

NephroGenex, Inc.
Form 10-Q
November 12, 2014

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, 2014

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.)

79. T.W. Alexander Drive

4401 Research Commons Building

Suite 290 P.O. Box 14188

Research Triangle Park

(Address of principal executive offices)

27709

(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 11, 2014 was 8,861,614.

NephroGenex, Inc.

Form 10-Q

For the Three and Nine Months Ended September 30, 2014

TABLE OF CONTENTS

PART I — FINANCIAL INFORMATION

<u>Item 1.</u>	<u>Financial Statements:</u>	
	<u>Balance Sheets as of September 30, 2014 (unaudited) and December 31, 2013</u>	<u>2</u>
	<u>Statements of Comprehensive Loss (unaudited) for the three and nine months ended September 30, 2014 and 2013</u>	<u>3</u>
	<u>Statement of Stockholders' Equity (Deficit) (unaudited) for the nine months ended September 30, 2014</u>	<u>4</u>
	<u>Statements of Cash Flows (unaudited) for the nine months ended September 30, 2014 and 2013</u>	<u>5</u>
	<u>Notes to Unaudited Financial Statements</u>	<u>6</u>
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>16</u>
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>24</u>
<u>Item 4.</u>	<u>Controls and Procedures</u>	<u>24</u>

PART II — OTHER INFORMATION

<u>Item 1.</u>	<u>Legal Proceedings</u>	<u>25</u>
<u>Item 1A.</u>	<u>Risk Factors</u>	<u>25</u>
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>25</u>
<u>Item 3.</u>	<u>Defaults Upon Senior Securities</u>	<u>25</u>
<u>Item 4.</u>	<u>Mine Safety Disclosures</u>	<u>25</u>
<u>Item 5.</u>	<u>Other Information</u>	<u>25</u>
<u>Item 6.</u>	<u>Exhibits</u>	<u>25</u>
	<u>Signatures</u>	<u>27</u>

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

NephroGenex, Inc.

Balance Sheets

(in thousands except share and per share information)

	September 30, 2014 (unaudited)	December 31, 2013
Assets		
Current assets		
Cash and cash equivalents	\$8,016	\$2,132
Short-term investments	18,606	—
Prepaid expenses and other assets	332	12
Total current assets	26,954	2,144
Property and equipment, net	15	11
Deferred initial public offering costs	—	461
Other assets	183	4
Total assets	\$27,152	\$2,620
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities		
Accounts payable	\$1,442	\$48
Accrued and other liabilities	1,518	1,858
Preferred stock warrant liability	—	6,983
Convertible notes payable	—	7,917
Total current liabilities	2,960	16,806
Stockholders' equity (deficit)		
Series A preferred stock: \$.001 par value; 32,690,676 shares authorized; 0 and 23,688,396 shares issued and outstanding as of September 30, 2014 and December 31, 2013, respectively	—	24
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; 8,855,114 and 319,882 shares issued and outstanding as of September 30, 2014 and December 31, 2013, respectively	9	—
Additional paid-in capital	76,733	26,789
Accumulated other comprehensive loss	(13) —
Accumulated deficit	(52,537) (40,999
Total stockholders' equity (deficit)	24,192	(14,186
Total liabilities and stockholders' equity (deficit)	\$27,152	\$2,620

(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,	
	2014	2013	2014	2013
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Expenses:				
Research and development	\$3,077	\$449	\$7,409	\$935
General and administrative	1,350	230	3,945	522
Total expenses	4,427	679	11,354	1,457
Loss from operations	(4,427) (679) (11,354) (1,457
Other income (expense):				
Change in value of preferred stock warrants	—	(95) (140) (436
Interest expense	—	(100) (78) (258
Interest income	12	—	34	—
Net loss	\$(4,415) \$(874) \$(11,538) \$(2,151
Net loss per share – basic and diluted	\$(0.50) \$(2.73) \$(1.55) \$(6.72
Weighted average shares outstanding – basic and diluted	8,855,114	319,882	7,448,208	319,882
Other comprehensive loss:				
Net loss	\$(4,415) \$(874) \$(11,538) \$(2,151
Unrealized gain (loss) on short-term investments	24	—	(13) —
Comprehensive loss	\$(4,391) \$(874) \$(11,551) \$(2,151

(See accompanying Notes to Financial Statements)

NephroGenex, Inc.

