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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2021

OR

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

For the transition period from ___ to ___

Commission File Number 001-37553

REGENXBIO Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**47-1851754**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
9804 Medical Center Drive **Rockville, MD**	
(Address of principal executive offices)	**20850** **(Zip Code)**

(240) 552-8181
(Registrant's telephone number, including area code)
Not Applicable
(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	RGNX	The Nasdaq Global Select Market

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

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

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

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

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

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

As of October 28, 2021, there were 42,769,208 shares of the registrant's common stock, par value $0.0001 per share, issued and outstanding.

REGENXBIO INC.
QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2021

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INFORMATION REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act). These statements express a belief, expectation or intention and are generally accompanied by words that convey projected future events or outcomes such as "believe," "may," "will," "estimate," "continue," "anticipate," "assume," "design," "intend," "expect," "could," "plan," "potential," "predict," "seek," "should," "would" or by variations of such words or by similar expressions. We have based these forward-looking statements on our current expectations and assumptions and analyses in light of our experience and our perception of historical trends, current conditions and expected future developments, as well as other factors we believe are appropriate under the circumstances. However, whether actual results and developments will conform with our expectations and predictions is subject to a number of risks, uncertainties, assumptions and other important factors, including, but not limited to:

- the impact of the COVID-19 pandemic on our business, operations and preclinical and clinical development timelines and plans;
- our ability to establish and maintain development partnerships, including our expectations regarding our proposed collaboration with AbbVie to develop and commercialize RGX-314;
- the ability to obtain and maintain regulatory approval of our product candidates and the labeling for any approved products;
- the timing of enrollment, commencement and completion and the success of our clinical trials;
- the timing of commencement and completion and the success of preclinical studies conducted by us and our development partners;
- the timely development and launch of new products;
- the scope, progress, expansion and costs of developing and commercializing our product candidates;
- our ability to obtain, maintain and enforce intellectual property protection for our product candidates and technology, and defend against third-party intellectual property-related claims;
- our expectations regarding the development and commercialization of product candidates currently being developed by third parties that utilize our technology;
- our anticipated growth strategies;
- our expectations regarding competition;
- the anticipated trends and challenges in our business and the market in which we operate;
- our ability to attract or retain key personnel;
- the size and growth of the potential markets for our product candidates and the ability to serve those markets;
- the rate and degree of market acceptance of any of our products that are approved;
- our expectations regarding our expenses and revenue;
- our expectations regarding the outcome of legal proceedings, including our ability to enforce the award from our arbitration with Abeona Therapeutics Inc. regarding unpaid license fees if Abeona does not comply with the arbitration tribunal's ruling;
- our expectations regarding regulatory developments in the United States and foreign countries; and
- our ability to accurately predict how long our existing cash resources will be sufficient to fund our anticipated operating expenses.

You should carefully read the factors discussed in the sections titled “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this Quarterly Report on Form 10-Q, our Annual Report on Form 10-K for the year ended December 31, 2020 and in our other filings with the U.S. Securities and Exchange Commission (the SEC) for additional discussion of the risks, uncertainties, assumptions and other important factors that could cause our actual results or developments to differ materially and adversely from those projected in the forward-looking statements. The actual results or developments anticipated may not be realized or, even if substantially realized, they may not have the expected consequences to or effects on us or our businesses or operations. Such statements are not guarantees of future performance and actual results or developments may differ materially and adversely from those projected in the forward-looking statements. These forward-looking statements speak only as of the date of this report. Except as required by law, we disclaim any duty to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Available Information

We file annual, quarterly, and current reports, proxy statements, and other documents with the SEC under the Exchange Act. You may obtain any reports, proxy and information statements, and other information that we file electronically with the SEC at www.sec.gov.

You also may view and download copies of our SEC filings free of charge at our website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. The information contained on, or that can be accessed through, our website will not be deemed to be incorporated by reference in, and is not considered part of, this Quarterly Report on Form 10-Q. Investors should also note that we use our website, as well as SEC filings, press releases, public conference calls and webcasts, to announce financial information and other material developments regarding our business. We use these channels, as well as any social media channels listed on our website, to communicate with investors and members of the public about our business. It is possible that the information that we post on our social media channels could be deemed material information. Therefore, we encourage investors, the media and others interested in our company to review the information that we post on our social media channels.

As used in this Quarterly Report on Form 10-Q, the terms “REGENXBIO,” “we,” “us,” “our” or the “Company” mean REGENXBIO Inc. and its subsidiaries, on a consolidated basis, unless the context indicates otherwise.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	September 30, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 228,387	$ 338,426
Marketable securities	111,473	137,314
Accounts receivable, net	46,017	42,999
Prepaid expenses	18,401	10,505
Other current assets	5,886	1,953
Total current assets	410,164	531,197
Marketable securities	193,640	46,809
Accounts receivable, net	2,730	3,267
Property and equipment, net	122,231	56,467
Operating lease right-of-use assets	61,742	63,815
Restricted cash	1,330	1,330
Other assets	8,558	5,279
Total assets	$ 800,395	$ 708,164
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$ 19,845	$ 10,622
Accrued expenses and other current liabilities	49,694	49,082
Deferred revenue	395	449
Operating lease liabilities	1,329	2,500
Liability related to sale of future royalties	35,508	18,794
Total current liabilities	106,771	81,447
Deferred revenue	3,531	3,783
Operating lease liabilities	83,880	70,153
Liability related to sale of future royalties	144,315	174,504
Other liabilities	484	524
Total liabilities	338,981	330,411
Stockholders' equity		
Preferred stock; $0.0001 par value; 10,000 shares authorized, and no shares issued and outstanding at September 30, 2021 and December 31, 2020	—	—
Common stock; $0.0001 par value; 100,000 shares authorized at September 30, 2021 and December 31, 2020; 42,752 and 37,476 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	4	4
Additional paid-in capital	917,950	667,181
Accumulated other comprehensive loss	(1,285)	(360)
Accumulated deficit	(455,255)	(289,072)
Total stockholders' equity	461,414	377,753
Total liabilities and stockholders' equity	$ 800,395	$ 708,164

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenues				
License and royalty revenue	$ 30,773	$ 98,912	$ 71,692	$ 133,122
Total revenues	30,773	98,912	71,692	133,122
Operating Expenses				
Cost of revenues	14,105	17,364	28,775	25,457
Research and development	47,855	43,968	133,459	119,114
General and administrative	21,030	15,859	57,293	46,246
Provision for credit losses and other	5,131	7,770	5,781	7,887
Total operating expenses	88,121	84,961	225,308	198,704
Income (loss) from operations	(57,348)	13,951	(153,616)	(65,582)
Other Income (Expense)				
Interest income from licensing	117	1,444	700	4,141
Investment income (loss)	5,535	(6,607)	6,514	(4,071)
Interest expense	(6,709)	—	(19,777)	—
Total other income (expense)	(1,057)	(5,163)	(12,563)	70
Income (loss) before income taxes	(58,405)	8,788	(166,179)	(65,512)
Income Tax Benefit (Expense)	—	3	(4)	503
Net income (loss)	$ (58,405)	$ 8,791	$ (166,183)	$ (65,009)
Other Comprehensive Income (Loss)				
Unrealized gain (loss) on available-for-sale securities, net	(30)	(487)	(925)	58
Total other comprehensive income (loss)	(30)	(487)	(925)	58
Comprehensive income (loss)	$ (58,435)	$ 8,304	$ (167,108)	$ (64,951)
Net income (loss) per share:				
Basic	$ (1.37)	$ 0.24	$ (3.93)	$ (1.75)
Diluted	$ (1.37)	$ 0.23	$ (3.93)	$ (1.75)
Weighted-average common shares outstanding:				
Basic	42,629	37,342	42,324	37,234
Diluted	42,629	38,877	42,324	37,234

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

REGENXBIO INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(unaudited)
(in thousands)

	Three Months Ended September 30, 2021					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at June 30, 2021	42,555	$ 4	$ 905,346	$ (1,255)	$ (396,850)	$ 507,245
Exercise of stock options	163	—	1,729	—	—	1,729
Issuance of common stock under employee stock purchase plan	35	—	1,141	—	—	1,141
Stock-based compensation expense	—	—	9,734	—	—	9,734
Unrealized loss on available-for-sale securities, net	—	—	—	(30)	—	(30)
Net loss	—	—	—	—	(58,405)	(58,405)
Balances at September 30, 2021	42,752	$ 4	$ 917,950	$ (1,285)	$ (455,255)	$ 461,414

	Three Months Ended September 30, 2020					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at June 30, 2020	37,291	$ 4	$ 648,729	$ 750	$ (251,622)	$ 397,861
Exercise of stock options	74	—	268	—	—	268
Issuance of common stock under employee stock purchase plan	38	—	1,192	—	—	1,192
Stock-based compensation expense	—	—	8,035	—	—	8,035
Unrealized loss on available-for-sale securities, net	—	—	—	(487)	—	(487)
Net income	—	—	—	—	8,791	8,791
Balances at September 30, 2020	37,404	$ 4	$ 658,224	$ 263	$ (242,831)	$ 415,660

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

REGENXBIO INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(unaudited)
(in thousands)

	Nine Months Ended September 30, 2021					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2020	37,476	$ 4	$ 667,181	$ (360)	$ (289,072)	$ 377,753
Issuance of common stock upon public offering, net of transaction costs of $14,194	4,899	—	216,059	—	—	216,059
Exercise of stock options	324	—	3,296	—	—	3,296
Issuance of common stock under employee stock purchase plan	54	—	1,768	—	—	1,768
Stock-based compensation expense	—	—	29,646	—	—	29,646
Unrealized loss on available-for-sale securities, net	—	—	—	(925)	—	(925)
Net loss	—	—	—	—	(166,183)	(166,183)
Balances at September 30, 2021	42,752	$ 4	$ 917,950	$ (1,285)	$ (455,255)	$ 461,414

	Nine Months Ended September 30, 2020					
	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balances at December 31, 2019	36,992	$ 4	$ 627,810	$ 205	$ (177,822)	$ 450,197
Exercise of stock options	356	—	4,247	—	—	4,247
Issuance of common stock under employee stock purchase plan	55	—	1,799	—	—	1,799
Stock-based compensation expense	—	—	24,368	—	—	24,368
Unrealized gain on available-for-sale securities, net	—	—	—	58	—	58
Net loss	—	—	—	—	(65,009)	(65,009)
Balances at September 30, 2020	37,404	$ 4	$ 658,224	$ 263	$ (242,831)	$ 415,660

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

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

	Nine Months Ended September 30,	
	2021	2020
Cash flows from operating activities		
Net loss	$ (166,183)	$ (65,009)
Adjustments to reconcile net loss to net cash used in operating activities		
Stock-based compensation expense	29,646	24,368
Depreciation and amortization	6,958	6,302
Provision for credit losses	5,532	7,678
Net amortization of premiums on marketable debt securities	4,377	586
Net losses (gains) on investments	(5,189)	8,207
Imputed interest income from licensing	(341)	(2,033)
Non-cash interest expense	19,777	—
Other non-cash adjustments	(51)	263
Changes in operating assets and liabilities		
Accounts receivable	(7,886)	(89,442)
Prepaid expenses	(7,896)	(9,637)
Other current assets	(3,307)	(2,998)
Operating lease right-of-use assets	3,780	1,986
Other assets	(4,402)	1,318
Accounts payable	6,503	9,907
Accrued expenses and other current liabilities	473	18,400
Operating lease liabilities	10,849	(2,222)
Other liabilities	(2)	(1,203)
Net cash used in operating activities	(107,362)	(93,529)
Cash flows from investing activities		
Purchases of marketable debt securities	(262,671)	(79,374)
Maturities of marketable debt securities	136,386	189,882
Sales of marketable debt securities	—	2,287
Sales of equity securities	5,563	12,374
Purchases of property and equipment	(69,561)	(13,980)
Net cash provided by (used in) investing activities	(190,283)	111,189
Cash flows from financing activities		
Proceeds from exercise of stock options	3,296	4,247
Proceeds from issuance of common stock under employee stock purchase plan	1,768	1,799
Proceeds from public offering of common stock, net of underwriting discounts and commissions	216,438	—
Issuance costs for public offering of common stock	(379)	—
Repayments under liability related to sale of future royalties	(33,252)	—
Transaction costs for sale of future royalties	(265)	—
Net cash provided by financing activities	187,606	6,046
Net increase (decrease) in cash and cash equivalents and restricted cash	(110,039)	23,706
Cash and cash equivalents and restricted cash		
Beginning of period	339,756	70,844
End of period	$ 229,717	$ 94,550
Supplemental disclosures of non-cash investing and financing activities		
Net additions to property and equipment through accounts payable and accrued expenses	$ 3,250	$ 46
Non-cash additions to property and equipment through tenant improvement allowance	$ —	$ 2,217
Non-cash consideration received for licenses granted	$ —	$ 1,123
Proceeds due to Company from sales of non-marketable equity securities	$ 646	$ —

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

REGENXBIO INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. Nature of Business

REGENXBIO Inc. (the Company) is a clinical-stage biotechnology company seeking to improve lives through the curative potential of gene therapy. The Company has developed a broad pipeline of gene therapy product candidates using its proprietary adeno-associated virus (AAV) gene delivery platform (NAV Technology Platform), which consists of exclusive rights to over 100 novel AAV vectors, including AAV7, AAV8, AAV9 and AAVrh10. In addition to its internal product development efforts, the Company also selectively licenses the NAV® Technology Platform to other leading biotechnology and pharmaceutical companies (NAV Technology Licensees). As of September 30, 2021, the NAV Technology Platform was being applied by NAV Technology Licensees in one commercially available product, Zolgensma®, and in the preclinical and clinical development of 20 licensed products. The Company was formed in 2008 in the State of Delaware and is headquartered in Rockville, Maryland.

As of September 30, 2021, the Company had generated an accumulated deficit of $455.3 million since inception. As the Company has incurred cumulative losses since inception, transition to recurring profitability is dependent upon achieving a level of revenues adequate to support the Company's cost structure, which depends heavily on the successful development, approval and commercialization of its product candidates. The Company may never achieve recurring profitability, and unless and until it does, the Company will continue to need to raise additional capital, to the extent possible. As of September 30, 2021, the Company had cash, cash equivalents and marketable securities of $533.5 million, which management believes is sufficient to fund operations for at least the next 12 months from the date these consolidated financial statements were issued.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements are unaudited and have been prepared in conformity with accounting principles generally accepted in the United States of America (GAAP). The interim unaudited consolidated financial statements have been prepared on the same basis as the annual audited consolidated financial statements as of and for the year ended December 31, 2020 included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020, which was filed with the SEC on March 1, 2021. Certain information and footnote disclosures required by GAAP which are normally included in the Company's annual consolidated financial statements have been omitted pursuant to SEC rules and regulations for interim reporting. In the opinion of management, the accompanying consolidated financial statements reflect all adjustments, which are normal and recurring in nature, necessary for fair financial statement presentation.

The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the full year, any other interim periods, or any future year or period. These interim consolidated financial statements should be read in conjunction with the audited consolidated financial statements as of and for the year ended December 31, 2020, and the notes thereto, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020.

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

Use of Estimates

The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities for the periods presented. Management bases its estimates on historical experience and on various other factors that it believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities, and other reported amounts, that are not readily apparent from other sources. Actual results may differ materially from these estimates. Significant estimates are used in the following areas, among others: license and royalty revenue, the allowance for credit losses, accrued research and development expenses and other accrued liabilities, stock-based compensation expense, non-cash interest expense, income taxes and the fair value of financial instruments.

The Company is actively monitoring the impact of the COVID-19 pandemic on its business, results of operations and financial condition. The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations and financial condition in the future is unknown at this time and will depend on future developments that are highly unpredictable. The most significant estimates affecting the Company's consolidated financial statements that may be impacted by the COVID-19 pandemic are related to the Company's assessment of credit losses on accounts receivable, contract assets and available-for-sale debt securities.

Restricted Cash

Restricted cash includes money market mutual funds used to collateralize irrevocable letters of credit as required by the Company's lease agreements. The following table provides a reconciliation of cash and cash equivalents and restricted cash as reported on the consolidated balance sheets to the total of these amounts as reported at the end of the period in the consolidated statements of cash flows (in thousands):

	September 30, 2021	September 30, 2020
Cash and cash equivalents	$ 228,387	$ 93,220
Restricted cash	1,330	1,330
Total cash and cash equivalents and restricted cash	$ 229,717	$ 94,550

Accounts Receivable

Accounts receivable primarily consist of consideration due to the Company resulting from its license agreements with NAV Technology Licensees. Accounts receivable include amounts invoiced to licensees as well as rights to consideration which have not yet been invoiced, including unbilled royalties, and for which payment is conditional solely upon the passage of time. If a licensee elects to terminate a license prior to the end of the license term, the licensed intellectual property is returned to the Company and any accounts receivable from the licensee which are not contractually payable to the Company are charged off as a reduction of license revenue in the period of the termination. Accounts receivable which are not expected to be received by the Company within 12 months from the reporting date are stated net of a discount to present value and recorded as non-current assets on the consolidated balance sheets. The present value discount is recognized as a reduction of revenue in the period in which the accounts receivable are initially recorded and is accreted as interest income from licensing over the term of the receivables.

Accounts receivable are stated net of an allowance for credit losses, if deemed necessary based on the Company's evaluation of collectability and potential credit losses. Management assesses the collectability of its accounts receivable using the specific identification of account balances, and considers the credit quality and financial condition of its significant customers, historical information regarding credit losses and the Company's evaluation of current and expected future economic conditions. If necessary, an allowance for credit losses is recorded against accounts receivable such that the carrying value of accounts receivable reflects the net amount expected to be collected. Accounts receivable balances are written off against the allowance for credit losses when the potential for collectability is considered remote. Please refer to Note 8 for further information regarding the allowance for credit losses related to accounts receivable.

Fair Value of Financial Instruments

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. Accounting Standards Codification (ASC) 820, *Fair Value Measurements and Disclosures*, establishes a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability, and are developed based on the best information available in the circumstances. The fair value hierarchy applies only to the valuation inputs used in determining the reported fair value of the investments and is not a measure of the investment credit quality. The three levels of the fair value hierarchy are described below:

- Level 1—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

- Level 2—Valuations based on quoted prices for similar assets or liabilities in markets that are not active or for which all significant inputs are observable, either directly or indirectly.
- Level 3—Valuations that require inputs that reflect the Company's own assumptions that are both significant to the fair value measurement and unobservable.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. The fair values of the Company's Level 2 instruments are based on quoted market prices or broker or dealer quotations for similar assets. These investments are initially valued at the transaction price and subsequently valued utilizing third party pricing providers or other market observable data. Please refer to Note 4 for further information on the fair value measurement of the Company's financial instruments.

Net Income (Loss) Per Share

Basic net income (loss) per share is calculated by dividing net income (loss) applicable to common stockholders by the weighted-average common shares outstanding during the period, without consideration for common stock equivalents. Diluted net income (loss) per share is calculated by adjusting the weighted-average common shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. Contingently convertible shares in which conversion is based on non-market-priced contingencies are excluded from the calculations of both basic and diluted net income (loss) per share until the contingency has been fully met. For purposes of the diluted net income (loss) per share calculation, common stock equivalents are excluded from the calculation of diluted net income (loss) per share if their effect would be anti-dilutive.

3. Marketable Securities

The following tables present a summary of the Company's marketable securities, which consist solely of available-for-sale debt securities (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
September 30, 2021				
U.S. government and federal agency securities	$ 25,003	$ —	$ (23)	$ 24,980
Certificates of deposit	2,939	10	(1)	2,948
Corporate bonds	274,592	41	(452)	274,181
Municipal securities	3,004	—	—	3,004
	$ 305,538	$ 51	$ (476)	$ 305,113

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
December 31, 2020				
U.S. government and federal agency securities	$ 12,782	$ 22	$ —	$ 12,804
Certificates of deposit	1,956	34	—	1,990
Corporate bonds	165,850	497	(55)	166,292
Municipal securities	3,035	2	—	3,037
	$ 183,623	$ 555	$ (55)	$ 184,123

As of September 30, 2021 and December 31, 2020, no available-for-sale debt securities had remaining maturities greater than three years. The amortized cost of marketable debt securities is adjusted for amortization of premiums and accretion of discounts to maturity, or to the earliest call date for callable debt securities purchased at a premium.

As of September 30, 2021 and December 31, 2020, the balance in the Company's accumulated other comprehensive loss consisted solely of unrealized gains and losses on available-for-sale debt securities, net of reclassification adjustments for realized gains and losses and income tax effects. The Company uses the aggregate portfolio approach to release the tax effects of unrealized gains and losses on available-for-sale debt securities in accumulated other comprehensive loss. Realized gains and losses from the sale or maturity of marketable securities are based on the specific identification method and are included in results of operations as investment income (loss). Unrealized gain (loss) on available-for-sale securities, net, as presented in the statements of operations and comprehensive income (loss) consisted of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Unrealized gain (loss) before reclassifications	$ (30)	$ (457)	$ (918)	$ 108
Realized gains reclassified to investment income (loss)	—	(30)	(7)	(50)
Income tax expense	—	—	—	—
Unrealized gain (loss) on available-for-sale securities, net	$ (30)	$ (487)	$ (925)	$ 58

The following tables present the fair values and unrealized losses of available-for-sale debt securities held by the Company in an unrealized loss position for less than 12 months and 12 months or greater (in thousands):

	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
September 30, 2021						
U.S. government and federal agency securities	$ 17,444	$ (23)	$ —	$ —	$ 17,444	$ (23)
Certificates of deposit	489	(1)	—	—	489	(1)
Corporate bonds	238,835	(452)	—	—	238,835	(452)
	$ 256,768	$ (476)	$ —	$ —	$ 256,768	$ (476)

	Less than 12 Months		12 Months or Greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
December 31, 2020						
Corporate bonds	$ 55,507	$ (55)	$ —	$ —	$ 55,507	$ (55)
	$ 55,507	$ (55)	$ —	$ —	$ 55,507	$ (55)

As of September 30, 2021, available-for-sale debt securities held by the Company in an unrealized loss position consisted of 47 investment grade security positions. The Company has the intent and ability to hold such securities until recovery, and based on the credit quality of the issuers and low severity of each unrealized loss position relative to its amortized cost basis, the Company did not identify any credit losses associated with its available-for-sale debt securities. The Company did not record an allowance for credit losses on its available-for-sale debt securities as of September 30, 2021 or December 31, 2020. The Company did not recognize any impairment or credit losses on available-for-sale debt securities during the three and nine months ended September 30, 2021 and 2020.

During the three and nine months ended September 30, 2020, the Company recognized total net realized and unrealized losses of $7.5 million and $8.3 million, respectively, related to its marketable equity securities of Prevail Therapeutics Inc. (Prevail), which were acquired as consideration for a license to the NAV Technology Platform granted to Prevail in August 2017. As of December 31, 2020, the Company had sold all of its Prevail equity securities.

4. Fair Value of Financial Instruments

Financial instruments reported at fair value on a recurring basis include cash equivalents and marketable securities. The following tables present the fair value of cash equivalents and marketable securities in accordance with the hierarchy discussed in Note 2 (in thousands):

	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
September 30, 2021				
Cash equivalents:				
Money market mutual funds	$ —	$ 187,123	$ —	$ 187,123
Total cash equivalents	—	187,123	—	187,123
Marketable securities:				
U.S. government and federal agency securities	—	24,980	—	24,980
Certificates of deposit	—	2,948	—	2,948
Corporate bonds	—	274,181	—	274,181
Municipal securities	—	3,004	—	3,004
Total marketable securities	—	305,113	—	305,113
Total cash equivalents and marketable securities	$ —	$ 492,236	$ —	$ 492,236

	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total
December 31, 2020				
Cash equivalents:				
Money market mutual funds	$ —	$ 96,307	$ —	$ 96,307
Total cash equivalents	—	96,307	—	96,307
Marketable securities:				
U.S. government and federal agency securities	—	12,804	—	12,804
Certificates of deposit	—	1,990	—	1,990
Corporate bonds	—	166,292	—	166,292
Municipal securities	—	3,037	—	3,037
Total marketable securities	—	184,123	—	184,123
Total cash equivalents and marketable securities	$ —	$ 280,430	$ —	$ 280,430

Management estimates that the carrying amounts of its current accounts receivable, accounts payable and accrued expenses and other current liabilities approximate fair value due to the short-term nature of those instruments. Accounts receivable which contain non-current portions are recorded at their present values using a discount rate that is based on prevailing market rates and the credit profile of the licensee on the date the amounts are initially recorded. Management does not believe there have been any significant changes in market conditions or credit quality that would cause the discount rates initially used to be materially different from those that would be used as of September 30, 2021 to determine the present value of the receivables. Accordingly, management estimates that the carrying value of its non-current accounts receivable approximates the fair value of those instruments.

Non-marketable Equity Securities

Non-marketable equity securities are measured at cost less impairment, adjusted for observable price changes for identical or similar investments of the same issuer. As of September 30, 2021, the Company did not hold any non-marketable equity securities. As of December 31, 2020, non-marketable equity securities had a carrying value of $1.1 million and were included in other assets on the consolidated balance sheet. The Company did not identify any observable price changes or changes in circumstances that would have had an adverse effect on the fair value of the securities as of December 31, 2020. No remeasurements or impairment losses were recorded on non-marketable equity securities during the three and nine months ended September 30, 2021 and 2020.

The Company's non-marketable equity securities as of December 31, 2020 consisted solely of equity securities of Corlieve Therapeutics SAS (Corlieve), which were acquired in June 2020 as consideration under a license and collaboration agreement with Corlieve. In July 2021, Corlieve was acquired by uniQure N.V. (uniQure). In exchange for its ownership in Corlieve, the Company received proceeds of €4.8 million ($5.6 million) from uniQure and is entitled to receive additional proceeds of €0.6 million ($0.6 million as of September 30, 2021) by July 2022. During the three and nine months ended September 30, 2021, the Company recorded a realized gain of $5.2 million as a result of the acquisition of its Corlieve securities by uniQure, which is included in investment income (loss) in the consolidated statements of operations and comprehensive income (loss). In connection with the acquisition, the Company is also eligible to receive payments of up to €37.1 million ($43.2 million as of September 30, 2021) from uniQure contingent upon the achievement of various development and regulatory milestones, none of which have been recognized in the consolidated financial statements as of September 30, 2021. Proceeds contingent upon the achievement of these milestones will be recognized as investment income in the period in which any uncertainty regarding realization is substantially resolved, which may not occur until the achievement of the underlying milestones. It is at least reasonably possible that some or all of the proceeds contingent upon these milestones will not be realized by the Company.

5. Property and Equipment, Net

Property and equipment, net consists of the following (in thousands):

	September 30, 2021	December 31, 2020
Laboratory and manufacturing equipment	$ 49,951	$ 26,306
Computer equipment and software	4,070	3,764
Furniture and fixtures	6,515	4,114
Leasehold improvements	88,131	44,957
Total property and equipment	148,667	79,141
Accumulated depreciation and amortization	(26,436)	(22,674)
Property and equipment, net	$ 122,231	$ 56,467

6. Liability Related to Sale of Future Royalties

In December 2020, the Company entered into a royalty purchase agreement (the Royalty Purchase Agreement) with entities managed by Healthcare Royalty Management, LLC (collectively, HCR). Under the agreement, HCR purchased the Company's rights to a capped amount of Zolgensma royalty payments under the Company's license agreement with Novartis Gene Therapies, Inc. (formerly AveXis, Inc.) (Novartis Gene Therapies), including $4.0 million of royalty payments received by the Company in the fourth quarter of 2020 (the Pledged Royalties). In consideration for these rights, HCR paid the Company $200.0 million (the Purchase Price), less $4.0 million representing the payment of the Pledged Royalties to HCR. Beginning upon the effective date of the agreement, Zolgensma royalty payments, up to a specified threshold, will be paid to HCR, net of upstream royalties payable by the Company to certain licensors in accordance with existing license agreements.

Pursuant to the Royalty Purchase Agreement, the total amount of royalty payments to be received by HCR under the agreement is subject to an increasing cap (the Cap Amount) equal to (i) $260.0 million applicable for the period from the effective date of the agreement through November 7, 2024, and (ii) $300.0 million applicable for the period from November 8, 2024 through the effective date of termination of the license agreement with Novartis Gene Therapies. If, on or prior to the defined dates for each Cap Amount, the total amount of royalty payments received by HCR equals or exceeds the Cap Amount applicable to such date, the Royalty Purchase Agreement will automatically terminate and all rights to the Zolgensma royalty payments will revert back to the Company. The Company has no obligation to repay any amounts to HCR if total future Zolgensma royalty payments are not sufficient to achieve the applicable Cap Amount prior to the termination of the license agreement with Novartis Gene Therapies.

The Company has a call option to repurchase its rights to the purchased royalties from HCR for a repurchase price equal to, as of the option exercise date, $300.0 million minus the total amount of royalty payments received by HCR; provided, however, that with respect to a call option exercised on or before November 7, 2024, in the event that the then applicable Cap Amount minus the total amount of royalty payments received by HCR is less than $1.0 million, the repurchase price shall equal such difference.

The proceeds received from HCR of $196.0 million were recorded as a liability, net of transaction costs of $3.5 million, which is amortized over the estimated life of the arrangement using the effective interest method. In order to determine the amortization of the liability, the Company is required to estimate the total amount of future royalty payments to be received by HCR, subject to the Cap Amount, over the life of the arrangement. The total amount of royalty payments received by HCR under the agreement, less the net proceeds received by the Company of $192.5 million, is recorded as non-cash interest expense over the life of the arrangement using the effective interest method. Due to its continuing involvement in the underlying license agreement with Novartis Gene Therapies, the Company continues to recognize royalty revenue on net sales of Zolgensma and records the royalty payments to HCR as a reduction of the liability when paid. As such payments are made to HCR, the balance of the liability will be effectively repaid over the life of the Royalty Purchase Agreement.

The Company estimates the effective interest rate used to record non-cash interest expense under the Royalty Purchase Agreement based on its estimate of future royalty payments to be received by HCR. As of September 30, 2021, the estimated effective interest rate under the agreement was 14.9%. Over the life of the arrangement, the actual effective interest rate will be affected by the amount and timing of the royalty payments received by HCR and changes in the Company's forecasted royalties. At each reporting date, the Company reassesses its estimate of total future royalty payments to be received by HCR at the applicable Cap Amount, and prospectively adjusts the effective interest rate and amortization of the liability, as necessary.

The following table presents the changes in the liability related to the sale of future royalties under the Royalty Purchase Agreement with HCR (in thousands):

	Nine Months Ended September 30, 2021
Liability related to sale of future royalties, beginning balance	$ 193,298
Zolgensma royalties paid to HCR	(33,252)
Non-cash interest expense	19,777
Liability related to sale of future royalties, ending balance	179,823
Current portion of liability related to sale of future royalties	(35,508)
Liability related to sale of future royalties, non-current	$ 144,315

7. Capitalization

In January 2021, the Company completed a public offering of 4,899,000 shares of its common stock (inclusive of 639,000 shares pursuant to the full exercise by the underwriters of their option to purchase additional shares) at a price of $47.00 per share. The aggregate net proceeds received by the Company from the offering, inclusive of the underwriters' option exercise, were $216.1 million, net of underwriting discounts and commissions and offering expenses payable by the Company.

8. License and Royalty Revenue

As of September 30, 2021, the Company's NAV Technology Platform was being applied by NAV Technology Licensees in one commercially available product, Zolgensma, and in the development of 20 other licensed products. Consideration to the Company under its license agreements may include: (i) up-front and annual fees, (ii) option fees to acquire additional licenses, (iii) milestone payments based on the achievement of certain development and sales-based milestones by licensees, (iv) sublicense fees and (v) royalties on sales of licensed products. Sublicense fees vary by license and range from a mid-single digit percentage to a low-double digit percentage of license fees received by licensees as a result of sublicenses. Royalties on net sales of commercialized products vary by license and range from a mid-single digit percentage to a low double-digit percentage of net sales by licensees.

Development milestone payments are evaluated each reporting period and are only included in the transaction price of each license and recognized as license revenue to the extent the milestones are considered probable of achievement. Sales-based milestones are excluded from the transaction price of each license agreement and recognized as royalty revenue in the period of achievement. As of September 30, 2021, the Company's license agreements, excluding additional licenses that could be granted upon the exercise of options by licensees, contained unachieved milestones which could result in aggregate milestone payments to the Company of up to $194.8 million, including (i) $23.3 million upon the commencement of various stages of clinical trials, (ii) $21.0 million upon the submission of regulatory approval filings, (iii) $93.5 million upon the approval of commercial products by regulatory agencies and (iv) $57.0 million upon the achievement of specified sales targets for licensed products. To the extent the milestone payments are realized by the Company, the Company will be obligated to pay sublicense fees to licensors based on a specified percentage of the fees earned by the Company. The achievement of milestones by licensees is highly dependent on the successful development and commercialization of licensed products and it is at least reasonably possible that some or all of the milestone fees will not be realized by the Company.

Changes in Accounts Receivable, Contract Assets and Deferred Revenue

The following table presents changes in the balances of the Company's net accounts receivable, contract assets and deferred revenue, as well as other information regarding revenue recognized during the periods presented (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Accounts receivable, net, current and non-current:				
Balance, beginning of period	$ 47,202	$ 46,494	$ 46,266	$ 42,303
Additions	30,385	100,243	71,544	137,220
Deductions	(28,840)	(21,057)	(69,063)	(53,843)
Balance, end of period	$ 48,747	$ 125,680	$ 48,747	$ 125,680
Contract assets:				
Balance, beginning of period	$ 702	$ 350	$ 350	$ —
Additions	407	—	1,109	350
Deductions	—	—	(350)	—
Balance, end of period	$ 1,109	$ 350	$ 1,109	$ 350
Deferred revenue, current and non-current:				
Balance, beginning of period	$ 4,025	$ 4,457	$ 4,232	$ 3,333
Additions	—	—	—	1,124
Deductions	(99)	(113)	(306)	(113)
Balance, end of period	$ 3,926	$ 4,344	$ 3,926	$ 4,344
Revenue recognized during the period from:				
Amounts included in deferred revenue at beginning of period	$ 99	$ 113	$ 306	$ —
Performance obligations satisfied in previous periods	$ 30,256	$ 98,799	$ 70,603	$ 125,555

Additions to accounts receivable during the periods presented consisted primarily of receivables recorded related to royalties on net sales of Zolgensma, new licenses granted by the Company, the achievement of development and sales-based milestones by licensees and interest income from licensing recognized during the period. Deductions to accounts receivable during the periods presented consisted primarily of amounts collected from licensees and increases in the allowance for credit losses, as discussed further below. Additions to contract assets during the periods presented consisted primarily of development milestones deemed probable of achievement by licensees during the period. Deductions to contract assets during the periods presented consisted of the achievement of such milestones and billing of the associated milestone payments by the Company.

As of September 30, 2021, the Company had recorded deferred revenue of $3.9 million which represents consideration received from licensees for performance obligations that have not yet been satisfied by the Company. Unsatisfied performance obligations consisted of (i) options granted to licensees that provide material rights to the licensee to acquire additional licenses from the Company, which will be satisfied upon the exercise or expiration of the options and (ii) research and development services to be performed by the Company related to licensed products, which will be satisfied as the research and development services are performed.

Revenue recognized from performance obligations satisfied in previous periods was primarily attributable to Zolgensma royalty revenues, the achievement of sales-based milestones for net sales of Zolgensma, sublicense fees earned from licensees and changes in the transaction prices of the Company's license agreements. Changes in transaction prices were primarily attributable to development milestones achieved or deemed probable of achievement during the periods, which were previously not considered probable of achievement.

Accounts Receivable, Contract Assets and the Allowance for Credit Losses

Accounts receivable, net consisted of the following (in thousands):

	September 30, 2021	December 31, 2020
Current accounts receivable:		
Billed to customers	$ 30,248	$ 30,573
Unbilled	28,979	20,104
Allowance for credit losses	(13,210)	(7,678)
Current accounts receivable, net	46,017	42,999
Non-current accounts receivable:		
Unbilled	2,730	3,267
Allowance for credit losses	—	—
Non-current accounts receivable, net	2,730	3,267
Total accounts receivable, net	$ 48,747	$ 46,266

The following table presents the changes in the allowance for credit losses related to accounts receivable and contract assets for the nine months ended September 30, 2021 (in thousands):

	Accounts Receivable	Contract Assets
Balance at December 31, 2020	$ 7,678	$ —
Provision for credit losses	5,532	—
Write-offs	—	—
Balance at September 30, 2021	$ 13,210	$ —

The Company's allowance for credit losses as of September 30, 2021 and December 31, 2020 was related solely to accounts receivable from Abeona Therapeutics Inc. (Abeona). Please refer to the section below, Abeona Therapeutics Inc., for further information regarding amounts due from Abeona and the associated allowance for credit losses. The Company's provision for credit losses was $5.0 million and $5.5 million for the three and nine months ended September 30, 2021, respectively, and $7.7 million and $7.7 million for the three and nine months ended September 30, 2020, respectively. The Company's provision for credit losses for the three and nine months ended September 30, 2021 and 2020 was related solely to changes in estimates regarding the collectability of the accounts receivable due from Abeona.

Novartis Gene Therapies, Inc.

In March 2014, the Company entered into an exclusive license agreement, as amended, (the March 2014 License) with Novartis Gene Therapies (formerly AveXis, Inc.). Under the March 2014 License, the Company granted Novartis Gene Therapies an exclusive, worldwide commercial license, with rights to sublicense, to the NAV Technology Platform, as well as other certain rights, for the treatment of spinal muscular atrophy (SMA) in humans by *in vivo* gene therapy. Novartis Gene Therapies launched commercial sales of Zolgensma, a licensed product under the March 2014 License, in the second quarter of 2019, upon which the Company began recognizing royalty revenue on net sales of the licensed product.

Pursuant to the March 2014 License, Novartis Gene Therapies was obligated to pay a sales-based milestone fee of $80.0 million to the Company upon the achievement of $1.0 billion in cumulative net sales of licensed products. Novartis Gene Therapies achieved cumulative net sales of Zolgensma of $1.0 billion in the third quarter of 2020, upon which the Company recognized revenue of $80.0 million related to the sales-based milestone fee. The $80.0 million milestone fee was recorded as accounts receivable as of September 30, 2020, and the Company received payment of the $80.0 million milestone fee from Novartis Gene Therapies in October 2020.

The Company recognized the following amounts under the March 2014 License with Novartis Gene Therapies (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Royalties on net sales of Zolgensma	$ 30,254	$ 18,799	$ 66,946	$ 40,723
Achievement of sales-based milestone for Zolgensma	—	80,000	—	80,000
Other license revenue	—	—	—	3,500
Total license and royalty revenue	$ 30,254	$ 98,799	$ 66,946	$ 124,223
Interest income from licensing	$ 5	$ 6	$ 17	$ 20

As of September 30, 2021 and December 31, 2020, the Company had recorded total accounts receivable of $28.4 million and $19.6 million, respectively, from Novartis Gene Therapies under the March 2014 License, which consisted primarily of unbilled receivables for Zolgensma royalties. Zolgensma royalties receivable recorded as of September 30, 2021 included $13.8 million expected to be paid to HCR in accordance with the Royalty Purchase Agreement discussed in Note 6. The Company recognizes royalty revenue from net sales of Zolgensma in the period in which the underlying products are sold by Novartis Gene Therapies, which in certain cases may require the Company to estimate royalty revenue for periods of net sales which have not yet been reported to the Company. Estimated royalties are reconciled to actual amounts reported in subsequent periods and royalty revenues are adjusted, as necessary.

Abeona Therapeutics Inc.

In November 2018, the Company entered into a license agreement with Abeona (as amended, the November 2018 License), for the treatment of various diseases using the NAV Technology Platform. Pursuant to the November 2018 License, Abeona was required to pay a license fee of $8.0 million to the Company no later than April 1, 2020. Abeona failed to make this payment, and in April 2020, the Company delivered to Abeona a notice of its breach of the license agreement and written demand for payment. Upon expiration of the applicable cure period in May 2020, the license agreement terminated. As a result of the termination, Abeona was required to pay an additional $20.0 million license fee to the Company within 15 days of the termination date, which otherwise would have been due to the Company in November 2020. As of September 30, 2021, the Company had not received any portion of the $28.0 million in license fees due from Abeona under the license agreement. Unpaid balances due under the November 2018 License accrue interest at 1.5% per month.

In May 2020, after the termination of the November 2018 License, Abeona filed a claim in arbitration alleging that the Company had breached certain responsibilities to communicate with Abeona regarding the Company's prosecution of licensed patents under the November 2018 License. The Company disputed Abeona's claim and filed a counterclaim in arbitration demanding payment of the $28.0 million of unpaid fees from Abeona, plus accrued interest. A binding arbitration was held in March 2021. In July 2021, the arbitration tribunal issued its ruling, which denied Abeona's claim and upheld the Company's counterclaim. The arbitration tribunal's ruling, which was subsequently amended to reflect a minor adjustment in the computation of accrued interest, awarded the Company a total of $33.6 million, which consisted of $28.0 million in damages and $5.6 million in accrued interest payable to the Company by Abeona. As of October 28, 2021, the Company had not received any portion of the $33.6 million arbitration award from Abeona.

