REXAHN PHARMACEUTICALS, INC. Form 10-Q August 05, 2016

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 June 30, 2016

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)

Delaware11-3516358(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 electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files). Yes No

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

Large Accelerated Filer Accelerated Filer Non-Accelerated Filer Smaller reporting company (Do not check if a smaller reporting company)

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: 213,308,785 shares as of August 5, 2016

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<u>Table of Contents</u> PART I. Financial Information Item 1. Financial Statements

REXAHN PHARMACEUTICALS, INC. Condensed Balance Sheet (Unaudited)

| | June 30, 2016 | December 31, 2015 |
|---|---|--|
| ASSETS | | |
| Current Assets: Cash and cash equivalents Marketable securities Prepaid expenses and other current assets Total Current Assets Security Deposits Equipment, Net Total Assets LIABILITIES AND STOCKHOLDERS' EQUITY Current Liabilities: | \$7,877,995 11,519,899 996,083 20,393,977 30,785 105,358 \$20,530,120 | \$ 10,199,440 13,240,086 1,221,818 24,661,344 30,785 112,900 \$ 24,805,029 |
| Accounts payable and accrued expenses | \$1,794,647 | \$ 2,661,298 |
| Deferred Research and Development Arrangement | 487,500 | 525,000 |
| Other Liabilities | 92,595 | 104,020 |
| Warrant Liabilities | 2,340,978 | 2,739,163 |
| Total Liabilities Commitments and Contingencies (note 14) Stockholders' Equity: | 4,715,720 | 6,029,481 |
| Preferred stock, par value \$0.0001, 100,000,000 authorized shares, none issued and outstanding | _ | _ |
| Common stock, par value \$0.0001, 500,000,000 authorized shares, 213,233,785 | _ | - |
| and 197,413,785 issued and outstanding Additional paid-in capital Accumulated other comprehensive income (loss) Accumulated deficit | 21,323 127,422,480 2,327 (111,631,730) | 19,741 124,490,712 (18,041) (105,716,864) |
| Total Stockholders' Equity | 15,814,400 | 18,775,548 |
| Total Liabilities and Stockholders' Equity | \$20,530,120 | \$ 24,805,029 |
| (See accompanying notes to the condensed financial statements) | | |

<u>Table of Contents</u> REXAHN PHARMACEUTICALS, INC. Condensed Statement of Operations (Unaudited)

| | For the Three June 30, | e Months Ended | For the Six Months Ended June 30, | | |
|--|------------------------|----------------|-----------------------------------|-----------------------|--|
| | 2016 | 2015 | 2016 | 2015 | |
| Revenues: | \$- | \$- | \$- | \$- | |
| Expenses: | | | | | |
| General and administrative | 1,675,749 | 1,584,852 | 3,071,155 | 3,109,552 | |
| Research and development | 2,237,033 | 3,235,088 | 5,705,607 | 6,128,096 | |
| Total Expenses | 3,912,782 | 4,819,940 | 8,776,762 | 9,237,648 | |
| Loss from Operations | (3,912,782 |) (4,819,940 |) (8,776,762 |) (9,237,648) | |
| Other Income (Expense) | | | | | |
| Interest income | 28,868 | 27,020 | 57,738 | 57,602 | |
| Unrealized gain on fair value of warrants | 2,118,090 | 1,558,760 | 2,974,045 | 1,674,175 | |
| Financing expense | - | - | (169,887 |) - | |
| Total Other Income (Expense) | 2,146,958 | 1,585,780 | 2,861,896 | 1,731,777 | |
| Net Loss Before Provision for Income Taxes Provision for income taxes | (1,765,824 |) (3,234,160 |) (5,914,866 |) (7,505,871) | |
| Net Loss | \$(1,765,824 |) \$(3,234,160 |) \$(5,914,866 | -) \$(7,505,871) | |
| Net loss per share, basic and diluted | \$(0.01 |) \$(0.02 |) \$(0.03 |) \$(0.04) | |
| Weighted average number of shares outstanding, basic and diluted | 213,184,334 | 4 179,849,433 | 207,885,571 | 179,475,741 | |
| (See accompanying notes to the condensed financial | statements) | | | | |

<u>Table of Contents</u> REXAHN PHARMACEUTICALS, INC. Condensed Statement of Comprehensive Loss (Unaudited)

| | For the Three Months Ended June 30, | | For the Six Months Ended June 30, | |
|--|-------------------------------------|---------------|-----------------------------------|---------------|
| | 2016 | 2015 | 2016 | 2015 |
| Net Loss | \$(1,765,824) | \$(3,234,160) | \$(5,914,866) | \$(7,505,871) |
| Unrealized gain on available-for-sale securities | 3,733 | 4,672 | 20,368 | 39,395 |
| Comprehensive Loss | \$(1,762,091) | \$(3,229,488) | \$(5,894,498) | \$(7,466,476) |
| | | | | |

(See accompanying notes to the condensed financial statements)

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REXAHN PHARMACEUTICALS, INC. Condensed Statement of Cash Flows (Unaudited)

| | For the Six Mor 2016 | nths | Ended June 30 2015 | , |
|---|-------------------------|------|-----------------------|---|
| Cash Flows from Operating Activities: | | | | |
| Net loss | \$ (5,914,866 |) | \$ (7,505,871 |) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | | |
| Compensatory stock | 64,949 | | 56,250 | |
| Depreciation and amortization | 15,053 | | 12,643 | |
| Amortization of premiums and discounts on marketable securities, net | 22,315 | | 13,900 | |
| Stock-based compensation | 694,187 | | 544,352 | |
| Amortization of deferred research and development arrangement | (37,500 |) | (37,500 |) |
| Unrealized gain on fair value of warrants | (2,974,045 |) | (1,674,175 |) |
| Financing expense | 169,887 | | - | |
| Amortization of deferred lease incentive | (6,222 |) | (6,221 |) |
| Deferred lease expenses | (5,203 |) | (3,290 |) |
| Changes in assets and liabilities: | | | | |
| Prepaid expenses and other assets | 225,735 | | (551,351 |) |
| Accounts payable and accrued expenses | (866,651 |) | 709,545 | |
| Net Cash Used in Operating Activities | (8,612,361 |) | (8,441,718 |) |
| Cash Flows from Investing Activities: | | | | |
| Purchase of equipment | (7,511 |) | (12,388 |) |
| Purchase of marketable securities | (1,721,760 |) | (740,825 |) |
| Redemption of marketable securities | 3,440,000 | | 7,625,000 | |
| Net Cash Provided by Investing Activities | 1,710,729 | | 6,871,787 | |
| Cash Flows from Financing Activities: | | | | |
| Issuance of common stock and units, net of issuance costs | 4,580,187 | | 1,005,715 | |
| Proceeds from exercise of stock options | - | | 708,617 | |
| Net Cash Provided by Financing Activities | 4,580,187 | | 1,714,332 | |
| Net (Decrease) Increase in Cash and Cash Equivalents | (2,321,445 |) | 144,401 | |
| Cash and Cash Equivalents – beginning of period | 10,199,440 | | 9,826,245 | |
| Cash and Cash Equivalents - end of period | \$ 7,877,995 | | \$ 9,970,646 | |
| Supplemental Cash Flow Information | | | | |
| Non-cash financing and investing activities: | | | | |
| Warrants issued | \$ 2,575,860 | | \$ - | |