Statement of Stockholders' Equity (Deficit)

(in thousands except share and per share information)

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount				
Balance at December 31, 2013	23,688,396	\$24	319,882	\$—	\$26,789	\$—	\$ (40,999)	\$(14,186)
Issuance of common stock at IPO, net of expenses of \$3,767 (unaudited)	—	—	3,100,000	3	33,430	—	—	33,433
Issuance of common stock for preferred stock warrant (unaudited)	—	—	593,589	1	7,123	—	—	7,124
Issuance of common stock for convertible notes and accrued interest (unaudited)	—	—	1,197,289	1	8,644	—	—	8,645
Issuance of common stock for preferred stock (unaudited)	(23,688,396)	(24)	3,644,354	4	20	—	—	—
Stock based compensation (unaudited)	—	—	—	—	727	—	—	727
Other comprehensive loss (unaudited)	—	—	—	—	—	(13)	—	(13)
Net loss (unaudited)	—	—	—	—	—	—	(11,538)	(11,538)
Balance at September 30, 2014 (unaudited)	—	\$—	8,855,114	\$9	\$76,733	\$ (13)	\$ (52,537)	\$24,192

(See accompanying Notes to Financial Statements)

NephroGenex, Inc.

Statements of Cash Flows

(in thousands except share and per share information)

	Nine Months Ended September 30,	
	2014 (unaudited)	2013 (unaudited)
Operating activities		
Net loss	\$(11,538) \$(2,151
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities)
Depreciation and amortization	2	4
Change in fair value of preferred stock warrants	140	436
Non-cash interest expense	78	258
Accretion of premium on investment activities	41	—
Accrued interest receivable	1	—
Stock based compensation expense	727	72
Changes in operating assets and liabilities		
Prepaid expenses and other assets	(499) 22
Accounts payable, accrued and other liabilities	2,136	(663
Net cash and cash equivalents used in operating activities	(8,912) (2,022
)
Investing activities		
Purchases of investments	(21,994) —
Sales of investments	3,333	—
Property and equipment purchases	(6) (12
Net cash and cash equivalents used in investing activities	(18,667) (12
)
Financing activities		
Proceeds from issuance of convertible notes payable	—	1,912
Payment of initial public offering costs	(3,737) —
Proceeds from issuance of common stock	37,200	—
Net cash and cash equivalents provided by financing activities	33,463	1,912
Net increase (decrease) in cash and cash equivalents	5,884	(122
Cash and cash equivalents at beginning of period	2,132	324
Cash and cash equivalents at end of period	\$8,016	\$202
Supplemental disclosure of noncash financing activities		
Conversion of convertible notes payable, accrued interest, preferred stock and warrants into common stock	\$15,792	\$—

(See accompanying Notes to Financial Statements)

NephroGenex, Inc.

Notes to Financial Statements

(in thousands except share and per share information)

1. The Company

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, 2014, has an accumulated deficit of \$52.5 million.

The Company currently has no commercially approved products and has recognized no revenue since its inception in 2004. 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. 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.

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. Accordingly, all share and per share amounts for all periods presented in these financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect the reverse stock split and adjustment of the preferred share conversion ratios.

6

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.

Investments

The Company invests in money market funds and certificates of deposits and considers all investments purchased with a maturity date greater than three months and less than one year to be short-term investments. Those investments with a maturity date greater than one year at each balance sheet date are considered to be long-term investments. As of September 30, 2014, all investments were classified as available-for-sale and had maturity dates less than one year. These investments are carried at estimated fair value with unrealized gains and losses included in stockholders' equity (deficit). 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 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, 2014, financial instruments consist of cash and cash equivalents, short-term investments, accounts receivable 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; 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 inputs that 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 investment 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, 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, 2014:

(in thousands)	Balance September 30, 2014	Quoted Prices in Active Markets	Significant Other Observable Inputs	Significant Unobservable Inputs
		For Identical Assets Level 1	Level 2	Level 3
Assets:				
Money Market Funds	\$6,734	\$6,734	\$—	\$—
Certificates of Deposit	19,888	—	19,888	—
	\$26,622	\$6,734	\$19,888	\$—

The Company believes the fair value of convertible notes payable approximates its carrying value as of December 31, 2013.

At December 31, 2013, certain warrants to purchase the Company’s capital stock were classified as liabilities and were recorded at estimated FV. The Company measured its warrant liability using significant unobservable inputs that were based on little or no verifiable market data, which is Level 3 in the FV hierarchy. 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 closing of the IPO.

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,

8

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 require 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. 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.

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 July 2013, the FASB issued Accounting Standards Update, or ASU, No. 2013-11, Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists. ASU 2013-11 provides explicit guidance on the financial statement presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. The guidance is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2013, with an option for early adoption. The Company adopted this guidance on January 1, 2014. The adoption did not impact the Company's financial position or results of operations.

