

NephroGenex, Inc.
Form 10-Q
November 12, 2015

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, 2015

OR

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

For the transition period from _____ to _____

Commission File Number 001-36303

NEPHROGENEX, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

20-1295171

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

3200 Beechleaf Court

Suite 900

Raleigh, NC

(Address of principal executive offices)

27604

(Zip Code)

(609) 986-1780

(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

Edgar Filing: NephroGenex, Inc. - Form 10-Q

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 the definitions of “large accelerated filer,” “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

The number of shares outstanding of the registrant’s common stock as of November 10, 2015 was 12,944,518.

NephroGenex, Inc.

Form 10-Q

For the Three and Nine Months Ended September 30, 2015

TABLE OF CONTENTS

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements:

Balance Sheets as of September 30, 2015 (unaudited) and December 31, 2014 2

Statements of Comprehensive Loss (unaudited) for the three and nine months ended September 30, 2015 and 2014 3

Statement of Stockholders' Equity (unaudited) for the nine months ended September 30, 2015 4

Statements of Cash Flows (unaudited) for the nine months ended September 30, 2015 and 2014 5

Notes to Unaudited Financial Statements 6

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations 17

Item 3. Quantitative and Qualitative Disclosures About Market Risk 27

Item 4. Controls and Procedures 27

PART II — OTHER INFORMATION

Item 1. Legal Proceedings 29

Item 1A. Risk Factors 29

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds 29

Item 3. Defaults Upon Senior Securities 30

Item 4. Mine Safety Disclosures 30

Item 5. Other Information 30

Item 6. Exhibits 31

Signatures 32

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

NephroGenex, Inc.

Balance Sheets

(in thousands except share and per share information)

| | September 30, 2015 (unaudited) | December 31, 2014 |
|--|--------------------------------------|----------------------|
| Assets | | |
| Current assets | | |
| Cash and cash equivalents | \$19,250 | \$13,978 |
| Restricted cash | 25 | — |
| Short-term investments | 1,652 | 14,698 |
| Prepaid expenses and other assets | 874 | 309 |
| Total current assets | 21,801 | 28,985 |
| Property and equipment, net | 41 | 36 |
| Other assets | 298 | 210 |
| Total assets | \$22,140 | \$29,231 |
| Liabilities and Stockholders' Equity | | |
| Current liabilities | | |
| Accounts payable | \$2,279 | \$1,750 |
| Accrued and other liabilities | 1,554 | 1,405 |
| Current portion of note payable | 2,060 | 293 |
| Total current liabilities | 5,893 | 3,448 |
| Note payable, less current portion | 4,792 | 6,442 |
| Other long-term liabilities | 23 | 10 |
| Total liabilities | 10,708 | 9,900 |
| Stockholders' equity | | |
| Preferred stock; \$.001 par value; 5,000,000 shares authorized; no shares issued and outstanding | — | — |
| Common stock; \$.001 par value; 100,000,000 shares authorized; 10,742,387 and 8,862,114 shares issued and outstanding as of September 30, 2015 and December 31, 2014, respectively | 11 | 9 |
| Additional paid-in capital | 86,140 | 77,149 |
| Accumulated other comprehensive loss | (1 |) (8 |
| Accumulated deficit | (74,718 |) (57,819 |
| Total stockholders' equity | 11,432 | 19,331 |
| Total liabilities and stockholders' equity | \$22,140 | \$29,231 |

(See accompanying Notes to Financial Statements)

NephroGenex, Inc.

Statements of Comprehensive Loss
(in thousands except share and per share information)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|-------------------------------------|---------------------|------------------------------------|---------------------|
| | 2015 (unaudited) | 2014 (unaudited) | 2015 (unaudited) | 2014 (unaudited) |
| Expenses: | | | | |
| Research and development | \$3,597 | \$3,077 | \$11,206 | \$7,409 |
| General and administrative | 1,612 | 1,350 | 5,284 | 3,945 |
| Total expenses | 5,209 | 4,427 | 16,490 | 11,354 |
| Loss from operations | (5,209 |) (4,427 |)(16,490 |) (11,354 |
| Other income (expense): | | | | |
| Change in value of preferred stock warrants | — | — | — | (140 |
| Interest expense | (142 |) — | (426 |) (78 |
| Interest income | 4 | 12 | 17 | 34 |
| Net loss | \$(5,347 |) \$(4,415 |) \$(16,899 |) \$(11,538 |
| Net loss per share – basic and diluted | \$(0.53 |) \$(0.50 |) \$(1.82 |) \$(1.55 |
| Weighted average shares outstanding – basic and diluted | 10,165,618 | 8,855,114 | 9,302,550 | 7,448,208 |
| Other comprehensive loss: | | | | |
| Net loss | \$(5,347 |) \$(4,415 |) \$(16,899 |) \$(11,538 |
| Unrealized gain/(loss) on short-term investments | 5 | 24 | 7 | (13 |
| Comprehensive loss | \$(5,342 |) \$(4,391 |) \$(16,892 |) \$(11,551 |

(See accompanying Notes to Financial Statements)

NephroGenex, Inc.

Statement of Stockholders' Equity

(in thousands except share information)

| | Common Stock | | Additional | Accumulated | | |
|--|--------------|--------|--------------------|--------------------------------|------------------------|-------------|
| | Shares | Amount | Paid-In Capital | Other Comprehensive Loss | Accumulated Deficit | Total |
| Balance at December 31, 2014 | 8,862,114 | \$9 | \$ 77,149 | \$(8 |) \$ (57,819 |) \$ 19,331 |
| Issuance of common stock for restricted stock units (unaudited) | 4,500 | — | — | — | — | — |
| Issuance of common stock in public offering, including warrants, net of offering expenses of \$964,000 (unaudited) | 1,612,500 | 2 | 7,097 | — | — | 7,099 |
| Issuance of common stock in at-the-market public offering, net of offering expenses of \$94,000 | 263,273 | — | 979 | — | — | 979 |
| Stock-based compensation (unaudited) | — | — | 915 | — | — | 915 |
| Other comprehensive income (unaudited) | — | — | — | 7 | — | 7 |
| Net loss (unaudited) | — | — | — | — | (16,899 |) (16,899 |
| Balance at September 30, 2015 (unaudited) | 10,742,387 | \$ 11 | \$ 86,140 | \$(1 |) \$ (74,718 |) \$ 11,432 |

(See accompanying Notes to Financial Statements)

NephroGenex, Inc.

Statements of Cash Flows
(in thousands)

| | Nine Months Ended September 30, | |
|---|------------------------------------|---------------------|
| | 2015 (unaudited) | 2014 (unaudited) |
| Operating activities | | |
| Net loss | \$(16,899 |) \$(11,538 |
| Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities | | |
| Depreciation and amortization | 8 | 2 |
| Loss on disposal of fixed assets | 2 | — |
| Change in fair value of preferred stock warrants | — | 140 |
| Non-cash interest expense | 149 | 78 |
| Accretion of premium on investment activities | 36 | 41 |
| Accrued interest receivable | 49 | 1 |
| Stock-based compensation expense | 915 | 727 |
| Changes in operating assets and liabilities | | |
| Prepaid expenses and other assets | (684 |) (499 |
| Accounts payable, accrued and other liabilities | 691 | 2,136 |
| Net cash and cash equivalents used in operating activities | (15,733 |) (8,912 |
| Investing activities | | |
| Change in restricted cash | (25 |) — |
| Purchases of investments | (10,335 |) (21,994 |
| Sales of short-term investments | 23,303 | 3,333 |
| Property and equipment purchases | (16 |) (6 |
| Net cash and cash equivalents provided by (used in) investing activities | 12,927 | (18,667 |
| Financing activities | | |
| Deferred offering costs | — | (3,737 |
| Proceeds from issuance of common stock and warrants | 8,078 | 37,200 |
| Net cash and cash equivalents provided by financing activities | 8,078 | 33,463 |
| Net increase in cash and cash equivalents | 5,272 | 5,884 |
| Cash and cash equivalents at beginning of period | 13,978 | 2,132 |
| Cash and cash equivalents at end of period | \$19,250 | \$8,016 |
| Supplemental disclosure of noncash investing and financing activities | | |
| Unrealized gain (loss) on investments | \$7 | \$(13 |
| Conversion of convertible notes payable, accrued interest, preferred stock and warrants into common stock | \$— | \$15,793 |

(See accompanying Notes to Financial Statements)

NephroGenex, Inc.

Notes to Financial Statements

(in thousands except share and per share information)

1. Description of Business

Description of Business

NephroGenex, Inc. (the “Company”) was incorporated in Delaware on May 25, 2004. The Company is a drug development company focused on developing novel therapies for kidney disease. The Company acquired commercial rights to Pyridorin™ and has initiated a Phase 3 clinical study in patients with diabetic nephropathy.

The Company’s primary efforts to date have been devoted to raising capital, recruiting senior management and staff and conducting research and development activities. The Company has experienced net losses since its inception and, as of September 30, 2015, had an accumulated deficit of \$74.7 million.

The Company currently has no commercially approved products and has recognized no revenue since its inception in 2004. The Company does not expect to generate revenue from product sales unless and until it successfully completes development and obtain marketing approval for one or more of its product candidates, which the Company expects will take a number of years and is subject to significant uncertainty. Developing and commercializing a product requires significant time and capital and is subject to regulatory review and approval. There can be no assurance that the Company’s current products in development, if approved, will be successfully commercialized due to a variety of factors, including competition from other biotechnology and pharmaceutical companies.