(See accompanying notes to the condensed financial statements)

<u>Table of Contents</u> 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, development and commercialization of innovative treatments for cancer. The Company had an accumulated deficit of \$111,631,730 at June 30, 2016 and anticipates incurring losses through fiscal year 2016 and beyond. The Company has not yet generated commercial revenues and has funded its operating losses to date through the sale of shares of its common stock and warrants to purchase shares of its common stock, convertible debt, financings, interest income from cash, cash equivalents and marketable securities, and proceeds from reimbursed research and development costs. The Company believes that its cash, cash equivalents, and marketable securities, will be sufficient to cover its cash flow requirements for its current activities for at least the next 12 months. Management believes it has the capability of managing the Company's operations within existing cash available by focusing on select research and development activities, selecting projects in conjunction with potential financings and milestones, and efficiently managing its general and administrative affairs.

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 June 30, 2016 and December 31, 2015 and of the results of operations and comprehensive loss for the three and six months ended June 30, 2016 and 2015, and the results of cash flows for the six months ended June 30, 2016 and 2015 have been included. Operating results for the three and six months ended June 30, 2016 are not necessarily indicative of results that may be expected for any other interim period or the full fiscal year ending December 31, 2016. 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, 2015 (the "2015 Form 10-K"). Information included in the condensed balance sheet as of December 31, 2015 has been derived from the Company's audited financial statements for the year ended December 31, 2015 Form 10-K.

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.

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2. Recent Accounting Pronouncements Affecting the Company

Revenue from Contracts with Customers

In May 2014, the Financial Accounting Standards Board ("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 defers 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. Early adoption of the standard is permitted, but not before the original effective date of December 15, 2016. The Company is currently evaluating the impact that the adoption of this guidance will have on its financial statements and future operating results.

Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern

In August 2014, the FASB issued ASU 2014-15, "Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern," which requires management to perform interim and annual assessments as to the entity's ability to continue as a going concern and provides related disclosure guidance. ASU 2014-15 will be effective for reporting periods beginning after December 15, 2016, with early adoption permitted. The Company is currently evaluating the impact the adoption of this guidance will have on its financial statements.

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.

Compensation-Stock Compensation

In March 2016, the FASB issued ASU 2016-09, "Compensation-Stock Compensation: Improvements to Employee Share Based Payment Accounting," which includes multiple provisions intended to simplify various aspects of accounting for share-based payments. The guidance is effective for reporting periods beginning after December 15, 2016, with early adoption permitted. The Company is currently evaluating the impact the adoption of this guidance will have on its financial statements.

3. Marketable Securities

Marketable securities are considered "available-for-sale" in accordance with FASB Accounting Standard 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 June 30, 2016 and December 31, 2015:

| | June 30, 2016 | | | |
|---|------------------------------|------------------------------|--|--|
| | | Gross | Gross | |
| | Cost | Unrealized | Unrealized Fair | |
| | Basis | Gains | Losses Value | |
| Certificates of Deposit | \$5,520,000 | \$ 2,219 | \$ (40) \$5,522,179 | |
| Commercial Paper | 2,992,580 | 954 | (604) 2,992,930 | |
| Corporate Bonds | 3,004,992 | 273 | (475) 3,004,790 | |
| Total Marketable Securities | \$11,517,572 | \$ 3,446 | \$ (1,119) \$11,519,899 | |
| | | | | |
| | December 31 | . 2015 | | |
| | December 31 | , 2015 Gross | Gross | |
| | December 31, Cost | | Gross Unrealized Fair | |
| | | Gross | | |
| Certificates of Deposit | Cost | Gross Unrealized | Unrealized Fair | |
| Certificates of Deposit Commercial Paper | Cost Basis | Gross Unrealized Gains | Unrealized Fair Losses Value | |
| | Cost Basis \$6,240,000 | Gross Unrealized Gains | Unrealized Fair Losses Value \$(5,575) \$6,234,996 | |

The Company typically invests in highly-rated securities, with the primary objective of minimizing the potential risk of principal loss. As of June 30, 2016, the Company had four certificates of deposit with a fair value of \$959,960 and unrealized losses of \$40, one commercial paper with a fair value of \$996,940 and an unrealized loss of \$604, and one corporate bond with a fair value of \$1,003,060 and an unrealized loss of \$425, all of which have been unrealized losses for less than 12 months. The Company has one corporate bond with a fair value of \$1,000,230 and an unrealized loss of \$50 which has been an unrealized loss 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 and does not consider any of its investments other-than-temporarily impaired, and anticipates that it will recover the entire amortized cost basis.

As of June 30 2016, all of the Company's marketable securities are due to mature in less than one year.