The Company has filed a petition to confirm the arbitration award and to enter judgment on it in the Supreme Court of the State of New York for New York County. The Company cannot be certain of the precise timing or amount of recovery and will continue to pursue enforcement of the award against Abeona. Abeona has filed an additional claim in a second arbitration to enforce a purported settlement relating to the unpaid fees, which the Company disputes.

As of September 30, 2021 and December 31, 2020, the Company had recorded gross accounts receivable of $30.1 million from Abeona under the November 2018 License, which consisted of the $8.0 million fee due April 1, 2020, the $20.0 million fee due within 15 days of the termination of the license agreement in May 2020 and accrued interest on the outstanding balances. While the Company anticipates taking appropriate measures to enforce the aforementioned arbitration award if Abeona does not comply with the tribunal's ruling, the Company assessed the collectability of the $30.1 million due from Abeona as it relates to credit risk. In performing this assessment, the Company evaluated Abeona's credit profile and financial condition, as well its expectations regarding Abeona's future cash flows and ability to satisfy this obligation. As a result of its analyses, the Company recorded an allowance for credit losses of $13.2 million and $7.7 million as of September 30, 2021 and December 31, 2020, respectively, related to the accounts receivable due from Abeona. The Company recorded a provision for credit losses of $5.0 million and $5.5 million for the three and nine months ended September 30, 2021, respectively, as a result of changes in estimates regarding the allowance during the periods.

As of September 30, 2021 and December 31, 2020, the Company had recognized interest income from licensing of $2.1 million related to the unpaid license fees from Abeona under the November 2018 License, which is included in the gross accounts receivable balance of $30.1 million. In accordance with its interest accrual policy, the Company ceased the recognition of interest income accrued under the license agreement subsequent to the establishment of the allowance for credit losses in the third quarter of 2020. The arbitration tribunal's ruling in July 2021, as subsequently adjusted, awarded the Company $5.6 million in accrued interest payable by Abeona, including $3.5 million of interest earned subsequent to the receivable being placed on non-accrual status which has not been recognized in the consolidated financial statements. As of September 30, 2021, the Company had continued to maintain the accounts receivable due from Abeona on non-accrual status and will not recognize any further interest income associated with the accounts receivable unless and until such amounts are deemed to be collectable.

Collaboration and License Agreement with AbbVie

In September 2021, the Company entered into a Collaboration and License Agreement with AbbVie Global Enterprises Ltd. (AbbVie), a subsidiary of AbbVie Inc., to develop and commercialize RGX-314, the Company's product candidate for the treatment of wet age-related macular degeneration (wet AMD), diabetic retinopathy (DR) and other chronic retinal diseases (the AbbVie Collaboration and License Agreement). The transaction is contingent upon the satisfaction of customary closing conditions, including the expiration or termination of the applicable waiting or suspension period under the Hart-Scott Rodino Antitrust Improvements Act of 1976, as amended, and any other applicable competition laws.

Pursuant to the AbbVie Collaboration and License Agreement, the parties will conduct certain activities for the development of products containing RGX-314 under a development plan determined in accordance with the AbbVie Collaboration and License Agreement. The Company and AbbVie will develop licensed products in the United States, and AbbVie will be responsible for the development of licensed products in specified markets outside the United States. Through December 31, 2022, the Company will be responsible for development expenses for certain ongoing trials of RGX-314 and the parties will share additional development expenses related to RGX-314. Beginning on January 1, 2023, AbbVie will be responsible for the majority of all RGX-314 development expenses.

The Company will lead the manufacturing of RGX-314 for clinical development and U.S. commercial supply, and AbbVie will lead manufacturing of RGX-314 for commercial supply outside the United States. Manufacturing expenses will be allocated between the parties in accordance with the terms of the AbbVie Collaboration and License Agreement and mutually agreed supply agreements. In the United States, the Company shall participate in commercialization of licensed products under a commercialization plan to be determined in accordance with the AbbVie Collaboration and License Agreement, and the parties will equally share net profits and net losses associated with commercialization of licensed products in the United States. Outside the United States, AbbVie will be responsible, at its sole cost, for the commercialization of licensed products.

The Company will receive an upfront payment of $370.0 million from AbbVie in connection with the closing of the AbbVie Collaboration and License Agreement. Additionally, the Company will be eligible to receive up to $1.38 billion in development, regulatory and commercial milestone payments, in the aggregate, for the achievement of specified milestones for the licensed products, of which $782.5 million are based on development and regulatory milestones, with the remainder based on commercial milestones. The Company will also be eligible to receive tiered royalties on net sales by AbbVie of licensed products outside the United States at percentages in the mid-teens to low twenties, subject to specified offsets and reductions. Royalties will be payable on a product-by-product and country-by-country basis outside the United States commencing on the date of first commercial sale of each licensed product, and ending on the later of (a) expiration of all valid claims of specified licensed patents in such country, (b) expiration of regulatory exclusivity in such country and (c)(x) if such country is in the European Union, 12 years following first commercial sale of such product in such country, or (y) if such country is outside the European Union, 10 years following the first commercial sale of such product in such country (the Royalty Term).

The AbbVie Collaboration and License Agreement will remain in effect, unless earlier terminated, on a country-by-country basis until (a) in the case of the United States, the later of (i) the 120th day after any quarter in which no licensed product is being developed or commercialized under such agreement, and (ii) the date that specified licensed patents for a licensed product expire in the United States, and (b) in the case of any country outside the United States, the date the Royalty Term for a licensed product expires in such country. The AbbVie Collaboration and License Agreement contains provisions for termination, including termination for convenience by AbbVie.

Contemporaneously with entering into the AbbVie Collaboration and License Agreement, in September 2021, the Company entered into a Sublicense Agreement with AbbVie (the AbbVie Sublicense Agreement) pursuant to which the Company granted AbbVie an exclusive sublicense to exploit licensed products in connection with the AbbVie Collaboration and License Agreement

under specified patents licensed to the Company from The Trustees of the University of Pennsylvania. The AbbVie Sublicense Agreement will be coterminous with the AbbVie Collaboration and License Agreement.

9. Stock-based Compensation

In January 2021, the Board of Directors authorized an additional 1,499,037 shares to be issued under the 2015 Equity Incentive Plan (the 2015 Plan). As of September 30, 2021, the total number of shares of common stock authorized for issuance under the 2015 Plan and the 2014 Stock Plan (the 2014 Plan) was 13,911,954, of which 2,392,917 remained available for future grants under the 2015 Plan.

Stock-based Compensation Expense

The Company's stock-based compensation expense by award type was as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Stock options	$ 8,920	$ 7,880	$ 27,010	$ 23,745
Restricted stock units	698	—	2,093	—
Employee stock purchase plan	116	155	543	623
	$ 9,734	$ 8,035	$ 29,646	$ 24,368

As of September 30, 2021, the Company had $75.7 million of unrecognized stock-based compensation expense related to stock options, restricted stock units and the 2015 Employee Stock Purchase Plan (the 2015 ESPP), which is expected to be recognized over a weighted-average period of 2.5 years.

The Company recorded aggregate stock-based compensation expense in the consolidated statements of operations and comprehensive income (loss) as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	$ 4,868	$ 4,110	$ 14,999	$ 12,442
General and administrative	4,866	3,925	14,647	11,926
	$ 9,734	$ 8,035	$ 29,646	$ 24,368

Stock Options

The following table summarizes stock option activity under the 2014 Plan and 2015 Plan (in thousands, except per share data):

	Shares	Weighted-average Exercise Price	Weighted-average Remaining Contractual Life (Years)	Aggregate Intrinsic Value (a)
Outstanding at December 31, 2020	6,361	$ 31.21	7.2	$ 101,356
Granted	1,373	$ 43.47		
Exercised	(325)	$ 11.21		
Cancelled or forfeited	(232)	$ 45.79		
Outstanding at September 30, 2021	7,177	$ 33.99	7.0	$ 74,141
Exercisable at September 30, 2021	4,408	$ 28.74	6.0	$ 67,896
Vested and expected to vest at September 30, 2021	7,177	$ 33.99	7.0	$ 74,141

(a) The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying options and the fair value of the common stock for the options that were in the money at the dates reported.

The weighted-average grant date fair value per share of options granted during the nine months ended September 30, 2021 was $26.28. During the nine months ended September 30, 2021, the total number of stock options exercised was 325,273, resulting in total proceeds of $3.3 million. The total intrinsic value of options exercised during the nine months ended September 30, 2021 was $10.1 million.

Restricted Stock Units

The following table summarizes restricted stock unit activity under the 2015 Plan (in thousands, except per share data):

	Shares	Weighted-average Grant Date Fair Value
Unvested balance at December 31, 2020	—	$ —
Granted	277	$ 44.17
Vested	—	$ —
Forfeited	(12)	$ 44.68
Unvested balance at September 30, 2021	265	$ 44.15

No restricted stock units vested during the three and nine months ended September 30, 2021 and 2020.

Employee Stock Purchase Plan

In January 2021, the Board of Directors authorized an additional 374,759 shares to be issued under the 2015 ESPP. As of September 30, 2021, the total number of shares of common stock authorized for issuance under the 2015 ESPP was 998,683, of which 769,174 remained available for future issuance. During the nine months ended September 30, 2021, 53,596 shares of common stock were issued under the 2015 ESPP.

10. Income Taxes

The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Based on the Company's history of operating losses, including three-year cumulative loss positions as of September 30, 2021 and December 31, 2020, the Company concluded that it is more likely than not that the benefit of its deferred tax assets will not be realized. Accordingly, the Company provided a full valuation allowance for its net deferred tax assets as of September 30, 2021 and December 31, 2020.

11. Related Party Transactions

FOXKISER LLP

Since 2016, the Company has been party to professional services agreements with FOXKISER LLP (FOXKISER), an affiliate of certain stockholders of the Company and an affiliate of a member of the Company's Board of Directors, pursuant to which the Company pays a fixed monthly fee in consideration for certain strategic services provided by FOXKISER. Effective January 2019, the Company entered into a new professional services agreement with FOXKISER with similar terms and conditions as the previous agreements. The agreement was amended effective June 2019 to expand the scope of the services provided and increase the monthly fee. Effective August 2020, the agreement was further amended to extend the term of the agreement by two years through December 2022. The agreement may be terminated by either party with six months' advanced written notice. Expenses incurred under the agreement with FOXKISER were $1.2 million and $3.6 million for the three and nine months ended September 30, 2021, respectively, and $1.2 million and $3.6 million for the three and nine months ended September 30, 2020, respectively, and were recorded as research and development expenses in the consolidated statements of operations and comprehensive income (loss).

12. Net Income (Loss) Per Share

The computations of basic and diluted net income (loss) per share were as follows (in thousands, except per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Basic net income (loss) per share:				
Net income (loss)	$ (58,405)	$ 8,791	$ (166,183)	$ (65,009)
Shares used in computation:				
Weighted-average common shares outstanding	42,629	37,342	42,324	37,234
Basic net income (loss) per share	$ (1.37)	$ 0.24	$ (3.93)	$ (1.75)
Diluted net income (loss) per share:				
Net income (loss)	$ (58,405)	$ 8,791	$ (166,183)	$ (65,009)
Shares used in computation:				
Weighted-average common shares outstanding	42,629	37,342	42,324	37,234
Stock options	—	1,529	—	—
Employee stock purchase plan	—	6	—	—
Weighted-average diluted common shares	42,629	38,877	42,324	37,234
Diluted net income (loss) per share	$ (1.37)	$ 0.23	$ (3.93)	$ (1.75)

For periods in which the Company incurred net losses, common stock equivalents were excluded from the calculation of diluted net loss per share as their effect would be anti-dilutive. Accordingly, basic and diluted net loss per share were the same for such periods. The following potentially dilutive common stock equivalents outstanding at the end of the period were excluded from the computations of weighted-average diluted common shares for the periods indicated as their effects would be anti-dilutive (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Stock options issued and outstanding	7,177	4,072	7,177	6,409
Unvested restricted stock units outstanding	265	—	265	—
Employee stock purchase plan	15	—	15	21
	7,457	4,072	7,457	6,430

13. Supplemental Disclosures

Accrued expenses and other current liabilities consisted of the following (in thousands):

	September 30, 2021	December 31, 2020
Accrued sublicense fees and royalties	$ 15,869	$ 12,160
Accrued personnel costs	14,034	13,155
Accrued purchases of property and equipment	8,303	7,853
Accrued external research and development expenses	8,069	9,738
Accrued external general and administrative expenses	2,974	2,865
Accrued income taxes payable	—	3,135
Other accrued expenses and current liabilities	445	176
	$ 49,694	$ 49,082

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 the financial statements and the notes thereto included elsewhere in this Quarterly Report on Form 10-Q and with our audited financial statements and the notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2020, which we filed with the SEC on March 1, 2021. In addition, you should read the "Risk Factors" and "Information Regarding Forward-Looking Statements" sections of this Quarterly Report on Form 10-Q and our Annual Report on Form 10-K for the year ended December 31, 2020 for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a leading clinical-stage biotechnology company seeking to improve lives through the curative potential of gene therapy. Our gene therapy product candidates are designed to deliver genes to cells to address genetic defects or to enable cells in the body to produce therapeutic proteins that are intended to impact disease. Through a single administration, our gene therapy product candidates are designed to provide long-lasting effects, potentially significantly altering the course of disease and delivering improved patient outcomes.

Overview of Product Candidates

We have developed a broad pipeline of gene therapy programs using our proprietary adeno-associated virus (AAV) gene therapy delivery platform (NAV Technology Platform) to address genetic diseases through two modalities: AAV-mediated antibody delivery and monogenic gene replacement. The AAV-mediated antibody delivery modality is designed to treat serious and chronic diseases by delivering the genes necessary for the sustained production of therapeutic antibodies *in vivo*. Our monogenic gene replacement approach builds upon the well-understood mechanism of replacing a dysfunctional or missing gene with a functional copy of the gene in order to enable sustained production of necessary proteins.

Gene therapy using NAV Vectors for AAV-mediated antibody delivery

- **RGX-314:** We are developing RGX-314 as a novel, single-administration gene therapy for the treatment of wet age-related macular degeneration (wet AMD), diabetic retinopathy (DR), and other additional chronic retinal conditions which cause total or partial vision loss. In September 2021, we announced a strategic partnership with AbbVie to develop and commercialize RGX-314 for the treatment of wet age-related macular degeneration (wet AMD), diabetic retinopathy (DR) and other chronic retinal diseases. The transaction is expected to close by the end of 2021, subject to the satisfaction of customary closing conditions, including applicable regulatory approvals. We are advancing two separate routes of administration of RGX-314 to the eye, through a standardized subretinal delivery procedure and by delivery to the suprachoroidal space using the SCS Microinjector™ licensed from Clearside Biomedical, Inc.

  We have initiated a pivotal program to evaluate the efficacy and safety of RGX-314 in patients with wet AMD using the subretinal delivery approach. We plan to conduct two randomized, well-controlled clinical trials to evaluate the efficacy and safety of RGX-314 in patients with wet AMD, in which we expect to enroll approximately 700 patients total. The first pivotal trial (ATMOSPHERE™) is enrolling patients and we are planning to initiate the second pivotal trial in the fourth quarter of 2021. Based on the outcome of these trials, the pivotal program is expected to support a Biologics License Application (BLA) filing in 2024.

  As of August 9, 2021, RGX-314 continued to be generally well-tolerated across all dose cohorts of the ongoing Phase I/II trial of RGX-314 for the treatment of wet AMD and its Long-Term-Follow-Up study. Durable treatment effect was observed in patients in Cohorts 4 and 5 at 2 years after administration of RGX-314, including stable visual acuity, decreased retinal thickness, and reductions in anti-VEGF injection burden. Long-term, durable treatment effect was demonstrated in Cohort 3 over three years, including mean improvement in vision and stable retinal thickness, and reductions in anti-VEGF treatment burden.

  We are also conducting a Phase II trial of the suprachoroidal delivery of RGX-314 using the SCS Microinjector for the treatment of wet AMD known as AAVIATE®. In October 2021, we presented positive initial data from patients enrolled in the ongoing Phase II AAVIATE trial. As of September 13, 2021, RGX-314 was reported to be well-tolerated across 50 patients dosed in Cohorts 1 through 3. At six months following one-time administration of RGX-314, stable visual acuity and retinal thickness, as well as a meaningful reduction in anti-VEGF treatment burden was observed in patients from Cohort 1 (dose level: $2.5x10^{11}$ genomic copies per eye (GC/eye)). Among patients in Cohort 1, common treatment emergent adverse events (TEAE) in the study eye were generally mild, and none were severe. Mild intraocular inflammation was observed in four out of 15 patients based on slit-lamp examination, and all cases were resolved within days to weeks on topical corticosteroids.

We plan to report interim results at six months of follow-up for patients in Cohort 2 at the American Academy of Ophthalmology 2021 Annual Meeting in New Orleans, LA, November 12-15, 2021. We have also completed dosing of patients in Cohort 3 which is evaluating the efficacy, safety and tolerability of RGX-314 in up to 20 patients who are neutralizing antibody (NAb) positive with the same dose evaluated in Cohort 2, $5.0x10^{11}$ GC/eye of RGX-314.

In October 2021, we announced that the AAVIATE trial expanded to include two additional cohorts (Cohorts 4 and 5) to evaluate RGX-314 at a dose level of $1.0x10^{12}$ GC/eye. Cohort 4 will enroll 15 patients who will be dosed with RGX-314 and Cohort 5 will evaluate the same dose level evaluated in Cohort 4 in 20 patients who are neutralizing antibody (NAb) positive. As in previous cohorts, patients will not receive prophylactic immune suppressive corticosteroid therapy before or after administration of RGX-314.

In addition, we are enrolling patients in ALTITUDE™, a Phase II trial of the suprachoroidal delivery of RGX-314 for the treatment of DR. In October 2021, we presented positive initial data from patients in Cohort 1 of the ongoing Phase II ALTITUDE trial. As of September 29, 2021, RGX-314 was reported to be well tolerated with no drug-related serious adverse events in the 15 patients dosed with RGX-314 in Cohort 1 (dose level: $2.5x10^{11}$ GC/ eye). No intraocular inflammation was observed on slit-lamp examination. Three months following one-time administration of RGX-314, five patients (33%) demonstrated a two-step or greater improvement from baseline on the Early Treatment Diabetic Retinopathy Study-Diabetic Retinopathy Severity Scale (ETDRS-DRSS), including one patient who had a four-step improvement. No patients in the observation control portion of the study demonstrated a two-step or greater improvement from baseline on the ETDRS-DRSS.

Enrollment of patients in Cohorts 2 and 3 is ongoing in ALTITUDE. Both cohorts will evaluate RGX-314 at a dose level of $5.0x10^{11}$ GC/eye. Cohort 2 will include 20 patients randomized to receive RGX-314 versus observational control at a 3:1 ratio. Cohort 3 will evaluate RGX-314 at the same dose level as Cohort 2 in 20 patients who are NAb positive. As in Cohort 1, patients in Cohorts 2 and 3 will not receive prophylactic immune suppressive corticosteroid therapy before or after administration of RGX-314.

- **AAV-Mediated Antibody Expression for the Treatment of Hereditary Angioedema (HAE):** We are developing a novel, one-time treatment utilizing a NAV Vector to deliver a gene encoding for a therapeutic antibody that targets and binds to plasma kallikrein, a key protein left unregulated in patients with HAE. HAE is a chronic and severe disease characterized by recurring severe swelling (angioedema), most commonly in the face, airway, intestines and limbs. We continue to conduct research and preclinical studies to advance a gene therapy candidate for the treatment of HAE.
- **AAV-Mediated Antibody Expression for the Treatment of Neurodegenerative Diseases:** We have established a research program in partnership with Neurimmune AG (Neurimmune) to jointly develop and commercialize novel gene therapies using NAV Vectors to deliver human antibodies for chronic neurodegenerative diseases, with an initial focus on diseases associated with the accumulation and deposition of the microtubule-associated protein tau (tauopathies) and alpha-synuclein (alpha-synucleinopathies).

Gene therapy programs for the potential treatment of rare monogenic diseases

- **RGX-202:** We are developing RGX-202 for the treatment of Duchenne Muscular Dystrophy (DMD), a severe, progressive, degenerative muscle disease caused by mutations in the gene which encodes dystrophin, a protein involved in muscle cell structure and function. Without functional dystrophin protein, muscles throughout the body degenerate and become weak. We expect to submit an Investigational New Drug (IND) application for this program by the end of 2021.
- **RGX-121:** We are developing RGX-121 for the treatment of the neurological symptoms of Mucopolysaccharidosis Type II (MPS II), a severe genetic lysosomal storage disease caused by deficiency of iduronate-2-sulfatase (I2S), an enzyme that is responsible for breakdown of cellular waste products.

  We are conducting a Phase I/II trial of RGX-121 in patients with MPS II up to the age of 5 years old. As reported in February 2021, RGX-121 was well-tolerated in Cohorts 1 and 2 of the Phase I/II trial, and no drug-related SAEs were reported. Biomarker data from patients in both cohorts indicated encouraging signals of I2S enzyme activity in the central nervous system following one-time administration of RGX-121, with consistent reductions of heparan sulfate (HS) and D2S6, a component of HS. Patients in Cohorts 1 and 2 also demonstrated continued neurocognitive development and evidence of I2S enzyme activity in plasma and urine following administration of RGX-121. We have expanded Cohort 3 of the ongoing Phase I/II trial to enroll up to 6 additional patients. Additional data from this trial is expected to be reported in the first half of 2022. In addition, we continue to enroll patients in a second Phase I/II trial of RGX-121, for the treatment of pediatric patients with MPS II over the age of 5 years old.

- **RGX-111:** We are developing RGX-111 for the treatment of the neurological symptoms of Mucopolysaccharidosis Type I (MPS I), a severe genetic lysosomal storage disease caused by deficiency of α-l-iduronidase (IDUA), an enzyme required for breakdown of cellular waste products. We have completed dosing of patients in the first cohort of a Phase I/II clinical trial for RGX-111 and enrollment is continuing in Cohort 2. We expect to share initial data from this trial in the first half of 2022.
- **RGX-181:** We are developing RGX-181 for the treatment of late-infantile neuronal ceroid lipofuscinosis type 2 (CLN2) disease, one of the most common forms of Batten disease, caused by mutations in the tripeptidyl peptidase 1 (TPP1) gene. An IND was submitted to the FDA, after which the FDA notified REGENXBIO that its proposed trial had been placed on clinical hold and the agency requested more information to support the initial dose selection and certain study drug administration procedures. We continue to evaluate the path forward for RGX-181 and plan to provide a program update in 2022.
- **RGX-381:** We are developing RGX-381 for the treatment of ocular manifestations of CLN2 disease. We are conducting additional preclinical studies of RGX-381 and are in discussions with regulatory agencies. We plan to provide a program update in 2022.

In addition to our product candidates described above, we have also funded, and plan to continue to fund, preclinical research on potential product candidate programs that may become part of our internal product development pipeline. We have partnered with a number of leading academic institutions and will continue to seek partnerships with innovative institutions to develop novel NAV gene therapy product candidates.

Overview of Our NAV Technology Platform

In addition to our internal product development efforts, we also selectively license the NAV Technology Platform to other leading biotechnology and pharmaceutical companies, which we refer to as NAV Technology Licensees. As of September 30, 2021, our NAV Technology Platform was being applied in one FDA approved product (Zolgensma®), and the preclinical and clinical development of 20 partnered programs. Licensing the NAV Technology Platform allows us to maintain our internal product development focus on our core disease indications and therapeutic areas while still expanding the NAV gene therapy pipeline, developing a greater breadth of treatments for patients, providing additional technological and potential clinical proof-of-concept for our NAV Technology Platform, and creating potential additional revenue.

Collaboration and License Agreement with AbbVie

In September 2021, we entered into a Collaboration and License Agreement with AbbVie Global Enterprises Ltd. (AbbVie), a subsidiary of AbbVie Inc., to develop and commercialize RGX-314 (the AbbVie Collaboration and License Agreement). The transaction is contingent upon the satisfaction of customary closing conditions, including the expiration or termination of the applicable waiting or suspension period under the Hart-Scott Rodino Antitrust Improvements Act of 1976, as amended, and any other applicable competition laws.

Pursuant to the AbbVie Collaboration and License Agreement, the parties will conduct certain activities for the development of products containing RGX-314 under a development plan determined in accordance with the AbbVie Collaboration and License Agreement. In the United States, the parties are required to use commercially reasonable efforts to develop one licensed product for the treatment of each of (a) wet AMD utilizing suprachoroidal delivery, (b) wet AMD utilizing subretinal delivery and (c) DR and, (d) following the achievement of specified milestone events, one licensed product for the treatment of an additional indication. In specified markets outside the United States, AbbVie is required to use commercially reasonable efforts to develop one licensed product for each such indication. Through December 31, 2022, we will be responsible for development expenses for certain ongoing trials of RGX-314 and the parties will share additional development expenses related to RGX-314. Beginning on January 1, 2023, AbbVie will be responsible for the majority of all RGX-314 development expenses.

We will lead the manufacturing of RGX-314 for clinical development and U.S. commercial supply, and AbbVie will lead manufacturing of RGX-314 for commercial supply outside the United States. The parties will equally share net profits and net losses associated with commercialization of licensed products in the United States. Outside the United States, AbbVie will be responsible, at its sole cost, for the commercialization of licensed products.

We will receive an upfront payment of $370.0 million from AbbVie in connection with the closing of the AbbVie Collaboration and License Agreement. Additionally, we will be eligible to receive up to $1.38 billion in development, regulatory and commercial milestone payments, in the aggregate, for the achievement of specified milestones for the licensed products, of which $782.5 million are based on development and regulatory milestones, with the remainder based on commercial milestones. We will also be eligible to

receive tiered royalties on net sales by AbbVie of licensed products outside the United States at percentages in the mid-teens to low twenties, subject to specified offsets and reductions.

Subject to the closing of the AbbVie Collaboration and License Agreement, we anticipate the agreement will have a material impact on our future revenues, research and development expenses, other operating expenses and operating cash flows associated with the development and commercialization of RGX-314. For additional information regarding the AbbVie Collaboration and License Agreement, please refer to Note 8, “License and Royalty Revenue—Collaboration and License Agreement with AbbVie” to the accompanying unaudited consolidated financial statements.

Impact of COVID-19

We are continuing to actively monitor the impact of the COVID-19 pandemic, including the emergence of variant strains, on our business, results of operations and financial condition. Our offices, laboratories, clinical trial sites, prospective clinical trial sites, contract research organizations (CROs), contract manufacturing organizations (CMOs) and other collaborators and partners are located in jurisdictions where quarantines, executive orders, shelter-in-place orders, guidelines, and other similar orders and restrictions intended to control the spread of the disease have been put in place by governmental authorities. At certain times during the COVID-19 pandemic, we have implemented a work-from-home policy for all employees who are not essential to be onsite, and we may take additional actions that alter our operations, as may be required by federal, state or local authorities or which we determine are in the best interests of our employees.

The COVID-19 pandemic has caused delays to our clinical trials and may further delay or prevent us from proceeding with our clinical trials. Our other business initiatives, such as preclinical development and manufacturing operations, may also be affected by the COVID-19 pandemic. For example, the construction of our current good manufacturing practice production facility has been delayed from our original estimates, and may be delayed further, due to various government orders and restrictions relating to the COVID-19 pandemic. In addition, if the business and operations of our licensees are adversely affected by the COVID-19 pandemic, our revenues could in turn be adversely affected. We are proactively taking measures to mitigate or reduce any adverse impact of the COVID-19 pandemic on the progress of our clinical trials and other business initiatives.

Our results of operations for the three and nine months ended September 30, 2021 and 2020 were not significantly impacted by the COVID-19 pandemic. However, the full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition in the future is unknown at this time and will depend on future developments that are highly unpredictable. Please refer to the “Risk Factors” section of our Annual Report on Form 10-K for the year ended December 31, 2020 for further discussion of the risks we face as a result of the COVID-19 pandemic.

Financial Overview

Revenues

Our revenues to date consist primarily of license and royalty revenue resulting from the licensing of our NAV Technology Platform. We have not generated any revenues from commercial sales of our own products. If we fail to complete the development of our product candidates in a timely manner or obtain regulatory approval and adequate labeling, our ability to generate future revenues will be materially compromised.

We license our NAV Technology Platform to other biotechnology and pharmaceutical companies. The terms of the licenses vary, and licenses may be exclusive or non-exclusive and may be sublicensable by the licensee. Licenses may grant intellectual property rights for purposes of internal and preclinical research and development only, or may include the rights, or options to obtain future rights, to commercialize drug therapies for specific diseases using the NAV Technology Platform. License agreements generally have a term at least equal to the life of the underlying patents, but are terminable at the option of the licensee. Consideration from licensees under our license agreements may include: (i) up-front and annual fees, (ii) option fees to acquire additional licenses, (iii) milestone payments based on the achievement of certain development and sales-based milestones by licensees, (iv) sublicense fees and (v) royalties on sales of licensed products.

Royalty revenue to date consists primarily of royalties on net sales of Zolgensma, which is marketed by Novartis Gene Therapies, Inc. (formerly AveXis, Inc.) (Novartis Gene Therapies), a wholly owned subsidiary of Novartis AG (Novartis), for the treatment of spinal muscular atrophy (SMA). Zolgensma is a licensed product under our license agreement with Novartis Gene Therapies for the development and commercialization of treatments for SMA.

Future license and royalty revenues are dependent on the successful development and commercialization of licensed products by our licensees, which is uncertain, and revenues may fluctuate significantly from period to period. Additionally, we may never receive consideration in our license agreements that is contemplated on option fees, development and sales-based milestone payments, royalties on sales of licensed products or sublicense fees, given the contingent nature of these payments. Our revenues are concentrated among a low number of licensees and licenses are terminable at the option of the licensee. The termination of our licenses by licensees may materially impact the amount of revenue we recognize in future periods.

Operating Expenses

Our operating expenses consist primarily of cost of revenues, research and development expenses and general and administrative expenses. Personnel costs including salaries, benefits, bonuses and stock-based compensation expense, comprise a significant component of research and development and general and administrative expenses. We allocate indirect expenses associated with our facilities, information technology costs, depreciation and other overhead costs between research and development and general and administrative categories based on employee headcount and the nature of work performed by each employee.

Cost of Revenues

Our cost of revenues consists primarily of upstream fees due to our licensors as a result of revenue generated from the licensing of our NAV Technology Platform, including sublicense fees, milestone payments and royalties on net sales of licensed products. Sublicense fees are based on a percentage of license fees received by us from NAV Technology Licensees and are recognized in the period that the underlying license revenue is recognized. Milestone payments are payable to licensors upon the achievement of specified milestones by NAV Technology Licensees and are recognized in the period the milestone is achieved or deemed probable of achievement. Royalties are based on a percentage of net sales of licensed products by NAV Technology Licensees and are recognized in the period that the underlying sales occur. Future costs of revenues are uncertain due to the nature of our license agreements and significant fluctuations in cost of revenues may occur from period to period.

Research and Development Expense

Our research and development expense primarily consists of:

- salaries and personnel-related costs, including benefits and stock-based compensation, for our scientific personnel performing research and development activities;
- costs related to executing preclinical studies and clinical trials;
- costs related to acquiring, developing and manufacturing materials for preclinical studies and clinical trials;
- fees paid to consultants and other third-parties who support our product candidate development;
- other costs in seeking regulatory approval of our product candidates; and
- allocated facility-related costs, depreciation expense and other overhead.

Up-front fees incurred in obtaining technology licenses for research and development activities, as well as associated milestone payments, are expensed as incurred if the technology licensed has no alternative future use.

We plan to increase our research and development expenses for the foreseeable future as we continue development of our product candidates. Our current and planned research and development activities include the following:

- Continued development of RGX-314 products, including:
    - a Phase I/II clinical trial and associated long-term follow-up study to evaluate the safety and efficacy of the subretinal delivery of RGX-314 for the treatment of wet AMD;
    - pivotal trials (ATMOSPHERE and one additional pivotal trial) to evaluate the safety and efficacy of the subretinal delivery of RGX-314 for the treatment of wet AMD;
    - Phase II clinical trials to evaluate the safety and efficacy of the suprachoroidal delivery of RGX-314 using the SCS Microinjector for the treatment of wet AMD (AAVIATE) and DR (ALTITUDE);
- preclinical research and development and a planned clinical trial for RGX-202 for the treatment of DMD;
- Phase I/II clinical trials to evaluate the safety and efficacy of RGX-121 for the treatment of MPS II;
- a Phase I/II clinical trial to evaluate the safety and efficacy of RGX-111 for the treatment of MPS I;
- preclinical research and development and planned clinical trials for RGX-181 for the treatment of CLN2 disease, and RGX-381 for the treatment of ocular manifestations of CLN2 disease;

- preclinical research and development for potential product candidates to treat HAE;
- preclinical research and development for potential product candidates to treat neurodegenerative diseases, including tauopathies and alpha-synucleinopathies, under our collaboration with Neurimmune;
- preclinical research and development for potential product candidates addressing other diseases across a range of therapeutics areas and other new technologies;
- continued investment in advanced manufacturing analytics and process development activities; and
- continued acquisition and manufacture of clinical trial materials in support of our anticipated clinical trials.

The following table summarizes our research and development expenses incurred during the three and nine months ended September 30, 2021 and 2020 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Direct Expenses				
RGX-314	$ 6,714	$ 6,472	$ 17,963	$ 16,189
RGX-202	2,831	3,713	6,607	8,080
RGX-121 and RGX-111	2,608	3,580	8,178	9,161
RGX-181 and RGX-381	191	1,767	1,078	3,958
Other product candidates	153	863	395	3,828
Total direct expenses	12,497	16,395	34,221	41,216
Unallocated Expenses				
Platform and new technologies	9,471	8,731	25,931	20,910
Personnel-related	19,955	15,731	57,770	47,752
Facilities and depreciation expense	5,189	2,829	13,813	8,151
Other unallocated	743	282	1,724	1,085
Total unallocated expenses	35,358	27,573	99,238	77,898
Total research and development	$ 47,855	$ 43,968	$ 133,459	$ 119,114

Platform and new technologies include direct costs not identifiable with a specific lead product candidate, including costs associated with our research and development platform used across programs, process development, manufacturing analytics and early research and development for prospective product candidates and new technologies. We typically utilize our employee and infrastructure resources across our development programs. We do not allocate personnel and other internal costs, such as facilities and other overhead costs, to specific product candidates or development programs.

General and Administrative Expense

Our general and administrative expense consists primarily of salaries and personnel-related costs, including benefits and stock-based compensation, for employees performing functions other than research and development. This includes certain personnel in executive, commercial, corporate development, finance, legal, human resources, information technology and administrative support functions. Other general and administrative expenses include facility-related and overhead costs not otherwise allocated to research and development expense, professional fees for accounting, legal and advisory services, expenses associated with obtaining and maintaining patents, insurance costs, costs of our information systems and other commercial and general corporate activities. We expect that our general and administrative expense will continue to increase as we continue to develop, and potentially commercialize, our product candidates.

Other Income (Expense)

Interest Income from Licensing

In accordance with our revenue recognition policy, interest income from licensing consists of imputed interest recognized from significant financing components identified in our license agreements with NAV Technology Licensees as well as interest income accrued on unpaid balances due from licensees.

Investment Income (Loss)

Investment income consists of interest income earned and gains and losses realized from our cash equivalents, marketable securities and non-marketable equity securities, as well as unrealized gains and losses on marketable equity securities. Cash equivalents are comprised of money market mutual funds and highly liquid debt securities with original maturities of 90 days or less at acquisition. Marketable securities are comprised of available-for-sale debt securities and equity securities.

Interest Expense

Interest expense consists of non-cash interest imputed on the liability related to the sale of future Zolgensma royalties to entities managed by Healthcare Royalty Management, LLC (collectively, HCR). Non-cash interest expense is recognized using the effective interest method, based on our estimate of total royalty payments expected to be received by HCR under the royalty purchase agreement.

Critical Accounting Policies and Significant Judgments and Estimates

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our consolidated financial statements, which we have prepared in accordance with accounting principles generally accepted in the United States of America (GAAP). The preparation of financial statements in conformity with GAAP requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities for the periods presented. 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, and other reported amounts, that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

Our significant accounting policies are fully described in Note 2 to the accompanying unaudited consolidated financial statements and in Note 2 to our audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2020. There have been no significant changes in our critical accounting policies since December 31, 2020.

Results of Operations

Our consolidated results of operations were as follows (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2021	2020	Change	2021	2020	Change
Revenues						
License and royalty revenue	$ 30,773	$ 98,912	$ (68,139)	$ 71,692	$ 133,122	$ (61,430)
Total revenues	30,773	98,912	(68,139)	71,692	133,122	(61,430)
Operating Expenses						
Cost of revenues	14,105	17,364	(3,259)	28,775	25,457	3,318
Research and development	47,855	43,968	3,887	133,459	119,114	14,345
General and administrative	21,030	15,859	5,171	57,293	46,246	11,047
Provision for credit losses and other	5,131	7,770	(2,639)	5,781	7,887	(2,106)
Total operating expenses	88,121	84,961	3,160	225,308	198,704	26,604
Income (loss) from operations	(57,348)	13,951	(71,299)	(153,616)	(65,582)	(88,034)
Other Income (Expense)						
Interest income from licensing	117	1,444	(1,327)	700	4,141	(3,441)
Investment income (loss)	5,535	(6,607)	12,142	6,514	(4,071)	10,585
Interest expense	(6,709)	—	(6,709)	(19,777)	—	(19,777)
Total other income (expense)	(1,057)	(5,163)	4,106	(12,563)	70	(12,633)
Income (loss) before income taxes	(58,405)	8,788	(67,193)	(166,179)	(65,512)	(100,667)
Income Tax Benefit (Expense)	—	3	(3)	(4)	503	(507)
Net income (loss)	$ (58,405)	$ 8,791	$ (67,196)	$ (166,183)	$ (65,009)	$ (101,174)

Comparison of the Three Months Ended September 30, 2021 and 2020

License and Royalty Revenue. License and royalty revenue decreased by $68.1 million, from $98.9 million for the three months ended September 30, 2020 to $30.8 million for the three months ended September 30, 2021. The decrease was primarily attributable to an $80.0 million milestone payment recognized as revenue in the third quarter of 2020 as a result of the achievement of $1.0 billion in cumulative net sales of Zolgensma during the period. The decrease was partially offset by an increase in Zolgensma royalty revenues, which increased by $11.5 million, from $18.8 million for the third quarter of 2020 to $30.3 million for the third quarter of 2021. As reported by Novartis, sales of Zolgensma for the third quarter of 2021 increased by 29% as compared to the third quarter of 2020, driven by geographic expansion of product access. The increase in Zolgensma sales also resulted in a higher effective royalty rate in the third quarter of 2021 as compared to the third quarter of 2020, as royalty rates are tiered based on specified thresholds of annual net sales.

Research and Development Expense. Research and development expenses increased by $3.9 million, from $44.0 million for the three months ended September 30, 2020 to $47.9 million for the three months ended September 30, 2021. The increase was primarily attributable to the following:

- an increase of $4.2 million for personnel-related costs as a result of increased headcount of research and development personnel, including a $0.8 million increase in stock-based compensation expense; and
- an increase of $3.3 million for laboratory costs and facilities used by research and development personnel, including depreciation expense allocated to research and development functions.

The increase in research and development expenses was partially offset by a $2.9 million decrease in external costs associated with preclinical studies and other early-stage research and development, and a $1.6 million decrease in external costs associated with manufacturing-related activities.

General and Administrative Expense. General and administrative expenses increased by $5.2 million, from $15.9 million for the three months ended September 30, 2020 to $21.0 million for the three months ended September 30, 2021. The increase was primarily attributable to the following:

- an increase of $2.3 million for personnel-related costs as a result of increased headcount of general and administrative personnel, including a $0.9 million increase in stock-based compensation expense; and
- an increase of $1.4 million for professional services, primarily related to legal and other advisory services.

Provision for Credit Losses and Other. Provision for credit losses and other decreased by $2.6 million during the three months ended September 30, 2021 as compared to the three months ended September 30, 2020. We recognized a provision for credit losses of $5.0 million and $7.7 million during the quarters ended September 30, 2021 and 2020, respectively, related to our accounts receivable from Abeona Therapeutics Inc. (Abeona). As of September 30, 2021, we had recorded total accounts receivable from Abeona of $30.1 million and a related allowance for credit losses of $13.2 million. For further information regarding the provision for credit losses, refer to Note 8, “License and Royalty Revenue—Abeona Therapeutics Inc.” to the accompanying unaudited consolidated financial statements.

Investment Income (Loss). Investment income was $5.5 million for the three months ended September 30, 2021 as compared to investment loss of $6.6 million for the three months ended September 30, 2020, a change of $12.1 million. The change was primarily attributable to a realized gain of $5.2 million recognized in the third quarter of 2021 upon the acquisition of our non-marketable equity securities of Corlieve Therapeutics SAS (Corlieve) by uniQure N.V. (uniQure) in July 2021, and net losses of $7.5 million recognized in the third quarter of 2020 related to our marketable equity securities of Prevail Therapeutics Inc. (Prevail). We sold all of our Prevail equity securities prior to the end of 2020. The change in investment income was partially offset by a decrease of $0.5 million in interest income for the third quarter of 2021, primarily attributable to lower yields on investments in cash equivalents and marketable debt securities.