Going Concern

The Company's financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The Company has incurred losses since its inception, expects to incur additional costs and requires additional capital to continue as a going concern. As a result, the Company will require additional funds and will continue to seek private or public equity, debt financing, research funding and revenue or expense sharing from collaborative agreements to meet its capital requirements. Even if the Company does not have an immediate need for additional cash, it may seek access to the private or public equity markets if and when conditions are favorable. If such funds are not available, management may need to reassess its business plans. There is no assurance that such additional funds will be available for the Company to finance its operations on acceptable terms, if at all.

2. Significant Accounting Policies

Basis of Presentation

The financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America (“U.S. GAAP”).

Unaudited Interim Financial Information

The accompanying interim financial statements and related disclosures are unaudited, have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair statement of the results of operations for the periods presented. The year-end balance sheet was derived from audited financial statements, but does not include all disclosures required by U.S. GAAP. The results of operations for any interim period are not necessarily indicative of the results to be expected for the full year or for any other future year or interim period.

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 disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Reverse Stock Split

On February 6, 2014, the Company effected a 1-for-6.5 reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the conversion ratio for the Company's outstanding Series A Preferred Stock. All share and per share amounts for the nine month period ended September 30, 2014 and notes thereto have been adjusted retroactively, where applicable, to reflect the reverse stock split and adjustment of the preferred share conversion ratios.

Initial Public Offering

On February 14, 2014, the Company completed its initial public offering of common stock (the "IPO") pursuant to a registration statement that was declared effective on February 10, 2014. The Company sold 3,100,000 shares of its common stock, at a price of \$12.00. The Company raised a total of \$33.4 million in net proceeds after deducting underwriting discounts and commissions and offering expenses of approximately \$3.8 million. Costs directly associated with the IPO were capitalized and recorded as deferred IPO costs prior to the closing of the IPO. These costs were recorded as a reduction of the proceeds received in arriving at the amount to be recorded as additional paid-in capital.

Upon completion of the IPO, 3,644,354 shares of common stock were issued for the conversion of all outstanding shares of Series A Preferred stock, 1,197,289 shares of common stock were issued for the conversion of outstanding convertible notes and accrued interest and 593,589 aggregate shares of common stock were issued in connection with the settlement of the Company's outstanding preferred stock warrant liability.

Warrant Liability

Certain warrants to purchase the Company's capital stock had historically been classified as liabilities and were recorded at estimated fair value. At each reporting period, any change in fair value of the freestanding warrants was recorded as other (expense) income. The preferred stock warrant liability was settled upon the closing of the IPO.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less to be cash equivalents.

Restricted Cash

Restricted cash consists of deposits held by a financial institution as collateral for the Company's corporate credit card.

Investments

The Company invests in money market funds and certificates of deposits and considers all investments purchased with original maturity dates greater than three months and less than one year to be short-term investments. Those

investments with original maturity dates greater than one year are considered to be long-term investments. As of September 30, 2015, all investments were classified as available-for-sale and had original maturity dates less than one year. These investments are carried at estimated fair value with unrealized gains and losses included in stockholders' equity. The amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity, which is included in interest income.

Concentration of Credit Risk

The Company invests its available cash balances in bank deposits, money market funds and certificates of deposit. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. Management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in

which those deposits are held. Additionally, the Company has established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity.

Property and Equipment

Property and equipment consists of furniture, fixtures and computers. Property and equipment are carried at cost less accumulated depreciation. Depreciation is calculated using the straight-line method over the respective asset's estimated useful life. Maintenance and repairs that do not improve or extend the life of assets are expensed as incurred. When an asset is retired or disposed of, the cost and related accumulated depreciation are removed from the accounts and any resulting gains or losses are reflected within the statement of operations.

Fair Value of Financial Instruments

As of September 30, 2015, financial instruments consist of cash and cash equivalents, short-term investments, a note payable and accounts payable.

The Company defines fair value ("FV") as the price that would be received to sell an asset or paid to transfer a liability ("the exit price") in an orderly transaction between market participants at the measurement date. The FV hierarchy for inputs maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the most observable inputs be used when available. The Company uses the following hierarchy of inputs to measure FV:

- Level 1: Quoted prices in active markets for identical assets or liabilities;

Level 2: Inputs, other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities in active markets; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and

- Level 3: Unobservable inputs that are supported by little or no market activity, which require the reporting entity to develop its own assumptions.

The Company values investments using the most observable inputs available that are current as of the measurement date and classifies them according to the lowest level of inputs used. Observable inputs are inputs that market participants would use in pricing the asset or liability developed from market data obtained from independent sources. Unobservable inputs are those which reflect the Company's judgment concerning the assumptions that market participants would use in pricing the asset or liability developed from the best information available under the circumstances.

The Company targets investments principally in Level 1 and Level 2 cash equivalents and financial instruments and records them at FV. The Company did not rely on Level 3 inputs for the valuation of any investments at September 30, 2015 or December 31, 2014. The Company expects that the carrying values of cash equivalents will approximate FV because of their short maturities.

The Company classifies as Level 2 investments in certificates of deposits and values them using the market approach based on significant other observable inputs including quoted prices in active markets for instruments that are similar or quoted prices in markets that are not traded on a daily basis for identical or similar instruments.

The following table sets forth our financial instruments carried at FV within the ASC 820 hierarchy and using the lowest level of input as of September 30, 2015:

Quoted Prices

Edgar Filing: NephroGenex, Inc. - Form 10-Q

| (in thousands) | Balance | in Active Markets For Identical Assets | Significant Other Observable Inputs | Significant Unobservable Inputs |
|-------------------------|--------------------|--|---|------------------------------------|
| | September 30, 2015 | Level 1 | Level 2 | Level 3 |
| Assets: | | | | |
| Certificates of Deposit | \$8,185 | \$— | \$8,185 | \$— |
| | \$8,185 | \$— | \$8,185 | \$— |

8

The following table sets forth our financial instruments carried at FV within the ASC 820 hierarchy and using the lowest level of input as of December 31, 2014:

| (in thousands) | Balance December 31, 2014 | Quoted Prices in Active Markets | Significant Other Observable Inputs | Significant Unobservable Inputs |
|-------------------------|------------------------------|---------------------------------------|---|------------------------------------|
| | | For Identical Assets Level 1 | Level 2 | Level 3 |
| Assets: | | | | |
| Certificates of Deposit | \$ 16,765 | \$— | \$ 16,765 | \$— |
| | \$ 16,765 | \$— | \$ 16,765 | \$— |

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses include personnel costs associated with research and development activities including non-cash share-based compensation, costs for third-party contractors to perform research, conduct clinical trials and manufacture drug supplies and materials. The Company accrues for costs incurred by external service providers, including contract research organizations and clinical investigators, based on its estimates of service performed and costs incurred. These estimates include the level of services performed by the third parties, patient enrollment in clinical trials, administrative costs incurred by the third parties, and other indicators of the services completed. Based on the timing of amounts invoiced by service providers, the Company may also record payments made to those providers as prepaid expenses that will be recognized as expense in future periods as the related services are rendered.

Stock-Based Compensation

The Company estimates the FV of stock options and stock purchase rights using a Black-Scholes option valuation model which requires the input of highly subjective assumptions, including the option's expected life and the price volatility of the underlying stock. The Company uses the simplified method for estimating the expected term as provided by the Securities and Exchange Commission's Staff Accounting Bulletin No. 107. The simplified method calculates the expected term as the average time-to-vesting and the contractual life of the options. The expected stock price volatility assumption was determined by examining the historical volatilities of a group of industry peers. The FV of each option grant is estimated on the date of grant using the Black-Scholes option valuation model, and the resulting FV is expensed using the straight-line attribution method over the vesting period, which is the same as the requisite service period. Restricted stock units are measured at the FV of the Company's common stock on the date of grant and expensed over the period of vesting, which is the same as the requisite service period using the straight-line attribution method.

The Company has also granted stock options to nonemployees. Grants to non employees are accounted for in accordance with Accounting Standards Codification ("ASC") 505-50 Equity – Based Payments to Non-Employees. The Company determines the fair value of share based awards granted to nonemployees similar to the way fair value of awards are determined for employees except that certain assumptions used in the Black-Scholes option-pricing model, such as expected life of the option, may be different and the fair value of each award is adjusted at the end of each period for any change in fair value from the previous valuation until the award vests.

Recent Accounting Pronouncements

Occasionally, new accounting standards are issued or proposed by the Financial Accounting Standards Board (the "FASB"), or other standards-setting bodies that the Company adopts by the effective date specified within the standard. Unless otherwise discussed, standards that do not require adoption until a future date are not expected to have a material impact on the Company's financial statements upon adoption.

In August 2014, FASB issued Accounting Standards Update (“ASU”) No. 2014-15, “Presentation of Financial Statements - Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern” (“ASU 2014-15”). ASU 2014-15 is intended to define management’s responsibility to evaluate whether there is substantial doubt about an entity’s ability to continue as a going concern and to provide related footnote disclosures. Specifically, ASU 2014-15 provides a definition of the term substantial doubt and requires an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). It also requires certain disclosures when

substantial doubt is alleviated as a result of consideration of management's plans and requires an express statement and other disclosures when substantial doubt is not alleviated. The new standard will be effective for annual periods ending after December 15, 2016, and interim periods thereafter, with early adoption permitted. Management is currently evaluating the impact of the adoption of ASU 2014-14 on the Company's financial statements and disclosures.

