200-212 and applicable regulations of Title 37 of the Code of Federal Regulations, to a non-exclusive, nontransferable
 - 2.7 Technology Transfer.

- (a) After the Effective Date, Novan agrees to use reasonable efforts to provide promptly to Licensee a copy of all Novan Know-How existing as of the Effective Date and requested by Licensee.
- (b) During the New Nitric Oxide Period, Novan shall keep Licensee informed of the status of any New Nitric Oxide Patents and New Nitric Oxide Know-How that would be licensee under the licensee granted by Novan in this Article 2 by providing, on each [***] anniversary of the Effective Date during the New Nitric Oxide Period (including on the [***] of the Effective Date), a copy of all such Patents filed by Novan or any of its Affiliates during the preceding [***] period, and a reasonable summary of all such Know-How.
- (c) During the New Nitric Oxide Period, Licensee shall keep Novan informed of the status of any Licensee New Nitric Oxide Patents and Licensee New Nitric Oxide Know-How that would be licensed to Novan under the licenses granted by Licensee in this Article 2 by providing, on each [***] anniversary of the Effective Date during the New Nitric Oxide Period (including on the [***] of the Effective Date), a copy of all such Patents filed by Licensee or any of its Affiliates during the preceding [***] period, and a reasonable summary of all such Know-How.
- 2.8 Right of First Negotiation. Licensee hereby grants to Novan a right of first negotiation during the New Nitric Oxide Period, as set forth below in this Section 2.8, with respect to New Device IP. During the New Nitric Oxide Period, if Licensee or any of its Affiliates [***] to sell, out-license or otherwise grant rights in or to any New Device IP for use in any portion or all of the Novan Retained Field (a "ROFN Opportunity"), then Licensee will notify Novan in writing of its intent to pursue such ROFN Opportunity. At the use in any portion or all of the Novan Retained Field (a "ROFN Opportunity"), then Licensee will notify Novan in writing of its intent to pursue such ROFN Opportunity. At the request of Novan, Licensee will [***]

 [***] and available to Licensee. Within [***] ([***]) days of Novan's receipt of the written notice, Novan will respond to Licensee in writing regarding Novan's interest in the ROFN Opportunity. If Novan indicates interest in pursuing the ROFN Opportunity, then the Parties will negotiate in good faith for a period of at least [***] ([***]) days to enter into a definitive agreement regarding such ROFN Opportunity. If, (i) Novan indicates no interest in the ROFN Opportunity or does not respond to Licensee's notice of the ROFN Opportunity within such [***] ([***]) day period, or (ii) Novan and Licensee do not enter into a definitive agreement within such [***] ([***]) day period, then Licensee will be free to pursue the ROFN Opportunity (including in the [***]) and will be deemed to have discharged its obligations under this Section 2.8 in full with respect to such ROFN Opportunity; provided, however, that if at the end of such [***] ([***]) day period the Parties are actively negotiating the terms of a definitive agreement, then such [***] ([***]) day period may be extended to a mutually acceptable time by the Parties in writing. For clarity, nothing in this Section 2.8 shall be construed as a license or other grant of rights by Novan under any Novan Patents or Novan Know-How, including in the Novan Retained Field.

2.9 Non-Compete During New Nitric Oxide Period.

- (a) Novan. During the New Nitric Oxide Period, Novan and its Affiliates shall not, directly or indirectly, manufacture commercial quantities of, or market, sell, promote or otherwise commercialize any nitric oxide-releasing chemistries, materials, formulations, products or devices for use in the Licensee Field.
- (b) Licensee. During the New Nitric Oxide Period, Licensee and its Affiliates shall not, directly or indirectly, manufacture commercial quantities of, or market, sell, promote or otherwise commercialize any nitric oxide-releasing chemistries, materials, formulations, products or devices for use in the Novan Retained Field. The foregoing restriction shall not apply to the subject matter of any ROFN Opportunity with respect to which Licensee has discharged its obligations under Section 2.8.
 - (c) Acquirers. For clarity, the restrictions in Section 2.9(a) and Section 2.9(b) shall not apply to any Acquirer of either Party or of any of its Affiliates.
- 2.10 Extension of New Nitric Oxide Period. The Parties acknowledge that the New Nitric Oxide Period may be extended by the Parties if mutually agreed. No extension of the New Nitric Oxide Period shall become effective unless mutually agreed in writing by both Parties.

3. PATENT PROSECUTION AND ENFORCEMENT OF NOVAN PATENTS

3.1 Prosecution of Novan Patents.

(a) Prosecution by Novan. Except as provided for in Section 3.1(b), Novan shall have the exclusive right to Prosecute the Novan Patents, as Novan determines in good faith, [***]. In the event that Novan desires not to continue to Prosecute any of the Novan Patents, Novan shall notify Licensee sufficiently in advance of any deadlines to afford Licensee an opportunity to request that Novan continue the Prosecution of such Patent prior to such Patent lapsing or becoming abandoned. If

requests in writing that Novan continue to Prosecute such Novan Patent, then Novan will continue to do so in accordance with this Section 3.1(a), [***].

- (b) Filing of Continuations, Divisionals and National Applications by Licensee. If Licensee desires to file a continuation, divisional or national Patent application to any of the Novan Patents that Novan has not filed, Licensee will notify Novan of such desire, and Novan may elect to Prosecute such Patent [***]. Novan will notify Licensee of its election whether or not to Prosecute such Patent within [***] ([***]) days of such notice from Licensee. If Novan does not elect to Prosecute such Patent within such [***] ([***]) day period, then Licensee may Prosecute such Patent [***]. Licensee shall control the Prosecution of such Patent (whether Prosecuted by Novan or by Licensee) in consultation with Novan; provided, however, that all Prosecution decisions will be subject to Novan's prior written approval (not to be unreasonably withheld). In no event will Licensee be permitted to undertake any act in the Prosecution of such Patent that may adversely affect the scope, enforceability or patentability of any other Novan Patent, as determined by Novan in good faith. For clarity, any Patent Prosecuted by either Party pursuant to this Section 3.1(b) shall be a Novan Patent and owned solely by Novan and licensed under Section 2.1 of this Agreement to Licensee.
- (c) Cooperation in Prosecution. The Party exercising the right to Prosecute Novan Patents pursuant to this Section 3.1 will (i) use reasonable efforts to apprise the other Party of any significant developments in the Prosecution of such Novan Patent, and (ii) copy the other Party, or have the other Party copied, on all official correspondence relating to the relevant Novan Patents received from or to be filed with the PTO, within [***] ([***]) days of receipt from the PTO and present a draft of any material proposed response to such correspondence at least [***] ([***]) days prior to filing with the PTO, respectively, including without limitation copies of each patent application, official action, response to official action, declaration, information disclosure statement, terminal disclaimer filing, and request for reexamination. The Party that is not Prosecution any particular Novan Patent shall cooperate reasonably with the Party that is conducting Prosecution of such Novan Patent. [***] shall satisfy its obligations under this Section 3.1 to fund Prosecution costs incurred by [***] by reimbursing [***] on a [***] basis within [***] ([***]) days of receipt of reasonable documentation of such Prosecution costs incurred by Novan in the prior [***].

3.2 Post Grant Proceedings.

- (a) Third Party Defense. In the event that Novan becomes aware that a Third Party has filed a Post Grant Proceeding with respect to any Novan Patent, Novan will notify Licensee in writing to that effect within [***] ([***]) days of becoming aware of such filing. Once such a Post Grant Proceeding has commenced, Novan shall have the first right to respond to and/or contest such proceeding; provided, however, that if Novan does not take action to respond to and/or contest such proceeding by [***] ([***]) days before the expiration of the time limit, if any, set forth in the applicable laws and regulations for such response or contest, then Licensee shall have the right to respond to and/or contest such proceeding. The Party that responds to and/or contests such Post Grant Proceeding shall provide the other Party: (i) with a copy of any action, communication, letter or other correspondence issued by the PTO or the Third Party within [***] ([***]) days of receipt thereof; (ii) with a copy of any proposed response, amendment, paper or other correspondence to be filed with the PTO no less than [***] ([***]) days prior to filing the same in the PTO, unless otherwise agreed by patent counsel for both Parties; provided that the other Party shall have the right to provide suggestions and recommendations regarding the content of the response, amendment, paper or other correspondence by no later than [***] ([***]) days prior to its filing; and (iii) with a copy of any response, amendment, paper or other correspondence by no later than [***] ([***]) days after the responding/contesting Party receives confirmation from the PTO that the response, amendment, paper or other correspondence has been filed.
- (b) Commencement of Post Grant Proceedings. If either Party desires that Novan commence a Post Grant Proceeding with respect to a Novan Patent, the Party shall notify the other Party of such desire. The Parties shall then consult with each other and consider each other's input with respect to whether such a Post Grant Proceeding should be commenced. Novan shall have the sole right to commence a Post Grant Proceeding with respect to a Novan Patent. Should such a proceeding be commenced: (i) Novan shall provide Licensee with a copy of any action, communication, letter or other correspondence issued by the PTO within at least [***] ([***]) days of receipt thereof; (ii) Novan shall provide Licensee with a copy of any proposed response, amendment, paper, or other correspondence to be filed with the PTO no less than [***] ([***]) days prior to filing the same in the PTO, unless otherwise agreed by patent counsel for both Parties; provided that Licensee shall have the right to provide suggestions and recommendations regarding the content for the response, amendment, paper or other correspondence by no later than [***] ([***]) days prior to its filing; (iii) Novan shall provide Licensee with a copy of any response, amendment, paper, or other correspondence as filed with the PTO

no more than [***] ([***]) days after Novan receives confirmation from the PTO that the response, amendment, paper, or other correspondence has been filed.

(c) Decision-Making Authority; Costs. Novan shall have final decision-making authority with respect to all aspects of Post Grant Proceedings related to the Novan Patents. Each Party shall bear its own costs incurred in connection with any Post Grant Proceeding under this Section 3.2.

3.3 Enforcement and Defense of Novan Patents.

- (a) Notice of Infringement. Each Party shall (i) notify the other Party promptly of any conduct on the part of a Third Party that it deems to be a potential infringement of any Novan Patent or receipt of any notice of a certification filed pursuant to 21 U.S.C. § 355(b)(2)(A) (vii)(IV) or its successor provisions or any similar provision in a country in the Territory other than the United States ("Paragraph IV Notice") claiming that any Novan Patents are invalid or otherwise unenforceable, or that infringement of Novan Patents will not arise from the manufacture, use, import or sale of a product by a Third Party (collectively, "Infringement"), and (ii) provide the other Party with such information in its possession regarding the potential Infringement and/or a copy of any Paragraph IV Notices within [***] ([***]) days of receipt thereof.
- (b) Enforcement by Novan. Novan will have the right (but not the obligation), at its sole discretion, to take any and all action it deems necessary to stop any Infringement (or respond to any Paragraph IV Notice), including the bringing of an action based on the Novan Patents in the Territory. Novan will exclusively control the prosecution or settlement of any such action; provided that if such Infringement is in the Licensee Field and does not involve Novan Particles, Novan agrees not to settle such action without the prior written approval of Licensee, not to be unreasonably withheld or delayed. Novan will be permitted to bring any such action in the name of Novan only or in the name of both Novan and Licensee. If such Infringement is in the Licensee Field and does not involve Novan Particles, Licensee shall have the right (but not obligation, other than use of its name as set forth in the immediately preceding sentence) to participate in such action in a consultative capacity through its own counsel at its cost. Licensee will provide [***] cooperation and assistance requested by Novan in connection with any action taken by Novan with respect to an Infringement, including by making relevant employees, inventors, documents, materials and information available to Novan.
- (c) Enforcement by Licensee in the Licensee Field. In the event of a material Infringement (including a Paragraph IV Notice) in the Licensee Field that does not involve Novan Particles, if Novan does not commence an action based on the Novan Patents within (i) [***] ([***]) days after notice of the Infringement or (ii) [***] ([***]) days before the expiration of the time limit, if any, set forth by applicable law for the filing of such action in response to a Paragraph IV Notice, whichever comes first, and in the case of an Infringement other than one arising by reason of a Paragraph IV Notice, such Infringement otherwise has not been abated, Licensee will have the right (but not the obligation), at its sole discretion and expense, to take any and all action it deems necessary to stop such Infringement (or respond to such Paragraph IV Notice), including the bringing of an action based on the Novan Patents. Licensee will control the prosecution or settlement of any such action in consultation with Novan; provided that Licensee agrees not to settle any such action without the prior written approval of Novan, not to be unreasonably withheld or delayed. Licensee will be permitted to bring such action in the name of Licensee only or in the name of both Licensee and Novan. Novan shall have the right (but not obligation, other than use of its name as set forth in the immediately preceding sentence) to participate in such action in a consultative capacity through its own counsel at its cost. Novan will provide [***] cooperation and assistance requested by Licensee in connection with any action taken by Licensee to an Infringement pursuant to this Section 3.3(c), including by making relevant employees, inventors, documents, materials and information available to Licensee.
- (d) Invalidity Claims. In the event that an action or claim alleging invalidity, unenforceability or non-infringement of any of the Novan Patents shall be brought or made against Novan or Licensee, Novan, at its sole discretion, shall have the right, but not be obligated, within [***] ([***]) days after the commencement of such action or claim, to take or regain control of the action or defend such claim at its own expense. If Novan shall determine not to exercise this right, then Licensee may take over or remain in control of the action or defense in consultation with Novan; provided that Licensee agrees not to settle any such action or defense without the prior written approval of Novan.
- (e) Infringement Costs and Proceeds. Each Party shall bear its own costs incurred in connection with any action initiated or defended under this Section 3.3. Any monetary proceeds, damages and other relief obtained by a Party in connection with such an action ("Proceeds") shall be applied in the following order of priority: (i) first, to reimburse each Party for such costs paid by that Party in connection with such action, and (ii) second, after application of the foregoing clause (i), the Party that initiated or defended the action [***].

(f) Novan Retained Rights. Except as expressly set forth in Section 3.3(c) and Section 3.3(d), Novan retains all rights with respect to enforcement and defense of the Novan Patents.

4. PATENT PROSECUTION AND ENFORCEMENT OF LICENSEE NEW NITRIC OXIDE PATENTS

4.1 Prosecution of Licensee New Nitric Oxide Patents

- (a) Prosecution by Licensee. Except as provided for in Section 4.1(b), Licensee shall have the exclusive right to Prosecute the Licensee New Nitric Oxide Patents, as Licensee determines in good faith, [***]. In the event that Licensee desires not to continue to Prosecute any of the Licensee New Nitric Oxide Patents, Licensee shall notify Novan sufficiently in advance of any deadlines to afford Novan an opportunity to request that Licensee continue the Prosecution of such Patent prior to such Patent lapsing or becoming abandoned. If Novan requests in writing that Licensee continue to Prosecute such Licensee New Nitric Oxide Patent, then Licensee will continue to do so in accordance with this Section 4.1(a), [***].
- (b) Filing of Continuations, Divisionals and National Applications by Novan. If Novan desires to file a continuation, divisional or national Patent application to any of the Licensee New Nitric Oxide Patents that Licensee has not filed, Novan will notify Licensee of such desire, and Licensee may elect to Prosecute such Patent [***]. Licensee will notify Novan of its election whether or not to Prosecute such Patent within [***] ([***]) days of such notice from Novan. If Licensee does not elect to Prosecute such Patent within such [***] ([***]) day period, then Novan may Prosecute such Patent [***]. Novan shall control the Prosecution of such Patent (whether Prosecuted by Novan or by Licensee) in consultation with Licensee; provided, however, that all Prosecution decisions will be subject to Licensee's prior written approval (not to be unreasonably withheld). In no event will Novan be permitted to undertake any act in the Prosecution of such Patent that may adversely affect the scope, enforceability or patentability of any other Licensee New Nitric Oxide Patent, as determined by Licensee in good faith. For clarity, any Patent Prosecuted by either Party pursuant to this Section 4.1(b) shall be a Licensee New Nitric Oxide Patent and owned solely by Licensee and licensed under Section 2.3 of this Agreement to Novan.
- (c) Cooperation in Prosecution. The Party exercising the right to Prosecute Licensee New Nitric Oxide Patents pursuant to this Section 4.1 will (i) use reasonable efforts to apprise the other Party of any significant developments in the Prosecution of such Licensee New Nitric Oxide Patent, and (ii) copy the other Party, or have the other Party copied, on all official correspondence relating to the relevant Licensee New Nitric Oxide Patents received from to to be filed with the PTO, within [***] ([***]) days of receipt from the PTO and present a draft of any material proposed response to such correspondence at least [***] ([***]) days prior to filing with the PTO, respectively, including without limitation copies of each patent application, official action, response to official action, declaration, information disclosure statement, terminal disclaimer filing, and request for reexamination. The Party that is not Prosecuting any particular Licensee New Nitric Oxide Patent shall cooperate reasonably with the Party that is conducting Prosecution of such Licensee New Nitric Oxide Patent. [***] shall satisfy its obligations under this Section 4.1 to fund Prosecution costs incurred by [***] by reimbursing [***] on a [***] basis within [***] ([***]) days of receipt of reasonable documentation of such Prosecution costs incurred by Licensee in the prior [***].

