
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, 2018**

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 No.:001-34079

Rexahn Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware

11-3516358

(State or Other Jurisdiction of Incorporation or Organization)

(I.R.S. Employer Identification No.)

**15245 Shady Grove Road, Suite 455
Rockville, MD 20850**

(Address of Principal Executive Offices, Including Zip Code)

Telephone: (240) 268-5300

(Registrant's Telephone Number, Including Area Code)

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 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 definition of "accelerated filer," "large 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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date: 37,521,170 shares as of November 2, 2018.

REXAHN PHARMACEUTICALS, INC.
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PART I. Financial Information**Item 1. Financial Statements****REXAHN PHARMACEUTICALS, INC.**

Condensed Balance Sheet

(Unaudited)

	<u>September 30, 2018</u>	<u>December 31, 2017</u>
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 4,591,722	\$ 8,899,154
Marketable securities	7,974,010	17,931,941
Prepaid expenses and other current assets	1,154,898	1,304,541
Total Current Assets	13,720,630	28,135,636
Security Deposits	30,785	30,785
Equipment, Net	123,480	121,460
Total Assets	\$ 13,874,895	\$ 28,287,881
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 3,331,646	\$ 3,233,926
Deferred Research and Development Arrangement	-	375,000
Other Liabilities	29,850	56,724
Warrant Liabilities	4,101,504	7,853,635
Total Liabilities	7,463,000	11,519,285
Commitments and Contingencies (note 14)		
Stockholders' Equity:		
Preferred stock, par value \$0.0001, 10,000,000 authorized shares, none issued and outstanding	-	-
Common stock, par value \$0.0001, 75,000,000 and 50,000,000 authorized shares, 31,751,939 and 31,725,114 issued and outstanding	3,175	3,173
Additional paid-in capital	158,008,879	157,141,021
Accumulated other comprehensive loss	(29,487)	(56,886)
Accumulated deficit	(151,570,672)	(140,318,712)
Total Stockholders' Equity	6,411,895	16,768,596
Total Liabilities and Stockholders' Equity	\$ 13,874,895	\$ 28,287,881

(See accompanying notes to the condensed financial statements)

REXAHN PHARMACEUTICALS, INC.
Condensed Statement of Operations
(Unaudited)

	For the Three Months Ended		For the Nine Months Ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Revenues:	\$ -	\$ -	\$ -	\$ -
Expenses:				
General and administrative	1,795,952	1,574,323	5,192,122	5,004,832
Research and development	2,887,955	2,644,999	10,379,081	7,451,656
Total Expenses	4,683,907	4,219,322	15,571,203	12,456,488
Loss from Operations	(4,683,907)	(4,219,322)	(15,571,203)	(12,456,488)
Other Income (Expense)				
Interest income	55,153	60,750	198,362	135,329
Other income	-	-	368,750	-
Unrealized (loss) gain on fair value of warrants	(710,065)	3,120,500	3,752,131	(9,047,831)
Financing expense	-	-	-	(333,050)
Total Other Income (Expense)	(654,912)	3,181,250	4,319,243	(9,245,552)
Net Loss Before Provision for Income Taxes	(5,338,819)	(1,038,072)	(11,251,960)	(21,702,040)
Provision for income taxes	-	-	-	-
Net Loss	\$ (5,338,819)	\$ (1,038,072)	\$ (11,251,960)	\$ (21,702,040)
Net loss per share, basic and diluted	\$ (0.17)	\$ (0.04)	\$ (0.35)	\$ (0.83)
Weighted average number of shares outstanding, basic and diluted	31,751,450	28,459,316	31,742,531	26,121,160

(See accompanying notes to the condensed financial statements)

REXAHN PHARMACEUTICALS, INC.
Condensed Statement of Comprehensive Loss
(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
Net Loss	\$ (5,338,819)	\$ (1,038,072)	\$ (11,251,960)	\$ (21,702,040)
Unrealized gain (loss) on available-for-sale securities	35,468	11,740	27,399	(7,843)
Comprehensive Loss	<u>\$ (5,303,351)</u>	<u>\$ (1,026,332)</u>	<u>\$ (11,224,561)</u>	<u>\$ (21,709,883)</u>

(See accompanying notes to the condensed financial statements)

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Condensed Statement of Cash Flows

(Unaudited)

	For the Nine Months Ended	
	September 30,	
	2018	2017
Cash Flows from Operating Activities:		
Net loss	\$ (11,251,960)	\$ (21,702,040)
Adjustments to reconcile net loss to net cash used in operating activities:		
Compensatory stock	22,650	31,200
Depreciation and amortization	37,204	30,963
Amortization of premiums and discounts on marketable securities, net	35,110	40,578
Stock-based compensation	845,210	790,006
Amortization and termination of deferred research and development arrangement	(375,000)	(56,250)
Unrealized (gain) loss on fair value of warrants	(3,752,131)	9,047,831
Financing expense	-	333,050
Amortization of deferred lease incentive	(9,332)	(9,333)
Deferred lease expenses	(17,542)	(8,314)
Changes in assets and liabilities:		
Prepaid expenses and other assets	149,643	(669,087)
Accounts payable and accrued expenses	97,720	456,277
Net Cash Used in Operating Activities	(14,218,428)	(11,715,119)
Cash Flows from Investing Activities:		
Purchase of equipment	(39,224)	(21,369)
Purchase of marketable securities	-	(15,008,660)
Redemption of marketable securities	9,950,220	8,720,000
Net Cash Provided by (Used In) Investing Activities	9,910,996	(6,310,029)
Cash Flows from Financing Activities:		
Issuance of common stock and units, net of issuance costs	-	9,241,271
Proceeds from exercise of stock warrants	-	5,354,093
Proceeds from exercise of stock options	-	77,500
Net Cash Provided by Financing Activities	-	14,672,864
Net Decrease in Cash and Cash Equivalents	(4,307,432)	(3,352,284)
Cash and Cash Equivalents – beginning of period	8,899,154	11,578,473
Cash and Cash Equivalents - end of period	\$ 4,591,722	\$ 8,226,189
Supplemental Cash Flow Information		
Non-cash financing and investing activities:		
Warrants issued	\$ -	\$ 4,107,488
Warrant liability extinguishment from exercise of warrants	\$ -	\$ 8,052,594

(See accompanying notes to the condensed financial statements)

REXAHN PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements
(Unaudited)

1. Operations and Organization

Operations

Rexahn Pharmaceuticals, Inc. (the “Company”), a Delaware corporation, is a biopharmaceutical company whose principal operations are the discovery and development of innovative treatments for cancer.

Liquidity and Going Concern

Accounting Standards Codification (“ASC”) 205-40, Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern (“ASC 205-40”), requires management to evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date that the financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management’s plans that have not been fully implemented as of the date the financial statements are issued. When substantial doubt exists under this methodology, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about the Company’s ability to continue as a going concern. The mitigating effect of management’s plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity’s ability to continue as a going concern within one year after the date that the financial statements are issued.

As of September 30, 2018, the Company had cash, cash equivalents and marketable securities of approximately \$12.6 million, working capital of approximately \$10.4 million and an accumulated deficit of approximately \$151.6 million, and anticipates incurring losses through fiscal year 2018 and beyond. The Company has incurred negative cash flow from operations since inception and not yet generated commercial revenues. The Company believes that its cash, cash equivalents, and marketable securities at September 30, 2018 and the proceeds received from its completed registered direct public offering in October 2018, will be sufficient to fund current operations through the third quarter of 2019 and that the Company would require additional capital to fund operations beyond that point. These conditions raise substantial doubt about the Company’s ability to continue as a going concern within one year from the date these financial statements are issued.

To meet its needs, the Company intends to raise additional capital through equity financings, collaborations, or partnerships. Under ASC 205-40, management’s plans must be approved before the date the financial statements are issued to be considered probable of being effectively implemented, and the future receipt of potential funding is not considered probable at this time because none of the Company’s current plans have been finalized at the time of filing this Quarterly Report on Form 10-Q. Accordingly, substantial doubt is deemed to exist about the Company’s ability to continue as a going concern within one year after the date these financial statements are issued.

REXAHN PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements
(Unaudited)

Basis of Presentation

The accompanying unaudited condensed financial statements of the Company have been prepared pursuant to the rules and regulations of the U.S. Securities and Exchange Commission for interim financial information. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States (“U.S. GAAP”) for complete financial statements. In the opinion of the Company’s management, all adjustments (consisting of only normal recurring accruals) considered necessary for a fair presentation of the Company’s financial position as of September 30, 2018 and December 31, 2017 and of the results of operations, and comprehensive loss for the three and nine months ended September 30, 2018 and 2017 and cash flows for the nine months ended September 30, 2018 and 2017 have been included. Operating results for the three and nine months ended September 30, 2018 are not necessarily indicative of results that may be expected for any other interim period or the full fiscal year ending December 31, 2018. The accompanying unaudited condensed financial statements should be read in conjunction with the audited financial statements and notes thereto included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2017 (the “2017 Form 10-K”). Information included in the condensed balance sheet as of December 31, 2017 has been derived from the Company’s audited financial statements for the year ended December 31, 2017 included in the 2017 Form 10-K. The unaudited condensed financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. These estimates are based on management’s best knowledge of current events and actions the Company may undertake in the future. Actual results may ultimately differ from these estimates. These estimates are reviewed periodically, and as adjustments become necessary, they are reported in earnings in the period in which they become available.

REXAHN PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements
(Unaudited)

2. Recent Accounting Pronouncements Affecting the Company

Revenue from Contracts with Customers

In May 2014, the Financial Accounting Standards Board (the “FASB”) issued Accounting Standards Update (“ASU”) 2014-09, “Revenue from Contracts with Customers,” a comprehensive new revenue recognition standard that will supersede nearly all existing revenue recognition guidance under U.S. GAAP. The standard’s core principle is that a company should recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods and services and provides a revenue recognition framework in accordance with this principle. On August 12, 2015, the FASB issued ASU 2015-14, which deferred the effective date of ASU 2014-09 by one year to December 15, 2017 for annual reporting periods beginning after that date and interim periods therein. The Company adopted this guidance for the quarterly reporting period ended March 31, 2018, using the modified retrospective method. As the Company does not have revenue contracts, the adoption of this guidance did not have a material impact on the operating results of the Company, there were no significant changes to disclosures, and there was no cumulative adjustment to the opening balance of retained earnings as of January 1, 2018.

Leases

In February 2016, the FASB issued ASU 2016-02, “Leases,” which requires an entity to recognize assets and liabilities arising from leases on the balance sheet and to provide additional disclosures about leasing arrangements. ASU 2016-02 will be effective for reporting periods beginning after December 15, 2018, with early adoption permitted. The Company is currently evaluating the impact the adoption of this guidance will have on its financial statements.

REXAHN PHARMACEUTICALS, INC.Notes to Condensed Financial Statements
(Unaudited)**3. Marketable Securities**

Marketable securities are considered “available-for-sale” in accordance with FASB Accounting Standards Codification (“ASC”) 320, “Debt and Equity Securities,” and thus are reported at fair value in the Company’s accompanying balance sheet, with unrealized gains and losses excluded from earnings and reported as a separate component of stockholders’ equity. Amounts reclassified out of accumulated other comprehensive income (loss) into realized gains and losses are accounted for on the basis of specific identification and are included in other income or expense in the statement of operations. The Company classifies such investments as current on the balance sheet as the investments are readily marketable and available for use in current operations.

The following table shows the Company’s marketable securities’ adjusted cost, gross unrealized gains and losses, and fair value by significant investment category as of September 30, 2018 and December 31, 2017:

	September 30, 2018			
	Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate Bonds	\$ 8,003,497	\$ -	\$ (29,487)	\$ 7,974,010

	December 31, 2017			
	Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial Paper	\$ 3,241,005	\$ -	\$ (2,505)	\$ 3,238,500
Corporate Bonds	14,747,822	-	(54,381)	14,693,441
Total Marketable Securities	\$ 17,988,827	\$ -	\$ (56,886)	\$ 17,931,941

The Company typically invests in highly-rated securities, with the primary objective of minimizing the potential risk of principal loss. As of September 30, 2018, the Company had six corporate bonds with an aggregate fair value of \$5,974,460 and unrealized losses of \$26,899 that have been unrealized losses for less than 12 months, and two corporate bonds with an aggregate fair value of \$1,999,550 and unrealized losses of \$2,588 that have been unrealized losses for greater than 12 months. The Company does not intend to sell its marketable securities in an unrealized loss position. Based upon these securities’ fair value relative to the cost, high ratings, and volatility of fair value, the Company considers the declines in market value of its marketable securities to be temporary in nature, does not consider any of its investments other-than-temporarily impaired, and anticipates that it will recover the entire amortized cost basis.

As of September 30, 2018, all of the Company’s marketable securities are due to mature in less than one year.

REXAHN PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements
(Unaudited)

4. Prepaid Expenses and Other Current Assets

	September 30, 2018	December 31, 2017
Deposits on contracts	\$ 520,677	\$ 793,940
Prepaid expenses and other current assets	634,221	510,601
	\$ 1,154,898	\$ 1,304,541

Deposits on contracts consist of deposits on research and development contracts for services that had not been incurred as of the balance sheet date. Prepaid expenses and other assets include prepaid general and administrative expenses, such as insurance, rent, investor relations fees and compensatory stock issued for services not yet incurred as of the balance sheet date.

5. Equipment, Net

	September 30, 2018	December 31, 2017
Furniture and fixtures	\$ 82,686	\$ 82,686
Office and computer equipment	159,489	171,724
Lab equipment	447,653	445,134
Leasehold improvements	131,762	133,762
Total equipment	821,590	833,306
Less: Accumulated depreciation and amortization	(698,110)	(711,846)
Net carrying amount	\$ 123,480	\$ 121,460

6. Accounts Payable and Accrued Expenses

	September 30, 2018	December 31, 2017
Trade payables	\$ 1,298,168	\$ 895,638
Accrued expenses	103,000	95,416
Accrued research and development contract costs	1,252,445	1,435,109
Payroll liabilities	678,033	807,763
	\$ 3,331,646	\$ 3,233,926

REXAHN PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements
(Unaudited)

7. Deferred Research and Development Arrangement

Rexgene Biotech Co., Ltd.

In 2003, the Company entered into a collaborative research agreement with Rexgene Biotech Co., Ltd. (“Rexgene”), a stockholder. Rexgene agreed to assist the Company with the research, development and clinical trials necessary for registration of the Company’s drug candidate RX-0201 (Archexin®) in Asia. In accordance with the agreement, Rexgene paid the Company a one-time fee of \$1,500,000 in 2003. The agreement provided that it would expire upon the later of (i) 20 years after the date of the agreement or (ii) the expiration of the patents relating to RX-0201. The amortization reduced research and development expenses for the periods presented. The payment from Rexgene was used in the cooperative funding of the costs of development of RX-0201.

On February 5, 2018, the Company and NEXT BT Co. Ltd., (“Next BT”) the successor in interest to Rexgene, terminated the agreement. In exchange for Next BT terminating its rights to RX-0201 in Asia, the Company agreed to pay Next BT a royalty in the low single digits of any net sales of RX-0201 the Company makes in Asia and 50% of the Company’s licensing revenue related to the licensing of RX-0201 in Asia, up to an aggregate of \$5,000,000. Upon termination of the agreement, the unamortized deferred research and development arrangement liability of \$368,750 was eliminated and recognized as other income.

The Company historically used 20 years as its basis for recognition and accordingly, for the nine months ended September 30, 2018, research and development expenses were reduced by \$6,250 for the period beginning January 1, 2018 up to the agreement’s termination. For the three and nine months ended September 30, 2017, \$18,750 and \$56,250, respectively was reduced from research and development expenses.

REXAHN PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements
(Unaudited)

8. Other Liabilities

Deferred Lease Incentive

In accordance with the Company's office lease agreement, as amended and further discussed in Note 14, the Company has been granted leasehold improvement allowances from the lessor to be used for the construction cost of improvements to the leased property, which included architectural and engineering fees, government agency plan check, permit and other fees, sales and use taxes, testing and inspection costs and telephone and data cabling and wiring in the premises. The Company accounted for the benefit of the leasehold improvement allowance as a reduction of rental expense over the term of the office lease.

The following table sets forth the cumulative deferred lease incentive:

	September 30, 2018	December 31, 2017
Deferred lease incentive	\$ 154,660	\$ 154,660
Less accumulated amortization	(145,327)	(135,995)
Balance	<u>\$ 9,333</u>	<u>\$ 18,665</u>

Deferred Office Lease Expense

The lease agreement, as amended, provided for an initial annual base rent with annual increases over the lease term. The Company recognizes rental expense on a straight-line basis over the term of the lease, which resulted in a deferred rent liability of \$20,517 and \$38,059 as of September 30, 2018 and December 31, 2017, respectively.

9. Net Loss per Common Share

Basic loss per common share is computed by dividing net loss by the weighted average number of shares of common stock outstanding for the period. Diluted loss per common share is computed by dividing net loss by the weighted average number of shares of common stock outstanding, plus the number of common share equivalents that would be dilutive. As of September 30, 2018, and December 31, 2017, there were stock options, restricted stock units and warrants to acquire, in the aggregate, 9,534,122 and 8,961,140 shares of the Company's common stock, respectively, that are potentially dilutive. However diluted loss per share is the same as basic loss per share for all periods presented because the inclusion of common share equivalents would be anti-dilutive.

REXAHN PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements
(Unaudited)

10. Common Stock

The following transactions occurred during the nine months ended September 30, 2018:

Authorized Shares

On August 30, 2018, the Company's shareholders approved an increase in the Company's authorized shares of stock from 50,000,000 to 75,000,000.

Compensatory Shares

During the nine months ended September 30, 2018, the Company issued 15,000 shares to a privately held investor relations firm in exchange for investor relations services. The aggregate market value of the stock issued was \$22,650.

Restricted Stock Units

During the nine months ended September 30, 2018, the Company issued 11,825 shares resulting from the vesting of restricted stock units ("RSUs").

REXAHN PHARMACEUTICALS, INC.Notes to Condensed Financial Statements
(Unaudited)**11. Stock-Based Compensation**

As of September 30, 2018, the Company had 2,599,038 options to purchase common stock and 35,475 RSUs outstanding.

At the Company's Annual Meeting of Shareholders held on June 10, 2013, the Company's shareholders voted to approve the Rexahn Pharmaceuticals, Inc. 2013 Stock Option Plan (the "2013 Plan"). Under the 2013 Plan, the Company grants equity awards to key employees, directors and consultants of the Company. At the Company's Annual Meeting held on June 9, 2016, the Company's shareholders voted to approve an amendment and restatement of the 2013 Plan, including to provide for awards of restricted stock and restricted stock units. The Company initially reserved 1,700,000 shares of common stock for issuance pursuant to the 2013 Plan, and on April 11, 2017, the Company's shareholders approved an increase of 1,700,000 shares of common stock reserved for issuance pursuant to the 2013 Plan. As of September 30, 2018, there were 2,287,038 options and 35,475 RSUs outstanding under the 2013 Plan, and 1,064,912 shares were available for issuance.

On August 5, 2003, the Company established a stock option plan (the "2003 Plan"). Under the 2003 Plan, the Company granted stock options to key employees, directors and consultants of the Company. With the adoption of the 2013 Plan, no new stock options may be issued under the 2003 Plan, but previously issued options under the 2003 Plan remain outstanding until their expiration. As of September 30, 2018, there were 300,000 options outstanding under the 2003 Plan.