4. Prepaid Expenses and Other Current Assets

| | June 30, 2016 | December 31, 2015 |
|--|----------------------|-----------------------|
| Deposits on contracts Prepaid expenses and other current assets | \$199,697 796,386 | \$ 501,170 720,648 |
| | \$996,083 | \$ 1,221,818 |

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

| | June 30, 2016 | December 31, 2015 |
|--|---|--|
| Furniture and fixtures Office and computer equipment Lab equipment Leasehold improvements | \$78,794 112,777 431,650 133,762 | \$ 78,794 105,266 431,650 133,762 |
| Total equipment Less: Accumulated depreciation and amortization | 756,983 (651,625) | 749,472 (636,572) |
| Net carrying amount | \$105,358 | \$ 112,900 |
| 6. Accounts Payable and Accrued Expenses | | |
| | June 30, 2016 | December 31, 2015 |
| Trade payables Accrued expenses Accrued research and development contract costs Payroll liabilities | \$598,843 64,139 967,930 163,735 | \$ 774,543 92,752 1,515,151 278,852 |
| | \$1,794,647 | \$ 2,661,298 |

<u>Table of Contents</u> REXAHN PHARMACEUTICALS, INC. Notes to Condensed Financial Statements (Unaudited)

7. Deferred Research and Development Arrangements

Rexgene Biotech Co., Ltd.

In 2003, the Company entered into a collaborative research agreement with Rexgene Biotech Co., Ltd. ("Rexgene"), a shareholder. Rexgene is engaged in the development of pharmaceutical products in Asia and has agreed to assist the Company with the research, development and clinical trials necessary for registration of the Company's drug candidate Archexin in Asia. This agreement provides Rexgene with exclusive rights to license, sublicense, make, have made, use, sell and import Archexin in Asia. In accordance with the agreement, Rexgene paid the Company a one-time fee of \$1,500,000 in 2003. The agreement terminates at the later of 20 years or the term of the patent. The amortization reduces research and development expenses for the periods presented.

The Company is using 20 years as its basis for recognition and accordingly research and development expenses were reduced by \$18,750 and \$37,500 for the three and six months ended June 30, 2016 and 2015, respectively. The remaining \$487,500 and \$525,000 to be amortized at June 30, 2016 and December 31, 2015, respectively, is reflected as a deferred research and development arrangement on the balance sheet. The payment from Rexgene is being used in the cooperative funding of the costs of development of Archexin. Royalties of 3% of net sales of licensed products will become payable by Rexgene to the Company on a quarterly basis once commercial sales of Archexin begin in Asia. The product is still under development and commercial sales in Asia are not expected to begin until at least 2017. Under the terms of the agreement, Rexgene does not receive royalties on the Company's net sales outside of Asia.

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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:

| | June 30, | December 31, |
|-------------------------------|-----------|--------------|
| | 2016 | 2015 |
| Deferred lease incentive | \$154,660 | \$ 154,660 |
| Less accumulated amortization | (117,330) | (111,108) |
| | | |
| Balance | \$37,330 | \$ 43,552 |

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 \$55,265 and \$60,468 as of June 30, 2016 and December 31, 2015, 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 June 30, 2016 and December 31, 2015, there were stock options and warrants to acquire, in the aggregate, 55,376,643 and 39,082,886 shares of the Company's common stock, respectively, that are potentially dilutive. However, diluted loss per share for all periods presented is the same as basic loss per share because the inclusion of common share equivalents would be anti-dilutive.

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10. Common Stock

The following transactions occurred since December 31, 2015:

Public Offering

On March 2, 2016 the Company closed on a registered direct public offering to issue and sell 15,625,000 shares of common stock and warrants to purchase up to 11,718,750 shares of common stock. The common stock and warrants were sold in units, consisting of common stock and a warrant to purchase 0.75 shares of common stock, at a price of \$0.32 per unit, and the warrants have an exercise price of \$0.42 per share. The total gross proceeds of the offering were \$5,000,000. The warrants issued are exercisable beginning six months after the closing date until the five-year anniversary of the initial exercise date and were recorded as liabilities at fair value.

A summary of the allocation of the proceeds of the offering is shown below:

| Gross Proceeds: | \$5,000,000 |
|---|------------------------|
| Allocated to warrant liabilities: Allocated to common stock and additional paid-in capital | 2,419,922 2,580,078 |
| Total allocated gross proceeds: | \$5,000,000 |

The closing costs of \$575,751 included 781,250 warrants valued at \$155,938 and \$419,813 for placement agent and other fees. Based upon the estimated fair value of the stock and warrants in the units, the Company allocated \$169,887 to financing expense and \$405,864 as stock issuance costs.

Compensatory Shares

During the six months ended June 30, 2016, the Company issued 195,000 shares to vendors in exchange for investor relations services. The aggregate market value of the stock issued was \$64,949. 11

<u>Table of Contents</u> REXAHN PHARMACEUTICALS, INC. Notes to Condensed Financial Statements (Unaudited)

11. Stock-Based Compensation

As of June 30, 2016, the Company had 16,384,739 options to purchase common stock outstanding.

At the Company's Annual Meeting of Stockholders held on June 10, 2013, the Company's stockholders 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. A total of 17,000,000 shares of common stock have been reserved for issuance pursuant to the 2013 Plan. As of June 30, 2016, there were 11,246,239 options outstanding under the 2013 Plan, and 5,746,261 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 June 30, 2016, there were 5,018,500 outstanding options under the 2003 Plan.

In March 2016, the Company granted to a third party an option to purchase up to 120,000 shares of the Company's common stock. Of the Company's outstanding options as of June 30, 2016, these were the only options that were not issued pursuant to the 2013 Plan or the 2003 Plan.

At the Company's Annual Meeting of the Stockholders held on June 9, 2016, the Company's stockholders voted to approve an amendment to the 2013 Plan, including to provide for awards of restricted stock and restricted stock units. As of June 30, 2016, no awards of restricted stock or restricted stock units had been granted.

For the majority of the option grants to employees, the vesting period is either (i) 30%, 30% and 40% on the first, second and third anniversaries of the grant date, respectively, or (ii) 25% each on the first four anniversaries of the grant date. With the exception of the options granted in March 2016, which have a three-year term, options expire between five and 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.

Accounting for Awards

Stock option compensation expense is the estimated fair value of options 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 six months ended June 30, 2016 and 2015 is as follows:

| | For the Three Months Ended June 30, | | For the Six Ended Jun | |
|------------------------------------|-------------------------------------|-----------|--------------------------|-----------|
| | 2016 2015 | | 2016 | 2015 |
| Statement of operations line item: | | | | |
| General and administrative | \$224,786 | \$175,666 | \$440,113 | \$365,705 |
| Research and development | 126,390 | 96,300 | 254,074 | 178,647 |
| Total | \$351,176 | \$271,966 | \$694,187 | \$544,352 |

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.