4.2 Post Grant Proceedings.

(a) Third Party Defense. In the event that Licensee becomes aware that a Third Party has filed a Post Grant Proceeding with respect to any Licensee New Nitric Oxide Patent, Licensee will notify Novan in writing to that effect within [***] ([***]) days of becoming aware of such filing. Once such a Post Grant Proceeding has commenced, Licensee shall have the first right to respond to and/or contest such proceeding; provided, however, that if Licensee does not take action to respond to and/or contest such proceeding by [***] ([***]) days before the expiration of the time limit, if any, set forth in the applicable laws and regulations for such response or contest, then Novan shall have the right to respond to and/or contest such proceeding. The Party that responds to and/or contests such Post Grant Proceeding shall provide the other Party: (i) with a copy of any action, communication, letter or other correspondence issued by the PTO or the Third Party within [***] ([***]) days of receipt thereof; (ii) with a copy of any proposed response, amendment, paper or other correspondence to be filed with the PTO no less than [***] ([***]) days prior to filing the same in the PTO, unless otherwise agreed by patent counsel for both Parties; provided that the other Party shall have the right to provide suggestions and recommendations regarding the content of the response, amendment, paper or other correspondence by no later than [***] ([***]) days prior to its filing; and (iii) with a copy of any response, amendment, paper or other correspondence by no later than [***] ([***]) days after the

responding/contesting Party receives confirmation from the PTO that the response, amendment, paper or other correspondence has been filed.

- (b) Commencement of Post Grant Proceedings. If either Party desires that Licensee commence a Post Grant Proceeding with respect to a Licensee New Nitric Oxide Patent, the Party shall notify the other Party of such desire. The Parties shall then consult with each other and consider each other's input with respect to whether such a Post Grant Proceeding should be commenced. Licensee shall have the sole right to commence a Post Grant Proceeding with respect to a Licensee New Nitric Oxide Patent. Should such a proceeding be commenced: (i) Licensee shall provide Novan with a copy of any action, communication, letter or other correspondence issued by the PTO within at least [***] ([***]) days of receipt thereof; (ii) Licensee shall provide Novan with a copy of any proposed response, amendment, paper, or other correspondence to be filed with the PTO no less than [***] ([***]) days prior to filing the same in the PTO, unless otherwise agreed by patent counsel for both Parties; provided that Novan shall have the right to provide suggestions and recommendations regarding the content for the response, amendment, paper, or other correspondence by no later than [***] ([***]) days prior to its filing; (iii) Licensee shall provide Novan with a copy of any response, amendment, paper, or other correspondence as filed with the PTO no more than [***] ([***]) days after Licensee receives confirmation from the PTO that the response, amendment, paper, or other correspondence has been filed.
- (c) Decision-Making Authority; Costs. Licensee shall have final decision-making authority with respect to all aspects of Post Grant Proceedings related to the Licensee New Nitric Oxide Patents. Each Party shall bear its own costs incurred in connection with any Post Grant Proceeding under this Section 4.2.

4.3 Enforcement and Defense of Licensee New Nitric Oxide Patents.

- (a) Notice of Infringement. Each Party shall (i) notify the other Party promptly of any conduct on the part of a Third Party that it deems to be a potential infiringement of any Licensee New Nitric Oxide Patent or receipt of any notice of a certification filed pursuant to 21 U.S.C. § 355(b)(2)(A) or 355(j)(2)(A) (vii)(IV) or its successor provisions or any similar provision in a country in the Territory other than the United States ("Paragraph IV Notice") claiming that any Licensee New Nitric Oxide Patents are invalid or otherwise unenforceable, or that infringement of Licensee New Nitric Oxide Patents will not arise from the manufacture, use, import or sale of a product by a Third Party (collectively, "Infringement"), and (ii) provide the other Party with such information in its possession regarding the potential Infringement and/or a copy of any Paragraph IV Notices within [***] ([****]) days of receipt thereof.
- (b) Enforcement by Licensee. Licensee will have the right (but not the obligation), at its sole discretion, to take any and all action it deems necessary to stop any Infringement (or respond to any Paragraph IV Notice), including the bringing of an action based on the Licensee New Nitric Oxide Patents in the Territory. Licensee will exclusively control the prosecution or settlement of any such action; provided that if such Infringement is in the Novan Retained Field, Licensee agrees not to settle such action without the prior written approval of Novan, not to be unreasonably withheld or delayed. Licensee will be permitted to bring any such action in the name of Licensee only or in the name of both Novan and Licensee. If such Infringement is in the Novan Retained Field, Novan shall have the right (but not obligation, other than use of its name as set forth in the immediately preceding sentence) to participate in such action in a consultative capacity through its own counsel at its cost. Novan will provide [***] cooperation and assistance requested by Licensee in connection with any action taken by Licensee with respect to an Infringement, including by making relevant employees, inventors, documents, materials and information available to Licensee.
- (c) Enforcement by Novan in the Novan Retained Field. In the event of a material Infringement (including a Paragraph IV Notice) in the Novan Retained Field, if Licensee does not commence an action based on the Licensee New Nitric Oxide Patents within (i) [***] ([***]) days after notice of the Infringement or (ii) [***] ([***]) days before the expiration of the time limit, if any, set forth by applicable law for the filing of such action in response to a Paragraph IV Notice, whichever comes first, and in the case of an Infringement other than one arising by reason of a Paragraph IV Notice, such Infringement otherwise has not been abated, Novan will have the right (but not the obligation), at its sole discretion and expense, to take any and all action it deems necessary to stop such Infringement (or respond to such Paragraph IV Notice), including the bringing of an action based on the Licensee New Nitric Oxide Patents. Novan will control the prosecution or settlement of any such action in consultation with Licensee; provided that Novan agrees not to settle any such action without the prior written approval of Licensee, not to be unreasonably withheld or delayed. Novan will be permitted to bring such action in the name of Novan only or in the name of both Licensee and Novan. Licensee shall have the right (but not obligation, other than use of its name as set forth in the immediately preceding sentence)

to participate in such action in a consultative capacity through its own counsel at its cost. Licensee will provide [***] cooperation and assistance requested by Novan in connection with any action taken by Novan with respect to an Infringement pursuant to this Section 4.3(c), including by making relevant employees, inventors, documents, materials and information available to Novan.

- (d) Invalidity Claims. In the event that an action or claim alleging invalidity, unenforceability or non-infringement of any of the Licensee New Nitric Oxide Patents shall be brought or made against Novan or Licensee, Licensee, at its sole discretion, shall have the right, but not be obligated, within [***] ([***]) days after the commencement of such action or claim, to take or regain control of the action or defend such claim at its own expense. If Licensee shall determine not to exercise this right, then Novan may take over or remain in control of the action or defense in consultation with Licensee; provided that Novan agrees not to settle any such action or defense without the prior written approval of Licensee.
- (e) Infringement Costs and Proceeds. Each Party shall bear its own costs incurred in connection with any action initiated or defended under this Section 4.3. Any monetary proceeds, damages and other relief obtained by a Party in connection with such an action ("Proceeds") shall be applied in the following order of priority: (i) first, to reimburse each Party for such costs paid by that Party in connection with such action, and (ii) second, after application of the foregoing clause (i), the Party that initiated or defended the action [***].
- (f) Licensee Retained Rights. Except as expressly set forth in Section 4.3(c) and Section 4.3(d), Licensee retains all rights with respect to enforcement and defense of the Licensee New Nitric Oxide Patents.

5. REPRESENTATIONS AND WARRANTIES

- 5.1 Power and Authority. Each Party represents and warrants to the other Party that: (a) it has the right, power, and authority to enter into and perform this Agreement, and to grant the licenses set forth herein, and that the person signing this Agreement on such Party's behalf has been duly authorized and empowered to enter into this Agreement; (b) the execution and delivery by such Party of this Agreement and the consummation by such Party of the transactions contemplated hereby have been duly authorized by all necessary corporate action on the part of such Party and no other corporate proceedings on the part of such Party are necessary to authorize this Agreement or to consummate the transactions contemplated hereby; (c) this Agreement has been duly executed and delivered by such Party and, assuming the due authorization, execution and delivery of this Agreement by the other Party, constitutes a legal, valid and binding obligation of such Party, enforceable against such Party in accordance with its terms; (d) the execution, delivery, and performance of and compliance with this Agreement will not, with or without the passage of time or giving of notice, (i) conflict with, or result in any violation of or default or loss of any benefit under, any provision of the certificate of incorporation or bylaws (or other company governing instruments) of such Party; (ii) conflict with, or result in any violation of or default or loss of any benefit under, any permit, concession, grant, franchise, law, rule or regulation, or any order to which such Party is a party or to which any of its property is subject; (iii) conflict with, or result in a breach or violation of or default or loss of any benefit under, or accelerate the performance required by, the terms of any agreement, contract, indenture or other instrument to which such Party is a party or to which any of its property is subject; or (iv) result in the suspension, revocation, impairment, forfeiture or nonrenewal of any material permit, license, authorization or
- 5.2 Disclaimers. EXCEPT AS SET FORTH IN SECTION 5.1 ABOVE, THE NOVAN PATENTS, THE NOVAN KNOW-HOW, THE LICENSEE NEW NITRIC OXIDE PATENTS, THE LICENSEE NEW NITRIC OXIDE KNOW-HOW AND THE NEW DEVICE IP ARE PROVIDED "AS IS", AND EACH PARTY DISCLAIMS ALL REPRESENTATIONS AND WARRANTIES WITH RESPECT TO THE NOVAN PATENTS, THE NOVAN KNOW-HOW, THE LICENSEE NEW NITRIC OXIDE PATENTS, THE LICENSEE NEW NITRIC OXIDE KNOW-HOW AND THE NEW DEVICE IP, WHETHER EXPRESS, IMPLIED OR STATUTORY, INCLUDING, BUT NOT LIMITED TO, ANY WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE, VALIDITY, NON-INFRINGEMENT, NON-INTERFERENCE AND/OR QUIET ENJOYMENT, OR ARISING FROM A COURSE OF DEALING, USAGE OR TRADE PRACTICES. WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, EACH PARTY EXPRESSLY DOES NOT REPRESENT OR WARRANT: (A) THE SAFETY OR USEFULNESS FOR ANY PURPOSE OF THE SUBJECT MATTER IT PROVIDES HEREUNDER; (B) THAT ANY PATENT WILL ISSUE ON ANY NOVAN PATENT, LICENSEE NEW NITRIC OXIDE PATENT OR NEW DEVICE IP; OR (C) THE VALIDITY OF ANY PATENT INCLUDED IN THE NOVAN PATENTS, LICENSEE NEW NITRIC OXIDE PATENTS OR NEW DEVICE IP.

6. LIMITATION OF LIABILITY. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, INCIDENTAL, PUNITIVE OR INDIRECT DAMAGES OR LOSS OF PROFITS ARISING FROM OR RELATING TO ANY BREACH OF THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES. NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS ARTICLE 6 IS INTENDED TO OR SHALL LIMIT OR RESTRICT THE DAMAGES AVAILABLE FOR A PARTY'S BREACH OF CONFIDENTIALITY OBLIGATIONS IN ARTICLE 7 OR [***].

7. CONFIDENTIALITY.

- **7.1 Confidential Information.** The Parties agree that, unless the Receiving Party obtains the prior written consent of the Disclosing Party, at all times during the term of this Agreement and for a [***] ([***]) year period following its expiration or earlier termination, the Receiving Party will keep completely confidential, will not publish or otherwise disclose and will not use directly or indirectly for any purpose other than as contemplated by this Agreement any Confidential Information of the Disclosing Party.
 - 7.2 Limited Disclosure Permitted. Each Party may disclose Confidential Information of the Disclosing Party to the extent that such disclosure is:
 - (a) required by applicable laws, in the opinion of legal counsel to the Receiving Party; provided, however, that the Receiving Party will first have given reasonable notice to the Disclosing Party (if practicable) and given the Disclosing Party a reasonable opportunity to obtain a protective order or confidential treatment requiring that the Confidential Information and documents that are the subject thereof be held in confidence by the recipient or, if disclosed, be used only for purposes required by such law; provided further, however, that if a protective order is not obtained, the Confidential Information so disclosed will be limited to that information that is legally required to be disclosed by applicable laws;
 - (b) made by Receiving Party to a governmental or regulatory authority as required to conduct clinical trials or obtain or maintain regulatory approval for products or services that are the subject of licenses granted to the Receiving Party under this Agreement;
 - (c) made by Receiving Party to a Third Party as may be necessary or useful in connection with the manufacture, development and commercialization of any products or services that are the subject of licenses granted to the Receiving Party under this Agreement, in connection with financing activities of the Receiving Party, or in connection with the transfer or sale of all or substantially all of the business of the Receiving Party to which this Agreement relates to a Third Party, whether by merger, sale of stock, sale or transfer of assets or otherwise; provided, however, that: (i) each such Third Party has, in the reasonable determination of the Receiving Party, a need to know such Confidential Information and is bound by an agreement containing confidentiality and non-use obligations no less protective than those set forth in this Agreement in any material respect; (ii) the Receiving Party informs each Third Party receiving Confidential Information of its confidential nature; and (iii) the Receiving Party or
 - (d) made by a Receiving Party in order to comply with applicable securities law disclosure requirement or any disclosure requirements of any applicable stock market or securities exchange.
- 7.3 Terms of Agreement. The Parties agree that the material terms of this Agreement shall be considered Confidential Information of both Parties, subject to the special authorized disclosure provisions set forth below in this Section 7.3 (in lieu of the authorized disclosure provisions set forth in Section 7.2, to the extent of any conflict) and without limiting the generality of the definition of Confidential Information set forth in Article 1. If either Party desires to make a public announcement concerning the terms of this Agreement, such Party shall give reasonable prior advance notice of the proposed text of such announcement to the other Party for its prior review and approval, such approval not to be unreasonably withheld. A Party shall not be required to seek the permission of the other Party to repeat or disclose any information as to the terms of this Agreement that has already been publicly disclosed by such Party in accordance with the foregoing or by the other Party, or any similar or comparable information. Either Party may disclose the terms of this Agreement to such Party's existing investors, lenders, directors and professional advisors and to potential investors, lenders, acquirors or merger partners and their professional advisors who are bound by written or professional obligations of non-disclosure and non-use that are at least as stringent as those contained in this Article 7 in all material respects.
- 7.4 Publications. Novan shall have the right to review and comment on any material proposed for disclosure or publication by Licensee, such as by oral presentation, manuscript or abstract, which includes data generated from

the use of the Novan Patents or Novan Know-How or any Confidential Information of Novan. Before any such material is submitted for publication, Licensee shall deliver a complete copy to Novan at least [***] ([***]) days prior to submitting the material to a publisher or initiating any other disclosure. Novan shall review any such material and give its comments to Licensee within [***] ([***]) days of the delivery of such material to Novan. Licensee shall comply with Novan's request to delete references to Novan'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 [***] ([***]) days for the purpose of preparing and filing appropriate Patent applications.

8. TERM AND TERMINATION

- **8.1 Term.** The term of this Agreement shall commence on the Effective Date and, unless earlier terminated in accordance with the provisions of this Article 8, shall expire upon the expiration of the last-to-expire of the Novan Patents. Upon such expiration (but not the earlier termination of this Agreement), the license granted under Section 2.2 shall continue in perpetuity on a non-exclusive basis in accordance with the terms of this Agreement.
- **8.2 Termination for Breach.** Each Party may terminate this Agreement by written notice to the other Party at any time, if the other Party breaches any provision of this Agreement and fails to cure such breach within thirty (30) days of receipt of a written notice thereof from the non-breaching Party.
- 8.3 Termination for Patent Challenge. Novan may terminate this Agreement by written notice if Licensee or its Affiliate or sublicensee directly, or through assistance granted to a Third Party, commences or participates (except as such participation may be required by applicable law) in any interference, pre- or post-grant opposition or other pre- or post-grant proceeding related to the validity, enforceability and/or patentability of, or challenges the validity or enforceability of, any Novan Patent before any tribunal or patent office.
- **8.4** Additional Termination by Licensee. Licensee may terminate this Agreement for any reason or no reason without penalty on ninety (90) days written notice to Novan. Such termination shall become effective at the end of such ninety (90) day period.
- **8.5 Effect of Termination.** Upon termination of this Agreement all licenses granted to Licensee and any sublicenses thereunder will cease to be in effect. In addition, upon termination of this Agreement, each Party shall return to the other Party, or destroy, all Confidential Information belonging to the other Party, in each case except as necessary for such Party's continued enjoyment of any license or right that survives termination of this Agreement.
- **8.6 Survival.** Expiration or termination of this Agreement for any reason will not relieve either Party of any obligation or liability accruing prior thereto and will be without prejudice to the rights and remedies of either Party with respect to any antecedent breach of the provisions of this Agreement. The provisions of Sections 2.2 (but only in connection with expiration of this Agreement and not its earlier termination), 2.3, 2.4, 2.5, 2.6, 2.8, 5.2, 8.5, 8.6, 8.7 and 8.8, and Articles 1 (to the extent required to enforce other surviving rights and obligations), 4, 6, 7 and 9, are intended to and shall survive termination or expiration of this Agreement in accordance with the terms of such Articles or Sections.
- **8.7 Bankruptcy Code.** All licenses granted under this Agreement will be deemed licenses of rights to intellectual property for purposes of Section 365(n) of the United States Bankruptcy Code and a licensee under this Agreement will retain and may fully exercise all of its rights and elections under the United States Bankruptcy Code.
- **8.8** Additional Remedies. The remedies set forth in this Article 8 or elsewhere in this Agreement will be in addition to, and will not be to the exclusion of, any other remedies available to the Parties at law, in equity or under this Agreement.