Interest Expense. Interest expense increased from zero for the three months ended September 30, 2020 to $6.7 million for the three months ended September 30, 2021. Interest expense consists solely of non-cash interest recognized under our royalty purchase agreement with HCR for the sale of future Zolgensma royalties which occurred in December 2020.

Comparison of the Nine Months Ended September 30, 2021 and 2020

License and Royalty Revenue. License and royalty revenue decreased by $61.4 million, from $133.1 million for the nine months ended September 30, 2020 to $71.7 million for the nine months ended September 30, 2021. The decrease was primarily attributable to an $80.0 million milestone payment recognized as revenue in the third quarter of 2020 as a result of the achievement of $1.0 billion in cumulative net sales of Zolgensma during the period. The decrease was partially offset by an increase in Zolgensma royalty revenues, which increased by $26.2 million, from $40.7 million for the nine months ended September 30, 2020 to $66.9 million for the nine months ended September 30, 2021. As reported by Novartis, sales of Zolgensma for the nine months ended September 30, 2021 increased by 52% as compared to the nine months ended September 30, 2020, driven by geographic expansion of product access.

Research and Development Expense. Research and development expenses increased by $14.3 million, from $119.1 million for the nine months ended September 30, 2020 to $133.5 million for the nine months ended September 30, 2021. The increase was primarily attributable to the following:

- an increase of $10.0 million for personnel-related costs as a result of increased headcount of research and development personnel, including a $2.6 million increase in stock-based compensation expense;
- an increase of $5.6 million for external costs associated with clinical trial and regulatory activities for our lead product candidates, primarily attributable to RGX-314 and RGX-121 clinical trials; and
- an increase of $5.8 million for laboratory costs and facilities used by research and development personnel, including depreciation expense allocated to research and development functions.

The increase in research and development expenses was partially offset by a $8.1 million decrease in external costs associated with manufacturing-related activities, primarily attributable to manufacturing of RGX-314 and RGX-121 clinical supply performed in 2020 for material to be used in our current and planned clinical trials for these product candidates.

General and Administrative Expense. General and administrative expenses increased by $11.0 million, from $46.2 million for the nine months ended September 30, 2020 to $57.3 million for the nine months ended September 30, 2021. The increase was primarily attributable to the following:

- an increase of $4.8 million for personnel-related costs as a result of increased headcount of general and administrative personnel, including a $2.7 million increase in stock-based compensation expense;
- an increase of $3.7 million for professional services, primarily related to legal and other advisory services; and
- an increase of $1.1 million for facilities used by general and administrative personnel, including depreciation expense allocated to general and administrative functions.

Provision for Credit Losses and Other. Provision for credit losses and other decreased by $2.1 million during the nine months ended September 30, 2021 as compared to the nine months ended September 30, 2020. We recognized a provision for credit losses of $5.5 million and $7.7 million during the nine months ended September 30, 2021 and 2020, respectively, related to our accounts receivable from Abeona. As of September 30, 2021, we had recorded total accounts receivable from Abeona of $30.1 million and a related allowance for credit losses of $13.2 million. For further information regarding the provision for credit losses, refer to Note 8, “License and Royalty Revenue—Abeona Therapeutics Inc.” to the accompanying unaudited consolidated financial statements.

Investment Income (Loss). Investment income was $6.5 million for the nine months ended September 30, 2021 as compared to investment loss of $4.1 million for the nine months ended September 30, 2020, a change of $10.6 million. The change was primarily attributable to a realized gain of $5.2 million recognized in the third quarter of 2021 upon the acquisition of our non-marketable equity securities of Corlieve by uniQure in July 2021, and net losses of $8.3 million recognized during the nine months ended September 30, 2020 related to our marketable equity securities of Prevail. We sold all of our Prevail equity securities prior to the end of 2020. The change in investment income was partially offset by a decrease of $2.8 million in interest income for the nine months ended September 30, 2021, primarily attributable to lower yields on investments in cash equivalents and marketable debt securities.

Interest Expense. Interest expense increased from zero for the nine months ended September 30, 2020 to $19.8 million for the nine months ended September 30, 2021. Interest expense consists solely of non-cash interest recognized under our royalty purchase agreement with HCR for the sale of future Zolgensma royalties which occurred in December 2020.

Liquidity and Capital Resources

Sources of Liquidity

As of September 30, 2021, we had cash, cash equivalents and marketable securities of $533.5 million, which were primarily derived from the sale of our common stock, license and royalty revenue and the monetization of our Zolgensma royalty stream. We expect that our cash, cash equivalents and marketable securities as of September 30, 2021, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months from the date of this report, based on our current business plan.

In January 2021, we completed a public offering of 4,899,000 shares of our common stock (inclusive of 639,000 shares pursuant to the full exercise by the underwriters of their option to purchase additional shares) at a price of $47.00 per share. The aggregate net proceeds from the offering, inclusive of the underwriters' option exercise, were $216.1 million, net of underwriting discounts and commissions and offering expenses payable by us.

We intend to devote the majority of our current capital to clinical development, seeking regulatory approval of our product candidates and capital expenditures to build out additional office, laboratory and manufacturing capacity, including the buildout of our corporate, manufacturing and research headquarters in Rockville, Maryland. Because of the numerous risks and uncertainties associated with the development and commercialization of gene therapy product candidates, we are unable to estimate the total amount of operating expenditures and capital outlays necessary to complete the development of our product candidates. Additionally, our estimates are based on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Furthermore, given the continuing uncertainty and volatile market and economic conditions caused by the COVID-19 pandemic, as well as the potential for further effects due to a resurgence in COVID-19 infections, we will continue to monitor the nature and extent of the impact of the COVID-19 pandemic on our liquidity and capital resources.

Cash Flows

Our consolidated cash flows were as follows (in thousands):

	Nine Months Ended September 30,	
	2021	2020
Net cash used in operating activities	$ (107,362)	$ (93,529)
Net cash provided by (used in) investing activities	(190,283)	111,189
Net cash provided by financing activities	187,606	6,046
Net increase (decrease) in cash and cash equivalents and restricted cash	$ (110,039)	$ 23,706

Cash Flows from Operating Activities

Our net cash used in operating activities for the nine months ended September 30, 2021 increased by $13.8 million from the nine months ended September 30, 2020. The increase was largely driven by an increase in operating expenses of $26.6 million in 2021. We expect to continue to incur regular net cash outflows from operations for the foreseeable future as we continue the development and advancement of our lead product candidates and other research programs.

For the nine months ended September 30, 2021, our net cash used in operating activities of $107.4 million consisted of a net loss of $166.2 million and changes in working capital of $1.9 million, offset by $60.7 million in adjustments for non-cash items. The changes in working capital include a $7.9 million increase in accounts receivable which was largely driven by an increase in Zolgensma royalties receivable at the end of the period, and a $7.9 million increase in prepaid expenses which was largely driven by advances paid during the period to service providers for clinical trial and manufacturing-related services to be performed in future periods. The changes in working capital were partially offset by an increase in operating lease liabilities of $10.8 million which was largely driven by funds received under our tenant improvement allowance related to the ongoing buildout of our new headquarters facility in Rockville, Maryland. Other changes in working capital were incurred in the normal course of business, primarily as a result of differences in the timing of payments to service providers and the period in which such costs are incurred. Adjustments for non-cash items primarily consisted of stock-based compensation expense of $29.6 million, non-cash interest expense recognized under our royalty purchase agreement with HCR of $19.8 million, depreciation and amortization expense of $7.0 million, a provision for credit losses of $5.5 million and net amortization of premiums on marketable debt securities of $4.4 million. Adjustments for non-cash items were partially offset by a realized gain of $5.2 million recognized upon the acquisition of our Corlieve equity securities by uniQure in July 2021.

For the nine months ended September 30, 2020, our net cash used in operating activities of $93.5 million consisted of a net loss of $65.0 million and changes in working capital of $73.9 million, offset by $45.4 million in adjustments for non-cash items. The changes in working capital include an increase in accounts receivable of $89.4 million which was largely driven by an increase in Zolgensma royalties receivable at the end of the period, and an $80.0 million sales-based milestone fee earned during the third quarter which was recorded in accounts receivable at the end of the period. Other changes in working capital were incurred in the normal

course of business, primarily as a result of differences in the timing of payments to service providers and the period in which such costs are incurred. Adjustments for non-cash items primarily consisted of stock-based compensation expenses of $24.4 million, depreciation and amortization expense of $6.3 million, net losses on our Prevail equity securities of $8.3 million and a provision for credit losses on accounts receivable of $7.7 million.

Cash Flows from Investing Activities

For the nine months ended September 30, 2021, our net cash used in investing activities consisted of $262.7 million to purchase marketable debt securities and $69.6 million to purchase property and equipment, offset by $136.4 million in maturities of marketable debt securities and $5.6 million of proceeds received from the acquisition of our Corlieve equity securities by uniQure in July 2021. The substantial majority of our capital expenditures for the nine months ended September 30, 2021 were related to the build out of our corporate, manufacturing and research headquarters at 9804 Medical Center Drive in Rockville, Maryland. We expect capital expenditures related to this project to continue for the remainder of 2021 and into 2022 as we complete build out of this facility. Total remaining capital expenditures to complete the build out of the facility, net of remaining amounts to be reimbursed by the landlord under our tenant improvement allowance, are expected to be in the low to mid-double-digit millions (USD). However, the actual amount and timing of these capital expenditures are uncertain and may differ materially from our current estimates.

For the nine months ended September 30, 2020, our net cash provided by investing activities consisted of $204.5 million in sales and maturities of marketable securities, offset by $79.4 million to purchase marketable debt securities and $14.0 million to purchase property and equipment.

Cash Flows from Financing Activities

For the nine months ended September 30, 2021, our net cash provided by financing activities primarily consisted of $216.1 million in net proceeds received from a public offering of our common stock completed in January 2021, net of underwriting discounts and commissions and other offering expenses paid during the period, and $5.1 million in proceeds received from the exercise of stock options and issuance of common stock under our employee stock purchase plan, and was partially offset by $33.3 million of Zolgensma royalties paid to HCR during the period under our royalty purchase agreement.

For the nine months ended September 30, 2020, net cash provided by financing activities consisted of $6.0 million in proceeds received from the exercise of stock options and issuance of common stock under our employee stock purchase plan.

Future Funding Requirements

We have incurred cumulative losses since our inception and had an accumulated deficit of $455.3 million as of September 30, 2021. Our transition to recurring profitability is dependent upon achieving a level of revenues adequate to support our cost structure, which depends heavily on the successful development, approval and commercialization of our product candidates. We do not expect to achieve such revenues, and expect to continue to incur losses, for at least the next several years. We expect that our research and development and general and administrative expenses will continue to increase for the foreseeable future as we continue the development of, and seek regulatory approval for, our product candidates. Subject to obtaining regulatory approval for our product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. Additionally, we expect our capital expenditures will continue to increase due to costs associated with building out additional office, laboratory and manufacturing capacity to further support the development of our product candidates and potential commercialization efforts, particularly with respect to the build out of our corporate, manufacturing and research headquarters as discussed above. As a result, we will need significant additional capital to fund our operations, which we may obtain through one or more equity offerings, debt financings or other third-party funding, including potential strategic alliances and licensing or collaboration arrangements.

Our future capital requirements will depend on many factors, including:

- the anticipated completion of our proposed transaction with AbbVie and the outcome of our proposed collaboration with AbbVie;
- the timing of enrollment, commencement and completion of our clinical trials;
- the results of our clinical trials;
- the results of our preclinical studies for our product candidates and any subsequent clinical trials;
- the scope, progress, results and costs of drug discovery, laboratory testing, preclinical development and clinical trials for our product candidates;
- the costs associated with building out additional laboratory and manufacturing capacity;

- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of future product sales, medical affairs, marketing, manufacturing and distribution activities for any of our product candidates for which we receive marketing approval;
- revenue, if any, received from commercial sales of our products, should any of our product candidates receive marketing approval;
- revenue received from commercial sales of Zolgensma and other revenue, if any, received in connection with commercial sales of our NAV Technology Licensees' products, should any of their product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- our current licensing agreements or collaborations remaining in effect;
- our ability to establish and maintain additional licensing agreements or collaborations on favorable terms, if at all; and
- the extent to which we acquire or in-license other product candidates and technologies.

Many of these factors are outside of our control. Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory and marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our product revenues, if any, and any commercial milestones or royalty payments under our licensing agreements, will be derived from or based on sales of products, the majority of which may not be commercially available for many years, if at all. In addition, revenue from our NAV Technology Platform sublicensing is dependent in part on the clinical and commercial success of our licensing partners. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives.

The issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common stock to decline. Adequate additional financing may not be available to us on acceptable terms, or at all. We also could be required to seek funds through arrangements with partners or otherwise that may require us to relinquish rights to our intellectual property, our product candidates or otherwise agree to terms unfavorable to us.

Contractual Obligations, Commitments and Contingencies

There have been no material changes to our contractual obligations, commitments and contingencies as of September 30, 2021 from the information provided in Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations," included in our Annual Report on Form 10-K for the year ended December 31, 2020.

Off-Balance Sheet Arrangements

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

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

For information regarding market risk, refer to Item 7A, "Quantitative and Qualitative Disclosures About Market Risk," included in our Annual Report on Form 10-K for the year ended December 31, 2020. There have been no material changes to our exposure to market risk during the nine months ended September 30, 2021.

Item 4. Controls and Procedures.

Conclusion Regarding the Effectiveness of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2021. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2021, our disclosure controls and procedures were effective at a reasonable assurance level.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the quarter ended September 30, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

Control systems, no matter how well conceived and operated, are designed to provide a reasonable, but not an absolute, level of assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. Because of the inherent limitations in any control system, misstatements due to error or fraud may occur and not be detected.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings.

For information regarding our legal proceedings with Abeona Therapeutics Inc., please refer to Note 8, “License and Royalty Revenue—Abeona Therapeutics Inc.,” to the accompanying unaudited consolidated financial statements.

Item 1A. Risk Factors.

Our material risk factors are disclosed in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2020 and Quarterly Report on Form 10-Q for the quarter ended June 30, 2021. There have been no material changes from the risk factors previously disclosed in such filings, except as follows:

Risks Related to Third Parties

We have in the past, and in the future may, enter into licensing agreements or collaborations with third parties licensing parts of our NAV Technology Platform for the development of product candidates. If these licensing arrangements or collaborations are not successful, our business could be harmed.

We have entered into agreements involving the licensing of parts of our NAV Technology Platform and relating to the development and commercialization of certain product candidates and plan to enter into additional licensing agreements or collaborations in the future. We have limited control over the amount and timing of resources that our current and future licensees and collaborators, including our NAV Technology Licensees, dedicate to the development or commercialization of product candidates or of products utilizing licensed components of our NAV Technology Platform. Our ability to generate revenues from these arrangements will depend on our and our licensees’ and collaborators’ abilities to successfully perform the functions assigned to each of us in these arrangements. In addition, our licensees and collaborators have the ability to abandon research or development projects and terminate applicable agreements. Moreover, an unsuccessful outcome in any clinical trial for which our licensee or collaborator is responsible could be harmful to the public perception and prospects of our NAV Technology Platform or product candidates.

In September 2021, we entered into a Collaboration and License Agreement with AbbVie Global Enterprises Ltd. (AbbVie), a subsidiary of AbbVie Inc., to develop and commercialize RGX-314 (the AbbVie Collaboration and License Agreement). The transaction is contingent upon the satisfaction of customary closing conditions, including the expiration or termination of the applicable waiting or suspension period under the Hart-Scott Rodino Antitrust Improvements Act of 1976, as amended, and any other applicable competition laws. If the transaction contemplated by the AbbVie Collaboration and License Agreement is not consummated or is delayed, our expectations regarding future revenues, research and development costs, other operating expenses and operating cash flows associated with the development and commercialization of RGX-314 would be materially affected. For additional information regarding the AbbVie Collaboration and License Agreement, please refer to Note 8, “License and Royalty Revenue—Collaboration and License Agreement with AbbVie” to the accompanying unaudited consolidated financial statements.

Any current or future licensing agreements or future collaborations we enter into may pose additional risks, including the following:

- subjects in clinical trials undertaken by licensees or future collaborators, including our NAV Technology Licensees, may suffer adverse effects, including death;
- licensees or collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the licensees’ or collaborators’ strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities;
- we may not have access to, or may be restricted from disclosing, certain information regarding product candidates being developed or commercialized under a collaboration and, consequently, may have limited ability to inform our stockholders about the status of such product candidates;
- licensees or collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the licensees or collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates developed in collaboration with us may be viewed by our licensees or collaborators as competitive with their own product candidates or products, which may cause licensees or collaborators to cease to devote resources to the commercialization of our product candidates;
- a licensee or collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of any such product candidate;

- licensees or collaborators may breach their reporting, payment, intellectual property or other obligations to us, which could prevent us from complying with our contractual obligations to GSK and Penn;
- disagreements with licensees or collaborators, including disagreements over intellectual property and other proprietary rights, payment obligations, contract interpretation or the preferred course of development of any product candidates, may cause delays or termination of the research, development or commercialization of such product candidates, may lead to additional responsibilities for us with respect to such product candidates or may result in litigation or arbitration, any of which would be time-consuming and expensive and could potentially lessen the value of such agreements and collaborations;
- licensees or collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- disputes may arise with respect to the ownership of our other rights to intellectual property developed pursuant to our licensing agreements or collaborations;
- licensees or collaborators may infringe or otherwise violate the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- licensing agreements or collaborations may be terminated for the convenience of the licensee or collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

If our licensing agreements or collaborations do not result in the successful development and commercialization of products, or if one of our licensees or collaborators terminates its agreement with us, we may not receive any future milestone or royalty payments, as applicable, under the license agreement or collaboration. If we do not receive the payments we expect under these agreements, our development of product candidates could be delayed and we may need additional resources to develop our product candidates. In addition, if one of our licensees or collaborators terminates its agreement with us, we may find it more difficult to attract new licensees or collaborators and the perception of us in the business and financial communities could be harmed. Each of our licensees and collaborators is subject to similar risks with respect to product development, regulatory approval and commercialization, and any such risk could result in its business being harmed, which could adversely affect our collaboration.

We may in the future decide to partner or collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of our product candidates. These relationships, or those like them, may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we could face significant competition in seeking appropriate collaborators and the negotiation process is time-consuming and complex. Our ability to reach a definitive licensing agreement or collaboration agreement will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a variety of factors.

We may not be successful in our efforts to establish such a strategic partnership or other alternative arrangements for our product candidates because our research and development pipeline may be insufficient, our product candidates may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy or market opportunity. In addition, we may be restricted under existing collaboration agreements from entering into future agreements with potential collaborators. If we license rights to product candidates, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate the licensed product candidates with our existing operations.

If we are unable to reach agreements with suitable licensees or collaborators on a timely basis, on acceptable terms or at all, we may have to curtail the development of a product candidate, reduce or delay its development program, delay its potential commercialization, reduce the scope of any sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not Applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description	Incorporated by Reference			Filed or Furnished Herewith
		Form	Exhibit Number	Filing Date	
3.1	Restated Certificate of Incorporation	8-K	3.1	6/7/21	
3.2	Amended and Restated Bylaws	8-K	3.2	9/22/15	
10.1†	Collaboration and License Agreement dated September 10, 2021 between the Company and AbbVie Global Enterprises Ltd.				X
31.1	Certification of the Chief Executive Officer, as required by Section 302 of the Sarbanes-Oxley Act of 2002				X
31.2	Certification of the Chief Financial Officer as required by Section 302 of the Sarbanes-Oxley Act of 2002				X
32.1	Certifications of the Chief Executive Officer and Chief Financial Officer as required by 18 U.S.C. 1350				X
101	The following materials from the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2021 formatted in Inline XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets (ii) Consolidated Statements of Operations and Comprehensive Income (Loss) (iii) Consolidated Statements of Stockholders' Equity (iv) Consolidated Statements of Cash Flows (v) Notes to Consolidated Financial Statements				X
104	The cover page from the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2021 formatted in Inline XBRL (included in Exhibit 101)				

† Portions of this exhibit have been omitted.

The certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q is not deemed filed with the SEC and is not to be incorporated by reference into any filing of REGENXBIO Inc. under the Securities Act or the Exchange Act, whether made before or after the date of this Quarterly Report on Form 10-Q, irrespective of any general incorporation language contained in such filing.

SIGNATURES

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

REGENXBIO Inc.

Dated: November 2, 2021

/s/ Kenneth T. Mills
Kenneth T. Mills
President and Chief Executive Officer
(Principal Executive Officer)

Dated: November 2, 2021

/s/ Vittal Vasista
Vittal Vasista
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

EXHIBIT 10.1

EXECUTED VERSION

Certain identified information has been excluded from this exhibit because such information both (i) is not material and (ii) would likely cause competitive harm if publicly disclosed. Excluded information is indicated with brackets and asterisks.

COLLABORATION AND LICENSE AGREEMENT

BETWEEN

REGENXBIO INC.

AND

ABBVIE GLOBAL ENTERPRISES LTD.

DATED AS OF September 10, 2021

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SCHEDULES

COLLABORATION AND LICENSE AGREEMENT

This Collaboration and License Agreement (the "**Agreement**") is made and entered into as of September 10, 2021 (the "**Execution Date**") by and between REGENXBIO Inc., a corporation organized under the laws of the State of Delaware ("**REGENX**") and AbbVie Global Enterprises Ltd., a Bermuda company ("**PARTNER**"). REGENX and PARTNER are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

Recitals

WHEREAS, REGENX has developed RGX-314 (as defined herein);

WHEREAS, REGENX owns and controls certain REGENX Patents (as defined herein) and REGENX Know-How (as defined herein) and other intellectual property rights with respect to RGX-314 in the Territory (as defined herein), as well as methods for its administration, manufacture and therapeutic uses; and

WHEREAS, REGENX and PARTNER wish to collaborate with respect to the Exploitation (as defined herein) of Licensed Products (as defined herein) in the Licensed Field (as defined herein) in the Territory in accordance with and subject to the terms and conditions set forth below; and

WHEREAS, PARTNER desires to obtain from REGENX an exclusive license under the REGENX Patents (as defined herein) and REGENX Know-How (as defined herein) under the terms set forth herein to Exploit Licensed Products in the Licensed Field in the Territory; and

WHEREAS, REGENX and PARTNER have contemporaneously herewith entered into a sublicense agreement pursuant to which REGENX has granted and PARTNER has accepted a license under the Penn Patents (as defined herein) to further Exploit Licensed Products in the Licensed Field in the Territory (the "**Penn Sublicense Agreement**"), in each case in accordance with the terms and conditions set forth below and in the Penn Sublicense Agreement.

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

ARTICLE 1
DEFINITIONS

Unless otherwise specifically provided herein, capitalized terms used in this Agreement have the meanings attributed to them in Schedule 1 (Definitions).

ARTICLE 2
EFFECTIVENESS OF THIS AGREEMENT

2.1 Effective Date. Notwithstanding anything to the contrary in this Agreement, except for the provisions of ARTICLE 1, this ARTICLE 2, ARTICLE 10, ARTICLE 11, and ARTICLE 14 which shall take effect as of the Execution Date and except as set forth in Section 2.1 (Effect of Agreement) of the Penn Sublicense Agreement, neither this Agreement nor the Penn Sublicense Agreement shall be binding on the Parties or otherwise take effect until the Effective Date. As used herein, the "**Effective Date**" means the first Business Day following such time as all of the following express conditions precedent to the effectiveness of this Agreement have been satisfied, including any and all of the following conditions that relate to the HSR Act and any other applicable Competition Laws:

2.1.1 The Parties shall have complied with all applicable requirements of the HSR Act and any applicable Competition Laws in connection with this Agreement and the Penn Sublicense Agreement;

2.1.2 the waiting or suspension period under the HSR Act and any applicable Competition Laws shall have expired or been terminated early, and any necessary consents or approvals under any applicable Competition Laws shall have been obtained;

2.1.3 the Parties are under no antitrust-related obligation to refrain from consummating the transaction under a timing agreement entered into with a reviewing Governmental Authority that prevents closing before a specified date or without specified notice;

2.1.4 no judicial or administrative proceeding opposing consummation of all or any part of this Agreement or Penn Sublicense Agreement is pending;

2.1.5 no injunction (whether temporary, preliminary or permanent) prohibiting consummation of the transactions contemplated by this Agreement, the Penn Sublicense Agreement or any material portion hereof is in effect; and

2.1.6 no requirements or conditions shall have been formally requested or imposed by the DOJ, FTC or any Governmental Authority in connection therewith that are not reasonably and mutually satisfactory to the Parties.

2.2 Antitrust Cooperation.

2.2.1 Obligations. Both Parties shall promptly file, as soon as reasonably practicable and advisable following the Execution Date (and in any event, within [****] after the Execution Date, unless the Parties mutually agree otherwise in writing), their respective notification and report forms with the FTC and DOJ pursuant to the HSR Act. PARTNER will make all mandatory filings (if any) required of it or any of its Affiliates under any other applicable Competition Laws in connection with this Agreement and the transactions contemplated hereby as soon as reasonably practicable, but in any event no later than [****] following the Effective Date, it being understood that such filing(s) may be made in draft where the submission of a draft filing is customary, and in the event that a Governmental Authority commences an investigation of the transaction(s) on its own initiative, or refers the transactions to

the European Commission, PARTNER will submit any required filing by the date on which a competition regulator asserts that a filing is required. [****]. Each Party shall promptly inform the other Party of any communication (whether oral or written) made to, or received by, such Party from any Governmental Authority regarding any of the transactions contemplated hereby, and promptly provide a copy of any such written communication, or a summary of any such oral communication, to the other Party.

2.2.2 Reasonable Efforts.

(a) If any objections are raised or asserted with respect to the transactions contemplated hereby under the HSR Act or any other applicable Competition Laws or if any action is instituted (or threatened to be instituted) by any Governmental Authority challenging the transactions contemplated hereby as being in violation of the HSR Act or any other applicable Competition Laws or which would otherwise prevent, impede or delay the consummation of the transactions contemplated hereby, the Parties shall use their commercially reasonable efforts to resolve any such objections or actions so as to permit consummation of the transactions contemplated hereby as soon as reasonably practicable; *provided* that, and notwithstanding anything to the contrary set forth herein, no Party shall be required to enter into any agreements or commitments or take any other actions to resolve any such objections or actions if such agreement, commitment or other action would reasonably be expected, individually or in the aggregate, to (i) prevent consummation of the transactions contemplated hereby, (ii) result in the transactions contemplated hereby being rescinded following the Execution Date, (iii) limit or otherwise adversely affect the right of PARTNER to be granted the licenses and other rights contemplated under this Agreement or the Penn Sublicense Agreement, or (iv) require or compel PARTNER or any Affiliate of PARTNER to (A) divest, dispose of, license or hold separate any portion of the businesses, operations, assets or product lines of PARTNER or its Affiliates (or a combination of the respective businesses, operations, assets or product lines of PARTNER and its Affiliates), (B) restrict, prohibit or limit the ability of PARTNER or any of its Affiliates to conduct their business or own their assets, or (C) impose limitations on the ability of PARTNER or any of its Affiliates to exercise the licenses or other rights granted to PARTNER or any of its Affiliates as contemplated under this Agreement or the Penn Sublicense Agreement. Notwithstanding the foregoing or any other provision of this Agreement to the contrary, in no event shall PARTNER or any of its Affiliates be obligated to (I) enter into any settlement, undertaking, consent decree, stipulation or agreement with any Governmental Authority in connection with the transactions contemplated hereby or (II) litigate or participate in the litigation of any action, whether judicial or administrative, brought by any Governmental Authority challenging or seeking to restrain, prohibit or place conditions on the consummation of the transactions contemplated hereby or the ownership or operation by PARTNER or any of its Affiliates of all or any portion of their respective businesses as presently conducted and as currently proposed to be conducted.

(b) The Parties agree to use reasonable efforts to consult and cooperate with one another, and consider in good faith the views of one another, in connection with any analyses, appearances, meetings, discussions, presentations, memoranda, briefs, filings, arguments, and proposals made by or on behalf of either Party before any Governmental Authority or the staff or regulators of any Governmental Authority in connection with the transactions contemplated hereby. Each Party shall use reasonable efforts to give sufficient notice to the other Party hereto with respect to any meeting, discussion, appearance or contact with any Governmental

Authority or the staff or regulators of any Governmental Authority in order to provide the other Party with the opportunity to attend and participate in such meeting, discussion, appearance or contact. Nothing in this Section 2.2.2(b) shall require (i) either Party to furnish copies of its respective filing under the HSR Act to the other Party, (ii) either Party to provide any Confidential Information contained in any other filing under applicable Competition Laws, or (iii) either Party to provide access to, or disclose any information to, the other Party or any of its Affiliates if such access or disclosure, in the good faith reasonable belief of such Party, (x) would cause significant competitive harm to such Party if the activities contemplated hereby are not consummated, (y) would result in the waiver of any legal privilege, or (z) would be in violation of Applicable Laws or the provisions of any agreement to which either Party is a party.

2.2.3 Costs. [****].

2.3 Delay in Effective Date. In the event that each of the conditions precedent to the Effective Date specified in Section 2.1 are not satisfied within [****] after the Execution Date, then either Party may terminate this Agreement and the Penn Sublicense Agreement and rescind its obligation to enter into the transactions contemplated by this Agreement and the Penn Sublicense Agreement upon written notice to the other Party and all provisions of this Agreement and the Penn Sublicense Agreement shall be of no force or effect.

ARTICLE 3
DEVELOPMENT AND REGULATORY ACTIVITIES

3.1 Development Activities.

3.1.1 Development Diligence Obligations.

(a) Subject to the terms and conditions of this Agreement, commencing on the Effective Date, the Parties shall use Commercially Reasonable Efforts to Develop, with the goal of receiving Regulatory Approval, one (1) Licensed Product for the treatment of each of (a) nAMD by means of nAMD Suprachoroidal Treatment, (b) nAMD by means of nAMD Subretinal Treatment, and (c) DR, in each case, in the United States. In addition, subject to the terms and conditions of this Agreement, following the achievement of both of the Initial Registration Enabling Trial Milestone Events, the Parties shall use Commercially Reasonable Efforts to Develop one (1) Licensed Product for the treatment of one (1) Additional Indication in the United States.

(b) Subject to the terms and conditions of this Agreement, commencing on the Effective Date, PARTNER shall use Commercially Reasonable Efforts to Develop, with the goal of receiving Regulatory Approval, one (1) Licensed Product for the treatment of each of (a) nAMD by means of nAMD Suprachoroidal Treatment, (b) nAMD by means of nAMD Subretinal Treatment, and (c) DR, in each case, in [****]. In addition, subject to the terms and conditions of this Agreement, following the achievement of both of the Initial Registration Enabling Trial Milestone Events, PARTNER shall use Commercially Reasonable Efforts to Develop one (1) Licensed Product for the treatment of one (1) Additional Indication in [****].

3.1.2 Development Plan Activities. Each Party shall use Commercially Reasonable Efforts to perform its Development activities set forth in the Development Plan and in accordance with the timelines set forth in the Development Plan. In addition, each Party shall perform or cause to be performed the Development activities allocated to it under the Development Plan in good scientific manner and in compliance with all Applicable Law. For clarity, no material Development activities relating to any Licensed Product for use in the Licensed Field shall be conducted by or on behalf of either Party except as set forth in the Development Plan [****].

3.2 Development Plan.

3.2.1 Development Plan. The Development Plan is attached hereto as Schedule 3.2.1 and describes the allocation of activities between the Parties for the initial Development of Licensed Products for use in the Licensed Field in the Territory, in each case as applicable for a Licensed Product for use in a particular Indication in the Licensed Field [****].

3.2.2 Development Plan Updates. The JDC shall review the Development Plan [****] for the purpose of considering appropriate amendments thereto, including revisions to existing Development activities and the addition of new Development activities. In addition, either Party, through its representatives on the JDC, may propose amendments to the Development Plan at any time. Any proposed amendment to the Development Plan shall be reviewed by the JDC. Any amendment to the Development Plan will not be binding on either Party until approved by the JDC [****] and upon such approval by the JDC [****], the updated Development Plan shall be deemed to be incorporated into this Agreement. With respect to any amendment to the Development Plan to add new Development activities (including any Development activities that are required to be conducted by a Regulatory Authority to support Regulatory Approval of a Licensed Product in a given jurisdiction) or modify any Development activities in a manner that would change the cost of such activities, such amendment shall include a corresponding amendment to the Budget for the Development Plan; [****].

3.2.3 Implementation. Without limitation of the foregoing, the Party responsible for activities in connection with the Development of Licensed Products for use in the Licensed Field as set forth in the Development Plan shall have the right, without seeking JDC approval, to make operational decisions consistent with the terms of this Agreement that reasonably implement the Development Plan but do not require a change thereto.

3.2.4 [****]

3.3 Development Expenses.

3.3.1 Reimbursable Development Expenses. Each Party shall be responsible for its share of Allowable Development Expenses *plus* Allowable Overruns (collectively, "**Reimbursable Development Expenses**") incurred by both Parties in connection with the Development of Licensed Products for use in the Licensed Field in the Territory as set forth in Schedule 3.3. The Development Plan attached hereto as Schedule 3.2.1 includes a detailed Budget for the initial period upon commencement of Development activities pursuant to Section 3.1.1 until [****].

3.3.2 Excess Development Expenses; Budget Amendments. In the event either Party incurs (or anticipates that it will incur) costs or expenses in the conduct of Development activities under the Development Plan that exceed the Reimbursable Development Expenses ("**Excess Development Expenses**"), [****].

3.4 Records and Reports.

3.4.1 Development Records. Each Party shall, and shall require its Affiliates and its and their sublicensees and Third Party subcontractors to, maintain, in good scientific manner, complete and accurate books and records pertaining to Development of Licensed Products for use in the Licensed Field ("**Development Records**"), in sufficient detail to verify compliance with its obligations under this Agreement. Such books and records shall (a) be appropriate for patent and regulatory purposes, (b) be in compliance with Applicable Law, (c) properly reflect all work done and results achieved in the performance of its Development activities hereunder, (d) record only such activities and not include or be commingled with records of activities outside the scope of this Agreement and (e) be retained, with respect to Development Records of a Party, by such Party for at least [****] after the expiration or termination of this Agreement in its entirety or for such longer period as may be required by Applicable Law. Each Party shall have the right, during normal business hours and upon reasonable notice, to inspect and copy all Development Records of a Party maintained pursuant to this Section 3.4.1 for the purpose of confirming compliance with this Agreement and fulfilling its obligations under this Agreement; *provided* that such Party shall maintain such records and information disclosed therein in confidence in accordance with ARTICLE 10 [****]. Without limiting the foregoing, each Party shall maintain such Development Records as is necessary to comply with each of the applicable provisions in this Agreement.

3.4.2 Development Reports.

(a) Each Party shall record and account for its FTE Costs and Out-of-Pocket Costs for the Development activities, in each case, in a manner that allocates costs to the extent possible to a specific activity in the Development Plan. [****]. Without limitation of Section 3.4.1, within [****] following the end of each [****] during which a Party is conducting Development activities hereunder, such Party shall provide the JDC with a detailed written report of (i) all Development activities such Party has performed, or caused to be performed during [****] and (ii) such Party's Reimbursable Development Expenses incurred in the performance of such Development activities during such [****], whereby it shall specify in reasonable detail all amounts included in such Reimbursable Development Expenses.

(b) [****], each Party further shall provide to the other Party a high-level summary of such Party's Development activities in process and anticipated Development activities during the following [****] period, in each case, for the Licensed Products in the Licensed Field in any jurisdiction(s) in the Territory.

3.5 Development Subcontracting. Subject to Section 9.4, (a) PARTNER shall have the right to subcontract its Development activities to a Third Party [****] and (b) REGENX shall have the right to subcontract its Development activities [****]. No such permitted subcontracting shall relieve either Party of any obligation (except to the extent such obligation is performed by such subcontractor) or any liability hereunder and such Party shall be and remain

fully responsible and liable therefor. Any agreement pursuant to which a Party engages any Third Party subcontractor must (a) be consistent in all material respects with the applicable terms and conditions of this Agreement and (b) contain terms obligating such subcontractor to comply with the confidentiality, intellectual property and all other relevant provisions of this Agreement. In addition, each Party shall use commercially reasonable efforts to contractually obligate such subcontractor to permit the other Party rights of inspection, access and audit substantially similar to those provided to the other Party in this Agreement. Each Party hereby waives any requirement that the other Party exhaust any right, power or remedy, or proceed against any subcontractor for any obligation or performance under this Agreement, prior to proceeding directly against such first Party.

3.6 Regulatory Approvals and Communications.

3.6.1 Responsibility for Regulatory Approvals. [****]

3.6.2 Meetings with Regulatory Authorities. [****]

3.6.3 Regulatory Filings. [****]

3.6.4 Regulatory Costs. For clarity, any Reimbursable Development Expenses incurred by the Parties to conduct the regulatory activities contemplated under this Section 3.6 shall be borne by the Parties in accordance with Section 3.3 and Schedule 3.3.

3.7 Recalls, Suspensions or Withdrawals. Each Party shall notify the other Party promptly (but in no event later than [****]) following its determination that any event, incident or circumstance has occurred that may result in the need for a recall, market suspension or market withdrawal of a Licensed Product for use in the Licensed Field in the Territory and shall include in such notice the reasoning behind such determination and any supporting facts. As between the Parties, PARTNER shall have the right to make the final determination of whether to voluntarily implement any such recall, market suspension or market withdrawal in the Licensed Field in the Territory; *provided* that prior to any implementation of such a recall, market suspension or market withdrawal in the United States, PARTNER shall consult with REGENX and shall consider REGENX's comments in good faith. If a recall, market suspension or market withdrawal is mandated by a Regulatory Authority in the Territory, as between the Parties, PARTNER shall initiate such a recall, market suspension or market withdrawal in compliance with Applicable Law. Any costs and expenses incurred by the Parties in the event of any recall, market suspension or market withdrawal of a Licensed Product for use in the Licensed Field will be borne by the Parties as follows:

3.7.1 in the event that a recall, market suspension, or market withdrawal resulted from a Party's or its Affiliate's breach of its obligations hereunder, under the Clinical Supply Agreement, the Commercial Supply Agreement, the Clinical Quality Agreement or the Commercial Quality Agreement or from such Party's or its Affiliate's gross negligence or willful misconduct, such Party shall bear the expense of such recall, market suspension, or market withdrawal;

3.7.2 subject to clause (a) above, in the event that a recall, market suspension, or market withdrawal occurs in a country prior to Marketing Authorization in such

country from the applicable Regulatory Authority, the expenses incurred by the Parties as a result of such recall, market suspension, or market withdrawal shall be included in the Allowable Development Expenses hereunder;

3.7.3 subject to clauses (a) and (b) above, with respect to any recall, market suspension, or market withdrawal of a Licensed Product in the United States, the expenses incurred by the Parties as a result of such recall, market suspension, or market withdrawal in the United States shall be included in Allowable US Expenses hereunder; and

3.7.4 subject to clause (a) above, with respect to any recall, market suspension, or market withdrawal of a Licensed Product that occurs in a country other than the United States after Marketing Authorization in such country from the applicable Regulatory Authority, PARTNER shall be responsible for any expenses incurred by the Parties as a result of such recall, market suspension, or market withdrawal.

3.8 Pharmacovigilance Agreement. [****] the Parties will execute a pharmacovigilance agreement [****] that will provide, among other things, [****] guidelines and procedures for the receipt, investigation, recordation, communication, and exchange (as between the Parties) of adverse event reports and any other information as determined by the Parties. Such guidelines and procedures shall be in accordance with, and enable the Parties to comply with and fulfill, all Applicable Laws and all local and national regulatory reporting obligations to Regulatory Authorities and other Governmental Authorities.

3.9 Global Safety Database. PARTNER shall establish, hold and maintain the global safety database for Licensed Products for use in the Licensed Field. REGENX shall provide PARTNER with information in the Control of REGENX as necessary for PARTNER to comply with its pharmacovigilance responsibilities in the Territory, including, as applicable, any adverse drug experiences (including those events or experiences that are required to be reported to the FDA under 21 C.F.R. sections 312.32 or 314.80 or to foreign Regulatory Authorities under corresponding Applicable Law outside the United States), from its Development of a Licensed Product, in each case, in the form reasonably requested by PARTNER. [****].

ARTICLE 4
COMMERCIALIZATION

4.1 Commercialization Activities. Subject to the remainder of this ARTICLE 4, as between the Parties, PARTNER shall have the sole right to Commercialize Licensed Products in the Licensed Field throughout the Territory. REGENX shall participate in the Commercialization of Licensed Products in the Licensed Field in the United States with the scope of such participation determined in advance by the JCC (subject to the applicable decision-making provisions of Section 7.4.3(g)).

4.2 Commercialization Strategies and Plans.

4.2.1 Global Commercialization Strategy. [****] PARTNER shall develop and provide to REGENX through the JCC a global commercialization strategy for such Licensed Product in a particular Indication throughout the Territory (each, a "**Global Commercialization Strategy**"), which Global Commercialization Strategy shall include [****].