In March 2016, the Company granted to a third party an option to purchase up to 12,000 shares of the Company's common stock. These were the only Company stock options outstanding as of September 30, 2018 that were not issued pursuant to the 2013 Plan or the 2003 Plan.

Accounting for Awards

Stock-based compensation expense is the estimated fair value of options and RSUs granted amortized on a straight-line basis over the requisite vesting service period for the entire portion of the award. Total stock-based compensation recognized by the Company for the three and nine months ended September 30, 2018 and 2017 is as follows:

	For the Three Months Ended September 30, 2018		For the Nine Months Ended September 30, 2018	
	2018	2017	2018	2017
Statement of operations line item:				
General and administrative	\$ 188,920	\$ 184,914	\$ 579,924	\$ 580,812
Research and development	92,562	42,700	265,286	209,194
Total	\$ 281,482	\$ 227,614	\$ 845,210	\$ 790,006

No income tax benefit has been recognized in the statement of operations for stock-based compensation arrangements as the Company has provided for a 100% valuation allowance on its deferred tax assets.

REXAHN PHARMACEUTICALS, INC.Notes to Condensed Financial Statements
(Unaudited)*Summary of Stock Option Transactions*

There were 860,307 stock options granted at exercise prices ranging from \$1.46 to \$2.29 with an aggregate fair value of \$1,089,851 during the nine months ended September 30, 2018. There were 483,260 stock options granted at exercise prices ranging from \$1.84 to \$6.18 with an aggregate fair value of \$738,937 during the nine months ended September 30, 2017.

For the majority of the grants to employees, the vesting period is 25% on the first anniversary of the grant date and, thereafter, one thirty-sixth of the remaining option vests in equal installments on the first business day of each month until fully vested. Options generally expire ten years from the date of grant. For the majority of grants to non-employee consultants of the Company, the vesting period is between one and three years, subject to the fulfillment of certain conditions in the individual stock agreements, or 100% upon the occurrence of certain events specified in the individual stock agreements.

The fair value of options at the date of grant was estimated using the Black-Scholes option pricing model. The Company took into consideration guidance under ASC 718, "Compensation-Stock Compensation," and Staff Accounting Bulletin No. 107 ("SAB 107") when reviewing and updating assumptions. The expected volatility is based upon historical volatility of the Company's stock. The expected term is based upon the simplified method as allowed under SAB 107.

The assumptions made in calculating the fair values of options are as follows:

	Nine Months Ended September 30,	
	2018	2017
Black-Scholes assumptions		
Expected dividend yield	0%	0%
Expected volatility	69-72%	69-79%
Risk-free interest rate	2.3-2.8%	1.8-2.0%
Expected term (in years)	5.5-6 years	5.5-6 years

A summary of stock option activity for the nine months ended September 30, 2018 is as follows:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding, January 1, 2018	1,814,231	\$ 5.33	7.1 years	\$ 53,883
Granted	860,307	\$ 1.96		
Exercised	-	\$ -		
Expired	(25,000)	\$ 21.78		
Cancelled	(50,500)	\$ 5.16		
Outstanding, September 30, 2018	2,599,038	\$ 4.06	7.5 years	\$ 50,870
Exercisable, September 30, 2018	1,345,721	\$ 5.71	6.1 years	\$ -

REXAHN PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements

(Unaudited)

There were no stock options exercised during the three and nine months ended September 30, 2018 or for the three months ended September 30, 2017. The total intrinsic value of options exercised was \$97,872 for the nine months ended September 30, 2017. The weighted average fair value of the options granted was \$1.27 and \$1.53 for the nine months ended September 30, 2018 and 2017, respectively.

A summary of the Company's unvested options as of September 30, 2018 and changes during the nine months ended September 30, 2018 is presented below:

	2018	
	Number of	Weighted Average Fair
	Options	Value at Grant Date
Unvested at January 1, 2018	727,543	\$ 2.39
Granted	860,307	\$ 1.27
Vested	(334,533)	\$ 2.89
Cancelled	-	\$ -
Unvested at September 30, 2018	<u>1,253,317</u>	<u>\$ 1.49</u>

As of September 30, 2018, there was \$1,494,158 of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted average vesting period of 2.5 years.

Summary of Restricted Stock Unit Transactions

The Company began granting RSUs to employees in 2017. The fair value of an RSU award is the closing price of the Company's common stock on the date of grant.

A summary of RSU activity for the nine months ended September 30, 2018 is as follows:

	Number of RSUs	Weighted Average Grant Date Fair Value
Outstanding, January 1, 2018	47,300	\$ 1.84
Granted	-	\$ -
Vested and Released	(11,825)	\$ 1.84
Cancelled	-	\$ -
Outstanding, September 30, 2018	<u>35,475</u>	<u>\$ 1.84</u>

As of September 30, 2018, there was \$51,512 of total unrecognized compensation cost related to unvested RSUs which is expected to be recognized over a weighted average vesting period of 2.4 years.

REXAHN PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements
(Unaudited)

12. Warrants

As of September 30, 2018, warrants to purchase up to 6,899,609 shares were outstanding, having exercise prices ranging from \$2.85 to \$12.80 and expiration dates ranging from October 16, 2018 to April 17, 2023.

	2018		2017	
	Number of warrants	Weighted average exercise price	Number of warrants	Weighted average exercise price
Balance, January 1	7,099,609	\$ 4.55	5,452,691	\$ 4.92
Issued during the period	-	\$ -	1,696,970	\$ 4.01
Exercised during the period	-	\$ -	(1,861,195)	\$ 3.51
Expired during the period	(200,000)	\$ 5.90	-	\$ -
Balance, September 30	6,899,609	\$ 4.51	5,288,466	\$ 5.13

At September 30, 2018, the weighted average remaining contractual life of the outstanding warrants was 3.4 years.

The warrants issued to investors in the November 2015, March 2016 and September 2016 offerings contain a provision for net cash settlement in the event of a fundamental transaction (contractually defined to include a merger, sale of substantially all assets, tender offer or share exchange). Pursuant to the November 2015, March 2016, and September 2016 warrants, if a fundamental transaction occurs, then the warrant holder has the option to receive cash, equal to the fair value of the remaining unexercised portion of the warrant. The June 2017 and October 2017 warrants contain a provision that allows the holder to opt for cash settlement in a fundamental transaction that was approved by, or required to be approved by, the board of directors of the Company. All of the Company's outstanding warrants provide the holder the option as to the type of consideration received if the holders of common stock receive an option as to their consideration. In addition, all of the Company's outstanding warrants contain a cashless exercise provision that is exercisable only in the event that a registration statement is not effective. That provision may not be operative if an effective registration statement is not available because an exemption under the U.S. securities laws may not be available to issue unregistered shares. As a result, net cash settlement may be required, and the warrants require liability classification.

ASC 820, "Fair Value Measurements and Disclosures," provides requirements for disclosure of liabilities that are measured at fair value on a recurring basis in periods subsequent to the initial recognition. Fair values for warrants were determined using the Binomial Lattice ("Lattice") valuation technique. The Lattice model provides for dynamic assumptions regarding volatility and risk-free interest rates within the total period to maturity. Accordingly, within the contractual term, the Company provided multiple date intervals over which multiple volatilities and risk-free interest rates were used. These intervals allow the Lattice model to project outcomes along specific paths that consider volatilities and risk-free rates that would be more likely in an early exercise scenario.

Significant assumptions are determined as follows:

Trading market values—Published trading market values;

Exercise price—Stated exercise price;

Term—Remaining contractual term of the warrant;

Volatility—Historical trading volatility for periods consistent with the remaining terms; and

Risk-free rate—Yields on zero coupon government securities with remaining terms consistent with the remaining terms of the warrants.

REXAHN PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements

(Unaudited)

Due to the fundamental transaction provision, which could provide for early redemption of the warrants, the model also considered the probability the Company would enter into a fundamental transaction during the remaining term of the warrant. Because the Company is not yet achieving positive cash flow, management believes the probability of a fundamental transaction occurring over the term of the warrant is unlikely and therefore estimates the probability of entering into a fundamental transaction to be 5%. For valuation purposes, the Company also assumed that if such a transaction did occur, it was more likely to occur towards the end of the term of the warrants.

The significant unobservable inputs used in the fair value measurement of the warrants include management's estimate of the probability that a fundamental transaction may occur in the future. Significant increases (decreases) in the probability of occurrence would result in a significantly higher (lower) fair value measurement.

The following table summarizes the fair value of the warrants as of the respective balance sheet dates:

Warrant Issuance:	Fair Value as of:	
	September 30, 2018	December 31, 2017
July 2013 Investor Warrants	\$ -	\$ 8,762
October 2013 Investor Warrants	-	26,288
January 2014 Investor Warrants	-	29,257
November 2015 Investor Warrants	399,278	1,260,050
November 2015 Placement Agent Warrants	591	2,936
March 2016 Investor Warrants	296,462	697,554
September 2016 Investor Warrants	592,513	1,054,083
June 2017 Investor Warrants	1,059,522	1,981,864
June 2017 Placement Agent Warrants	115,769	221,591
October 2017 Investor Warrants	1,476,646	2,305,552
October 2017 Placement Agent Warrants	160,723	265,698
Total:	\$ 4,101,504	\$ 7,853,635

REXAHN PHARMACEUTICALS, INC.Notes to Condensed Financial Statements
(Unaudited)

The following table summarizes the number of shares indexed to the warrants as of the respective balance sheet dates:

Warrant Issuance	Number of Shares indexed as of:	
	September 30, 2018	December 31, 2017
July 2013 Investor Warrants	-	200,000
October 2013 Investor Warrants	231,732	231,732
January 2014 Investor Warrants	476,193	476,193
November 2015 Investor Warrants	1,250,001	1,250,001
November 2015 Placement Agent Warrants	3,334	3,334
March 2016 Investor Warrants	607,806	607,806
September 2016 Investor Warrants	805,000	805,000
June 2017 Investor Warrants	1,515,152	1,515,152
June 2017 Placement Agent Warrants	181,818	181,818
October 2017 Investor Warrants	1,632,654	1,632,654
October 2017 Placement Agent Warrants	195,919	195,919
Total:	6,899,609	7,099,609

The assumptions used in calculating the fair values of the warrants are as follows:

	September 30, 2018	December 31, 2017
Trading market prices	\$ 1.78	\$ 2.02
Estimated future volatility	101%	104%
Dividend	-	-
Estimated future risk-free rate	3.02-3.04%	2.14-2.45%
Equivalent volatility	49-76%	85-104%
Equivalent risk-free rate	1.10-2.70%	1.30-1.89%

REXAHN PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements

(Unaudited)

Changes in the fair value of the warrant liabilities, carried at fair value, reported as “unrealized (loss) gain on fair value of warrants” in the statement of operations:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
Expired and Fully Exercised Warrants	\$ -	\$ 7,306	\$ -	\$ (855,010)
July 2013 Investor Warrants	-	125,686	8,762	(55,362)
October 2013 Investor Warrants	-	135,683	26,288	(102,608)
January 2014 Investor Warrants	-	177,900	29,257	(125,148)
November 2015 Investor Warrants	5,971	797,688	860,772	(1,304,350)
November 2015 Placement Agent Warrants	211	1,691	2,345	(366,694)
March 2016 Investor Warrants	(38,943)	356,472	401,092	(2,873,309)
September 2016 Investor Warrants	(109,915)	506,353	461,570	(4,807,246)
June 2017 Investor Warrants	(178,869)	894,076	922,342	1,277,485
June 2017 Placement Agent Warrants	(22,518)	117,645	105,822	164,411
October 2017 Investor Warrants	(331,671)	-	828,906	-
October 2017 Placement Agent Warrants	(34,331)	-	104,975	-
Total:	\$ (710,065)	\$ 3,120,500	\$ 3,752,131	\$ (9,047,831)

REXAHN PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements
(Unaudited)

13. Income Taxes

No provision for federal and state income taxes was required for the three and nine months ended September 30, 2018 and 2017 due to the Company's operating losses and increased deferred tax asset valuation allowance. At September 30, 2018 and December 31, 2017, the Company had unused net operating loss carry-forwards of approximately \$142,488,000 and \$127,877,000 respectively. Some of this amount may be subject to annual limitations under certain provisions of the Internal Revenue Code related to "changes in ownership."

As of September 30, 2018 and December 31, 2017, the deferred tax assets related to the aforementioned carry-forwards have been fully offset by valuation allowances, because significant utilization of such amounts is not presently expected in the foreseeable future.

Deferred tax assets and valuation allowances consist of:

	September 30, 2018	December 31, 2017
Net Operating Loss Carryforwards	\$ 39,897,000	\$ 35,805,000
Stock Compensation Expense	1,558,000	1,458,000
Book tax differences on assets and liabilities	209,000	365,000
Valuation Allowance	(41,664,000)	(37,628,000)
Net Deferred Tax Assets	\$ -	\$ -

The Company files income tax returns in the U.S. federal and Maryland state jurisdictions. Tax years for fiscal 2015 through 2017 are open and potentially subject to examination by the federal and Maryland state taxing authorities.

REXAHN PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements
(Unaudited)

14. Commitments and Contingencies

- a) The Company has contracted with various vendors for services, with terms that require payments over the terms of the agreements, usually ranging from two to 36 months. The costs to be incurred are estimated and are subject to revision. As of September 30, 2018, the total estimated cost to complete these agreements was approximately \$6,980,000. All of these agreements may be terminated by either party upon appropriate notice as stipulated in the respective agreements.
- b) On June 22, 2009, the Company entered into a License Agreement with Korea Research Institute of Chemical Technology (“KRICT”) to acquire the rights to all intellectual property related to quinoxaline-piperazine derivatives that were synthesized under a Joint Research Agreement. The initial license fee was \$100,000, all of which was paid as of December 31, 2009. The agreement with KRICT calls for a one-time milestone payment of \$1,000,000 within 30 days after the first achievement of marketing approval of the first commercial product arising out of or in connection with the use of KRICT’s intellectual property. As of September 30, 2018, the milestone has not occurred.
- c) *Office Space Lease*

On June 5, 2009, the Company entered into a commercial lease agreement for 5,466 square feet of office space in Rockville, Maryland. The lease was amended on June 7, 2013 to extend the term until June 30, 2019.

On July 26, 2014 the lease was amended to add 1,727 square feet of office space for a term beginning on September 1, 2014 and ending on August 31, 2015. The lease of additional space was subsequently renewed through June 30, 2019. Under the lease agreement, the Company pays its allocable portion of real estate taxes and common area operating charges.

Rent paid under the Company’s lease during the three months ended September 30, 2018 and 2017 was \$53,850 and \$52,172, respectively, and rent paid during the nine months ended September 30, 2018 and 2017 was \$159,247 and \$153,968 respectively.

Laboratory Lease

On April 20, 2015, the Company signed a five-year lease agreement for 2,552 square feet of laboratory space commencing on July 1, 2015 and ending on June 30, 2020. Under the lease agreement, the Company pays its allocable portion of real estate taxes and common area operating charges. Rent paid under this lease during the three months ended September 30, 2018 and 2017 was \$16,732 and \$16,244, respectively, and rent paid during the nine months ended September 30, 2018 and 2017 was \$49,221 and \$47,787, respectively.

REXAHN PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements

(Unaudited)

Future rental payments over the next five years for all leases are as follows:

For the remaining three months ending December 31:	2018	\$	70,806
For the year ending December 31:	2019		176,080
	2020		<u>34,468</u>
	Total	\$	<u>281,354</u>

- d) The Company has established a 401(k) plan for its employees. The Company has elected to match 100% of the first 3% of an employee's compensation plus 50% of an additional 2% of the employee's deferral. Expense related to this matching contribution aggregated to \$29,425 and \$31,453 for the three months ended September 30, 2018 and 2017, respectively, and \$99,702 and \$92,203 for the nine months ended September 30, 2018 and 2017, respectively.
- e) In July 2013, the Company entered into an exclusive license agreement with the University of Maryland, Baltimore for a novel drug delivery platform, Nano-Polymer Drug Conjugate Systems. As of September 30, 2018, no development milestones have occurred.
- f) In October 2013, the Company signed an exclusive license agreement with the Ohio State Innovation Foundation, for a novel oligonucleotide drug delivery platform, Lipid-Coated Albumin Nanoparticle. The agreement requires the Company to make payments to the Ohio State Innovation Foundation if any products from the licensed delivery platform achieve development milestones. As of September 30, 2018, no development milestones have occurred.
- g) On February 5, 2018, the Company and Next BT terminated the research collaboration agreement between the Company and Rexgene. In exchange for Next BT terminating its rights to RX-0201 in Asia, the Company agreed to pay Next BT a royalty in the low single digits of any net sales of RX-0201 the Company makes in Asia and 50% of the Company's licensing revenue related to licensing of RX-0201 in Asia, up to an aggregate of \$5,000,000.

REXAHN PHARMACEUTICALS, INC.Notes to Condensed Financial Statements
(Unaudited)**15. Fair Value Measurements**

ASC 820 defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date, not adjusted for transaction costs. ASC 820 also establishes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three broad levels giving the highest priority to quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3).

The three levels are described below:

- Level 1 Inputs — Unadjusted quoted prices in active markets for identical assets or liabilities that are accessible by the Company;
- Level 2 Inputs — Quoted prices in markets that are not active or financial instruments for which all significant inputs are observable, either directly or indirectly; and
- Level 3 Inputs — Unobservable inputs for the asset or liability including significant assumptions of the Company and other market participants.

The following tables present assets and liabilities that are measured at fair value on a recurring basis and are categorized using the fair value hierarchy. There have been no changes in the methodologies used at September 30, 2018 and December 31, 2017.

Fair Value Measurements at September 30, 2018

	Total	Level 1	Level 2	Level 3
Assets:				
Corporate Bonds	\$ 7,974,010	\$ -	\$ 7,974,010	\$ -
Liabilities:				
Warrant Liabilities	\$ 4,101,504	\$ -	\$ -	\$ 4,101,504

Fair Value Measurements at December 31, 2017

	Total	Level 1	Level 2	Level 3
Assets:				
Commercial Paper	3,238,500	-	3,238,500	-
Corporate Bonds	14,693,441	-	14,693,441	-
Total Assets:	\$ 17,931,941	\$ -	\$ 17,931,941	\$ -
Liabilities:				
Warrant Liabilities	\$ 7,853,635	\$ -	\$ -	\$ 7,853,635

REXAHN PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements

(Unaudited)

The fair value of the Company's Level 2 marketable securities is determined by using quoted prices from independent pricing services that use market data for comparable securities in active or inactive markets. A variety of data inputs, including benchmark yields, interest rates, known historical trades and broker dealer quotes are used with pricing models to determine the quoted prices.

The fair value methodology for the warrant liabilities is disclosed in Note 12.

The carrying amounts reported in the financial statements for cash and cash equivalents (Level 1), and accounts payable and accrued expenses approximate fair value because of the short-term maturity of these financial instruments.

The following table sets forth a reconciliation of changes for the nine months ended September 30, 2018 and 2017 in the fair value of the liabilities classified as Level 3 in the fair value hierarchy:

	<u>Warrant Liabilities</u>
Balance at January 1, 2018	\$ 7,853,635
Additions	-
Unrealized gains, net	(3,752,131)
Transfers out of level 3	-
Balance at September 30, 2018	<u>\$ 4,101,504</u>

	<u>Warrant Liabilities</u>
Balance at January 1, 2017	\$ 1,573,366
Additions	4,107,488
Unrealized losses, net	9,047,831
Transfers out of level 3	(8,052,594)
Balance at September 30, 2017	<u>\$ 6,676,091</u>

Additions consist of the fair value of warrant liabilities upon issuance. Transfers out of Level 3 for warrant liabilities consist of warrant exercises, where the liability is converted to additional paid-in capital upon exercise. The Company's policy is to recognize transfers in and transfers out as of the actual date of the event or change in circumstance that caused the transfer.