9. GENERAL

- **9.1 Independent Contractors.** The Parties are and at all times will be and remain independent contractors as to each other, and at no time will either Party be deemed to be the agent or employee of the other. No joint venture, partnership, agency, or other relationship will be created or implied as a result of this Agreement.
- 9.2 Governing Law. Any questions, claims, disputes, or litigation concerning or arising from this Agreement shall be governed by the laws of the State of North Carolina without giving effect to the conflicts of laws principles of that state or other country. Subject to Section 9.3, all disputes with respect to this Agreement shall be brought and heard exclusively either in the North Carolina state courts located in Durham Country, North Carolina, or the federal district court for the Middle District of North Carolina located in Wake Country, North Carolina. The Parties each consent to the *in personam* jurisdiction and venue of such courts exclusively.

9.3 Dispute Resolution.

- (a) Organization Resolution. The Parties will try to settle their differences amicably between themselves. In the event of any controversy or claim arising out of or relating to any provision of this Agreement or the performance or alleged non-performance of a Party of its obligations under this Agreement ("Dispute"), a Party may notify the other Party in writing of such Dispute. Upon a Party's receipt of written notice of a Dispute, the Dispute will be referred to the respective representatives of the Parties with authority to resolve the Dispute. If the designated representatives of the Parties are unable to resolve the Dispute within [***] ([***]) days of receipt of the written notice by the other Party, the Dispute will be referred to the Chief Executive Officers of each of the Parties (or any other ([***]) days of receipt of the written notice by the other Party, the Dispute will be referred to the Chief Executive Officers of each of the Parties (or any other representative designated by the board of directors of the applicable Party) who will use their good faith efforts to resolve the Dispute within [***] ([***]) days after it was referred to the Chief Executive Officers (or other such representative).
- (b) Arbitration. Any Dispute that is not resolved as provided in Section 9.3(a), whether before or after termination of this Agreement, will be resolved by final and binding arbitration. Each Party may refer such Dispute for arbitration by written notice to the other Party. Such Disputes will be finally settled by the American Arbitration Association ("AAA") under its Commercial Arbitration Rules and Mediation Procedures (the "Rules"), or by such other arbitration tribunal or arbitration rules as the Parties may agree upon. Arbitration proceedings will be held in Raleigh, North Carolina, U.S.A, or in another place which is mutually agreeable to the Parties. The arbitration shall be conducted and the award shall be rendered in English. The arbitration will be conducted by three (3) arbitrators agreed to by the Parties Parties. The arbitration shall be conducted and the award shall be rendered in English. The arbitration will be conducted by three (3) arbitrators agreed to by the Parties within [***] ([***]) days of receipt by respondents of the request for arbitration or, in default of such agreement, according to the Rules' Expedited Procedures for the Appointment and Qualifications of Arbitrators. [***] selected shall be a lawyer with pharmaceutical and medical device industry legal experience. During the period beginning with the selection of the arbitrators and ending upon the conclusion of the arbitration proceedings, the Parties may conduct such discovery as is permitted under the Rules; provided, however, that the Parties shall be entitled, without any further showing of good cause to the arbitrators, to [***]. In conducting the arbitration, the arbitrators will apply the Rules as they apply to matters of evidence. The decision by the arbitrators shall be final and binding upon the Parties, their successors and permitted assigns and the Parties will comply with such decision in good faith. The award may be entered and enforced in any court having jurisdiction. Without limitation of the foregoing, each Party hereby submits itself to the jurisdiction of the courts of the place where the arbitration is held, but only for the entry of judgment with respect to the decision of the arbitrators hereunder. The fees and expenses of the arbitrators, the fees and expenses of a court reporter, and any expenses for a hearing room, will be [***]. The Parties will otherwise bear [***].
- (c) [***] Arbitration for Certain Matters. Notwithstanding the foregoing provisions of Section 9.3(b), any Disputes related to [***] of this Agreement shall be resolved through binding arbitration administered by the AAA as follows:
 - (i) Within [***] ([***]) days of receipt by respondent of the request for arbitration, the Parties shall designate in writing a single arbitrator to resolve the dispute. If the Parties cannot agree on an arbitrator within such [***]-day period, or if the arbitrator agreed to by the Parties declines to serve, an arbitrator shall be selected, within [***] ([***]) days after notice from either Party of such inability to agree on an arbitrator willing to serve, by the AAA. The arbitrator shall be a lawyer with pharmaceutical and medical device industry legal experience who is available to serve on the timetable established in this Section 9.3(c), and shall not be an Affiliate, or an employee, consultant, legal advisor, officer, director or stockholder of, or have any conflict of interest with respect to, any Party. Arbitration proceedings will be held in Raleigh, North Carolina, U.S.A, or in another place which is mutually agreeable to the Parties
 - (ii) The Party submitting a dispute to arbitration shall include with its notice pursuant to Section 9.3(b) a written summary of the disputed issues, not to exceed [***] ([***]) pages per disputed issue, and a proposed ruling on the merits of each such issue. Within [***] ([***]) days thereafter, the other Party shall provide a written response, not to exceed [***] ([***]) pages per disputed issue, as well as such other Party's proposed ruling on the merits of each disputed issue, to the Party initiating such arbitration and to the arbitrator.
 - (iii) Within [***] ([***]) days after the selection of the arbitrator and in any event within [***] ([***]) days after the notice initiating the arbitration, the arbitrator and the Parties shall meet. During such meeting, the arbitrator shall establish a schedule for discovery. Unless the Parties otherwise agree, the arbitrator shall limit discovery by each Party to [***] [***]. The Parties shall have [***] ([***]) days to respond to written discovery. Depositions shall be scheduled at the mutual convenience of the Parties and the

witnesses; provided that all discovery shall be conducted so as to be completed within [***] ([***]) days after the initiation of arbitration.

- (iv) The arbitrator shall set a date for a hearing, which shall be no later than [***] ([***]) days after the notice initiating the arbitration pursuant to Section 9.3(b). At the hearing, in accordance with a schedule established by the arbitrator, the Parties shall present evidence with respect to each of the disputed issues.
- (v) Within [***] ([***]) days following the close of the hearing, the Parties shall submit post-hearing briefs to the arbitrator. The post-hearing briefing shall not exceed twenty double-spaced pages. Within [***] ([***]) days after the timely submission of post-hearing briefs, the arbitrator shall enter a written award that rules on each disputed issue and that sets forth the grounds for the decision, applying the law of the State of North Carolina. The determination of the arbitrator as to the resolution of any dispute shall be binding and conclusive upon all Parties. Either Party may bring an action in any court of competent jurisdiction to enforce a final award entered by the arbitrator. The Parties expressly agree that the state and federal courts located in the State of North Carolina have jurisdiction to confirm the arbitration award and enter judgment thereon. The Parties hereby waive any and all objections and defenses to such jurisdiction regardless of the nature of such objection or defense.
- (vi) The (i) [***], (ii) [***] and (iii) [***], shall be borne by the non-prevailing Party or, if neither Party is the prevailing Party as to all disputed issues, by the Parties in inverse proportion to the proportion of the dispute on which they prevailed, respectively, as determined by the arbitrator. Prior to such determination, each Party shall bear its own [***] and [***]; provided that the arbitrator shall, in his or her final award, require the non-prevailing Party (or the Party that prevails on [***]) to reimburse the other Party for the excess share of such costs and expenses borne by such other Party prior to such determination.
 - (vii) Except as modified by this Section 9.3(c), Disputes subject to arbitration hereunder shall be governed by the Rules.
- (d) Confidentiality. Except as may be required by applicable law, neither a Party nor the arbitrator(s) may disclose the existence, content or results of any arbitration award without the prior written consent of both Parties, unless to protect or pursue a legal right.

(e) Disputes Not Subject to Arbitration.

- (i) IP Disputes. Notwithstanding the Parties' agreement to arbitrate, unless the Parties agree in writing in any particular case, claims and disputes between the Parties relating to or arising out of, or for which resolution depends in whole or in part on a determination of the interpretation, validity, enforceability or infringement of, Patents or the misappropriation of trade secrets, shall not be subject to arbitration under this Agreement, and the Parties may pursue whatever rights and remedies may be available to them under law or equity, including litigation in a court of competent jurisdiction, with respect to such claims and disputes.
- (ii) Emergency Relief. Notwithstanding the Parties' agreement to arbitrate, the Parties hereby agree that either Party may apply to any court of law or equity of competent jurisdiction for specific performance or injunctive relief to enforce or prevent any violation of this Agreement. Without prejudice to such provisional remedies as may be available under the jurisdiction of a court, the arbitral tribunal under this Section 9.3 shall have full authority to grant provisional remedies and to direct the Parties to request that any court modify or vacate any temporary or preliminary relief issued by such court, and to award damages for the failure of any Party to respect the arbitral tribunal's orders to that effect.
- 9.4 No Assignment. Neither Party may assign, delegate or otherwise transfer, in whole or in part, any rights or obligations under this Agreement, by operation of law or otherwise, without the other Party's express prior written consent, which shall not be unreasonably withheld; provided, however, that a Party may assign or transfer its rights and delegate its obligations under this Agreement without such consent: (a) to the transferee or successor entity to such Party upon the transfer or sale of all or substantially all of the business of such Party to which this Agreement relates to a Third Party, whether by merger, sale of stock, sale or transfer of assets or otherwise; or (b) to an Affiliate, provided that the assigning Party shall remain liable and responsible to the other Party for the performance and observance of all such duties and obligations by such Affiliate for so long as such entity remains an Affiliate of the assigning Party. In the case of any permitted assignment or transfer of or under this Agreement, this Agreement shall be binding upon, and inure to the benefit of, the transferees, successors and assigns of the Parties hereto. Any

attempted assignment, delegation, or transfer in violation of the foregoing will be null and void. In connection with any assignment or transfer of this Agreement by a Party, the Patents and Know-How licensed by such Party to the other Party under this Agreement shall not include any Patents or Know-How Controlled by the transferee, successor or assignee of, or any Acquirer of, such Party (or any Affiliate thereof, excluding Licensee as a result of such transaction) prior to such assignment or transfer or developed outside of any activities under this Agreement.

9.5 Compliance with Laws. Each Party will comply with all applicable federal, state, provincial and local laws, rules, and regulations in performance of its obligations under this Agreement.

9.6 Notices. All notices or reports permitted or required under this Agreement will be in writing and will be delivered by personal delivery, telecopier, facsimile transmission, or by certified or registered mail, return receipt requested, and shall be deemed given upon personal delivery, five days after deposit in the mail, or upon acknowledgment of receipt of electronic transmission. Notices shall be sent to the addresses set forth below. Either party may amend its address upon written notice to the other.

If to Novan: If to Licensee:

Novan, Inc. KNOW Bio, LLC

4222 Emperor Boulevard, Suite 200 627 Davis Drive, Suite 400 Durham, NC 27703 Morris ville, NC 27560

Attn: [***] Attn: [***]

9.7 Waivers; Amendment. No waiver of any terms or conditions of this Agreement will be valid or binding on a Party unless such Party makes the waiver in writing. Any such waiver shall constitute a waiver only with respect to the specific matter described therein and shall in no way impair the rights of the Party granting such waiver in any other respect or at any other time. The failure of one Party to enforce any of the provisions of this Agreement, or the failure to require at any time the performance of the other Party of any of the provisions of this Agreement, will in no way be construed to be a present or future waiver of such provisions, nor in any way affect the ability of a Party to enforce each and every provision thereafter. This Agreement may not be altered, amended, modified, or otherwise changed in any way except by a written instrument signed by the authorized representatives of each Party.

- 9.8 Severability. If any provision of this Agreement is found or held to be invalid or unenforceable by any tribunal of competent jurisdiction, then the meaning of such provision will be construed, to the extent feasible, so as to render the provision enforceable, and if no feasible interpretation would save such provision, it will be severed from the remainder of this Agreement, which will remain in full force and effect.
- 9.9 Construction. The headings of sections of this Agreement are included solely for convenience of reference and are not to be used to interpret, construe, define, or describe the scope of any aspect of this Agreement. As used in this Agreement, the word "including" means "including but not limited to". Each Party represents that it has had the opportunity to participate in the preparation of this Agreement, and any rule of construction to the effect that ambiguities are to be resolved against the drafting Party will not be followed in connection with the construction or interpretation of this Agreement. For purposes of this Agreement, the word "will" shall be equivalent in meaning to the word "shall," both of which describe an act or forbearance which is mandatory under this Agreement. The word "may" describes an act or forbearance which is optional under this Agreement. Unless otherwise expressly stated to the contrary herein, all remedies are cumulative, and the exercise of any express remedy by either Party does not by itself waive such Party's right to exercise its other rights and remedies available at law or in equity.
- **9.10 Entire Agreement.** This Agreement, including its attached exhibit, constitutes the entire agreement and final understanding of the Parties with respect to the subject matter hereof, and supersedes any other and all prior or contemporaneous negotiations, representations, understandings, discussions, offers, and agreements between the Parties, whether written or oral, express or implied, relating in any way to the subject matter hereof. This Agreement is intended by the Parties to be a complete and wholly integrated expression of their understanding and agreement.
- 9.11 Counterparts. This Agreement may be executed in counterparts (by facsimile transmission or in Adobe Portable Document Format (PDF) sent by electronic mail), each of which will be considered an original, but all of which together will constitute one and the same instrument.

Signature Page to Follow

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives.

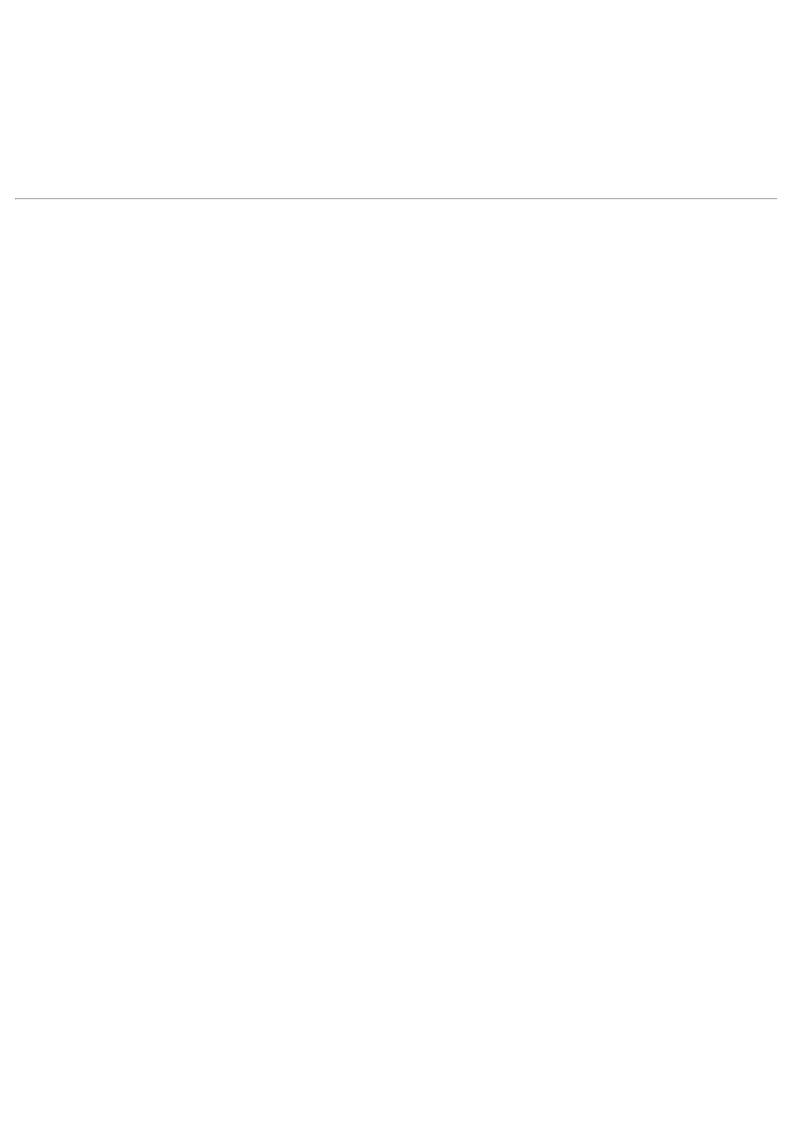
Novan, Inc.		KNOW Bio, LLC	
Ву:	/s/ Nathan Stasko	By:	/s/ Neal Hunter
Name:	Nathan Stasko, PhD	Name:	Neal Hunter
Title:	President	Title:	Managing Director