Summary of Stock Option Transactions

There were 4,487,090 stock options granted at exercise prices ranging from \$0.27 to \$0.37 with an aggregate fair value of \$927,644 during the six months ended June 30, 2016. There were 3,726,316 stock options granted at exercise prices ranging from \$0.68 to \$0.89 with an aggregate fair value of \$1,835,853 during the six months ended June 30, 2015.

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:

| | Six Months Ended June 30, | | | , |
|---------------------------|---------------------------|---|---------|---|
| | 2016 | | 2015 | |
| Black-Scholes assumptions | | | | |
| Expected dividend yield | 0 | % | 0 | % |
| Expected volatility | 32-75 | % | 77-80 | % |
| Risk free interest rate | 0.6-1.4 | % | 1.3-1.7 | % |
| Expected term (in years) | 2-6 years | | 6 years | |

The following table summarizes share-based transactions:

| | Number of Options | Weighted Average Exercise Price | Weighted Average Remaining Contractual Term | Aggregate Intrinsic Value |
|------------------------------|----------------------|--|---|---------------------------------|
| Outstanding, January 1, 2016 | 12,590,982 | \$ 0.83 | 6.8 years | \$ 26,500 |
| Granted | 4,487,090 | 0.33 | | |
| Exercised | - | - | | |
| Expired | (610,000) | 1.20 | | |
| Cancelled | (83,333) | 0.51 | | |
| Outstanding, June 30, 2016 | 16,384,739 | \$ 0.68 | 7.4 years | \$ - |
| Exercisable, June 30, 2016 | 8,120,929 | \$ 0.82 | 5.8 years | \$ - |

There were no stock options exercised during the three and six months ended June 30, 2016. The total intrinsic value of the options exercised was \$1,844 and \$99,895 for the three and six months ended June 30, 2015, respectively. The weighted average fair value of the options granted was \$0.21 and \$0.49 for the six months ended June 30, 2016 and 2015 respectively.

A summary of the Company's unvested options as of June 30, 2016 and changes during the six months ended June 30, 2016 is presented below:

| | 2016 Number of | Weig | hted Average Fair |
|-----------------------------|-------------------|------|-------------------|
| | Options | C | e at Grant Date |
| Unvested at January 1, 2016 | 5,888,432 | \$ | 0.51 |
| Granted | 4,487,090 | \$ | 0.21 |
| Vested | (2,066,504) | \$ | 0.45 |
| Cancelled | (45,208) | \$ | 0.35 |
| | | | |
| Unvested at June 30, 2016 | 8,263,810 | \$ | 0.36 |

As of June 30, 2016 there was \$2,444,014 of total unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted average vesting period of 2.3 years.

12. Warrants

As of June 30, 2016, warrants to purchase 38,991,904 shares were outstanding, having exercise prices ranging from \$0.40 to \$1.50 and expiration dates ranging from July 5, 2016 to September 2, 2021.

| | 2016 | | | 2015 | | |
|-----------------------------|------------|-----|----------------|------------|-----|-----------------|
| | | We | eighted | | | |
| | Number of | ave | erage exercise | Number of | We | eighted average |
| | warrants | pri | ce | warrants | exe | ercise price |
| Balance, January 1 | 26,491,904 | \$ | 0.80 | 13,205,871 | \$ | 1.07 |
| Issued during the period | 12,500,000 | \$ | 0.42 | - | \$ | - |
| Exercised during the period | - | \$ | - | - | \$ | - |
| Expired during the period | - | \$ | - | - | \$ | - |
| | | | | | | |
| Balance, June 30 | 38,991,904 | \$ | 0.68 | 13,205,871 | \$ | 1.07 |

At June 30, 2016 the weighted average remaining contractual life of the outstanding warrants was 3.9 years.

The warrants issued to investors in the March 2011, December 2012, November 2015 and March 2016 offerings contain a provision for net cash settlement in the event that there is a fundamental transaction (contractually defined as a merger, sale of substantially all assets, tender offer or share exchange). If a fundamental transaction occurs in which the consideration issued consists principally of cash or stock in a non-public company, then the warrant holder has the option to receive cash, equal to the fair value of the remaining unexercised portion of the warrant. Due to this contingent redemption provision, the warrants require liability classification in accordance with ASC 480 and are recorded at fair value. The warrants issued to investors in the July 2013, October 2013 and January 2014 offerings contain a fundamental transaction provision, but the warrant holders only have an option as to the type of consideration received if the holders of common stock receive an option as to their consideration. In addition, the warrants issued in the March 2011, December 2012, July 2013, October 2013, January 2014, November 2015 and March 2016 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 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.

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Significant assumptions are determined as follows: <u>Trading market values</u>—Published trading market values; <u>Exercise price</u>—Stated exercise price; <u>Term</u>—Remaining contractual term of the warrant; <u>Volatility</u>—Historical trading volatility for periods consistent with the remaining terms; and <u>Risk-free rate</u>—Yields on zero coupon government securities with remaining terms consistent with the remaining terms of the warrants.

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:

| | Fair Value as June 30, | s of: |
|-------------------------------------|---------------------------|-------------------|
| Warrant Issuance: | 2016 | December 31, 2015 |
| March 31, 2011 financing: | | |
| Warrants to institutional investors | \$ - | \$ 30 |
| December 4, 2012 financing: | | |
| Warrants to institutional investors | 2,540 | 9,818 |
| Warrants to placement agent | - | 1,206 |
| July 26, 2013 financing: | | |
| Warrants to institutional investors | 27,520 | 121,420 |
| Warrants to placement agent | - | 384 |
| October 16, 2013 financing: | | |
| Warrants to institutional investors | 39,742 | 169,349 |
| Warrants to placement agent | - | 970 |
| January 21, 2014 financing: | | |
| Warrants to institutional investors | 13,762 | 131,476 |
| November 12, 2015 financing: | | |
| Warrants to institutional investors | 964,750 | 2,169,375 |
| Warrants to placement agent | 54,975 | 135,135 |
| March 2, 2016 financing: | | |
| Warrants to institutional investors | 1,167,656 | - |
| Warrants to placement agent | 70,033 | - |
| Total: | \$2,340,978 | \$ 2,739,163 |
| | | |