REXAHN PHARMACEUTICALS, INC.

Notes to Condensed Financial Statements
(Unaudited)

16. Collaboration Agreement

On August 16, 2018, the Company entered into a clinical trial collaboration and supply agreement (the “Collaboration Agreement”) with Merck Sharp & Dohme B.V. (“Merck”) to conduct a Phase 2 clinical trial to evaluate the safety and efficacy of the combination of RX-5902 with Merck’s anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in patients with metastatic triple negative breast cancer (TNBC). Under the terms of the Collaboration Agreement, the Company will sponsor the clinical trial and Merck will supply the Company with KEYTRUDA for use in the trial at no cost to the Company. The Collaboration Agreement provides that the Company and Merck will jointly own clinical data generated from the clinical trial.

17. Subsequent Event

On October 19, 2018, the Company closed a registered direct offering of 5,769,231 shares of common stock and warrants to purchase up to 5,769,231 shares of common stock, resulting in gross proceeds to the Company of approximately \$7,500,000. The common stock and warrants were sold in units, consisting of a share of common stock and a warrant to purchase a share of common stock, at a price of \$1.30 per unit, with an exercise price for the warrants of \$1.67 per share. The warrants will become exercisable April 19, 2019 and will remain exercisable through April 19, 2024. The Company also issued warrants to purchase up to 346,154 shares of the Company’s common stock, at an exercise price of \$1.625 per share, to designees of the placement agent in the offering.

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

OVERVIEW

The following discussion should be read in conjunction with the unaudited condensed financial statements and notes thereto set forth in Item 1 of this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2017.

Except for the historical information contained herein, the matters discussed in this Quarterly Report on Form 10-Q may be deemed to be forward-looking statements that involve risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. In this Quarterly Report on Form 10-Q, words such as “believe”, “estimate”, “expect”, “anticipate”, “will”, “may”, “intend” and other similar expressions, are intended to identify forward-looking statements. We caution that forward-looking statements are based largely on our expectations and are subject to a number of known and unknown risks and uncertainties that are subject to change based on factors that are, in many instances, beyond our control. Actual results, performance or achievements may differ materially from those contemplated, expressed or implied by the forward-looking statements.

Although we believe that the expectations reflected in our forward-looking statements are reasonable as of the date we make them, actual results could differ materially from those currently anticipated due to a number of factors, including risks relating to:

- our understandings and beliefs regarding the role of certain biological mechanisms and processes in cancer;*
- our drug candidates being in early stages of development, including in pre-clinical development;*
- our ability to initially develop drug candidates for orphan indications to reduce the time-to-market and take advantage of certain incentives provided by the U.S. Food and Drug Administration;*
- our ability to transition from our initial focus on developing drug candidates for orphan indications to candidates for more highly prevalent indications;*
- our ability to successfully and timely complete clinical trials for our drug candidates in clinical development;*
- uncertainties related to the timing, results and analyses related to our drug candidates in pre-clinical development;*
- our ability to obtain the necessary U.S. and international regulatory approvals for our drug candidates;*
- our reliance on third-party contract research organizations and other investigators and collaborators for certain research and development services;*
- our ability to maintain or engage third-party manufacturers to manufacture, supply, store and distribute supplies of our drug candidates for our clinical trials;*

- *our ability to form strategic alliances and partnerships with pharmaceutical companies and other partners for sales and marketing of certain of our product candidates;*
- *demand for and market acceptance of our drug candidates;*
- *the scope and validity of our intellectual property protection for our drug candidates and our ability to develop our candidates without infringing the intellectual property rights of others;*
- *our lack of profitability and the need for additional capital to operate our business;*
- *our ability to continue as a going concern; and*
- *other risks and uncertainties, including those set forth herein and in our Annual Report on Form 10-K for the year ended December 31, 2017 under the caption “Risk Factors” and those detailed from time to time in our filings with the Securities and Exchange Commission.*

These forward-looking statements are made only as of the date hereof, and we undertake no obligation to update or revise the forward-looking statements, whether as a result of new information, future events or otherwise.

We are a clinical stage biopharmaceutical company dedicated to the discovery and development of innovative treatments for cancer. Our mission is to improve the lives of cancer patients by developing next-generation cancer therapies that are designed to maximize efficacy while minimizing the toxicity and side effects traditionally associated with cancer treatment. Our pipeline features two oncology product candidates in Phase 2 clinical development and additional compounds in pre-clinical development. Our strategy is to continue building a significant pipeline of innovative oncology product candidates that we intend to commercialize with partners. Our clinical stage drug candidates in active development are RX-3117 and RX-5902 (Supinoxin™).

- *RX-3117 is a novel, oral, small molecule nucleoside compound. Once intracellularly activated (phosphorylated) by the enzyme UCK2, it is incorporated into the DNA or RNA of cells and inhibits both DNA and RNA synthesis, which induces apoptotic cell death of tumor cells. Because UCK2 is overexpressed in multiple human tumors, but has a very limited presence in normal tissues, RX-3117 offers the potential for a targeted anti-cancer therapy with an improved efficacy and safety profile, and we believe it has therapeutic potential in a broad range of cancers, including pancreatic, bladder, colon, and lung cancer. In January 2018, we reported final data from a Phase 2a clinical trial of RX-3117 in patients with relapsed or refractory metastatic pancreatic cancer. In this trial, encouraging progression free survival and evidence of tumor shrinkage were observed in patients with metastatic pancreatic cancer that was resistant to gemcitabine and who had failed on multiple prior treatments. RX-3117 is currently the subject of a Phase 2a clinical trial in combination with Abraxane® (paclitaxel protein-bound) in patients newly diagnosed with metastatic pancreatic cancer. The second stage of this clinical trial began in May 2018, and in October 2018, we released preliminary data illustrating the combined administration of RX-3117 and Abraxane, appears safe and well tolerated and showed evidence of clinical activity. In February 2018 updated safety and efficacy data from the ongoing two-stage Phase 2a clinical trial of RX-3117 in advanced urothelial (bladder) cancer were reported. In this trial, encouraging progression free survival and evidence of tumor shrinkage were observed in patients with advanced bladder cancer who had failed on multiple prior treatments including immunotherapy and gemcitabine. RX-3117 has received “orphan drug designation” from the U.S. Food and Drug Administration (“FDA”) and from the European Commission for pancreatic cancer. Orphan drug designation in the U.S. provides tax incentives for clinical research and a waiver from user fees under certain circumstances. In addition, an orphan drug generally receives seven years of exclusivity in the U.S. after approval for a designated use, during which time, the FDA generally cannot approve another product with the same active moiety for the same indication.*

- RX-5902 is a potential first-in-class small molecule inhibitor of phosphorylated-p68, a protein that we believe plays a key role in cancer cell growth, progression and metastasis through its interaction with beta-catenin. Phosphorylated p68, which is highly expressed in cancer cells, but not in normal cells, results in up-regulation of cancer-related genes and a subsequent proliferation of cancer cells and tumor growth. RX-5902 selectively blocks the interaction of phosphorylated p68 with beta-catenin, thereby decreasing the proliferation or growth of cancer cells in preclinical models. In addition, multiple pre-clinical models suggest that RX-5902 enhances the efficacy of immunotherapy. We have evaluated RX-5902 in a Phase 1 dose escalation study in patients with a diverse range of metastatic, treatment-refractory tumors, including breast, ovarian, colorectal, and neuro-endocrine tumors. In February 2017, we initiated a Phase 2a clinical trial of RX-5902 in patients with metastatic triple negative breast cancer (“TNBC”). Preliminary data on this trial announced in June 2018 showed five of the first 10 evaluable patients exhibited clinical response and indicated that RX-5902 was well tolerated in the study. As of October 12, 2018, 17 patients have been enrolled in the trial, with 13 of these patients evaluable and six showing a clinical response. In August 2018, we entered into a collaboration with Merck Sharp & Dohme B.V. (“Merck”) to evaluate the combination of RX-5902 and Merck’s anti-PD-1 therapy, Keytruda® (pembrolizumab) in a Phase 2 trial in patients with metastatic triple negative breast cancer.
- RX-0201 is a potential best-in-class, potent inhibitor of the protein kinase Akt-1, which we believe plays a critical role in cancer cell proliferation, survival, angiogenesis, metastasis and drug resistance. RX-0201 is the subject of a research and development collaboration with Zhejiang Haichang Biotechnology Co., Ltd (“Haichang”) for the development of RX-0201 to conduct certain pre-clinical and clinical activities through completion of a Phase 2a proof-of-concept clinical trial in hepatocellular carcinoma (“HCC”) and pursuant to which the parties will share any downstream licensing fees and royalties paid by third parties in connection with the further development and commercialization of RX-0201 for the treatment of HCC. RX-0201 has received orphan drug designation from the FDA for renal cell carcinoma (“RCC”), glioblastoma, ovarian cancer, stomach cancer and pancreatic cancer. In February 2018, in response to the changing treatment landscape for metastatic RCC over the past two years with the approval of new therapies by the FDA, we announced plans to discontinue the internally funded programs of RX-0201 and ceased enrolling patients in a Phase 2a proof-of-concept clinical trial of RX-0201 in patients with metastatic RCC.

Since our inception, our efforts and resources have been focused primarily on developing our pharmaceutical technologies, raising capital and recruiting personnel. We have no product sales to date, and we will not generate any product sales until we receive approval from the FDA or equivalent foreign regulatory bodies to begin selling our pharmaceutical candidates. Our major sources of working capital have been proceeds from various private and public financings, and licensing and collaboration agreements with our strategic investors and partners.

Recently Issued Accounting Standards

See Note 2, “Recent Accounting Pronouncements Affecting the Company,” in the Notes to Condensed Financial Statements for a discussion of recent accounting pronouncements.

Results of Operations**Comparison of the Three and Nine Months Ended September 30, 2018 and September 30, 2017****Total Revenues**

We had no revenues for the three and nine months ended September 30, 2018 or 2017.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related expenses for executive, finance and other administrative personnel, recruitment expenses, professional fees and other corporate expenses, including business development, investor relations, and general legal activities.

General and administrative expenses increased approximately \$222,000, or 14.1%, to \$1,796,000 for the three months ended September 30, 2018 from \$1,574,000 for the three months ended September 30, 2017. General and administrative expenses increased approximately \$187,000, or 3.7% to \$5,192,000 for the nine months ended September 30, 2018 from \$5,005,000 for the nine months ended September 30, 2017. The increase for the three and nine months ended September 30, 2018 was primarily attributable to increased professional fees and shareholder meeting costs.

Research and Development Expenses

Research and development expenses increased approximately \$243,000, or 9.2%, to \$2,888,000 for the three months ended September 30, 2018, from \$2,645,000 for the three months ended September 30, 2017. The increase is primarily attributable to an increase in clinical trial costs and patient enrollments from the advancement of our RX-3117 and RX-5902 clinical trials. Research and development expenses increased approximately \$2,927,000, or 39.3%, to \$10,379,000 for the nine months ended September 30, 2018, from \$7,452,000 for the nine months ended September 30, 2017, partially due to increases in drug manufacturing costs. During the nine months ended September 30, 2018, we incurred approximately \$2,514,000 of drug manufacturing costs, compared to approximately \$1,324,000 for the nine months ended September 30, 2017. The increase is also attributable to an increased clinical trial costs. During the nine months ended September 30, 2018, we incurred approximately \$4,293,000 in clinical trial costs, compared to approximately \$3,013,000 for the nine months ended September 30, 2017.

The table below summarizes the approximate amounts incurred in each of our research and development projects for the three and nine months ended September 30, 2018 and 2017:

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2018	2017	2018	2017
Project Candidates:				
RX-3117	\$ 1,405,900	\$ 1,245,500	\$ 5,002,800	\$ 3,134,000
RX-5902	632,200	492,000	2,496,200	1,189,800
RX-0201	82,100	123,200	399,100	422,000
Preclinical, Personnel and Overhead	767,755	784,299	2,480,981	2,705,856
Total Research and Development Expenses	\$ 2,887,955	\$ 2,644,999	\$ 10,379,081	\$ 7,451,656

Interest Income

Interest income decreased approximately \$6,000 or 9.2% for the three months ended September 30, 2018 compared to the same period in 2017. Interest income increased approximately \$63,000 or 46.6% for the nine months ended September 30, 2018 compared to the same period in 2017. The increase for the nine months ended September 30, 2018 was primarily attributable to higher interest rates on cash and cash equivalents and marketable securities for the nine months ended September 30, 2018 compared to the same period in 2017.

Other Income

During the nine months ended September 30, 2018, we recorded approximately \$369,000 of other income related to the termination of our collaborative agreement with NEXT BT Co. Ltd, the successor in interest to Rexgene Biotech Co., Ltd. See Note 7, "Deferred Research and Development Arrangement," in the Notes to Condensed Financial Statements for a discussion of the termination of this agreement.

Unrealized (Loss) Gain on Fair Value of Warrants

Our warrants are recorded as liabilities at fair value, and the warrants are valued using a lattice model. Changes in the fair value of warrants are recorded as an unrealized gain or loss in our statement of operations. During the three months ended September 30, 2018 and 2017, we recorded unrealized (losses) gains on the fair value of our warrants of approximately (\$710,000) and \$3,121,000. During the nine months ended September 30, 2018 and 2017, we recorded unrealized gains (losses) on the fair value of our warrants of approximately \$3,752,000 and \$(9,048,000). Estimating fair values of warrants requires the development of significant and subjective estimates that may, and are likely to, change over the duration of the warrants due to related changes to external market factors. The large unrealized loss for the nine months ended September 30, 2017 primarily resulted from a significant increase in the stock price of the underlying common stock at September 30, 2017 compared to December 31, 2016. An increase in volatility of the common stock during that period also had an impact on the large unrealized loss for the nine months ended September 30, 2017.

Financing Expense

We incurred approximately \$333,000 in financing expenses during the nine months ended September 30, 2017 related to our registered direct offering in June 2017. We did not incur financing expenses during the three months ended September 30, 2017 or the three and nine months ended September 30, 2018.

Net Loss

As a result of the above, net loss for the three and nine months ended September 30, 2018 was approximately \$5,339,000 and \$11,252,000, or \$0.17 and \$0.35 per share, respectively, compared to approximately \$1,038,000 and \$21,702,000, or \$0.04 and \$0.83 per share, respectively, for the three and nine months ended September 30, 2017, respectively. As previously discussed, included in the net loss for the three and nine months ended September 30, 2017 are non-cash charges of approximately \$3,121,000 and (\$9,048,000) in unrealized gains (losses) on the fair value of warrants, compared to unrealized (losses) gains of (710,000) and 3,752,000 for the three and nine months ended September 30, 2018, respectively.

Research and Development Projects

Research and development costs are expensed as incurred. These costs consist primarily of salaries and related personnel costs, costs to acquire pharmaceutical products and product rights for development and amounts paid to contract research organizations (“CROs”), hospitals and laboratories for the provision of services and materials for drug development and clinical trials. Costs incurred in obtaining the license rights to technology in the research and development stage that have no alternative future uses are expensed as incurred. Our research and development programs are related to our oncology drug candidates. As we expand our clinical studies, we expect to enter into additional development agreements. Significant additional expenditures will be required if we complete our clinical trials, start new trials, apply for regulatory approvals, continue development of our technologies, expand our operations and bring our products to market. The eventual total cost of each clinical trial is dependent on a number of uncertainties such as trial design, the length of the trial, the number of clinical sites and the number of patients. The process of obtaining and maintaining regulatory approvals for new therapeutic products is lengthy, expensive and uncertain. Because the successful development of our most advanced drug candidates, RX-3117 and RX-5902, is uncertain, we are unable to estimate the costs of completing our research and development programs, the timing of bringing such programs to market and, therefore, when material cash inflows could commence from the sale of these drug candidates, if any. If these projects are not completed as planned, our results of operations and financial condition would be negatively affected.

RX-3117

RX-3117 is a novel, investigational oral small molecule nucleoside compound. We believe RX-3117 has therapeutic potential in a broad range of cancers including pancreatic, bladder, cervical, non-small cell lung cancer and colon cancer. We are evaluating RX-3117 in combination with Abraxane in Phase 2a proof-of-concept clinical trial in patients with newly diagnosed with metastatic pancreatic cancer, as well as a Phase 2a trial in patients with advanced bladder cancer.

Expenses related to RX-3117 increased during the three and nine months ended September 30, 2018 compared to the same periods in 2017 due to increased clinical trial and patient enrollments resulting from the progression of our pancreatic and bladder cancer clinical trials, as well as manufacturing costs for new campaigns. We expect that expenses related to RX-3117 will remain flat for the remainder of 2018 compared to the three months ended September 30, 2018 and decrease compared to the nine months ended September 30, 2018 as we expect drug manufacturing costs to comparatively decrease due to the completion of manufacturing campaigns.

RX-5902

RX-5902 is a potential first-in-class small molecule inhibitor of phosphorylated p68, a protein that we believe plays a key role in cancer growth, progression and metastasis through its interaction with beta-catenin. Phosphorylated p68 results in up-regulation of cancer-related genes and a subsequent proliferation of cancer cells and tumor growth. In February 2017, we initiated a Phase 2a clinical study of RX-5902 in patients with metastatic TNBC.

Expenses related to RX-5902 increased during the three and nine months ended September 30, 2018 compared to the same periods in 2017. The increase is primarily attributable to increased clinical trial costs for the Phase 2a study, as well as increased manufacturing costs for new manufacturing campaigns. We expect that expenses related to RX-5902 will slightly decrease in the remainder of 2018 compared to the three and nine months ended September 30, 2018 as we expect drug manufacturing costs to decrease as manufacturing campaigns are completed.

RX-0201

RX-0201 is a potential best-in-class, potent inhibitor of the protein kinase Akt-1, which we believe plays a critical role in cancer cell proliferation, survival, angiogenesis, metastasis and drug resistance. RX-0201 is the subject of a research and development collaboration with Haichang for the development of RX-0201 to conduct certain pre-clinical and clinical activities through completion of a Phase 2a proof-of-concept clinical trial in HCC.

Expenses related to RX-0201 slightly decreased during the three and nine months ended September 30, 2018 compared to the same periods in 2017. We expect that expenses related to RX-0201 will remain flat for the remainder of 2018 compared to the three and nine months ended September 30, 2018 as we wind down our Phase 2a clinical trial of RX-0201 in patients with metastatic RCC.

Pre-clinical Pipeline

Expenses related to our pre-clinical candidates decreased for the three and nine months ended September 30, 2018 compared to the same periods in 2017 primarily as a result of decreased research activities. We expect that expenses related to our pre-clinical pipeline will remain flat for the remainder of 2018 compared to the three and nine months ended September 30, 2018 as we continue testing and development.

Research and Development Process

We have engaged third-party CROs and other investigators and collaborators, such as universities medical institutions and other life science companies, to conduct our pre-clinical studies, toxicology studies and clinical trials. Engaging third party contract research organizations is typical practice in our industry. However, relying on such organizations means that the clinical trials and other studies described above are being conducted at external locations and that the completion of these trials and studies is not within our direct control. Trials and studies may be delayed due to circumstances outside our control, and such delays may result in additional expenses for us.