In April 2015, the FASB issued ASU No. 2015-03, "Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs". The amendments in this ASU require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by the amendments in this ASU. The new standard will be effective for reporting periods beginning after December 15, 2015, with early adoption permitted. The amendments should be applied on a retrospective basis, wherein the balance sheet of each individual period presented should be adjusted to reflect the period-specific effects of applying the new guidance. The Company does not expect ASU No. 2015-03 to have a material impact on the Company's financial statements upon adoption.

3. Earnings Per Share

Basic net loss per share is calculated by dividing the net loss by the weighted average number of shares of the Company's common stock outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common share equivalents outstanding for the period determined using the treasury-stock method. Under the treasury-stock method earnings per share data is computed as if the common share equivalents were outstanding at the beginning of the period (or at the time of issuance, if later) and as if the funds obtained from exercise of the common stock equivalents were used to purchase common stock at the average market price during the period. If there is little or no market for the common stock, a reasonable estimate of FV shall be used.

For purposes of this calculation, preferred stock, stock options, restricted stock units and warrants to purchase capital stock are considered to be common stock equivalents and are only included in the calculation of diluted net loss per share when their effect is dilutive.

The following table sets forth the computation of basic and diluted net loss per share in thousands, except share and per share data:

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|-------------------------------------|-----------|------------------------------------|------------|
| | 2015 | 2014 | 2015 | 2014 |
| Historical Numerator: | | | | |
| Net loss | \$(5,347 |)\$(4,415 |) \$(16,899 |)\$(11,538 |
| Denominator: | | | | |
| Weighted average common shares outstanding | 10,165,618 | 8,855,114 | 9,302,550 | 7,448,208 |
| Net loss per share-basic and diluted | \$(0.53 |)\$(0.50 |) \$(1.82 |)\$(1.55 |

Potentially dilutive securities not included in the calculation of diluted net loss per common share because to do so would be anti-dilutive are as follows (in common equivalent shares on a weighted-average basis):

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|----------------------|-------------------------------------|---------|------------------------------------|---------|
| | 2015 | 2014 | 2015 | 2014 |
| Common stock options | 1,424,329 | 874,278 | 1,359,899 | 792,316 |

Edgar Filing: NephroGenex, Inc. - Form 10-Q

| | | | | |
|------------------------|-----------|--------|---------|--------|
| Restricted stock units | 13,250 | 24,000 | 14,750 | 24,000 |
| Common stock warrants | 1,449,853 | 62,000 | 567,229 | 51,780 |

In addition to the potentially dilutive securities noted above, the Company has excluded from the table above 3,644,354 shares of common stock that were issued for the conversion of all outstanding shares of Series A Preferred stock, 1,197,289 shares of common stock that were issued for convertible notes and accrued interest and 593,589 aggregate shares of common stock that were issued in connection with the settlement of the Company's outstanding warrant obligations upon closing of the IPO.

4. Balance Sheet Items

Investments

The following table summarizes the Company's available-for-sale investments as of September 30, 2015 (in thousands):

| | Maturity (in years) | Amortized Cost | Unrealized Gains | Unrealized Loss | Estimated Fair Value |
|------------------------|------------------------|-------------------|---------------------|--------------------|-------------------------|
| Short-term Investments | 1 or less | 1,653 | — | (1 |) 1,652 |
| Total Investments | | \$1,653 | \$— | \$(1 |) \$1,652 |

The following table summarizes the Company's available-for-sale investments as of December 31, 2014 (in thousands):

| | Maturity (in years) | Amortized Cost | Unrealized Gains | Unrealized Loss | Estimated Fair Value |
|------------------------|------------------------|-------------------|---------------------|--------------------|-------------------------|
| Short-term Investments | 1 or less | 14,706 | — | (8 |) 14,698 |
| Total Investments | | \$14,706 | \$— | \$(8 |) \$14,698 |

At each reporting date, the Company performs an evaluation of impairment to determine if the unrealized losses are other-than-temporary. For debt securities, management determines whether it intends to sell the impaired securities, and if there is no intent or expected requirement to sell, management considers whether it is likely that the amortized cost will be recovered. The Company does not consider unrealized losses on its debt investment securities to be credit-related. These unrealized losses relate to changes in interest rates and market spreads subsequent to purchase. The Company has not made a decision to sell securities with unrealized losses and believes it is more likely than not it would not be required to sell such securities before recovery of its amortized cost. There have been no other than temporary losses recognized in earnings.

Accrued Liabilities

Accrued liabilities were as follows (in thousands):

| | September 30, 2015 | December 31, 2014 |
|---------------------------------|-----------------------|----------------------|
| Accrued clinical trial expenses | \$888 | \$393 |
| Accrued compensation | 630 | 909 |
| Other accruals | 36 | 103 |
| Total | \$1,554 | \$1,405 |

5. License Agreements

The University of South Carolina Research Foundation, Corp.

During 2007, the Company licensed certain technology from the University of South Carolina Research Foundation, Corp. ("USCRF") to the Company. The license gives the Company worldwide rights to use the technology as defined in the agreement. The agreement was amended in August 2013. The Company is obligated to pay an annual licensing fee of \$120,000. Upon the achievement of certain defined product development milestones for diabetic neuropathy or hyperlipidemia, the Company would be obligated to make up to \$6.1 million of payments to USCRF. The Company will be obligated to pay USCRF a one-time fee of \$35,000 upon execution of a sublicense and would pay to USCRF 25% of any non-royalty sublicense payments received from a sub-licensee. The term of the agreement expires on the expiration of the underlying USCRF patents. The Company can terminate the license at any time upon three months prior written notice to USCRF. As of September 30, 2015, no development milestones have been paid or

accrued nor does the Company expect to

11

achieve any development milestones during the next few years. The Company paid \$30,000 and \$90,000 for each of the three month and nine month periods ended September 30, 2015 and 2014, respectively, for licensing fees due under this agreement.

Vanderbilt University

During 2006, the Company entered into a licensing agreement with Vanderbilt University ("Vanderbilt") for the rights to use certain technology. The agreement, as amended, requires the Company to make milestone payments totaling approximately \$1.1 million in the event certain defined events occur. Should the Company successfully develop a product for AKI (or other indications that the Company is not currently pursuing) using the licensed technology, Vanderbilt will be due royalties based on net sales at a rate of 5%. The Company must also pay Vanderbilt 25% of non royalty sub licensee payments received from a sub licensee. Annual minimum royalties due under the licensing agreement are \$10,000 and will increase to \$25,000 when a claim in the licensed patent rights is issued in a major market country, as defined. The licensing agreement expires when the underlying patents to the licensed technology expire. The Company may terminate the agreement upon sixty days written notice to Vanderbilt.

Certain milestones can be paid in stock or are creditable against future royalties due based on net sales. As of September 30, 2015, no milestone or royalty payments have been paid or accrued.

6. Convertible Notes Payable

On February 14, 2014, in connection with the closing of the Company's IPO, \$7.9 million of convertible promissory notes and \$728,000 of accrued interest were converted into 1,197,289 shares of common stock.

Interest expense for the nine months ended September 30, 2015 and 2014 relating to the notes was approximately \$0 and \$78,000, respectively.

7. Term Loan

On November 20, 2014, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with East West Bank ("East West") for a term loan (the "Initial Term Loan") with an aggregate principal amount of \$7.0 million and, subject to the terms and conditions set forth in the agreement, a second term loan (the "Second Term Loan") with an aggregate principal amount of \$5.0 million. Each term loan shall accrue interest at a rate of 2.25% per annum plus the greater of 3.25% or the current prime rate. As of September 30, 2015, the interest rate on the loan was 5.5%. As security for its obligations under the Loan Agreement, the Company granted East West a lien on substantially all of its assets, including owned and licensed intellectual property.

The Loan Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among others, covenants that limit or restrict the Company's ability to incur indebtedness, grant liens, merge or consolidate, dispose of assets, make investments, make acquisitions, enter into certain transactions with affiliates, pay dividends or make distributions, or repurchase stock, in each case subject to customary exceptions for a loan facility of this size and type. In addition, the Loan Agreement contains customary events of default that entitle East West to cause any or all of the Company's indebtedness under the Loan Agreement to become immediately due and payable. The events of default include, among others, non-payment, inaccuracy of representations and warranties, covenant defaults, the occurrence of a material adverse effect (as defined in the Loan Agreement), cross-default to material agreements, cross-default to material indebtedness, bankruptcy and insolvency, material judgment defaults, discontinuation of the Phase 3 Pyridorin trial and defaults related to certain actions taken against the Company by the Food and Drug Administration or other equivalent governmental authority.

On November 20, 2014, East West funded the Initial Term Loan, which matures on October 1, 2018. Interest only payments are due during the first twelve months of the Initial Term Loan (the "Interest Only Term") and beginning on November 1, 2015, the Company is required to make thirty-six (36) equal monthly payments of principal and interest. The Interest Only Term may be extended under the Loan Agreement if certain conditions are met. The Company paid a \$120,000 facility fee which was recorded as a debt discount to be amortized as interest expense over the term of the loan using the effective interest rate method.