For the avoidance of doubt, this Section 4.2.1 shall apply for each Licensed Product for use in a particular (different) Indication in the Licensed Field (e.g. if a Global Commercialization Strategy has been established for a Licensed Product for use in nAMD, this Section 4.2.1 shall apply again for a Licensed Product for use in DR). Each Global Commercialization Strategy shall be non-binding and shall be used solely to facilitate discussion between the Parties regarding PARTNER's Commercialization plans in the Territory.

4.2.2 Commercialization Plans. [****] the JCC shall develop an initial comprehensive plan and Budget for Commercialization of such Licensed Product in the United States for such Indication (each, a "**Commercialization Plan**"), which initial Commercialization Plan shall cover [****] of Commercialization activities after the First Commercial Sale of such Licensed Product in the United States for such Indication and shall include (in each case, for such Indication and solely with respect to the United States): [****]. The JCC shall review each Commercialization Plan [****] and shall develop any amendments to each Commercialization Plan.

4.3 Diligence.

4.3.1 In the case of any Commercialization activities performed in or for the United States, each Party shall use Commercially Reasonable Efforts to Commercialize such Licensed Product in the United States in accordance with the applicable Commercialization Plan for such Licensed Product for such Indication. Once an application for Regulatory Approval for a Licensed Product in an Indication has been submitted to a Regulatory Authority in [****].

4.3.2 Following receipt of Regulatory Approval for a Licensed Product for a given Indication in the United States, [****], PARTNER shall use Commercially Reasonable Efforts to Commercialize such Licensed Product for the treatment of such Indication in the Licensed Field in such country; *provided* that such obligation with respect to [****]. For clarity, with respect to any Indication, the Parties acknowledge that the foregoing diligence obligations shall not require separate Commercially Reasonable Efforts with respect to different delivery methods (e.g., subretinal and suprachoroidal) for the treatment of the same Indication.

4.4 Commercialization Records and Reports.

4.4.1 Commercialization Records. Without limitation of Section 8.11, each Party shall maintain complete and accurate books and records pertaining to its Commercialization of Licensed Products hereunder, in sufficient detail to verify compliance with its obligations under this Agreement, which books and records shall be in compliance with Applicable Law and properly reflect all work done and results achieved in the performance of its Commercialization activities. Such records shall be retained by a Party for at least [****] after the expiration or termination of this Agreement in its entirety or for such longer period as may be required by Applicable Law. Each Party shall have the right, during normal business hours and upon reasonable notice, to inspect and copy all such books and records maintained by the other Party pursuant to this Section 4.4.1 for the sole purpose of confirming compliance with this Agreement; *provided* that each Party shall maintain such records and information disclosed therein in confidence in accordance with ARTICLE 10, [****].

4.4.2 Commercialization Updates. Without limitation of Section 4.4.1, for the time period during which a Party is conducting Commercialization activities hereunder, such Party shall update the JCC at each regularly scheduled meeting of the JCC regarding its Commercialization activities with respect to the Licensed Products in the Licensed Field in the United States Each such update will summarize such Party's significant Commercialization activities with respect to Licensed Products in the Licensed Field in the United States to the extent that such Party has the right to disclose such information to the other Party without violating any confidentiality or other obligations to any Third Party.

4.5 Commercialization Costs; Booking of Sales; Distribution.

4.5.1 Global Commercialization Costs. As between the Parties, PARTNER shall be responsible for all costs and expenses in connection with the Commercialization of Licensed Products in the Licensed Field throughout all countries in the Territory other than the United States.

4.5.2 United States Commercialization Costs. The Parties shall be responsible for all Allowable US Expenses in accordance with Section 8.4. All expenses incurred by PARTNER that would be Allowable US Expenses save for the fact that such expenses were not provided in or consistent with the Commercialization Plan or related Budget shall be deemed Allowable US Expenses under this Agreement. In the event REGENX incurs (or anticipates that it will incur) costs or expenses in the conduct of Commercialization activities under the Commercialization Plan that exceed the Allowable US Expenses for such activities under the Commercialization Plan ("**Excess Commercialization Expenses**"), REGENX may provide notice of the expected Excess Commercialization Expenses to the JCC which notice shall include reasonable detail and background information sufficient to enable the JCC to evaluate the basis for such Excess Commercialization Expenses. The Parties shall, through the JCC, discuss in good faith whether to amend the Budget for the Commercialization Plan or whether to otherwise treat such Excess Commercialization Expenses as Allowable US Expenses. [****].

4.5.3 Booking of Sales; Distribution. Subject to the Commercialization Plan (solely with respect to the United States), PARTNER shall invoice and book Net Sales, establish all terms of sale (including pricing and discounts) and warehouse and distribute Licensed Products for use in the Licensed Field in the Territory and perform or cause to be performed all related services. Subject to Section 3.7, PARTNER shall be responsible for conducting and managing all returns, recalls, suspensions or withdrawals, order processing, invoicing, collection, distribution and inventory management with respect to Licensed Products for use in the Licensed Field in the Territory.

4.6 Commercial Subcontracting. Subject to Section 9.4, (a) PARTNER shall have the right to subcontract its Commercial activities to a Third Party [****] and (b) REGENX shall have the right to subcontract its Commercial activities to a Third Party [****]. No such permitted subcontracting shall relieve either Party of any obligation (except to the extent satisfactorily performed by such subcontractor) or any liability hereunder and such Party shall be and remain fully responsible and liable therefor. Any agreement pursuant to which a Party engages any Third Party subcontractor must (x) be consistent in all material respects with this Agreement and (y) contain terms obligating such subcontractor to comply with the confidentiality, intellectual

property and all other relevant provisions of this Agreement. In addition, each Party shall use commercially reasonable efforts to contractually obligate such subcontractor to permit the other Party rights of inspection, access and audit substantially similar to those provided to the other Party in this Agreement. Each Party hereby waives any requirement that the other Party exhaust any right, power or remedy, or proceed against any subcontractor for any obligation or performance under this Agreement prior to proceeding directly against such first Party.

4.7 Compliance with Applicable Law. Each Party shall, and shall require its Affiliates and sublicensees to, comply with all Applicable Law with respect to the Exploitation of Licensed Products in the Licensed Field in the Territory.

4.8 Markings. To the extent requested by REGENX in writing and permitted under Applicable Law or otherwise required by Applicable Law, the Promotional Materials (including web and social media content), packaging and Product Labeling for a Licensed Product used by PARTNER, its Affiliates and its and their Sublicensees in connection with Commercialization in the United States shall contain the Corporate Name (and logo) as designated by REGENX with equal prominence to the Trademarks of PARTNER or its Affiliates, in a manner approved in writing by the Parties.

ARTICLE 5
MANUFACTURING AND SUPPLY

5.1 Clinical Supply.

5.1.1 In General. Except as expressly set forth in this Agreement, REGENX shall Manufacture and supply, or supply from Existing Inventory, all requirements of Licensed Products (including Licensed Compounds therein) necessary for the Parties to conduct their Development activities under this Agreement ("**Clinical Supply**"). REGENX represents and warrants that it has the amounts of Licensed Product on hand as of the Execution Date (such Licensed Product, "**Existing Inventory**") as set forth on Schedule 5.1.1 and that all Existing Inventory satisfies the Product Warranty as of the Execution Date. REGENX hereby represents, warrants and covenants that the Existing Inventory will satisfy the Product Warranty upon its delivery to PARTNER for use, or upon its use by or on behalf of REGENX, in Development activities under this Agreement. REGENX will supply Existing Inventory for the conduct of Development activities under this Agreement and will use Existing Inventory solely for such purpose. Subject to Section 5.1.2, REGENX will deliver, or cause to be delivered, all requirements of Clinical Supply to sites conducting any of the Clinical Trials under the Development Plan. A material breach of REGENX's obligations under this Section 5.1.1 will be deemed a Material Breach. Upon the effective date of the Clinical Supply Agreement, the provisions of this Section 5.1 shall be replaced and superseded by the terms and conditions of the Clinical Supply Agreement. [****].

5.1.2 Clinical Supply Agreement. [****] the Parties shall enter into (a) one or more clinical supply agreement(s) (the "**Clinical Supply Agreement**") pursuant to which REGENX shall Manufacture and supply Clinical Supply and supply Delivery Systems for such Clinical Supply to PARTNER for Development activities under this Agreement, including Clinical Trials under the Development Plan, and (b) [****] quality assurance agreement setting

forth the terms and conditions on which the Parties shall conduct their quality activities in connection with the applicable Clinical Supply Agreement (the "**Clinical Quality Agreement**"). [****]. Without limitation of the foregoing, the Clinical Supply Agreement(s) shall include terms and conditions that conform in all material respects to those set forth on Schedule 5.1.2 and in the event that Clinical Supply or Delivery Systems for such Clinical Supply are required by PARTNER prior to the execution of the Clinical Supply Agreement, this Agreement, including the terms set forth on Schedule 5.1.2, shall govern the Manufacture and supply of such Clinical Supply.

5.1.3 Clinical Manufacturing Costs. Any Reimbursable Development Expenses incurred by the Parties to Manufacture Clinical Supply under this Section 5.1, including [****], will be allocated to the Parties in accordance with Section 3.3 and Schedule 3.3; [****].

5.1.4 Use of Clinical Supply. The Parties agree that: (a) any Clinical Supply shall be used solely for the Development of Licensed Products in the Licensed Field pursuant to this Agreement; and (b) any Clinical Supply shall not be made available by either Party to any Third Party except in connection with Clinical Trial(s) pursuant to the Development Plan or as expressly consented to in writing by the other Party, such approval not to be unreasonably withheld, delayed or conditioned.

5.2 Commercial Supply.

5.2.1 In General.

(a) **Commencement of Commercial Supply Discussions**. [****] the Parties, through their representatives on the JCC and JMC, shall (i) discuss the timing for commencing Process Development activities for commercial supply of such Licensed Product (and Licensed Compound therein) in the Territory (or, as indicated where appropriate, in the United States or outside of the United States) (the "**Commercial Supply**"), (ii) discuss the timing for commencing Manufacture and supply of such Commercial Supply in the Territory, taking into account anticipated global sales of such Licensed Product and such other factors as may be determined by the JCC and JMC, and (iii) commence good faith negotiations to enter into a Commercial Supply Agreement and quality assurance agreement in respect of such Commercial Supply, as further described in Section 5.2.2. For the avoidance of doubt, this Section 5.2.1(a) shall apply for each Licensed Product for use in a particular (different) Indication in the Licensed Field (e.g. if the Parties have discussed timing for commencing Process Development and Manufacture and Commercial Supply for a Licensed Product for use in nAMD, Section 5.2.1(a) shall apply again for a Licensed Product for use in DR).

(b) **Commercial Supply in the United States** Subject to the remainder of this Section 5.2 and the terms and conditions of the Commercial Supply Agreement: (i) REGENX shall Manufacture (or have Manufactured) and supply [****] of the Parties' requirements of Commercial Supply for Licensed Products (including Licensed Compounds therein) for use in the Licensed Field in the United States, and shall perform Process Development with respect thereto; and (ii) PARTNER shall Manufacture (or have Manufactured) and supply [****] of the Parties' requirements of Commercial Supply for Licensed Products (including

Licensed Compounds therein) for use in the Licensed Field in the United States except as otherwise mutually agreed by the Parties. The Commercial Supply Agreement will set forth in further detail the allocation of Commercial Supply responsibilities between the Parties in the United States, but will in all cases be consistent with the foregoing sentence except as otherwise mutually agreed by the Parties. The JCC and the JMC shall determine the timeline pursuant to which commercial Process Development shall commence with respect to the first Licensed Product for use in the Licensed Field and shall provide written notice of such determination to REGENX.

(c) **Commercial Supply Outside of the United States** Subject to the remainder of this Section 5.2 and the terms and conditions of the Commercial Supply Agreement: (i) REGENX shall Manufacture (or have Manufactured) and supply [****] of the requirements of the Commercial Supply for Licensed Products (including Licensed Compounds therein) for use in the Licensed Field outside of the United States; and (ii) PARTNER shall Manufacture (or have Manufactured) and supply [****] of the Parties' requirements of Commercial Supply for Licensed Products (including Licensed Compounds therein) for use in the Licensed Field outside of the United States, in each case except as mutually agreed by the Parties. The Commercial Supply Agreement will set forth in further detail the allocation of Commercial Supply responsibilities between the Parties in the Territory outside of the United States, but will in all cases be consistent with the foregoing sentence except as mutually agreed by the Parties.

(d) **Reassessment of Commercial Supply Allocation.** In the event that there is no Manufacturing facility (whether of REGENX or a CMO designated by REGENX) both fully enabled to Manufacture Commercial Supply and approved by the applicable Regulatory Authority for the Manufacture of Commercial Supply as of a reasonable period of time prior to launch of a Licensed Product using such Commercial Supply, then the JMC will reassess and determine the appropriate split in such Commercial Supply production volumes between the Parties from the production volumes set forth in this Agreement.

5.2.2 Commercial Supply Agreement.

(a) In accordance with the timelines set forth in Section 5.2.1(a) above, the Parties shall [****] (i) enter into one or more commercial supply agreement(s) (the "**Commercial Supply Agreement**") setting forth the terms and conditions on which REGENX shall Manufacture and supply the Commercial Supply of Licensed Products (including Licensed Compounds therein) and Delivery Systems for Commercial Supply, and (ii) enter into [****] quality assurance agreement setting forth the terms and conditions on which the Parties shall conduct their quality activities in connection with the Commercial Supply Agreement (the "**Commercial Quality Agreement**"). [****]. Without limitation of the foregoing, the Commercial Supply Agreement shall include terms and conditions that conform in all material respects with this Section 5.2 and to those set forth on Schedule 5.2.2(a). Upon the effective date of the Commercial Supply Agreement, the provisions of Section 5.2.1 and this Section 5.2.2 shall be replaced and superseded by the terms and conditions of the Commercial Supply Agreement. In the event that Commercial Supply or Delivery Systems for Commercial Supply are required to be Manufactured or supplied in PARTNER's reasonable discretion prior to the execution of the Commercial Supply Agreement, this Agreement, including the terms set forth on Schedule 5.2.2(a), shall govern the Manufacture and supply of such Commercial Supply.

(b) [****]

5.2.3 [****]

5.2.4 **Commercial Manufacturing Costs**.

(a) The costs and expenses relating to the Manufacture of Commercial Supply shall be incurred and paid pursuant to the Commercial Supply Agreement or, if no Commercial Supply Agreement is in place, under the terms of this Agreement. For the avoidance of doubt, any such costs and expenses with respect to any given unit of Licensed Product shall be payable only once (whether under this Agreement or under the Commercial Supply Agreement).

(b) [****].

5.3 **Certain Components.** With respect to certain components, the Parties agree to comply with the terms of Schedule 5.3.

ARTICLE 6
EXCLUSIVITY

6.1 **Generally.** Subject to Sections 6.2 and 6.3, in any country in the Territory, no Party will, and each Party will cause its Affiliates to not, for a period of [****] following the Effective Date, (a) directly or indirectly, Develop, Manufacture, Commercialize or otherwise Exploit or (b) license, authorize, appoint or otherwise enable any Third Party to directly or indirectly, Develop, Manufacture, Commercialize or otherwise Exploit, in either case of (a) or (b), any AAV-based delivery product or service that targets VEGF in the field of ophthalmology (such product "**Competing Products**", and such activities "**Competing Activities**").

6.2 [****]

6.3 [****]

ARTICLE 7
GOVERNANCE

7.1 **Joint Development Committee.** Within [****] after the Effective Date, the Parties shall establish a joint development committee (the "**Joint Development Committee**" or "**JDC**"), which shall consist of [****] representatives from each of the Parties, each with the requisite experience and seniority to enable such person to make decisions on behalf of the Parties with respect to the issues falling within the jurisdiction of the JDC. From time to time, each Party may substitute [****] of its representatives to the JDC on written notice to the other Party. [****] shall appoint [****] of its representatives to serve as a co-chairperson of the JDC, and [****] may change its appointed co-chairperson from time to time upon written notice [****]. The JDC shall:

7.1.1 serve as a forum for discussing and coordinating Development of Licensed Products for use in the Licensed Field in the United States and discussing Development of Licensed Products for use in the Licensed Field in the Royalty Territory, including

by overseeing the conduct of the Development activities as set forth in Section 3.1 and reviewing Development reports as set forth in Section 3.4.2;

7.1.2 [****];

7.1.3 [****];

7.1.4 develop and determine whether to approve any amendment to the Development Plan and corresponding Budget as set forth in Section 3.2.2 or, if applicable, 3.3.2;

7.1.5 review and discuss the Parties' regulatory activities in the United States, including any updates regarding any material, non-recurring submissions and filings (e.g., INDs, BLAs, major supplements or amendments to the foregoing, material labeling supplements, Regulatory Authority meeting requests and core data sheets and filings related to new Indications and proposed labeling) that PARTNER proposes to submit or has submitted to any Regulatory Authority in the United States;

7.1.6 [****];

7.1.7 conduct responsibilities delegated to another Joint Committee under this Agreement if such Joint Committee is not yet formed; and

7.1.8 perform such other functions as are set forth herein or as the Parties may mutually agree in writing, except where in conflict with any provision of this Agreement.

7.2 Joint Commercialization Committee. [****] the Parties shall establish a joint commercialization committee (the "**Joint Commercialization Committee**" or "**JCC**"), which shall consist of [****] representatives from each of the Parties, each with the requisite experience and seniority to enable such person to make decisions on behalf of the Parties with respect to the issues falling within the jurisdiction of the JCC. From time to time, each Party may substitute [****] of its representatives to the JCC upon written notice to the other Party. [****] shall appoint [****] of its representatives to serve as a co-chairperson of the JCC, and [****] may change its appointed co-chairperson from time to time upon written notice [****]. The JCC shall:

7.2.1 discuss the Global Commercialization Strategy prepared by PARTNER and submitted in accordance with Section 4.2.1;

7.2.2 serve as a forum for discussing and coordinating the Commercialization of Licensed Products in the Licensed Field in the United States as set forth in Section 4.3;

7.2.3 discuss, together with the JMC, the timing for commencement of Manufacturing and supply of Commercial Supply and commercial Process Development in the Territory and serve as a forum for discussing and coordinating the Manufacturing and supply as set forth in Section 5.2.1;

7.2.4 develop the Commercialization Plans and the Budgets therefor for Licensed Products for use in the Licensed Field in the United States and any amendments thereto as set forth in Section 4.2.2 or, if applicable, 4.5.2;

7.2.5 discuss and determine Commercialization activities under the Commercialization Plan for which REGENX is responsible;

7.2.6 [****];

7.2.7 [****];

7.2.8 with respect to the Commercialization of Licensed Products for use in the Licensed Field in the United States, review and discuss the Commercialization costs and expenses incurred by the Parties in connection with such Commercialization, including against Budgets set forth in Commercialization Plans; and

7.2.9 perform such other functions as are set forth herein or as the Parties may mutually agree in writing, except where in conflict with any provision of this Agreement.

7.3 Joint Manufacturing Committee. [****] the Parties shall establish a joint manufacturing committee (the "**Joint Manufacturing Committee**" or "**JMC**"), which shall consist of [****] representatives from each of the Parties, each with the requisite experience and seniority to enable such person to make decisions on behalf of the Parties with respect to the issues falling within the jurisdiction of the JMC. From time to time, each Party may substitute [****] of its representatives to the JMC on written notice to the other Party. [****] shall appoint [****] of its representatives to serve as a co-chairperson of the JMC, and [****] may change its appointed co-chairperson from time to time upon written notice [****]. The JMC shall:

7.3.1 discuss, together with the JCC, the timing for commencement of Manufacturing and supply of Commercial Supply and commercial Process Development in the Territory; and serve as a forum for discussing and coordinating the Manufacturing and supply as set forth in Section 5.2.1;

7.3.2 discuss and develop the plan of Clinical Supply, Commercial Supply (at least [****] prior to anticipated applicable launch) [****];

7.3.3 [****];

7.3.4 with respect to the Manufacturing of a Licensed Product for use in the Licensed Field, review and discuss the Clinical Supply costs, Commercial Supply costs, Process Development costs and other expenses incurred by the Parties in connection with such Manufacturing, including against Budgets developed by the JDC and JCC therefor;

7.3.5 [****]; and

7.3.6 perform such other functions as are set forth herein or as the Parties may mutually agree in writing, except where in conflict with any provision of this

Agreement.

7.4 General Provisions Applicable to Joint Committees

7.4.1 Meetings and Minutes. Each Joint Committee shall hold meetings at such times as the Parties shall determine, but in no event less frequently than [****] during the Term or as otherwise agreed by the Parties, with respect to the JDC, JCC and JMC, commencing from and after the time such Joint Committee is established as provided herein. Meetings of each Joint Committee may be conducted by telephone, by video-conference, or in-person as determined by such Joint Committee. In-person meetings of each Joint Committee, unless otherwise agreed, shall alternate between REGENX's offices and PARTNER's offices. The co-chairpersons of the Joint Committees shall be responsible for calling meetings on no less than [****] notice unless exigent circumstances require shorter notice. Each Party shall make all proposals for agenda items at least [****] in advance of the applicable meeting; *provided* that under exigent circumstances requiring input by a Joint Committee, a Party may provide its agenda items to the other Party within a shorter period of time in advance of the meeting or may propose that there not be a specific agenda for a particular meeting, so long as the other Party consents to such later addition of such agenda items or the absence of a specific agenda for such meeting (which consent shall not be unreasonably withheld, conditioned or delayed). The co-chairpersons of each Joint Committee shall prepare and circulate for review and approval of the Parties' minutes of each meeting within [****] after the meeting. The Parties shall agree on the minutes of each meeting promptly, [****].

7.4.2 Procedural Rules. Each Joint Committee shall have the right to adopt such standing rules as shall be necessary for its work, to the extent that such rules are not inconsistent with this Agreement. A quorum of each Joint Committee shall exist whenever there is present at a meeting [****] appointed by each Party. Subject to a Party having final decision-making authority with respect to a matter, each Party shall have [****] with respect to any matters properly before each Joint Committee. [****]. Subject to Section 7.4.3, each Joint Committee shall take action by consensus of the representatives present at a meeting at which a quorum exists, [****] or by a written resolution signed by [****] appointed by each Party. Alliance Managers or other employees or consultants of a Party who are not representatives of the Parties on a Joint Committee may attend meetings of such Joint Committee; *provided, however*, that such attendees (a) shall not vote in such Joint Committee and (b) are bound by obligations of confidentiality and non-disclosure at least as protective of the other Party as those set forth in ARTICLE 10. For clarity, each Party shall have the right to make operational, day-to-day decisions with respect to the performance of its activities under this Agreement.

7.4.3 Dispute Resolution. If a Joint Committee, after a period of [****], cannot, or does not, reach consensus on a matter that is expressly within its jurisdiction under this ARTICLE 7 (such consensus shall consist of [****] in mutual agreement), either Party may require that the dispute be submitted to the Senior Officers for resolution by providing written notice to the other Party formally requesting that the dispute be resolved by the Senior Officers and specifying the nature of the dispute. If a dispute is referred to the Senior Officers, then the Senior Officers shall diligently and in good faith attempt to resolve the referred dispute within [****] after receiving written notification of such dispute or such longer period of time as the Senior Officers may agree in writing. Any final decision mutually agreed to by the Senior Officers

with respect to a dispute and set forth in writing shall be conclusive and binding on the Parties. If the Senior Officers cannot resolve such dispute within such [****] or such other period as agreed by the Senior Officers, then subject to Section 7.4.4, such dispute will be resolved as follows: [****].

7.4.4 Limitations on Authority. Without limitation of the foregoing, the Parties hereby agree that Legal Disputes and matters explicitly reserved to the consent, approval or other decision-making authority of one or both Parties, as expressly provided in this Agreement, are outside the jurisdiction and authority of the Joint Committees, including [****].

7.4.5 Alliance Managers. Each Party shall appoint a person(s) who shall oversee contact between the Parties for all matters between meetings of the Joint Committees and shall have such other responsibilities as the Parties may agree in writing after the Effective Date, which person(s) may be replaced at any time by notice in writing to the other Party (each an "**Alliance Manager**"). The Alliance Managers shall work together to manage and facilitate the communication between the Parties under this Agreement, including the resolution (in accordance with the terms of this Agreement) of issues between the Parties that arise in connection with this Agreement. The Alliance Managers shall not have final decision-making authority with respect to any matter under this Agreement.

7.4.6 Discontinuation; Disbandment; Annual Reports. Subject to the remainder of this Section 7.4.6 or as otherwise expressly set forth in this Agreement, each Joint Committee shall continue to exist until the Parties mutually agree to disband the applicable Joint Committee. Upon such mutual agreement (a) the applicable Joint Committee shall disband, have no further responsibilities or authority under this Agreement and will be considered dissolved by the Parties, (b) any requirement of a Party to provide Information or other materials to such Joint Committee shall be deemed a requirement to provide such Information or other materials to the other Party and, (c) with respect to any matter that is subject to the review or approval by such Joint Committee hereunder, after consultation with the other Party and taking the other Party's comments, if any, into consideration in good faith, the Party with decision-making authority with respect to such matter as set forth in Section 7.4.3 shall have the right to decide such matter.

ARTICLE 8
PAYMENTS AND RECORDS

8.1 Upfront Payment. Within [****] following the Effective Date, PARTNER shall pay REGENX a nonrefundable and non-creditable upfront amount equal to Three Hundred Seventy Million Dollars ($370,000,000).

8.2 Milestones.

8.2.1 Development and Regulatory Milestones. In partial consideration of the obligations imposed on REGENX and rights granted to PARTNER hereunder and under the Penn Sublicense Agreement, PARTNER shall pay to REGENX the following one-time payments within [****] after the achievement of each of the following milestone events by or on behalf of the Parties, any of their Affiliates or any Sublicensee in activities under this Agreement during the Term with respect to the applicable Licensed Product for use in the Licensed

Field, which shall be nonrefundable, non-creditable and fully earned upon the achievement of the applicable milestone event:

Milestone Event (nAMD)	Milestone Payment
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]

Milestone Event (DR)	Milestone Payment
[****]	[****]
[****]	[****]
[****]	[****]

[****]	[****]

Milestone Event (Additional Indication)	Milestone Payment
[****]	[****]
[****]	[****]
[****]	[****]
[****]	[****]

Each of the milestone payments set forth in the tables above will be payable one (1) time only (regardless of the number of Licensed Products or Indications with respect to which, or the number of times with respect to any Licensed Product or Indication, the specified milestone event occurs).

8.2.2 Commercial Milestones. In partial consideration of the obligations imposed on REGENX and rights granted to PARTNER hereunder and under the Penn Sublicense Agreement, PARTNER shall pay to REGENX the following one-time payments after the achievement of the following milestone events by or on behalf of PARTNER, any of its Affiliates or any Sublicensees in activities under this Agreement during the Term, which shall be nonrefundable, non-creditable and fully earned upon such achievement of the applicable milestone event:

Milestone Event	Milestone Payment
(a) [****] Net Sales of any and all Licensed Products for use in the Licensed Field in the Royalty Territory exceed [****].	[****]

Milestone Event	Milestone Payment
(b) [****] Net Sales of any and all Licensed Products for use in the Licensed Field in the Royalty Territory exceed [****].	[****]
(c) [****] Net Sales of any and all Licensed Products for use in the Licensed Field in the Royalty Territory exceed [****].	[****]

In the event that more than one (1) of the foregoing thresholds set forth in clauses (a) through (c) of this Section 8.2.2 is exceeded [****], PARTNER shall pay to REGENX a separate milestone payment with respect to each such threshold that is exceeded. Each such milestone payment shall be due within [****] of the end of the [****] in which such milestone was achieved. For clarity, no amounts will be due for subsequent or repeated achievements of a milestone event in the table above in this Section 8.2.2 for any Licensed Product or Products once such milestone event has already been achieved by any Licensed Product or Products.

8.2.3 Determination that Milestones Have Occurred. PARTNER shall notify REGENX promptly of the achievement of each of the events identified as a milestone in Section 8.2.1 or Section 8.2.2. In the event that, notwithstanding the fact that PARTNER has not provided REGENX such a notice, REGENX believes that any such milestone has been achieved, it shall so notify PARTNER in writing, and the Parties will work in good faith to resolve such dispute in accordance with Section 14.5.

8.3 Royalties.

8.3.1 Royalty Rates. Subject to Section 8.3.3, as further consideration of the obligations imposed on REGENX and rights granted to PARTNER hereunder and under the Penn Sublicense Agreement, commencing upon the First Commercial Sale of a Licensed Product for use in the Licensed Field in any country in the Royalty Territory, PARTNER shall pay to REGENX a royalty on Net Sales of each Licensed Product for use in the Licensed Field in the Royalty Territory during [****] in the Royalty Term for each such Licensed Product in the applicable country in the Royalty Territory, at the following rates:

Aggregate Net Sales of Licensed Products in a [****]	Royalty Rate
For that portion of [****] Net Sales in the Royalty Territory in a [****] equal to or less than [****]	[****]
For that portion of [****] Net Sales in the Royalty Territory in a[****] greater than [****] but equal to or less than [****]	[****]

Aggregate Net Sales of Licensed Products in a [****]	Royalty Rate
For that portion of [****] Net Sales in the Royalty Territory in a[****] greater than [****] but equal to or less than [****]	[****]
For that portion of [****] Net Sales in the Royalty Territory in a [****] greater than [****]	[****]

8.3.2 Royalty Term. PARTNER shall have no obligation to pay any royalty with respect to Net Sales of a Licensed Product for use in the Licensed Field in any country in the Royalty Territory after the Royalty Term for such Licensed Product for use in the Licensed Field in such country has expired. Upon termination of the Royalty Term with respect to a Licensed Product for use in the Licensed Field for a given country in the Royalty Territory, the license grants to PARTNER in Section 9.1 of this Agreement and in Section 2.2 (Sublicense Grant to PARTNER) of the Penn Sublicense Agreement with respect to such Licensed Product in such country shall become fully paid-up, perpetual and irrevocable in such country.

8.3.3 Reductions. Subject to Section 8.3.4, on a [****] and country-by-country basis, during the Royalty Term for a Licensed Product for use in the Licensed Field in a given country in the Royalty Territory, in the event that:

(a) there is no Valid Claim within the Royalty-Bearing Patents that Covers such Licensed Product in a given country in the Royalty Territory during a given [****], then the royalty rates set forth in Section 8.3.1 with respect to such Licensed Product in such country in the Royalty Territory during such [****] shall be reduced by [****];

(b) there is (i) a sale of one or more Biosimilar Products with respect to a Licensed Product in a given country in the Royalty Territory and (ii) (x) a decrease in revenue of [****] then the royalty rates set forth in Section 8.3.1 with respect to such Licensed Product in such country in the Royalty Territory shall be reduced by [****] for the remainder of the Royalty Term for such Licensed Product in such country; and

(c) PARTNER obtains a license or otherwise acquires rights from any Third Party to any Patent or Information that is [****] to Exploit such Licensed Product in a country in the Royalty Territory [****], PARTNER shall be entitled to deduct from [****] payable hereunder in a given [****] with respect to such Licensed Product in such country [****] of the payments (including any upfront payments, milestone payments and royalties) paid to such Third Party during such [****], solely to the extent that such payments are directly attributable or otherwise reasonably allocable to the Exploitation of such Licensed Product in such country ("**Third Party Payments**").

8.3.4 Maximum Amount of Royalty Reduction. In no event shall the amounts payable to REGENX under Section 8.3.1 for a Licensed Product be reduced by more than [****] of what would otherwise be due by operation of Section 8.3.1 for a Licensed Product

without regard to Section 8.3.3. [****].

8.3.5 Royalty Payments and Reports. PARTNER (a) shall provide REGENX, no later than [****] after the end of each [****], with a preliminary, good faith estimate of all amounts payable to REGENX pursuant to Section 8.3.1 at the end of such [****] and (b) shall calculate all amounts payable to REGENX pursuant to Section 8.3.1 at the end of each [****], which amounts shall be converted to Dollars, in accordance with Section 8.6. PARTNER shall provide REGENX, no later than [****] after the end of each [****], with a statement specifying, on a country-by-country basis, [****], in each case attributable to a Licensed Product for use in each Indication of the Licensed Field in each country in the Royalty Territory during the applicable [****] (including such amounts expressed in local currency and as converted to Dollars) and a calculation of the amount of royalty payment due on such Net Sales for such [****]. PARTNER shall pay to REGENX the royalty amounts due with respect to a given [****] within [****] after the end of such [****]. Without limitation of the generality of the foregoing, PARTNER shall require its Affiliates and Sublicensees to account for their Net Sales and to provide such reports with respect thereto, as if such sales were made by PARTNER.

8.4 United States Profit and Loss Share. Each Party will receive its respective portion of the United States Profit and Loss Share set forth in Schedule 8.4 determined on a [****] basis and without regard to whether there is a net profit or net loss with respect to any Licensed Product for use in the Licensed Field in the United States for such [****].

8.5 Calculation and Payment of US Net Sales, Allowable US Expenses and Allowable Development Expenses Share.

8.5.1 Reports. Each Party shall prepare and deliver to the other Party the applicable periodic reports specified below:

(a) no later than [****] after the end of each [****] during which a Party performs any activities with respect to which Allowable Development Expenses or Allowable US Expenses are incurred by such Party, or during which a Party Manufactures or has Manufactured Commercial Supply, each Party shall provide to the other Party a preliminary non-binding written report summarizing the material Development or Commercialization activities undertaken by such Party under this Agreement during such [****], together with a preliminary, non-binding good faith estimate of (i) Allowable US Expenses and Reimbursable Development Expenses incurred by such Party during such [****] and (ii) US Net Sales;

(b) within [****] after the end of each [****] during which a Party performs any activities with respect to which Reimbursable Development Expenses or Allowable US Expenses are incurred by such Party, each Party shall provide to the other Party a written report summarizing the material Development or Commercialization activities undertaken by such Party under this Agreement during such [****], together with a statement of Allowable US Expenses and Reimbursable Development Expenses incurred by such Party during such [****];

(c) within [****] after the end of each [****] commencing with the [****] in which the First Commercial Sale of any Licensed Product for use in the Licensed Field occurs in the United States, PARTNER shall provide to REGENX a written report setting

forth [****];

(d) within [****] after the end of each [****], PARTNER shall provide to REGENX a written report setting forth [****]. In the event that, based on PARTNER's audited financials for such [****], any adjustments or reconciliations with respect for amounts reported in prior [****] are recognized in such [****], PARTNER shall notify REGENX without undue delay and any reconciliation payments shall be addressed in the [****] in which they are identified;

(e) within [****] after the end of each [****] for which a report is provided pursuant to Section 8.5.1(a) or Section 8.5.1(c), (i) the Parties shall prepare a written report combining the information reported by each Party pursuant to this Section 8.5.1 and showing the calculation of any payments to be made by the Parties for such [****] (including showing the sharing of (x) total Reimbursable Development Expenses, (y) total Allowable US Expenses of the Parties and (z) US Net Sales) and, if applicable, providing for the netting of such payments and (ii) the Party to whom payment is owed under such report in accordance with Section 8.5.2 shall provide an invoice to the other Party consistent with such agreed upon report.

8.5.2 Payments. Within [****] following issuance of the invoice delivered by the owed Party pursuant to Section 8.5.1(e), the Parties shall make such payments to one another in accordance with Section 8.6 as may be necessary to achieve the sharing of Reimbursable Development Expenses in accordance with Section 3.3 and the sharing of US Net Sales and Allowable US Expenses with respect to Licensed Products for use in the Licensed Field in the United States provided for in Section 8.4. In the event that, based on a Party's [****], any adjustments or reconciliations with respect to amounts reported in prior [****] are recognized in such [****], the relevant Party shall notify the other Party without undue delay and then the Parties shall make reconciling payments to one another no later than [****] after the end of the [****] in which such adjustments or reconciliations were recognized, if and as necessary to ensure that each Party receives for such [****] its share of US Net Sales and bears its share of Allowable US Expenses in accordance with Section 8.4 and bears its share of Reimbursable Development Expenses in accordance with Section 3.3.

8.5.3 General Principles. In no event shall the same costs and expenses be included more than once in calculating the reconciliation of Net Sales, Allowable US Expenses and Reimbursable Development Expenses, collectively, with respect to any [****], even if such costs and expenses could be applied to either reconciliation of Allowable US Expenses, Net Sales or Reimbursable Development Expenses.

8.5.4 FTE Records and Calculations. Each Party shall record and account for FTE efforts that are included in Reimbursable Development Expenses and Allowable US Expenses in accordance with this Agreement and in the same manner as used for other products developed by such Party. Each Party shall report such FTE effort to the JDC, JCC or JMC, as applicable, if requested (such request not to be more than on a [****] basis).

8.6 Mode of Payment; Offsets. All payments to either Party under this Agreement shall be made by deposit of Dollars in the requisite amount to such bank account as the receiving Party may from time to time designate by notice to the paying Party. For the purpose

of calculating any sums due under, or otherwise reimbursable pursuant to, this Agreement (including the calculation of Net Sales expressed in currencies other than Dollars), a Party shall convert any amount expressed in a foreign currency into Dollar equivalents using its, its Affiliate's or Sublicensee's standard conversion methodology consistent with Accounting Standards. Each Party shall have the right to offset any payment that is owed by the other Party but not paid against any payments owed by the first Party pursuant to Section 8.5.2, if any, under this Agreement.

8.7 Reimbursement. For all costs for which a Party (the "**Owing Party**") is obligated to reimburse the other Party (the "**Owed Party**") pursuant to this Agreement for which no specific provision is made hereunder for such payment, the Owed Party shall send to the Owing Party an invoice for such amount within [****] of the last day of a [****] during which Owed Party determines that such amount is payable by the Owing Party, which invoice shall include a reference to the section of this Agreement under which the Owed Party is requesting reimbursement or payment and be accompanied by reasonable documentation of the incurrence or accrual of the costs to be reimbursed. Payment with respect to each such invoice shall be due within [****] after receipt by the Owing Party thereof and shall be made in accordance with Section 8.6; *provided, however*, that if the Owing Party in good faith disputes any portion of any such invoice, it shall pay the undisputed portion and shall provide the Owed Party with written notice of the disputed portion and its reasons therefor, and the Owing Party shall not be obligated to pay such disputed portion unless and until such dispute is resolved in favor of the Owed Party. The Parties shall use good faith efforts to resolve any such disputes promptly.

8.8 Finance Working Group. With respect to the financial reporting activities between the Parties, the JDC will establish a finance working group (the "**Finance Working Group**") to provide support for review and discussion by the JDC of Budgets pursuant to Section 7.1.2 and by the JMC pursuant to Section 7.3.3 and coordinate the activities and reporting by the Parties as set forth in Section 8.5 through Section 8.7 and to assist the JCC in its responsibilities with respect to the review and resolution of financial matters. In particular, the Finance Working Group will:

8.8.1 facilitate the creation of each Budget pursuant to the Development Plan and the Commercialization Plans;

8.8.2 reconcile financial and accounting matters between the Parties;

8.8.3 initiate and execute an effective and efficient revenue and cost-sharing process (cross-charges);

8.8.4 review and recommend for the Parties' consideration modifications to the FTE Rate and tracking of FTE Costs;

8.8.5 cooperate to ensure that all Budgets for a [****] (or any other given period) can be interpreted for the purposes of both Parties' internal financial and audit reporting requirements, including each Party's fiscal year reporting;

8.8.6 implement a series of reporting requirements for actual and forecasted financial information, available at times to be agreed by the Parties through the Finance Working Group;

8.8.7 monitor the Budget, expense and revenue reporting requirements between the Parties related to Licensed Products to ensure that each Party is able to comply with its respective internal financial and audit reporting requirements and, as appropriate, recommending to the JCC, JDC or JMC, as applicable, for approval, changes to the reporting requirements under this Agreement; and

8.8.8 undertake such other tasks as may be necessary or desirable with respect to the calculation, implementation and reporting for United States Profit and Loss Share.

8.9 Taxes.

8.9.1 General. Any amounts due to be paid to a Party (the "**Recipient**") hereunder (each, a "**Payment**") shall be paid free and clear of any and all taxes (which, for clarity, shall be the responsibility of the paying Party (the "**Payor**")), except for any withholding taxes required by Applicable Law. Except as provided in this Section 8.9, Recipient shall be solely responsible for paying any and all taxes (other than withholding taxes required by Applicable Law to be deducted from Payments and remitted by Payor) levied on account of, or measured in whole or in part by reference to, any Payments it receives. Payor shall deduct or withhold from the Payments any taxes that it is required by Applicable Law to deduct or withhold. Notwithstanding the foregoing, if Recipient is entitled under any applicable tax treaty to a reduction of rate of, or the elimination of, applicable withholding tax, it may deliver to Payor or the appropriate Governmental Authority (with the assistance of Payor to the extent that this is reasonably required and is requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve Payor of its obligation to withhold such tax and Payor shall apply the reduced rate of withholding or dispense with withholding, as the case may be; *provided* that Payor has received evidence of Recipient's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least [****] prior to the time that the Payments are due. If, in accordance with the foregoing, Payor withholds any amount, it shall pay to Recipient the balance when due, make timely payment to the proper taxing authority of the withheld amount and send to Recipient proof of such payment within [****] following such payment. In the event that a government authority retroactively determines that a payment made by Payor to Recipient pursuant to this Agreement should have been subject to withholding or similar (or to additional withholding or similar) taxes, and Payor remits such withholding or similar taxes to the government authority, including any interest and penalties that may be imposed thereon (together with the tax paid, the "**Amount**"), Payor will have the right (a) to offset the Amount against future payment obligations of Payor under this Agreement, (b) to invoice Recipient for the Amount (which shall be payable by Recipient within [****] of its receipt of such invoice) or (c) to pursue reimbursement of the Amount by any other available remedy.