Liquidity and Capital Resources

Current and Future Financing Needs

We have incurred negative cash flow from operations since we started our business. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our planned product development efforts, our clinical trials and our research and development efforts. We will need to raise additional capital through public or private equity or debt offerings or through arrangements with strategic partners or other sources in order to continue to develop our drug candidates. There can be no assurance that additional capital will be available when needed or on terms satisfactory to us, if at all. We believe that our cash, cash equivalents, and marketable securities will be sufficient to fund current operations through the third quarter of 2019, and we would require additional capital to fund operations beyond that point. These conditions raise substantial doubt about our ability to continue as a going concern within one year from the date these financial statements are issued.

The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control. These factors include the following:

- the progress of our product development activities;
- the number and scope of our product development programs;
- the progress of our pre-clinical and clinical trial activities;
- the progress of the development efforts of parties with whom we have entered into collaboration agreements;
- our ability to maintain current collaboration programs and to establish new collaboration arrangements;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and
- the costs and timing of regulatory approvals.

Cash Flows

Cash used in operating activities was approximately \$14,218,000 for the nine months ended September 30, 2018. The operating cash flows during the nine months ended September 30, 2018 reflect a net loss of \$11,252,000, an unrealized gain on the fair value of warrants of \$3,752,000, and a net increase of cash components of working capital and non-cash charges totaling \$786,000. Cash used in operating activities was approximately \$11,715,000 for the nine months ended September 30, 2017. The operating cash flows during the nine months ended September 30, 2017 reflect our net loss of \$21,702,000, offset by an unrealized loss on the fair value of warrants of \$9,048,000 and a net increase of cash components of working capital and other non-cash charges totaling \$939,000.

Cash provided by investing activities was approximately \$9,911,000 for the nine months ended September 30, 2018, which consisted of \$9,950,000 from the redemption of marketable securities, offset by \$39,000 from the purchase of equipment. Cash used in investing activities was approximately \$6,310,000 for the nine months ended September 30, 2017, which consisted of \$15,009,000 and \$21,000 for the purchases of marketable securities and equipment, respectively, offset by \$8,720,000 from the redemption of marketable securities.

There was no cash provided by financing activities for the nine months ended September 30, 2018. Cash provided by financing activities was approximately \$14,673,000 for the nine months ended September 30, 2017, which consisted of \$9,241,000 from our registered direct public offering in June 2017, and \$5,354,000 and \$78,000 from the exercise of stock warrants and options, respectively.

After September 30, 2018, we closed a registered direct offering of 5,769,231 shares of common stock and warrants to purchase up to 5,769,231 shares of common stock, resulting in gross proceeds to us of approximately \$7,500,000.

Contractual Obligations

We have a variety of contractual obligations, as more fully described in our 2017 Form 10-K. These obligations include, but are not limited to, contractual obligations in connection with license agreements (including related milestone payments), lease payments, employee compensation and incentive program expenses, and contracts with various vendors for services. As of September 30, 2018, the total estimated cost to complete our contracts with vendors for research and development services was approximately \$6,980,000 under the terms of the applicable agreements. All of these agreements may be terminated by either party upon appropriate notice as stipulated in the respective agreements.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements or holdings in variable interest entities.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

For quantitative and qualitative disclosures about market risk, refer to “Quantitative and Qualitative Disclosures About Market Risk” in our 2017 Form 10-K. Our exposures to market risk have not changed materially since December 31, 2017.

Item 4. Controls and Procedures.

Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer (“CEO”) and Chief Financial Officer (“CFO”), we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this report. Based upon that evaluation, our CEO and CFO concluded that our disclosure controls and procedures as of the end of the period covered by this report were effective such that the information required to be disclosed by us in reports filed under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission’s (the “SEC’s”) rules and forms and (ii) accumulated and communicated to our management, including our CEO and CFO, as appropriate to allow timely decisions regarding disclosure. A controls system cannot provide absolute assurance, however, that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. Other Information

Item 1A. Risk Factors.

Investing in our stock involves a high degree of risk. You should carefully consider the following discussion of risk factors, in its entirety. In addition to the other information set forth in this report, you should carefully consider the factors set forth in the Risk Factors section of our 2017 Form 10-K, as well as other information contained in the 2017 Form 10-K and in other reports we file with the SEC.

Our ability to continue as a going concern will require us to raise additional capital to fund our current operations, which may be unavailable on acceptable terms, or at all.

We have incurred negative cash flow from operations since we started our business and have an accumulated deficit. Based on our current levels of operating expenses, we believe that our cash, cash equivalents and marketable securities at September 30, 2018 and the proceeds received from our completed registered direct public offering in October 2018 will be sufficient to fund current operations through the third quarter of 2019 and that we would require additional capital to fund operations beyond that point. These conditions raise substantial doubt about our ability to continue as a going concern, as discussed in Note 1, “Operations and Organization,” in the Notes to Condensed Financial Statements. Our ability to continue as a going concern in the near term is largely dependent on our ability to obtain additional capital, and over time will be impacted by our ability to attain operating efficiencies, control expenditures, and, ultimately, to generate revenue. However, no assurance can be given that additional financing will be available, or, if available, will be on terms acceptable to us. Our financial statements do not include any adjustments that might be necessary if we are unable to continue as a going concern.

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

Pursuant to a consulting agreement, we issued 7,500 shares of common stock during the three months September 30, 2018 to a privately held investor relations firm in consideration for investor relations services. The shares of common stock were not registered under the Securities Act of 1933, as amended (the “Securities Act”), pursuant to the exemption from registration requirements provided by Section 4(a)(2) of the Securities Act, as a transaction not involving a public offering.

Item 6. Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
4.1	Form of Warrant, filed as Exhibit 4.1 to the Company's Current Report on Form 8-K filed on October 19, 2018 is herein incorporated by reference
10.1	Form of Securities Purchase Agreement, dated October 17, 2018, by and between Rexahn Pharmaceuticals, Inc. and the purchasers identified on the signature pages thereto, filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 19, 2018, is incorporated herein by reference.
10.2	Clinical Trial Collaboration and Supply Agreement, dated August 13, 2018, by and between Merck Sharp & Dohme B.V., and Rexahn Pharmaceuticals, Inc.*
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) / 15d-14(a)
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) / 15d-14(a)
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	The following materials from Rexahn Pharmaceuticals, Inc.'s Quarterly Report on Form 10-Q, formatted in Extensible Business Reporting Language ("XBRL"): (i) Condensed Balance Sheet; (ii) Condensed Statement of Operations; (iii) Condensed Statement of Comprehensive Loss; (iv) Condensed Statement of Cash Flows; and (v) Notes to the Financial Statements.

* Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

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.

REXAHN PHARMACEUTICALS, INC.
(Registrant)

Date: November 2, 2018

By: /s/ Peter D. Suzdak
Peter D. Suzdak
Chief Executive Officer
(principal executive officer)

Date: November 2, 2018

By: /s/ Douglas J. Swirsky
Douglas J. Swirsky
President and Chief Financial Officer
(principal financial and accounting officer)

[***] INDICATES MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

EXECUTION COPY

CLINICAL TRIAL COLLABORATION AND SUPPLY AGREEMENT

by and between

Merck Sharp & Dohme B.V.,

and

Rexahn Pharmaceuticals, Inc.

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Exhibits

Exhibit A – Protocol Synopsis
Exhibit B – Supply of Compound
Exhibit C – Rexahn Press Release

Schedules

Schedule I Data Sharing and Sample Testing Schedule
Schedule 2.4 Rexahn Third Parties

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CLINICAL TRIAL COLLABORATION AND SUPPLY AGREEMENT

This CLINICAL TRIAL COLLABORATION AND SUPPLY AGREEMENT (this “**Agreement**”), is entered into as of the date of last signature hereunder (the “**Effective Date**”), by and between Merck Sharp & Dohme B.V., having a place of business at Waarderweg 39, 2031 BN Haarlem, Netherlands (“**Merck**”), and Rexahn Pharmaceuticals, Inc., having a place of business at 15245 Shady Grove Road, Suite 455, Rockville, MD 20850, United States (“**Rexahn**”). Merck and Rexahn are each referred to herein individually as “**Party**” and collectively as “**Parties**”.

RECITALS

- A. Merck holds intellectual property rights with respect to the Merck Compound (as defined below).
- B. Rexahn is developing the Rexahn Compound (as defined below) for the treatment of certain tumor types.
- C. Merck is developing the Merck Compound for the treatment of certain tumor types.
- D. Rexahn desires to sponsor a clinical trial in which the Rexahn Compound and the Merck Compound would be dosed concurrently or in combination.
- E. Merck and Rexahn, consistent with the terms of this Agreement, desire to collaborate as more fully described herein, including by providing the Merck Compound and the Rexahn Compound for the Study (as defined below).

NOW, THEREFORE, in consideration of the premises and of the following mutual promises, covenants and conditions, the Parties, intending to be legally bound, mutually agree as follows:

1. Definitions.

For all purposes of this Agreement, the capitalized terms defined in this Article 1 and throughout this Agreement shall have the meanings herein specified.

1.1 “**Affiliate**” means, with respect to either Party, a person, firm, corporation, partnership or other entity that, now or hereafter, directly or indirectly owns or controls said Party, or, now or hereafter, is owned or controlled by said Party, or is under common ownership or control with said Party. The word “control” as used in this definition means (a) the direct or indirect ownership of fifty percent (50%) or more of the outstanding voting securities of a legal entity, or (b) possession, directly or indirectly, of the power to direct the management or policies of a legal entity, whether through the ownership of voting securities, contract rights, voting rights, corporate governance or otherwise.

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1.2 “**Agreement**” means this agreement, as amended by the Parties from time to time, and as set forth in the preamble.

1.3 “**Alliance Manager**” has the meaning set forth in Section 3.10.3.

1.4 “**Applicable Law**” means all federal, state, local, national and regional statutes, laws, rules, regulations and directives applicable to a particular activity hereunder, including performance of clinical trials, medical treatment and the processing and protection of personal and medical data, that may be in effect and/or updated from time to time, including those promulgated by the United States Food and Drug Administration (“**FDA**”), national regulatory authorities, the European Medicines Agency (“**EMA**”) and any successor agency to the FDA or EMA or any agency or authority performing some or all of the functions of the FDA or EMA in any jurisdiction outside the United States or the European Union (each a “**Regulatory Authority**” and collectively, “**Regulatory Authorities**”), and including cGMP and GCP (each as defined below); all data protection requirements such as those specified in the EU General Data Protection Regulation and the regulations issued under the United States Health Insurance Portability and Accountability Act of 1996 (“**HIPAA**”); export control and economic sanctions regulations which prohibit the shipment of United States-origin products and technology to certain restricted countries, entities and individuals; anti-bribery and anti-corruption laws pertaining to interactions with government agents, officials and representatives; laws and regulations governing payments to healthcare providers; securities laws, rules and regulations including that of the Securities and Exchange Commission (“**SEC**”) or similar governmental agency in the United States or abroad; and any country’s or jurisdiction’s successor or replacement statutes, laws, rules, regulations and directives relating to the foregoing.

1.5 “**Business Day**” means any day other than a Saturday, Sunday, or a day on which commercial banks located in the country where the applicable obligations are to be performed are authorized or required by law to be closed.

1.6 “**cGMP**” means the current Good Manufacturing Practices officially published and interpreted by EMA, FDA and other applicable Regulatory Authorities that may be in effect from time to time and are applicable to the Manufacture of the Compounds.

1.7 “**Clinical Data**” means all data (including raw data) and results [***] generated by or on behalf of either Party or at either Party’s direction, or by or on behalf of the Parties together or at their direction, in the course of each such Party’s performance of the Study.

1.8 “**Clinical Quality Agreement**” has the meaning set forth in Section 8.2.

1.9 “**CMC**” means “**Chemistry Manufacturing and Controls**” as such term of art is used in the pharmaceutical industry.

1.10 “**Combination**” means the use or method of using the Rexahn Compound and the Merck Compound in concomitant and/or sequential administration.

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1.11 [***].

1.12 “**Compounds**” means the Rexahn Compound and the Merck Compound. A “**Compound**” means either the Rexahn Compound or the Merck Compound, as applicable.

1.13 “**Confidential Information**” means any information, Know-How or other proprietary information or materials furnished to one Party (“**Receiving Party**”) by or on behalf of the other Party (“**Disclosing Party**”) in connection with this Agreement, except to the extent that such information or materials: (a) was already known to the Receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the Disclosing Party, as demonstrated by competent evidence; (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party; (c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the Receiving Party in breach of this Agreement; (d) was disclosed to the Receiving Party by a Third Party who had no obligation to the Disclosing Party not to disclose such information to others; or (e) was subsequently developed by the Receiving Party without use of the Disclosing Party Confidential Information, as demonstrated by competent evidence.

1.14 [***].

1.15 “**Control**” or “**Controlled**” means, with respect to particular information or intellectual property, that the applicable Party owns or has a license to such information or intellectual property and has the ability to grant a right, license or sublicense to the other Party as provided for herein without violating the terms of any agreement or other arrangement with any Third Party.

1.16 “**CTA**” means an application to a Regulatory Authority for purposes of requesting the ability to start or continue a clinical trial.

1.17 “**Data Sharing and Sample Testing Schedule**” means the schedule attached hereto as Schedule I.

1.18 “**Defending Party**” has the meaning set forth in Section 14.2.3.

1.19 “**Delivery**” with respect to the Merck Compound has the meaning set forth in Section 8.4.1, and with respect to the Rexahn Compound has the meaning set forth in Section 8.4.2.

1.20 [***].

1.21 “**Disclosing Party**” has the meaning set forth in the definition of Confidential Information.

1.22 “**Effective Date**” has the meaning set forth in the preamble.

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- 1.23 “**EMA**” has the meaning set forth in the definition of Applicable Law.
- 1.24 “**European Union**” means the European Union, as its membership may be constituted from time to time, and any successor thereto.
- 1.25 “**Excluded Merck Results**” has the meaning set forth in Schedule I.
- 1.26 “**Exclusions List**” has the meaning set forth in the definition of Violation.
- 1.27 “**FDA**” has the meaning set forth in the definition of Applicable Law.
- 1.28 [***].
- 1.29 “**Final Study Report**” has the meaning set forth in Section 3.11.2.
- 1.30 “**Force Majeure**” has the meaning set forth in Article 16.
- 1.31 “**GAAP**” has the meaning set forth in Section 6.11.
- 1.32 “**GCP**” means the Good Clinical Practices officially published by EMA, FDA and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) that may be in effect from time to time and are applicable to the testing of the Compounds.
- 1.33 “**Government Official**” means: (a) any officer or employee of a government or any department, agency or instrument of a government; (b) any Person acting in an official capacity for or on behalf of a government or any department, agency, or instrument of a government; (c) any officer or employee of a company or business owned in whole or part by a government; (d) any officer or employee of a public international organization such as the World Bank or United Nations; (e) any officer or employee of a political party or any Person acting in an official capacity on behalf of a political party; and/or (f) any candidate for political office; who, when such Government Official is acting in an official capacity, or in an official decision-making role, has responsibility for performing regulatory inspections, government authorizations or licenses, or otherwise has the capacity to make decisions with the potential to affect the business of either of the Parties.
- 1.34 “**HIPAA**” has the meaning set forth in the definition of Applicable Law.
- 1.35 “**IND**” means any Investigational New Drug Application filed or to be filed with the FDA as described in Title 21 of the U.S. Code of Federal Regulations, Part 312, and the equivalent application in the jurisdictions outside the United States, including an “Investigational Medicinal Product Dossier” filed or to be filed with Regulatory Authorities in the European Union.
- 1.36 [***].

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1.37 “**Inventions**” means all inventions and discoveries, whether or not patentable, that are made, conceived, or first actually reduced to practice by or on behalf of a Party, or by or on behalf of the Parties together, (a) in the design or performance of the Study or in the design or performance of any [***]; (b) through use of unpublished [***] Clinical Data; or (c) or through use of Sample Testing Results that are shared between the Parties pursuant to the Data Sharing and Sample Testing Schedule.

1.38 “**Joint Development Committee**” or “**JDC**” has the meaning set forth in Section 3.10.1.

1.39 [***].

1.40 [***].

1.41 [***].

1.42 “**Know-How**” means any proprietary invention, innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, including manufacturing, use, process, structural, operational and other data and information, whether or not written or otherwise fixed in any form or medium, regardless of the media on which contained and whether or not patentable or copyrightable, that is not generally known or otherwise in the public domain.

1.43 “**Liability**” has the meaning set forth in Section 14.2.1.

1.44 “**Manufacture,**” “**Manufactured,**” or “**Manufacturing**” means all activities related to the manufacture of a Compound, including planning, purchasing, manufacture, processing, compounding, storage, filling, packaging, waste disposal, labeling, leafleting, testing, quality assurance, sample retention, stability testing, release, dispatch and supply, as applicable.

1.45 “**Manufacturer’s Release**” or “**Release**” has the meaning ascribed to such term in the Clinical Quality Agreement.

1.46 “**Manufacturing Site**” means the facilities where a Compound is Manufactured by or on behalf of a Party, as such Manufacturing Site may change from time to time in accordance with Section 8.7.

1.47 “**Merck**” has the meaning set forth in the preamble.

1.48 “**Merck Background Patents**” has the meaning set forth in Section 10.4.2.

1.49 “**Merck Compound**” means pembrolizumab, a humanized anti-human PD-1 monoclonal antibody[***].

1.50 “**Merck Inventions**” has the meaning set forth in Section 10.3.

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1.51 “**NDA**” means a New Drug Application, Biologics License Application, Marketing Authorization Application, filing pursuant to Section 510(k) of the United States Federal Food, Drug and Cosmetic Act, or similar application or submission for a marketing authorization of a product filed with a Regulatory Authority to obtain marketing approval for a biological, pharmaceutical or diagnostic product in that country or in that group of countries.

1.52 “**Non-Conformance**” means, with respect to a given unit of Compound, (a) an event that deviates from an approved cGMP requirement with respect to the applicable Compound, such as a procedure, Specification, or operating parameter, or that requires an investigation to assess impact to the quality of the applicable Compound, or (b) that such Compound failed to meet the applicable representations and warranties set forth in Section 2.3. Classification of the Non-Conformance is detailed in the Clinical Quality Agreement.

1.53 [***].

1.54 [***].

1.55 “**Other Party**” has the meaning set forth in Section 14.2.3.

1.56 “**Party**” has the meaning set forth in the preamble.

1.57 “**Patent**” means a patent, extension, registration, supplementary protection certificate or the like that issues from a given Patent Application.

1.58 “**Patent Application**” means a patent application (including any provisional, substitution, divisional, continuation, continuation in part, reissue, renewal, reexamination, extension, supplementary protection certificate and the like) in respect of a given invention.

1.59 “**PD-1 Antagonist**” means any small or large molecule that [***].

1.60 “**Person**” means any individual, sole proprietorship, partnership, corporation, business trust, joint stock company, trust, unincorporated organization, association, limited liability company, institution, public benefit corporation, joint venture, entity or governmental entity.

1.61 “**Pharmacovigilance Agreement**” has the meaning set forth in Section 5.1.

1.62 “**Project Manager**” has the meaning set forth in Section 3.10.1.

1.63 “**Protocol**” means the written documentation that describes the Study and sets forth specific activities to be performed as part of the conduct of the Study.

1.64 “**Receiving Party**” has the meaning set forth in the definition of Confidential Information.

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1.65 “**Regulatory Approvals**” means, with respect to a Compound or a Combination and a country, any and all permissions (other than the Manufacturing approvals) required to be obtained from Regulatory Authorities and any other competent authority for the development, registration, importation, use (including use in clinical trials), distribution, sale and marketing of such Compound or Combination in such country, including any pricing or reimbursement approvals (even if not legally required to sell Compound or Combination).