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

| | Number of Shar | es indexed as of: |
|-------------------------------------|----------------|-------------------|
| Warrant Issuance | June 30, 2016 | December 31, 2015 |
| March 31, 2011 financing: | | |
| Warrants to institutional investors | 3,333,333 | 3,333,333 |
| December 4, 2012 financing: | | |
| Warrants to institutional investors | 174,300 | 174,300 |
| Warrants to placement agent | 40,000 | 40,000 |
| July 26, 2013 financing: | | |
| Warrants to institutional investors | 2,000,000 | 2,000,000 |
| Warrants to placement agent | 124,032 | 124,032 |
| October 16, 2013 financing: | | |
| Warrants to institutional investors | 2,317,309 | 2,317,309 |
| Warrants to placement agent | 407,692 | 407,692 |
| January 21, 2014 financing: | | |
| Warrants to institutional investors | 4,761,905 | 4,761,905 |
| November 12, 2015 financing: | | |
| Warrants to institutional investors | 12,500,000 | 12,500,000 |
| Warrants to placement agent | 833,333 | 833,333 |
| March 2, 2016 financing: | | |
| Warrants to institutional investors | 11,718,750 | - |
| Warrants to placement agent | 781,250 | - |
| Total: | 38,991,904 | 26,491,904 |

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

| | June 30, 2016 | 5 | December 31, 20 | 15 |
|---------------------------------|---------------|---|-----------------|----|
| Trading market prices | \$ 0.25 | | \$ 0.36 | |
| Estimated future volatility | 105 | % | 105 | % |
| Dividend | - | | - | |
| Estimated future risk-free rate | 0.20-1.36 | % | 0.82-2.38 | % |
| Equivalent volatility | 43-62 | % | 44-65 | % |
| Equivalent risk-free rate | 0.01-0.63 | % | 0.22-1.11 | % |
| - | | | | |
| 18 | | | | |

Changes in the fair value of the warrant liabilities, carried at fair value, as reported as "unrealized gain on fair value of warrants" in the statement of operations:

| | For the Three Months Ended June 30, | | For the Six M June 30, | Ionths Ended |
|-------------------------------------|-------------------------------------|--------------|---------------------------|--------------|
| | 2016 | 2015 | 2016 | 2015 |
| March 31, 2011 financing: | | | | |
| Warrants to institutional investors | 33 | 202,963 | 30 | 305,040 |
| December 4, 2012 financing: | | | | |
| Warrants to institutional investors | 5,911 | 32,568 | 7,278 | 29,671 |
| Warrants to placement agent | 529 | 5,434 | 1,206 | 5,577 |
| July 26, 2013 financing: | | | | |
| Warrants to institutional investors | 63,246 | 289,146 | 93,900 | 264,360 |
| Warrants to placement agent | 64 | 15,209 | 384 | 19,554 |
| October 16, 2013 financing: | | | | |
| Warrants to institutional investors | 103,166 | 323,698 | 129,607 | 305,938 |
| Warrants to placement agent | 145 | 48,918 | 970 | 64,097 |
| January 21, 2014 financing: | | | | |
| Warrants to institutional investors | 92,428 | 640,824 | 117,714 | 679,938 |
| November 12, 2015 financing: | | | | |
| Warrants to institutional investors | 875,913 | - | 1,204,626 | - |
| Warrants to placement agent | 58,276 | - | 80,160 | - |
| March 2, 2016 financing: | | | | |
| Warrants to institutional investors | 860,121 | - | 1,252,266 | - |
| Warrants to placement agent | 58,258 | - | 85,904 | - |
| Total: | \$ 2,118,090 | \$ 1,558,760 | \$2,974,045 | \$1,674,175 |

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13. Income Taxes

No provision for federal and state income taxes was required for the three and six months ended June 30, 2016 and 2015 due to the Company's operating losses and increased deferred tax asset valuation allowance. At June 30, 2016 and December 31, 2015, the Company had unused net operating loss carry-forwards of approximately \$107,101,000 and \$98,954,000, respectively, which expire at various dates through 2036. 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 June 30, 2016 and December 31, 2015, 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:

| | June 30, 2016 | December 31, 2015 |
|---|--|--|
| Net Operating Loss Carryforwards Stock Compensation Expense Book tax differences on assets and liabilities Valuation Allowance | \$41,769,000 1,905,000 309,000 (43,983,000) | \$38,592,000 1,891,000 380,000 (40,863,000) |
| Net Deferred Tax Assets | \$- | \$- |

The Company files income tax returns in the U.S. federal and Maryland state jurisdictions. Tax years for fiscal 2012 through 2015 are open and potentially subject to examination by the federal and Maryland state taxing authorities.

14. Commitments and Contingencies

The Company has contracted with various vendors for research and development services, the terms which require payments over the terms of the agreements, usually ranging from two to 36 months. The costs to be incurred are a) estimated and are subject to revision. As of June 30, 2016, the total estimated cost to complete these agreements was approximately \$6,440,000. All of these agreements may be terminated by either party upon appropriate notice as stipulated in the respective agreements.

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 properties. As of June 30, 2016, the milestone has not occurred.

c)Office Space Lease

On June 7, 2013, the Company signed the first amendment to its commercial lease agreement for 5,466 square feet of office space in Rockville, Maryland. The amendment extends the lease term until June 30, 2019. Under the lease agreement, the Company pays its allocable portion of real estate taxes and common area operating charges.

On July 26, 2014 the Company entered into the second amendment to the lease agreement. According to the terms of this amendment, the Company leased an additional 1,637 square feet of office space, beginning on September 1, 2014 and ending on August 31, 2015. The Company subsequently renewed the lease for this space for additional one-year terms, beginning on September 1, 2015 and 2016.

Rent paid under the Company's lease during the three months ended June 30, 2016 and 2015 was \$51,301 and \$50,058, respectively, and rent paid during the six months ended June 30, 2016 and 2015 was \$102,603 and 100,117, respectively.