8.9.2 Gross Up. If either Party assigns this Agreement to an Affiliate or Third Party (the "**Assigning Party**"), sublicenses any rights granted to it hereunder or undergoes a Change of Control and, as a result of such assignment, sublicense or Change of Control, Payments made hereunder are subject to additional withholding tax, the Assigning Party shall be responsible for the resulting additional withholding taxes; *provided, however*, that if the non-Assigning Party derives a tax benefit (including through the use of foreign tax credit) determined on a with and without basis as a result of such additional withholding, then such non-Assigning Party shall promptly reimburse Assigning Party for the amount of such benefit; *provided, further*,

that the non-Assigning Party shall take all commercially reasonable actions necessary to obtain any tax benefit (including through the use of foreign tax credit) with respect to such additional withholding taxes and to defend such benefit in a tax audit; *provided, further*, that the amount of additional withholding tax shall be determined by taking into account the reduction in the rate of, or the elimination of, the withholding tax pursuant to a tax treaty to which the non-Assigning Party would be entitled had it claimed such benefit under the tax treaty. For purposes hereof, "tax benefit" shall mean any refund or credit of taxes to be paid or reduction in the amount of taxes which otherwise would be owed by the non-Assigning Party, as applicable, in each case computed at the highest marginal tax rates applicable to non-Assigning Party.

8.9.3 Value Added Tax. Notwithstanding anything contained in Section 8.9.1 or Section 8.9.2, this Section 8.9.3 shall apply with respect to value added tax ("**VAT**"). All Payments are exclusive of VAT. If any VAT is chargeable in respect of any Payments, Payor shall pay VAT at the applicable rate in respect of any such Payments following the receipt of a VAT invoice in the appropriate form issued by Recipient in respect of those Payments, such VAT to be payable on the later of the due date of the payment of the Payments to which such VAT relates and [****] after the receipt by Payor of the applicable invoice relating to that VAT payment, but Payor shall not reduce any Payment for the payment of VAT. If the VAT originally paid or otherwise borne by Payor are in whole or in part subsequently determined not to have been chargeable, all necessary steps will be taken by Recipient to receive a refund of the undue VAT from the applicable Governmental Authority or other fiscal authority and any amount of undue VAT repaid by such authority to Recipient will be transferred to Payor within [****] of receipt.

8.10 Interest on Late Payments. If any payment due to either Party under this Agreement is not paid when due, then such paying Party shall pay interest thereon (before and after any judgment) at an annual rate (but with interest accruing on a daily basis) of [****] (or the maximum allowed by Applicable Law, if less), such interest to run from the date on which payment of such sum became due until payment thereof in full together with such interest.

8.11 Financial Records. Without limitation of Section 8.5.1, each Party shall, and shall cause its Affiliates and require its and their Sublicensees to, keep complete and accurate financial books and records pertaining to the Development, Process Development, Manufacture and Commercialization of a Licensed Product hereunder, including books and records of [****], in sufficient detail to calculate and verify all amounts payable hereunder. Such books and records shall be retained by such Party and its Affiliates (and with respect to PARTNER, its Sublicensees) until the later of (a) [****] after the end of the period to which such books and records pertain, (b) [****] after the submission of any financial report to which such books and record pertain required to be made to the other Party under this Agreement or to a Third Party Licensor under an applicable Third Party License Agreement, (c) the expiration of the applicable tax statute of limitations (or any extensions thereof) and (d) for such period as may be required by Applicable Law.

8.12 Audit. At the request of the other Party, the GSK Licensor or the Penn Licensor, each Party shall, and shall cause its Affiliates to (and in the case of PARTNER, shall require its Sublicensees to), permit an independent public accounting firm of nationally recognized standing designated by the other Party and reasonably acceptable to the audited Party, [****], to audit the books and records maintained pursuant to Section 8.11 to ensure the accuracy of all

reports and payments made hereunder. Such examinations may not (a) be conducted for any [****], (b) be conducted more than once in any [****] period (unless a previous audit during such [****] period revealed an underpayment with respect to such period) or (c) be repeated for any [****]. The accounting firm shall disclose to the auditing Party only whether the reports are correct or not, and the specific details concerning any discrepancies. No other information shall be shared. Except as provided below, the cost of this audit shall be borne by the auditing Party, unless the audit reveals a variance of more than [****] from the reported amounts or [****], in which case the audited Party shall bear the cost of the audit. Unless disputed pursuant to Section 8.13 below, if such audit concludes that (x) additional amounts were owed by the audited Party, the audited Party shall pay the additional amounts, with interest from the date originally due as provided in Section 8.10, or (y) excess payments were made by the audited Party, the auditing Party shall reimburse such excess payments, in either case ((x) or (y)), within [****] after the date on which such audit is completed by the auditing Party.

8.13 Audit Dispute. In the event of a dispute with respect to any audit under Section 8.12, REGENX and PARTNER shall work in good faith to resolve the disagreement. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within [****], the dispute shall be submitted for resolution to a certified public accounting firm jointly selected by each Party's certified public accountants or to such other Person as the Parties shall mutually agree (the "**Auditor**"). The decision of the Auditor shall be final and the costs of such arbitration as well as the initial audit shall be borne between the Parties in such manner as the Auditor shall determine. Not later than [****] after such decision and in accordance with such decision, the audited Party shall pay the additional amounts, with interest from the date originally due as provided in Section 8.10, or the auditing Party shall reimburse the excess payments, as applicable.

ARTICLE 9
LICENSES; INTELLECTUAL PROPERTY

9.1 License Grant to PARTNER. Subject to the terms and conditions of this Agreement, including Section 9.2, REGENX hereby grants to PARTNER an exclusive, sublicensable, with the right to sublicense through multiple tiers (pursuant to Section 9.4), non-transferable (except as provided in Section 14.3), royalty-bearing, worldwide license or sublicense (as applicable) under REGENX Technology and Joint Technology to Exploit Licensed Compounds and Licensed Products solely for use in the Licensed Field in the Territory.

9.2 [****]. Except for the rights and licenses specified in Section 9.1, no license or other rights are granted to PARTNER under this Agreement under any REGENX Technology or other intellectual property of REGENX, excluding the Penn Patents, whether by implication, estoppel, or otherwise and whether such intellectual property is subordinate, dominant, or otherwise useful for the practice of the REGENX Technology as licensed under Section 9.1. Notwithstanding anything to the contrary in this Agreement, but subject to ARTICLE 6, REGENX may use and permit others to use, and PARTNER shall not be granted the right under this Agreement to use or to grant others the right to use, the REGENX Technology for any research, Development, Commercialization, Manufacturing or other purposes, or otherwise practice the REGENX Technology, outside of the Licensed Field. [****]

9.3 Government Rights. PARTNER acknowledges that the United States government retains certain rights in certain GSK Patents funded in whole or part under any contract, grant, or similar agreement with a federal agency. Any rights granted in this Agreement, including the license grants hereunder, are expressly subject to all applicable United States government rights, including any applicable requirement that products resulting from such intellectual property sold in the United States must be substantially manufactured in the United States.

9.4 Sublicensing

9.4.1 The license granted pursuant to Section 9.1 is sublicensable by PARTNER to any of its Affiliates or Third Parties; *provided* that any such sublicense must comply with the provisions of this Section 9.4 (including Section 9.4.2).

9.4.2 The right to sublicense granted to PARTNER under this Agreement is subject to the following conditions:

(a) PARTNER may only grant sublicenses pursuant to a written sublicense agreement with the Sublicensee. Any further sublicenses granted by any Sublicensees (to the extent permitted hereunder) must comply with the provisions of this Section 9.4 (including this Section 9.4.2) to the same extent as if PARTNER granted such sublicense directly.

(b) In each sublicense agreement, the Sublicensee must be required to comply with the applicable provisions of this Agreement, to the same extent as PARTNER has agreed.

(c) The official language of any sublicense agreement shall be English.

(d) Within [****] after entering into a sublicense or an amendment thereof, [****].

(e) PARTNER's execution of a sublicense agreement will not relieve PARTNER of any of its obligations under this Agreement except to the extent such Sublicensee satisfies such obligations on behalf of PARTNER. Notwithstanding the exception in the foregoing sentence, PARTNER is and shall remain [****] to REGENX for all of PARTNER's duties and obligations contained in this Agreement and for any act or omission of an Affiliate or Sublicensee that would be a breach of this Agreement if performed or omitted by PARTNER, and, PARTNER will be deemed to be in breach of this Agreement, as applicable, as a result of such act or omission.

9.5 License Grant to REGENX

9.5.1 Subject to the terms and conditions of this Agreement, PARTNER hereby grants to REGENX and its Affiliates a non-exclusive, sublicensable, royalty-free, worldwide license or sublicense (as applicable) under the PARTNER Patents and the PARTNER Know-How solely for purposes of performing REGENX's obligations under this Agreement.

9.5.2 PARTNER hereby grants to REGENX a non-exclusive, worldwide, royalty-free, transferable, sublicensable (solely to the extent necessary to satisfy its obligations under the GSK Agreement), irrevocable, perpetual license to use any [****]; *provided* that REGENX shall solely be permitted to exercise this license to the extent necessary to satisfy its obligations under the GSK Agreement.

9.6 Section 365(n) of the Bankruptcy Code

9.6.1 Applicability of 11 U.S.C. § 365(n). All intellectual property granted or licensed under or pursuant to this Agreement, including all rights and licenses to use improvements or enhancements developed during the Term, are intended to be, and shall otherwise be deemed to be, for purposes of the Bankruptcy Code or any analogous provisions in any other country or jurisdiction, licenses of rights to "intellectual property" as defined under Section 101(35A) of the Bankruptcy Code. The Parties agree that the licensee of such intellectual property under this Agreement shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code, including Section 365(n) of the Bankruptcy Code, or any analogous provisions in any other country or jurisdiction. All of the rights granted to either Party under this Agreement shall be deemed to exist immediately before the occurrence of any bankruptcy case in which the other Party is the debtor.

9.6.2 Rights of non-Debtor Party in Bankruptcy. If a bankruptcy proceeding is commenced by or against either Party under the Bankruptcy Code or any analogous provisions in any other country or jurisdiction, the non-debtor Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) any intellectual property and all embodiments of such intellectual property, which, if not already in the non-debtor Party's possession, shall be delivered to the non-debtor Party within [****] of such request; *provided* that the debtor Party is excused from its obligation to deliver the intellectual property to the extent the debtor Party continues to perform all of its obligations under this Agreement and the Agreement has not been rejected pursuant to the Bankruptcy Code or any analogous provision in any other country or jurisdiction.

9.7 Obligations Under Third Party Agreements. PARTNER acknowledges that certain REGENX Technology is or will be licensed to REGENX pursuant to the applicable Third Party License Agreements (the "**Sublicensed IP**") and will be sublicensed to PARTNER hereunder. [****]. Notwithstanding any provision in this Agreement to the contrary, REGENX shall be solely responsible for all payments that may be due and payable by REGENX to any Third Party, including the REGENX Licensors, under any Third Party Agreements.

9.8 Ownership and Disclosure of Intellectual Property

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9.8.1 Ownership of Technology. As between the Parties, (a) REGENX shall solely own and retain all right, title and interest in and to any and all REGENX Collaboration Know-How and REGENX Collaboration Patents, (b) subject to Section 9.8.3, PARTNER shall solely own and retain all right, title and interest in and to any and all PARTNER Collaboration Know-How and PARTNER Collaboration Patents, and (c) each Party shall solely own and retain all other Information, inventions, Patents and other intellectual property rights that are owned or otherwise Controlled (other than pursuant to the license grants in this Agreement) by such Party or its Affiliates or its or their respective (sub)licensees or Sublicensees, as applicable,

outside of this Agreement.

9.8.2 Ownership of Joint Patents and Joint Know-How. Subject to Section 9.8.3, as between the Parties, each of REGENX and PARTNER shall own an equal, undivided interest in and to any and all Joint Know-How and Joint Patents. In the event that any issues, objections or rejections arise concerning obviousness-type double patenting in the United States involving the Joint Patents, the Parties shall reasonably cooperate with each other to resolve or take any action necessary to overcome any such issues, objections or rejections.

9.8.3 Ownership of REGENX NAV Platform Patents and REGENX NAV Platform Know-How. As between the Parties, REGENX shall solely own and retain all right, title and interest in and to any and all REGENX NAV Platform Patents and REGENX NAV Platform Know-How.

9.8.4 United States Law. The determination of inventorship and whether Information and other inventions are conceived, created, discovered, developed or otherwise made by or on behalf of a Party or its Affiliates and its and their respective (sub)licensees and Sublicensees, as applicable, for the purpose of allocating proprietary rights (including Patent, copyright or other intellectual property rights) therein, shall, for purposes of this Agreement, be made in accordance with the United States patent law and other Applicable Law in the United States irrespective of where such conception, creation, discovery, development or making occurs. In case of a dispute between the Parties with respect to inventorship that cannot be resolved within [****], the Parties shall, within [****] after the expiration of such [****] period, jointly select a patent attorney registered before the United States Patent and Trademark Office to resolve such matter. Within [****] after selection of such patent attorney, the Parties will submit such dispute to such patent attorney for resolution of the inventorship thereof under United States patent law and cooperate to facilitate his or her determination thereof. Notwithstanding the foregoing, the Parties shall during the pendency of such claim proceed to file such Patents, with PARTNER having the right on an interim basis to make such filing until the patent attorney's decision is rendered. The decision of such patent attorney with respect to inventorship will be treated as final with respect to the Parties, and his or her decision shall be used for determining the Parties' respective rights to file, prosecute, maintain and enforce Patents under this ARTICLE 9. The Parties will share equally the expenses of engaging such patent attorney. For clarity, the decision of such patent attorney will not be binding with respect to Third Party challenges in court to the inventorship of a given Patent or with respect to the Parties' response to court challenges to the inventorship of such Patent.

9.8.5 Assignment.

(a) Each Party shall, and does hereby, assign, and shall cause its Affiliates and its and their respective (sub)licensees and Sublicensees, as applicable, to so assign, to the other Party, without additional compensation, such right, title and interest in and to any Information and other inventions as well as any intellectual property rights with respect thereto, as is necessary to fully effect, as applicable, (i) the sole ownership provided for in Section 9.8.3, (ii) the joint ownership provided for in Section 9.8.2, and (iii) any such ownership provided for in Section 9.8.1 if and as applicable; *provided* that clause (iii) shall not apply to (sub)licensees or Sublicensees except for subcontractors as set forth in Section 9.8.5(b).

(b) Each Party shall cause all Persons who perform any activities under this Agreement, including any and all Development activities (including regulatory activities), Manufacturing activities, and Commercialization activities, for, or on behalf of, such Party under this Agreement, or who conceive, create, discover, develop or otherwise make any Information or other inventions by or on behalf of either Party or its Affiliates and its and their respective (sub)licensees and Sublicensees, as applicable, under this Agreement to assign (or if such Party is unable to cause such Person to assign despite such Party using commercially reasonable efforts to negotiate such assignment, then be under an obligation to assign, or, if such Party is unable to cause such Person to agree to such assignment obligation despite such Party using commercially reasonable efforts to negotiate such assignment obligation, then to grant an exclusive license with the right to sublicense through multiple tiers) their rights in any Collaboration Know-How developed or invented by such Person to such Party, except where Applicable Law requires otherwise and except in the case of governmental, not-for-profit and public institutions that have standard policies against such an assignment (in which case, a suitable license or right to obtain such a license shall be obtained).

9.8.6 Disclosure.

(a) PARTNER shall provide prompt notice to REGENX, and shall cause its Affiliates and its and their respective (sub)licensees and Sublicensees, as applicable, to so notify, [****].

(b) PARTNER shall promptly disclose to REGENX in writing, and shall cause its Affiliates and its and their respective (sub)licensees and Sublicensees, as applicable, to so disclose, [****].

(c) Each Party shall promptly disclose to the other Party in writing and shall cause its Affiliates and its and their respective (sub)licensees or Sublicensees, as applicable, to so disclose, the creation, discovery, development, conception, reduction to practice, or otherwise making (each as applicable) of any Collaboration Know-How or Collaboration Patents.

9.8.7 Ownership of Product Trademarks. Subject to Section 13.4.2, as between the Parties, PARTNER shall own all right, title and interest to the Product Trademarks in the Territory.

9.8.8 Ownership of Corporate Names. As between the Parties, (a) REGENX shall retain all right, title and interest in and to its Corporate Names and (b) PARTNER shall retain all right, title and interest in and to its Corporate Names.

9.8.9 REGENX-Penn Jointly Owned Patents. Notwithstanding anything to the contrary in this Agreement, ARTICLE 5 of the Penn Sublicense Agreement, and not Sections 9.9 through 9.12 of this Agreement, shall govern prosecution, infringement, invalidity or unenforceability defenses or actions of any REGENX Patent that is co-owned by REGENX or its Affiliates, on one hand, and Penn, on the other hand.

9.9 Prosecution

9.9.1 .

9.9.1 REGENX Prosecution Rights. As between the Parties, and subject to Section 9.9.3, REGENX shall have the first right, but not the obligation, to Prosecute the REGENX NAV Platform Patents and the GSK Patents. REGENX shall (a) provide PARTNER with a reasonable opportunity to review and provide comments in connection with such Prosecution, (b) keep PARTNER reasonably informed as to all material developments with respect to such Prosecution, and (c) consider in good faith PARTNER's comments with respect to such Prosecution. Notwithstanding the foregoing, if REGENX determines in its sole discretion to abandon or not maintain in any country or jurisdiction of the Territory any Patent subject to Prosecution under this Section 9.9.1, to the extent available and allowable under the applicable Third Party License Agreements, REGENX will provide PARTNER with timely prior written notice of such determination and PARTNER, upon written notice to REGENX, will thereafter have the right, but not the obligation, at its sole discretion [****], to Prosecute such Patent, and PARTNER will thereafter be the "Prosecuting Party" with respect to such Patent for all purposes under this Agreement.

9.9.2 PARTNER Prosecution Rights. As between the Parties, and subject to Section 9.9.3, PARTNER shall have (i) the sole right, but not the obligation, to Prosecute the PARTNER Patents including the PARTNER Collaboration Patents, and (ii) the first right, but not the obligation to Prosecute the REGENX Patents (excluding REGENX NAV Platform Patents and GSK Patents) and Joint Patents. PARTNER shall (a) provide REGENX with a reasonable opportunity to review and provide comments in connection with the Prosecution of such Patents, and (b) keep REGENX reasonably informed as to all material developments with respect to such Patents and, (c) consider in good faith REGENX's comments with respect to such Prosecution. Notwithstanding the foregoing, if PARTNER determines in its sole discretion to abandon or not maintain in any country or jurisdiction of the Territory any such REGENX Patent or Joint Patent, PARTNER will provide REGENX with timely prior written notice of such determination and REGENX, upon written notice to PARTNER, will thereafter have the right, but not the obligation, at its sole discretion [****], to Prosecute such Patent, and REGENX will thereafter be the "Prosecuting Party" with respect to such Patent for all purposes under this Agreement.

9.9.3 Third Party Control of Prosecution. Notwithstanding anything to the contrary herein, the rights and obligations under this Section 9.9 are subject to the rights of the REGENX Licensors other than Penn and the limitations imposed on REGENX, its Affiliates and its and their respective sublicensees that are set forth in the Third Party License Agreements other than the Penn Agreement; *provided* that if such Third Party License Agreements provide REGENX with an option or right to Prosecute a REGENX Patent under certain conditions, REGENX, if it determines in its sole discretion that exercise of such option or right would be reasonably necessary to effectively manage prosecution of such REGENX Patent, will use good faith efforts to exercise such option or obtain such right so as to allow PARTNER to Prosecute such REGENX Patent pursuant to Section 9.9.2.

9.9.4 Cooperation. [****]. The non-Prosecuting Party shall, and shall cause its Affiliates and its and their respective (sub)licensees or Sublicensees, as applicable, to, assist and cooperate with the Prosecuting Party, as the Prosecuting Party may reasonably request from time to time, in the Prosecution of Patents under this Section 9.9 in the Territory, including that the non-Prosecuting Party shall, and shall ensure that its Affiliates and its and their sublicensees or Sublicensees, as applicable, (a) offer comments, if any, promptly, (b) provide

access to relevant documents and other evidence and make its employees available at reasonable business hours, and (c) execute all such documents and instruments and perform such acts as may be reasonably necessary in order to permit the Prosecuting Party to conduct any such Prosecution; *provided*, *however*, that neither Party shall be required to provide legally privileged information unless and until procedures reasonably acceptable to such Party are in place to protect such privilege; [****].

9.9.5 Patent Listings. In connection with a Licensed Product, PARTNER shall have the sole right to determine and make all listings or filings with Regulatory Authorities or patent agencies in the Territory with respect to REGENX Patents, PARTNER Patents, and Joint Patents, including as required or allowed in the United States, in the FDA's Orange Book or Purple Book, or under other international equivalents. REGENX shall (a) provide to PARTNER all Information, including a correct and complete list of REGENX Patents covering the Licensed Product or otherwise necessary or reasonably useful to enable PARTNER to make such listing or filings with Regulatory Authorities or patent agencies in the Territory with respect to such Patents, and (b) cooperate with PARTNER in connection therewith, including using commercially reasonable efforts to make any submission deadlines, in each case ((a) and (b)), to the extent required or permitted by Applicable Law.

9.9.6 Patent Term Extension and Supplementary Protection Certificate. With respect to a Licensed Product, and subject to Section 9.9.3, PARTNER shall be responsible for making decisions regarding patent term extensions, including supplementary protection certificates, pediatric exclusivity, and any other extensions that are now or become available in the future, wherever applicable, for REGENX Patents, PARTNER Patents, and any Joint Patents, in any country or other jurisdiction. PARTNER shall have the sole responsibility of applying for, and REGENX shall have no right to apply for, any extension (including patent term extension, supplementary protection certificate, and pediatric exclusivity) with respect to any Patents in the Territory in connection with the Licensed Product. PARTNER shall keep REGENX fully informed of its efforts to obtain such extension. REGENX shall provide prompt and reasonable assistance as reasonably requested by PARTNER and as required under any Applicable Law to obtain any such extension. [****].

9.9.7 Joint Research Agreements. The Parties acknowledge and agree that this Agreement is, collectively, a "joint research agreement" as defined in 35 U.S.C. 100(h).

9.10 Infringement Actions Against Third Parties.

9.10.1 Notice. Each Party shall notify the other Party promptly of any alleged or threatened Infringement of any REGENX Patent, PARTNER Patent or Joint Patent in the Licensed Field in the Territory that may come to such Party's attention. However, neither Party is under any obligation to search for potential infringers.

9.10.2 PARTNER Sole Right. As between REGENX and PARTNER, PARTNER shall have the sole right, but not the obligation, to prosecute any Infringement with respect to any PARTNER Patent in the Licensed Field in the Territory, as well as any infringement of any PARTNER Patent with respect to a product that is biosimilar to or competes against a

Licensed Product in the Licensed Field in the Territory, and PARTNER shall retain control of the prosecution of such claim, suit or proceeding. In the event PARTNER prosecutes any such Infringement, REGENX shall have the right to join as a party to such claim, suit, or proceeding in the Territory and participate with its own counsel [****]; *provided* that PARTNER shall retain control of the prosecution of such claim, suit, or proceeding. Subject to Section 9.10.3(b), REGENX shall not assert any Patent in such claim, suit or proceeding, or against the same potential or actual infringer in connection with the same product in a different claim, suit, or proceeding, in each case without PARTNER's prior written consent.

9.10.3 PARTNER First Right.

(a) As between REGENX and PARTNER, but subject to Section 9.10.6, PARTNER shall have the first right, but not the obligation, to prosecute any Infringement in the Licensed Field in the Territory of any REGENX Patent that is not a GSK Patent, any Collaboration Patent that is not a REGENX NAV Platform Patent, and any Joint Patent. In the event PARTNER prosecutes any such Infringement, REGENX shall have the right to join as a party to such claim, suit or proceeding in the Licensed Field in the Territory and participate with its own counsel [****].

(b) If PARTNER either (i) declines to prosecute an Infringement of any of the Patents set forth in (a) above, (ii) fails to take action with respect to such Infringement within [****] following the first notice provided above with respect to such Infringement, or (iii) if [****] before the deadline, if any, set forth in Applicable Law, PARTNER fails to take action in connection with such Infringement, whichever of the events described in clauses (i)-(iii) come first, then REGENX has the right, but not the obligation, to prosecute such Infringement. In the event REGENX prosecutes such Infringement, PARTNER shall have the right to join as a party to such claim, suit or proceeding in the Territory and participate with its own counsel [****].

(c) [****].

(d) PARTNER shall have the first right to make decisions regarding the Opt Out or Opt-In under the Article 83(4) of the Agreement on a Unified Patent Court between the participating Member States of the European Union (2013/C 175/01), with respect to any of the Patents set forth in Section 9.10.3(a), and pay all fees and make all submissions associated with such decisions. REGENX shall assist PARTNER in such submissions [****], including providing all necessary documents and making all necessary submissions as a Patent owner where applicable. If REGENX controls the prosecution of an Infringement of any of the Patents set forth in Section 9.10.3(a) above, then REGENX shall have the right to make such decision [****].

(e) Notwithstanding anything to the contrary in this Section 9.10.3, as between the Parties, PARTNER has the first right, but not the obligation, to control the defense of a claim or counterclaim, arising from and related to the prosecution of an Infringement of any of the Patents set forth in Section 9.10.3(a), that challenges the scope, validity, title, or enforceability of any of the Patents set forth in Section 9.10.3(a) above. If PARTNER either (i) declines to defend such challenge of any of the Patents set forth in Section 9.10.3(a) above, (ii) fails to take action with respect to such challenge within [****] following the first notice

provided above with respect to such challenge, or (iii) if [****] before the deadline, if any, set forth in Applicable Law, PARTNER fails to take action in connection with such challenge, whichever of the events described in clauses (i)-(iii) come first, then REGENX has the right, but not the obligation, to defend such challenge [****]. In the event REGENX defends such challenge, PARTNER shall have the right to join as a party to such action, suit or proceeding in the Territory and participate with its own counsel [****].

9.10.4 REGENX Sole Right.

(a) As between REGENX and PARTNER, but subject to Section 9.10.6, REGENX shall have the sole right, but not the obligation, to prosecute any Infringement in the Licensed Field in the Territory of any REGENX Patent that is a GSK Patent, or any REGENX NAV Platform Patent. In the event REGENX prosecutes any such Infringement, PARTNER shall have the right to join as a party to such claim, suit or proceeding in the Licensed Field in the Territory and participate with its own counsel [****].

(b) [****].

(c) REGENX shall have the sole right to make decisions regarding the Opt Out or Opt-In under the Article 83(4) of the Agreement on a Unified Patent Court between the participating Member States of the European Union (2013/C 175/01), with respect to any of the Patents set forth in Section 9.10.4(a), and pay all fees and make all submissions associated with such decisions. PARTNER shall assist REGENX in such submissions [****], including providing all necessary documents and making all necessary submissions as a Patent owner where applicable.

(d) Notwithstanding anything to the contrary in this Section 9.10.4, as between the Parties, REGENX has the sole right, but not the obligation, to control the defense of a claim or counterclaim, arising from and related to the prosecution of an Infringement of any of the Patents set forth in Section 9.10.4(a), that challenges the scope, validity, title, or enforceability of any of the Patents set forth in Section 9.10.4(a) above.

9.10.5 Expenses and Recovery. [****].

9.10.6 Third Party Control of Enforcement. Notwithstanding anything to the contrary herein, the rights and obligations under this Section 9.10 are subject to [****].

9.10.7 Cooperation. For purposes of this Section 9.10, the Party prosecuting any infringement with respect to a Patent shall be the "**Enforcing Party**." The Parties will cooperate fully in any infringement action pursuant to this Section 9.10, including by making the inventors, applicable records and documents (including laboratory notebooks) with respect to the relevant Patents enforceable under this Section 9.10 and available to the Enforcing Party at the Enforcing Party's request. With respect to an action controlled by the applicable Enforcing Party, the other Party shall, and shall cause its Affiliates to, assist and cooperate with the Enforcing Party, as the Enforcing Party may reasonably request from time to time, in connection with its activities set forth in this Section 9.10, including where necessary, furnishing a power of attorney solely for such purpose or joining in, or being named as a necessary party to, such action, providing access

to relevant documents and other evidence and making its employees available at reasonable business hours; [****]. In connection with any activities with respect to an Infringement action prosecuted by the applicable Enforcing Party pursuant to this Section 9.10, the Enforcing Party shall (a) consult with the other Party as to the strategy for the prosecution of such claim, suit or proceeding, (b) consider in good faith any comments from the other Party with respect thereto and (c) keep the other Party reasonably informed of any material steps taken and provide copies of all material documents filed, in connection with such action.

9.10.8 Right to Settle. Unless otherwise set forth herein, the Enforcing Party shall have the right to settle such claim; *provided* that neither Party shall have the right to settle any Infringement litigation (including related defensive claims and counterclaims) under this Section 9.10 with respect to any Patent [****]. Furthermore, the Enforcing Party shall not settle or compromise any claim or Infringement litigation (including related defensive claims and counterclaims) under this Section 9.10 with respect to any Patent [****].

9.10.9 Biosimilar Competition. (i) Subject to this Section 9.10, including Sections 9.10.2, 9.10.3, 9.10.4 and 9.10.6, PARTNER shall have the right, but not the obligation, to prosecute, manage and settle any litigation with respect to Biosimilar Products in the Licensed Field and the Territory and any proceedings associated therewith, in connection with any Patents, including any invalidity, unpatentability or unenforceability challenges, oppositions and post-grant proceedings in connection therewith. If either Party receives a notice or a copy of an application submitted to the FDA or its foreign counterpart for a Biosimilar Product (a "**Biosimilar Application**") for which a Licensed Product is a "reference product" as such term is used in Section 351(i)(4) of the PHSA, or an equivalent under its foreign counterpart, whether or not such notice or copy is provided under any Applicable Laws, or otherwise becomes aware that such a Biosimilar Application has been submitted to a Regulatory Authority for Regulatory Approval, such Party shall, within [****], notify the other Party and provide the other Party with copies of such notice or communication to the extent permitted by Applicable Law. PARTNER shall carry out any such rights and responsibilities of the "reference product sponsor," as defined in Section 351(l)(1)(A) of the PHSA, for purposes of such Biosimilar Application, *provided* that PARTNER's rights to bring an action for patent Infringement under Section 351(l)(6) of the PHSA based on any REGENX Patents, Collaboration Patents or Joint Patents are subject to REGENX's applicable sole or first rights to bring an action for patent Infringement under Sections 9.10.3 and 9.10.4, and to the rights of the applicable REGENX Licensors and the limitations imposed on REGENX, its Affiliates and its and their respective sublicensees that are set forth in the applicable Third Party License Agreements. The Parties shall cooperate seeking to obtain access to the Biosimilar Application and related confidential information, including in accordance with Section 351(l)(1)(B)(iii) of the PHSA, if applicable. If permitted pursuant to Applicable Law, upon one Party's request, the other Party shall assist the requesting Party in identifying and listing any and all relevant Patents pursuant to Section 351(l)(1)(3)(A) or Section 351(l)(7) of the PHSA, in preparing, pursuant to section 351(l)(3)(C) of the PHSA, a detailed statement regarding the reference product sponsor's opinion that any such Patent will be infringed and a response to the statement by the filer of the Biosimilar Application concerning validity and enforceability, in negotiating with the filer of the Biosimilar Application pursuant to Section 351(l)(4) of the PHSA, and in selecting Patents enforceable under this Section 9.10 for and conducting litigation pursuant to Section 351(l)(5), Section 351(l)(6), and Section 351(l)(9) of the PHSA, to the extent applicable, and shall cooperate with the requesting Party in responding to relevant communications with

respect to such lists and statements from the filer of the Biosimilar Application. The Parties shall cooperate and assist each other in seeking an injunction against any commercial marketing by the filer of a Biosimilar Application as permitted pursuant to Section 351(l)(8)(B) of the PHSA or in filing an action for infringement against the filer of such Biosimilar Application.

9.11 Defense of Infringement Claims. In the event PARTNER or REGENX becomes aware that PARTNER's or any of its Affiliates' or any Sublicensees' Exploitation of the Licensed Product in the Licensed Field is the subject of a claim for patent infringement by a Third Party, that Party shall promptly notify the other Party, [****]. Unless the Party against whom a Third Party infringement claim is filed seeks indemnification for such claim covered pursuant to ARTICLE 12, subject to compliance with the provisions of this Section 9.11, the alleged infringing Party shall have the sole right, but not the obligation, to defend and control the defense of any such claim, suit or proceeding. Without limitation of the foregoing, if the alleged infringing Party finds it necessary or desirable to join the other Party as a party to any such action, the other Party shall execute all papers and perform such acts as shall be reasonably required. Each Party shall keep the other Party reasonably informed of all material developments in connection with any such claim, suit, or proceeding. [****]. Notwithstanding anything to the contrary herein, the rights and obligations under this Section 9.11 are subject to the rights of the applicable REGENX Licensors and the limitations imposed on REGENX, its Affiliates and its and their respective sublicensees that are set forth in the applicable Third Party License Agreements and the alleged infringing Party shall not settle or compromise any claim for patent infringement (including related defensive claims and counterclaims) under this Section 9.11 with respect to any Patent [****].

9.12 Invalidity or Unenforceability Defenses or Actions.

9.12.1 Notice. Each Party shall promptly notify the other Party in writing of any alleged or threatened assertion of invalidity, unpatentability or unenforceability of any of the REGENX Patents, PARTNER Patents, or Joint Patents by a Third Party, in each case in the Territory and of which such Party becomes aware. Notwithstanding anything to the contrary herein, the rights and obligations under this Section 9.12 are subject to the rights of the applicable REGENX Licensors and the limitations imposed on REGENX, its Affiliates and its and their respective sublicensees that are set forth in the applicable Third Party License Agreements.

9.12.2 Defense of Patents. Subject to the terms and conditions of this Agreement, the Prosecuting Party shall have the first right, but not the obligation, to defend and control the defense of the validity, patentability and enforceability of the Patents being Prosecuted by such Prosecuting Party under this Section 9.12 in the Territory. The non-Prosecuting Party may participate in any such claim, suit, or proceeding in the Territory with counsel of its choice at its own expense; *provided* that the Prosecuting Party shall retain control of the defense in such claim, suit, or proceeding. If the Prosecuting Party elects not to defend or control the defense of such Patent (other than a PARTNER Patent) in a claim, suit or proceeding brought in the Territory, or otherwise fails to initiate and maintain the defense of any such claim, suit, or proceeding, then the non-Prosecuting Party may become the controlling Party and conduct and control the defense of any such claim, suit, or proceeding.

9.12.3 Cooperation. Each Party shall assist and cooperate with the other Party as such other Party may reasonably request from time to time in connection with its

activities set forth in this Section 9.12, including by being joined as a necessary party in such claim, suit or proceeding, providing access to relevant documents and other evidence, and making its employees available at reasonable business hours. In connection with any such defense or claim or counterclaim, the controlling Party shall consider in good faith any comments from the other Party and shall keep the other Party reasonably informed of any material steps taken. Subject to the other terms and conditions of this Agreement, the controlling Party shall have the right to settle such claim, suit or proceeding under this Section 9.12, *provided* that the controlling Party shall not settle any such claim, suit or proceeding in a manner that imposes any out-of-pocket costs or liability on, or involves any admission by, the other Party, without the express written consent of such other Party. Furthermore, the controlling Party shall not settle or compromise any such claim, suit or proceeding under this Section 9.12 with respect to any Patent in a manner that imposes any obligations or other restrictions on an applicable REGENX Licensor, or that has a material adverse effect on the validity, scope of patent claims, or enforceability of any of the GSK Patents, or grants any rights to the GSK Patents, other than any permitted sublicenses, without the applicable REGENX Licensor's prior written permission as set forth in the applicable Third Party License Agreements. [****].

9.13 Third Party Patent Rights. If in the reasonable opinion of either Party, a license under any Patent or other intellectual property right of a Third Party in any country in the Territory is necessary or reasonably useful to Exploit the Licensed Product for use in the Licensed Field in the Territory in accordance with this Agreement (such right, a "**Third Party Patent Right**"), then the Parties shall meet and discuss the strategy for obtaining such Third Party Patent Right. The Parties shall negotiate in good faith to reach agreement with respect to such strategy. If no agreement has been reached after [****] following commencement of such discussions, then [****]. If either Party determines not to enter into such an agreement under the foregoing clauses (a) or (b), then it shall promptly notify the other Party thereof, and the other Party shall thereafter have the right to enter into such an agreement. Each Party shall ensure that any such license entered into under this Section 9.13 shall be freely sublicensable to the other Party and its Affiliates to enable such other Party and its Affiliates to fully exercise its rights and perform its obligations under this Agreement and shall promptly provide the other Party with a copy of any Third Party agreement entered into under this Section 9.13 with redactions permitted to the extent not reasonably necessary for the other Party to understand its obligations under such agreement or such agreement's relevance to this Agreement. If the grant of a sublicense under a Third Party agreement entered into by either Party under this Section 9.13 would result in the other Party having any different or additional obligations or being subject to any additional terms as a result of being a sublicensee under such agreement, the other Party shall have [****] after receipt of a copy of such agreement to notify the Party that entered into the Third Party agreement as to whether it accepts such sublicensed rights. Notwithstanding anything to the contrary in this Agreement, unless and until the other Party notifies the Party that entered into the Third Party agreement within such [****] period that it wishes to receive a sublicense under the Third Party agreement entered into under this Section 9.13, Information and Patents licensed by the Party that entered into the Third Party agreement from a Third Party will not be deemed "Controlled" by the Party that entered into the Third Party agreement or its Affiliates under this Agreement and the other Party shall not be granted any rights, or have any obligations, under such Third Party agreement. [****]. If in the reasonable opinion of PARTNER, a Third Party Patent Right may relate to the Exploitation of a Licensed Product by PARTNER or its Affiliates, then PARTNER or its Affiliates shall have the sole right, but not the obligation, to challenge the patentability,

validity or enforceability of such Patent in any court of competent jurisdiction or before any supra-national, federal, national, regional, state, provincial and local governmental body of competent jurisdiction including the United States Patent and Trademark Office and the European Patent Office. REGENX shall not challenge the patentability, validity or enforceability of such Patent in any court or governmental body without PARTNER's prior written consent, *provided*, *however*, that notwithstanding the foregoing, REGENX will not be prevented from challenging the patentability, validity or enforceability of any such Third Party Patent Right to the extent unrelated to the Licensed Product and the Indications in the Licensed Field. REGENX shall assist and cooperate with PARTNER as PARTNER may reasonably request from time to time in connection with the activities set forth in this Section 9.13.

9.14 International Nonproprietary Name. As between the Parties, PARTNER shall have the sole right and responsibility to select the International Nonproprietary Name or other name or identifier for any Licensed Product. PARTNER shall have the sole right and responsibility to apply for submission to the World Health Organization for the International Nonproprietary Name, and submission to the United States Adopted Names Council for the United States Adopted Name.

9.15 Product Trademarks. PARTNER shall be responsible for the registration, prosecution, and maintenance of the Product Trademarks using counsel of its own choice. PARTNER shall have the sole right and responsibility to take such action as PARTNER reasonably deems necessary against a Third Party based on any alleged, threatened or actual infringement, dilution, misappropriation or other violation of or unfair trade practices or any other like offense relating to, the Product Trademarks by a Third Party using counsel of its own choice. PARTNER shall have the sole right and responsibility to defend against and settle any alleged, threatened or actual claim by a Third Party that the use or registration of the Product Trademarks in the Territory infringes, dilutes, misappropriates or otherwise violates any Trademark or other right of that Third Party or constitutes unfair trade practices or any other like offense or any other claims as may be brought by a Third Party against a Party in connection with the use of the Product Trademarks with respect to the Licensed Product for use in the Licensed Field in the Territory using counsel of its choice. [****].