At the Company's option, the Company had the ability to borrow the Second Term Loan on or before May 29, 2015, if the Company had met certain clinical milestones. The Company did not meet the clinical milestones for the Second Term Loan. However, the Company is discussing with East West amending the clinical milestones necessary for incurrence of the Second Term Loan. The Company may prepay each term loan in full with no prepayment penalty. Upon payment of the final monthly installment of the loan, or the remaining balance in the case of a prepayment, the Company would pay an end-of-term fee of approximately \$60,000.

In connection with the Initial Term Loan, the Company issued warrants to purchase an aggregate of 56,603 shares of the Company's common stock at an exercise price of \$4.24 per share. The warrants are immediately exercisable and will expire on November 20, 2021. The Company determined the fair value of the warrants to be \$192,450 using the Black-Scholes pricing model and recorded the warrants as a debt discount to be amortized as interest expense over the term of the Initial Term Loan using the effective interest rate method. The Company also paid \$50,000 in debt issuance costs, which were capitalized as a deferred asset and are being amortized over the expected remaining life of the loan using the effective interest method.

The Company recognized \$142,000 and \$426,000 in interest expense related to the term loan for the three and nine month periods ended September 30, 2015, respectively.

8. Stockholders' equity

Series A Preferred Stock

In connection with the completion of the IPO, 3,644,354 shares of common stock were issued for the conversion of all outstanding shares of the Company's Series A Preferred stock.

Warrants

On January 16, 2014, an agreement was reached among the Company's significant shareholders to cancel warrants held by its majority shareholder, Care Capital Investments III, LP, together with its affiliates (collectively, Care Capital), and by funds affiliated with Rho Venture Partners (Rho). Pursuant to this agreement, an aggregate of 593,589 shares of the Company's common stock were issued to Care Capital and Rho concurrently with the completion of the Company's IPO in return for cancelling the warrants. In connection with the cancellation of the warrants, the Company settled the preferred stock warrant liability on its balance sheet.

On February 10, 2014, the Company, in connection with the IPO, issued to employees of the underwriter warrants to purchase up to 62,000 shares of common stock. The warrants are exercisable at any time commencing one year from the effective date of the Company's IPO. The warrants are exercisable at a price of \$15.00 per share and expire on February 10, 2018.

On November 20, 2014, the Company, in connection with the issuance of a term loan, issued warrants to East West to purchase up to an aggregate of 56,603 shares of the Company's common stock at an exercise price of \$4.24 per share. The warrants are immediately exercisable and will expire on November 20, 2021.

On July 22, 2015, the Company, in connection with the sale of common stock, issued warrants to purchase 1,725,000 shares of the Company's common stock at an exercise price of \$6.25 per share. The warrants are immediately exercisable and expire on July 22, 2020.

As of September 30, 2015, the following warrants to purchase common stock were outstanding:

| Issuance Date | Shares | Exercise Price | Expiration |
|----------------------------|-----------|----------------|------------|
| 2/10/2014 | 62,000 | \$ 15.00 | 2/10/2018 |
| 11/20/2014 | 56,603 | \$ 4.24 | 11/20/2021 |
| 7/22/2015 | 1,725,000 | \$ 6.25 | 7/22/2020 |
| Total warrants outstanding | 1,843,603 | | |

Common Stock

On February 14, 2014, the Company filed an Amended and Restated Certificate of Incorporation which authorizes the issuance of 100,000,000 shares of common stock, and 5,000,000 shares of undesignated preferred stock.

On July 22, 2015, the Company completed a public offering of common stock and sold 1,500,000 shares of common stock and warrants to purchase common stock at a price of \$5.00 per share and accompanying warrant for total gross proceeds of \$7.5 million. Concurrent with closing of the offering, the underwriters exercised their option to purchase 225,000 warrants for \$0.01 per share for total gross proceeds to the Company of \$2,250. On July 31, 2015, the underwriters partially exercised their over-allotment to purchase 112,500 shares of common stock at \$4.99 per share for total gross proceeds of \$561,375. Total

net proceeds from the public offering were approximately \$7.1 million after deducting underwriting discounts, commissions and offering expenses of approximately \$1.0 million.

During the nine month period ended September 30, 2015, the Company issued 4,500 shares of common stock to its chief executive officer for restricted stock units that vested during the period.

At Market Issuance Sales Agreement

On August 7, 2015, the Company entered into an At Market Issuance Sales Agreement (the “Agreement”), with MLV & Co. LLC, as sales agent (“MLV”), pursuant to which the Company may offer and sell, from time to time, through MLV, shares of the Company’s common stock, (the “ATM Shares”), up to an aggregate offering price of \$18.0 million. The Company intends to use the net proceeds received from any issuance of ATM shares under the Agreement for working capital and general corporate purposes.

Under the Agreement, MLV may sell the ATM Shares by methods deemed to be an “at-the-market” offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended (the “Securities Act”), including sales made directly on the NASDAQ Capital Market, on any other existing trading market for the ATM Shares or to or through a market maker. In addition, under the Agreement, MLV may sell the Shares by any other method permitted by law, including in privately negotiated transactions. Subject to the terms and conditions of the Agreement, MLV will use commercially reasonable efforts, consistent with its normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of the NASDAQ Capital Market, to sell the ATM Shares from time to time, based upon the Company's instructions (including any price, time or size limits or other customary parameters or conditions the Company may impose).

The Company is not obligated to make any sales of the ATM Shares under the Agreement. The offering of ATM Shares pursuant to the Agreement will terminate upon the earlier of (1) the sale of all of the ATM Shares subject to the Agreement or (2) the termination of the Agreement by MLV or the Company. The Company will pay MLV a commission of up to 3.0% of the gross sales price per ATM Share sold and has agreed to provide MLV with customary indemnification and contribution rights.

As of September 30, 2015, the Company had sold 263,273 ATM Shares of common stock at an average sales price of \$4.07 per ATM Share for total net proceeds of approximately \$1.0 million after deducting discounts and commissions and estimated offering expenses of approximately \$94,000.

Shares Reserved for Future Issuance

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

| | September 30, 2015 |
|---|--------------------|
| Stock options outstanding | 1,442,500 |
| Shares available for grant under stock option plans | 1,030,250 |
| Restricted stock units | 12,500 |
| Common stock warrants | 1,843,603 |
| Total shares reserved for future issuance | 4,328,853 |

Stock-Based Compensation

In 2005, the Company adopted the NephroGenex, Inc. 2005 Stock Option Plan. On May 15, 2014, the 2005 Stock Option Plan, was amended and restated to the 2007 Equity Incentive Plan (the “Plan”). The amendment authorized an increase of 673,923 shares and provided for the granting of up to 1,283,226 shares of common stock to employees and

consultants of the Company in the form of incentive and nonqualified stock options and shares of restricted stock. On March 24, 2015, the Company's Board of Directors adopted, and stockholders subsequently approved, an amendment to the Company's Amended and Restated 2007 Equity Incentive Plan, as amended (the "Stock Plan") to increase the number of shares authorized for issuance of awards under the Stock Plan from 1,283,226 to an aggregate of 2,483,226 shares of common stock. As of September 30, 2015, there were 1,030,250 shares available for issuance under the Plan.

The table below summarizes stock option activity for the nine month period ended September 30, 2015:

| | Number of Shares | Weighted Average Exercise Price |
|--------------------------------------|---------------------|--|
| Outstanding as of December 31, 2014 | 1,272,581 | \$4.19 |
| Granted | 317,550 | 6.08 |
| Exercised | — | — |
| Expired | (4,865 |) 15.20 |
| Forfeited | (142,766 |) 5.76 |
| Outstanding as of September 30, 2015 | 1,442,500 | 4.46 |
| Exercisable | 688,969 | \$2.88 |

The weighted-average assumptions used in the Black-Scholes valuation model for equity awards granted during the three and nine month periods ended September 30, 2015 and 2014 are shown in the table below.

| | Three Months Ended September 30, | | Nine Months Ended September 30, | | |
|-------------------------|-------------------------------------|--------|------------------------------------|-------|---|
| | 2015 | 2014 | 2015 | 2014 | |
| Expected volatility | 95.94 | %93.94 | %96.72 | %83.9 | % |
| Expected dividends | — | — | — | — | |
| Expected life in years | 5.8 | 6.3 | 5.9 | 6.8 | |
| Risk-free interest rate | 1.70 | %2.04 | %1.70 | %2.11 | % |

The Company determines the options' life based upon the use of the simplified method. As a newly public company, sufficient history to estimate the volatility and dividend yield of the Company's common stock is not available. The Company uses a pool of comparable companies as a basis for the expected volatility assumption and dividend yield. The Company intends to continue to consistently apply this process using the comparable companies until sufficient amount of historical information becomes available. The risk-free interest rate is based upon the yield of an applicable Treasury instrument.

In November 2013, the Company issued 24,000 Restricted Stock Units (RSU) to its CEO in connection with his employment agreement. The RSU represent the right to receive shares of common stock, subject to the terms and conditions of a restricted stock unit agreement and grant notice and were not issued under the Plan. The RSU's are subject to time-based vesting with 25% of the RSU's vesting on October 21, 2014 and the remaining 75% vesting in equal monthly installments on the first day of each calendar month beginning on November 1, 2014. During the nine month period ended September 30, 2015, the Company issued 4,500 shares of common stock for RSUs that vested during the period.