Prior Laboratory Lease

On August 26, 2014, the Company signed a one-year renewal to use laboratory space commencing on July 1, 2014 and ending on June 30, 2015. The lease required monthly rental payments of \$4,554. Rent paid under the Company's lease during the three and six months ended June 30, 2015 was \$13,662 and \$27,324, respectively.

Current 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 and six months ended June 30, 2016 was \$15,312 and \$30,624, respectively.

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

| For the remaining six months ending December 31: | 2016 | 134,264 |
|--|-------|-----------|
| For the year ending December 31: | 2017 | 255,731 |
| | 2018 | 233,923 |
| | 2019 | 152,955 |
| | 2020 | 34,468 |
| | | |
| | Total | \$811,341 |

The Company has established a 401(k) plan for its employees. The Company has elected to match 100% of the d) 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 \$31,587 and \$34,799 for the three months ended June 30, 2016 and 2015, respectively, and \$63,089 and \$64,158 for the six months ended June 30, 2016 and 2015.

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. RX-21101 is the Company's first drug e)candidate utilizing this platform. The agreement requires the Company to make payments to the University of Maryland if RX-21101 or any products from the licensed delivery platform achieve development milestones. As of June 30, 2016, no development milestones have occurred.

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 f) the Company to make payments to the Ohio State Innovation Foundation or any products from the licensed delivery platform achieve development milestones. As of June 30, 2016, no development milestones have occurred.

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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:

1

| 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 June 30, 2016 and December 31, 2015.

| de | | | | | |
|--|---|---------|-------------------|--|------------------------|
| Fair Value Measuremen | nts at June 30, | 201 | 6 | | |
| | Total | Le | vel 1 | Level 2 | Level 3 |
| Assets: | | | | | |
| Certificates of Deposit | \$5,522,179 | \$ | - | \$5,522,179 | \$- |
| Commercial Paper | 2,992,930 | | - | 2,992,930 | - |
| Corporate Bonds | 3,004,790 | | - | 3,004,790 | - |
| Total Assets: | \$11,519,899 | \$ | - | \$11,519,899 | \$ - |
| Liabilities: | | | | | |
| Warrant Liabilities | \$2,340,978 | | - | - | \$2,340,978 |
| | | | | | |
| | Fair Value M | eası | ıremer | nts at Decembe | er 31, 2015 |
| | Fair Value Me Total | | uremer Level 1 | | er 31, 2015 Level 3 |
| Assets: | | | | | · |
| Assets: Certificates of Deposit | Total | L | | Level 2 | Level 3 |
| | Total | L | Level 1 | Level 2 | Level 3 \$- |
| Certificates of Deposit Commercial Paper | Total \$ 6,234,996 | L | Level 1 | Level 2 \$6,234,996 | Level 3 \$- - |
| Certificates of Deposit Commercial Paper | Total \$ 6,234,996 2,977,570 | L | Level 1 | Level 2 \$6,234,996 2,977,570 | Level 3 \$- - |
| Certificates of Deposit Commercial Paper Corporate Bonds | Total \$ 6,234,996 2,977,570 4,027,520 | L \$ | Level 1 | Level 2 \$6,234,996 2,977,570 4,027,520 | Level 3 \$- - |

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), prepaid expenses, and other assets 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 in the six months ended June 30, 2016 and 2015 in the fair value of the liabilities classified as Level 3 in the fair value hierarchy:

| | Warrant Liabilities |
|---|-------------------------------------|
| Balance at January 1, 2016 | \$ 2,739,163 |
| Additions | 2,575,860 |
| Unrealized gains, net | (2,974,045) |
| Transfers out of level 3 | - |
| Balance at June 30, 2016 | \$ 2,340,978 |
| | |
| | Warrant Liabilities |
| Balance at January 1, 2015 | Warrant Liabilities \$ 3,768,351 |
| Balance at January 1, 2015 Additions | |
| • | |
| Additions | \$ 3,768,351 |

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.

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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, 2015.

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;

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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; and

other risks and uncertainties, including those set forth herein and in our Annual Report on Form 10-K under the \cdot 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, development and commercialization 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 clinical pipeline features one product candidate in Phase II clinical development, one product candidate in Phase Ib/IIa clinical development, one product candidate in Phase Ib/IIa clinical development. Our strategy is to continue building a significant pipeline of innovative oncology product candidates that we will commercialize alone or with partners. Our three clinical stage drug candidates in active development are Archexin®, RX-3117 and SupinoxinTM (RX-5902).

Archexin 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. Archexin has received "orphan drug" designation from the U.S. Food and Drug Administration (the "FDA") for renal cell carcinoma ("RCC"), glioblastoma, ovarian cancer, stomach cancer and pancreatic cancer. Orphan drug designation provides tax incentives for clinical research and a waiver from user fees under certain circumstances. In addition, an orphan drug receives seven years of exclusivity after approval, during which the FDA generally cannot approve another product with the same active moiety for the same indication. We have completed a pilot Phase IIa clinical trial of Archexin for the treatment of pancreatic cancer. We are currently conducting a Phase IIa proof-of-concept clinical trial of Archexin in patients with metastatic renal cell carcinoma to evaluate its safety and efficacy in combination with everolimus.

RX-3117 is a small molecule nucleoside compound that we believe has therapeutic potential in a broad range of cancers, including pancreatic, bladder, colon, and lung cancer. We completed an exploratory Phase I clinical study of •RX-3117 that showed a level of oral bioavailability of RX-3117 in humans with no adverse effects reported. We recently identified the maximum tolerated dose ("MTD") of RX-3117, which we are now evaluating in a Phase Ib/IIa proof-of-concept clinical trial in patients with relapsed and refractory pancreatic cancer and advanced bladder cancer.

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Supinoxin, or 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. We are currently conducting a Phase I clinical trial of Supinoxin to evaluate its safety and efficacy in patients with solid tumors.

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 Six Months Ended June 30, 2016 and June 30, 2015

Total Revenues

We had no revenues for the three and six months ended June 30, 2016 or 2015.