9.16 [****]

ARTICLE 10
CONFIDENTIALITY AND NON-DISCLOSURE

10.1 Confidentiality Obligations. At all times during the Term and for a period of [****] following termination or expiration hereof in its entirety, each Party shall, and shall cause its officers, directors, employees and agents to, keep confidential and not publish or otherwise disclose to a Third Party and not use, directly or indirectly, for any purpose, any Confidential Information furnished or otherwise made known to it, directly or indirectly, by the other Party, except to the extent such disclosure or use is expressly permitted by the terms of this Agreement or the Penn Sublicense Agreement. "**Confidential Information**" means any confidential and proprietary technical, business or other information provided by or on behalf of one Party to the other Party in connection with this Agreement or the Penn Sublicense Agreement, whether prior to, on or after the Effective Date, including the terms of this Agreement or the Penn Sublicense

Agreement (subject to Section 10.2.4 and Section 10.4), confidential and proprietary information relating to any Licensed Product (including the Regulatory Documentation), any Development or Commercialization of any Licensed Product, any confidential and proprietary Information with respect thereto developed by or on behalf of the disclosing Party or its Affiliates (including PARTNER Know-How and REGENX Know-How, as applicable) or the confidential and proprietary scientific, regulatory or business affairs or other activities of either Party. Notwithstanding the foregoing, (a) Joint Know-How and the terms of this Agreement shall be deemed to be the Confidential Information of both Parties and both Parties shall be deemed to be the receiving Party and the disclosing Party with respect thereto, (b) any Information solely relating to Licensed Products (including the Regulatory Documentation) or the Exploitation thereof ([****]) ("**Product Information**") shall be deemed to be the Confidential Information of both Parties and both Parties shall be deemed to be the receiving Party and the disclosing Party with respect thereto and (c) [****] (and REGENX shall be deemed to be the disclosing Party and PARTNER shall be deemed the receiving Party with respect thereto). Notwithstanding the foregoing, Confidential Information shall not include any information that:

10.1.1 is or becomes part of the public domain by public use, publication, general knowledge or the like through no breach of this Agreement or the Penn Sublicense Agreement by the receiving Party;

10.1.2 can be demonstrated by documentation or other competent proof to have been in the receiving Party's possession prior to disclosure by the disclosing Party without any obligation of confidentiality with respect to such information; *provided* that the foregoing exception shall not apply with respect to Product Information, Joint Know-How or REGENX NAV Platform Know-How, in each case, generated by the receiving Party with respect thereto as set forth in Section 10.1;

10.1.3 is subsequently received by the receiving Party from a Third Party who is not bound by any obligation of confidentiality with respect to such information;

10.1.4 has been published by a Third Party or otherwise enters the public domain through no fault of the receiving Party in breach of this Agreement or the Penn Sublicense Agreement; or

10.1.5 can be demonstrated by documentation or other competent evidence to have been independently developed by or for the receiving Party without reference to the disclosing Party's Confidential Information; *provided* that the foregoing exception shall not apply with respect to Product Information, Joint Know-How or REGENX NAV Platform Know-How, in each case, generated by the receiving Party with respect thereto as set forth in Section 10.1.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the receiving Party. Further, Confidential Information shall not be considered in the public domain or in the possession of the receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the receiving Party unless the

combination of these elements and its principles are in the public domain or in the possession of the receiving Party.

10.2 Permitted Disclosures. Each Party may disclose Confidential Information to the extent that such disclosure is:

10.2.1 made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial and local governmental or regulatory body of competent jurisdiction or, if in the reasonable opinion of the receiving Party's legal counsel, such disclosure is otherwise required by Applicable Law, including by reason of filing with securities regulators; *provided, however*, except with respect to securities filings (which are addressed in Section 10.4 below), that as promptly as reasonably practicable and to the extent not prohibited by Applicable Law or judicial or administrative process, the receiving Party shall first have given notice to the disclosing Party and given the disclosing Party a reasonable opportunity to quash such order or to obtain a protective order or confidential treatment requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued; and *provided, further,* that the Confidential Information disclosed in response to such court or governmental order shall be limited to that information which is legally required to be disclosed in response to such court or governmental order;

10.2.2 made by or on behalf of the receiving Party to the Regulatory Authorities as required in connection with the conduct of a Clinical Trial or any filing, application or request for Regulatory Approval; *provided, however*, that reasonable measures shall be taken to assure confidential treatment of such information to the extent practicable and consistent with Applicable Law;

10.2.3 made by or on behalf of the receiving Party to a patent authority as may be reasonably necessary or useful for purposes of Prosecuting or enforcing a Patent under and in accordance with this Agreement or the Penn Sublicense Agreement; *provided, however*, that reasonable measures shall be taken to assure confidential treatment of such information, to the extent such protection is available;

10.2.4 made by or on behalf of the receiving Party to [****]; *provided, however*, that such persons shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information substantially similar to the obligations of confidentiality and non-use of the receiving Party pursuant to this ARTICLE 10 (with a duration of confidentiality and non-use obligations as appropriate that is no less than [****] from the date of disclosure); or

10.2.5 to allow the receiving Party to exercise its rights or perform its obligations hereunder, *provided* that such disclosure is covered by terms of confidentiality and non-use at least as restrictive as those set forth herein.

10.3 Use of Name.

10.3.1 General. Except as expressly provided herein, neither Party shall mention or otherwise use the name, logo or Trademark of the other Party or any of its Affiliates or any of its or their (sub)licensees (or Sublicensees) (or any abbreviation or adaptation

thereof) in any publication, press release, marketing and Promotional Material or other form of publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this Section 10.3 shall not prohibit (a) either Party from making any disclosure identifying the other Party to the extent required in connection with its exercise of its rights or obligations under this Agreement or the Penn Sublicense Agreement and (b) either Party from making any disclosure identifying the other Party that is required by Applicable Law or the rules of a stock exchange on which the securities of the disclosing Party are listed (or to which an application for listing has been submitted).

10.3.2 REGENX Names. PARTNER, its Affiliates and all of their respective employees and agents must not use the name, seal, logo, trademark, or service mark (or any adaptation thereof) of REGENX or the GSK Licensor in any way without the prior written consent of REGENX; *provided*, *however,* that PARTNER may acknowledge the existence and general nature of this Agreement and the Penn Sublicense Agreement, subject to ARTICLE 10.

10.3.3 PARTNER Names. REGENX, its Affiliates and all of their respective employees and agents must not use PARTNER's name, seal, logo, trademark, or service mark (or any adaptation thereof) in any way without the prior written consent of PARTNER; *provided*, *however* that REGENX may acknowledge the existence and general nature of this Agreement and the Penn Sublicense Agreement, subject to ARTICLE 10.

10.4 Public Announcements. The Parties have agreed upon the content of one (1) or more press releases which shall be issued substantially in the form(s) attached hereto as Schedule 10.4, the release of which the Parties shall coordinate in order to accomplish such release promptly upon execution of this Agreement. Neither Party shall issue any other public announcement, press release or other public disclosure regarding this Agreement, the Penn Sublicense Agreement or their respective subject matters without the other Party's prior written consent, such consent not to be unreasonably withheld, conditioned or delayed, except for any such disclosure that is, in the opinion of the disclosing Party's counsel, required by Applicable Law or the rules of a stock exchange on which the securities of the disclosing Party are listed (or to which an application for listing has been submitted). In the event a Party is, in the opinion of its counsel, required by Applicable Law or the rules of a stock exchange on which its securities are listed (or to which an application for listing has been submitted) to make such a public disclosure, such Party shall submit the proposed disclosure in writing to the other Party as far in advance as reasonably practicable (and in no event less than [****] prior to the anticipated date of disclosure) so as to provide a reasonable opportunity to comment thereon. In addition, in the event REGENX is, in the opinion of its counsel, required by Applicable Law or the rules of a stock exchange on which its securities are listed (or to which an application for listing has been submitted) to publicly file this Agreement or the Penn Sublicense Agreement, REGENX shall submit its proposed redactions to this Agreement or the Penn Sublicense Agreement, as applicable, in writing to PARTNER as far in advance as reasonably practicable (and in no event less than [****] prior to the anticipated date of disclosure) so as to provide a reasonable opportunity to comment thereon. REGENX shall incorporate all comments of PARTNER with respect thereto except to the extent inconsistent with Applicable Law, and shall use reasonable efforts to obtain confidential treatment for the terms of this Agreement or the Penn Sublicense Agreement, as applicable, so redacted. Neither Party shall be required to seek the permission of the other Party to repeat any information regarding the terms of this Agreement, the Penn Sublicense Agreement or any amendment hereto

or thereto that has already been publicly disclosed by such Party or by the other Party, in accordance with this Section 10.4; *provided* that such information remains accurate as of such time and provided the context and form of such disclosure are the same as the previously approved context and form.

10.5 Publications.

10.5.1 Generally. With respect to the activities under the Development Plan that are not (a) Global Clinical Trials or (b) Development activities solely intended to support Regulatory Approval in any jurisdiction(s) outside the United States, a Party (a "**Publishing Party**") will, prior to publishing, publicly presenting or otherwise publicly disclosing any paper, publication, oral presentation, abstract, poster, manuscript or other presentation relating to the results of any such Development activities, provide the other Party (a "**Reviewing Party**") an opportunity to review such publication to determine whether such publication contains the Confidential Information of the Reviewing Party. The Publishing Party will deliver to the Reviewing Party a copy of any such proposed publication or an outline of the proposed oral disclosure at least [****] prior to submission for publication or presentation for review by the Reviewing Party. The Reviewing Party will have the right, in its sole discretion, to: (i) require the removal of its Confidential Information from any such publication by the Publishing Party; or (ii) request a reasonable delay in publication or presentation in order to protect patentable information. If the Reviewing Party requests such a delay, the Publishing Party will delay submission or presentation for a period of [****] after its provision of the copy of the proposed publication to enable the filing of one (1) or more patent applications protecting the Reviewing Party's rights in such information. In addition, the Publishing Party shall give due regard to comments furnished by the Reviewing Party and such comments shall not be unreasonably rejected. For all Independent Studies, Global Clinical Trials and Development activities solely intended to support Regulatory Approval in any jurisdiction(s) outside the United States, any proposed publication (whether written, electronic, oral or otherwise) by PARTNER or any of its Affiliates related to activities under this Agreement or the Licensed Products will be at the sole discretion of PARTNER.

10.5.2 Referral to Disclosed Results. Notwithstanding anything to the contrary herein, each Party has the right to publish (through press releases, scientific journals, or otherwise) and refer to any clinical, regulatory, or research results related to a Licensed Product that have been publicly disclosed by either Party, including referring to the other Party by name as a licensee or licensor, as applicable, of such Publishing Party, which publication or referral by such Party shall not require the prior consent of the other Party.

10.6 Return of Confidential Information. Upon the effective date of the expiration or termination of this Agreement for any reason, either Party may request in writing and the non-requesting Party shall either, with respect to Confidential Information to which such non-requesting Party does not retain rights under the surviving provisions of this Agreement, at the requesting Party's election, (a) promptly destroy all copies of such Confidential Information in the possession or control of the non-requesting Party and confirm such destruction in writing to the requesting Party or (b) promptly deliver to the requesting Party, at the non-requesting Party's sole cost and expense, all copies of such Confidential Information in the possession or control of the non-requesting Party. Notwithstanding the foregoing, the non-requesting Party shall be permitted

to retain such Confidential Information (x) to the extent necessary or useful for purposes of performing any continuing obligations or exercising any ongoing rights hereunder and, in any event, a single copy of such Confidential Information for archival purposes and (y) any computer records or files containing such Confidential Information that have been created solely by such non-requesting Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with such non-requesting Party's standard archiving and back-up procedures, but not for any other uses or purposes. All Confidential Information shall continue to be subject to the terms of this Agreement for the period set forth in Section 10.1.

ARTICLE 11
REPRESENTATIONS, WARRANTIES AND COVENANTS

11.1 Mutual Representations and Warranties. REGENX and PARTNER each represents and warrants to the other, as of the Execution Date, and covenants, that:

11.1.1 it is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization and has all requisite power and authority, corporate or otherwise, to execute, deliver and perform this Agreement;

11.1.2 the execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby and thereby have been duly authorized by all necessary corporate action and do not violate: (a) such Party's charter documents, bylaws or other organizational documents; (b) any agreement, instrument or contractual obligation to which such Party is bound; (c) any requirement of any Applicable Law, subject to compliance with the HSR Act as set forth herein; or (d) any order, writ, judgment, injunction, decree, determination or award of any court or Governmental Authority presently in effect applicable to such Party, subject to compliance with the HSR Act as set forth herein;

11.1.3 Subject to ARTICLE 2, this Agreement is a legal, valid and binding obligation of such Party enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance and general principles of equity (whether enforceability is considered a proceeding at law or equity); and

11.1.4 it is not under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent with the terms of this Agreement or that would impede the diligent and complete fulfillment of its obligations hereunder and thereunder.

11.2 Additional Representations and Warranties of REGENX. REGENX further represents and warrants to PARTNER, as of the Execution Date, that:

(a) all REGENX Existing Patents are set forth on Schedule 1.188. All REGENX Existing Patents are subsisting and to the knowledge of REGENX are not invalid or unenforceable in whole or in part, and, except as set forth on Schedule 1.188, REGENX solely owns all right, title and interest in the REGENX Existing Patents. REGENX has the right to grant the licenses and sublicenses specified herein;

(b) except as otherwise disclosed in Schedule 11.2(b): (i) there are no claims, judgments, or settlements against, or amounts with respect thereto, owed by REGENX or any of its Affiliates relating to the Regulatory Documentation, the REGENX Existing Patents, or the REGENX Know-How; (ii) REGENX has not received any written claim or demand alleging that (A) the REGENX Existing Patents, or the REGENX Know-How are invalid or unenforceable or (B) the Development, Manufacture or Commercialization of a Licensed Compound or Licensed Product for use in the Licensed Field as contemplated herein will violate, infringe, misappropriate or otherwise conflict or interfere with any Patent or other intellectual property or proprietary right owned by any Third Party;

(c) to the Knowledge of REGENX, no Third Party has any rights, interest, or claim in or to such REGENX Existing Patents in the Licensed Field that are inconsistent with those granted to PARTNER under this Agreement;

(d) to the Knowledge of REGENX, no Person is in a material way infringing or threatening to infringe or misappropriating or threatening to misappropriate the REGENX Existing Patents, the REGENX Know-How, or the Regulatory Documentation;

(e) to the Knowledge of REGENX, REGENX has the right to use all Information, and Patents necessary to conduct the Development activities allocated to REGENX under the Development Plan and to Manufacture any Licensed Compounds and Licensed Products as contemplated herein;

(f) to the Knowledge of REGENX (but, with respect to Patents or other intellectual property or proprietary right in any jurisdiction outside of the US, [****], without any further duty of inquiry), the Development, Manufacture and Commercialization of the Licensed Compounds and Licensed Products (for clarity, including the use of the Delivery System identified in the Development Plan as of the Execution Date in the administration thereof) as contemplated herein would not infringe any Patent (with the exception of invalid claims of a Patent) or other intellectual property or proprietary right of any Person;

(g) to the Knowledge of REGENX, the conception, development, and reduction to practice of the Regulatory Documentation, the REGENX Existing Patents and REGENX Know-How existing as of the Execution Date have not constituted or involved the misappropriation of trade secrets or other rights or property of any Person;

(h) the REGENX Existing Patents Prosecuted by REGENX and, to the Knowledge of REGENX, all other REGENX Existing Patents, are being diligently prosecuted in the respective patent offices in the Territory in accordance with Applicable Law. The REGENX Existing Patents have been filed and maintained properly and correctly and all applicable fees have been paid on or before the due date for payment;

(i) to the Knowledge of REGENX, each of the REGENX Existing Patents and Penn Patents properly identifies each and every inventor of the claims thereof as determined in accordance with the laws of the jurisdiction in which such REGENX Existing Patent and Penn Patent is issued or such application is pending;

(j) with respect to the REGENX Existing Patents Prosecuted by REGENX and, to the Knowledge of REGENX, all other REGENX Existing Patents, true, materially complete, and correct copies of: (i) the file wrapper and other documents and materials relating to the prosecution, defense, maintenance, validity, and enforceability of the REGENX Existing Patents; (ii) all Regulatory Documentation existing as of the Execution Date; and (iii) all material adverse information with respect to the safety and efficacy of the Licensed Compounds and Licensed Products known to REGENX, in each case ((i) through (iii)) that have been requested by PARTNER have been provided or made available to PARTNER prior to the Execution Date;

(k) to the Knowledge of REGENX, REGENX and its Affiliates have generated, prepared, maintained, and retained all Regulatory Documentation that is required to be maintained or retained pursuant to and in accordance with good laboratory and clinical practice and Applicable Law, and all such information is true, complete and correct and what it purports to be;

(l) the REGENX Existing Patents and Penn Patents represent all the Patents that REGENX or its Affiliates own, Control or otherwise have rights to as of the Execution Date that Cover the Exploitation of a Licensed Compound or Licensed Product for use in the Licensed Field in the manner contemplated as of the Execution Date, the REGENX Know-How as of the Execution Date represents all the Information that REGENX or its Affiliates own, Control or otherwise has rights to as of the Execution Date that relate to the Exploitation of a Licensed Compound or Licensed Product for use in the Licensed Field in the manner contemplated as of the Execution Date and REGENX solely owns the REGENX Know-How existing as of the Execution Date;

(m) to the Knowledge of REGENX, neither REGENX nor any of its Affiliates, nor any of its or their respective officers, employees, or agents has made an untrue statement of material fact or fraudulent statement to the FDA or any other Regulatory Authority with respect to the Development of the Licensed Products, failed to disclose a material fact required to be disclosed to the FDA or any other Regulatory Authority with respect to the Development of the Licensed Compounds or Licensed Products, or committed an act, made a statement, or failed to make a statement with respect to the Development of the Licensed Compounds or Licensed Products that could reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities", set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto or any analogous laws or policies in the Territory;

(n) to the Knowledge of REGENX, REGENX and its Affiliates have conducted, and their respective contractors and consultants have conducted, all Development of the Licensed Compounds and Licensed Products that they have conducted prior to the Execution Date in material compliance with good laboratory and clinical practice and Applicable Law. REGENX has conducted, and has caused its contractors and consultants to conduct, any and all pre-clinical and Clinical Trials related to the Licensed Products in material compliance with good laboratory and clinical practice and Applicable Law. REGENX and its Affiliates have employed Persons with appropriate education, knowledge and experience to conduct and to oversee the conduct of the pre-clinical and Clinical Trials with respect to the Licensed Compounds and Licensed Products;

(o) Except with respect to the certain GSK Patents described in Section 9.3 and to the Knowledge of REGENX, the inventions claimed or covered by the REGENX Existing Patents (i) were not conceived, discovered, developed, or otherwise made in connection with any research activities funded, in whole or in part, by the federal government of the United States or any agency thereof, (ii) are not a "subject invention" as that term is described in 35 U.S.C. Section 201(f), and (iii) are not otherwise subject to the provisions of the Bayh-Dole Act;

(p) (i) REGENX has implemented confidentiality policies that are materially consistent with industry standards, and (ii) to the Knowledge of REGENX, no material breach of such confidentiality has been committed by any Third Party;

(q) REGENX has made available to PARTNER all Regulatory Documentation requested by PARTNER related to the Licensed Products;

(r) all Third Party License Agreements are listed on Schedule 11.2(r);

(s) (i) the licenses to REGENX in the Third Party Agreements are in full force and effect and by their terms and the Third Party License Agreements are sublicensable to PARTNER as contemplated by this Agreement and the Penn Sublicense Agreement, (ii) REGENX is not in breach under any such Third Party Agreements, nor, to REGENX's Knowledge, is any counterparty thereto, (iii) REGENX has not received any written notice of breach under any such Third Party Agreements from the counterparty thereto, and (iv) to REGENX's Knowledge, no facts or circumstances exist that would reasonably be expected to give rise to any such challenge, violation or breach. The rights and obligations of the Parties hereunder are fully consistent with and are not limited in any material respect to such Third Party Agreements;

(t) no provision of any Third Party License Agreement conflicts with PARTNER's rights, as set forth in Section 9.4 of this Agreement, to grant further sublicenses of the applicable REGENX Technology in compliance with the terms for such permitted further sublicensing under this Agreement, the Penn Sublicense Agreement, and the Third Party License Agreements, as applicable, and through multiple tiers;

(u) there is no Information licensed to REGENX under the Penn Agreement that, to the Knowledge of REGENX, is necessary or reasonably useful for the performance of PARTNER's obligations, Exploitation of any Licensed Compound or Licensed Product for use in the Licensed Field or exercise of PARTNER's rights hereunder;

(v) the Processing of Personal Data by REGENX (including, without limitation, any transfer of Personal Data across national borders) in connection with the Licensed Compounds and Licensed Products is and has been in material compliance with Data Security and Privacy Laws in all countries and jurisdictions in the Territory, all privacy related consents and notices that apply to the Licensed Compounds or Licensed Products, and the requirements of any contract or codes of conduct to which REGENX is a party ("**Privacy and Security Obligations**"). To the Knowledge of REGENX, REGENX has provided all necessary privacy notices related to research participants and has an appropriate legal basis under Data

Security and Privacy Laws to Process all Personal Data in connection with the Licensed Compounds and Licensed Products. REGENX has developed, implemented and maintains a compliance program, policies and procedures, and training programs to ensure ongoing compliance with the Privacy and Security Obligations. REGENX has commercially reasonable physical, technical, organizational and administrative security measures and policies in place to protect all Personal Data collected by it or on its behalf from and against unauthorized Processing. REGENX is and has complied in all material respects with all Privacy and Security Obligations relating to Data Breach reporting and notification obligations;

(w) in the last [****], REGENX has not received written notice of any alleged material violation from a Regulatory Authority or other Third Party of any Privacy and Security Obligations. To the Knowledge of REGENX, REGENX is not under investigation by any Regulatory Authority for a violation of Data Security and Privacy Laws;

(x) REGENX has disclosed all material adverse events relating to the safety and efficacy of the Licensed Compounds and Licensed Products of which REGENX or any of its Affiliates has any Knowledge as of the Execution Date;

(y) the execution and delivery of this Agreement and the other agreements and instruments contemplated hereby complies with the Privacy and Security Obligations; and

(z) Without limiting any other representation or warranty made by REGENX under this Agreement, to the Knowledge of REGENX, there are no facts or circumstances that exist as of the Execution Date that would reasonably be expected to have an adverse effect in any material respect on the Exploitation of the Licensed Compound or Licensed Product as contemplated under this Agreement that have not been disclosed to PARTNER, including via the [****] data room established by or on behalf of REGENX (or any subfolders thereof) on or prior to the [****] prior to the Execution Date.

11.3 Additional Representation and Warranty of PARTNER. PARTNER has or has access to financial resources sufficient to meet PARTNER's payment obligations under Section 8.1 and Section 8.2.1 of this Agreement when such obligations become due.

11.4 DISCLAIMER OF WARRANTIES. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH HEREIN AND IN THE PENN SUBLICENSE AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL OR EXPRESS OR IMPLIED, INCLUDING ANY CONDITIONS AND WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR NON-INFRINGEMENT.

11.5 REGENX Covenants. REGENX hereby covenants to PARTNER as follows:

11.5.1 REGENX will not assign, transfer, convey or grant any license or other rights to its rights, title and interests in or to the REGENX Patents, Penn Patents or

REGENX Know-How (or agree to do any of the foregoing) in any way that would conflict with any of the rights or licenses granted to PARTNER under this Agreement;

11.5.2 REGENX will not, and will cause its Affiliates not to incur or permit to exist, with respect to any REGENX Patents, Penn Patents or REGENX Know-How, any lien, encumbrance, charge, security interest, mortgage, liability, or other restriction (including in connection with any indebtedness) that would conflict with any of the rights or licenses granted to PARTNER under this Agreement;

11.5.3 REGENX will not (a) amend, modify or terminate any Third Party Agreement, (b) breach any such Third Party Agreement or otherwise take or omit any action under any such Third Party Agreement, (c) exercise, waive, release, or assign any rights or claims under any such Third Party Agreement or (d) enter into another agreement with respect to any Penn Patent or GSK Patent (including any rights or obligations related to any sublicensed rights), in each case ((a) through (d)), in a manner that would adversely affect PARTNER's rights or impose any additional obligations on PARTNER hereunder, or under the Penn Sublicense Agreement, Clinical Supply Agreement or Commercial Supply Agreement, without first obtaining PARTNER's written consent;

11.5.4 if REGENX or its Affiliate receives notice of an alleged breach or default by REGENX or its Affiliate under any Third Party Agreement or any notice asserting a Third Party's right to (a) terminate such Third Party Agreement or (b) diminish the scope or exclusivity of the licenses granted to REGENX or its Affiliate under any such Third Party Agreement in any way that would conflict with any of the rights or licenses granted to PARTNER under this Agreement or would otherwise adversely affect PARTNER's rights or impose any additional obligations on PARTNER hereunder, then REGENX will promptly, but in no event less than [****] thereafter, provide written notice thereof to PARTNER; and

11.5.5 REGENX will comply with the terms set forth on Schedule 11.5.5.

11.6 Mutual Covenants. Each Party hereby covenants to the other Party that it will, and will ensure that its Affiliates and subcontractors will, obtain written agreements from any and all Persons involved in or performing any Development activities by or on behalf of such Party hereunder that assign, to the extent legally permissible, (or exclusively license, with a right to grant sublicenses) such Person's rights, title and interests in and to any Information or other intellectual property rights developed or invented in the performance of such activities that specifically relate to the Licensed Compounds, Licensed Products or their use, Manufacture or sale to such Party prior to any such Person performing such activities.

11.7 Anti-Bribery and Anti-Corruption Compliance. [****]

11.8 Debarment. [****]

(a) A "**Debarred Individual**" is an individual who has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from providing services in any capacity to a Person that has an approved or pending drug or biological product application.

(b) A "**Debarred Entity**" is a corporation, partnership or association that has been debarred by the FDA pursuant to 21 U.S.C. §335a (a) or (b) from submitting or assisting in the submission of any abbreviated drug application, or a subsidiary or affiliate of a Debarred Entity.

(c) An "**Excluded Individual**" or "**Excluded Entity**" is (A) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General (OIG/HHS) of the U.S. Department of Health and Human Services, or (B) is an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration (GSA).

(d) A "**Convicted Individual**" or "**Convicted Entity**" is an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of 21 U.S.C. §335a (a) or 42 U.S.C. §1320a - 7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible.

(e) "**FDA's Disqualified/Restricted List**" is the list of clinical investigators restricted from receiving investigational drugs, biologics, or devices if the FDA has determined that the investigators have repeatedly or deliberately failed to comply with regulatory requirements for studies or have submitted false Information to the study sponsor or the FDA.

11.9 Data Privacy and Security.

11.9.1 Covenants. For all Personal Data collected, Processed, hosted, or transmitted in performance by the Parties of this Agreement, including, but not limited to, in connection with the conduct of the Development activities and Clinical Trials, each Party shall:

(a) comply at all times with the Data Security and Privacy Laws;

(b) to the extent permitted by Applicable Law, notify the other Party, as soon as practicable and in any event prior to making the relevant disclosure, if it is obliged to make a disclosure of the Personal Data under Applicable Law;

(c) make timely notification to, and obtain any necessary authorizations from, any applicable Regulatory Authority where required under applicable Data Security and Privacy Laws of its collection and other Processing of Personal Data in order to comply with its obligations under this Agreement;

(d) at all times, act in a manner such that it is not subject to any prohibition or restriction that (i) prevents or restricts it from disclosing or transferring the Personal Data to the other Party, as required under this Agreement; or (ii) prevents or restricts either Party from Processing the Personal Data as envisaged under this Agreement. If either Party becomes aware of any circumstances that it believes, acting reasonably, may give rise to such a prohibition or restriction, it shall promptly notify the other Party of the same and take all reasonable steps, to ensure that it does not impact its performance of its obligations under this Section 11.9.1;

(e) ensure that all fair Processing or required notices or informed consent have been obtained and are maintained and are sufficient in scope, and that each Party has an appropriate legal basis under Data Security and Privacy Laws, sufficient in scope to enable the other Party to Process the Personal Data as required in order to comply with its obligation under this Agreement to obtain the benefit of its rights and to fulfil its obligations under this Agreement (including the transfer of all applicable Personal Data), in each case, in accordance with the Data Security and Privacy Laws;

(f) implement and maintain reasonable administrative, technical, and physical safeguards designed to (i) maintain the security and confidentiality of the Personal Data; (ii) protect against reasonably anticipated threats or hazards to the security or integrity of the Personal Data; and (iii) protect against unauthorized access to or use of Personal Data;

(g) notify the other Party promptly, and in any event within [****] of receipt of (i) any correspondence from a data protection regulator in relation to the Processing of Personal Data related to this Agreement, or (ii) a request or notice from a data subject exercising his rights under the Data Security and Privacy Laws, including to access, rectify or delete his Personal Data in relation to the Personal Data Processed under this Agreement; and

(h) refrain from taking actions related to the Processing of the Personal Data that would be reasonably likely to damage or impair the other Party's reputation.

11.9.2 Data Agreements. At the reasonable request of either Party, the Parties shall cooperate to enter into any necessary joint controller agreements or controller-processor agreements with respect to such Personal Data as necessary to comply with Applicable Law, including the cross-border transfer of Personal Data requirements set forth in the Data Security and Privacy Laws.

11.9.3 Security Breach Notification. Each Party shall notify the other Party by email to [****] or [****], as applicable, immediately, and in any event no later than [****], upon learning of any actual or suspected misappropriation or unauthorized access to, or disclosure or use of the Personal Data collected, Processed, hosted, or transmitted by a Party related to the performance of this Agreement, including the conduct of the Development Plan (a "**Data Breach**"). Each Party shall promptly investigate each Data Breach that it becomes aware of or has reason to suspect may have occurred and, in the case of an actual Data Breach, shall, at the other Party's request, provide reasonable levels of access and information to the other Party in connection with any independent investigation that such Party may desire to conduct with respect to such Data Breach. Each Party shall cooperate with the other Party in identifying any reasonable steps that should be implemented to limit, stop or otherwise remedy any actual or suspected Data Breach. Such Party shall perform all remediation efforts required by Data Security and Privacy Laws, and shall be responsible for all liabilities, costs, and expenses associated with the Data Breach. Neither Party shall make any statements or notifications about the Data Breach to any affected individual, a Regulatory Authority, the public, or any Third Party without the other Party's prior written approval.

ARTICLE 12
INDEMNITY

12.1 Indemnification of REGENX. PARTNER shall indemnify REGENX, its Affiliates, and its and their respective directors, officers, employees and agents (collectively, "**REGENX Indemnitees**") and defend and save each of them harmless, from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) (collectively, "**Losses**") to which any REGENX Indemnitee becomes subject as a result of any and all suits, investigations, claims or demands of Third Parties (collectively, "**Third Party Claims**") arising from or occurring as a result of: [****], except, [****], for those Losses for which REGENX has an obligation to indemnify PARTNER pursuant to Section 12.2 hereof, as to which Losses each Party shall indemnify the other to the extent of their respective liability.

12.2 Indemnification of PARTNER. REGENX shall indemnify PARTNER, its Affiliates, and its and their respective directors, officers, employees and agents (collectively, "**PARTNER Indemnitees**") and defend and save each of them harmless, from and against any and all Losses to which any PARTNER Indemnitee becomes subject as a result of any and all Third Party Claims arising from or occurring as a result of: [****], except, [****], for those Losses for which PARTNER has an obligation to indemnify REGENX pursuant to Section 12.1 hereof, as to which Losses each Party shall indemnify the other to the extent of their respective liability for the Losses.

12.3 Certain Losses. [****]. If either Party learns of any Third Party Claim with respect to Losses covered by this Section 12.3, such Party shall provide the other Party with prompt written notice thereof. The Parties shall confer with respect to how to respond to such Third Party Claim and how to handle such Third Party Claim in an efficient manner. In the absence of such an agreement, each Party shall have the right to take such action as it deems appropriate.

12.4 Indemnification Procedures.

12.4.1 Notice of Claim. All indemnification claims in respect of a REGENX Indemnitee or PARTNER Indemnitee shall be made solely by REGENX or PARTNER, respectively (the "**Indemnified Party**"). The Indemnified Party shall give the indemnifying Party prompt written notice (an "**Indemnification Claim Notice**") of any Losses or discovery of fact upon which such Indemnified Party intends to base a request for indemnification under this ARTICLE 12, but in no event shall the indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss is known at such time). The Indemnified Party shall furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Losses and Third Party Claims.

12.4.2 Control of Defense. The indemnifying Party shall have the right to assume the defense of any Third Party Claim by giving written notice to the Indemnified Party within [****] after the indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the indemnifying Party shall not be construed as an acknowledgment that the indemnifying Party is liable to indemnify the Indemnified Party in respect of the Third Party Claim, nor shall it constitute a waiver by the

indemnifying Party of any defenses it may assert against the Indemnified Party's claim for indemnification. Upon assuming the defense of a Third Party Claim, the indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the indemnifying Party; *provided* that it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). In the event that the indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party shall immediately deliver to the indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party in connection with the Third Party Claim. Should the indemnifying Party assume the defense of a Third Party Claim, except as provided in Section 12.4.3, the indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense or settlement of the Third Party Claim unless specifically requested in writing by the indemnifying Party. In the event that it is ultimately determined that the indemnifying Party is not obligated to indemnify, defend or hold harmless the Indemnified Party from and against the Third Party Claim, the Indemnified Party shall reimburse the indemnifying Party for any and all reasonable and verifiable costs and expenses (including attorneys' fees and costs of suit) and any Losses incurred by the indemnifying Party in accordance with this ARTICLE 12 in its defense of the Third Party Claim.

12.4.3 Right to Participate in Defense. Any Indemnified Party shall be entitled to participate in the defense of such Third Party Claim and to employ counsel of its choice for such purpose; *provided*, *however*, that such employment shall be at the Indemnified Party's sole cost and expense unless (a) the employment thereof has been specifically authorized in writing by the indemnifying Party (in which case, the defense shall be controlled as provided in Section 12.4.2), (b) the indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 12.4.2 (in which case the Indemnified Party shall control the defense) or (c) the interests of the indemnitee and the indemnifying Party with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both Parties under Applicable Law, ethical rules or equitable principles (in which case, the Indemnified Party shall control its defense).

12.4.4 Settlement. With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim and that shall not result in the applicable indemnitee(s) becoming subject to injunctive or other relief or otherwise adversely affecting the business of the Indemnified Party in any manner and as to which the indemnifying Party shall have acknowledged in writing the obligation to indemnify the applicable indemnitee hereunder, the indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Losses in connection with Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 12.4.2, the indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss; *provided* that it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). If the indemnifying Party does not assume and conduct the defense of a Third Party Claim as provided above, the Indemnified Party may defend against such Third Party Claim; *provided* that the Indemnified Party shall not settle any Third Party Claim without the prior written consent of the indemnifying Party (which consent shall not be

unreasonably withheld, conditioned or delayed).

12.4.5 Cooperation. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall and shall cause each indemnitee to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim and making indemnitees and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder and the indemnifying Party shall reimburse the Indemnified Party for all its, its Affiliates' and its and their (sub)licensees' or their respective directors', officers', employees' and agents', as applicable, reasonable and verifiable out-of-pocket expenses in connection therewith.

12.4.6 Expenses. Except as provided above, the costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party and its Affiliates and its and their (sub)licensees and their respective directors, officers, employees and agents, as applicable, in connection with any claim shall be reimbursed on a [****] basis by the indemnifying Party, without prejudice to the indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

12.5 Special, Indirect and Other Losses. EXCEPT (a) IN THE EVENT THE WILLFUL MISCONDUCT OR FRAUD OF A PARTY OR OF A PARTY'S BREACH OF ITS OBLIGATIONS UNDER ARTICLE 10 OR ARTICLE 6, (b) AS PROVIDED UNDER SECTION 14.10, OR (c) TO THE EXTENT ANY SUCH DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS ARTICLE 12, (x) NEITHER PARTY NOR ANY OF ITS AFFILIATES OR (SUB)LICENSEES SHALL BE LIABLE IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE FOR ANY SPECIAL OR PUNITIVE DAMAGES OR FOR LOSS OF PROFITS SUFFERED BY THE OTHER PARTY, AND (y) NEITHER THE GSK LICENSOR OR THE PENN LICENSOR SHALL BE LIABLE TO PARTNER, PARTNER'S SUCCESSORS OR ASSIGNS, ANY SUBLICENSEES, OR ANY THIRD PARTY WITH RESPECT TO ANY CLAIM ARISING FROM USE OF THE REGENX TECHNOLOGY OR PENN PATENTS, LICENSED PRODUCTS, AND ANY OR ALL RIGHTS LICENSED UNDER THIS AGREEMENT OR THE PENN SUBLICENSE AGREEMENT FOR THE DEVELOPMENT, TESTING, MANUFACTURE, USE, SALE, COMMERCIALIZATION OR OTHER EXPLOITATION OF LICENSED PRODUCTS.

12.6 Insurance. Each Party shall obtain and carry in full force and effect the minimum insurance requirements set forth herein from an insurance company properly licensed to provide the required insurance. Such insurance (a) shall be primary insurance with respect to each Party's own participation under this Agreement, (b) shall be issued by a recognized insurer rated by A.M. Bests [****] (or its equivalent) or better and (c) shall list PARTNER as an additional insured under the General Liability policy. The types of insurance and minimum limits are set

forth below:

(a) **Required Coverages**. Each Party shall at all times maintain in force any insurance policy that is required by any Applicable Law and at all times remain fully compliant with any such Applicable Law.

(b) **Clinical Trials Insurance**. Effective at least [****] prior to the launch of any Clinical Trial, each Party shall maintain in force Clinical Trial insurance, with a minimum limit of [****] in the aggregate to be maintained in force throughout the life of any such Clinical Trials, such insurance to be effected, maintained and documented to the other Party in compliance with this Agreement and in compliance with any and all local requirements in any territory in which such trials are conducted.

(c) **Product Liability Insurance**. Effective at least [****] prior to First Commercial Sale of Licensed Product, each Party shall maintain in force product liability insurance with a minimum limit of [****] in the aggregate.

Certificates of insurance evidencing compliance with the above requirements in this Section 12.6 shall be provided upon request. The insurance policies shall be under an occurrence form, but if only a claims-made form is available, then the Parties shall continue to maintain such insurance after the expiration or termination of this Agreement for a period of [****] following termination or expiration of this Agreement in its entirety. Notwithstanding the above, PARTNER shall have the right to self-insure any of the insurance requirements under this Agreement.

ARTICLE 13
TERM AND TERMINATION

13.1 Term and Expiration. Subject to ARTICLE 2, this Agreement shall commence on the Effective Date and, unless earlier terminated in accordance herewith, shall continue in force and effect on a country-by-country basis until (a) in the case of the United States, the later of (i) the one hundred twentieth (120th) day following the completion of any Calendar Quarter in which (A) neither Party nor any of its Affiliates or its or their sublicensees has conducted any Exploitation of a Licensed Compound or Licensed Product in the Licensed Field in the United States, (B) neither Party nor any of its Affiliates or its or their sublicensees incurred any Reimbursable Development Expenses or Allowable US Expenses in connection with the Development, Commercialization or Exploitation of Licensed Compounds or Licensed Products in the Licensed Field in the United States and (C) there is no Development Plan or Commercialization Plan in effect, *provided* that clauses (A) and (C) both remain true on such one hundred twentieth (120th) day, and (ii) the date on which there is no Royalty-Bearing Patent with respect to any Licensed Product in the United States; and (b) in the case of any country in the Royalty Territory, the date the Royalty Term for a Licensed Product for use in the Licensed Field has expired in such country (the "**Term**").

13.2 Termination.

13.2.1 Termination for Patent Challenge. In the event that PARTNER or any of its Affiliates voluntarily commences any Challenge of [****], REGENX shall have the right to immediately terminate this Agreement [****] upon written notice to

PARTNER. For the purposes of this Section 13.2.1, "**Challenge**" shall mean, with respect to a Patent, a challenge to the validity or enforceability of such Patent; *provided* that Challenge shall not include arguments, or any other statements or allegations, made by or on behalf of PARTNER or its Affiliate that: (a) distinguish the inventions claimed in Patents owned or controlled by PARTNER or its Affiliate from those claimed in such Patent (as applicable) (i) in the ordinary course of ex parte prosecution of such patents or patent applications owned or controlled by PARTNER or its Affiliate, including any reissue or reexamination patents or patent applications, or (ii) in *inter partes*, post grant review proceedings, oppositions, nullity proceedings, reissue proceedings, reexamination proceedings, and other similar proceedings before the U.S. Patent & Trademark Office or other agency or tribunal in any jurisdiction, or in any arbitration or litigation, wherein such patents or patent applications owned or controlled by PARTNER or its Affiliate have been challenged by Penn, REGENX or REGENX's Affiliates; (b) are made in connection with a response to a claim or allegation that PARTNER or its Affiliate or any of their respective direct or indirect customers infringes or may infringe any Patents controlled or enforceable by Penn, REGENX, its Affiliates, or any of their respective successors or assigns or (c) relate to the inventorship of inventions claimed in a patent or patent application or as to whether a patent or patent application should or does claim priority to another patent.