Appendix A

Novan Patents

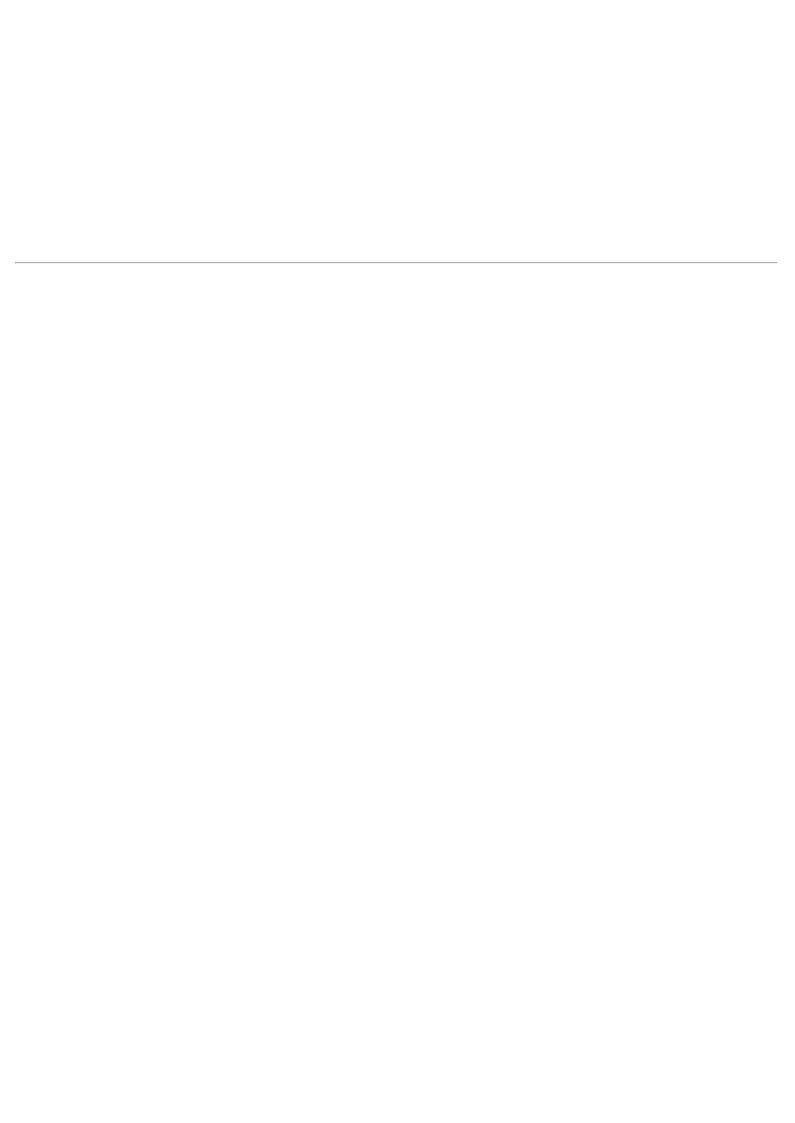
[***]



Appendix B

Separately-Licensed Patents

[***]



Appendix C

Additional UNC Patents

[***]

Certain confidential information contained in this exhibit have been omitted by means of redacting a portion of the text and replacing it with [***], pursuant to Regulation S-K Item 601(b) of the Securities Act of 1933, as amended. Certain confidential information has been excluded from this exhibit because it is: (i) not material; and (ii) the registrant treats such information as private or confidential.

MASTER MANUFACTURING AND SUPPLY AGREEMENT

Between

ALLERGAN SALES, LLC

And

DPT LABORATORIES, LTD.

Effective Date August 16, 2018

AGREEMENT

This Master Manufacturing and Supply Agreement is entered into as of the 16th day of August, 2018 ("Effective Date") by and between **Allergan Sales, LLC**("Allergan"), a Delaware limited liability company, and **DPT Laboratories, Ltd.**("Contractor"), a Texas limited partnership (the "Agreement"). The Parties agree that the Agreement is entered into on behalf of the Parties and their respective Affiliates.

WHEREAS, Allergan (i) has either obtained regulatory approval to market the pharmaceutical products listed in the Product Schedules attache hereto, or (ii) intends to seek regulatory approval to market the Products in the United States of America and other countries as listed in the applicable Produc Schedule; and

WHEREAS, Contractor has the necessary facilities, equipment, personnel and professional expertise to manufacture, package, distribute, test, an ship Product; and

WHEREAS, Allergan desires to establish Contractor as manufacturer and/or packager of the Product as indicated in the Attachments;

NOW, THEREFORE, in consideration of the above and of the promises and mutual covenants, agreements, guarantees and representations containe herein and intending to be legally bound, the Parties agree as follows:

ARTICLE 1 INTERPRETATION/DEFINITIONS

The following terms shall, unless the context otherwise requires, have the following meanings, respectively:

"Affiliate" Affiliate shall mean

- (a) A business entity which owns, directly or indirectly, a controlling interest in a Party to this Agreement, by stock ownership or otherwise; or
 - (b) A business entity which is owned by a Party to this Agreement, either directly or indirectly, by stock ownership or otherwise; or
- (c) A business entity, the majority ownership of which is directly or indirectly common to the majority ownership of a Party to this Agreement.

"Allergan Material" means any material, including but not limited to, API, excipients, Intermediate Product and packaging components provided by Allergan to contractor at no cost for use in the Processing of the product.

"API" API shall mean the compound, as further described in the Product Schedules attached hereto with respect to a specific Product, that, unless the Parties agree otherwise in a Product Schedule with respect to a specific Product, has been released by Allergan and provided to Contractor, along with ϵ certificate of analysis, as provided hereafter in this Agreement.

"API and/or Intermediate Product Value' API and/or Intermediate Product Value shall mean the monetary value of the API and/or Intermediate Product as detailed on the applicable Product Schedule.

"Approval Date" Approval Date shall mean the date on which a Batch of Product is approved for release by Contractor Quality Assurance Contractor Quality Assurance shall not approve or release a Batch of Product until it has reviewed and approved the completed Batch Record for the relevan Product.

"Batch" Batch shall mean one (1) production lot of a specific Product.

"Batch Record" Batch Record shall mean the document(s) created as and after each Batch is processed and/or packaged that, when complete and accurate, reflects and incorporates all aspects of the Master Batch Record and/or Master Packaging Record, the Certificate of Analysis, Certificate of Manufacture, Certificate of Sampling, and any Manufacturing Investigation or Deviation reports issued, with respect to such Batch.

"Calendar Year" Calendar Year shall mean any twelve month period commencing on January 1.

"Certificate of Analysis" Certificate of Analysis shall mean a certificate issued by Contractor stating that a Batch has been Processed and/or Packaged in accordance with the Master Batch Record and/or Master Packaging Record and stating the final release results.

"Certificate of Manufacture" Certificate of Manufacture shall mean a certificate issued by Contractor stating that a batch has been Processed and/or Packaged in accordance with registration documents and in conformity with GMPs.

"Certificate of Sampling" Certificate of Sampling shall mean a certificate issued by Contractor stating that product sampling for a batch has beer performed in accordance with an Allergan-approved sampling plan and procedure.

"Change Control" Change Control shall mean the quality assurance process by which any change which affects a specific Product or its regulatory filings, including but not limited to changes in the Specifications, Process, Packaging, Raw Materials, Containers, Components, or Facility is agreed to reviewed and approved in writing prior to implementation by both Allergan and Contractor as specified in the Quality Agreement.

"Components" Components shall mean the materials used for Packaging a specific Product as identified in the Master Batch Record or Maste Packaging Record.

"Confidential Information" Confidential Information shall mean a Party's technology, data, know-how, or information whether written or oral, technical or non-technical, including, but not limited to, financial statements, reports, pricing, trade secrets, secret processes, formulae, samples, customer data (including customer lists), and the like, that is disclosed to the other Party.

"Containers" Containers shall mean packaging boxes and shipping containers.

"Contract Manufacturing Services" means all operations (including but not limited to Materials testing and release, receiving, processing, packaging, quality control testing, storage documentation, and/or shipment and stability testing) required to produce the Products.

"Contract Year" Contract Year shall mean a twelve (12) month period commencing on each anniversary of the Effective Date during the term of this Agreement.

"Directions for Testing" Directions for Testing shall mean the quality control analytical methods used for testing of a specific Product, Raw Materials, Components and Containers with respect thereto.

"Equipment" Equipment shall mean any and all of the equipment used in the Processing and/or Packaging and testing of a specific Product, whether such Equipment is the property of Contractor or Allergan.

"Facility" Facility shall mean Contractor's facility as identified in the applicable Product Schedule attached hereto.

"FDA" FDA shall mean the United States Food and Drug Administration.

"Finished Product" Finished Product shall mean a specific Product at the completion of Processing and/or Packaging into the final form to be supplied by Contractor.

"GMPs shall mean the then-current good manufacturing practices applicable to the manufacture of pharmaceutical products for human use as laid down in U.S. C.F.R. (Title 21, Parts 210-211) and European Community Guide to Good Manufacturing Practices.

"Hazardous Waste" Hazardous Waste shall mean all hazardous waste, as defined by applicable federal, state, and local laws and regulations, to the extent the same arise out of Contractor's Processing and/or Packaging of a specific Product in accordance with this Agreement.

"Intermediate Product' Intermediate Product shall mean a material supplied by Allergan to Contractor for further Processing and/or Packaging which Intermediate Product shall be set forth on the applicable Product Schedule, attached hereto, or incorporated by reference and made part of this Agreement, with respect to the specific Product.

"Initial Term" Initial Term is as set forth in Section 14.

"Labeling" Labeling shall mean all printed labeling, including but not limited to, labels, package inserts and cartons, for a specific Product.

"Latent Defect" means Product which is defective such that the related non-conformance of Product or defect is not readily discoverable based on Allergan's normal incoming-goods inspections.

"Lot Number" Lot Number shall mean the unique number applied to a Batch of Product by Allergan and/or Contractor; provided, however, that al Batches with respect to a Product shall reference the Allergan number.

"Manufacturing Investigation or Deviation Report' Manufacturing Investigation or Deviation Report shall mean a report indicating any deviation from the Processing and/or Packaging procedures with respect to a Product as set forth in the Quality Agreement.

"Manufacturing Schedule" Manufacturing Schedule shall mean the [***] or [***] rolling schedule for Processing and/or Packaging of a specific Product at the Facility as prepared by Contractor and accepted by Allergan.

"Master Batch Record' Master Batch Record shall mean the document containing the formula (listing API and/or Intermediate Product and Rav Materials), procedures for the Processing, quality control and assurance of a specific Product, and in-process and finished

Product Specifications for such Product as set forth in the applicable Product Schedule with respect to such Product, and reviewed and approved by botl Contractor and Allergan Quality Assurance.

"Master Packaging Record' Master Packaging Record shall mean the document containing a specific Product description (listing Intermediate Product, Components, Containers and Labeling), procedures for the Packaging, quality control and assurance of a specific Product, and in-process and finished Specifications for the Product as set forth in the applicable Product Schedule with respect to such Product; and reviewed and approved by both Contractor and Allergan Quality Assurance.

"Materials Fee" is quoted in single final Product unit increments and is defined as [***].

"NDA" NDA shall mean the New Drug Application filed by Allergan with the FDA and any amendments thereto.

"Non-Hazardous Waste" Non-Hazardous Waste shall mean all rejects or wastes arising out of Processing and/or Packaging, including without limitation, rejected or unusable Raw Materials or API and/or Intermediate Product, disposable manufacturing equipment (including filters used in Processin and/or Packaging), wash rinse, and previously used or discarded protective clothing, except to the extent that any of the foregoing is Hazardous Waste.

"Package and/or Packaging" Package and Packaging shall mean the act of inspecting, filling a specific Product into Components, placing the Labeling on and with such Product, and final packing such Product into Containers in accordance with the Master Packaging Record or the registration o Validation protocol, in each case with respect to such Product.

"Party and/or Parties" Party and/or Parties shall mean Allergan and/or Contractor.

"Process and/or Processing" Process and Processing shall mean the pharmaceutical manufacturing procedures, or any part thereof, involved in manufacturing the Product from the API and/or Intermediate Product and Raw Materials in accordance with the Master Batch Record or registration c Validation protocol.

"Product" Product shall mean a pharmaceutical product that Allergan desires to have Processed and/or Packaged pursuant to this Agreement and which is described in an applicable Product Schedule (in the form of Exhibit A) which is incorporated hereto by reference and made an integral part of this Agreement.

"Product Change Control Request" Product Change Control Request shall mean a form filled out and submitted by one Party to the other Party fo the purposes of proposing making any change to an approved process or equipment used to Process and/or Package a specific Product. Each party shal submit to the other Allergan using their own respective Product Change Control Request Form for the use of Processing and/or Packaging changes or change to the Master Batch Record or Master Packaging Records. All such Product Change Control Requests shall go through proper procedures as described each Party's internal operating procedures prior to implementation.

"Product Schedules" Schedules shall mean the schedules, in the form set forth in Exhibit A (Form of Product Schedule) and exhibits attached hereto and incorporated herein by this reference, each of which will relate to a specific Product hereunder.

"Production Fees/Manufacturing Fees" Production Fees or Manufacturing Fees may be used interchangeably and shall mean the amounts charged by Contractor for its services as

detailed on the applicable Product Schedule attached hereto, and/or incorporated by reference, for a specific Product.

"Purchase Order" Purchase Order shall mean the firm, written orders for Processing and/or Packaging of a specific Product submitted by Allergan to Contractor.

"Quality Agreement' Quality Agreement shall mean the document agreed to between the Allergan and Contractor Quality Assurance groups outlining the operational responsibilities of each group in regards to the Products and the Processing and/or Packaging of such Products in Contractor's Facility.

"Raw Materials" Raw Materials shall mean the excipients other than the API and/or Intermediate Product necessary for the Processing of a specifi Product, as listed in the Master Batch Record with respect to such Product.

"Regulatory Authorities" Regulatory Authorities shall mean the U.S. Food and Drug Administration and European Union regulatory agencies a applicable to the Product.

"SDS" SDS shall mean the safety data sheets for the API for a specific Product and a Finished Product.

"Specifications" Specifications shall mean the API and/or Intermediate Product, Raw Material, Components, Labeling, and Containers specification and the in-process and finished Product specifications for testing and release and stability as approved by Allergan and Regulatory Authorities for a specific Product.

"Standard Cost" or "Standard Costs" means the reasonable, actual cost to Contractor of materials (such as Raw Materials, API, Components Containers, and Labeling) plus incoming freight, scrap/yield loss adjustments and any other recurring costs directly attributable to acquiring such material(s), as reasonably documented by Contractor.

"Technology Transfer" Technology Transfer shall have the meaning specified in Section 15.

"<u>Unit Cost</u>" Unit Cost shall mean the cost charged by Contractor for production and/or packaging services per unit of a specific Product as detailed on the applicable Product Schedule attached hereto.

"Validation" Validation shall mean all installation qualification (IQ), operational qualification (OQ), performance under load qualification (PQ), cleaning Validation, and method Validation procedures for the Facility, Equipment, Processing and/or Packaging processes, and analytical testing methods for quality control and cleaning that may affect a specific Product.

"Work-In-Process" Work-In-Process shall mean the API and/or Intermediate Product and Raw Materials, or bulk Product and Components Labeling and Containers, with respect to a Batch of a specific Product during the time period beginning at the time Contractor begins work in accordance with the Master Batch Record or Master Packaging Record with respect to such Product and ending at the Approval Date.

ARTICLE 2 PRODUCTION/PACKAGING ARRANGEMENT

2.1 Scope of Work. Contractor shall Process, Package and store, and shall analyze for quality control, release and stability testing, a Product it accordance with the specifications

contained in the Master Batch Record, the Master Packaging Record and the Directions for Testing as listed in the applicable Product Schedule attache hereto with respect to such Product and release such product for delivery to Allergan in accordance with the terms and conditions of this Agreement and Contractor shall perform these services at the Production Fees listed in the applicable Product Schedule (such Production Fees being subject to adjustment i accordance with the terms hereof). Contractor shall not be obligated to perform Services which would involve any countries that are targeted by the comprehensive sanctions, restrictions or embargoes administered by the United Nations, European Union, United Kingdom or the United States.