1.66 “**Regulatory Authorities**” has the meaning set forth in the definition of Applicable Law.

1.67 “**Regulatory Documentation**” means, with respect to a Compound (or Compounds), all submissions to Regulatory Authorities in connection with the development of such Compound(s), including all INDs and amendments thereto, NDAs and amendments thereto, drug master files, correspondence with regulatory agencies, periodic safety update reports, adverse event files, complaint files, inspection reports and manufacturing records, in each case together with all supporting documents (including documents that include Clinical Data).

1.68 “**Related Agreements**” means the Pharmacovigilance Agreement and the Clinical Quality Agreement.

1.69 “**Rexahn**” has the meaning set forth in the preamble.

1.70 “**Rexahn Background Patents**” has the meaning set forth in Section 10.4.1.

1.71 “**Rexahn Class Compound**” means any small or large molecule inhibitor of phosphorylated p-68.

1.72 “**Rexahn Compound**” means RX-5902 (Supinoxin™), [***].

1.73 “**Rexahn Inventions**” has the meaning set forth in Section 10.2

1.74 “**Right of Reference**” means the “right of reference” defined in 21 CFR 314.3(b), including with regard to a Party, allowing the applicable Regulatory Authority in a country to have access to relevant information (by cross-reference, incorporation by reference or otherwise) contained in Regulatory Documentation (and any data contained therein) filed with such Regulatory Authority with respect to a Party’s Compound, only to the extent necessary for the conduct of the Study in such country or as otherwise expressly permitted or required under this Agreement to enable a Party to exercise its rights or perform its obligations hereunder.

1.75 “**SAEs**” has the meaning set forth in Section 5.2.

1.76 “**Sample Testing**” means the analyses to be performed by each Party using the applicable Samples, as described in the Data Sharing and Sample Testing Schedule.

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- 1.77 “**Sample Testing Results**” means those data and results arising from the Sample Testing performed by a Party [***].
- 1.78 “**Samples**” means biological specimens collected from subjects participating in the Study, including urine, blood and tissue samples.
- 1.79 “**Specifications**” means, with respect to a given Compound, the set of requirements for such Compound as set forth in the Clinical Quality Agreement.
- 1.80 “**Study**” means the Phase II clinical trial described in the Protocol to evaluate the safety, pharmacokinetics, pharmacodynamics, and/or preliminary efficacy of the concomitant and/or sequential administration of the combination of the Merck Compound and the Rexahn Compound in patients with metastatic Triple Negative Breast Cancer (TNBC) and described herein in Exhibit A.
- 1.81 “**Study Completion**” means database lock of the Study results.
- 1.82 “**Subcontractors**” has the meaning set forth in Section 2.4.
- 1.83 [***].
- 1.84 [***].
- 1.85 [***].
- 1.86 “**Term**” has the meaning set forth in Section 6.1.
- 1.87 “**Third Party**” means any Person or entity other than Rexahn, Merck or their respective Affiliates.
- 1.88 “**Third Party Infringement**” has the meaning set forth in Section 10.1.2(a).
- 1.89 “**Third Party Study**” has the meaning set forth in Section 3.14.1.
- 1.90 [***].
- 1.91 “**Toxicity & Safety Data**” means all clinical adverse event information and/or patient-related safety data included in the Clinical Data, as more fully described in the Pharmacovigilance Agreement.
- 1.92 “**VAT**” has the meaning set forth in Section 8.16.1.
- 1.93 “**Violation**” means that a Party or any of its officers or directors or any other personnel (or other permitted agents of a Party performing activities hereunder) has been: (a) convicted of any of the felonies identified among the exclusion authorities listed on the U.S. Department of Health and Human Services, Office of Inspector General (OIG) website, including 42 U.S.C. 1320a-7(a) (<http://oig.hhs.gov/exclusions/authorities.asp>); (b) identified in the OIG List of Excluded Individuals/Entities (LEIE) database (<http://exclusions.oig.hhs.gov/>) or listed as having an active exclusion in the System for Award Management (<http://www.sam.gov>); or (c) listed by any US Federal agency as being suspended, proposed for debarment, debarred, excluded or otherwise ineligible to participate in Federal procurement or non-procurement programs, including under 21 U.S.C. 335a (http://www.fda.gov/ora/compliance_ref/debar/) ((a), (b) and (c) collectively the “Exclusions Lists”).

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2. Scope of the Agreement.

2.1 Generally. Each Party shall: (a) contribute to the Study such resources as are necessary to fulfill its obligations set forth in this Agreement; and (b) act in good faith in performing its obligations under this Agreement and each Related Agreement to which it is a Party.

2.2 Manufacturing Delay. Each Party shall notify the other Party as promptly as possible in the event of any Manufacturing delay that is likely to adversely affect supply of its Compound as contemplated by this Agreement.

2.3 Compound Commitments.

2.3.1 Rexahn agrees to Manufacture and supply the Rexahn Compound for purposes of the Study in accordance with Article 8, and Rexahn hereby represents and warrants to Merck that, at the time of Delivery of the Rexahn Compound, such Rexahn Compound shall have been Manufactured and supplied in compliance with: (a) the Specifications for the Rexahn Compound; (b) the Clinical Quality Agreement; and (c) all Applicable Law, including cGMP and health, safety and environmental protections.

2.3.2 Merck agrees to Manufacture and supply the Merck Compound for purposes of the Study in accordance with Article 8, and Merck hereby represents and warrants to Rexahn that, at the time of Delivery of the Merck Compound, such Merck Compound shall have been Manufactured and supplied in compliance with: (a) the Specifications for the Merck Compound; (b) the Clinical Quality Agreement; and (c) all Applicable Law, including cGMP and health, safety and environmental protections.

2.3.3 Without limiting the foregoing, each Party is responsible for obtaining all regulatory approvals (including facility licenses) that are required to Manufacture its Compound in accordance with Applicable Law (provided that, for clarity, Rexahn shall be responsible for obtaining Regulatory Approvals for the Study as set forth in Section 3.4).

2.4 Delegation of Obligations. Each Party shall have the right to delegate any portion of its obligations hereunder as follows: (a) to such Party's Affiliates; (b) to Third Parties to the extent related to the Manufacture of such Party's Compound; and (c) to Third Parties upon the other Party's prior written consent (such consent not to unreasonably withheld). [***] Any and all Third Parties to whom a Party delegates any of its obligations hereunder are referred to as "Subcontractors". Notwithstanding any delegation of its obligations hereunder, each Party shall remain solely and fully liable for the performance of its Affiliates and Subcontractors to which such Party delegates the performance of its obligations under this Agreement. Each Party shall ensure that each of its Affiliates and Subcontractors performs such Party's obligations pursuant to the terms of this Agreement, including the Appendices and Schedules attached hereto. Each Party shall use reasonable efforts to obtain and maintain copies of documents relating to the obligations performed by such Affiliates and Subcontractors that are required to be provided to the other Party under this Agreement.

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2.5 Compounds. This Agreement does not create any obligation on the part of Merck to provide the Merck Compound for any activities other than the Study, nor does it create any obligation on the part of Rexahn to provide the Rexahn Compound for any activities other than the Study.

3. Conduct of the Study.

3.1 Sponsor. Rexahn shall act as the sponsor of the Study under its own IND for the Rexahn Compound with a Right of Reference to the IND of the Merck Compound, as necessary, as further described in Section 3.4; provided, however, that in no event shall Rexahn file an additional IND for the Study unless required by Regulatory Authorities to do so. If a Regulatory Authority requests an additional IND for the Study, the Parties shall meet and mutually agree on an approach to address such requirement.

3.2 Performance. Rexahn shall ensure that the Study is performed in accordance with this Agreement, the Protocol and all Applicable Law, including GCP.

3.3 Debarred Personnel; Exclusions Lists. Notwithstanding anything to the contrary contained herein, neither Party shall employ or subcontract with any Person that is excluded, debarred, suspended, proposed for suspension or debarment, in Violation or otherwise ineligible for government programs for the performance of any activities under this Agreement or the Related Agreements. Each Party hereby certifies that it has not employed or otherwise used in any capacity and will not employ or otherwise use in any capacity, the services of any Person suspended, proposed for debarment, or debarred under United States law, including 21 USC 335a, or any foreign equivalent thereof, in performing any activities under this Agreement or the Related Agreements and that such Party has, as of the Effective Date, screened itself, and its officers and directors, against the Exclusions Lists and that it has informed the other Party whether it or any of its officers or directors has been in Violation. Each Party shall notify the other Party in writing immediately if any such suspension, proposed debarment, debarment or Violation occurs or comes to its attention, and shall, with respect to any Person so suspended, proposed for debarment, debarred or in Violation, promptly remove such Person from performing in any capacity related to activities under this Agreement or the Related Agreements.

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3.4 Regulatory Matters. Rexahn shall: (a) obtain, prior to initiating the Study, all Regulatory Approvals from all Regulatory Authorities, ethics committees and/or institutional review boards with jurisdiction over the Study; and (b) [***] follow all directions from any such Regulatory Authorities, ethics committees and/or institutional review boards. Merck shall have the right (but not the obligation) to participate in any discussions (including meetings) with a Regulatory Authority regarding matters related to the Study and the Merck Compound and to collaborate on questions posed to Regulatory Authorities regarding the design and conduct of the Study. If a Right of Reference is necessary for the conduct of the Study or for seeking Regulatory Approvals involving the Study, each Party shall provide to the other Party a cross-reference letter or similar communication to the applicable Regulatory Authority if needed to effectuate the Right of Reference. Notwithstanding anything to the contrary in this Agreement, neither Party shall have any right to access the other Party's CMC data with respect to such other Party's Compound. Merck shall authorize FDA and other applicable Regulatory Authorities to cross-reference the appropriate Merck Compound INDs and CTAs to provide data access to Rexahn sufficient to support conduct of the Study. If Merck's CTA is not available in a given country, Merck will file its CMC data with the Regulatory Authority for such country, referencing Rexahn's CTA as appropriate (however, Rexahn shall have no right to directly access the CMC data).

3.5 Documentation. Rexahn shall maintain reports with respect to the Study and all related documentation in good scientific manner and in compliance with Applicable Law. Rexahn shall provide to Merck all Study information and documentation reasonably requested by Merck to enable Merck to (a) comply with any of its legal, regulatory and/or contractual obligations, or respond to any request by any Regulatory Authority, in each case related to the Merck Compound, and (b) determine whether the Study has been performed in accordance with this Agreement.

3.6 Copies. Rexahn shall provide to Merck copies of all Clinical Data, in electronic form or other mutually agreeable alternate form and on the timelines specified in the Data Sharing and Sample Testing Schedule (if applicable) or upon mutually agreeable timelines; *provided*, however, that a complete copy of the Clinical Data shall be provided to Merck no later than [***] following Study Completion. Rexahn shall ensure that (a) all patient authorizations and consents required under HIPAA, the EU General Data Protection Regulation or any other similar Applicable Law in connection with the Study permit such sharing of Clinical Data with Merck, and (b) it complies with any applicable safe harbor under Applicable Law related to transferring personal data in connection with sharing the Clinical Data, including by entering into a data protection agreement after the Effective Date but prior to initiation of clinical activities under the Study.

3.7 Sample Testing.

3.7.1 Rexahn shall provide Samples to Merck as specified in the Protocol or as agreed to by the Joint Development Committee. Each Party shall (a) use the Samples only for the Sample Testing, and (b) conduct the Sample Testing assigned to such Party on the Data Sharing and Sample Testing Schedule solely in accordance with the Data Sharing and Sample Testing Schedule and the Protocol. All Sample Testing Results shall be [***] under the Sample Testing Results. If such assignment cannot or does not occur, including in circumstances where such assignment is precluded by Applicable Law, the Party with the obligation to assign hereby grants the other Party [***]. Excluded Merck Results shall be solely owned by Merck.

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3.7.2 [***] Merck shall provide to Rexahn the Sample Testing Results for the Sample Testing conducted by or on behalf of Merck, in electronic form or other mutually agreeable [***]

3.7.3 [***] Rexahn shall provide to Merck the Sample Testing Results for the Sample Testing conducted by or on behalf of Rexahn, in electronic form or other mutually agreeable alternate form, on the timelines specified in the Data Sharing and Sample Testing Schedule or [***].

3.8 Ownership and Use of Clinical Data.

3.8.1 All Clinical Data shall be jointly owned by Rexahn and Merck. [***].

3.8.2 Notwithstanding the foregoing, [***] *provided, however*, that the foregoing shall not limit or restrict either Party's ability to (i) use or disclose the Clinical Data as may be necessary to comply with Applicable Law or with such Party's internal policies and procedures with respect to pharmacovigilance and adverse event reporting, or (ii) share with Third Parties or Affiliates Toxicity and Safety Data where because of severity, frequency or lack of reversibility either Party needs to use such Toxicity and Safety Data with respect to its own Compound or the Combination to ensure patient safety. The Parties will furthermore consult and cooperate fully with each other on the provisions of this Agreement to be redacted in any filings required to be made by the Parties with the Securities and Exchange Commission or similar governmental agency in the U.S. or abroad, or as otherwise required by Applicable Law to protect to the fullest extent possible the Confidential Information of the Parties.

3.8.3 Notwithstanding anything to the contrary in this Section 3.8, [***].

3.8.4 If either Party desires to [***] which is not in accordance with this Section 3.8, such [***] shall require: (A) the advanced written consent of the other Party (which shall be at such Party's sole discretion); and (B) such Third Party must be under obligations of confidentiality and non-use at least as stringent as those set forth in Section 9.1 of this Agreement.

3.9 Regulatory Submission. It is understood and acknowledged by the Parties that positive Clinical Data could be used to obtain label changes for the Compounds, and each Party may propose a [***] in connection therewith in accordance with Section 3.14.

3.10 Joint Development Committee; Alliance Managers.

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3.10.1 The Parties shall form a joint development committee (the “**Joint Development Committee**” or “**JDC**”) made up of an equal number of representatives of Merck and Rexahn, which shall have responsibility for coordinating all regulatory and other activities under, and pursuant to, this Agreement. The JDC will review and finalize the Protocol in accordance with Section 4.1. Each Party shall designate a project manager (the “**Project Manager**”) who shall be responsible for implementing and coordinating activities and facilitating the exchange of information between the Parties with respect to the Study and shall be a member of the JDC. Other JDC members will be agreed by both Parties.

3.10.2 The JDC shall meet as soon as practicable after the Effective Date and then no less than twice yearly, and more often as reasonably considered necessary at the request of either Party, to provide an update on the progress of the Study. The JDC may meet in person or by means of teleconference, Internet conference, videoconference or other similar communications equipment. Prior to any such meeting, Rexahn’s Project Manager shall provide an update in writing to Merck’s Project Manager, which update shall contain information about the overall progress of the Study, recruitment status, interim analysis (if results available), final analysis (if results available) and other information relevant to the conduct of the Study.

3.10.3 In addition to a Project Manager, each Party shall designate an alliance manager (the “**Alliance Manager**”), who shall endeavor to ensure clear and responsive communication between the Parties and the effective exchange of information and shall serve as the primary point of contact for any issues arising under this Agreement. The Alliance Managers shall have the right to attend all JDC meetings and may bring to the attention of the JDC any matters or issues either of them reasonably believes should be discussed and shall have such other responsibilities as the Parties may mutually agree in writing.

3.10.4 In the event that an issue arises and the Alliance Managers cannot or do not, after good faith efforts, reach agreement on such issue [***] or if there is a decision to be made by the JDC on which the members of the JDC cannot unanimously agree [***], the issue shall be elevated to the Vice President of Clinical Oncology for Merck and the Chief Executive Officer for Rexahn, who shall confer and use good faith efforts to reach a resolution or consensus. In the event such escalation does not result in resolution or consensus [***]: (a) Merck shall have final decision-making authority with respect to issues related to the Merck Compound; and (b) Rexahn shall have final decision-making authority with respect to issues related to the Rexahn Compound [***]. Notwithstanding the foregoing, neither the JDC nor either Party, in the exercise of their final decision-making authority, shall have any power to amend or modify the terms or provisions of this Agreement unless such amendment is duly authorized and executed in writing by authorized signatories of both Parties.

3.11 Certain Memoranda and Reports. Without limiting any other provision of this Agreement requiring Rexahn to provide to Merck documentation related to the Study, Rexahn shall provide to Merck drafts and final versions of the top-line results memorandum and final study report for the Study as described below.

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3.11.1 *Top-Line Results Memo.* Promptly following Study Completion, Rexahn shall provide to Merck an electronic draft of the top-line results memorandum for the Study, and Merck shall have [***] to provide comments thereon. Rexahn shall consider in good faith any comments provided by Merck on such draft top-line results memorandum and shall not include any statements therein relating to the Merck Compound that have not been approved by Merck. Rexahn shall deliver to Merck a final version of the top-line results memorandum promptly following finalization thereof.

3.11.2 *Final Study Report.* Rexahn shall provide Merck with an electronic draft of the final study report promptly, but in no case later than [***] following Study Completion, and Merck shall [***] to provide comments thereon. Rexahn shall consider in good faith any comments provided by Merck on the draft final study report and shall not include any statements therein relating to the Merck Compound that have not been approved by Merck. Rexahn shall deliver to Merck a final version of the final study report promptly following finalization thereof (the “**Final Study Report**”).

3.12 Relationship. Except as expressly set forth in this Agreement, nothing in this Agreement shall: (a) prohibit either Party from performing clinical studies other than the Study relating to its own Compound, either individually or in combination with any other compound or product, in any therapeutic area; or (b) create an exclusive relationship between the Parties with respect to any Compound. Each Party acknowledges and agrees that nothing in this Agreement shall be construed as a representation or inference that the other Party will not develop for itself, or enter into business relationships with other Third Parties regarding, any products, programs, studies (including combination studies), technologies or processes that are similar to or that may compete with the Combination or any other product, program, technology or process, including with respect to Rexahn Class Compounds or PD-1 Antagonists, *provided* that [***] are not used or disclosed in connection therewith in violation of this Agreement.

3.13 Licensing. Nothing in this Agreement shall prohibit or restrict a Party from licensing, assigning or otherwise transferring to an Affiliate or Third Party such Party’s Compound or any Inventions, [***], owned solely by such Party. A Party may license, assign or transfer to an Affiliate or Third Party such Party’s interest in the [***], and in connection therewith share the shared Sample Testing Results owned by the other Party, solely to the extent such licensee, assignee or transferee agrees in writing to be bound by the terms of this Agreement with respect to such [***] and shared Sample Testing Results. For purposes of clarity, any assignment or transfer of this Agreement must comply with Section 18 of this Agreement.

3.14 [***].

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4. Protocol, Statistical Analysis Plan and Informed Consent; Certain Covenants.