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 \$91,000, or 5.7%, to \$1,676,000 for the three months ended June 30, 2016 from \$1,585,000 for the three months ended June 30, 2015. The increase is primarily attributable to recruiting costs in 2016. General and administrative expenses decreased approximately \$39,000 or 1.2%, to \$3,071,000 for the six months ended June 30, 2016 from \$3,110,000 for six three months ended June 30, 2015. The decrease is primarily attributable to higher personnel costs in 2015, offset by increases in recruiting fees and overhead expenses.

Research and Development Expenses

Research and development expenses decreased approximately \$998,000, or 30.9%, to \$2,237,000 for the three months ended June 30, 2016, from \$3,235,000 for the three months ended June 30, 2015. Research and development expenses decreased \$422,000, or 6.9%, to \$5,706,000 for the six months ended June 30, 2016, from \$6,128,000 for the six months ended June 30, 2016 were primarily attributable to lower manufacturing costs for our drug candidates due to a significant supply of our drug candidates already being available to us from earlier manufacturing costs, compared to approximately \$1,853,000 during the three months ended June 30, 2015. During the six months ended June 30, 2016, we incurred approximately \$559,000 of drug manufacturing costs, compared to approximately \$1,853,000 during the three months ended June 30, 2015. During the six months ended June 30, 2016, we incurred approximately and furging costs, compared to approximately \$1,967,000 of drug manufacturing costs, compared to approximately \$3,043,000 during the six months ended June 30, 2015. Because the volume and timing of drug manufacturing does not correlate directly with the level and timing of clinical trial activity, we expect expenses related to drug manufacturing costs to vary from period to period based not only on the progress of clinical trials, but also when we engage in manufacturing

activities. We expect expenses to increase in the remaining quarters of 2016 compared to the quarter ended June 30, 2016 due to increased patient enrollments in our clinical trials and new manufacturing campaigns.

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The table below summarizes the approximate amounts incurred on each of our research and development projects for the three and six months ended June 30, 2016 and 2015:

| | For the Three Months Ended June 30, | | For the Six Months Ended June 30, | |
|---|-------------------------------------|--------------|-----------------------------------|-------------|
| | 2016 | 2015 | 2016 | 2015 |
| Clinical Candidates: | | | | |
| Archexin | \$ 226,000 | \$ 579,200 | \$1,083,600 | \$1,081,500 |
| RX-3117 | 487,500 | 1,035,200 | 1,434,700 | 2,204,900 |
| Supinoxin | 593,300 | 691,300 | 1,329,400 | 1,078,000 |
| Preclinical, Personnel and Overhead | 930,233 | 929,388 | 1,857,907 | 1,763,696 |
| Total Research and Development Expenses | \$ 2,237,033 | \$ 3,235,088 | \$5,705,607 | \$6,128,096 |

Interest Income

Interest income remained relatively flat, increasing \$1,848 and \$136, or 6.8% and 0.2%, respectively, from the three and six months ended June 30, 2016, respectively, compared to the same periods in 2015.

Unrealized 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 June 30, 2016 and 2015, we recorded unrealized gains on the fair value of our warrants of approximately \$2,118,000 and \$1,559,000 respectively. During the six months ended June 30, 2016 and 2015, we recorded unrealized gains on the fair value of approximately \$2,974,000 and \$1,674,000 respectively. 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 unrealized gains for the three and six months ended June 30, 2016 primarily resulted from a decreased price of the underlying common stock at June 30, 2016 and an increase in the number of outstanding warrants.

Financing Expense

We incurred approximately \$170,000 of financing expenses during the six months ended June 30, 2016 related to our registered direct offering in March 2016.

Table of Contents Net Loss

As a result of the above, net loss for the three and six months ended June 30, 2016 was approximately \$1,766,000 and \$5,915,000, or \$0.01 and \$0.03 per share, respectively, compared to approximately \$3,234,000 and \$7,506,000, or \$0.02 and \$0.04, respectively, for the three and six months ended June 30, 2015, 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, 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 clinical stage drug candidates, Archexin, RX-3117 and Supinoxin, and our pre-clinical stage drug candidate, RX-21101. 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, Archexin, RX-3117 and Supinoxin, is uncertain, and because RX-21101 is in early-stage development, 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.

Archexin

Archexin 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. We are currently conducting a Phase IIa proof-of-concept clinical trial of Archexin in patients with metastatic RCC to evaluate its safety and efficacy. The trial is being conducted in two stages. Stage 1, which we completed in January 2016, was a dose ranging study, with up to three dose groups with three RCC patients each, to determine Archexin's MTD in combination with everolimus. Stage 2, which commenced in January 2016, is a randomized, open-label, two-arm dose expansion study of everolimus versus Archexin in combination with everolimus to determine safety and efficacy of the combination. Stage 2 is anticipated to enroll up to 30 RCC patients who will be randomized to receive either Archexin in combination with everolimus, or everolimus alone, in a ratio of 2:1 The MTD of 250 mg/m²/day of Archexin, which was identified in Stage 1, will be administered in Stage 2 along with 10 mg of everolimus compared to 10 mg everolimus alone.

Expenses related to Archexin decreased during the three months ended June 30, 2016 compared to the three months ended June 30, 2015 which was primarily attributable to decreased manufacturing costs due to a significant supply of drug product already available from earlier manufacturing campaigns. Expenses related to Archexin remained essentially flat during the six months ended June 30, 2016 compared to the six months ended June 30, 2015. We expect that expenses related to Archexin will increase for the remainder of 2016 compared to the three months ended June 30, 2016 as we continue Stage 2 of the ongoing Archexin clinical trial.

Table of Contents 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. During the six months ended June 30, 2016, we identified the MTD of RX-3117, which we are now evaluating in a Phase Ib/IIa proof-of-concept clinical trial in patients with relapsed and refractory pancreatic cancer and advanced bladder cancer.

Expenses related to RX-3117 decreased during the three and six months ended June 30, 2016 compared to the same period in 2015 primarily attributable to decreased manufacturing costs incurred in connection with our Phase I and Phase Ib/IIa trials. However, we expect expenses will increase in the remainder of 2016 compared to the three months ended June 30, 2016 due to patient enrollment costs.