- 2.2 Lot Numbering/Expiration Dates With respect to Packaging, Contractor shall make arrangements for and implement the imprinting of Lot Numbers and expiration dates as applicable on the packaging of each Product shipped. Such Lot Numbers and expiration dates shall be affixed on the Product packaging and on the shipping carton of each product as is required by GMPs and consistent with the Allergan Specifications. Electronic on-lin verification of the Lot Number and expiration date will be performed by Contractor. If Contractor places an internal Lot Number on a Product or package that is different from the Allergan Lot Number referenced in the Purchase Order for that Batch of Product, Contractor shall provide a cross-reference for the Allergan Lot Number on all documents associated with the Batch of Product.
- 2.3 <u>Sub-Contracting</u>. Contractor shall not, without prior written approval of Allergan, sub-contract any part of its responsibilities under this Agreement to another party.
- 2.4 <u>Changes to Master Batch Record or Master Packaging Record or Specifications</u> Any proposed change to the Master Batch Record, Master Packaging Record or Specifications must be approved by both Parties through the issuance and acceptance of a Product Change Control Request.
- (a) <u>Difference in Cost</u>. Allergan shall notify Contractor in writing of any proposed changes to the Master Batch Record, Master Packaging Record, or the Specifications and Contractor shall, within [***] of receipt of such notice, notify Allergan in writing whether and the extent to which its production costs for a specific Product will increase or decrease as a result of such revision. Any increase or decrease in Contractor's production costs shall be supported by documentation in form and content reasonably satisfactory to Allergan. If Allergan elects to adopt the revision, the Production Fees will be increased or decreased by the amount of such additional or reduced production costs, and the related Product Schedules will be amended accordingly.
- (b) <u>Contractor Unable to Comply.</u> If Contractor determines it is technically unable to comply with a proposed revision of the Master Batch Record or Master Packaging Record, or the Specifications or if Allergan is unwilling to accept any increase in the Production Fees that might otherwise caus a Product deletion or discontinuance arising therefrom, Allergan may choose in its sole discretion to either withdraw the proposed revision or terminate the Agreement in accordance with Section 14.
- (c) <u>Regulatory Submission</u>. No revisions to the Specifications that would affect the Processing and/or Packaging of a specific Product shal be submitted to any Regulatory Authorities unless approved by both Parties in writing. It is understood by both Parties that changes mandated by Regulatory Authorities shall be acted upon with due diligence.

2.5 Changes and Modifications to Facility or Equipment by Contractor.

(a) Change in Location Contractor shall not change the Facility at which it Processes and/or Packages a Product and shall not move the physical location within its Facility

for Processing and/or Packaging a specific Product without obtaining Allergan's prior written approval which approval shall not be unreasonably withheld. It any changes are proposed by Contractor and agreed to by Allergan in regard to movement of Processing and/or Packaging to a different facility in a different geographic location or within Contractor's Facility, the costs of any Validation activities required in connection with such change will be the responsibility of Contractor.

- (b) <u>Modifications to Facility.</u> Contractor shall notify Allergan of any planned or pending modifications to parts of the Facility used for Processing, Packaging or storage of a specific Product to the extent such modifications impact or otherwise affect the Product at least 180 calendar days prior to the proposed implementation.
- (c) <u>Material Changes</u> Contractor shall not implement any material changes relating to a specific Product (including modifications to the Equipment) without obtaining Allergan's prior written approval as outlined in the Quality Agreement, which approval shall not be unreasonably withheld. A material change is defined as any change that (a) impacts the regulatory commitments made to Regulatory Authorities for a specific Product; (b) may require Validation or re-Validation; (c) may affect the quality, purity, identity or strength of the in-process or finished Product; or (d) would necessarily result in changing or modifying the Allergan or Contractor sampling procedures, standard operating procedures, or the Master Batch Record, Master Packaging Record, or Directions for Testing with respect to a specific Product. Contractor shall pay for any expenses associated with any modifications or material changes initiated by Contractor, including, but not limited, to Product Validation or re-Validation. Notwithstanding the foregoing, however, the parties agree that any regulatory filings incident to any such change shall be the sole responsibility of Allergan.
- 2.6 No Volume Guarantee. Notwithstanding anything else contained in this Section 2, Contractor acknowledges that Allergan is not guaranteeing any volume of Product will be ordered by Allergan and the volumes of a specific Product ordered shall be dictated by market demand.
- 2.7 <u>Initiatives and Projects</u>. Allergan will communicate to Contractor product initiatives or projects that Allergan desires to conduct at Contractor's Plant. Upon mutual agreement of the Parties, planning for implementation of such project activity will be included as part of production planning for Allergan requirements at Contractor's Plant. Allergan may require the participation of other outside contractors in initiatives or project work conducted at Contractor's Plant; provided, however, Contractor must agree in advance to the use of such outside contractors at the Contractor's Plant. Upon Contractor's agreement (not to be unreasonably withheld), access to the Plant and participation by such contractors will not be prohibited by Contractor subject to execution of appropriate confidential disclosure agreement(s) and Allergan providing Contractor reasonable notice of such contractor(s).

ARTICLE 3 RAW MATERIALS, API, COMPONENTS, CONTAINERS AND LABELING

3.1 <u>Supply</u>. Unless otherwise agreed to in writing, Contractor, at Allergan's expense, shall acquire and test the Raw Materials, API, Components Containers, and Labeling required for Processing and/or Packaging a specific Product from vendors mutually agreed to in writing by the Parties. A list o Allergan-approved vendors, if required, is provided in the applicable Product Schedule. All Contractor supplied materials (i.e. Raw Materials, API Components, Containers, and Labeling) will be billed to Allergan on the respective invoice for Product, into which the Contractor supplied materials was converted, as part of the Materials Fee, and in addition to the Production Fee, all in accordance with the provisions of Article 7 below.

3.2 <u>Testing, Verification, and Documentation</u>.

- (a) <u>Testing</u>. Requirements are addressed as part of the Quality Agreement.
- (b) <u>Transmissible Spongiform Encephalopathies (TSE) Documentation</u>. Requirements are addressed as part of the Quality Agreement.
- (c) <u>Materials of Ruminant Origin Documentation</u>. Requirements are addressed as part of the Quality Agreement.
 - (i) <u>Material Conformance</u>. Requirements are addressed as part of the Quality Agreement.
 - (ii) <u>Certificate of Suitability</u>. Requirements are addressed as part of the Quality Agreement.
- (d) Future Documentation. Requirements are addressed as part of the Quality Agreement.
- 3.3 <u>Labeling</u>. Allergan shall be responsible for supplying Contractor with copy for Labeling with respect to a Product and for ensuring that the copy for Labeling conforms to all applicable laws, rules, regulations, and requirements of all appropriate Regulatory Authorities. Contractor shall be responsible for ordering and paying for sufficient quantities of Labeling as required based upon the first [***] Forecast requirement (Firm Commitment) for a Product Allergan shall review and approve proofs for Labeling. The Labeling shall be shipped directly from the vendor to Contractor. Contractor shall store the Labeling as required by any relevant laws or regulations and shall place the Labeling on and with a specific Product as specified by Allergan.
- (a) <u>Contractor's Name</u>. Contractor's name shall not appear on the Labeling or anywhere else on a specific Product unless required by a Regulatory Authority, governmental agency or other applicable laws or regulations.
- (b) <u>Labeling Changes</u> Allergan may, in its sole discretion, make changes to labels, product inserts and other Labeling for a specific Product, for which changes Allergan shall obtain approval of all applicable Regulatory Authorities responsible for the approval of a specific Product, as required.
- 3.4 Obsolete Components. Notwithstanding any change implemented in accordance with the terms of Section 2.4, Allergan agrees to purchase, at Contractor's cost, all inventory of Raw Materials, Containers, Components and Labeling, utilized under the changed Specifications, and purchased o maintained by Contractor in order to fill up to [***] of forecasted requirements or an associate minimum order quantity or any other purchase quantities agreed to in writing, to the extent that such inventory can no longer be utilized under any revised Specifications required by Allergan or elsewhere in the Contractor's operation. Open purchase orders for Raw Materials, Containers, Components and Labeling no longer required under any revised Specifications which were placed by Contractor with suppliers in order to fill Purchase Orders or in accordance with Section 5.5 shall be canceled where possible, and where such orders are not subject to cancellation without penalty, shall be assigned to and satisfied by Allergan.

ARTICLE 4 ACTIVE PHARMACEUTICAL INGREDIENT AND/OR INTERMEDIATE PRODUCT

- 4.1 Allergan Supplies. In the event that Allergan is the supplier of API, pursuant to a written agreement of the parties as set forth in Section 3. Allergan shall, at its sole cost and expense, deliver the material listed on the applicable Product Schedule hereto (the API and/or Intermediate Product) to Contractor in the quantities specified herein at least [***] prior to the start date of Processing and/or Packaging for a Batch set forth in the Manufacturing Schedule, which such material shall be held by Contractor on behalf of Allergan on the terms and conditions herein contained. The Parties acknowledge and agree that title to the API and/or Intermediate Product shall at all times belong to and remain with Allergan.
- 4.2 Sole Use. Contractor agrees that any API and/or Intermediate Product received by it shall only be used by Contractor to Process and/o Package and test the Product. Contractor shall not allow any samples of the API and/or Intermediate Product to be used or tested by any party not under it direct supervisory control for any purpose without the prior written consent of Allergan and shall perform only such tests and analyses as it deems necessary in order to satisfy any of Contractor's obligations under this Agreement and shall maintain the confidentiality of such test results in compliance with Section 21 of this Agreement.
- 4.3 <u>Verification</u>. A certificate of analysis shall be provided for each shipment of API and/or Intermediate Product supplied. Contractor shall verify the quantity, appearance, and chemical identity of all API and/or Intermediate Product received by Contractor according to the methods and procedures se forth in the applicable Product Schedule within [***] of receipt of API and/or Intermediate Product by Contractor. Within such [***] period, Contractor sha inform Allergan in writing of any discrepancies in the description, quantity and/or identity of the API and/or Intermediate Product received and the information contained in the documents accompanying each shipment of such API and/or Intermediate Product.
- 4.4 **Discrepancy**. If Contractor notifies Allergan of a discrepancy in the quantity, appearance or identity of the API and/or Intermediate Produc within such [***] period, Allergan shall endeavor in good faith to ship additional API and/or Intermediate Product within the time period necessary for Contractor to Process and/or Package the Product in accordance with the scheduled manufacturing date in accordance with the applicable Purchase Order. I Contractor informs Allergan of any discrepancies in the quantity, appearance or identity of the API and/or Intermediate Product after such [***] period, ther Allergan shall endeavor to supply the Contractor with additional APT and/or Intermediate Product sufficient to Process and/or Package the scheduled Product in accordance with the applicable Purchase Order, but if Allergan is unable to supply such additional API and/or Intermediate Product, Allergan may postpone the scheduled Processing and/or Packaging without any liability to Contractor for such delay.
- 4.5 <u>Damage</u>. If Contractor fails to inform Allergan of any damage to the API and/or Intermediate Product within the foregoing [***] period and Contractor cannot prove that such damage occurred prior to delivery to Contractor or if any such damage is the result of Contractor's failure to handle the API and/or Intermediate Product in accordance with the terms of this Agreement, then Contractor shall remedy such failure or damage in accordance with Section 4.7.
- 4.6 Other Damage or Loss Except for any damage or loss resulting from fire (other than one cause by the negligence of Contractor), flood, tornado, earthquake, or other act of God beyond Contractor's ability to control or to the extent caused by Allergan's negligence or willful misconduct, Contractor shall assume all responsibility and liability for, and shall defend, indemnify and hold Allergan harmless from and against, any loss of or damage to the API and/or Intermediate Product, Work-In-Process, Bulk and/or Finished Product. Such responsibility and liability shall commence upon the receipt of the API and/or Intermediate Product at the Facility and end upon

the release of a specific Product by Contractor to Allergan's carrier at the Contractor's dock for delivery to Allergan.

4.7 **Remedy**. If any loss or damage to the API and/or Intermediate Product occurs as described in Sections 4.4, 4.5, (a) Contractor shall, a Contractor's option, return the API and/or Intermediate Product to Allergan or dispose of same according to Allergan's instructions and (b) if Contractor is responsible for any damage or loss described in Sections 4.5 or 4.6, the remedy shall be recovery by Allergan for the value for such API and/or Intermediate Product as outlined in the applicable Product Schedule.

ARTICLE 5 FORECASTS AND ORDERS

- 5.1 Forecasts. On or before the [***] of each month of each Contract Year, Allergan shall provide Contractor with a written non-binding [***] rolling forecast of the volume of each Product that Allergan anticipates will be required to be produced and delivered to Allergan during each of the next [***]. In the event the Contractor cannot fulfill the requirements of Allergan requests, then Contractor will respond in writing to Allergan within [***] of the receipt of the [***] forecast. The first [***] of such Rolling Forecast shall constitute a binding order for the quantities of Product specified therein ("Firm Commitment") regardless of receipt of Allergan's actual purchase order and the remaining [***] of the Rolling Forecast shall be used by Contractor for purposes of material acquisition on behalf of Allergan and Contractor's Processing and/or Packaging planning. The Contractor should make every effort to work with Allergan to the contrary, including Section 5.3 below, the parties acknowledge that certain materials may have long lead times and/or require a minimum order quantity. Therefore, Contractor may order the chemical and packaging components necessary to support up to [***] of Allergan's Rolling Forecast, or the applicable minimum order quantity, whichever is greater. Should Allergan subsequently reduce its Rolling Forecast, Allergan will be financially responsible for any material purchased by Contractor on Allergan's behalf. Any such material which is subsequently rendered excess due to a reduction in Allergan's Rolling Forecast may be subject to storage and inventory carrying fees for which Contractor may require a deposit.
- 5.2 Manufacturing Schedule. Within [***] of Contractor's receipt of the Rolling Forecast from Allergan, Contractor shall supply Allergan with ϵ Manufacturing Schedule on a rolling basis for the following [***].
- 5.3 Purchase Orders. On or before the [***] of each month of each Contract Year, subject to the terms of this Agreement, Allergan will provide Contractor with firm written Purchase Orders for each specific Product to be Processed and/or Packaged and delivered during the [***] following the month in which such written order is submitted or [***] from Allergan's Requested date of receipt. The Purchase Orders submitted by Allergan shall specify the Allergan purchase order number, the quantity of Product to be Processed and/or Packaged for a specific Product, the time in which such Processing and/or Packaging must be completed, the monthly delivery schedule, the approximate amount to be paid as specified in the applicable Product Schedule and any other elements necessary to ensure the timely production and delivery of a specific Product. Upon written verification of the receipt of the Purchase Order by Contractor, the following aspects of such Purchase Order shall be binding and shall become part of this Agreement: the number of Batches ordered, the estimated Production Fees, the commencement date of manufacturing and the delivery date. Contractor shall Process and/or Package in accordance with sucl Purchase Order. Within [***] after the receipt of each Purchase Order, Contractor shall provide Allergan with an expected delivery date for such Batches. I there is a conflict between this Agreement and the Purchase Orders, this Agreement shall govern.

Notwithstanding anything contained herein to the contrary and with consideration for the remaining shelf life required of a Product at delivery, Allergan agree that Contractor may produce Product up to [***] prior to the requested delivery date in order to accommodate fluctuations in production demands.

- 5.4 Permitted Amount to be Ordered The minimum size of any Purchase Order for a specific Product shall be [***]. The maximum quantities ordered will be no more than [***] of the forecast for such month or an additional batch, whichever is greater. Contractor will use its reasonable efforts, but shall be under no obligation, to supply Product in excess of [***] of the Firm Commitment.
- 8.5.5 Reliance by Contractor: Allergan understands and acknowledges that Contractor will rely upon the Purchase Orders submitted pursuant to Section 5.3 in ordering Raw Materials, API, Containers, Components and Labeling required to meet such orders. In addition, Allergan understands that to ensure an orderly supply of such Raw Materials, API, Containers, Components and Labeling with long lead time requirements and/or to achieve economies of scale in the costs therefore, it may be desirable for Contractor to purchase such Raw Materials, Containers, API, Components and Labeling in sufficient volumes to meet the production requirements for the Product during part or all of the forecasted periods referred to in Section 5.1 or to meet the production requirements of any longer forecasted period as Contractor and Allergan may agree to. Accordingly Allergan agrees that purchases may be made by Contractor in respect of the Raw Materials, API, Containers, Components and Labeling identified in Schedule A to satisfy the production requirements for the Product for such forecasted periods as may be agreed to in writing from time to time by Allergan at the request of Contractor. In such circumstances, if such Raw Materials, Containers, API, Components and Labeling are not included in the Finished Product purchased by Allergan within [***] after the forecast is respect of which such purchases have been made (or such longer period as the Parties may have agreed to), Allergan will pay to Contractor its costs thereof and, in the event such Raw Materials, Containers, Components and Labeling are incorporated into the Product subsequently purchased by Allergan, Allergan will receive credit for any of such costs previously paid to Contractor by Allergan.