In accounting for stock options to non-employees, the fair value of services related to the options granted are generally recorded as an expense as these services are provided to the Company over the relating service periods. The Company re-measures any unvested, non-employee options to fair value at the end of each reporting period using the Black-Scholes pricing model.

The Company recognized non-cash share-based compensation expense in its research and development and general and administrative expenses as follows:

| (in thousands) | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|----------------|-------------------------------------|------|------------------------------------|------|
| | 2015 | 2014 | 2015 | 2014 |

Edgar Filing: NephroGenex, Inc. - Form 10-Q

| | | | | |
|----------------------------|-------|-------|-------|-------|
| Research and development | \$51 | \$40 | \$183 | \$77 |
| General and administrative | 281 | 147 | 732 | 650 |
| Total | \$332 | \$187 | \$915 | \$727 |

9. Commitments

Lease

On September 12, 2014, the Company entered into an agreement to lease office space at 3200 Beechleaf Court, Raleigh, North Carolina for the period from December 1, 2014 through May 31, 2020. These premises serve as the Company's

15

corporate headquarters. The lease provides for abatement of rent during certain periods and escalating rent payments during the lease term. The Company records rent expense on a straight-line basis over the life of the lease.

Rent expense was approximately \$30,000 and \$85,000 for each of the three and nine month periods ended September 30, 2015, respectively, and approximately \$13,000 and \$39,000 for each of the three and nine month periods ended September 30, 2014, respectively.

10. Related Party Transactions

Prior to June 30, 2014, the Company reimbursed Care Capital, LLC (“Care”), an affiliate of the majority shareholder of the Company, for services of a Care employee and reimbursed Care for such personnel services incurred by Care on behalf of the Company. Total expense recognized in operating results for the three and nine month periods ended September 30, 2014 in connection with services provided by Care was \$0 and \$70,000, respectively.

11. Subsequent Event - Issuance of Common Stock

From September 30, 2015 to November 10, 2015, the Company sold under the ATM sales agreement with MLV, 45,268 shares of common stock at an average gross sales price of \$3.05 per share for total net proceed of approximately \$133,000 after deducting commissions and other fees of approximately \$5,000.

On November 6, 2015, the Company sold 2,156,863 shares of common stock pursuant to a securities purchase agreement to certain institutional investors at a purchase price of \$2.55 per share for total gross proceeds of approximately \$5.5 million. Pursuant to the securities purchase agreement, the Company issued the following warrants to purchase common stock:

| Description | Warrants | Exercise Price | Date Exercisable | Expiration | Term |
|-------------------|-----------|----------------|------------------|------------------|-------------------|
| Series A Warrants | 1,617,647 | \$3.56 | May 6, 2016 | November 6, 2021 | 5 years |
| Series B Warrants | 2,156,863 | \$3.56 | May 6, 2016 | November 7, 2016 | 12 months + 1 day |
| Series C Warrants | 2,156,863 | \$3.56 | May 6, 2016 | May 6, 2017 | 18 months |
| Series D Warrants | 2,156,863 | \$3.56 | May 6, 2016 | July 6, 2016 | 8 months |
| Total | 8,088,236 | | | | |

The warrants contain limitations that prevent the holder from acquiring shares upon exercise of a warrant that would result in the number of shares beneficially owned by it and its affiliates exceeding 4.99%, or 9.99% upon notice to the Company, of the total number of shares of the Company’s common stock then issued and outstanding (which limit may be adjusted upon the request of the holder).

In connection with the transactions described above, the Company also entered into a registration rights agreement with the investors pursuant to which the Company agreed to register the shares of common stock acquired from the Company (including upon any exercise of the warrants). The Company is required to file a registration statement for the resale of such securities within 30 days following the closing date and to use its commercially reasonable efforts to cause each such registration statement to be declared effective no later than 90 days following the closing date (or 120 days following closing date, if the Securities and Exchange Commission determines to review the registration statement). The Company may incur liquidated damages if it does not meet certain deadlines with respect to its registration obligations under the agreement or if certain other events occur. The Company also agreed to other customary obligations regarding registration, including indemnification and maintenance of the effectiveness of the

registration statement.

In addition, the Company issued warrants to purchase up to an aggregate of 107,843 share of common stock with the same terms as the Series A Warrants to H.C. Wainwright & Co., LLC and its representatives, as placement agent for the transaction.

16

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in the forward-looking statements as a result of certain factors. We discuss factors that we believe could cause or contribute to these differences below and elsewhere in this quarterly report or in our Annual Report on Form 10-K.

Overview

We are a pharmaceutical company focused on the development of therapeutics to treat kidney disease, an area of significant unmet medical need. Since our inception, we have collaborated with the world's leading experts in kidney disease and leveraged our knowledge of pathogenic oxidative chemistries to build a strong portfolio of intellectual property and to advance the development of our drug candidates. We believe that our comprehensive effort to develop a new generation of therapeutics that target kidney disease provides us with a leadership position in this large and attractive market.

We have devoted substantially all of our resources to development efforts relating to our product candidate, including conducting clinical trials of our product candidate, providing general and administrative support for these operations and protecting our intellectual property. We do not have any products approved for sale and have not generated any revenue from product sales. We have funded our operations primarily through proceeds from public offerings of our common stock and the private placement of preferred stock, common stock, convertible notes and a term loan. In February 2014, we completed our initial public offering, or IPO, pursuant to a registration statement on Form S-1, and raised approximately \$33.4 million in net proceeds, after deducting underwriting discounts, commissions and offering expenses. On July 22, 2015, we completed a public offering of stock pursuant to a registration statement on Form S-1, and raised approximately \$7.1 million in net proceeds, after deducting underwriting discounts, commissions and offering expenses. In addition, during the third quarter of 2015, we raised approximately \$1.0 million in net proceeds after deducting commissions and other fees, from an at-the-market equity offering of common stock.

We have incurred net losses in each year since our inception in 2004. Our net losses for the nine months ended September 30, 2015 and 2014 were \$16.9 million and \$11.5 million, respectively. As of September 30, 2015, we had an accumulated deficit of approximately \$74.7 million. Our net losses have resulted primarily from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

We expect to continue to incur significant expenses and have increasing operating losses for at least the next several years. We anticipate that our expenses will increase substantially as we:

- continue the development of our lead product candidate, Pyridorin, for the treatment of diabetic nephropathy in patients with type 2 diabetes including the completion of preclinical and Phase 3 clinical trial activities ;

- continue the development of an intravenous formulation of Pyridorin for the treatment of AKI including pre-clinical and clinical development;

- seek to obtain regulatory approvals for Pyridorin;

- outsource the commercial manufacturing of Pyridorin for any indications for which we receive regulatory approval;

• contract with third parties for the sales, marketing and distribution of Pyridorin for any indications for which we receive regulatory approval;

• maintain, expand and protect our intellectual property portfolio;

• continue our research and development efforts;

- add operational, financial and management information systems and personnel, including personnel to support our product development and commercialization efforts; and

- continue to operate as a public company.

We do not expect to generate revenue from product sales unless and until we successfully complete development and obtain marketing approval for one or more of our product candidates, which we expect will take a number of years and is subject to significant uncertainty. Accordingly, we will need to raise additional capital prior to completing the development and commercialization of Pyridorin or any other product candidate. Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our operating activities through a combination of equity offerings, debt financings, government or other third-party funding, commercialization, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to complete our clinical development plan and develop other product candidates.

Financial Overview

Revenue

We have not generated any revenue since our inception on May 25, 2004. Our ability to generate revenue in the future will depend almost entirely on our ability to successfully develop, obtain regulatory approval and commercialize Pyridorin in the United States.

Research and Development Expenses

Our research and development activities have included conducting nonclinical studies and clinical trials, manufacturing development efforts and activities related to regulatory filings for Pyridorin. We recognize research and development expenses as they are incurred. Our research and development expenses consist primarily of:

- salaries and related overhead expenses for personnel in research and development functions, including costs related to stock options or other stock-based compensation;

- fees paid to consultants and CROs for our nonclinical and clinical trials, and other related clinical trial fees, including investigator grants, laboratory work, clinical trial database management, clinical trial material management and statistical compilation and analysis;

- costs related to acquiring and manufacturing clinical trial materials; and

- costs related to compliance with regulatory requirements.

We plan to increase our research and development expenses for the foreseeable future as we continue the development of Pyridorin for the treatment of diabetic nephropathy in patients with type 2 diabetes, AKI and other indications, subject to the availability of additional funding.

The table below summarizes our research and development expenses for Pyridorin for the periods indicated. Our research and development expenses consist principally of costs paid to third-party service providers, including fees paid to CROs, investigative sites, consultants, central laboratories and other vendors in connection with our clinical trials, and costs related to acquiring and manufacturing clinical trial materials. We do not allocate personnel related

expenses including salaries and stock-based compensation or other indirect costs related to our research and development function to specific product candidates.

18

| (in thousands) | Three Months Ended September | | Nine Months Ended September | |
|---|------------------------------|---------|-----------------------------|---------|
| | 30, 2015 | 2014 | 30, 2015 | 2014 |
| Direct research and development expense | \$3,065 | \$2,494 | \$9,314 | \$5,987 |
| Personnel costs | 421 | 485 | 1,532 | 1,255 |
| Indirect research and development expense | 111 | 98 | 360 | 167 |
| Total research and development expense | \$3,597 | \$3,077 | \$11,206 | \$7,409 |

The successful development of our clinical and preclinical product candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs of the efforts that will be necessary to complete the remainder of the development of any of our clinical or preclinical product candidates or the period, if any, in which material net cash inflows from these product candidates may commence. This is due to the numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress and expense of our ongoing, as well as any additional, clinical trials and other research and development activities;

- future clinical trial results; and

- the timing and receipt of any regulatory approvals.