4.1 Protocol and Statistical Analysis Plan. A synopsis of the initial Protocol for the Study has been agreed to by the Parties as of the Effective Date and is attached hereto as Exhibit A. Through the JDC, Rexahn shall (a) provide any draft versions of the Protocol or statistical analysis plan (and any subsequent revisions thereof) to Merck for Merck's review and comment, (b) consider in good faith any changes to the draft Protocol or statistical analysis plan requested by Merck, and (c) incorporate any changes requested by Merck with respect to the Merck Compound. Any proposed final version of the Protocol [***] having any amendment from that of Exhibit A related to the Merck Compound) or statistical analysis plan shall be submitted by Rexahn to the JDC for final approval. To the extent the JDC cannot agree unanimously on the Protocol or statistical analysis submitted for final approval: (i) Rexahn shall have final decision-making authority with respect to matters in the Protocol or statistical analysis plan related to [***] (ii) Merck shall have final decision-making authority with respect to matters in the Protocol or statistical analysis plan related to [***] and (iii) all other matters in respect of the Protocol or statistical analysis plan on which the JDC cannot agree shall be resolved in accordance with Section 3.10.4. Once the final Protocol has been approved in accordance with this Section 4.1, any material changes to such approved final Protocol or statistical analysis plan (other than material changes relating solely to the Rexahn Compound) and any changes to the final Protocol (whether or not material) or statistical analysis plan relating to the Merck Compound shall require Merck's prior written consent. Any such proposed changes will be sent in writing to Merck's Project Manager and Merck's Alliance Manager. Merck will provide such consent, or a written explanation for why such consent is being withheld, [***] of receiving a copy of Rexahn's requested changes.

4.1.1 Notwithstanding anything to the contrary contained herein, Merck, in its sole discretion, shall have the sole right to determine the dose and dosing regimen for the Merck Compound and shall have the final decision on all matters relating to the Merck Compound (including quantities of Merck Compound to be supplied pursuant to Article 8) and any information regarding the Merck Compound included in the Protocol.

4.1.2 Notwithstanding anything to the contrary contained herein, Rexahn, in its sole discretion, shall have the sole right to determine the dose and dosing regimen for the Rexahn Compound and shall have the final decision on all matters relating to the Rexahn Compound (including quantities of Rexahn Compound to be supplied pursuant to Article 8) and any information regarding the Rexahn Compound included in the Protocol.

4.2 Informed Consent. Rexahn shall prepare the patient informed consent form for the Study (which shall include provisions regarding the use of Samples in Sample Testing) in consultation with Merck (it being understood and agreed that the portion of the informed consent form relating to the Sample Testing of the Merck Compound shall be provided to Rexahn by Merck). Any proposed changes to such form that relate to the Merck Compound, including Sample Testing of the Merck Compound, shall be subject to Merck's prior written consent. Any such proposed changes will be sent in writing to Merck's Project Manager and Merck's Alliance Manager. Merck will provide such consent, or a written explanation for why such consent is being withheld, within [***]

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4.3 Financial Disclosure. Rexahn shall (a) track and collect financial disclosure information from all “clinical investigators” involved in the Study and (b) prepare for submission (and submit as applicable) the certification and/or disclosure of the same in accordance with all Applicable Law, including, but not limited to, Part 54 of Title 21 of the United States Code of Federal Regulations (Financial Disclosure by Clinical Investigators) and related FDA Guidance Documents. Prior to the initiation of clinical activities under the Study, but in any event [***] the Parties shall determine whether Rexahn shall track and collect from all “clinical investigators” involved in the Study separate certification and/or disclosure forms for each of Merck and Rexahn or one (1) “combined” certification and/or disclosure form for both Merck and Rexahn. For purposes of this Section 4.3, the term “clinical investigators” shall have the meaning set forth in Part 54.2(d) of Title 21 of the United States Code of Federal Regulations.

4.4 Transparency Reporting.

4.4.1 With respect to any annual reporting period in which Rexahn is not an entity that is required to make a Transparency Report under Applicable Law, Rexahn will: (a) notify Merck, in writing, [***] that Rexahn is not so required; and (b) during such reporting period Rexahn will track and provide to Merck data regarding payments or other transfers of value by Rexahn to health care providers and health care professionals, but only to the extent such payments or other transfers of value were required, instructed, directed or otherwise caused by Merck pursuant to this Agreement in the format requested by Merck and provided on a basis to be agreed upon by both Parties. Rexahn represents and warrants that any data provided by Rexahn to Merck pursuant to Section 4.4.1(b) above will be complete and accurate to the best of Rexahn’s knowledge.

4.4.2 With respect to any annual reporting period in which Rexahn is required to make a Transparency Report under Applicable Law, Rexahn will provide to Merck, in writing, Rexahn’s point of contact for purposes of receiving information from Merck pursuant to this Section 4.4, along with such contact’s full name, email address, and telephone number. Rexahn may update such contact from time to time by notifying Merck in writing pursuant to Section 22 (Notices). Where applicable, Merck will provide to such Rexahn contact all information regarding the value of the Merck Compound provided for use in the Study and any other information that may be required for Rexahn to satisfy its obligations under Applicable Law for such reporting. In the event that the value of the Merck Compound provided pursuant to this Section 4.4.2 changes, Merck shall notify Rexahn of such revised value and the effective date thereof.

4.4.3 For purposes of this Section 4.4, “**Transparency Report**” means a transparency report in connection with reporting payments and other transfers of value made to health care providers or health care professionals, including, as applicable and without limitation, Study sites, investigators, steering committee members, data monitoring committee members, and consultants in connection with the Study in accordance with reporting requirements under Applicable Law, including, without limitation, the Physician Payment Sunshine Act and state gift laws, and the European Federation of Pharmaceutical Industries and Associations Disclosure Code, or a Party’s applicable policies.

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5. Adverse Event Reporting.

5.1 Pharmacovigilance Agreement. Rexahn will be solely responsible for compliance with all Applicable Laws pertaining to safety reporting to the Rexahn IND for the Study. The Parties (or their respective Affiliates) will execute a pharmacovigilance agreement (the “**Pharmacovigilance Agreement**”) prior to the initiation of clinical activities under the Study, but in any event [***] to ensure the exchange of relevant safety data within appropriate timeframes and in an appropriate format to enable the Parties to fulfill local and international regulatory reporting obligations and to facilitate appropriate safety reviews. In the event of any inconsistency between the terms of this Agreement and the Pharmacovigilance Agreement, the terms of this Agreement shall control. The Pharmacovigilance Agreement will include safety data exchange procedures governing the coordination of collection, investigation, reporting, and exchange of information concerning any adverse experiences, pregnancy reports, and any other safety information arising from or related to the use of the Merck Compound and Rexahn Compound in the Study, consistent with Applicable Law. Such guidelines and procedures shall be in accordance with, and enable the Parties and their Affiliates to fulfill, local and international regulatory reporting obligations to Regulatory Authorities.

5.2 Transmission of SAEs. Rexahn will transmit to Merck all serious adverse events (“SAEs”) as follows:

5.2.1 For drug-related fatal and life-threatening SAEs, Rexahn will send a processed case (on a CIOMS-1 form in English) [***] by Rexahn of such SAEs.

5.2.2 For all other SAEs, including non-drug-related fatal and life-threatening SAEs, Rexahn will send a processed case (on a CIOMS-1 form in English) [***] by Rexahn of such SAEs.

6. Term and Termination.

6.1 Term. The term of this Agreement shall commence on the Effective Date and shall continue in full force and effect until delivery of the Final Study Report by Rexahn to Merck, unless terminated earlier by either Party pursuant to this Article 6 (the “**Term**”).

6.2 Merck Termination for Safety. In the event that Merck in good faith believes that the Merck Compound is being used in the Study in an unsafe manner, Merck shall provide written notice thereof to Rexahn including a detailed description of the reasons for Merck’s concerns and any changes to the Protocol or other actions as applicable, requested by Merck in order to address such concerns. If Rexahn fails to, promptly after receipt of Merck’s written notice, incorporate changes into the Protocol requested by Merck to address such issue [***] or to otherwise address such issue reasonably and in good faith, Merck may terminate this Agreement and the supply of the Merck Compound immediately upon written notice to Rexahn.

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6.3 Termination for Material Breach. Either Party may terminate this Agreement if the other Party commits a material breach of this Agreement, and such material breach continues for [***] from the non-breaching Party; *provided* that if such material breach cannot reasonably be cured [***] the breaching Party shall be given a reasonable period of time to cure such breach; *provided further*, that if such material breach is incapable of cure, then the notifying Party may terminate this Agreement effective after the expiration of such [***].

6.4 Termination for Patient Safety. If either Party determines in good faith, based on a review of the Clinical Data, or other Study-related Know-How or other information, that the Study may unreasonably affect patient safety, such Party shall promptly notify the other Party of such determination. The Party receiving such notice may propose modifications to the Study to address the safety issue identified by the other Party and, if the notifying Party agrees, shall act to implement immediately such modifications; *provided, however*, that if the notifying Party, in its sole discretion, believes that there is imminent danger to patients, such Party need not wait for the other Party to propose modifications and may instead terminate this Agreement immediately upon written notice to such other Party. Furthermore, if the notifying Party, in its sole discretion, believes that any modifications proposed by the other Party will not resolve the patient safety issue, such Party may terminate this Agreement effective upon written notice to such other Party.

6.5 Termination for Regulatory Action; Other Reasons. Either Party may terminate this Agreement immediately upon written notice to the other Party in the event that any Regulatory Authority takes any action, or raises any objection, that prevents the terminating Party from supplying its Compound for purposes of the Study or that any Regulatory Authority revokes or suspends the Regulatory Approvals necessary to conduct the Study or requires that the Study be terminated or suspended. Additionally, either Party shall have the right to terminate this Agreement immediately upon written notice to the other Party in the event that it determines in its sole discretion to withdraw any applicable Regulatory Approval for its Compound or to discontinue development of its Compound, for medical, scientific or legal reasons.

6.6 Termination related to Anti-Corruption Obligations. Either Party shall have the right to terminate this Agreement immediately upon written notice to the other Party, if such other Party fails to perform any of its obligations under Section 13.4 or breaches any representation or warranty contained in Section 13.4. Except as set forth in Section 6.11, the non-terminating Party shall have no claim against the terminating Party for compensation for any loss of whatever nature by virtue of the termination of this Agreement in accordance with this Section 6.6.

6.7 Return of Merck Compound. In the event that this Agreement is terminated, or in the event Rexahn remains in possession (including through any Affiliate or Subcontractor) of Merck Compound at the time this Agreement expires, Rexahn shall, at Merck's sole discretion, promptly either return or destroy all unused Merck Compound pursuant to Merck's instructions. If Merck requests that Rexahn destroy the unused Merck Compound, Rexahn shall provide written certification of such destruction. Notwithstanding the foregoing, (a) in the event this Agreement is terminated by Merck pursuant to Section 6.2, Section 6.3 or Section 6.6 and Merck requests that all unused Merck Compound be returned or destroyed, Rexahn shall promptly return to Merck or destroy the unused Merck Compound [***], or (b) in the event this Agreement is terminated by Rexahn pursuant to Section 6.3 or Section 6.6 and Merck requests that all unused Merck Compound be returned or destroyed, Rexahn shall promptly return to Merck or destroy the unused Merck Compound [***].

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6.8 Survival. The provisions of Sections 3.4 through 3.8 (inclusive), 3.13, 3.14, 6.7 through 6.11 (inclusive), 8.5.2, 8.11, 8.14 through 8.16 (inclusive), 12.2, 13.4.6, 13.5, 14.2, and 14.3, and Articles 1, 5, 9 through 12 (inclusive), 17, and 20 through 25 (inclusive) shall survive the expiration or termination of this Agreement.

6.9 No Prejudice. Termination of this Agreement shall be without prejudice to any claim or right of action of either Party against the other Party for any prior breach of this Agreement.

6.10 Confidential Information. Upon termination of this Agreement, each Party and its Affiliates shall promptly return to the Disclosing Party or destroy any Confidential Information of the Disclosing Party [***] furnished to the Receiving Party by the Disclosing Party; *provided, however* that the Receiving Party may retain one copy of such Confidential Information in its confidential files, solely for purposes of exercising the Receiving Party's rights hereunder, satisfying its obligations hereunder or complying with any legal proceeding or requirement with respect thereto, and *provided further* that the Receiving Party shall not be required to erase electronic files created in the ordinary course of business during automatic system back-up procedures pursuant to its electronic record retention and destruction practices that apply to its own general electronic files and information so long as such electronic files are (a) maintained only on centralized storage servers (and not on personal computers or devices), (b) not accessible by any of its personnel (other than its information technology specialists), and (c) are not otherwise accessed subsequently except with the written consent of the Disclosing Party or as required by law or legal process. Such retained copies of Confidential Information shall remain subject to the confidentiality and non-use obligations herein.

6.11 Manufacturing Costs. [***].

7. Costs of Study.

The Parties agree that: (a) Merck shall provide the Merck Compound for use in the Study, as described in Article 8 below; (b) [***]; and (c) Rexahn shall bear[***]other costs associated with the conduct of the Study[***].

8. Supply and Use of the Compounds.

8.1 Supply of the Compounds. Subject to the terms and conditions of this Agreement, each of Rexahn and Merck will use commercially reasonable efforts to supply, or cause to be supplied, the quantities of its respective Compound as are set forth in Exhibit B, on the timelines set forth in Exhibit B, in each case for use in the Study; *provided, however*, that no Merck Compound shall be Delivered until after an IND has been obtained by Rexahn in accordance with Section 3.1. If the Protocol is changed in accordance with Article 4 in such a manner that may affect the quantities of Compound to be provided or the timing for providing such quantities, the Parties shall amend Exhibit B to reflect any changes required to be consistent with the Protocol. Each Party shall also provide to the other Party a contact person for the supply of its Compound under this Agreement. Notwithstanding the foregoing, or anything to the contrary herein, in the event that a Party is: (a) not supplying its Compound in accordance with the terms of this Agreement, then the other Party shall have no obligation to supply its Compound; or (b) allocating under Section 8.10, then the other Party may allocate proportionally.

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8.2 Clinical Quality Agreement. Within [***] days after the Effective Date of this Agreement, but in any event before any supply of Merck Compound hereunder, the Parties (or their respective Affiliates) shall enter into a quality agreement that shall address and govern issues related to the quality of clinical drug supply to be supplied by the Parties for use in the Study (the “Clinical Quality Agreement”). In the event of any inconsistency between the terms of this Agreement and the Clinical Quality Agreement, the terms of this Agreement shall control. The Clinical Quality Agreement shall, among other things: (a) detail classification of any Compound found to have a Non-Conformance; (b) include criteria for Manufacturer’s Release and related certificates and documentation; (c) include criteria and timeframes for acceptance of Merck Compound; (d) include procedures for the resolution of disputes regarding any Compounds found to have a Non-Conformance; and (e) include provisions governing the recall of Compounds.

8.3 Minimum Shelf Life Requirements. Each Party shall use commercially reasonable efforts to supply its Compound hereunder with an adequate remaining shelf life at the time of Delivery to meet the Study requirements.

8.4 Provision of Compounds.

8.4.1 Merck will, at its own cost, deliver the Merck Compound [***] to Rexahn’s, or its designee’s, location as specified by Rexahn (“**Delivery**” with respect to such Merck Compound). Title and risk of loss for the Merck Compound shall transfer from Merck to Rexahn at Delivery. All costs associated with the subsequent transportation, warehousing and distribution of Merck Compound shall be borne by Rexahn. Rexahn will, or will cause its designee to: (a) take delivery of the Merck Compound supplied hereunder; (b) perform the acceptance (including testing) procedures allocated to it under the Clinical Quality Agreement; (c) subsequently label and pack the Merck Compound (in accordance with Section 8.5), and promptly ship the Merck Compound to the Study sites for use in the Study, in compliance with cGMP, GCP and other Applicable Law and the Clinical Quality Agreement; and (d) provide, from time to time at the reasonable request of Merck, the following information: any applicable chain of custody forms, in-transport temperature recorder(s), records and receipt verification documentation, such other transport or storage documentation as may be reasonably requested by Merck, and usage and inventory reconciliation documentation related to the Merck Compound.

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8.4.2 Rexahn is solely responsible, at its own cost, for supplying (including all Manufacturing, acceptance and release testing) the Rexahn Compound for the Study, and the subsequent handling, storage, transportation, warehousing and distribution of the Rexahn Compound supplied hereunder. Rexahn shall ensure that all such activities are conducted in compliance with cGMP, GCP and other Applicable Law and the Clinical Quality Agreement. For purposes of this Agreement, the “**Delivery**” of a given quantity of the Rexahn Compound shall be deemed to occur when such quantity is packaged for shipment to a Study site.

8.5 Labeling and Packaging; Use, Handling and Storage.

8.5.1 The Parties’ obligations with respect to the labeling and packaging of the Compounds are as set forth in the Clinical Quality Agreement. Notwithstanding the foregoing or anything to the contrary contained herein, Merck shall provide the Merck Compound to Rexahn in the form of unlabeled vials, and Rexahn shall be responsible for labeling, packaging and leafleting such Merck Compound in accordance with the terms and conditions of the Clinical Quality Agreement and otherwise in accordance with all Applicable Law, including cGMP, GCP, and health, safety and environmental protections.

8.5.2 Rexahn shall: (a) use the Merck Compound solely for purposes of performing the Study; (b) not use the Merck Compound in any manner that is inconsistent with this Agreement or for any commercial purpose; and (c) label, use, store, transport, handle and dispose of the Merck Compound in compliance with Applicable Law and the Clinical Quality Agreement, as well as all written instructions of Merck. Rexahn shall not reverse engineer, reverse compile, disassemble or otherwise attempt to derive the composition or underlying information, structure or ideas of the Merck Compound, and in particular shall not analyze the Merck Compound by physical, chemical or biochemical means except as necessary to perform its obligations under the Clinical Quality Agreement.

8.6 Product Specifications. A certificate of analysis shall accompany each shipment of the Merck Compound to Rexahn. Upon request, Rexahn shall provide Merck with a certificate of analysis covering each shipment of Rexahn Compound used in the Study.

8.7 Changes to Manufacturing. Each Party may make changes from time to time to its Compound or the Manufacturing Site, provided that such changes shall be in accordance with the Clinical Quality Agreement.

8.8 Product Testing; Noncompliance.

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8.8.1 *After Manufacturer's Release.* After Manufacturer's Release of the Merck Compound and concurrently with Delivery of the Compound to Rexahn, Merck shall provide Rexahn with such certificates and documentation as are described in the Clinical Quality Agreement. Rexahn shall, within the time defined in the Clinical Quality Agreement, perform, with respect to the Merck Compound, the acceptance (including testing) procedures allocated to it under the Clinical Quality Agreement. Subject to Section 2.3.2, Rexahn shall be responsible for taking all steps necessary to determine that Merck Compound or Rexahn Compound, as applicable, is suitable for release before making such Merck Compound or Rexahn Compound, as applicable, available for human use, and Merck shall provide cooperation or assistance as reasonably requested by Rexahn in connection with such determination with respect to the Merck Compound. Rexahn shall be responsible for storage and maintenance of the Merck Compound until it is tested and/or released, which storage and maintenance shall be in compliance with (a) the Specifications for the Merck Compound, the Clinical Quality Agreement and Applicable Law and (b) any written specific storage and maintenance requirements as may be provided by Merck from time to time. Rexahn shall be responsible for any failure of the Merck Compound to meet the Specifications to the extent caused by shipping, storage or handling conditions after Delivery to Rexahn hereunder.

8.8.2 *Non-Conformance.*

(a) In the event that either Party becomes aware that any Compound may have a Non-Conformance, despite testing and quality assurance activities (including any activities conducted by the Parties under Section 8.8.1), such Party shall immediately notify the other Party in accordance with the procedures of the Clinical Quality Agreement. The Parties shall investigate any Non-Conformance in accordance with Section 8.9 (Investigations) and any discrepancy between them shall be resolved in accordance with Section 8.8.3.