ARTICLE 6 DELIVERY AND PAYMENT TERMS

- 6.1 **Storage**. Subject to Section 6.2 below, Contractor may store a specific Product at no charge for up to [***] at Contractor's sole discretion after Contractor's Quality Assurance Approval Date for each Batch of Product or up to [***] after all the reports are completed for Validation Batches of Batches where issues necessitate additional work.
- 6.2 Shipping. Shipment of a specific Product shall be in accordance with Allergan's instructions, provided that shipment is made in accordance with all relevant statutory requirements. A specific Product will be shipped to Allergan or its designee immediately upon release, freight collect. At Allergan's request, Contractor may hold the specific Product in Contractor's warehouse for a storage fee. If Allergan requests DPT to make any miscellaneous sma shipments of the specific Product, material, or other items on Allergan's behalf, Allergan agrees to reimburse Contractor for any shipping charges incurred. The delivery terms hereof shall be Ex Works ("EXW" Incoterms 2010) Contractor's Facility, freight collect. Title to, and risk of loss for, the specific Product materials, or other items shipped, shall transfer from Contractor to Allergan when Contractor delivers the specific Product, material, or other items, to Allergan's carrier at Contractor's Facility. Allergan shall bear all risk of loss, delay, or damage in transit, as well as cost of freight and insurance. Accordingly, the weights, tares and tests affixed by Contractor's invoice shall govern unless established to be incorrect. Claims relating to

quantity, weight and loss or damage to any specific Product sold under this Agreement shall be waived by Allergan unless made within [***] of receipt of the specific Product by Allergan. Contractor shall release for shipment to Allergan only the Product Processed and/or Packaged in accordance with all applicable Specifications of the Product. Unless agreed by Allergan in writing, Contractor shall ship no Product prior to Contractor Quality Assurance approva Additional shipping costs resulting from expedited deliveries or use of alternate carriers will be at Contractor's expense where the cause was within Contractor's control or at Allergan's expense where required by Allergan for reasons not within Contractor's control.

- (a) Shipping Documentation. The shipping labels for each shipment shall contain information as specified in writing by Allergan. In addition, each shipment of a Batch of Product shall include a copy of the Certificate of Analysis for that Batch.
- (b) <u>Transport Verification</u>. At the time of release to the freight carrier, if it is part of Contractor's responsibility under this Agreement, Contractor shall verify that the transport vehicle meets the proscribed Product storage conditions prior to the loading of a specific Product onto the transport vehicle. Contractor will also provide notice of Shipping to Allergan, if applicable.
- Invoices. Payment for all specific Products released for shipment, or any other payment for which Contractor is required to issue an invoice under this Agreement, shall be made in U.S. Dollars (USD), Net [***] after the date of Contractor's invoice therefor. On or after each Contractor Qualit Assurance Approval Date for each Batch of Product, Contractor shall invoice Allergan for the fees applicable to the batch, which shall be based on the fees set forth in the applicable Purchase Order and in accordance with applicable Product Schedule. Each such invoice shall, to the extent applicable, identify the Allergan Purchase Order number, Product name, quantity and Lot Number, Unit Price, freight charges and the total amount to be remitted by Allergan. I applicable, Contractor shall also provide Allergan with an invoice covering any inventory or Raw Materials, Containers, Components or Labeling purchased by Contractor in accordance with the terms of this Agreement.

Payments shall be made by certified check, via wire transfer or through other instrument accepted by Contractor. Fund transfers by wire should be made to the following:

Account name:	[***]
Account number:	[***]
Bank name:	[***]
	[***]
SWIFT code:	[***]
Bank location:	[***]
Contact:	[***]

6.4 Late Payment. A late fee of [***] of total invoice can be added each month for late payments. Contractor, at its sole discretion, has the right to discontinue Allergan's credit on future orders and to put a hold on any Processing and/or Packaging services if Allergan's account is not current. Such hold on Processing and/or Packaging shall not constitute a breach of this Agreement by Contractor. In the event credit is discontinued, a [***] material deposit paid by Allergan to Contractor will be required prior to Contractor ordering materials. ill addition, a [***] Production Fees deposit will be required prior to Contractor providing Processing and/or Packaging services and the balance of the invoice must be paid in full prior to release for shipment.

- 6.5 Sales and Use Taxes. Allergan shall be responsible for the payment of any sales and use taxes on the Product shipped to Allergan.
- 6.6 Shelf Life at Delivery. Allergan expects the Contractor to be able to release for delivery to Allergan the specific Product within [***] from the date that shelf life of the Product begins in order to optimize shelf life for market availability. Such shelf life will be identified in the applicable Product Schedule.

ARTICLE 7 PRICING

- 7.1 First Year Pricing. The cost for the Processing and/or Packaging of a Product during the first Contract Year of this Agreement shall be [***] subject to the adjustments provided for in Section 7.3 below.
- 7.2 Production Pricing for Subsequent Years. The parties hereto agree that the Production Fees set forth in the applicable Product Schedule shal be re-negotiated, in good faith, prior to the beginning of each calendar year. If the parties are unable to agree on a re-negotiated price at least [***] prior to the start of a new twelve (12) month period, then this Agreement, effective the first day of January of the new twelve (12) month period, shall continue in force with prices being adjusted to reflect the change in the most recently published monthly Producer Price Index [***], issued by the Bureau of Labor Statistics US Department of Labor ("PPI"), or comparable successor index, in July of the preceding year as compared to the same month of the year prior thereto unt such time as to when price negotiation can be completed or [***], whichever is less.
- 7.3 Adjustments to Pricing During any year of this Agreement, the Material Fees set forth in the applicable Product Schedule shall be subject to adjustment in accordance with the following:
- (a) <u>Materials Fees</u>. The Materials Fee will be adjusted once annually at the beginning of each calendar year and the Product Schedule shal be amended accordingly based on changes in [***]. In the event, however, the total underlying costs of Material Fee for a Product increases or decreases during any calendar year by more than [***], Contractor will provide documented cost justifications to Allergan in connection with such cost change(s). The fees may not be increased by more than [***] unless agreed to in writing by Allergan and if Allergan does not so agree, then the parties shall negotiate in good faith to resolve any issues. Contractor may promptly upon the effective date of such increase (decrease) of less than [***] adjust its Materials Fee for said Product to Allergan to compensate for the increase (decrease).

ARTICLE 8 QUALITY ASSURANCE

- 8.1 Quality Agreement. The Quality Agreement, attached as Exhibit A to this Agreement, shall be used by both Parties to assign the day-to-day responsibilities and manage the operations of both the Allergan and Contractor Quality Assurance groups in regards to the Processing and/or Packaging of a specific Product by Contractor for Allergan. The Quality Agreement will cover roles and responsibilities for both Allergan and Contractor for subject including, but not limited to, Master Batch Records and/or Master Packaging Records, Manufacturing Investigation or Deviation Reports, Validation activities Batch release, and Equipment qualification.
- 8.2 Contractor Responsibility. Contractor shall be responsible to ensure that it's Processing and/or Packaging and testing Facilities, Equipmen and systems meet regulatory

requirements for GMPs for the United States and European Union. Contractor shall be responsible for Validation of its Facility, Equipment, Processing and/c packaging processes as well as testing methods that apply and the costs of such Validation shall be absorbed by Contractor and/or agreed to in writing by Allergan. In addition, Contractor shall be responsible for all necessary education and training of its employees and contractors in regards to the Facility, Equipment, Processing and/or Packaging, and testing methods that apply to a specific Product. The costs of such education and training will be absorbed by Contractor. Contractor shall be responsible for storage of all API and/or Intermediate Product, Raw Materials, Containers, Components and Labeling, an Processing and/or Packaging, holding, release testing, storage and post market stability of a specific Product in accordance with (a) Contractor's interna systems and standard operating procedures relating to quality assurance in its manufacturing operations, (b) Allergan Specifications and (c) GMPs established by the United States and the European Union regulatory agencies and is addressed in the Quality Agreement.

8.3 <u>Inspection and Auditing Rights</u>.

- (a) <u>Monitoring of Operations</u>. Requirements are addressed as part of the Quality Agreement.
- (b) <u>GMP Audits</u>. Requirements are addressed as part of the Quality Agreement.
- (c) <u>Audits for Cause</u>. Requirements are addressed as part of the Quality Agreement.
- (d) <u>Audit Reports</u>. Requirements are addressed as part of the Quality Agreement.
- (e) Non-Compliance. Requirements are addressed as part of the Quality Agreement.
- (f) <u>Annual Product Review</u>. Requirements are addressed as part of the Quality Agreement.
- 8.4 Facility Qualification Contractor shall, at no cost to Allergan, take all such actions to qualify (and thereafter to maintain qualification of) the facility (or facilities) at which Contractor manufactures any specific Product hereunder, as required under applicable law in the United States to enable Allergar to obtain and maintain all applicable regulatory approvals for any specific Product, as applicable.

ARTICLE 9 TESTING AND INSPECTION OF THE PRODUCT

- 9.1 Outside Laboratory. Requirements are addressed as part of the Quality Agreement.
- 9.2 <u>Samples for Testing</u>. Requirements are addressed as part of the Quality Agreement.
- 9.3 **Timing**. Requirements are addressed as part of the Quality Agreement.
- 9.4 Rejected Products.

- (a) Rejection of Product by Allergan: Allergan may reject a specific Product which fails to meet the Specifications, provided that such failure impairs the safety or efficacy of the Product ("Rejected Product"). Allergan shall, within [***] after its receipt of any shipment of the specific Product and related Certificate of Analysis of the Product batch, notify Contractor in writing of any claim relating to rejected Product batch and, failing such notification shall be deemed to have accepted such Product batch. Such notice to Contractor shall specify how the Product batch failed to meet Specifications. Allergan shall grant to Contractor the right to inspect or test said Product batch. All Products contained in the specific Product batch shall be submitted to inspection and evaluation in accordance with Contractor's SOP's to determine whether or not said Products meet the Specifications.
- (b) <u>Replacement of Rejected Product</u>: As to any Rejected Product pursuant to Paragraph 9.4(a) above (including phases of or complete batches of bulk product), Contractor shall replace such Rejected Product (in an agreed upon batch order quantity, but in no event less than full batch increments) promptly after all materials, including but not limited to the API and/or Intermediate Product, are available to Contractor for the Processing and/o Packaging. If requested, Contractor shall make arrangements with Allergan for the return or disposal of Rejected Product.

(c) <u>Responsibility for Costs</u>:

- (i) In the event a Rejected Product is due to information, formulation, API and/or Intermediate Product, or any other material supplied by Allergan, then Allergan shall bear [***] of all costs directly related to and invoiced for Rejected Product including, but not limited to cost of API and/or Intermediate Product and cost of destruction of the Rejected Product, which shall be conducted by Allergan in accordance with all applicable laws and regulations. Additionally, Allergan shall be responsible for the costs of any rejected un-validated Product where the cause of rejection is not a result of Contractor's breach of cGMPS.
- (ii) Upon the completion of all necessary validation batches, and in the event a specific validated Product is rejected due to Contractor's failure to comply with the specifications, Contractor shall bear [***] of the Production Fees, including manufacturing costs, costs of all materials directly related to the Rejected Product and costs of destruction, plus any expenses associated with the Product return to include without limitation, reimbursement of custom and freight charges.
- (iii) In the event a validated Product does not meet final Specifications and results in a Rejected Product, but such failure is not due to either Allergan supplied API and/or Intermediate Product (or any other materials) or Contractor's failure to comply with written procedures or comply with its obligations under this Agreement, Allergan shall bear all cost of materials, including but not limited to API and/or Intermediate Product cost, with Contractor bearing all manufacturing costs related to Rejected Product, and with destruction cost to be paid by Allergan.
- (iv) Destruction of Rejected Product shall be in accordance with all applicable laws and regulations and the party conducting the destruction shall indemnify the other party hereto for any liability, costs or expenses, including attorney's fees and court costs, relating to a failure to dispose of such Product in accordance with such laws and regulations. The party conducting the destruction shall also provide to the other party hereto all manifests and other applicable evidence of proper destruction as may be requested by applicable law.
- 9.5 **Resolution of Conflict.** If the Parties disagree concerning whether a specific Product meets Specifications or the cause of such failure to mee Specifications or whether the Batch Records are complete, either Party may request, in writing, at any time, that an

independent laboratory/ consultant (the "Laboratory") be used to determine whether a specific Product meets the Specifications. Such Laboratory must be mutually acceptable to both Parties and shall meet all the requirements of an outside laboratory as specified in Section 9.1.

- (a) <u>Product Meets Specifications</u> If the Laboratory determines that a specific Product meets Specifications, or that the failure to mee Specifications is not due to an error on the part of the Contractor Allergan shall (a) pay to Contractor the amount invoiced for such Product pursuant to Section 6.3, and (b) pay to the Laboratory the amount of the fees charged by the Laboratory for such testing.
- (b) <u>Product Fails Specifications</u> If the Laboratory determines that a specific Product does not meet Specifications, and that failure is due to Contractor's failure to follow specifications, Contractor shall (a) pay to Allergan the then current replacement value (in accordance to the replacement value outlined in the specific Product Schedule) to Allergan of the API and/or Intermediate Product used to Process and/or Package such Product, (b) pay to the Laboratory the amount of the fees charged by the Laboratory for such testing, and (c) dispose of the non-conforming Product, at Contractor's out-of-pocket cost, in accordance with Allergan's instructions.
- (c) <u>Inconclusive Determination</u> If results from the Laboratory are inconclusive, final resolution will be settled in accordance with the provisions of Section 20 below.
- 9.6 <u>Latent Defects</u>. As soon as either party becomes aware of a Latent Defect in any Batch for a specific Product, it shall immediately notify the other party and the Batch involved, at Allergan election, shall be deemed rejected as of the date of such notice and be treated as Rejected Products ir accordance with Section 9.4 above, subject to the provisions of Paragraph 9.4(c).
 - 9.7 Long Term Stability Studies. Requirements are addressed as part of the Quality Agreement.
 - 9.8 **Retained Samples**. Requirements are addressed as part of the Quality Agreement.

ARTICLE 10 REGULATORY COMPLIANCE AND RELATED MATTERS

- 10.1 <u>Product Regulatory Approvals</u>. Allergan shall be responsible for obtaining all product regulatory approvals relating to registration of each Product, shall pay any applicable user fees for such, and shall own the regulatory filing. All regulatory filings including, but not limited to, NDAs, ANDAs an amendments thereto, shall be the sole property of Allergan.
 - 10.2 **Regulatory Communications**. Requirements are addressed as part of the Quality Agreement.
- 10.3 <u>Submissions to Regulatory Authorities</u>. If Allergan is required to submit to the Regulatory Authorities any information concerning the Processing and/or Packaging and marketing of a Product, Contractor will provide Allergan copies of such documentation, data and other information with respect to the Processing and/or Packaging and the Facility as shall be necessary for such submission to the Regulatory Authorities. Contractor shall also make available its cooperation and consultation if reasonably requested by Allergan and/or required by the Regulatory Authorities for development of additional data or performance of studies concerning such Product, and Allergan shall pay Contractor's reasonable costs therefore. Contractor shall also provide, if required by the Regulatory Authorities, information concerning

its Processing and/or Packaging and quality control procedures with respect to such Product. Contractor shall provide Allergan all documentation, data and information referred to in this Section reasonably in advance of their required submission to allow for Allergan's review and comments. Contractor shall endeavor in good faith to satisfactorily resolve all Allergan comments prior to submission if such submission is to be made by Allergan.

- Responsibility for Compliance. Allergan shall be responsible for and shall ensure the compliance of the API and/or Intermediate Product and the Master Batch Record and/or Master Packaging Record, including Specifications and Labeling, with the requirements of applicable Regulator Authorities; provided, however, that the foregoing shall not in any way limit any of Contractor's obligations hereunder. Contractor shall comply with all applicable laws and regulations, rules, ordinances, injunctions, orders and decrees, and shall maintain in effect all required governmental permits, licenses, orders, applications and approvals regarding a specific Product and the use of its Facility to Process and/or Package and store such Product, and Contracto shall Process and/or Package and store such Product in accordance with all such permits, licenses, applications and approvals.
 - 10.5 **Inspections**. Requirements are addressed as part of the Quality Agreement.
 - 10.6 <u>Contractor Communications</u>. Requirements are addressed as part of the Quality Agreement.
 - 10.7 **Record Retention**:
 - (a) <u>By Contractor</u>: Requirements are addressed as part of the Quality Agreement.
 - (b) By Allergan: Requirements are addressed as part of the Quality Agreement.
- 10.8 **Registration Assistance**. Upon the reasonable request of Allergan, Contractor promptly shall, at no cost to Allergan, provide Allergan with such information, samples and technical assistance, and otherwise reasonably cooperate with Allergan, in connection with the preparation, prosecution and maintenance of all applicable regulatory support.

ARTICLE 11 ENVIRONMENTAL HEALTH AND SAFETY

- 11.1 Environmental Health and Safety Procedures Contractor shall adhere to its internal environmental, health and safety procedures for Processing and/or Packaging and the handling of the Raw Materials, Containers, Components, Labeling, API and/or Intermediate Product, Hazardous Wast Non- Hazardous Waste and Product. Such procedures shall comply with all applicable federal, state and local environmental laws and regulations (including without limitation federal, state and local health and safety laws and regulations). Contractor shall use engineering controls to limit API and/or Intermediate Product exposures to workers and the community. If engineering controls are not in place, appropriate respiratory protection and other personal protective equipment (PPE) shall be used in the interim. Contractor shall obtain, keep current and comply with any environmental permits (e.g. air, water, waste) necessary to Process and/or Package a Product.
- 11.2 <u>SDS</u>: Allergan shall provide Contractor with the applicable SDSs for the API, Intermediate Product, and the Product and any amendments t such as may be made from time to time. Contractor shall comply with the procedures set forth in these SDSs, including but not limited to worker protection spill control and waste disposal.