A change in the outcome of any of these variables with respect to the development of a product candidate could result in a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

Pyridorin

Our research and development resources are primarily focused on the Phase 3 Pyridorin program and our other planned clinical and nonclinical studies for AKI and other work needed to submit Pyridorin for the treatment of diabetic nephropathy in patients with type 2 diabetes for regulatory approval in the United States and Europe. We have incurred and expect to continue to incur expense in connection with these efforts, including:

- working with our CROs to complete our Phase 3 clinical program;

- working with third-party service providers to produce sufficient clinical trial supply for our Phase 3 clinical program and other contemplated trials; and

- working with our clinical nephrology academic research organization that provides scientific and clinical oversight on the conduct of the Pyridorin Phase 3 program.

In addition, we are evaluating the application of an intravenous formulation of Pyridorin to specific types of acute renal failure in which pathogenic oxidative chemistries have been identified as likely causative factors in the onset, severity and progression of this condition. These include contrast-dye and drug-induced acute renal injury, and ischemia-reperfusion acute renal injury, which can arise in cardiac and vascular surgeries. In connection with these efforts, we have incurred and expect to incur significant expenses relating to:

working with research institutions with expertise using animal models of various types of acute renal injury to
•conduct studies to determine where Pyridorin would have the most beneficial effect in ameliorating the severity and
progression of the induced acute renal injury; and

working with a third-party drug formulator to produce intravenous Pyridorin solutions for preclinical and clinical studies.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for employees in executive, and finance functions. Other significant general and administrative expenses include facilities costs, insurance, accounting and legal services and other consulting services related to our corporate governance activities.

We expect that our general and administrative expenses may increase in the future as we expand our operating activities, maintain and expand our patent portfolio, and incur additional costs associated with public company support, including legal and accounting fees and director and officers' liability insurance.

Other Income (expense)

Other income consists of interest income earned on our cash and cash equivalents. Other expense includes interest expense accrued for our convertible notes, term loan and the change in value of our preferred stock warrant liability.

Critical Accounting Policies and Estimates

The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities, and expenses incurred during the reported periods. On an ongoing basis, we evaluate our estimates and judgments related to preclinical, nonclinical and clinical development costs and drug manufacturing costs. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. We discussed accounting policies and assumptions that involve a higher degree of judgment and complexity in the notes to our audited financial statements our Management's Discussion and Analysis of Financial Condition and Results of Operations as filed in our Annual report on Form 10-K for the year ended December 31, 2014. There have been no material changes to our critical accounting policies and estimates as disclosed in our notes to our audited financial statements.

JOBS Act

On April 5, 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended (the Securities Act), for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period for complying with new or revised accounting standards under Section 102(b)(1) of the JOBS Act. This election allows us to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates.

We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, as an "emerging growth company," we intend to rely on certain of these exemptions, including without limitation, (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley

Act and (ii) complying with any requirement that may be adopted by the PCAOB regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of \$1 billion or more; (ii) December 31, 2019; (iii) the date on which we have issued more than \$1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission.

Results of Operations

Comparison of the Three Months Ended September 30, 2015 and the Three Months Ended September 30, 2014

The following table summarizes our results of operations for each of the three months ended September 30, 2015 and 2014, together with the changes in those items in dollars and as a percentage:

| (in thousands) | Three Months Ended September 30, | | Dollar | | % Change |
|----------------------------|-------------------------------------|-------------|-----------|---------|----------|
| | 2015 | 2014 | Change | | |
| Expenses: | | | | | |
| Research and development | \$3,597 | \$3,077 | \$520 | 16.9 | % |
| General and administrative | 1,612 | 1,350 | 262 | 19.4 | % |
| Loss from operations | (5,209 |) (4,427 |) (782 |) 17.7 | % |
| Other income (expense): | | | | | |
| Interest expense | (142 |) — | (142 |) — | % |
| Interest income | 4 | 12 | (8 |) (66.7 |)% |
| Net loss | \$ (5,347 |) \$ (4,415 |) \$ (932 |) 21.1 | % |

Research and Development Expenses

Research and development expenses were approximately \$3.6 million and \$3.1 million for the three months ended September 30, 2015 and 2014, respectively. The increase in research and development expense is primarily due to pre-clinical development activities for Pyridorin for the treatment of AKI and an increase in costs associated with the manufacturing of clinical supplies.

General and Administrative Expenses

General and administrative expenses were approximately \$1.6 million and \$1.4 million for the three months ended September 30, 2015 and 2014, respectively. The increase in general and administrative expenses was primarily a result of an increase in non-cash share-based compensation expense and other expenses related to our corporate governance activities.

Other Income (Expense)

Interest income for the three months ended September 30, 2015 and 2014 was approximately \$4,000 and \$12,000, respectively from interest received on our cash, cash equivalents and investments. Interest expense for the three months ended September 30, 2015 was for interest on our term loan.

Comparison of the Nine Months Ended September 30, 2015 and the Nine Months Ended September 30, 2014

The following table summarizes our results of operations for each of the nine months ended September 30, 2015 and 2014, together with the changes in those items in dollars and as a percentage:

| (in thousands) | Nine Months Ended September 30, | | Dollar | | |
|---|---------------------------------|------------|-----------|----------|---|
| | 2015 | 2014 | Change | % Change | |
| Expenses: | | | | | |
| Research and development | \$11,206 | \$7,409 | \$3,797 | 51.2 | % |
| General and administrative | 5,284 | 3,945 | 1,339 | 33.9 | % |
| Loss from operations | (16,490) | (11,354) | (5,136) | 45.2 | % |
| Other income (expense): | | | | | |
| Change in value of preferred stock warrants | — | (140) | 140 | (100.0) | % |
| Interest expense | (426) | (78) | (348) | 446.2 | % |
| Interest income | 17 | 34 | (17) | (50.0) | % |
| Net loss | \$(16,899) | \$(11,538) | \$(5,361) | 46.5 | % |

Research and Development Expenses

Research and development expenses were approximately \$11.2 million and \$7.4 million for the nine months ended September 30, 2015 and 2014, respectively. The \$3.8 million increase in research and development expense is primarily due to our Phase 3 clinical development activities for Pyridorin, pre-clinical development activities for Pyridorin for the treatment of AKI and an increase in personnel-related expenses for employees involved in our research and development activities.

General and Administrative Expenses

General and administrative expenses were approximately \$5.3 million and \$3.9 million for the nine months ended September 30, 2015 and 2014, respectively. The \$1.4 million increase in general and administrative expenses was primarily a result of an increase in our corporate governance expenses including an increase in our legal fees incurred for public company activities and consulting fees incurred for completion of a Pyridorin marketing study.

Other Income (Expense)

Interest income for the nine months ended September 30, 2015 and 2014, was approximately \$17,000 and \$34,000 respectively, from interest received on our cash, cash equivalents and investments. Interest expense for the nine months ended September 30, 2015 was for interest on our term loan. Interest expense for the nine months ended September 30, 2014, was for interest accrued on our convertible promissory notes, which were converted into common stock upon closing of our IPO in February 2014. The change in fair value of our preferred stock warrant liability for the nine months ended September 30, 2014 was \$140,000. The preferred stock warrant liability was settled upon the closing of our IPO.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred losses and cumulative negative cash flows from operations since inception and as of September 30, 2015, we had an accumulated deficit of approximately \$74.7 million. We anticipate that we will continue to incur

losses for at least the next several years. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may seek to obtain through a combination of equity offerings, debt financings, government or other third-party funding, commercialization, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements.

We have funded our operations principally from the sale of common stock, preferred stock and promissory notes. As of September 30, 2015, we had cash and cash equivalents and short-term investments of approximately \$20.9 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation. Currently, our funds are held in cash, money market bank accounts, and certificates of deposits held at various banks that do not exceed the Federal Deposit Insurance Corporation insurance limit.

On February 14, 2014, we completed an IPO and sold 3,100,000 shares of common stock at a price of \$12.00 per share for total gross proceeds of \$37.2 million, less underwriting discounts, commissions and offering expenses totaling \$3.8 million.

Sale of common stock in public offering

On July 22, 2015, we completed a public offering of common stock and sold 1,500,000 shares of common stock and warrants to purchase common stock at a price of \$5.00 per share and accompanying warrant for total gross proceeds of \$7.5 million. Concurrent with closing of the offering, the underwriters exercised their option to purchase 225,000 warrants for \$0.01 per share for total gross proceeds to the Company of \$2,250. On July 31, 2015, the underwriters partially exercised their over-allotment to purchase 112,500 shares of common stock at \$4.99 per share for total gross proceeds of \$561,375. Total net proceeds from the public offering were approximately \$7.1 million after deducting underwriting discounts, commissions and offering expenses of approximately \$1.0 million.