(b) In the event that any proposed or actual shipment of the Merck Compound (or portion thereof) shall be agreed or determined to have a Non-Conformance at the time of Delivery to Rexahn, then unless otherwise agreed to by the Parties, Merck shall replace such Merck Compound as is found to have a Non-Conformance (with respect to Merck Compound that has not yet been administered in the course of performing the Study). Unless otherwise agreed to by the Parties in writing, the sole and exclusive remedies of Rexahn with respect to any Merck Compound that is found to have a Non-Conformance at the time of Delivery shall be (i) [***] *provided* that, for clarity, Rexahn shall not be deemed to be waiving any rights under Section 8.15. In the event Merck Compound is lost or damaged by Rexahn after Delivery, Merck shall provide additional Merck Compound (if available for the Study) to Rexahn; *provided* that Rexahn shall [***] of such replaced Merck Compound; and *provided further* that Merck shall have no obligation to [***]. Except as set forth in the foregoing sentence, Merck shall have no obligation to provide replacement Merck Compound for any Merck Compound supplied hereunder other than such Merck Compound as has been agreed or determined to have a Non-Conformance at the time of Delivery to Rexahn.

(c) Rexahn shall be responsible for, and Merck shall have no obligation or liability with respect to, any Rexahn Compound supplied hereunder that is found to have a Non-Conformance. Rexahn shall replace any Rexahn Compound as is found to have a Non-Conformance (with respect to Rexahn Compound that has not yet been administered in the course of performing the Study). Unless otherwise agreed to by the Parties in writing, the sole and exclusive remedies of Merck with respect to any Rexahn Compound that is found to have a Non-Conformance at the time of Delivery shall be (i) [***], (ii) [***], and (iii) [***] *provided* that, for clarity, Merck shall not be deemed to be waiving any rights under Section 8.15.

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8.8.3 Resolution of Discrepancies. Disagreements regarding any determination of Non-Conformance by Rexahn shall be resolved in accordance with the provisions of the Clinical Quality Agreement.

8.9 Investigations. The process for investigations of any Non-Conformance shall be handled in accordance with the Clinical Quality Agreement.

8.10 Shortage; Allocation. In the event that a Party's Compound is in short supply such that a Party reasonably believes in good faith that it will not be able to fulfill its supply obligations hereunder with respect to its Compound, such Party will provide prompt written notice to the other Party thereof (including the shipments of Compound hereunder expected to be impacted and the quantity of its Compound that such Party reasonably determines it will be able to supply) and the Parties will promptly discuss such situation (including how the quantity of Compound that such Party is able to supply hereunder will be allocated within the Study). In such event, the Party experiencing such shortage shall (i) use its commercially reasonable efforts to remedy the situation giving rise to such shortage and to take action to minimize the impact of the shortage on the Study, and (ii) [***].

8.11 Records; Audit Rights. Rexahn shall maintain complete and accurate records pertaining to its use and disposition of Merck Compound (including its storage, shipping (cold chain) and chain of custody activities) and, upon request of Merck, shall make such records open to review by Merck for the purpose of conducting investigations for the determination of Merck Compound safety and/or efficacy and Rexahn's compliance with this Agreement with respect to the Merck Compound.

8.12 Quality. Quality matters related to the Manufacture of the Compounds shall be governed by the terms of the Clinical Quality Agreement in addition to the relevant quality provisions of this Agreement.

8.13 Quality Control. Each Party shall implement and perform operating procedures and controls for sampling, stability and other testing of its Compound, and for validation, documentation and release of its Compound and such other quality assurance and quality control procedures as are required by the Specifications, cGMPs and the Clinical Quality Agreement.

8.14 Audits and Inspections. The Parties' audit and inspection rights related to this Agreement shall be governed by the terms of the Clinical Quality Agreement.

8.15 Recalls. Recalls of the Compounds shall be governed by the terms of the Clinical Quality Agreement.

8.16 VAT.

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8.16.1 It is understood and agreed between the Parties that any payments made and any other consideration given under this Agreement are each exclusive of any value added or similar tax (“VAT”), which shall be added thereon as applicable and at the relevant rate. Subject to Section 8.16.1, where VAT is properly charged by the supplying Party and added to a payment made or other consideration provided (as applicable) under this Agreement, the Party making the payment or providing the other consideration (as applicable) will pay the amount of VAT properly chargeable only on receipt of a valid tax invoice from the supplying Party issued in accordance with the laws and regulations of the country in which the VAT is chargeable. Each Party agrees that it shall provide to the other Party any information and copies of any documents within its Control to the extent reasonably requested by the other Party for the purposes of (i) determining the amount of VAT chargeable on any supply made under this Agreement, (ii) establishing the place of supply for VAT purposes, or (iii) complying with its VAT reporting or accounting obligations.

8.16.2 Where one Party or its Affiliate (the “**First Party**”) is treated as making supply of goods or services in a particular jurisdiction (for VAT purposes) for no consideration, and the other Party or its Affiliate (the “**Second Party**”) is treated as receiving such supply in the same jurisdiction, thus resulting in an amount of VAT being properly chargeable on such supply, the Second Party shall only be obliged to pay to the First Party the amount of VAT properly chargeable on such supply (and no other amount). The Second Party shall pay such VAT to the First Party on receipt of a valid VAT invoice from the First Party (issued in accordance with the laws and regulations of the jurisdiction in which the VAT is properly chargeable). Each Party agrees to (i) use its reasonable efforts to determine and agree the value of the supply that has been made and, as a result, the corresponding amount of VAT that is properly chargeable and (ii) provide to the other Party any information or copies of documents in its Control as are reasonably necessary to evidence that such supply will take, or has taken, place in the same jurisdiction (for VAT purposes).

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9. Confidentiality.

9.1 Confidential Information. Subject to Sections 3.8 and 13.4.8, Rexahn and Merck agree to hold in confidence any Confidential Information provided by or on behalf of the other Party, and neither Party shall use Confidential Information of the other Party except to fulfill such Party's obligations under this Agreement or exercising its rights. Without limiting the foregoing, the Receiving Party may not, without the prior written permission of the Disclosing Party, disclose any Confidential Information of the Disclosing Party to any Third Party except to the extent disclosure (i) is required by Applicable Law; (ii) is pursuant to the terms of this Agreement; or (iii) is necessary for the conduct of the Study, and in each case ((i) through (iii)) *provided* that the Receiving Party shall provide reasonable advance notice to the Disclosing Party before making such disclosure. For the avoidance of doubt, Rexahn may, without Merck's consent, disclose Confidential Information to clinical trial sites and clinical trial investigators performing the Study, Subcontractors, the data safety monitoring and advisory board relating to the Study, and Regulatory Authorities working with Rexahn on the Study, in each case to the extent necessary for the performance of the Study and *provided* that such Persons (other than governmental entities) are bound by an obligation of confidentiality at least as stringent as the obligations contained herein.

9.2 Inventions. Notwithstanding the foregoing: (i) Inventions that constitute Confidential Information and are jointly owned by the Parties, shall constitute the Confidential Information of both Parties and each Party shall have the right to use and disclose such Confidential Information consistent with Articles 10, 11 and 12; and (ii) Inventions that constitute Confidential Information and are solely owned by one Party shall constitute the Confidential Information of that Party and each Party shall have the right to use and disclose such Confidential Information consistent with Articles 10, 11 and 12.

9.3 Personal Identifiable Data. All Confidential Information containing personal identifiable data shall be handled in accordance with all data protection and privacy laws, rules and regulations applicable to such data.

The Parties agree that the material terms of this Agreement are the Confidential Information of both Parties, subject to the exceptions in Section 9.1 and Section 9.2.

10. Intellectual Property.

10.1 [***].

(d) Except as expressly provided in Section 10.1.1(c) and in furtherance and not in limitation of Section 9.1, each Party agrees to make no Patent Application based on the other Party's Confidential Information, and to give no assistance to any Third Party for such application, without the other Party's prior written authorization.

10.1.2 *Patent Enforcement.*

[*] INDICATES MORE THAN ONE PAGE OF MATERIAL THAT WAS OMITTED AND FOR WHICH CONFIDENTIAL TREATMENT WAS REQUESTED. ALL SUCH OMITTED MATERIAL WAS FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION PURSUANT TO RULE 24b-2 UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.**

(a) Each Party shall promptly notify the other in writing of any actual or threatened infringement or misappropriation by a Third Party of any [***] of which such Party becomes aware (“**Third Party Infringement**”).

(b) Rexahn shall have the first right to initiate legal action to enforce all [***]. In the event that Rexahn fails to initiate or defend such action by the earlier of (i) [***] after first being notified or made aware of such Third Party Infringement and (ii) [***] before the expiration for initiating or defending such action, Merck shall have the right to initiate or defend such action at its sole expense.

(c) Merck shall have the first right to initiate legal action to enforce all [***]. In the event that Merck fails to initiate or defend such action by the earlier of (i) [***] after first being notified or made aware of such Third Party Infringement and (ii) [***] before the expiration for initiating or defending such action, Rexahn shall have the right to do so at its sole expense.

(d) The Parties shall cooperate in good faith to jointly control legal action to enforce all [***] against any Third Party Infringement where such Third Party Infringement results from the development or sale of a product(s) that [***]. Notwithstanding the foregoing, either Party shall have the right to opt-out of controlling such legal action by providing written notice to the other Party by the earliest of (1) [***] after first being noticed of such Third Party Infringement, (2) [***] before the expiration date for filing such action, (3) [***] before the expiration date for filing an answer to a complaint in a declaratory judgment action, and (4) [***] after receipt of an application to the FDA under Section 351(k) of the U.S. Public Health Services Act (42 U.S.C. 262(k)), or to a similar agency under any similar provisions in another country, seeking approval of a biosimilar or interchangeable biological product of the Merck Compound, whichever comes first.

(e) If one Party brings any prosecution or enforcement action or proceeding against a Third Party with respect to [***] the second Party agrees to be joined as a party plaintiff where necessary and to give the first Party reasonable assistance and authority to file and prosecute the suit. The costs and expenses of the Party bringing suit under this Section 10.1.2 shall be borne by such Party, and any damages or other monetary awards recovered relating to [***] shall be [***]. A settlement or consent judgment or other voluntary final disposition of a suit under this Section 10.1.2 may not be entered into without the consent of the Party not bringing the suit.

10.2 Inventions Owned by Rexahn. Notwithstanding anything to the contrary contained in Section 10.1, the Parties agree that all rights to Inventions relating solely to, or covering solely, the Rexahn Compound [***] are the exclusive property of Rexahn (“**Rexahn Inventions**”). Rexahn shall (a) be entitled to file and prosecute in its own name Patent Applications in respect of Rexahn Inventions and (b) own Patents that issue from any such Patent Applications in respect of Rexahn Inventions. [***] Merck hereby assigns its right, title and interest to any and all Rexahn Inventions to Rexahn.

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10.3 Inventions Owned by Merck. Notwithstanding anything to the contrary contained in Section 10.1, the Parties agree that all rights to Inventions relating solely to, or covering solely, the Merck Compound [***] are the exclusive property of Merck (“**Merck Inventions**”). Merck shall (a) be entitled to file and prosecute in its own name Patent Applications in respect of Merck Inventions and (b) own Patents that issue from any such Patent Applications in respect of Merck Inventions. [***] Rexahn hereby assigns its right, title and interest to any and all Merck Inventions to Merck.

10.4 Mutual Freedom to Operate for Combination Inventions.

10.4.1 *Rexahn License to Merck.* Rexahn hereby grants to Merck a non-exclusive, worldwide, royalty-free, fully paid-up, transferable and sublicensable license to any patent Controlled by Rexahn that [***] (the “**Rexahn Background Patents**”) solely for the purposes of: [***] *provided, however*, that in no event shall Merck or their assignee or sublicensee have the right to exploit Rexahn Background Patents to sell the Rexahn Compound or any Rexahn Class Compound, either alone or as part of a combination (including the Combination).

10.4.2 *Merck License to Rexahn.* Merck hereby grants to Rexahn a non-exclusive, worldwide, royalty-free, fully paid-up, transferable and sublicensable license to any patent Controlled by Merck that [***] (the “**Merck Background Patents**”) solely for the purposes of: [***] *provided, however*, that in no event shall Rexahn or their assignee or sublicensee have the right to exploit Merck Background Patents to sell the Merck Compound or any PD-1 Antagonist, either alone or as part of a combination (including the Combination).

10.4.3 *No Other Rights.* For clarity, the terms of this Section 10.4 do not provide Merck or Rexahn with any rights, title or interest or any license to the other Party’s intellectual property rights which [***].

10.4.4 *Termination.* Any and all licenses granted under this Section 10.4 shall terminate upon the expiration or earlier termination of this Agreement and shall not survive such expiration or termination; *provided, however* that [***] shall survive expiration of this Agreement.

10.5 Ownership of Other Inventions. Ownership of all Inventions other than [***] Merck Inventions and Rexahn Inventions shall be based on inventorship as determined under United States patent law.

11. Reprints; Rights of Cross-Reference.

Consistent with applicable copyright and other laws, each Party may use, refer to, and disseminate reprints of scientific, medical and other published articles and materials from journals, conferences and/or symposia relating to the Study that disclose the name of a Party, *provided, however*, that such use does not constitute an endorsement of any commercial product or service by the other Party.

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12. Publications; Press Releases.

12.1 Clinical Trial Registry. Rexahn shall register the Study with the Clinical Trials Registry located at www.clinicaltrials.gov and is committed to timely publication of the results following Study Completion, after taking appropriate action to secure intellectual property rights (if any) arising from the Study. The publication of the results of the Study will be in accordance with the Protocol.

12.2 Publication. Each Party shall use reasonable efforts to publish or present scientific papers dealing with the Study in accordance with accepted scientific practice. The Parties agree that prior to submission of the results of the Study for publication or presentation or any other dissemination of such results including oral dissemination, the publishing Party shall invite the other to comment on the content of the material to be published, presented, or otherwise disseminated according to the following procedure:

12.2.1 At least [***] prior to submission for publication [***], the publishing Party shall provide to the other Party the full details of the proposed publication, presentation, or dissemination in an electronic version (cd-rom or email attachment). Upon written request from the other Party, the publishing Party agrees not to submit data for publication/presentation/dissemination for an additional [***] in order to allow for actions to be taken to preserve rights for patent protection.

12.2.2 The publishing Party shall give reasonable consideration to any request by the other Party made within the periods mentioned in Section 12.2.1 to modify the publication and the Parties shall work in good faith and in a timely manner to resolve any issue regarding the content for publication.

12.2.3 The publishing Party shall remove all Confidential Information of the other Party before finalizing the publication.

12.3 Press Releases. Promptly following the Effective Date, Rexahn may issue the press release attached hereto as Exhibit C. Unless otherwise required by Applicable Law or permitted under the terms of this Agreement, neither Party shall make any other public announcement concerning this Agreement without the prior written consent of the other Party. To the extent a Party desires to make such public announcement that requires the prior written consent of the Party, such Party shall provide the other Party with a draft thereof [***] prior to the date on which such Party would like to make the public announcement[***].

13. Representations and Warranties; Disclaimers.

13.1 Due Authorization. Each of Rexahn and Merck represents and warrants to the other that: (a) it has the corporate power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; (b) it has taken all necessary corporate action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and (c) this Agreement has been duly executed and delivered on behalf of such Party and constitutes a legal, valid and binding obligation of such Party that is enforceable against it in accordance with its terms.

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13.2 Compounds.

13.2.1 *Rexahn Compound.* Rexahn hereby represents and warrants to Merck that: (a) Rexahn has the full right, power and authority to grant all of the licenses granted to Merck under this Agreement; and (b) Rexahn Controls the Rexahn Compound.

13.2.2 *Merck Compound.* Merck hereby represents and warrants to Rexahn that: (a) Merck has the full right, power and authority to grant all of the licenses granted to Rexahn under this Agreement; and (b) Merck Controls the Merck Compound.

13.3 Results. Rexahn does not undertake that the Study shall lead to any particular result, nor is the success of the Study guaranteed. Neither Party shall be liable for any use that the other Party may make of the Clinical Data nor for advice or information given in connection therewith.

13.4 Anti-Corruption and Anti-Bribery.

13.4.1 In performing their respective obligations hereunder, the Parties acknowledge that the corporate policies of Rexahn and Merck and their respective Affiliates require that each Party's business be conducted within the letter and spirit of the law. By signing this Agreement, each Party agrees to conduct the business contemplated herein in a manner that is consistent with all Applicable Law, including the Stark Act, Anti-Kickback Statute, Sunshine Act, and the U.S. Foreign Corrupt Practices Act, good business ethics, and its ethics and other corporate policies and agrees to abide by the spirit of the other Party's guidelines, which may be provided by such other Party from time to time.

13.4.2 Specifically, each Party represents and warrants that it has not, and covenants that it, its Affiliates, and its and its Affiliates' directors, employees, officers, and anyone acting on its behalf, will not, in connection with the performance of this Agreement, directly or indirectly, make, promise, authorize, ratify or offer to make, or take any action in furtherance of, any payment or transfer of anything of value for the purpose of influencing, inducing or rewarding any act, omission or decision to secure an improper advantage; or improperly assisting it in obtaining or retaining business for it or the other Party, or in any way with the purpose or effect of public or commercial bribery.

13.4.3 Neither Party shall contact, or otherwise knowingly meet with, any Government Official for the purpose of discussing activities arising out of or in connection with this Agreement, without the prior written approval of the other Party, except where such meeting is consistent with the purpose and terms of this Agreement and in compliance with Applicable Law.

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13.4.4 Each Party represents and warrants that it (a) is not excluded, debarred, suspended, proposed for suspension or debarment, in Violation or otherwise ineligible for government programs; and (b) has not employed or subcontracted with any Person for the performance of the Study who is excluded, debarred, suspended, proposed for suspension or debarment, or is in Violation or otherwise ineligible for government programs.

13.4.5 Each Party represents and warrants that, except as disclosed to the other in writing prior to the Effective Date, such Party: (a) does not have any interest that directly or indirectly conflicts with its proper and ethical performance of this Agreement; (b) shall maintain arm's length relations with all Third Parties with which it deals for or on behalf of the other in performance of this Agreement; and (c) has provided complete and accurate information and documentation to the other Party, the other Party's Affiliates and its and their personnel in the course of any due diligence conducted by the other Party for this Agreement, including disclosure of any officers, employees, owners or Persons directly or indirectly retained by such Party in relation to the performance of this Agreement who are Government Officials or relatives of Government Officials. Each Party shall make all further disclosures to the other Party as are necessary to ensure the information provided remains complete and accurate throughout the Term. Subject to the foregoing, each Party agrees that it shall not hire or retain any Government Official to assist in its performance of this Agreement, with the sole exception of conduct of or participation in clinical trials under this Agreement, *provided* that such hiring or retention shall be subject to the completion by the hiring or retaining Party of a satisfactory anti-corruption and bribery (e.g., FCPA) due diligence review of such Government Official. Each Party further covenants that any future information and documentation submitted to the other Party as part of further due diligence or a certification shall be complete and accurate.

13.4.6 Each Party shall have the right during the Term, and for a period of [***] of this Agreement, to conduct an investigation and audit of the other Party's activities, books and records, to the extent they relate to that other Party's performance under this Agreement, to verify compliance with the terms of this Section 13.4. [***]

13.4.7 Each Party shall use commercially reasonable efforts to ensure that all transactions under the Agreement are properly and accurately recorded in all material respects on its books and records and that each document upon which entries in such books and records are based is complete and accurate in all material respects. Each Party further represents, warrants and covenants that all books, records, invoices and other documents relating to payments and expenses under this Agreement are and shall be complete and accurate and reflect in reasonable detail the character and amount of transactions and expenditures. Each Party shall maintain a system of internal accounting controls reasonably designed to ensure that no off-the-books or similar funds or accounts will be maintained or used in connection with this Agreement.