- 11.3 Training. Contractor shall educate and train all affected employees and contractors about the potential hazards associated with the handling of the API and/or Intermediate Product, Raw Materials, Containers, Components, Hazardous Waste, Non-Hazardous Waste and the Processing and/or Packaging, analyzing and handling of a specific Product, and on the proper use of engineering controls, Processing and Packaging equipment and persona protective equipment referenced in the SDS. Contractor shall make the SDS available to all such employees and contractors. Contractor shall maintain record of such training for review by Allergan. The Master Batch Record and/or Master Packaging Record shall specify procedures and protections that are required in connection with Processing and/or Packaging. Allergan shall have no responsibility for education, training, or ensuring knowledge of any Contractor employees and contractors about the potential hazards associated with the handling of the API and/or Intermediate Product, Raw Materials, Containers Components, Hazardous Waste, Nonhazardous Waste and the Processing and/or Packaging, analyzing or handling of such Product, and on the proper use or engineering controls, Processing and Packaging equipment and personal protective equipment as referenced in the SDS. The Master Batch Record and/or Master Packaging Record shall specify procedures and protections that are required in connection with Processing and/or Packaging.
- Audit and Responsiveness. In addition to Allergan auditing rights listed in Section 12.3, Allergan shall have the right to audit Contractor's facilities for compliance with this Section 11. If Allergan personnel or their representatives at the Facility observe any employee of Contractor acting in violation of the SDS or the Master Batch Record and/or Master Packaging Record or any state or federal law or regulation, Contractor shall take prompt action a Contractor deems appropriate to respond to such observations. Allergan shall document the observations in writing and Contractor shall document the response in writing, and shall provide Allergan with a copy of such writing in a timely manner.
- 11.5 <u>Air Emissions and Wastewater Management</u> Contractor shall properly handle and manage air emissions and wastewater effluents to minimize risks to the environment. Contractor shall comply with applicable local, state, and federal monitoring, control and reporting requirements as well as applicable policies, regulations, laws, and permit conditions.

ARTICLE 12 WASTE HANDLING AND DISPOSAL

- 12.1 <u>Waste Handling by Contractor</u>: Contractor shall handle, package, label, store and coordinate transportation of all Hazardous Waste and Non-Hazardous Waste in accordance with all applicable federal, state and local laws and regulations. Contractor shall arrange for the delivery of the Hazardous Waste to a waste contractor for transport and disposal (the "Waste Contractor"). Contractor shall ensure disposal of all Allergan waste is in accordance with all applicable federal, state, and local laws and regulations. Incineration shall be the primary means of disposal for Allergan waste. Alternative means of disposal shall be discussed with Allergan.
- 12.2 <u>Waste Contractor</u>. The Waste Contractor shall be a contractor who is appropriately licensed to transport and dispose of the Waste. The disposal site shall be selected from the list of approved Allergan locations.
- 12.3 Audit Rights. In addition to Allergan auditing rights listed in Sections and 11.4, Allergan retains the right to inspect Contractor's waste handling, packaging, storing, transportation and disposal activities and any and all records pertaining thereto, as they pertain to a specific Product, and shall have the right to make copies thereof. Contractor shall maintain copies of the waste manifest and certificates of destruction, if any, from the approved incineration facility on file for inspection by Allergan. Contractor will inform Allergan promptly of any environmental or regulatory issues that it becomes aware of that could jeopardize

Contractor's ability to produce such Product pursuant to this Agreement or impact Allergan's reputation.

ARTICLE 13 RECALLS, FIELD ALERTS AND COMPLAINTS

- 13.1 Recall and Field Alert Responsibility. If any Product must be recalled by reason of failure to meet any requirements of any regulatory authority or any other requirements of law or if an NDA Field Alert (as defined in 21 CFR 314.81) must be issued, Allergan shall have the sole responsibilit to effect such recall or issue such Field Alert. Contractor shall cooperate as reasonably required in Allergan's efforts in accordance with Sections 13.1 (a) and 13.1 (b).
- (a) Allergan's Responsibility. If the failure to meet applicable legal requirements resulting in a recall or issuance of an NDA Field Alert for a Product is not caused by the act or omission of Contractor, then Allergan shall reimburse Contractor for any costs reasonably expended by Contractor to affect the recall. Allergan shall bear the cost of (a) any API and/or Intermediate Product involved in such a recall and (b) the Production Fees for any Product that is recalled and (c) reimburse Contractor on a time and materials basis which shall not exceed the Production Fees, for any Work-in-Process, Finished bu non-approved Product, or Product that cannot be shipped due to the condition requiring the recall, provided that as of the date that the Processing and/or Packaging was suspended as a result of the recall, such Work-in-Process had been otherwise Processed and/or Packaged in accordance with the Master Batch Record and/or Master Packaging Record, and the non-approved Product and/or unshipped Product conforms in all material aspects to th Specifications and was Processed and/or Packaged in accordance with the Processing and/or Packaging, quality assurance and Validation procedures se forth in the Specifications and with any applicable regulations of any Regulatory Authorities, including GMPs.
- (b) <u>Contractor's Responsibility</u>. If the failure to meet applicable legal requirements resulting in a recall or issuance of an NDA Field Alert is caused by an act or omission of Contractor or if a Product failed to conform as of the Contractor Approval Date to any of the Specifications resulting in a recall or issuance of an NDA Field Alert, Contractor shall reimburse Allergan for (a) any cost reasonably expended by Allergan to effect the recall or issue the NDA Field Alert up to the amount of [***].
 - (c) <u>Cooperation</u>. Requirements are addressed as part of the Quality Agreement.
 - 13.2 Questions and Complaints. Requirements are addressed as part of the Quality Agreement.

ARTICLE 14 TERM AND TERMINATION

- 14.1 **Term.** This Agreement shall become effective as of the Effective Date. Subject to any extension pursuant to Section 14.2, this Agreement shall expire [***] from the Effective Date hereof (the "Initial Term"), unless terminated by one of the Parties as provided herein, except that, as long as any Produc Schedule is in effect in accordance with its terms, the terms of this Agreement shall remain in effect with respect to such Product Schedule.
- 14.2 **Extension**. This Agreement shall thereafter automatically renew for periods of [***], unless any party shall give notice to the other to the contrary at least [***] prior to the expiration of the Initial Term or any renewal term of the Agreement.

14.3 Termination Without Cause. Each Party shall have the right to terminate this Agreement without cause upon written notice to the other Party of its intention to terminate at least [***] prior to the end of the then current term; provided, however, that in no event shall this Agreement be terminated by Contractor until the earlier of (a) the date that an alternate manufacturing site chosen by Allergan is approved by the FDA or (b) [***] from the date of such written notice of termination. In the case of termination without cause by Contractor within the Initial Term, Contractor shall reimburse Allergan [***] of technical transfer costs incurred. In the case of termination without cause by Contractor in any term of the Agreement, Contractor shall cooperate fully in the transfer of technology to a new manufacturing site chosen by Allergan as detailed in Section 15. Notwithstanding cooperation in transferring the Product to a new location, Contractor shall continue to supply the Product according to the forecast for the entire period until approval at an alternate site or [***] following the termination notice unless the Parties agree in writing to a different schedule providing, however, that Allergan may order up to a maximum of [***] of the amount ordered in the [***] preceding the termination notice for any subsequent [***] period.

14.4 **Termination for Cause**.

- (a) <u>Material Breach</u> Either Party shall have the right to terminate this Agreement or as applicable, a specific Product Schedule, upor immediate written notice if the other Party is in material breach or default of any of the obligations or provisions of this Agreement and fails to cure the same within [***] following receipt of written notice of such breach.
- (b) <u>Insolvency</u>. Either Party at its sole option may immediately terminate this Agreement upon written notice, but without prior advance notice, to the other Party in the event that (a) the other Party is declared insolvent or bankrupt by a court of competent jurisdiction; (b) a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by such other Party; or (c) this Agreement is assigned by such other Party for the benefit of creditors.
- (c) <u>Agency Action</u> Allergan may terminate this Agreement as to any specific Product and the applicable Product Schedule upon [***] written notice in the event that any governmental agency takes any action, or raises any objection, that prevents Allergan from importing, exporting, purchasing or selling such Product.
- (d) <u>Assignment</u>. Contractor may terminate this Agreement on [***] prior written notice if Allergan assigns its rights and obligations, or any part thereof, under this Agreement to an assignee that is, in the opinion of Contractor acting reasonably, not a credit worthy substitute for Allergan or with whom Contractor has had prior unsatisfactory business relations.
- 14.5 <u>Outstanding Obligations</u>. Any expiration or termination of this Agreement shall not affect any outstanding obligations or payments due hereunder prior to such expiration or termination, nor shall it prejudice any other remedies that the Parties may have under this Agreement. In the event that the Agreement is terminated due to a breach of this Agreement according to Section 14.4 by Contractor, Contractor shall cooperate fully with Allergan to transfer all processes and documentation relating to this Agreement back to Allergan or another manufacturing site in accordance with Section 15.
- 14.6 <u>Inventory Transfer</u>. Upon expiration or termination of this Agreement, Contractor shall transfer all remaining Product and Raw Materials Containers, Components and Labeling, in its possession, directly relating the services hereunder, to Allergan as provided below:

- (a) <u>API and/or Intermediate Product</u>. At Allergan's expense in accordance with Allergan's instructions at Contractors cost of acquisition if applicable.
 - (b) Raw Materials, Components, Containers and Labeling. At Contractor's cost of acquisition.
- (c) <u>Work-in-Process</u>. If the termination is by Contractor due to a breach of this Agreement according to Section 14.4 by Allergan Allergan shall pay for Work-in-Process on a time and material basis to be agreed between the Parties; provided, that the fee shall not exceed the Production Fees applicable to any such Work-in-Process. If the termination is by Allergan due to a breach of this Agreement according to Section 14.4 by Contractor, Allergan may elect to cancel any Work-in-Process and owe no money for such Work-in-Process or elect to require Contractor to complete the Work-in-Process and upon the Contractor Approval Date, pay Contractor the Production Fees at the yearly forecasted manufacturing rate in effect immediately prior to such breach by Contractor for such Product in accordance with Section 6.3.
- (d) <u>Finished Product</u>. At Contractor's then current Production Fees; provided, however, that Allergan shall not be obligated to purchase any Product that is nonconforming to Specification or written procedures due to Contractor's fault.
- (e) <u>Equipment</u>. If this Agreement expires or is terminated for any reason, Allergan will have the option to: (i) convey title to all or any portion of the Equipment it owns to Contractor at a price to be agreed by the parties; or (ii) remove or arrange to remove from Contractor's Facility a Allergan's expense, all such Equipment that is not conveyed to Contractor. For the avoidance of doubt, nothing herein shall obligate Contractor to take title to or purchase such Equipment from Allergan and in the event Contractor refuses to take title, Allergan shall be responsible, at its sole expense including, but not limited to, any applicable Facility restoration and storage cost, to remove the Equipment from Contractor's Facility.

ARTICLE 15 TECHNOLOGY TRANSFER

- 15.1 <u>Contractor Cooperation</u>. If, at any time during this Agreement, Allergan plans to move the Processing and/or Packaging of a Product to ar alternate site, either to an Allergan site or to a new contractor's site, Contractor shall cooperate reasonably with Allergan to assist in the transfer of all Allergan owned technology relating to the Product to the alternate site.
- 15.2 <u>Technical Assistance</u>. To facilitate an orderly transfer of Processing and/or Packaging to an alternate site, Contractor shall provide the alternate site with reasonable assistance in the form of reasonable access to Contractor's facilities and consulting services to be provided by Contractor personnel at the alternate location. The consulting services provided under this Section 15.2 shall relate to the Processing and/or Packaging, quality control quality assurance, and the CMC (chemistry, manufacturing and control) part of the Product registration process.
- 15.3 <u>Allergan Payment</u>. Allergan will compensate Contractor for services provided under this Section 15 on a time and material basis. Allergan also agrees to reimburse Contractor for all reasonable out-of-pocket expenses incurred in connection with Contractor personnel consulting with Allergan as contemplated under this Section 15.

ARTICLE 16 REPRESENTATIONS AND WARRANTIES

- 16.1 Authority. Each Party represents and warrants that it has the full right and authority to enter into this Agreement and that it is not aware of any impediment that would inhibit its ability to perform its obligations hereunder.
- 16.2 Contractor Warranties. Contractor represents and warrants that work it performs hereunder will be in accordance with Section 8.2, and that the Product Processed and/or Packaged pursuant to this Agreement will have been Processed and/or Packaged in accordance with the Specifications for the release of the Product or pursuant to exceptions approved by Allergan at the time of Processing and/or Packaging. Contractor further warrants that, subject to the provisions of Section 16.4 below, all Products shall have been manufactured by Contractor in compliance with applicable regulations of the United States and European Union regulatory authorities and cGMPs.
- 16.3 **Debarment**. Contractor represents and warrants that it does not use the services of any persons debarred or suspended under 21 U.S.C. § 335a (a) or (b) in any capacity associated with or related to the Processing and/or Packaging of a Product. Contractor further represents and warrants that i shall not hire or retain as an officer or 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 United States Food, Drug, and Cosmetic Act.
- Allergan Warranties. Allergan represents and warrants that it is lawfully permitted to disclose the Allergan Specifications to Contractor. Allergan further represents and warrants that any trademarks utilized in conjunction with a Product are lawfully used as directed by Allergan. Allergan acknowledges that it bears sole responsibility for the validity of all test methods and appropriateness of all Specifications, and also bears sole responsibility for all regulatory approvals, fillings, and registrations and adequacy of all validation, stability, and preservative efficacy studies. In conjunction thereto, therefore, Allergan further represents and warrants that the Allergan Specifications for a Product conform to all applicable laws and regulations, and that such Product i labeled and formulated in accordance with Allergan Specifications and Processed and/or Packaged in compliance with applicable GMPs may be lawfully sole and distributed in every jurisdiction covered by this Agreement.
- 16.5 <u>Disclaimer</u>: EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT OR ATTACHMENTS THI ALLERGAN AND CONTRACTOR MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EXPI IMPLIED, WITH REGARD TO THE PRODUCT INCLUDING ANY WARRANTIES OF MERCHANTABILITY OR FITNESS PARTICULAR PURPOSE.

ARTICLE 17 INDEMNIFICATION

- 17.1 <u>Allergan</u>. Allergan agrees to defend, indemnify and hold Contractor, its officers, employees and agents harmless against any and all losses, damages, fines, costs, claims, demands, judgments and liability to, from and in favor of third parties resulting from, or relating to Allergan performance in breach of its duties, representations or warranties under this Agreement, except to the extent that any such losses, damages, fines, costs, claims, demands, judgments and liability are due to the gross negligence, willful misconduct and/or wrongful act(s) or omission(s) of Contractor, its officers, employees or agents.
- 17.2 <u>Contractor</u>. Contractor agrees to defend, indemnify and hold Allergan, its officers, employees and agents harmless against any and all losses, damages, fines, costs, claims, demands, judgments and liability to, from and in favor of third parties resulting from, or relating to Contractor performance in breach of its duties, representations or warranties under this Agreement except to the extent that any such losses, damages, fines, costs, claims, demands,

judgments and liability are due to the gross negligence, willful misconduct and/or wrongful act(s) or omission(s) of Allergan, its officers, employees or agents.

17.3 Indemnification Process. A party (the "indemnitee") that intends to claim indemnification under this Article 17 shall notify the other party (the "indemnitor") promptly in writing of any action, claim or liability in respect of which the indemnitee believes it is entitled to claim indemnification, provided that the failure to give timely notice to the indemnitor shall not release the indemnitor from any liability to the indemnitee except to the extent the indemnitor is prejudiced thereby. The indemnitor shall have the right, by notice to the indemnitee, to assume the defense of any such action or claim within the fifteen (15) day period after the indemnitor's receipt of notice of any action or claim with counsel of the indemnitor's choice and at the sole cost of the indemnitor. If the indemnitor so assumes such defense, the indemnitee may participate therein through counsel of its choice, but at the sole cost of the indemnitee. The party not assuming the defense of any such claim shall render all reasonable assistance to the party assuming such defense, and all reasonable out-of-pocket costs of such assistance shall be for the account of the indemnitor. No such claim shall be settled other than by the party defending the same, and then only with the consent of the other party which shall not be unreasonably withheld; provided that the indemnitee shall have no obligation to consent to any settlement of any such action or claim which imposes on the indemnitee any liability or obligation which cannot be assumed and performed in full by the indemnitor, and the indemnitee shall have no right to withhold its consent to any settlement of any such action or claim if the settlement involves only the payment of money by the indemnitor or its insurer.