13.2.2 Material Breach.

(a) **Breach Notice**. If either Party (the "**Non-Breaching Party**") believes that the other Party (the "**Breaching Party**") is in Material Breach, then in addition to any other right and remedy the Non-Breaching Party may have, the Non-Breaching Party may deliver notice of such Material Breach to the Breaching Party that specifies the breach and its claim of right to terminate (the "**Termination Notice**"). With regard to any Material Breach by PARTNER that constitutes a material breach under the GSK Agreement, PARTNER shall have [****] (the "**GSK Notice Period**") following the receipt of such Termination Notice to cure such Material Breach. With regard to any Material Breach by PARTNER that constitutes a material breach under the Penn Agreement, PARTNER shall have [****] (the "**Penn Notice Period**") following the receipt of such Termination Notice to cure such Material Breach. With regard to any other Material Breach by either Party, the Breaching Party shall have [****] (the "**Notice Period**") following the receipt of such Termination Notice to cure such Material Breach, *provided* that for all Material Breaches other than a payment breach, if such breach cannot be reasonably cured during such [****] period but is capable of cure within [****], then the Breaching Party may submit to the Non-Breaching Party a reasonable cure plan to remedy such Material Breach that is reasonably acceptable to the Non-Breaching Party, and upon such submission, the applicable cure period will automatically be extended for so long as the Breaching Party continues to use commercially reasonable efforts to cure such Material Breach in accordance with such cure plan, but for no more than [****] from receipt of such Termination Notice (subject to the dispute resolution procedures set forth in Section 13.2.2(b) below). [****]. If the Breaching Party is REGENX and REGENX fails to cure such Material Breach within the applicable cure period set forth above, then, as applicable and subject to Section 13.2.2(b) below, PARTNER may terminate this Agreement and the Penn Sublicense Agreement in their entirety effective on written notice thereof to REGENX. [****].

(b) **Disputes Regarding Material Breach**. In each case other than with regard to a sublicense granted by REGENX to PARTNER under the Penn Agreement or

the GSK Agreement, the Breaching Party may dispute occurrence of such Material Breach, and in such case the Breaching Party shall give written notice of such dispute no later than [****] after its receipt of the Termination Notice and the issue of whether the Non-Breaching Party may properly terminate this Agreement on expiration of the applicable cure period will be resolved in accordance with Section 14.5. If as a result of such dispute resolution process, it is determined that the Breaching Party committed a Material Breach and the Breaching Party does not cure such Material Breach within (i) [****] in the case of a failure to make a payment set forth in this Agreement or (ii) [****] in the case of any other Material Breach, as applicable, after the date of such determination, (the "**Additional Cure Period**"), then such termination will be effective as of the expiration of the Additional Cure Period. Except for [****], this Agreement will remain in full force and effect during the pendency of any such dispute resolution proceeding and the cure periods set forth in this Section 13.2.2, and any Additional Cure Period, in each case, will be tolled during any such dispute resolution proceeding, such proceeding will not suspend any obligations of either Party hereunder, and each Party will use reasonable efforts to mitigate any damage. If as a result of such dispute resolution proceeding it is determined that the Breaching Party did not commit such Material Breach (or such Material Breach was cured in accordance with this Section 13.2.2), then no termination will be effective, and this Agreement will continue in full force and effect. With regard to any sublicense granted by REGENX to PARTNER under the Penn Agreement or the GSK Agreement, [****]. The issue of whether the Non-Breaching Party may properly terminate this Agreement on expiration of the applicable cure period will be resolved in accordance with Section 14.5, [****].

(c) **Invocation of Termination for Material Breach.** Notwithstanding the foregoing, the Parties agree that termination pursuant to this Section 13.2.2 is a remedy to be invoked only if the breach cannot be adequately remedied through a combination of specific performance and the payment of money damages.

(d) **Limitation on Diligence Breach Termination.** Notwithstanding anything to the contrary in this Agreement, in the event a breach by PARTNER of its diligence obligations in [****] the US [****] under Section 3.1.1 or Section 4.3 is determined to constitute a Material Breach and such Material Breach remains uncured in the applicable time period set forth in this Section 13.2.2, REGENX shall be entitled to terminate this Agreement and the Penn Sublicense Agreement solely with respect to the applicable country or countries [****], and this Agreement and the Penn Sublicense Agreement will remain in full force and effect with respect to all other countries in the Territory.

13.2.3 Termination for Convenience. PARTNER may terminate this Agreement in its entirety at any time after the Effective Date upon [****] prior written notice to REGENX thereof.

13.2.4 Termination for Safety Reasons. PARTNER may terminate this Agreement in its entirety effective immediately upon written notice to REGENX in the event that PARTNER in good faith believes that it is not advisable for PARTNER to continue to Develop or Commercialize the Licensed Products as a result of a Safety Issue; *provided* that prior to delivery of such written notice, the Senior Officers shall meet and discuss the alleged Safety Issue in good faith for not less than [****].

13.2.5 Termination for Insolvency. In the event that either Party (a) files for protection under bankruptcy or insolvency laws, (b) makes an assignment for the benefit of creditors, (c) appoints or suffers appointment of a receiver or trustee over substantially all of its property that is not discharged within [****] after such filing, (d) proposes a written agreement of composition or extension of its debts, (e) proposes or is a party to any dissolution or liquidation, (f) files a petition under any bankruptcy or insolvency act or has any such petition filed against that is not discharged within [****] of the filing thereof or (g) admits in writing its inability generally to meet its obligations as they fall due in the general course, then the other Party may terminate this Agreement and the Penn Sublicense Agreement in their entireties effective immediately upon written notice to such Party.

13.2.6 [****]

13.3 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by PARTNER or REGENX are and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that the Parties, as licensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, the Party hereto that is not a Party to such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in the non-subject Party's possession, shall be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon the non-subject Party's written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under clause (a) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party.

13.4 Consequences of Termination.

13.4.1 General. In the event of a termination of this Agreement pursuant to Section 13.2 (but, for clarity, not a termination of rights sublicensed under the GSK Agreement as described in Section 13.2.6) and subject to the proviso at the end of this Section 13.4.1:

(a) subject to clause (c) below, all of the applicable rights and licenses granted by REGENX to PARTNER hereunder and under the Penn Sublicense Agreement shall immediately terminate; *provided* that PARTNER and its Affiliates shall have the right to continue to sell their existing inventories of Licensed Product for use in the Licensed Field for a period of not more than [****] after the effective date of the termination of this Agreement or the Penn Sublicense Agreement; *provided, further*, that, at the end of such [****] period, any remaining inventories of Licensed Product may be purchased by REGENX at a price equal to PARTNER's Cost of Goods for such Licensed Products;

(b) the terms of Section 10.6 shall apply;

(c) upon the request of any Sublicensee, REGENX will enter into a direct license from REGENX to such Sublicensee on the same terms as this Agreement and, as applicable, the Penn Sublicense Agreement, taking into account any difference in license scope, territory, and duration of sublicense grant (each a "**New License Agreement**"), *provided* that such Sublicensee is not at the time of such termination in breach of its sublicense agreement. Under any such New License Agreement between REGENX and such former Sublicensee, such Sublicensee will be required to pay to REGENX the same amounts in consideration for such direct grant as REGENX would have received from PARTNER pursuant to this Agreement and, as applicable, the Penn Sublicense Agreement on account of such Sublicensee's Exploitation of Licensed Products had this Agreement and the Penn Sublicense Agreement not been terminated. Under such New License Agreement, REGENX will not be bound by any grant of rights broader than, and will not be required to perform any obligation other than those rights and obligations contained in this Agreement and the Penn Sublicense Agreement and all applicable rights of REGENX set forth in this Agreement and the Penn Sublicense Agreement shall be included in such New License Agreement. Notwithstanding the foregoing, REGENX will not be obligated to enter into a New License Agreement with a Sublicensee unless such Sublicensee notifies REGENX within [****] after the termination of this Agreement and the Penn Sublicense Agreement that it wishes to enter into a New License Agreement. All sublicenses granted by PARTNER to its Sublicensees not requested to be converted into a New License Agreement within such [****] period shall terminate; and

(d) for the avoidance of doubt, all licenses granted by PARTNER to REGENX under this Agreement with regard to the Licensed Back Improvements shall survive any termination of this Agreement; and

(e) PARTNER shall pay all monies then owed to REGENX under this Agreement within [****] of the date of such termination;

provided that, if termination of this Agreement and the Penn Sublicense Agreement is solely with respect to a country or countries as described in Section 13.2.2(d), then (x) the provisions of this Section 13.4.1 shall only apply with respect to such country or countries; *provided, further*, that, in all other cases, the provisions of this Section 13.4.1 shall apply with respect to all Terminated Products and all countries and (y) all licenses and other rights granted by REGENX to PARTNER under this Agreement and the Penn Sublicense Agreement shall (i) automatically be deemed to be amended to exclude the right to market, promote, detail, distribute, import, sell, offer for sale, or seek any Regulatory Approval for, such Terminated Product in such terminated country or countries, and (ii) otherwise survive and continue in effect in such terminated country or countries solely for purposes of supporting the Exploitation of the Licensed Compound and Licensed Product in the Licensed Field in the rest of the Territory.

13.4.2 Termination by PARTNER for Convenience or by REGENX Due to PARTNER's Patent Challenge, Material Breach or Insolvency. Subject to the rights granted to a Sublicensee who is a party to a New License Agreement and the proviso at the end of this Section 13.4.2, in the event of a termination of this Agreement and the Penn Sublicense Agreement by REGENX pursuant to Section 13.2.1, Section 13.2.2 or Section 13.2.5,

or by PARTNER pursuant to Section 13.2.3:

(a) [****];

(b) On a country-by-country and Terminated Product-by-Terminated Product basis, REGENX will pay to PARTNER a royalty on Net Sales of Terminated Products in the Territory of [****]. For the purposes of this Section 13.4.2, the definitions of "Net Sales" and the terms set forth in Section 8.3 and Sections 8.5 through 8.13 shall apply *mutatis mutandis* to the calculation, payment, recording and auditing of REGENX's obligations to make payments under this Section 13.4.2 as they apply to PARTNER under such Sections and, solely for such purpose, each reference in each such Section (and any related definitions) to (i) PARTNER will be deemed a reference to REGENX and (ii) REGENX will be deemed to be a reference to PARTNER. The obligation of REGENX to make any royalty payments with respect to any Terminated Product under this Section 13.4.2 shall terminate on a Terminated Product-by-Terminated Product and country-by-country basis, upon the expiration of the last-to-expire Valid Claim within the [****] that claims (i) the composition of matter of such Terminated Product in such country or (ii) methods of use for the treatment of all Indications for which such Terminated Product has received Regulatory Approval in such country with respect to the specific mode of administration (e.g., subretinal or suprachoroidal) of such Terminated Product;

(c) to the extent not already provided to REGENX under this Agreement, PARTNER shall use reasonable efforts to transfer to REGENX copies of any Information to the extent relating to a Terminated Product (including Product Information relating to such Licensed Product which became a Terminated Product) or included within the [****] and shall use reasonable efforts to provide to REGENX access and rights to Exploit any preclinical and clinical data, safety data and all other supporting data, including pharmacology and biology data, and Product Information, customer lists and customer contact information, in PARTNER's or its Affiliates' Control to the extent necessary for REGENX to continue the Development or Commercialization, as applicable, of Terminated Products for use in the Licensed Field;

(d) PARTNER shall and hereby does, and shall cause its Affiliates to, when and as requested by REGENX, assign to REGENX or is designee all of its right, title and interest in and to (i) each Product Trademark and the goodwill associated therewith and (ii) all Regulatory Documentation (including any Regulatory Approvals, filings and dossiers) solely and specifically related to any Terminated Product then Controlled by PARTNER or any of its Affiliates; *provided* that if any such Regulatory Documentation or Regulatory Approval is not immediately transferable in a country, PARTNER shall (A) grant REGENX or its designee a right of reference or use to any such Regulatory Documentation or Regulatory Approvals and use reasonable efforts to provide REGENX or its designee with all other benefits of such Regulatory Documentation or Regulatory Approval, as applicable, and (B) provide REGENX or its designee with such assistance and cooperation as necessary or reasonably requested by REGENX to timely transfer such Regulatory Documentation or Regulatory Approval, as applicable, to REGENX or its designee (including sign, and cause its Affiliates to sign, any instruments reasonably requested by REGENX in order to effect the above) or, at REGENX's option, to enable REGENX to obtain a substitute for such Regulatory Documentation or Regulatory Approval, as applicable, without disruption to REGENX's Exploitation of a Terminated Product, including, if requested by REGENX at its sole discretion, by appointing REGENX or its designee as the exclusive distributor

of a Terminated Product in the Territory and grant REGENX the right to appoint sub-distributors, until such time as all Regulatory Approvals in the Territory with respect to a Terminated Product have been transferred to REGENX or its designee thereto, but not to exceed [****] after the effective date of termination;

(e) unless expressly prohibited by any Regulatory Authority, at REGENX's written request, PARTNER shall and hereby does, and shall cause its Affiliates to, (i) transfer control to REGENX of any or all Clinical Trials for a Terminated Product being conducted by or on behalf of PARTNER or its Affiliates as of the effective date of termination or (ii) if such transfer is expressly prohibited by the applicable Regulatory Authority, [****], following the effective date of termination; *provided* that REGENX shall not have any obligation to continue any Clinical Trial unless required by Applicable Law;

(f) at REGENX's written request, PARTNER shall, and shall cause its Affiliates and require its and their Sublicensees to, assign to REGENX all Terminated Product Agreements, unless, with respect to any such Terminated Product Agreement, such Terminated Product Agreement expressly prohibits such assignment, in which case PARTNER (or such Affiliate, as applicable) shall cooperate with REGENX in all reasonable respects to secure the consent of the applicable Third Party to such assignment; and

(g) at REGENX's written request, if REGENX is not supplying Commercial Supply as of the date of such termination and the applicable Terminated Product Agreement(s) related to the supply of Terminated Product have not been assigned to REGENX under Section 13.4.2(f), PARTNER shall use reasonable efforts to supply to REGENX any unsold or unused inventory [****] at PARTNER's actual, fully-burdened cost (excluding costs for general overhead, communications, operating supplies or other equipment) to Manufacture a Terminated Product until the earlier of [****];

(h) *provided* that, if termination of this Agreement and the Penn Sublicense Agreement is solely with respect to a country or countries as described in Section 13.2.2(d), then the provisions of this Section 13.4.2 shall only apply with respect to the Terminated Products in such country or countries; *provided, further* that, in all other cases of a termination of this Agreement and the Penn Sublicense Agreement by REGENX pursuant to Section 13.2.1, Section 13.2.2 or Section 13.2.5, or by PARTNER pursuant to Section 13.2.3, the provisions of this Section 13.4.2 shall apply with respect to all Terminated Products and all countries.

13.5 Remedies. Except as otherwise expressly provided herein, termination of this Agreement and the Penn Sublicense Agreement in accordance with the provisions hereof shall not limit remedies that may otherwise be available in law or equity.

13.6 Alternative Remedy in Lieu of Termination. If PARTNER has the right to terminate this Agreement pursuant to Section 13.2.2 or Section 13.2.5, then in lieu of terminating this Agreement PARTNER may, in its sole discretion, exercise an alternative remedy as follows:

13.6.1 PARTNER may retain all of its licenses and other rights granted under this Agreement and the Penn Sublicense Agreement, subject to all of its payment and other obligations, and, except that (a) [****] effective from and after the delivery of the applicable notice

of breach, and (b) PARTNER's obligations under Section 3.1 and Section 4.3 will terminate, [****];

13.6.2 PARTNER will have the right to conduct any activities allocated to REGENX under the Development Plan or the Commercialization Plan, and all activities under such plan will be deemed to be allocated to PARTNER for the purposes of this Agreement;

13.6.3 PARTNER will have the right to assume all obligations allocated to REGENX under this Agreement, the Clinical Supply Agreement or the Commercial Supply Agreement with respect to the Manufacture and supply of Clinical Supply or Commercial Supply;

13.6.4 Upon PARTNER's written request, REGENX shall, at its expense, (a) transfer to PARTNER or any such designee all REGENX Know-How that is necessary or reasonably useful to conduct the activities set forth in Section 13.6.2 or 13.6.3 above so as to enable PARTNER to conduct such activities, and (b) provide such support as may be necessary or reasonably useful to PARTNER or any of its Affiliates or subcontractors to conduct the activities set forth in Section 13.6.2 or 13.6.3;

13.6.5 [****]; and

13.6.6 any Confidential Information of PARTNER provided to REGENX pursuant to this Agreement will be promptly returned to PARTNER or destroyed.

For the avoidance of doubt, except as set forth in this Section 13.6, if PARTNER exercises the alternative remedy set forth above in this Section 13.6, then all rights and obligations of both Parties under this Agreement and the Penn Sublicense Agreement will continue unaffected, unless and until this Agreement and the Penn Sublicense Agreement are subsequently terminated by either Party pursuant to this ARTICLE 13.

13.7 Assumption of Development and Manufacturing Activities Following Termination of Third Party License Agreements. Without limiting any other remedy of PARTNER under this Agreement (including Section 13.6) or Applicable Law, if any Third Party Licensor terminates its respective Third Party License Agreement with REGENX, and such termination is through no fault of PARTNER or any of its Affiliates or Sublicensees (including any termination for any failure by REGENX to pay any amounts due thereunder), then in addition to any other remedies available to PARTNER at law or in equity, PARTNER may, by written notice to REGENX, elect to continue this Agreement and the Penn Sublicense Agreement as modified by Section 13.6, in which case, effective as of the date PARTNER delivers such notice of such election to PARTNER:

13.7.1 PARTNER will have the right to conduct any activities allocated to REGENX under the Development Plan or the Commercialization Plan, and all activities under such plan will be deemed to be allocated to PARTNER for the purposes of this Agreement with PARTNER having final decision-making authority at the Joint Committees for such activities but with the cost sharing allocation for such activities remaining the same as prior to PARTNER's assumption of such activities;

13.7.2 PARTNER will have the right to assume all obligations allocated to REGENX under this Agreement, the Clinical Supply Agreement or the Commercial Supply Agreement with respect to the Manufacture and supply of Clinical Supply or Commercial Supply;

13.7.3 Upon PARTNER's written request, REGENX shall, at its own expense (a) transfer to PARTNER or any such designee all REGENX Know-How that is necessary or reasonably useful to conduct the activities set forth in Section 13.7.1 or 13.7.2 above so as to enable PARTNER to conduct such activities, and (b) provide such support as may be necessary or reasonably useful to PARTNER or any of its Affiliates or subcontractors to conduct the activities set forth in Section 13.7.1 or 13.7.2; and

13.7.4 [****].

13.8 Accrued Rights; Surviving Obligations. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination or expiration. Such termination or expiration shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement. Without limitation of the foregoing, Sections 3.4.1 (with respect to, and for the duration, that Development Records are required to be maintained following the effective date of termination or expiration of this Agreement), 3.7 (with respect to Licensed Product under this Agreement), 4.4.1 (with respect to, and for the duration, that Commercialization records are required to be maintained following the effective date of termination or expiration of this Agreement), 8.2-8.7 (only to the extent related to an obligation arising (or activities conducted) prior to the effective date of termination or expiration of this Agreement), 8.9, 8.10, 8.11 (for the specified duration set forth therein), 8.12 (for the specified duration set forth therein), 8.13, 9.5.2, 9.7 (with respect to PARTNER's obligations, solely to the extent that the [****] expressly extend beyond the effective date of termination or expiration), 9.8, 10.1 (for the specified duration set forth therein), 10.2, 10.6, 11.5 (except for Section 11.5.5 and solely in the event of an expiration of this Agreement to the extent any relevant licenses under REGENX Know-How continue to be granted to PARTNER), 13.3-13.7 and this Section 13.8, ARTICLE 12 and ARTICLE 14, and Schedule 1 (only to the extent such defined terms are used in the surviving provisions) of this Agreement shall survive the termination or expiration of this Agreement for any reason.

ARTICLE 14
MISCELLANEOUS

14.1 Force Majeure. Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement (other than an obligation to make payments) when such failure or delay is caused by or results from events beyond the reasonable control of the non-performing Party, including fires, floods, earthquakes, hurricanes, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, civil commotion, strikes (whether involving the workforce of the non-performing Party or of any other Person), acts of God or acts, omissions or delays in acting by any Governmental Authority (except to the extent such delay results from the breach by the non-performing Party or any of its Affiliates of any term or condition of this Agreement). [****]. The

non-performing Party shall notify the other Party of such force majeure within [****] after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use commercially reasonable efforts to remedy its inability to perform.

14.2 Export Control. This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries that may be imposed on the Parties from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other Governmental Authority in accordance with Applicable Law.

14.3 Assignment. Neither Party may assign its rights or, except as provided in Section 3.5, Section 4.6, [****], delegate its obligations under this Agreement, whether by operation of law or otherwise, in whole or in part without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed, except that each Party shall have the right, without such consent, (a) to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any of its Affiliates, and (b) assign any or all of its rights and delegate any or all of its obligations hereunder to any of its Affiliates or to any successor in interest (whether by merger, acquisition, asset purchase or otherwise) to all or substantially all of the business to which this Agreement relates; *provided* that such Party shall provide written notice to the other Party within [****] after such assignment or delegation. Any permitted successor of a Party or any permitted assignee of all of a Party's rights, in each case except for an Affiliate, under this Agreement that has also assumed all of such Party's obligations hereunder in writing shall, upon any such succession or assignment and assumption, be deemed to be a party to this Agreement as though named herein in substitution for the Assigning Party, whereupon the Assigning Party shall cease to be a party to this Agreement and shall cease to have any rights or obligations under this Agreement. All validly assigned rights of a Party shall inure to the benefit of and be enforceable by, and all validly delegated obligations of such Party shall be binding on and be enforceable against, the permitted successors and assigns of such Party. Any attempted assignment or delegation in violation of this Section 14.3 shall be void and of no effect.

14.4 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom and (d) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties. To the fullest extent permitted by Applicable Law, each Party hereby waives any provision of law that would render any provision hereof illegal, invalid or unenforceable in any respect.

14.5 Dispute Resolution.

14.5.1 General. Except as provided in Section 8.13 or Section 14.10, if a dispute arises in connection with or relating to this Agreement or any document or instrument delivered in connection herewith (a "**Dispute**"), then such Dispute shall be resolved pursuant to this Section 14.5. Any Dispute shall first be referred to the Senior Officers of the Parties, who shall confer in good faith on the resolution of the issue. Any final decision mutually agreed to by the Senior Officers shall be conclusive and binding on the Parties. If the Senior Officers are not able to agree on the resolution of any such issue within [****] (or such other period of time as mutually agreed by the Senior Officers) after such issue was first referred to them, then, subject to Section 14.5.5, either Party may, by written notice to the other Party, elect to initiate an alternative dispute resolution ("**ADR**") proceeding pursuant to the procedures set forth in Section 14.5.2 for purposes of having the matter settled.

14.5.2 ADR. Any ADR proceeding under this Agreement shall take place pursuant to the procedures set forth in Schedule 14.5.2.

14.5.3 Adverse Ruling. Any determination pursuant to this Section 14.5 that a Party is in Material Breach shall specify a (nonexclusive) set of actions to be taken to cure such Material Breach, if feasible.

14.5.4 Interim Relief and Tolling. Notwithstanding anything herein to the contrary, nothing in this Section 14.5 shall preclude either Party from seeking interim or provisional relief, including a temporary restraining order, preliminary injunction or other interim equitable relief concerning a Dispute following the ADR procedures set forth in Section 14.5.2, if necessary to protect the interests of such Party. This Section shall be specifically enforceable.

14.5.5 Intellectual Property Disputes. In the event that a Dispute arises with respect to the validity, patentability, or enforceability of any Patent, and such Dispute cannot be resolved in accordance with Section 14.5.1, unless otherwise agreed by the Parties in writing, such Dispute shall not be submitted to an ADR proceeding in accordance with Section 14.5.2 and instead, either Party may initiate litigation or proceeding in a court or governmental agency of competent jurisdiction, notwithstanding Section 14.6, in any country or other jurisdiction in which such rights apply.

14.6 Governing Law, Jurisdiction and Service.

14.6.1 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. The Parties agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.

14.6.2 Jurisdiction. Subject to Section 14.5 and Section 14.10, the Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of the courts of the State of New York for any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement and agree not to commence any action, suit or proceeding (other than appeals therefrom) related thereto except in such courts. The Parties irrevocably and

unconditionally waive their right to a jury trial.

14.6.3 Venue. The Parties further hereby irrevocably and unconditionally waive any objection to the laying of venue of any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement in the courts of the State of New York and hereby further irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum.

14.6.4 Service. Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 14.7.2 shall be effective service of process for any action, suit or proceeding brought against it under this Agreement in any such court.

14.7 Notices.

14.7.1 Notice Requirements. Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if delivered by hand or sent by internationally recognized overnight delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in Section 14.7.2 or to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section 14.7.1. Such notice shall be deemed to have been given as of the date delivered by hand or on the [****] (at the place of delivery) after deposit with an internationally recognized overnight delivery service. This Section 14.7.1 is not intended to govern the day-to-day business communications necessary between the Parties in performing their obligations under the terms of this Agreement.

14.7.2 Address for Notice.

If to PARTNER, to:

AbbVie Global Enterprises Ltd.
4th floor, Washington House
16 Church Street
Hamilton HM 11
Bermuda

with a copy (which shall not constitute notice) to:

AbbVie Inc.
1 North Waukegan Road
North Chicago, Illinois 60064
United States
Attention: General Counsel

Ropes & Gray LLP
800 Boylston Street, Prudential Tower
Boston, MA 02199
United States
Attention: Amanda F. Austin

If to REGENX, to:

REGENXBIO Inc.
9804 Medical Center Drive
Rockville, MD 20850
United States
Attention: Chief Executive Officer

with a copy (which shall not constitute notice) to:

REGENXBIO Inc.
9804 Medical Center Drive
Rockville, MD 20850
United States
Attention: Chief Legal Officer

14.8 Entire Agreement; Amendments. This Agreement, together with the Penn Sublicense Agreement and the Schedules attached hereto and thereto, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understandings, promises and representations, whether written or oral, with respect thereto are superseded hereby. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth in this Agreement, the Penn Sublicense Agreement and the Schedules attached hereto and thereto. No amendment, modification, release or discharge shall be binding on the Parties unless in writing and duly executed by authorized representatives of both Parties. All Schedules to this Agreement are expressly and hereby incorporated by reference into this Agreement and all references to the "Agreement" (whether in the body of the Agreement or the Schedules hereto), shall refer to the body of this Agreement and all Schedules hereto collectively.

14.9 English Language. This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

14.10 Equitable Relief. Each Party acknowledges and agrees that the restrictions set forth in ARTICLE 6 and ARTICLE 10 of this Agreement are reasonable and necessary to protect the legitimate interests of the other Party and that such other Party would not have entered into this Agreement in the absence of such restrictions and that any breach or threatened breach of any provision of such Articles may result in irreparable injury to such other Party for which there will be no adequate remedy at law. Nothing in this Section 14.10 is intended or should be construed, to limit either Party's right to equitable relief or any other remedy for a breach of any other provision of this Agreement.

14.11 Waiver and Non-Exclusion of Remedies. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party hereto of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set forth herein.

14.12 No Benefit to Third Parties. Except as provided in ARTICLE 12, covenants and agreements set forth in this Agreement are for the sole benefit of the Parties hereto and their successors and permitted assigns and they shall not be construed as conferring any rights on any other Persons.

14.13 Further Assurances. Each Party shall duly execute and deliver or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be reasonably necessary to carry out the intent and purposes of this Agreement.

14.14 Relationship of the Parties. It is expressly agreed that REGENX, on the one hand and PARTNER, on the other hand, are not Affiliates, shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency, including for all tax purposes. Neither REGENX, on the one hand, nor PARTNER, on the other hand, shall have the authority to make any statements, representations or commitments of any kind, or to take any action, that will be binding on the other, without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such first Party.

14.15 References. Unless otherwise specified, (a) references in this Agreement to any Article, Section or Schedule shall mean references to such Article, Section or Schedule of this Agreement, (b) references in any Section to any clause are references to such clause of such Section and (c) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently amended, replaced or supplemented from time to time, as so amended, replaced or supplemented and in effect at the relevant time of reference thereto.

14.16 Construction. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including," "include," or "includes" as used herein shall mean including, without limitation of the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party hereto.

14.17 Counterparts. This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed by PDF format via email or other electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were original signatures.

[SIGNATURE PAGE FOLLOWS.**]**

THIS AGREEMENT IS EXECUTED by the authorized representatives of the Parties as of the date first written above.

ABBVIE GLOBAL ENTERPRISES LTD.	**REGENXBIO INC.**
By: /s/ Jonathan C. Clipper	By: /s/ Kenneth Mills
Name: Jonathan C. Clipper	Name: Kenneth Mills
Title: Director	Title: President & CEO

Schedule 1
Definitions

1.1. "**AAV8**" means (a) the recombinant adeno-associated virus serotype 8 vector with the specified sequence set forth in GenBank [****] and (b) any recombinant adeno-associated virus derivatives of such serotype 8 vector that are Covered by the claims of the REGENX Patents or Penn Patents.

1.2. "**Accounting Standards**" means, with respect to a Party, that such Party shall maintain records and books of accounts in accordance with United States Generally Accepted Accounting Principles.

1.3. "**Additional Cure Period**" shall have the meaning set forth in Section 13.2.2.

1.4. "**Additional Indication**" means a disease in humans treated by *in vivo* gene therapy using any Licensed Compound or Licensed Product in the field of ophthalmology via administration to the eye, excluding DR and nAMD.

1.5. "**ADR**" shall have the meaning set forth in Section 14.5.1.

1.6. "**Affiliate**" means, with respect to a Person, any other Person that, directly or indirectly, through one (1) or more intermediaries, controls, is controlled by or is under common control with such first Person for so long as such other Person controls, is controlled by or is under common control with such first Person. For purposes of this definition, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" means: (a) the possession, directly or indirectly, of the power to direct the management or policies of a business entity, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance or otherwise; or (b) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of a business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity).

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

1.8. "**Alliance Manager**" has the meaning set forth in Section 7.4.5.

1.9. "**Allowable Development Expenses**" means, with respect to a Party, the following expenses determined in accordance with the Accounting Standards that are incurred by such Party and are directly attributable or reasonably allocable to the Development of a Licensed Product for use in the Licensed Field in accordance with the Development Plan. Except in the case of Development costs incurred in accordance with clause (g) below, Development costs shall be limited to Development activities that are specifically identified or otherwise referenced in the Development Plan; *provided* that such costs shall be included in Allowable Development Expenses only to the extent less than or equal to the amounts set forth in the applicable Development Plan and related Budget for such Development activities. Subject to the foregoing, Allowable

Development Expenses shall include such costs in connection with the following activities, as applicable:

[****]. The components of Allowable Development Expenses shall be calculated in accordance with the applicable definition thereof and the applicable terms of this Agreement. [****]. If any cost or expense is directly attributable and reasonably allocable to more than one (1) category under "Allowable Development Expenses" such cost or expense shall only be counted as an Allowable Development Expense with respect to one (1) such category.

1.10. "**Allowable Overruns**" means, with respect to any Allowable Development Expenses, any amounts incurred by or on behalf of a Party in the performance of activities allocated to such Party under the Development Plan in a given [****] that (a) are not attributable to any breach of this Agreement, and (b) are in excess of the aggregate amount budgeted in the Development Plan for such Party in such [****] (i) by an amount not to exceed [****] or (ii) that are otherwise approved [****] (in the case of Allowable Development Expenses).

1.11. "**Allowable US Expenses**" means, with respect to a Party and a particular period of time during the Term, the following expenses (x) that are incurred by such Party during such period and are directly attributable and reasonably allocable to the Commercialization of a Licensed Product for use in the Licensed Field in the United States and (y) with respect to clauses (a) through (h), solely to the extent provided for in and consistent with the applicable Commercialization Plan and the related Budget:

[****]. The components of Allowable US Expenses shall be calculated in accordance with the applicable definition thereof and the applicable terms of this Agreement. [****]. If any cost or expense is directly attributable and reasonably allocable to more than one (1) category under "Allowable US Expenses" such cost or expense shall only be counted as an Allowable US Expense with respect to one (1) such category.

1.12. "**Amount**" has the meaning set forth in Section 8.9.1.

1.13. "**Anti-Corruption Laws**" means the U.S. Foreign Corrupt Practices Act, as amended, the UK Bribery Act 2010, as amended, and any other applicable anti-corruption laws and laws for the prevention of fraud, racketeering, money laundering or terrorism.

1.14. "**Applicable Law**" means applicable laws, rules, regulations, including any rules, regulations, guidelines, or other requirements of the Regulatory Authorities, and generally acceptable industry codes, including the PhRMA Code, that may be in effect from time to time, including the FFDCA and the Anti-Corruption Laws.

1.15. "**Assigning Party**" has the meaning set forth in Section 8.9.2.

1.16. "**Auditor**" has the meaning set forth in Section 8.13.

1.17. "**Bayh-Dole Act**" means the Patent and Trademark Law Amendments Act of 1980, as amended, codified at 35 U.S.C. §§ 200-212, as amended, as well as any regulations promulgated pursuant thereto, including in 37 C.F.R. Part 401.

1.18. "**Biosimilar Application**" has the meaning set forth in Section 9.10.9.

1.19. "**Biosimilar Product**" means, with respect to a Licensed Product for use in a particular Indication in the Licensed Field in a particular country in the Territory, any pharmaceutical product that is claimed to be biosimilar to or interchangeable with such Licensed Product (including a product that is the subject of an application submitted under Section 351(k) of the PHSA in the United States or under Article 10(4) of Directive 2001/83/EC in the European Union or any member state thereof, in each case citing such Licensed Product as the reference product).

1.20. "**BLA**" means (a) a Biologics License Application submitted to the FDA pursuant to 21 CFR § 601.2 (or an successor regulation thereto) or a New Drug Application filed with the FDA as described in 21 C.F.R. § 314., (b) any equivalent of a United States BLA in other countries or regulatory jurisdictions, as applicable, and (c) all supplements, amendments, variations, extensions and renewals thereof that may be filed with respect to the foregoing.

1.21. "**Board of Directors**" has the meaning set forth in the definition of Change of Control.

1.22. "**Breaching Party**" has the meaning set forth in Section 13.2.2.

1.23. "**Budget**" means, as the context requires, the total budgeted costs and expenses for (a) Development, (b) Manufacturing or (c) Commercialization, in each case as agreed by the Parties and as attached to, as applicable, the Development Plan or the Commercialization Plan, which Budget (i) shall define the amount of funds to be paid by each Party as well as the allocation and use of such funds and (ii) may be amended from time to time through the JDC (in the case of the Budget for the Development Plan) or JCC (in the case of the Budget for the Commercialization Plan).

1.24. "**Business Day**" means a day other than a Saturday or Sunday or a day on which banking institutions in Chicago, Illinois or New York, New York are permitted or required to be closed.

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

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

1.27. "**Change of Control**" with respect to a Party, shall be deemed to have occurred if any of the following occurs after the Effective Date:

1.27.1. any "person" or "group" (as such terms are defined below) (a) is or becomes the "beneficial owner" (as defined below, except that a "person" or "group" shall be deemed to have "beneficial ownership" of all shares of capital stock or other equity interests if such person or group has the right to acquire, whether such right is exercisable immediately or only after the passage of time), directly or indirectly, shares of capital stock or other interests (including partnership interests) of such Party then outstanding and normally entitled (without regard to the occurrence of any contingency) to vote in the election of the directors, managers or similar supervisory positions ("**Voting Stock**") of such Party representing fifty percent (50%) or more of the total voting power of all outstanding classes of Voting Stock of such Party or (b) has the power, directly or indirectly, to elect a majority of the members of the Party's board of directors or similar governing body ("**Board of Directors**");

1.27.2. such Party enters into a merger, consolidation or similar transaction with another Person (whether or not such Party is the surviving entity) and as a result of such merger, consolidation or similar transaction (a) the members of the Board of Directors of such Party immediately prior to such transaction constitute less than a majority of the members of the Board of Directors of such Party or such surviving Person immediately following such transaction or (b) the Persons that beneficially owned, directly or indirectly, the shares of Voting Stock of such Party immediately prior to such transaction cease to beneficially own, directly or indirectly, shares of Voting Stock of such Party representing at least a majority of the total voting power of all outstanding classes of Voting Stock of the surviving Person in substantially the same proportions as their ownership of Voting Stock of such Party immediately prior to such transaction;

1.27.3. such Party sells or transfers to any Third Party, in one or more related transactions, properties or assets representing all or substantially all of such Party's consolidated total assets to which this Agreement relates; or

1.27.4. the holders of capital stock of such Party approve a plan or proposal for the liquidation or dissolution of such Party.

For the purpose of this definition of Change of Control: (a) "person" and "group" have the meanings given such terms under Section 13(d) and 14(d) of the United States Securities Exchange Act of 1934 and the term "group" includes any group acting for the purpose of acquiring, holding or disposing of securities within the meaning of Rule 13d-5(b)(1) under the aforesaid Act; (b) a "beneficial owner" shall be determined in accordance with Rule 13d-3 under the aforesaid Act; and (c) the terms "beneficially owned" and "beneficially own" shall have meanings correlative to that of "beneficial owner."

1.28. [****]

1.29. [****]

1.30. "**Clinical Quality Agreement**" has the meaning set forth in Section 5.1.2.

1.31. "**Clinical Supply**" has the meaning set forth in Section 5.1.1.

1.32. "**Clinical Supply Agreement**" has the meaning set forth in Section 5.1.2.

1.33. "**Clinical Trial**" means, with respect to a therapeutic, a human clinical trial of such therapeutic intended to determine safety and efficacy in the target patient population, including the trials referred to in 21 C.F.R. §312.21, as amended.

1.34. "**CMC Data**" means the chemistry, manufacturing and controls data for a Licensed Product required by Applicable Law to be included or referenced in, or that otherwise supports, an IND or application for Regulatory Approval.

1.35. "**Collaboration Know-How**" means any Information that is (a) not generally known and (b) developed or invented during the Term by or on behalf of a Party or any of its Affiliates, either alone or jointly, in the performance of any activities relating to the Exploitation of any Licensed Compound or Licensed Product under this Agreement.

1.36. "**Collaboration Patents**" means any Patent that (a) has a priority date after the Effective Date and (b) claims an invention made during the Term by or on behalf of a Party or any of its Affiliates, either alone or jointly, in the performance of any activities relating to the Exploitation of any Licensed Compound or Licensed Product under this Agreement.

1.37. "**Combination Product**" means a Licensed Product that is comprised of or contains a Licensed Compound as an active ingredient together with one (1) or more other active ingredients and is sold either as a fixed dose/unit or as separate doses/units as one (1) product.

1.38. "**Commercial Quality Agreement**" has the meaning set forth in Section 5.2.2(a).

1.39. "**Commercial Sale**" means, with respect to a Licensed Product for use in the Licensed Field, a *bona fide* sale, use, lease, transfer or other disposition for value of a Licensed Product for use in the Licensed Field by PARTNER, its Affiliates or any Sublicensees to a Third Party. Sales between or among PARTNER and its Affiliates or any Sublicensees shall not be deemed a "Commercial Sale", except where such Affiliates or Sublicensees are end users, but "Commercial Sales" shall include the subsequent final sales to Third Parties by such Affiliates or Sublicensees.

1.40. "**Commercial Supply**" has the meaning set forth in Section 5.2.1(a)

1.41. "**Commercial Supply Agreement**" has the meaning set forth in Section 5.2.2(a).

1.42. "**Commercialization**" means any and all activities related to the preparation for sale of, offering for sale of or sale of a product or service, including activities related to marketing, using, selling, offering to sell, final (commercial and secondary) packaging and labeling (both in and outside of the United States), promoting, warehousing, distributing, having imported, importing, exporting, having exported or other commercialization of such product or service, and interacting with Regulatory Authorities or other Governmental Authorities regarding any of the foregoing, but excluding Development and Process Development. When used as a verb, "**to Commercialize**" and "**Commercializing**" means to engage in Commercialization and "**Commercialized**" has a corresponding meaning.

1.43. "**Commercialization Plan**" has the meaning set forth in Section 4.2.2.

1.44. "**Commercially Reasonable Efforts**" [****].

1.45. "**Competing Activities**" has the meaning set forth in Section 6.1.

1.46. "**Competing Products**" has the meaning set forth in Section 6.1.

1.47. "**Competition Laws**" means any antitrust or competition related Applicable Laws intended to prevent market distortion caused by anti-competitive practices on the part of businesses, including the HSR Act.

1.48. "**Confidential Information**" has the meaning set forth in Section 10.1.

1.49. "**Control**" means, subject to Section 9.13, with respect to any item of Information, Regulatory Documentation, material, Patent or other intellectual property right, possession of the right, whether directly or indirectly and whether by ownership, license or otherwise (other than by operation of the license and other grants in this Agreement and the Penn Sublicense Agreement), to grant a license, sublicense or other right (including the right to reference Regulatory Documentation) to or under such Information, Regulatory Documentation, material, Patent or other intellectual property right as provided for herein without violating the terms of any agreement with any Third Party or Applicable Law. Notwithstanding any provision set forth in this Agreement to the contrary, a Person will not be deemed to "Control" any Information, Regulatory Documentation, material, Patent or other intellectual property right that is owned or in-licensed by any Third Party that becomes an Affiliate of such Person after the Effective Date as a result of a Change of Control of such Person or any Third Party that obtains an assignment of this Agreement in accordance with Section 14.3 unless (a) prior to the consummation of such Change of Control or assignment, such acquired (or assigning) Person or any of its Affiliates also Controlled such Information, Regulatory Documentation, material, Patent or other intellectual property rights owned or in-licensed by such Third Party, (b) any such Information, Regulatory Documentation, material, Patent or other intellectual property rights owned or in-licensed by such Third Party was generated by employees or consultants of such Third Party in the performance of activities under this Agreement after such Change of Control or assignment or (c) the Information, Regulatory Documentation, material, Patent or other intellectual property rights owned or in-licensed by such Third Party were not used in the performance of activities under this Agreement prior to the consummation of such Change of Control or assignment, but after the consummation of such Change of Control or assignment, such acquired (or assigning) Person or any of its Affiliates uses any such Information, Regulatory Documentation, material, Patent or other intellectual property rights in the performance of activities under this Agreement.