13.4.8 Each Party agrees that in the event that the other Party believes in good faith that there has been a possible violation of any provision of Section 13.4, such other Party may make full disclosure of such belief and related information needed to support such belief at any time and for any reason to any competent government bodies and agencies, and to anyone else such Party determines in good faith has a legitimate need to know.

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13.4.9 Each Party shall comply with its own ethical business practices policy and any corporate integrity agreement (if applicable) to which it is subject, and shall conduct its Study-related activities in accordance with Applicable Law. Each Party shall ensure that all of its employees involved in performing its obligations under this Agreement are made specifically aware of the compliance requirements under this Section 13.4. In addition, each Party shall ensure that all such employees participate in and complete mandatory compliance training to be conducted by each Party, including specific training on anti-bribery and corruption, prior to his/her performance of any obligations or activities under this Agreement. Each Party shall certify its continuing compliance with the requirements under this Section 13.4 on a periodic basis during the Term in such form as may be reasonably specified by the other Party.

13.4.10 Each Party shall have the right to terminate this Agreement immediately upon violation of this Section 13.4 in accordance with Section 6.6.

13.5 DISCLAIMER. EXCEPT AS EXPRESSLY PROVIDED HEREIN, MERCK MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF NON-INFRINGEMENT OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WITH RESPECT TO THE MERCK COMPOUND, AND REXAHN MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF NON-INFRINGEMENT OR MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WITH RESPECT TO THE REXAHN COMPOUND.

14. Insurance; Indemnification; Limitation of Liability.

14.1 Insurance. Each Party warrants that it maintains a policy or program of insurance or self-insurance at levels sufficient to support the indemnification obligations assumed herein. Upon request, a Party shall provide evidence of such insurance.

14.2 Indemnification.

14.2.1 Indemnification by Rexahn. Rexahn agrees to defend, indemnify and hold harmless Merck, its Affiliates, and its and their employees, directors, subcontractors and agents from and against any loss, damage, reasonable costs and expenses (including reasonable attorneys' fees and expenses) incurred in connection with any claim, proceeding, or investigation by a Third Party arising out of this Agreement or the Study (a "**Liability**"), except to the extent that such Liability was directly caused by (a) negligence or willful misconduct on the part of Merck (or any of its Affiliates, or its and their employees, directors, subcontractors or agents); (b) a breach on the part of Merck of any of its representations and warranties or any other covenants or obligations of Merck under this Agreement; or (c) a breach of Applicable Law by Merck.

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14.2.2 *Indemnification by Merck.* Merck agrees to defend, indemnify and hold harmless Rexahn, its Affiliates, and its and their employees, directors, Subcontractors and agents from and against any Liability to the extent such Liability was directly caused by (a) negligence or willful misconduct on the part of Merck (or any of its Affiliates, or its and their employees, directors, Subcontractors or agents); (b) a breach on the part of Merck of any of its representations and warranties or any other covenants or obligations of Merck under this Agreement; or (c) a breach of Applicable Law by Merck.

14.2.3 *Procedure.* The obligations of Merck and Rexahn under this Section 14.2 are conditioned upon the delivery of written notice to Merck or Rexahn, as the case might be, of any potential Liability within a reasonable time after a Party becomes aware of such potential Liability. The indemnifying Party will have the right to assume the defense of any suit or claim related to the Liability (using counsel reasonably satisfactory to the indemnified Party) if it has assumed responsibility for the suit or claim in writing; *provided* that the indemnified Party may assume the responsibility for such defense to the extent the indemnifying Party does not do so in a timely manner). The indemnified Party may participate in (but not control) the defense thereof at its sole cost and expense. The Party controlling such defense (the “**Defending Party**”) shall keep the other Party (the “**Other Party**”) advised of the status of such action, suit, proceeding or claim and the defense thereof and shall consider recommendations made by the Other Party with respect thereto. The Defending Party shall not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the Other Party, which shall not be unreasonably withheld. The Defending Party, but solely to the extent the Defending Party is also the indemnifying Party, shall not agree to any settlement of such action, suit, proceeding or claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Other Party from all liability with respect thereto or that imposes any liability or obligation on the Other Party without the prior written consent of the Other Party.

14.2.4 *Study Subjects.* Rexahn shall not offer compensation on behalf of Merck to any Study subject or bind Merck to any indemnification obligations in favor of any Study subject. Merck shall not offer compensation on behalf of Rexahn to any Study subject or bind Rexahn to any indemnification obligations in favor of any Study subject.

14.3 **LIMITATION OF LIABILITY.** IN NO EVENT SHALL EITHER PARTY (OR ANY OF ITS AFFILIATES OR SUBCONTRACTORS) BE LIABLE TO THE OTHER PARTY UNDER ANY THEORY FOR, NOR SHALL ANY INDEMNIFIED PARTY HAVE THE RIGHT TO RECOVER, ANY SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR OTHER SIMILAR DAMAGES OR ANY PUNITIVE DAMAGES OR ANY LOST PROFIT, LOST SALE OR LOST OPPORTUNITY DAMAGES (WHETHER SUCH CLAIMED DAMAGES ARE DIRECT OR INDIRECT), WHETHER ARISING DIRECTLY OR INDIRECTLY OUT OF (A) THE MANUFACTURE OR USE OF ANY COMPOUND SUPPLIED HEREUNDER OR (B) ANY BREACH OF OR FAILURE TO PERFORM ANY OF THE PROVISIONS OF THIS AGREEMENT OR ANY REPRESENTATION, WARRANTY OR COVENANT CONTAINED IN OR MADE PURSUANT TO THIS AGREEMENT, EXCEPT THAT SUCH LIMITATION SHALL NOT APPLY TO DAMAGES PAID OR PAYABLE TO A THIRD PARTY BY AN INDEMNIFIED PARTY FOR WHICH THE INDEMNIFIED PARTY IS ENTITLED TO INDEMNIFICATION HEREUNDER OR WITH RESPECT TO DAMAGES ARISING OUT OF OR RELATED TO A PARTY’S BREACH OF ITS OBLIGATIONS UNDER THIS AGREEMENT WITH RESPECT TO USE, DISCLOSURE, LICENSE, ASSIGNMENT OR OTHER TRANSFER OF [***].

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15. Use of Name.

Except as otherwise provided herein, neither Party shall have any right, express or implied, to use in any manner the name or other designation of the other Party or any other trade name, trademark or logo of the other Party for any purpose in connection with the performance of this Agreement without the other Party's prior written consent.

16. Force Majeure.

If, in the performance of this Agreement, one of the Parties is prevented, hindered or delayed by reason of any cause beyond such Party's reasonable control (e.g., war, riots, fire, strike, acts of terror, governmental laws), such Party shall be excused from performance to the extent that it is necessarily prevented, hindered or delayed ("**Force Majeure**"). The non-performing Party shall notify the other Party of such Force Majeure [***] 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 will 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.

17. Entire Agreement; Amendment; Waiver.

This Agreement, together with the Appendices and Schedules hereto and the Related Agreements, constitutes the sole, full and complete agreement by and between the Parties with respect to the subject matter of this Agreement, and all prior agreements, understandings, promises and representations, whether written or oral, with respect thereto are superseded by this Agreement. In the event of a conflict between a Related Agreement and this Agreement, the terms of this Agreement shall control. No amendments, changes, additions, deletions or modifications to or of this Agreement shall be valid unless reduced to writing and signed by the Parties hereto. 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 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 said other Party whether of a similar nature or otherwise.

18. Assignment and Affiliates.

Neither Party shall assign or transfer this Agreement without the prior written consent of the other Party, such consent [***]; *provided, however*, that either Party may assign all or any part of this Agreement to one or more of its Affiliates without the other Party's consent, and any and all rights and obligations of either Party may be exercised or performed by its Affiliates, provided that such Affiliates agree to be bound by this Agreement.

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19. Invalid Provision.

If any provision of this Agreement is held to be illegal, invalid or unenforceable, the remaining provisions shall remain in full force and effect and will not be affected by the illegal, invalid or unenforceable provision. In lieu of the illegal, invalid or unenforceable provision, the Parties shall negotiate in good faith to agree upon a reasonable provision that is legal, valid and enforceable to carry out as nearly as practicable the original intention of the entire Agreement.

20. No Additional Obligations.

Rexahn and Merck have no obligation to renew this Agreement or apply this Agreement to any clinical trial other than the Study. Nothing in this Agreement obligates the Parties to enter into any other agreement (other than the Related Agreements) at this time or in the future.

21. Governing Law; Dispute Resolution.

21.1 The Parties shall attempt in good faith to settle all disputes arising out of or in connection with this Agreement in an amicable manner. Any claim, dispute or controversy arising out of or relating to this Agreement, including the breach, termination or validity hereof or thereof, shall be governed by and construed in accordance with the substantive laws of the State of New York, without giving effect to its choice of law principles.

21.2 Nothing contained in this Agreement shall deny either Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed or maintained notwithstanding any ongoing discussions between the Parties.

22. Notices.

All notices or other communications that are required or permitted hereunder shall be in writing and delivered personally, sent by facsimile (and promptly confirmed by personal delivery or overnight courier), or sent by internationally-recognized overnight courier addressed as follows:

If to Rexahn, to:

Rexahn Pharmaceuticals, Inc.
15245 Shady Grove Road, Suite 455
Rockville, MD 20850
United States
Attention: Chief Executive Officer

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

Hogan Lovells US LLP
100 International Drive
Suite 2000
Baltimore, MD 21202
Attention: Asher M. Rubin

If to Merck, to:

Merck Sharp & Dohme B.V.
Waarderweg 39
2031 BN Haarlem
Netherlands
Attention: Director
[***]

With copies (which shall not constitute notice) to:

Merck Sharp & Dohme Corp.
One Merck Drive
PO Box 100
Whitehouse Station, NJ 08889-0100
Attention: Office of Secretary

Merck Sharp & Dohme Corp.
351 North Summeytown Pike
Mailstop UG4CD-16
North Wales, PA 19454-2505
Attention: Senior Vice President, Research Science

Merck Sharp & Dohme Corp.
2000 Galloping Hill Road
Mailstop K-1-3045
Kenilworth, NJ 07033-1310
Attention: Assistant General Counsel, Corporate Transactions

23. Relationship of the Parties.

The relationship between the Parties is and shall be that of independent contractors, and does not and shall not constitute a partnership, joint venture, agency or fiduciary relationship. Neither Party shall have the authority to make any statements, representations or commitments of any kind, or take any actions, that are binding on the other Party, except with the prior written consent of the other Party to do so. All Persons employed by a Party will be the employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

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24. Counterparts and Due Execution.

This Agreement and any amendment may be executed in any number of counterparts (including by way of facsimile or electronic transmission), each of which shall be deemed an original, but all of which together shall constitute one and the same instrument, notwithstanding any electronic transmission, storage and printing of copies of this Agreement from computers or printers. When executed by the Parties, this Agreement shall constitute an original instrument, notwithstanding any electronic transmission, storage and printing of copies of this Agreement from computers or printers. For clarity, facsimile signatures and signatures transmitted via PDF shall be treated as original signatures.

25. Construction.

Except where the context otherwise requires, wherever used, the singular will include the plural, the plural the singular, the use of any gender will 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**” as used herein shall be deemed to be followed by the phrase “**without limitation**” or like expression. The term “**will**” as used herein means shall. The terms “**hereof**”, “**hereto**”, “**herein**” and “**hereunder**” and words of similar import when used in this Agreement refer to this Agreement as a whole and no to any particular provision of this Agreement. References to “**Article**,” “**Section**,” “**Exhibit**” or “**Schedule**” are references to the numbered sections of this Agreement and the appendices attached to this Agreement, unless expressly stated otherwise. Except where the context otherwise requires, references to this “**Agreement**” shall include the appendices attached to this Agreement. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction will be applied against either Party hereto.

[Remainder of page intentionally left blank.]

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IN WITNESS WHEREOF, the respective representatives of the Parties have executed this Agreement as of the Effective Date.

Rexahn Pharmaceuticals, Inc.

By: /s/ Peter Suzdak _____

Peter Suzdak _____

Name

CEO _____

Title

8/13/18 _____

Date

Merck Sharp & Dohme B.V.

By: /s/ K.J.F. Natland _____

K.J.F. Natland _____

Name

Managing Director _____

Title

16/8/18 (August) _____

Date

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Sponsor: Rexahn Pharmaceuticals, Inc.

Title: An Open Label Phase 2 Study of RX-5902 Administered in Combination With Pembrolizumab in Subjects with Metastatic Triple Negative Breast Cancer (TNBC)

Protocol Number: RX5902-002 (KN-908)

IND Number: TBD

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[***]

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Rexahn Pharmaceuticals Announces Clinical Collaboration with Merck to Evaluate RX-5902 (Supinoin™) in combination with KEYTRUDA® (pembrolizumab) for Triple Negative Breast Cancer

ROCKVILLE, MD -- -----, 2018 – Rexahn Pharmaceuticals, Inc. (NYSE American: RNN), a clinical stage biopharmaceutical company developing innovative, targeted therapeutics for the treatment of cancer, today announced that it has entered into a clinical trial collaboration agreement with Merck (known as MSD outside the United States and Canada) to evaluate the combination of Rexahn’s RX-5902 and Merck’s anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) in a Phase 2 trial in patients with metastatic triple negative breast cancer (TNBC).

“Rexahn is excited to announce this collaboration with Merck, an established leader in the field of immuno-oncology,” said Peter D. Suzdak, Ph.D., chief executive officer of Rexahn. “RX-5902 has both antitumor and immune-modulatory effects and augments the efficacy of checkpoint inhibitors in animal models. Based on the mechanism of action of RX-5902 and our observations in preclinical studies, we are optimistic that the combination of RX-5902 with KEYTRUDA may provide meaningful clinical benefit in patients with metastatic triple negative breast cancer – a cancer that is notoriously difficult to treat”.

The study will evaluate the safety and efficacy of the combination of RX-5902 and KEYTRUDA in patients with metastatic TNBC who have progressed following at least one prior treatment. Under the terms of the agreement, Rexahn will sponsor the RX-5902 and KEYTRUDA study.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA.

About RX-5902

RX-5902 (Supinoin) is an orally administered, potential first-in-class, small molecule inhibitor of phosphorylated-p68(P-p68). P-p68, which is selectively overexpressed in cancer cells and is absent in normal tissue, modulates the activity of the β -catenin/Wnt pathway and plays a role in tumor progression, metastasis and tumor immunogenicity.

In preclinical studies, RX-5902 has been shown to inhibit the growth and proliferation of multiple human cancer cell lines (including triple negative breast cancer), decrease tumor growth in patient derived xenograft models and potentiate the activity of immune checkpoint inhibitors and other anti-tumor agents. RX-5902 is currently being evaluated as monotherapy in a Phase 2 clinical trial in patients with metastatic TNBC. Preliminary data was presented at ASCO (American Society for Clinical Oncology) Annual Meeting in June 2018. Additional information on RX-5902 can be found at: <https://rexahn.com/cms/portfolio/rx-5902/>.

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About Rexahn Pharmaceuticals, Inc.

Rexahn Pharmaceuticals Inc. (NYSE American:RNN) is a clinical stage biopharmaceutical company dedicated to developing novel, targeted therapeutics for the treatment of cancer. The company's mission is to improve the lives of cancer patients by developing next-generation cancer therapies that are designed to maximize efficacy while minimizing the toxicity and side effects traditionally associated with cancer treatment. Rexahn's product candidates work by targeting and neutralizing specific proteins believed to be involved in the complex biological cascade that leads to cancer cell growth. Preclinical studies show that certain of Rexahn's product candidates may be effective against multiple types of cancer, including drug resistant cancers, and difficult-to-treat cancers, and others may augment the effectiveness of current FDA-approved cancer treatments. The company has two oncology product candidates, RX-3117 and RX-5902, in Phase 2 clinical development and additional compounds in preclinical development including RX-0201. For more information about the Company and its oncology programs, please visit www.rexahn.com.

Safe Harbor

To the extent any statements made in this press release deal with information that is not historical, these are forward-looking statements under the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about Rexahn's plans, objectives, expectations and intentions with respect to cash flow requirements, future operations and products, enrollments in clinical trials, the path of clinical trials and development activities, and other statements identified by words such as "will," "potential," "could," "can," "believe," "intends," "continue," "plans," "expects," "anticipates," "estimates," "may," other words of similar meaning or the use of future dates. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Uncertainties and risks may cause Rexahn's actual results to be materially different than those expressed in or implied by Rexahn's forward-looking statements. For Rexahn, particular uncertainties and risks include, among others, understandings and beliefs regarding the role of certain biological mechanisms and processes in cancer; drug candidates being in early stages of development, including clinical development; the ability to initially develop drug candidates for orphan indications to reduce the time-to-market and take advantage of certain incentives provided by the U.S. Food and Drug Administration; the ability to transition from our initial focus on developing drug candidates for orphan indications to candidates for more highly prevalent indications; and the expecting timing of results from our clinical trials. More detailed information on these and additional factors that could affect Rexahn's actual results are described in Rexahn's filings with the Securities and Exchange Commission, including its most recent annual report on Form 10-K and subsequent quarterly reports on Form 10-Q. All forward-looking statements in this news release speak only as of the date of this news release. Rexahn undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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DATA SHARING AND SAMPLE TESTING SCHEDULE

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Schedule 2.4
REXAHN THIRD PARTIES

[***]

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**CERTIFICATION PURSUANT TO RULES 13A-14(D)
AND 15D-14(D)**

I, Peter D. Suzdak, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Rexahn Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer 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 that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 2, 2018

/s/ Peter D. Suzdak

Peter D. Suzdak

Chief Executive Officer

**CERTIFICATION PURSUANT TO RULES 13A-14(D)
AND 15D-14(D)**

I, Douglas J. Swirsky certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Rexahn Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer 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 that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 2, 2018

/s/ Douglas J. Swirsky

Douglas J. Swirsky

President and Chief Financial Officer

CERTIFICATION OF
CHIEF EXECUTIVE OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350

SECTION 1350 CERTIFICATION*

In connection with the Quarterly Report of Rexahn Pharmaceuticals, Inc. (the “Company”) on Form 10-Q for the quarter ended September 30, 2018 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Peter D. Suzdak, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my 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 Company.

Dated: November 2, 2018

By: /s/ Peter D. Suzdak

Peter D. Suzdak,
Chief Executive Officer

* This Certification is being furnished as required by Rule 13a-14(b) under the Securities Exchange Act of 1934 (the “Exchange Act”) and Section 1350 of Chapter 63 of Title 18 of the United States Code, and shall not be deemed “filed” for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that section. This Certification shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Exchange Act, except as otherwise stated in such filing.

A signed original of this written statement required by 18 U.S.C. § 1350 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

CERTIFICATION OF
CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350

SECTION 1350 CERTIFICATION*

In connection with the Quarterly Report of Rexahn Pharmaceuticals, Inc. (the “Company”) on Form 10-Q for the quarter ended September 30, 2018 as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Douglas J. Swirsky, President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my 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 Company.

Dated: November 2, 2018

By: /s/ Douglas J. Swirsky

Douglas J. Swirsky,
President and Chief Financial Officer

* This Certification is being furnished as required by Rule 13a-14(b) under the Securities Exchange Act of 1934 (the “Exchange Act”) and Section 1350 of Chapter 63 of Title 18 of the United States Code, and shall not be deemed “filed” for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that section. This Certification shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Exchange Act, except as otherwise stated in such filing.

A signed original of this written statement required by 18 U.S.C. § 1350 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.