At Market Issuance Sales Agreement

On August 7, 2015, the Company entered into an At Market Issuance Sales Agreement (the "Agreement"), with MLV & Co. LLC, as sales agent ("MLV"), pursuant to which the Company may offer and sell, from time to time, through MLV, shares of the Company's common stock, (the "ATM Shares"), up to an aggregate offering price of \$18,000,000.0 million. The Company intends to use the net proceeds received from any issuance of ATM shares under the Agreement for working capital and general corporate purposes.

Under the Agreement, MLV may sell the ATM Shares by methods deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended (the "Securities Act"), including sales made directly on the NASDAQ Capital Market, on any other existing trading market for the ATM Shares or to or through a market maker. In addition, under the Agreement, MLV may sell the Shares by any other method permitted by law, including in privately negotiated transactions. Subject to the terms and conditions of the Agreement, MLV will use commercially reasonable efforts, consistent with its normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of the NASDAQ Capital Market, to sell the ATM Shares from time to time, based upon the Company's instructions (including any price, time or size limits or other customary parameters or conditions the Company may impose).

The Company is not obligated to make any sales of the ATM Shares under the Agreement. The offering of ATM Shares pursuant to the Agreement will terminate upon the earlier of (1) the sale of all of the ATM Shares subject to the Agreement or (2) the termination of the Agreement by MLV or the Company. The Company will pay MLV a commission of up to 3.0% of the gross sales price per ATM Share sold and has agreed to provide MLV with customary indemnification and contribution rights.

As of September 30, 2015, the Company had sold 263,273 ATM Shares of common stock at an average sales price of \$4.07 per ATM Share for total net proceeds of approximately \$1.0 million after deducting discounts and commissions and estimated offering expenses of approximately \$94,000.

Securities Purchase Agreement

On November 6, 2015, the Company sold 2,156,863 shares of common stock pursuant to a securities purchase agreement to certain institutional investors at a purchase price of \$2.55 per share for total gross proceeds of approximately \$5.5 million. Pursuant to the securities purchase agreement the Company issued the following warrants

to purchase common stock:

| Description | Warrants | Exercise Price | Date Exercisable | Expiration | Term |
|-------------------|-----------|----------------|------------------|------------------|-------------------|
| Series A Warrants | 1,617,647 | \$3.56 | May 6, 2016 | November 6, 2021 | 5 years |
| Series B Warrants | 2,156,863 | \$3.56 | May 6, 2016 | November 7, 2016 | 12 months + 1 day |
| Series C Warrants | 2,156,863 | \$3.56 | May 6, 2016 | May 6, 2017 | 18 months |
| Series D Warrants | 2,156,863 | \$3.56 | May 6, 2016 | July 6, 2016 | 8 months |
| Total | 8,088,236 | | | | |

The warrants contain limitations that prevent the holder from acquiring shares upon exercise of a warrant that would result in the number of shares beneficially owned by it and its affiliates exceeding 4.99%, or 9.99% upon notice to the

Company, of the total number of shares of the Company's common stock then issued and outstanding (which limit may be adjusted upon the request of the holder).

In connection with the transactions described above, the Company also entered into a registration rights agreement with the investors pursuant to which the Company agreed to register the shares of Common Stock acquired from the Company (including upon any exercise of the warrants). The Company is required to file a registration statement for the resale of such securities within 30 days following the closing date and to use its commercially reasonable efforts to cause each such registration statement to be declared effective no later than 90 days following the closing date (or 120 days following closing date, if the Securities and Exchange Commission determines to review the registration statement). The Company may incur liquidated damages if it does not meet certain deadlines with respect to its registration obligations under the agreement or if certain other events occur. The Company also agreed to other customary obligations regarding registration, including indemnification and maintenance of the effectiveness of the registration statement.

In addition, the Company issued warrants to purchase up to an aggregate of 107,843 share of common stock with the same terms as the Series A Warrants to H.C. Wainwright & Co., LLC and its representatives, as placement agent for the offering.

Cash Flows

The following table sets forth the significant sources and uses of cash for the periods set forth below:

| (in thousands) | Nine Months Ended September 30, | |
|---|---------------------------------|------------|
| | 2015 | 2014 |
| Net cash provided by (used in): | | |
| Operating activities | \$(15,733) | \$(8,912) |
| Investing activities | 12,927 | (18,667) |
| Financing activities | 8,078 | 33,463 |
| Net increase in cash and cash equivalents | \$5,272 | \$5,884 |

Operating Activities.

Net cash used in operating activities for the nine months ended September 30, 2015 was \$15.7 million primarily due to our net losses from the operation of our business of \$16.9 million, including expenses incurred for the development of Pyridorin, partially offset by changes in working capital including an increase in our accrued liabilities, and non-cash charges, including non-cash interest expense for our term loan and stock-based compensation expense. Cash used in operating activities for the nine months ended September 30, 2014 was \$8.9 million primarily related to our net loss of \$11.5 million during such period, and changes in working capital, partially offset by non-cash charges including interest for our convertible notes, stock-based compensation expense and changes in our preferred stock warrant liability.

Investing Activities. Net cash provided by investing activities during the nine months ended September 30, 2015 was primarily related to the proceeds received from the sale of available-for-sale investments. Net cash used in investing activities during the nine months ended September 30, 2014 was primarily related to the purchase of available-for-sale investments.

Financing Activities. Cash provided by financing activities for the nine months ended September 30, 2015 consisted of approximately \$8.1 million in net proceeds received from the sales of common stock. Net cash provided by

financing activities for the nine months ended September 30, 2014 consisted of approximately \$33.5 million in net proceeds received from the issuance of common stock in our IPO.

Credit Facilities

On November 20, 2014, we entered into a Loan Agreement with East West, pursuant to which East West agreed to extend the Initial Term Loan to us with an aggregate principal amount of \$7.0 million and, subject to the terms and conditions set forth in the Loan Agreement, a Second Term Loan with an aggregate principal amount of \$5.0 million. Each term loan shall accrue interest at a rate of 2.25% per annum plus the greater of 3.25% or the current prime rate. As of September 30, 2015, the interest rate on the loan was 5.5%. As security for our obligations under the Loan Agreement, we granted East West a lien on substantially all of our assets, including owned and licensed intellectual property.

On November 20, 2014, East West funded the Initial Term Loan which provided us with approximately \$6.9 million of net loan proceeds. The Loan Facility matures on October 1, 2018. Interest only payments are due during the first twelve months of the Initial Term Loan and beginning on November 1, 2015, we are required to make 36 equal monthly payments of principal and interest. The Interest Only Term may be extended under the Loan Agreement if certain conditions are met. Upon payment of the final monthly installment under the Loan Agreement, or the remaining balance in the case of a prepayment, we would pay an end-of-term fee of approximately \$60,000.

As of September 30, 2015, \$7.0 million of principal remains outstanding on the loan.

At our option, we had the ability to borrow the Second Term Loan on or before May 29, 2015, if we had met certain milestones for enrollment and recruitment of Phase 3 Pyridorin trial patients and achieved positive TQT cardiac safety study results. We may prepay each term loan in full with no prepayment penalty. As of the date hereof, we did not meet the clinical milestones for the Second Term Loan. However, we are discussing amending the clinical milestones with East West for incurrence of the Second Term Loan.

The Loan Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among others, covenants that limit or restrict our ability to incur indebtedness, grant liens, merge or consolidate, dispose of assets, make investments, make acquisitions, enter into certain transactions with affiliates, pay dividends or make distributions, or repurchase stock, in each case subject to customary exceptions for a loan facility of this size and type. In addition, the Loan Agreement contains customary events of default that entitle East West to cause any or all of our indebtedness under the Loan Agreement to become immediately due and payable. The events of default include, among others, non-payment, inaccuracy of representations and warranties, covenant defaults, the occurrence of a material adverse effect (as defined in the Loan Agreement), cross-default to material agreements, cross-default to material indebtedness, bankruptcy and insolvency, material judgment defaults, discontinuation of the Phase 3 Pyridorin trial and defaults related to certain actions taken against us by the FDA or other equivalent governmental authority.

As of September 30, 2015, we were in compliance with all covenants under the Loan Agreement.

Pursuant to the terms of the Loan Agreement, we issued to East West warrants to purchase up to 56,603 shares of our common stock at an exercise price equal to \$4.24 per share. The warrants are immediately exercisable and expire on November 20, 2021.

Future Funding Requirements

To date, we have not generated any revenue. We do not know when, or if, we will generate any revenue from product sales. We do not expect to generate significant revenue from product sales unless and until we obtain regulatory approval of and commercialize Pyridorin or any of our other product candidates. At the same time, we expect our expenses to increase in connection with our ongoing development activities, particularly as we continue the research, development and clinical trials of, and seek regulatory approval for, our product candidates. We expect to continue to incur costs associated with operating as a public company. In addition, subject to obtaining regulatory approval of any of our product candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. We anticipate that we will need substantial additional funding in connection with our continuing operations.

Based upon our current operating plan and approximately \$33.5 million of net proceeds received from our IPO completed in February 2014, \$6.9 million received from our term loan and approximately \$13.2 million received from our recent sales of common stock, we believe that our existing cash, cash equivalents and short-term investments, will enable us to fund our operating expenses and capital expenditure requirements into mid-2016. We intend to devote our cash to fund our Phase 3 Pyridorin program and our planned clinical trials and nonclinical studies and other work needed to submit applications for Pyridorin for the treatment of diabetic nephropathy in patients with type 2 diabetes for regulatory approval in the United States and Europe; to fund the pre-IND work for the program on an intravenous formulation of Pyridorin for AKI; and for general corporate purposes, general and administrative expenses, capital expenditures, working capital and prosecution and maintenance of our intellectual property. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development of our product candidates.