1.50. "**Corporate Names**" means (a) with respect to REGENX, the Trademarks, names and logos identified on Schedule 1.50(a) and such other Trademarks, names and logos as REGENX may designate in writing from time to time, and (b) with respect to PARTNER, the Trademarks, names and logos identified on Schedule 1.50(b) and such other Trademarks, names and logos as PARTNER may designate in writing from time to time.

1.51. "**Cost of Goods**" means, with respect to a product:

1.51.1. to the extent such product is Manufactured by a Third Party for a Party, [****]

1.51.2. to the extent such product is Manufactured directly by a Party or any of its Affiliates, [****].

1.52. "**Cover**" means, with respect to any particular subject matter at issue and any relevant Patent or individual claim in such Patent, as applicable, that the Development, Manufacture, Commercialization, use, sale, offer for sale, importation, or other Exploitation of such subject matter would, but for ownership of or a license under such Patent or such individual claim, infringe such Patent or such individual claim.

1.53. "**Data Breach**" has the meaning set forth in Section 11.9.3.

1.54. "**Data Security and Privacy Laws**" means all Applicable Laws relating to the privacy, Processing and security of Personal Data.

1.55. "**Delivery System**" means any delivery system meant to assist in the administration of a Licensed Compound or Licensed Product in the Licensed Field.

1.56. "**Detail**" means, with respect to a Licensed Product for use in the Licensed Field in the United States, a direct contact between a sales representative and a physician or other medical professional licensed to prescribe drugs, during which a detail is made to such person, in each case as measured by each Party's internal recording of such activity in accordance with the Commercialization Plan; *provided* that such meeting is consistent with and in accordance with the requirements of Applicable Law and this Agreement. When used as a verb, "**Detail**" means to engage in a Detail.

1.57. "**Development**" means all activities related to research, pre-clinical and other non-clinical testing, test method development and stability testing, toxicology, formulation, Clinical Trials, including Manufacturing in support thereof, statistical analysis and report writing, the preparation and submission of INDs and BLAs, regulatory affairs with respect to the foregoing and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Regulatory Approval, excluding Process Development (other than Process Development included by way of reference to Manufacturing in support in Clinical Trials). When used as a verb, "**Develop**" means to engage in Development.

1.58. "**Development Plan**" means, with respect to a Licensed Product for use in the Licensed Field, the written plan for conducting Development activities with respect to a Licensed Product for use in the Licensed Field as further described in Section 3.2.

1.59. "**Development Records**" has the meaning set forth in Section 3.4.1.

1.60. "**Dispute**" has the meaning set forth in Section 14.5.1.

1.61. [****].

1.62. "**Distribution Costs**" means, to the extent not included in a Party's Cost of Goods for a Licensed Product for use in the Licensed Field for sale or distribution in the United States, or a Permitted Deduction, the FTE Costs (charged in accordance with Section 8.5.4), and the direct Out-of-Pocket Costs recorded as an expense by a Party or any of its Affiliates after the Effective Date, during the Term pursuant to this Agreement (as agreed to by the Parties from time to time) that are directly attributable and reasonably allocable to the following activities for the commercial distribution of a Licensed Product for use in the Licensed Field to a Third Party in the United States: [****].

1.63. "**DOJ**" means the United States Department of Justice, or any successor United States governmental agency performing similar functions.

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

1.65. "**Domain Antibody**" [****].

1.66. "**DR**" means diabetic retinopathy without diabetic macular edema.

1.67. "**DR Suprachoroidal Treatment**" means the treatment of DR in humans by *in vivo* gene therapy using any Licensed Compound or Licensed Product delivered suprachoroidally.

1.68. "**Effective Date**" has the meaning set forth in Section 2.1.

1.69. "**EMA**" means the European Medicines Agency and any successor agency thereto in the European Union with responsibilities comparable to those of the European Medicines Agency.

1.70. "**Enforcing Party**" has the meaning set forth in Section 9.10.7.

1.71. "**European Union**" or "**EU**" means the economic, scientific and political organization of member states as it may be constituted from time to time and for the purposes of this Agreement shall include the United Kingdom ("**UK**").

1.72. "**Excess Commercialization Expenses**" has the meaning set forth in Section 4.5.2.

1.73. "**Excess Development Expenses**" has the meaning set forth in Section 3.3.2.

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

1.75. [****].

1.76. "**Existing Inventory**" has the meaning set forth in Section 5.1.1.

1.77. "**Exploit**" means to make, have made, import, use, sell or offer for sale, including to research, Develop, have Developed, Commercialize, have Commercialized, register,

Manufacture, have Manufactured, hold or keep (whether for disposal or otherwise), have used, export, transport, distribute, promote, market or have sold or otherwise dispose of. "**Exploitation**" means the act of Exploiting a compound, product or process.

1.78. "**FDA**" means the United States Food and Drug Administration and any successor agency thereto in the United States with responsibilities comparable to those of the United States Food and Drug Administration.

1.79. "**FFDCA**" means the United States Federal Food, Drug, and Cosmetic Act, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).

1.80. "**Finance Working Group**" has the meaning set forth in Section 8.8.

1.81. "**First Commercial Sale**" means, with respect to a Licensed Product for use in a particular Indication in the Licensed Field and a country, the first Commercial Sale of such Licensed Product in such country after Regulatory Approval for such Licensed Product has been obtained in such country. Sales prior to receipt of Regulatory Approval for a Licensed Product for use in a particular Indication in the Licensed Field, such as so-called "treatment IND sales," "named patient sales," and "compassionate use sales," shall not be construed as a First Commercial Sale.

1.82. "**FTC**" means the United States Federal Trade Commission, or any successor United States governmental agency performing similar functions.

1.83. "**FTE**" means the equivalent of the work of one (1) employee full time for one (1) Calendar Year (consisting of at least a total of [****]) of work directly related to the Development, Commercialization or Manufacturing of a Licensed Product for use in the Licensed Field. No additional payment shall be made with respect to any person who works more than [****] and any person who devotes less than [****] (or such other number as may be agreed by the Parties, as applicable) shall be treated as an FTE on a pro rata basis based upon the actual number of hours worked divided by [****].

1.84. "**FTE Costs**" means, with respect to a Party for any period, the applicable FTE Rate multiplied by the applicable number of FTEs of such Party performing Development, Commercialization or Manufacturing activities during such period in accordance with the Development Plan and applicable Commercialization Plan, including the Budget therefor.

1.85. "**FTE Rate**" means [****], which represents the fully burdened rate for such FTE and includes all Included FTE Costs and Expenses for such FTE. [****].

1.86. "**Global Clinical Trial**" means any Clinical Trial that is intended to support a Regulatory Approval for a Licensed Product in the Licensed Field both in the United States and in any other country in the Territory.

1.87. "**Global Commercialization Strategy**" has the meaning set forth in Section 4.2.1.

1.88. "**GMP**" means current good manufacturing practices as specified in 21 C.F.R. Parts 11, 210 and 211, ICH Guideline Q7A, or equivalent laws, rules or regulations of an applicable Regulatory Authority at the time of manufacture.

1.89. "**Governmental Authority**" means any supranational, national, state, municipal, local or foreign government, any court, tribunal, arbitrator, administrative agency, commission or other governmental official, authority or instrumentality, in each case whether domestic or foreign, any stock exchange or similar self-regulatory organization or any quasi-governmental or private body exercising any regulatory, taxing or other governmental or quasi-governmental authority.

1.90. "**GSK Agreement**" means that certain License Agreement entered into between REGENX and SmithKline Beecham Corporation, effective on March 6, 2009, as amended by that certain Amendment to License Agreement dated April 15, 2009, and as further amended from time to time in accordance with this Agreement.

1.91. "**GSK Licensor**" means SmithKline Beecham Corporation (or any assignee or successor thereto under the GSK Agreement), if any REGENX Patents are sublicensed pursuant the GSK Agreement.

1.92. "**GSK Notice Period**" has the meaning set forth in Section 13.2.2.

1.93. "**GSK Patents**" means any REGENX Existing Patents that are licensed to REGENX pursuant to the GSK Agreement.

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

1.95. "**Included FTE Costs and Expenses**" means the sum of all costs and expenses for the employee performing any Development, Commercialization or Manufacturing, as applicable, activities hereunder, including [****] to the extent required for the performance of the applicable Development, Commercialization or Manufacturing activities.

1.96. "**IND**" means an application filed with a Regulatory Authority for authorization to commence Clinical Trials, including (a) an Investigational New Drug Application as defined in the FFDCA or any successor application or procedure filed with the FDA, (b) any equivalent of a United States IND in other countries or regulatory jurisdictions, (e.g., clinical trial application (CTA)) and (c) all supplements, amendments, variations, extensions and renewals thereof that may be filed with respect to the foregoing.

1.97. "**Indemnification Claim Notice**" has the meaning set forth in Section 12.4.1.

1.98. "**Indemnified Party**" has the meaning set forth in Section 12.4.1.

1.99. [****]

1.100. [****]

1.101. "**Indication**" means any disease in humans, including (a) nAMD, (b) DR, and (c) any Additional Indication.

1.102. "**Information**" means all technical, scientific and other know-how and information, inventions, trade secrets, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other material, including: biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, pre-clinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols, assays and biological methodology, in each case (whether or not confidential, proprietary, patented or patentable) in written, electronic or any other form now known or hereafter developed.

1.103. "**Infringement**" means any infringement of a REGENX Patent, Penn Patent, Joint Patent or PARTNER Patent related to the Development, Commercialization, Manufacture, having Manufactured or other Exploitation of a Licensed Compound or Licensed Product in the Licensed Field in the Territory.

1.104. "**Initial Registration Enabling Trial Milestone Events**" means each of the following milestone events, as further described in Section 8.2.1: (a) [****] patient dosed with a Licensed Product in the first Registration Enabling Trial for nAMD Suprachoroidal Treatment; and (b) [****] patient dosed with a Licensed Product in the first Registration Enabling Trial for DR Suprachoroidal Treatment.

1.105. "**Initiation**" means, with respect to a Clinical Trial, the [****] dosing of the [****] human subject with a Licensed Product in such Clinical Trial.

1.106. "**Invoiced Sales**" has the meaning set forth in the definition of "Net Sales."

1.107. "**Joint Commercialization Committee**" or "**JCC**" has the meaning set forth in Section 7.2.

1.108. "**Joint Committees**" means each of the Joint Development Committee, Joint Commercialization Committee, and Joint Manufacturing Committee.

1.109. "**Joint Development Committee**" or "**JDC**" has the meaning set forth in Section 7.1.

1.110. "**Joint Know-How**" means any and all Collaboration Know-How developed or invented jointly by or on behalf of REGENX or any of its Affiliates on the one hand, and PARTNER or any of its Affiliates on the other hand, but excluding REGENX NAV Platform Know-How.

1.111. "**Joint Manufacturing Committee**" or "**JMC**" has the meaning set forth in Section 7.3.

1.112. "**Joint Patents**" means any Collaboration Patents that claim inventions made jointly by or on behalf of REGENX or any of its Affiliates on one hand, and PARTNER or any of its Affiliates on the other hand, but excluding REGENX NAV Platform Patents.

1.113. "**Joint Technology**" means the Joint Know-How and Joint Patents.

1.114. "**Knowledge**" means with respect to REGENX, [****] of its [****], or any personnel holding positions equivalent to such job titles.

1.115. "**Lead Regulatory Party**" means, with respect to a particular Regulatory Approval, the Party responsible for the day-to-day implementation and operational management for the preparation, obtaining and maintenance of such Regulatory Approval and all Regulatory Documentation relating thereto.

1.116. "**Legal Dispute**" means (a) any dispute, controversy or claim related to compliance with this Agreement or the validity, breach, termination or interpretation of this Agreement, (b) any dispute, controversy or claim with respect to any intellectual property (including trade secrets, Patents and copyrights) that is subject to resolution pursuant to ARTICLE 9, and (c) any disputed matters specifically identified as a "Legal Dispute" hereunder.

1.117. "**Licensed Back Improvements**" means any [****]. For clarity, Licensed Back Improvements shall not include any Information or Patents directed to a Licensed Compound or Licensed Product, or Exploitation thereof.

1.118. "**Licensed Compound**" means (a) RGX-314, and (b) any AAV8 vector encoding for a modified form of the RGX-314 transgene coding sequence.

1.119. "**Licensed Field**" means all human and non-human diagnostic, prophylactic, and therapeutic uses.

1.120. "**Licensed Product**" means (a) any product that contains, alone or in combination with one or more other active ingredients, any Licensed Compound as an active ingredient, in any and all forms, presentations, dosages, and formulations or (b) any service with respect to the administration of any Licensed Compound to patients.

1.121. "**Losses**" has the meaning set forth in Section 12.1.

1.122. [****].

1.123. "**Manufacture**" and "**Manufacturing**" means all activities related to the production, making, manufacture, processing, filling, finishing, packaging, labeling, shipping and holding of a product or any intermediate thereof, including process development (including, with respect to Licensed Products for use in the Licensed Field, Process Development), process qualification and validation, scale-up, pre-clinical, clinical and commercial manufacture and analytic development, product characterization, stability testing, quality assurance and quality control, excluding final (commercial and secondary) packaging and labeling.

1.124. "**Manufacturing Information**" means all Information with respect to the Manufacture of a Licensed Compound or Licensed Product for use in the Licensed Field, including [****] the CMC Data.

1.125. [****]

1.126. [****]

1.127. "**Marketing Authorization**" means all approvals, licenses, registrations or authorizations of any federal, state or local regulatory agency, department, bureau or other governmental entity, necessary for the manufacturing, use, storage, import, transport, marketing and sale of a Licensed Product for use in the Licensed Field in a country or regulatory jurisdiction.

1.128. "**Material Breach**" means a breach of this Agreement or the Penn Sublicense Agreement that is material to the rights and obligations of the Parties and the transactions contemplated by this Agreement and the Penn Sublicense Agreement, taken as a whole.

1.129. "**Medical Affairs Activities**" means, with respect to the United States, the coordination of medical information requests and field based medical scientific liaisons with respect to a Licensed Product for use in the Licensed Field in the United States, including activities of medical scientific liaisons and the provision of medical information services with respect to a Licensed Product for use in the Licensed Field.

1.130. "**Medical Affairs Costs**" means those FTE Costs (charged in accordance with Section 8.5.4 and the direct Out-of-Pocket Costs) incurred by a Party or any of its Affiliates in accordance with Accounting Standards after the Effective Date, during the Term pursuant to this Agreement that are directly attributable and reasonably allocable to Medical Affairs Activities with respect to a Licensed Product for use in the Licensed Field in the United States.

1.131. "**Modified Party**" has the meaning set forth in Section 6.3.

1.132. "**Mono Product**" has the meaning set forth in the definition of "Net Sales."

1.133. "**nAMD**" means neovascular age-related macular degeneration.

1.134. "**nAMD Subretinal Treatment**" means the treatment of nAMD in humans by *in vivo* gene therapy using any Licensed Compound or Licensed Product delivered subretinally.

1.135. "**nAMD Suprachoroidal Treatment**" means the treatment of nAMD in humans by *in vivo* gene therapy using any Licensed Compound or Licensed Product delivered suprachoroidally.

1.136. "**Net Sales**" means, with respect to a Licensed Product for use in the Licensed Field for any period, the total amount billed or invoiced on Commercial Sales of such Licensed Product in the Licensed Field (including fees for services within the definition of "Licensed Product") during such period by PARTNER, its Affiliates or any Sublicensees (each, a "**Selling Party**") to Third Parties, in bona fide arm's length transactions, less the following

deductions, in each case in accordance with the standard internal policies and procedures of the applicable Selling Party, which must be in accordance with Accounting Standards, related specifically to the Licensed Product ("**Invoiced Sales**") and actually allowed and taken by such Third Parties and not otherwise recovered by or reimbursed to PARTNER, its Affiliates, or Sublicensees:

[****] (each deduction specified in (a) – (i) a "**Permitted Deduction**").

[****].

In the event a Licensed Product is a Combination Product, the Net Sales for such Combination Product shall be calculated as follows:

(i) If the Selling Party separately sells in such country or other jurisdiction, (A) a product containing as its sole active ingredient a Licensed Compound contained in such Combination Product (the "**Mono Product**") and (B) products containing as their sole active ingredients the other active ingredients in such Combination Product, the Net Sales attributable to such Combination Product shall be calculated by [****].

(ii) If the Selling Party separately sells in such country or other jurisdiction the Mono Product but does not separately sell in such country or other jurisdiction products containing as their sole active ingredients the other active ingredients in such Combination Product, the Net Sales attributable to such Combination Product shall be calculated by [****].

(iii) If the Selling Party does not separately sell in such country or other jurisdiction the Mono Product but do separately sell products containing as their sole active ingredients the other active ingredients contained in such Combination Product, the Net Sales attributable to such Combination Product shall be calculated by [****].

If the Selling Party does not separately sell in such country or other jurisdiction both the Mono Product and the other active ingredient or ingredients in such Combination Product, the Net Sales attributable to such Combination Product shall be determined by [****].

1.137. "**New License Agreement**" has the meaning set forth in Section 13.4.1.

1.138. [****]

1.139. [****]

1.140. [****]

1.141. "**Non-Breaching Party**" has the meaning set forth in Section 13.2.2(a).

1.142. "**Non-Shared Development Activities**" means any Development activities conducted under this Agreement in which REGENX is solely responsible for the Reimbursable Development Expenses therefor, as further described in Schedule 3.3. [****].

1.143. "**Notice Period**" shall have the meaning set forth in Section 13.2.2.

1.144. "**Opt-In**" means opting into the jurisdiction of Unified Patent Court, such as through withdrawal under Article 83(4) of the Agreement on a Unified Patent Court between the participating Member States of the European Union (2013/C 175/01) of the Opt-Out of a Patent.

1.145. "**Opt-Out**" means opting out of the jurisdiction of Unified Patent Court, such as the opt-out of a Patent right from the exclusive competence of the Unified Patent Court under Article 83(3) of the Agreement on a Unified Patent Court between the participating Member States of the European Union (2013/C 175/01).

1.146. "**Out-of-Pocket Costs**" means costs and expenses paid to Third Parties (or payable to Third Parties and accrued in accordance with the Accounting Standards consistently applied) by PARTNER (or its Affiliate) or REGENX (or its Affiliate) directly incurred in, to the extent reasonably allocable to, the conduct of any applicable activities under this Agreement; [****].

1.147. "**Owed Party**" has the meaning set forth in Section 8.7.

1.148. "**Owing Party**" has the meaning set forth in Section 8.7.

1.149. "**PARTNER**" has the meaning set forth in the preamble hereto.

1.150. "**PARTNER Collaboration Know-How**" means any Collaboration Know-How developed or invented solely by or on behalf of PARTNER or any of its Affiliates, but excluding any REGENX NAV Platform Know-How.

1.151. "**PARTNER Collaboration Patents**" means any Collaboration Patent that claims an invention made solely by or on behalf of PARTNER or any of its Affiliates, but excluding any REGENX NAV Platform Patents.

1.152. "**PARTNER Indemnitees**" has the meaning set forth in Section 12.2.

1.153. "**PARTNER Know-How**" means all Information that is Controlled by PARTNER or any of its Affiliates as of the Execution Date or at any time during the Term that is necessary for the performance of REGENX's obligations hereunder, but excluding (a) any Information to the extent published in PARTNER Patents or Joint Patents or otherwise generally known or (b) any Joint Know-How. PARTNER Know-How includes PARTNER Collaboration Know-How but excludes REGENX NAV Platform Know-How.

1.154. "**PARTNER Patents**" means any Patents Controlled by PARTNER or any of its Affiliates as of the Execution Date or at any time during the Term that are necessary (or, with respect to patent applications, would be necessary if such patent applications were to issue as patents) for the performance of REGENX's obligations under this Agreement, but excluding any Joint Patents. PARTNER Patents include PARTNER Collaboration Patents but exclude REGENX NAV Platform Patents.

1.155. [****].

1.156. "**Party**" and "**Parties**" have the meaning set forth in the preamble hereto.

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

1.158. "**Payment**" has the meaning set forth in Section 8.9.1.

1.159. "**Payor**" has the meaning set forth in Section 8.9.1.

1.160. "**Penn Agreement**" means that certain License Agreement entered into between REGENX and The Trustees of the University of Pennsylvania, effective on February 24, 2009, as amended by that letter agreement dated March 6, 2009, by that certain Second Amendment to License Agreement effective on September 9, 2014, by that certain Third Amendment to License Agreement effective on April 29, 2016, by that certain Fourth Amendment to License Agreement effective on April 4, 2019, by that certain Fifth Amendment to the License Agreement effective on September 11, 2020, and as further amended from time to time in accordance with this Agreement.

1.161. "**Penn Licensor**" or "**Penn**" means The Trustees of the University of Pennsylvania (or any successor thereto under the Penn Agreement) if any Penn Patents are sublicensed pursuant to the Penn Agreement.

1.162. "**Penn Notice Period**" has the meaning set forth in Section 13.2.2.

1.163. "**Penn Patents**" means any Patents that are licensed to REGENX pursuant to the Penn Agreement and which are set forth on Schedule 1.163 (Penn Patents), and any re-examination certificates thereof, and their foreign counterparts and extensions, continuations, divisionals, continuations-in-part, continuing, and re-issue applications; *provided, however*, that with respect to a Penn Patent that is jointly owned by REGENX or its Affiliate, on one hand, and Penn, on the other hand, only Penn's interest in such Patent shall be a "Penn Patent" and, for clarity, REGENX's interest in such Patent shall be a "REGENX Patent," subject to Section 9.8.9.

1.164. "**Penn Sublicense Agreement**" has the meaning set forth in the recitals.

1.165. "**Permitted Deduction**" has the meaning set forth in the definition of "Net Sales."

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

1.167. "**Personal Data**" means (a) all information identifying, or in combination with other information, identifiable to an individual, including pseudonymized (key-coded) clinical data containing such information; and (b) any other information that is governed, regulated or protected by one or more Data Security and Privacy Laws.

1.168. "**PhRMA Code**" means the PhRMA Code on Interactions with Healthcare Professionals.

1.169. "**PHSA**" means the Public Health Service Act as set forth at 42 U.S.C. Chapter 6A, as may be amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions and modifications thereto).

1.170. "**Privacy and Security Obligations**" has the meaning set forth in Section 11.2(v).

1.171. "**Process Development**" means, with respect to a product, all process development, process improvements, manufacturing scale-up, qualification and validation and quality assurance/quality control with respect to such product.

1.172. "**Processing**" (or its conjugates) means any operation or set of operations that is performed upon Personal Data, whether or not by automatic means, such as collection, recording, organization, storage, adaptation or alternation, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction.

1.173. "**Product Information**" has the meaning set forth in Section 10.1.

1.174. "**Product Labeling**" means, with respect to a Licensed Product for use in a particular Indication in the Licensed Field in a country in the Territory, (a) the Regulatory Authority-approved full prescribing information for such Licensed Product in such country, including any required patient information, and (b) all labels and other written, printed, or graphic matter upon a container, wrapper, or any package insert utilized with or for such Licensed Product in such country.

1.175. "**Product Patent**" means any (a) REGENX Patent, (b) Penn Patent, (c) PARTNER Patent or (d) Joint Patent, in each case (a)-(d), that claims a Licensed Compound or a Licensed Product, or the Exploitation thereof.

1.176. "**Product Trademarks**" means the Trademark(s) used or to be used by PARTNER or its Affiliates or its or their Sublicensees for the Commercialization of a Licensed Product for use in the Licensed Field in the Territory and any registrations thereof or any pending applications relating thereto in the Territory (excluding, in any event, any Corporate Names and any Trademarks that consist of or include any corporate name or corporate logo of the Parties or their Affiliates or its or their (sub)licensees (or Sublicensees)).

1.177. "**Product Warranty**" means, with respect to a Licensed Product at a specified time, that such Licensed Product at such time is (a) in conformity with the applicable specifications for such Licensed Product as mutually agreed upon by the Parties; (b) Manufactured in conformance with GMP, all other Applicable Law, this Agreement and the relevant Quality Agreement (as applicable); (c) Manufactured in facilities that are in compliance with Applicable Law at the time of such Manufacture (including applicable inspection requirements of FDA and other Regulatory Authorities); (d) not adulterated or misbranded under the FFDCA, and similar provisions of the laws of other countries as to which any Regulatory Approval has been granted or such Licensed Product will be used; and (e) able to be introduced into interstate commerce pursuant to the FFDCA, and similar provisions of the laws of other countries as to which any Regulatory Approval has been granted or such Licensed Product will be used.

1.178. "**Promotion**" means, with respect to a Licensed Product for use in the Licensed Field, Detailing, activities with respect to product sampling, detail aids, coupons, discount cards, journal advertising, direct mail programs, direct-to-consumer advertising, convention exhibits and other forms of marketing, advertising, public relations and other similar promotional activities undertaken by a Party with respect to a Licensed Product for use in the Licensed Field. When used as a verb, "**Promote**" means to engage in Promotion.

1.179. "**Promotional Materials**" means, with respect to a Licensed Product for use in a particular Indication in the Licensed Field and country in which such Licensed Product is or will be sold, promotional, advertising, communication and educational materials relating to such Licensed Product for use in connection with the marketing, Promotion and sale of such Licensed Product in such country, and the content thereof, and shall include promotional literature, product support materials and promotional giveaways.

1.180. "**Prosecute**" or "**Prosecution**" means preparation, filing, and prosecuting Patent applications and maintaining Patents, including any reexaminations, reissues, oppositions, post-grant review, inter partes review, interferences, and applications for extension of Patent term (including but not limited to, applications for Patent term extension, supplementary protection certificate, and patent supplementary protection).

1.181. "**Prosecuting Party**" means the Party controlling Prosecution of a Patent under this Agreement.

1.182. "**Publishing Party**" has the meaning set forth in Section 10.5.1.

1.183. "**Recipient**" has the meaning set forth in Section 8.9.1.

1.184. "**REGENX**" has the meaning set forth in the preamble hereto.

1.185. "**REGENX Collaboration Know-How**" means any Collaboration Know-How developed or invented solely by or on behalf of REGENX or any of its Affiliates.

1.186. "**REGENX Collaboration Patents**" means any Collaboration Patent that claims any REGENX Collaboration Know-How.

1.187. "**REGENX Competitor**" [****].

1.188. "**REGENX Existing Patents**" means (a) any REGENX Patents existing as of the Execution Date, which are set forth on Schedule 1.188, and (b) any re-examination certificates thereof, and their foreign counterparts and extensions, continuations, divisionals, continuations-in-part, continuing, and re-issue applications.

1.189. "**REGENX Indemnitees**" has the meaning set forth in Section 12.1.

1.190. "**REGENX Know-How**" means all Information Controlled by REGENX or any of its Affiliates as of the Execution Date or at any time during the Term that is necessary or reasonably useful for the performance of PARTNER's obligations, Exploitation of any Licensed Compound or Licensed Product for use in the Licensed Field or exercise of PARTNER's rights hereunder, but excluding (a) any Information to the extent published in REGENX Patents, Penn Patents or Joint Patents or otherwise generally known or (b) any Joint Know-How. REGENX Know-How includes REGENX Collaboration Know-How.

1.191. "**REGENX Licensors**" means, as applicable, the GSK Licensor, the Penn Licensor, or any other Third Party Licensor under any Third Party License Agreement to which REGENX or its Affiliates is a Party.

1.192. "**REGENX NAV Platform**" means the REGENX proprietary gene delivery platform that utilizes recombinant AAV8 for gene therapy applications. For clarity, REGENX NAV Platform shall not include any Licensed Compound, Licensed Product or Exploitation in each case thereof.

1.193. "**REGENX NAV Platform Know-How**" means any Collaboration Know-How that solely and specifically relates to the REGENX NAV Platform (including the process for Manufacture of any products generated using the REGENX NAV Platform), but excluding any Information that is directed to a Licensed Compound or Licensed Product for use in the Licensed Field or the Exploitation thereof.

1.194. "**REGENX NAV Platform Patents**" means any Collaboration Patents that solely and specifically claim inventions directed to the REGENX NAV Platform Know-How, but excluding any Collaboration Patents that claim any Licensed Compound or Licensed Product, or the Exploitation thereof.

1.195. "**REGENX Patents**" means any Patents Controlled by REGENX or any of its Affiliates as of the Execution Date or at any time during the Term that (a) Cover REGENX Know-How (without regard to the exclusion with respect to REGENX Patents in clause (a) thereof), or (b) are necessary or reasonably useful (or, with respect to patent applications, would be necessary or reasonably useful if such patent applications were to issue as Patents) for the

performance of PARTNER's obligations, Exploitation of any Licensed Compound or Licensed Product for use in the Licensed Field or exercise of PARTNER's rights hereunder, but, in each case ((a) and (b)), excluding any Penn Patents and Joint Patents. REGENX Patents include REGENX Collaboration Patents.

1.196. "**REGENX Technology**" means the REGENX Patents and the REGENX Know-How.

1.197. "**Registration Enabling Trial**" means, with respect to a Licensed Product for use in a particular Indication in the Licensed Field in a given country in the Territory, a Clinical Trial for such Licensed Product for which the applicable Regulatory Authority in such country has provided guidance that the design of such Clinical Trial and results of such Clinical Trial, together with prior data and information concerning such Licensed Product, (a) are sufficient to establish that such Licensed Product is safe and effective for its intended use, and (b) forms the primary basis (alone or with one (1) or more additional Registration Enabling Trials) of an effectiveness claim in support of Regulatory Approval for such Licensed Product, regardless of whether such Clinical Trial is referred to as a Phase 2, Phase 2b or Phase 3 clinical trial. If a Clinical Trial of a Licensed Product does not meet the definition of a Registration Enabling Trial as of the date it is Initiated but later meets the definition of a Registration Enabling Trial, then for the purposes of Section 8.2, such Clinical Trial shall be deemed to be a Registration Enabling Trial as of the date the applicable Regulatory Authority accepts the submission of the BLA in which such Clinical Trial forms the primary basis of an effectiveness claim in support of Regulatory Approval for such Licensed Product.

1.198. "**Regulatory Approval**" means, with respect to a country in the Territory, any and all approvals (including BLAs), licenses, registrations or authorizations of any Regulatory Authority necessary to commercially distribute, sell or market a Licensed Product for use in the Licensed Field in such country, including, where applicable, (a) pricing or reimbursement approval in such country, (b) pre- and post-approval Marketing Authorizations (including any prerequisite Manufacturing approval or authorization related thereto) and (c) labeling approval.

1.199. "**Regulatory Authority**" means any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other Governmental Authorities regulating or otherwise exercising authority with respect to the Exploitation of a Licensed Product for use in the Licensed Field in the Territory, including the FDA and the EMA.

1.200. "**Regulatory Documentation**" means: all (a) applications (including all INDs and BLAs), registrations, licenses, authorizations and approvals (including Regulatory Approvals); (b) correspondence and reports submitted to or received from Regulatory Authorities (including minutes and official contact reports relating to any communications with any Regulatory Authority) and all supporting documents with respect thereto, including all adverse event files and complaint files; and (c) clinical and other data contained or relied upon in any of the foregoing; in each case ((a), (b) and (c)), relating to a Licensed Compound or Licensed Product for use in the Licensed Field. Regulatory Documentation includes, for clarity, documentation relating to a Delivery System used in the administration of a Licensed Compound or Licensed

Product for use in the Licensed Field and any information received or authorized by a Third Party in support of applications for Licensed Product Regulatory Approvals.

1.201. "**Regulatory Exclusivity Period**" means, with respect to a Licensed Product for use in a particular Indication in the Licensed Field in any country in the Territory, any period of data, market or other regulatory exclusivity (other than Patent exclusivity) granted or afforded by Applicable Law or by a Regulatory Authority in such country that confers exclusive marketing rights with respect to such Licensed Product in such country and prevents another Person from marketing such Licensed Product without the prior written consent of the BLA-holder.

1.202. "**Reimbursable Development Expenses**" has the meaning set forth in Section 3.3.1.

1.203. [****].

1.204. "**Reviewing Party**" has the meaning set forth in Section 10.5.1.

1.205. "**RGX-314**" means the AAV8 vector containing a gene encoding for an antibody fragment that is designed to bind VEGF as described in [****].

1.206. "**Royalty Term**" means, on a country-by-country and Licensed Product-by-Licensed Product basis, the period beginning on the date of the First Commercial Sale of a Licensed Product in a particular country and ending on the latest to occur of: (a) the expiration of the last-to-expire Valid Claim within the REGENX Patents, Penn Patents or Joint Patents that claims (i) the composition of matter of such Licensed Product in such country or (ii) methods of use for the treatment of all Indications for which such Licensed Product has received Regulatory Approval in such country with respect to the specific mode of administration (e.g., subretinal or suprachoroidal) of such Licensed Product (collectively, the "**Royalty-Bearing Patents**"); (b) the expiration of Regulatory Exclusivity Period in such country for such Licensed Product in the Licensed Field; and (c) (x) if such country is in the European Union, the twelfth (12th) anniversary of the First Commercial Sale of such Licensed Product in the Licensed Field in such country or (y) if such country is outside the European Union, the tenth (10th) anniversary of the First Commercial Sale of such Licensed Product in the Licensed Field in such country.

1.207. "**Royalty Territory**" means, with respect to a Licensed Product for use in the Licensed Field, the Territory excluding the United States.

1.208. "**Royalty-Bearing Patents**" has the meaning set forth in the definition of "Royalty Term."

1.209. "**Safety Issue**" means, with respect to a Licensed Product, any clinical hold or mandatory marketing withdrawal imposed by a Regulatory Authority in the United States, the European Union [****], in each case, relating to a significant safety concern or serious adverse event that is clinically relevant to the benefit risk assessment for the Licensed Product which, in the case of a clinical hold, is not lifted within [****] of the notice of such hold.

1.210. "**Sales and Marketing Costs**" means those FTE Costs (charged in accordance with Section 8.5.4) and the direct Out-of-Pocket Costs recorded as an expense by a Party or any of its Affiliates in accordance with Accounting Standards, after the Effective Date and during the Term pursuant to this Agreement that are compliant with Applicable Law and, in each case, are directly attributable and reasonably allocable to the following sales and marketing activities for a Licensed Product for use in the Licensed Field in the United States: [****]

Sales and Marketing Costs shall include costs of such activities that are incurred at any time after the Effective Date and during the Term of this Agreement (including prior to Regulatory Approval of a Licensed Product for use in the Licensed Field in the United States); *provided* that such costs shall be included in "Sales and Marketing Costs" for a Licensed Product for use in the Licensed Field in the United States solely to the extent provided for in and consistent with the applicable Commercialization Plan. If any cost or expense is directly attributable and reasonably allocable to more than one (1) category under "Sales and Marketing Costs" such cost or expense shall only be counted as a Sales and Marketing Cost with respect to one (1) such category.

1.211. "**Selling Party**" has the meaning set forth in Section 1.136.

1.212. "**Senior Officer**" means, (a) with respect to REGENX, its [****] and (b) with respect to PARTNER, its [****].

1.213. "**Shared Development Activities**" means any Development activities set forth in the Development Plan in which the Parties are each sharing a portion of the Reimbursable Development Expenses therefor, as further described in Schedule 3.3. [****].

1.214. "**Sublicensed IP**" has the meaning set forth in Section 9.7.

1.215. "**Sublicensee**" means (a) any Third Party or Affiliate to whom PARTNER grants a sublicense of some or all of the rights granted to PARTNER under this Agreement as permitted herein or the Penn Sublicense Agreement as permitted therein; and (b) any other Third Party or Affiliate to whom a Sublicensee described in clause (a) has granted further sublicenses as permitted in this Agreement, but excluding, in each case ((a) and (b)), any [****].

1.216. [****].

1.217. [****]

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

1.219. "**Terminated Product Agreement**" means, with respect to a Terminated Product for use in the Licensed Field, any agreement entered into by and between PARTNER or any of its Affiliates, on the one hand and one (1) or more Third Parties, on the other hand, that pertains solely to the Terminated Products and is necessary or reasonably useful for the Exploitation of such Terminated Product in the Territory.

1.220. "**Terminated Products**" means all Licensed Products that are Mono Products and are being Developed or Commercialized under this Agreement as of the effective

date of termination of this Agreement, in the form and formulation in which such Licensed Products exist as of such effective date of termination.

1.221. "**Termination Notice**" has the meaning set forth in Section 13.2.2.

1.222. "**Territory**" means, subject to Section 13.2.2(d), the entire world.

1.223. "**Third Party**" means any Person other than REGENX, PARTNER and their respective Affiliates.

1.224. "**Third Party Agreement**" means, as applicable, any Third Party License Agreement [****].

1.225. "**Third Party Claims**" has the meaning set forth in Section 12.1.

1.226. "**Third Party License Agreement**" means, as applicable, the GSK Agreement, the Penn Agreement, or any agreement with a Third Party (a "**Third Party Licensor**") that a Party enters into in accordance with Section 9.13 (except to the extent that PARTNER does not take a sublicense under such agreement as described under Section 9.13), as such agreement is amended from time to time in accordance with this Agreement.

1.227. "**Third Party Licensor**" has the meaning set forth in the definition of "Third Party License Agreement."

1.228. "**Third Party Patent Right**" has the meaning set forth in Section 9.13.

1.229. "**Third Party Payments**" has the meaning set forth in Section 8.3.3(c).

1.230. [****]

1.231. "**Trademark**" means any word, name, symbol, color, shape, designation or any combination thereof, including any trademark, service mark, trade name, brand name, sub-brand name, trade dress, product configuration rights, program name, delivery form name, certification mark, collective mark, logo, tagline, slogan, design or business symbol, that functions as an identifier of source, origin or quality, whether or not registered, and all statutory and common law rights therein and all registrations and applications therefor, together with all goodwill associated with, or symbolized by, any of the foregoing.

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

1.233. "**United States Profit and Loss Share**" means the allocation of profits and losses for the sale of a Licensed Product for use in the Licensed Field in the United States set forth in Section 8.4.

1.234. "**US Net Sales**" means all Net Sales with respect to Licensed Products for use in the Licensed Field in the United States.

1.235. "**Valid Claim**" means (a) a claim of an issued and unexpired Patent (including any Patent claim the term of which is extended by any extension, supplementary protection certificate, patent term restoration, or the like) included within the REGENX Patents, the Penn Patents, the PARTNER Patents, or the Joint Patents that has not lapsed, been abandoned, canceled, dedicated to the public, disclaimed, revoked, or held unenforceable, unpatentable or invalid by a non-appealable decision or an appealable decision from which no appeal was taken within the time allowed for such appeal of a court or other governmental agency of competent jurisdiction or (b) a claim of a pending Patent application included within the REGENX Patents, the Penn Patents, the PARTNER Patents or the Joint Patents, filed and Prosecuted in good faith and no more than [****] have elapsed from its earliest priority date. For clarity, a holding is a non-appealable decision or an appealable decision from which no appeal was taken within the time allowed for such appeal, or is a holding from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari or a similar appeal the consideration of which is subject to the discretion of the higher court) can be or has been taken.

1.236. "**VAT**" has the meaning set forth in Section 8.9.3.

1.237. "**VEGF**" means vascular endothelial growth factor.

1.238. "**Voting Stock**" has the meaning set forth in the definition of "Change of Control."

Schedule 8.4
United States Profit and Loss Share

REGENX's portion of the United States Profit and Loss Share shall be one-half of an amount which is calculated as all US Net Sales less all Allowable US Expenses.

PARTNER's portion of the United States Profit and Loss Share shall be one-half of an amount which is calculated as all US Net Sales less all Allowable US Expenses.

EXHIBIT 31.1

CERTIFICATION

I, Kenneth T. Mills, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of REGENXBIO Inc.;

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

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

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

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

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

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

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

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

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

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

Date: November 2, 2021

/s/ Kenneth T. Mills

Kenneth T. Mills
President and Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION

I, Vittal Vasista, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of REGENXBIO Inc.;

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

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

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

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

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

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

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

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

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

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

Date: November 2, 2021

/s/ Vittal Vasista

Vittal Vasista
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT 32.1

CERTIFICATION

In connection with the Quarterly Report of REGENXBIO Inc. (the "Registrant") on Form 10-Q for the quarter ended September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Kenneth T. Mills, President, Chief Executive Officer and Director of the Registrant, and Vittal Vasista, Chief Financial Officer of the Registrant, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to their respective knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Date: November 2, 2021

/s/ Kenneth T. Mills

Kenneth T. Mills
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 2, 2021

/s/ Vittal Vasista

Vittal Vasista
Chief Financial Officer
(Principal Financial and Accounting Officer)

This certification is made solely for the purposes of 18 U.S.C. Section 1350, subject to the knowledge standard contained therein, and not for any other purpose. A signed original of this written statement required by Section 906 has been provided to the Registrant and will be retained by the Registrant and furnished to the United States Securities and Exchange Commission or its staff upon request.

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