17.4 <u>Limitations of Liability</u>.

- (a) NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR INDIRECT, INCIDENTAL, SPECIAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF ITS PERFORMANCE UNDER THIS AGREEMENT, INCLUDING WITHOUT LIMITATION I REVENUES, COST OF COVER, LOSS OF PROFITS OR DATA, LOSS OF USE, WHETHER IN CONTRACT OR IN TORT, INC NEGLIGENCE, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.
- (b) WITH THE EXCEPTION OF GROSS NEGLIGENCE AND WILLFUL MISCONDUCT, CONTRACTOR'S LI UNDER THIS AGREEMENT FOR FIRST PARTY DAMAGES OF ANY KIND, INCLUDING, WITHOUT LIMITATION, RESTITUTION NOT EXCEED, THE AMOUNT OF MANUFACTURINGES PAID BY ALLERGAN TO CONTRACTOR UNDER THIS AGREEMENT LA MAXIMUM AMOUNT OF [***].

ARTICLE 18 INSURANCE

- 18.1 <u>Contractor's Insurance Requirements</u>. Contractor shall have, at a minimum, the insurance coverage listed below:
 - (a) Worker Compensation, including Occupational Disease.
 - (i) <u>Statutory Limits</u>. Statutory Limits of the State in which the Product will be Processed and/or Packaged and
- (ii) Employers Liability Insurance Employers Liability Insurance with minimum limits of [***] each accident and a [***] disease policy limit.

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- (b) <u>Comprehensive General Liability Insurance</u> Comprehensive General Liability Insurance with minimum limits of [***] for bodily injury and property damage..
- (c) Products Liability Insurance Products Liability insurance including bodily injury and property damage for all products and completed operations and work supplied under this agreement with a minimum policy limit of [***] per occurrence and [***] in the annual aggregate.
- (d) Comprehensive Automobile Liability Insurance. Covering Contractor for claims arising from owned, hired, and non-owned vehicles for bodily injury and property damage with minimum limits of [***] per occurrence and [***] aggregate.
- (e) <u>Excess Liability Insurance</u> Contractor may fulfill its insurance obligations under Section 18 by use of Umbrella or Excess Liability policies but as long as such Umbrella or Excess Policy Form is Follow Form the coverages provided in the primary policies.
- (f) <u>Certificates of Insurance</u> Certificates of the above insurance must be filed with Allergan within five (5) days BEFORE THE TIM PERFORMANCE UNDER THIS AGREEMENT IS COMMENCED. Contractor represents (1) that all policies of insurance required hereunder sl appropriate endorsement, or otherwise, provide for thirty (30) days prior written notice of cancellation to Allergan, and (2) that the Contractual Liability Insurance required hereunder, shall, by appropriate endorsement, or otherwise, specifically insure the terms and conditions as expressed in this Agreement, and (3) that all insurance policies, except Worker's Compensation, shall identify Allergan as an additional insured under such policies. This Insurance Certificate shall be an integral part of this Agreement to which it is attached or incorporated by reference.
- Allergan's Insurance Requirements. While this Agreement is in full force and effect, and for a period of [***] following termination if written on a claims made basis, Allergan shall maintain commercial general liability insurance covering bodily injury and property damage, premises liability and personal/advertising injury in an amount not less than [***] per occurrence with an annual aggregate amount of not less than [***]; products liability coverage provided under this contract coverage in an amount not less than [***] per occurrence with an annual aggregate amount of not less than [***]. Notwithstanding the foregoing, Allergan can satisfy such insurance requirements through a program of self-insurance. Such evidence of insurance coverage can be in the form of the original policy or a Certificate of Insurance which shall name DPT as an additional insured. Concurrent with the execution of this Agreement, Allergan shall provide evidence of the foregoing insurance coverage to:

[***]

ARTICLE 19 FORCE MAJEURE

- 19.1 **Excusing Performance**. Neither Party shall be liable for the failure to perform its obligations under this Agreement if such failure is occasioned by a contingency beyond such Party's reasonable control, including, but not limited to, strikes or other labor disturbances, lockouts, riots, wars, fires, floods, storms or other natural disasters, or failure of public utilities or common carriers.
- 19.2 Notice. A Party claiming a right to excused performance under Section 19.1 shall immediately notify the other Party in writing of the extent of its inability to perform, which notice shall specify the occurrence beyond its reasonable control that prevents such performance.

19.3 **Resumption**. Each Party shall employ all reasonable efforts, at its cost, toward resumption of its performance hereunder if such performance is delayed or interrupted by reason of force majeure. In the event that any Force Majeure circumstance cannot be removed or overcome within [***] (or such other period as the parties jointly shall determine from the date the party affected first became affected), then either party may, as the expiration of such period by notice to the other party terminate the term of this Agreement and neither Contractor nor Allergan shall be liable to the other for damages.

ARTICLE 20 DISPUTE RESOLUTION

20.1 **Non-Legal Dispute Resolution** In the case of any dispute between the Parties regarding any section of this Agreement or any Batch of Product, which has not been resolved by reasonable negotiation between the involved personnel of Allergan and Contractor or by the use of an independent laboratory, the Vice President of Technical Operations of Allergan or his nominee will meet with the corresponding Vice President of Contractor to make all reasonable efforts to resolve the dispute before any other action is taken.

ARTICLE 21 CONFIDENTIALITY

- 21.1 <u>Disclosure</u>. During and in furtherance of this Agreement, each of the Parties hereto may disclose certain of its Confidential Information to the other Party.
- 21.2 <u>Use of Confidential Information and Term</u> During term of this Agreement and for a period of [***] from the termination thereof unless superseded by a general CDA, each of the Parties hereto agrees (a) to use the Confidential Information only in connection with the terms of and performance of this Agreement; (b) to treat the Confidential Information as it would its own proprietary information; and (c) to take all reasonable precautions to prevent the disclosure of the Confidential Information to any individual or entity, (except to such of its employees and contractors who reasonably require same for purposes hereof and who are bound in writing to that Party by like obligations as to confidentiality and non-use), without the prior written consent of the other Party.
- 21.3 Exceptions to Confidential Information Each of Allergan and Contractor shall be relieved of any and all obligations under Section 21.2 regarding Confidential Information which (a) was lawfully in the possession of the other Party as evidenced by the written records of such Party, and which was not acquired directly or indirectly from the disclosing Party's group or any of the representatives or advisors to the disclosing Party, or in violation of any confidentiality agreement (b) at the time of disclosure, was generally available to the public; or which after disclosure hereunder becomes generally available to the public through no fault attributable to a Party hereto; (c) is hereafter made available for use or disclosure from any third party having a right, to the best of receiving Party's knowledge, to do so, or (d) is required to be disclosed by the law or the rules of any applicable regulatory organization, provided, however, that the receiving Party shall so notify the disclosing party of its intent and cooperate with the disclosing Party on reasonable measures to protect the confidentiality of the information.

ARTICLE 22 INTELLECTUAL PROPERTY

22.1 Allergan IP. For purposes hereof, "Allergan IP" means all intellectual property and embodiments thereof owned by or licensed to Allergan as of the date hereof or developed by Allergan other than in connection with this Agreement. The Product and all related documents, processes, technology or know how supplied by Allergan hereunder shall only be used by

Contractor as specified in this Agreement, and shall be returned to Allergan upon request or upon termination of this Agreement.

- 22.2 Contractor IP, Invention or Discovery. "Contractor IP" means all intellectual property and embodiments thereof owned by or licensed to Contractor as of the date hereof or developed by Contractor other than in connection with this Agreement. Contractor shall promptly disclose only to Allergar any discovery or invention resulting from performance of this Agreement. The entire right, title, and interest in and to any invention resulting from performance of this Agreement shall be owned by Allergan. Allergan shall have the sole and exclusive right to obtain, at its option, patent protection in the United States and foreign counties on any such invention. Contractor shall assign to Allergan all right, title and interest in and to any invention or discovery relating to a specific Product. Contractor shall also render all reasonable assistance to Allergan in the filing and prosecution of U.S. and foreign counterpart patent applications.
- 22.3 <u>Contractor's Business Model</u>. Notwithstanding the foregoing, or any provision contained herein, to the contrary, Allergan acknowledges that as a contract manufacturing organization, Contractor's business involves the application of its expertise, technology and know-how to numerous pharmaceutical and other products and that Contractor retains the right (subject to its obligations under the applicable confidentiality provision) to apply such expertise, technology and know-how to a variety of products or services.

ARTICLE 23 OMITTED

ARTICLE 24 ADDITIONAL TERMS AND PROVISIONS

- 24.1 <u>Currency</u>. Unless otherwise indicated, all dollar amounts in this Agreement are expressed in the lawful currency of the United States of America.
- 24.2 <u>Headings</u>. The titles and headings herein are for convenience only and shall not be used to interpret or construe the terms and conditions of this Agreement.
- 24.3 <u>Singular Terms</u>. Except as otherwise expressly provided herein or unless the context otherwise requires, all references to the singular shall include the plural as well.
- 24.4 <u>Trademarks</u>. Allergan and Contractor hereby acknowledge that neither Party has, nor shall it acquire, any interest in any of the other Party's copyrighted materials, trademarks, trade names, or other intellectual property unless expressly agreed to in writing. The Parties agree not to use any trademark or trade name of the other Party, except as specifically authorized by the other Party.
- 24.5 <u>Independent Contractors</u>. The Parties shall be deemed to be independent contractors, and this Agreement shall not be construed to create between Allergan and Contractor any other relationship such as, by way of example only, that of employer-employee, principal and agent, joint-venturer, copartners or any similar relationship, the existence of which is expressly denied by the Parties hereto. Neither party shall have authority to conclude contracts or otherwise to act for or bind the other party in any manner, whatsoever, as agent or otherwise. Any and all contracts and agreements entered into by either party shall be for that party's sole account and risk and shall not bind the other party in any respect.
- 24.6 **Public Statements.** Neither Party shall use or refer to, without the other Party's prior written consent, the name of such other Party in any public statements, whether oral or

written, including, but not limited to, shareholders reports, communications with stock market analysts, press releases or other communications with the media, or prospectuses; provided, however, that each Party may disclose to any authorized third party the existence and subject matter of this Agreement.

- Allergan, provided that Contractor may not assign this Agreement or any of its rights or obligations hereunder except with the written consent of Allergan, provided that Contractor may assign its rights under this Agreement without the consent of Allergan pursuant to an internal corporate reorganization. Subject to the provisions of Section 14.4(d), Allergan may assign this Agreement or any of its rights or obligations hereunder without approval from Contractor, provided, however, that Allergan shall give prior written notice of any assignment to Contractor, and any assignee shall covenant in writing with Contractor to be bound by the term of this Agreement. Notwithstanding the foregoing provisions of this Section, either Party may assign this Agreement to any of its Affiliates or to a successor to all or substantially all of its business, provided that such assignee executes an agreement with the non-assigning Party hereto whereby it agrees to be bound hereunder.
- 24.8 Governing Law. This Agreement shall be construed and enforced in accordance with the laws of the state of Delaware (regardless of its or any other jurisdiction's choice of law principles). The parties shall initially attempt in good faith to resolve any significant controversy, claim, allegation of breach or dispute arising out of or relating to this Agreement through nonlegal dispute resolution in accordance the provisions of Section 20 and other applicable provisions of this Agreement. If the dispute is not resolved within thirty (30) days (or such other period of time mutually agreed upon by the parties) of notice of the dispute, then the parties agree to submit the dispute to arbitration as provided herein. Unless otherwise mutually agreed by the parties, only if the dispute is not resolved through negotiations as set forth herein, may a party resort to arbitration. All disputes relating in any way to this Agreement shall be resolved exclusively through arbitration conducted in accordance with the Commercial Arbitration Rules of the American Arbitration Association as then in effect. In the event either party demands arbitration, it shall do so within thirty (30) days after the expiration of the notice of the dispute (or any mutually agreed extension) and shall include a request that such arbitration be held within thirty (30) days of such demand. The arbitration hearing shall be held as soon as practicable. The arbitration hearing shall be held in New Jersey and shall be before a single arbitrator selected by the parties in accordance with the Commercial Arbitration Rules of the American Arbitration Association pursuant to its rules on selection of arbitrators. The arbitrator shall render a formal, binding non-appealable resolution and award on each issue as expeditiously as possible but not more than ten (10) business days after the hearing. In any arbitration costs to a minimum
- 24.9 <u>Notices</u>. Any notice, approval, instruction or other written communication required or <u>permitted</u> hereunder shall be sufficient if made or given to the other Party by personal delivery or nationally recognized courier service to the mailing address set forth below:

II to Allergan:	If to	Allergan:
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Address: [***]

With a copy to:

General Counsel

Fax number: [***]

If to Contractor:

Address: [***]

or to such other addresses provided to the other Party in accordance with the terms of this Section. Notices of written communication made or given by personal delivery or courier service shall be deemed to have been sufficiently made or given when sent (receipt acknowledged).

In addition, a fax copy shall be sent to the other party. If the fax is lengthy, a fax notice shall be sent to the other party at the fax number listed herein alerting them that a written communication has been made or given.

- 24.10 Additional Product. The Parties covenant and agree that additional Product may be added to this Agreement (through use of a Produc Schedule similar to the one attached hereto as Exhibit A) and such additional Product shall be governed by the general conditions hereof with any special terms (including, without limitation, fees) governed by an addendum hereto and signed by both parties.
- 24.11 Entire Agreement. This Agreement and any Exhibits, Product Schedules and other attachments hereto, constitutes the full, complete, fina and integrated agreement between the Parties hereto relating to the subject matter hereof and supersedes all previous written or oral negotiations, commitments, agreements, transactions, or understandings with respect to the subject matter hereof. Any modification, amendment, or supplement to this Agreement must be in writing and signed by authorized representatives of both Parties. If there is any conflict between this Agreement and the terms and conditions contained on any Purchase Order or in any Schedule hereto, the terms and conditions of this Agreement shall prevail.
- 24.12 <u>Amendments: No Waiver</u>. No provision of this Agreement may be amended, revoked or waived except in writing signed and delivered by an authorized officer of each Party. No failure or delay on the part of either Party in exercising any right hereunder will operate as a waiver of, or impair, any such right. No single or partial exercise of any such right will preclude any other or further exercise thereof or the exercise of any other right. No waiver of any such right will be deemed a waiver of any other right hereunder.
- 24.13 **Validity**. Should any part or provision of this Agreement be held unenforceable or invalid, the invalid or unenforceable provision shall be replaced with a provision which accomplishes, to the extent possible, the original business purpose of such provision in a valid and enforceable manner, and the remainder of this Agreement shall remain binding upon the Parties.
- 24.14 <u>Headings</u>. The descriptive headings in this Agreement are inserted for the convenience of reference only and are not intended to be part of or affect the meaning of or interpretation of this Agreement.
- 24.15 **Execution in Counterparts**. This Agreement may be executed, either by original or by facsimile signature, in one or more counterparts, each of which shall be deemed to be an

original, but all of which together shall constitute one and the same instrument. If by facsimile, an original shall be sent to each Party as soon as reasonably possible for its permanent files.		
24.16 Performance Review Representatives of Allergan and Contractor shall meet quarterly to review performance metrics, resolution of past issues, action plans for current issues and any business issues relating to the work being performed by Contractor for Allergan.		
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IN WITNESS WHEREOF, the duly authorized representatives of the Parties have executed this Agreement.

Allergan Sales, LLC DPT Laboratories, Ltd.

By: /s/ Stuart Glickman By: /s/ Paul Josephs Stuart Glickman Paul Josephs Name: Name: VP, Global Supply Chain Title: Title: Head of CDMO, Global Bus. Dev. November 29, 2018 August 16, 2018 Date: Date:

CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Paula Brown Stafford, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Novan, Inc. (the "registrant");
- 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: May 16, 2022

/s/ Paula Brown Stafford

Paula Brown Stafford

Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, John M. Gay, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Novan, Inc. (the "registrant");
- 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: May 16, 2022

/s/ John M. Gay

John M. Gay

Chief Financial Officer

(Principal Financial Officer)

CERTIFICATION PURS UANT TO 18 U.S.C. SECTION 1350 AS ADOPTED PURS UANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Paula Brown Stafford, Chief Executive Officer of Novan, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- (1) the Quarterly Report on Form 10-Q of the Company for the quarter ended March 31, 2022 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Date: May 16, 2022

/s/ Paula Brown Stafford

Paula Brown Stafford Chief Executive Officer (Principal Executive Officer)

This certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Report, irrespective of any general incorporation language contained in such filing.

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 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.

CERTIFICATION PURS UANT TO 18 U.S.C. SECTION 1350 AS ADOPTED PURS UANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, John M. Gay, Chief Financial Officer of Novan, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- (1) the Quarterly Report on Form 10-Q of the Company for the quarter ended March 31, 2022 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Date: May 16, 2022

/s/ John M. Gay

John M. Gay Chief Financial Officer (Principal Financial Officer)

This certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Report, irrespective of any general incorporation language contained in such filing.

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 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.