Supinoxin (RX-5902)

Supinoxin 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. Phosphorylated p68 results in up-regulation of cancer-related genes and a subsequent proliferation of cancer cells and tumor growth. Supinoxin is currently being evaluated in a Phase I dose-escalation clinical trial in cancer patients with solid tumors designed to evaluate its safety, tolerability, dose-limiting toxicities and MTD. Secondary endpoints include pharmacokinetic analyses and an evaluation of the preliminary anti-tumor effects of Supinoxin. We plan to commence a Phase Ib/IIa clinical study to evaluate the safety and efficacy of Supinoxin in patients with triple negative breast cancer and relapsed/refractory ovarian cancer.

Expenses related to Supinoxin decreased during the three months ended June 30, 2016 compared to the three months ended June 30, 2015 primarily attributable to decreased manufacturing costs due to a significant supply of drug product already available from earlier manufacturing campaigns. Expenses related to Supinoxin increased during the six months ended June 30, 2016 compared to the six months ended June 30, 2015 primarily attributable to patient enrollment costs and a manufacturing campaign completed in the first quarter of 2016. We expect that expenses related to Supinoxin will increase in the remainder of 2016 compared to the three months ended June 30, 2016 as we expect to reach the MTD or recommended Phase Ib/IIa dose in 2016 and expect to continue development with our planned Phase Ib/IIa study.

Pre-clinical Pipeline

Expenses related to our pre-clinical candidates increased for the three and six months ended June 30, 2016 compared to the same period in 2015 as we continued development of our pipeline. We expect that expenses related to our pre-clinical pipeline, including RX-21101, will increase slightly in 2016 compared to 2015 as we continue testing and development.

Research and Development Process

We have engaged third-party contract research organizations and other investigators and collaborators, such as universities and medical institutions, 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.

<u>Table of Contents</u> Liquidity and Capital Resources

Cash Flows

Cash used in operating activities was approximately \$8,612,000 for the six months ended June 30, 2016. The operating cash flows during the six months ended June 30, 2016 reflect a net loss of \$5,915,000, an unrealized gain on the fair value of warrants of \$2,974,000 and a net increase of cash components of working capital and non-cash charges totaling \$277,000. Cash used in operating activities was approximately \$8,442,000 for the six months ended June 30, 2015. The operating cash flows during the six months ended June 30, 2015 reflect our net loss of \$7,506,000, and a net decrease of cash components of working capital and other non-cash charges totaling \$936,000.

Cash provided by investing activities was approximately \$1,711,000 for the six months ended June 30, 2016, which consisted of \$3,440,000 from the redemption of marketable securities, offset by \$1,722,000 and \$7,000 for the purchases of marketable securities and equipment, respectively. Cash provided by investing activities was approximately \$6,872,000 for the six months ended June 30, 2015, which consisted of \$7,625,000 from the redemption of marketable securities, offset by \$741,000 and \$12,000 for the purchases of marketable securities and equipment, respectively.

Cash provided by financing activities was approximately \$4,580,000 for the six months ended June 30, 2016, which consisted of net proceeds from our registered direct public offering in March 2016. Cash provided by financing activities was approximately \$1,714,000 for the six months ended June 30, 2015, which consisted of \$1,006,000 in proceeds from the sale of common stock and \$708,000 from the exercise of stock options.

Contractual Obligations

We have a variety of contractual obligations, as more fully described in our 2015 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 research and development services. As of June 30, 2016, the total estimated cost to complete our contracts with vendors for research and development services was approximately \$6,440,000 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.

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. If we are not able to raise sufficient additional capital, we will have to reduce our research and development activities. We believe our cash, cash equivalents, and marketable securities will be sufficient to cover our cash flow requirements for our current activities for at least the next 12 months.

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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.

Off-Balance Sheet Arrangements

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

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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 2015 Form 10-K. Our exposures to market risk have not changed materially since December 31, 2015.

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 Rule 13a-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 Rule 13a-15(f) under the Exchange Act) during the quarter ended June 30, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

<u>Table of Contents</u> PART II. Other Information

Item 1A. Risk Factors.

Investing in our stock involves a high degree of risk. 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 2015 Form 10-K, as well as other information contained in the 2015 Form 10-K and in other reports we file with the SEC. We do not believe that there have been any material changes to the risk factors disclosed in our 2015 Form 10-K.

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

Pursuant to consulting agreements, we issued 60,000 shares of common stock during the three months ended June 30, 2016 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 transactions not involving a public offering.

Item 5. Other Information

On August 2, 2016, we entered into a letter agreement with Ely Benaim, M.D., our Chief Medical Officer, pursuant to which we will pay him a discretionary bonus of \$100,000 in a single payment, net of applicable taxes and other deductions (the "Net Amount"). Dr. Benaim will be required to repay (a) the Net Amount if he resigns for other than Good Reason or is terminated for Cause (each as defined under the terms of Dr. Benaim's existing employment agreement) on or prior to August 2, 2017, and (b) half the Net Amount if he resigns for other than Good Reason or is terminated for Cause 3, 2017, and (b) half the Net Amount if he resigns for other than Good Reason or is terminated for Cause 3, 2017, and (b) half the Net Amount if he resigns for other than Good Reason or is terminated for Cause 3, 2017, and (b) half the Net Amount if he resigns for other than Good Reason or is terminated for Cause 4, 2017, and (b) half the Net Amount if he resigns for other than Good Reason or is terminated for Cause 4, 2017, and (b) half the Net Amount if he resigns for other than Good Reason or is terminated for Cause 4, 2017, and 5, 2017, 2017, 2018.

Item 6. Exhibits.

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which is incorporated herein by reference.

Table of Contents 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)

By:/s/ Peter D. Suzdak
Peter D. Suzdak
Peter D. Suzdak
Chief Executive Officer
(principal executive officer)
By:/s/ Tae Heum Jeong
Tae Heum Jeong
Chief Financial Officer and Secretary
(principal financial and accounting officer)

Table of Contents EXHIBIT INDEX

Exhibit No. Description

10.1 Fourth Amendment to Lease Agreement, dated April 4, 2016, by and between Rexahn Pharmaceuticals, Inc. and SG Plaza Holdings, LLC.

- *10.2 Bonus Letter Agreement, dated August 2, 2016, by and between Rexahn Pharmaceuticals, Inc. and Ely Benaim, M.D.
- 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)
- <u>32.1</u> 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
- <u>32.2</u> 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

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.

*Indicates management contract or compensatory plan arrangement