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

the progress, costs, results of and timing of our pre-clinical and clinical development for our Pyridorin program for the treatment of diabetic nephropathy in patients with type 2 diabetes, and the pre-clinical and clinical development of an intravenous formulation of Pyridorin for AKI;

the willingness of the EMA or other regulatory agencies outside the United States to accept our Phase 3 Pyridorin program, as well as our other completed and planned clinical and nonclinical studies and other work, as the basis for review and approval of Pyridorin in the European Union for the treatment of diabetic nephropathy in patients with type 2 diabetes;

the outcome, costs and timing of seeking and obtaining FDA, EMA and any other regulatory approvals;

the number and characteristics of product candidates that we pursue, including our product candidates in preclinical development;

the ability of our product candidates to progress through clinical development successfully;

our need to expand our research and development activities;

the costs associated with securing and establishing commercialization and manufacturing capabilities;

market acceptance of our product candidates;

the costs of acquiring, licensing or investing in businesses, products, product candidates and technologies;

our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;

- our need and ability to hire additional management and scientific and medical personnel;
- the effect of competing technological and market developments;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and
- the economic and other terms, timing of and success of our existing licensing arrangements and any collaboration, licensing or other arrangements into which we may enter in the future.

Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our cash needs through a combination of equity offerings, debt financings, government or other third-party funding, commercialization, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our common stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through government or other third-party funding, commercialization, marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us.

Contractual Obligations and Commitments

There have been no other material changes to our contractual obligations and commitments outside the ordinary course of business from those disclosed under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations — Contractual Obligations and Commitments” in our Annual Report on Form 10-K for the year ended December 31, 2014, filed with the Securities and Exchange Commission.

Off-Balance Sheet Arrangements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Market Risk

Our cash and cash equivalents and short-term investments as of September 30, 2015, consisted primarily of cash, cash equivalents, money market funds and certificates of deposits. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of United States interest rates. However, because of the short-term nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our financial condition and/or results of operations.

Item 4. Controls and Procedures

Management’s Evaluation of our Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934 is (1) recorded, processed,

summarized, and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

As of September 30, 2015, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934). Our management recognizes that any controls and procedures, no matter

how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of September 30, 2015, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

During the quarter ended September 30, 2015, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Securities Exchange Act of 1934, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, the Company may be involved in disputes, including litigation, relating to claims arising out of operations in the normal course of our business. Any of these claims could subject the Company to costly legal expenses and, while the Company believes that it has adequate insurance to cover many different types of liabilities, our insurance carriers may deny coverage or our policy limits may be inadequate to fully satisfy any damage awards or settlements. If this were to happen, the payment of any such awards could have a material adverse effect on the Company's results of operations and financial position. Additionally, any such claims, whether or not successful, could damage our reputation and business. The Company is currently not a party to any legal proceedings.

Item 1A. Risk Factors

The discussion of our business and operations should be read together with the risk factors contained in Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2014 and contained in Item 1A of our Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2015 and June 30, 2015 which describe various risks and uncertainties to which we are or may become subject. These risks and uncertainties have the potential to affect our business, financial condition, results of operations, cash flows, strategies or prospects in a material and adverse manner. There have been no material changes to the risk factors set forth in the above-referenced filing as of September 30, 2015.

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

We completed a public offering of common stock that was effected through a Registration Statement on Form S-1 (File No. 333-205709) that was declared effective by the SEC on July 16, 2015, which registered an aggregate of 1,500,000 shares of our common stock and warrants to purchase 1,500,000 shares of common stock at an aggregate gross offering price to the public of \$7.5 million. All of the 1,500,000 shares of common stock registered under the Registration Statement were sold at a price to the public of \$5.00 per share and accompanying warrant. The offering closed on July 22, 2015. We granted a 45-day option to the representatives of the underwriters to purchase up to 225,000 additional shares of common stock at a purchase price to the public of \$4.99 per share and/or additional warrants to purchase up to 225,000 shares of common stock at a purchase price to the public of \$0.01 per warrant to cover over-allotments. On July 22, 2015, the underwriters partially exercised their over-allotment option and purchased an additional 225,000 warrants for aggregate gross proceeds of \$2,250. The warrants have an exercise price of \$6.25 per share and expire on July 22, 2020. On July 31, 2015, the underwriters partially exercised their over-allotment option and purchased an additional 112,500 shares of common stock at \$4.99 per share for aggregate gross proceeds of approximately \$561,000. Aegis Corp. acted as sole book-running manager for the offering. There were no selling stockholders in the offering.

Net proceeds received were approximately \$7.1 million, after underwriting fees and estimated offering expenses of approximately \$1.0 million. No offering expenses were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates. We intend to use the net proceeds received from this offering for working capital and general corporate purposes.

There has been no material change in our planned use of proceeds from the public offering as described in the final prospectus filed with the SEC pursuant to Rule 424(b) on July 17, 2015.

On November 6, 2015, we completed a private placement of common stock with certain institutional investors for the sale of 2,156,863 shares of common stock at \$2.55 per share for total gross proceeds for approximately \$5.5 million. In addition, we issued 8,196,079 warrants to purchase common stock for a exercise price of \$3.56 per share. The

warrants are exercisable six months from the date of issuance and expire from eight months to 5 years from date of issuance. We intend to use the net proceeds received from this offering for working capital purposes.

The warrants contain limitations that prevent the holder from acquiring shares upon exercise of a warrant that would result in the number of shares beneficially owned by it and its affiliates exceeding 4.99%, or 9.99% upon notice to us, of the total number of shares of our common stock then issued and outstanding (which limit may be adjusted upon the request of the holder).

The securities described above were offered and will be sold pursuant to an exemption from the registration requirements of the Securities Act of 1933, as amended (the "Securities Act"), pursuant to Section 4(2) of the Securities Act and/or Regulation D promulgated thereunder on the basis that, among other things, the transaction did not involve a public offering, the investors are accredited investors, the investors took the securities for investment and not resale, and we took appropriate measures to restrict the transfer of the securities.

In connection with the transactions described above, we also entered into a registration rights agreement with the Investors (the "Registration Rights Agreement"), pursuant to which we agreed to register the shares of common stock acquired from the Company (including upon any exercise of warrants). We are required to file a registration statement for the resale of such securities within 30 days following the closing date and to use its commercially reasonable efforts to cause each such registration statement to be declared effective no later than 90 days following the closing date (or 120 days following closing date, if the Securities and Exchange Commission determines to review the registration statement). We may incur liquidated damages if it does not meet certain deadlines with respect to its registration obligations under the Registration Rights Agreement or if certain other events occur. We also agreed to other customary obligations regarding registration, including indemnification and maintenance of the effectiveness of the registration statement.

In November 2013, we issued 24,000 Restricted Stock Units (RSUs) to our CEO in connection with his employment agreement. The RSUs represent the right to receive shares of common stock, subject to the terms and conditions of a restricted stock unit agreement and grant notice, and were not issued under our Stock Plan. The RSUs are exempt from registration pursuant to Rule 701 under the Securities Act. The RSUs are subject to time-based vesting with 25% of the RSU's vesting on October 21, 2014 and the remaining 75% vesting in equal monthly installments on the first day of each calendar month beginning on November 1, 2014. During the nine month period ended September 30, 2015, we issued 4,500 shares of common stock for RSUs that vested during the period.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibits required by Item 601 of Regulation S-K.

EXHIBIT INDEX

| Exhibit No. | Description |
|-------------|--|
| 4.1 | Form of Warrant (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K filed with the SEC on November 6, 2015). |
| 10.1 | Executive Employment Agreement between the Registrant and Jaikrishana Patel, dated July 2, 2015 (incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 12, 2015). |
| 10.2 | At Market Sales Agreement, dated as of August 7, 2015 between the registrant and MLV & CO. LLC (incorporated by reference to Exhibit 1.1 of the Registrant's Current Report on Form 8-K filed with the SEC on August 7, 2015). |
| 31.1* | Certification of Principal Executive Officer Required Under Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended, and pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 31.2* | Certification of Principal Financial Officer Required Under Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended, and pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. |
| 32** | Certification of Principal Executive Officer and Principal Financial Officer Required Under Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350. |
| 101+ | Financials in XBRL format |

#Indicates management contract or compensatory plan

*Filed herewith

**Furnished herewith

+ Attached as Exhibits 101 to this report are the following financial statements from our Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, formatted in XBRL (eXtensible Business Reporting Language): (i) the Balance Sheets, (ii) the Statements of Comprehensive Loss, (iii) the Statements of Cash Flows and (iv) and related notes to these financial statements.

The XBRL related information in Exhibits 101 to this Quarterly Report on Form 10-Q shall not be deemed "filed" or a part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended ("Securities Act") and is not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended ("Exchange Act"), or otherwise subject to the liabilities of those sections.

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.

NEPHROGENEX, INC.
(Registrant)

Date: November 12, 2015

By: /s/ Pierre Legault
Pierre Legault
Chief Executive Officer
(Principal Executive Officer)

Date: November 12, 2015

By: /s/ John P. Hamill
John P. Hamill
Chief Financial Officer
(Principal Financial and Accounting Officer)