In July 2014, the FASB issued ASU No. 2014-10, Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810, Consolidation. The amendments in this ASU remove all incremental financial reporting requirements from U.S. GAAP for development stage entities, including the removal of Topic 915, Development Stage Entities, from the FASB Accounting Standards Codification™. A development stage entity is one that devotes substantially all of its efforts to establishing a new business and for which: (a) planned principal operations have not commenced; or (b) planned principal operations have commenced, but have produced no significant revenue. Current U.S. GAAP requires a development stage entity to present the same basic financial statements and apply the same recognition and measurement rules as established companies. In addition, U.S. GAAP requires a development stage entity to present inception-to-date information about income statement line items, cash flows, and equity transactions. For public business entities, the presentation and disclosure requirements in Topic 915 will no longer be required for the first annual period beginning after December 15, 2014. The revised consolidation standards are effective one year later, in annual periods beginning after December 15, 2015. Early adoption is permitted. The Company adopted the guidance for the quarterly periods ended June 30, 2014. The adoption did not impact the Company's financial position or results of operations.

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		Nine Months Ended	
	September 30,		September 30,	
	2014	2013	2014	2013
Historical				
Numerator:				
Net loss	\$ (4,415) \$ (874) \$ (11,538) \$ (2,151
Denominator:				
Weighted average common shares outstanding	8,855,114	319,882	7,448,208	319,882
Net loss per share-basic and diluted	\$ (0.50) \$ (2.73) \$ (1.55) \$ (6.72

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		Nine Months Ended	
	September 30,		September 30,	
	2014	2013	2014	2013
Common stock options	874,278	563,453	792,316	523,004
Restricted stock units	24,000	—	24,000	—
Common stock warrants	62,000	—	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, 2014 (in thousands):

	Maturity	Amortized	Unrealized	Unrealized	Estimated
	(in years)	Cost	Gains	Loss	Fair Value
Short-term Investments	1 or less	\$—	\$—	\$—	\$—
Money Market	1 or less	18,619	—	(13) 18,606
Certificates of Deposit		\$18,619	\$—	\$(13) \$18,606
Total Investments					

Accrued Liabilities

Accrued liabilities were as follows (in thousands):

	September 30, 2014	December 31, 2013
Accrued clinical trial expenses	\$631	\$209
Accrued compensation	782	365
Interest	—	650
Other accruals	105	634
Total	\$1,518	\$1,858

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 paid an annual licensing fee of \$30,000 through 2008, \$60,000 from 2009 through 2010, \$62,000 from 2011 through 2012 and \$122,000 in 2013. The Company is obligated to pay an annual licensing fee of \$120,000 thereafter. Upon the achievement of certain defined product development milestones, 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, 2014, no development milestones have been paid or accrued nor does the Company expect to achieve any development milestones during the next few years. The Company paid \$30,000 and \$122,000 for the three month periods ended September 30, 2014 and 2013, respectively, for licensing fees due under this agreement. The Company paid \$90,000, and \$122,000 for the nine month periods ended September 30, 2014 and 2013, respectively.

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 accrued interest were converted into 1,197,289 shares of common stock.

The Company had accrued interest of approximately \$650,000 as of December 31, 2013 which is included in accrued and other liabilities on the accompanying balance sheets. Interest expense for the three and nine months ended September 30, 2014 and the three and nine months ended September 30, 2013 relating to the notes was approximately \$0, \$78,000, \$100,000 and \$258,000, respectively.

7. Stockholders' equity (deficit)

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 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.

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.

Shares Reserved for Future Issuance

The Company has reserved shares of its common stock for future issuance as of September 30, 2014 as follows:

	September 30, 2014
Stock options outstanding	921,701
Shares available for grant under stock option plans	351,049
Restricted stock units	24,000
Common stock warrants	62,000
Total shares reserved for future issuance	1,358,750

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. As of September 30, 2014 there were 351,049 shares available for issuance from the Plan.

The table below summarizes stock option activity for the nine month period ended September 30, 2014.

13

	Number of Shares	Weighted Average Exercise Price
Outstanding as of December 31, 2013	563,453	\$ 1.18
Granted	358,248	8.52
Exercised	—	—
Canceled	—	—
Outstanding as of September 30, 2014	921,701	\$ 4.03
Exercisable as of September 30, 2014	548,629	\$ 1.80

During the nine months ended September 30, 2014, the Company's Board of Directors granted 358,248 stock options to employees and Directors of the Company with a weighted average fair value of \$7.22 per share. The weighted-average assumptions used in the Black-Scholes valuation model for equity awards granted during the nine month period ended September 30, 2014 are shown in the table below. No stock options were issued during the nine month period ended September 30, 2013.

	Nine Months Ended September 30, 2014	
Expected volatility	83.9	%
Expected dividends	—	
Expected life in years	6.8	
Risk-free interest rate	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 our 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% will vest in equal monthly installments on the 1st day of each calendar month beginning November 1, 2014.

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,	
	2014	2013	2014	2013
Research and development	\$ 40	\$ 15	\$ 77	\$ 45
General and administrative	147	9	650	27
Total	\$ 187	\$ 24	\$ 727	\$ 72

8. Commitments

Lease

The Company's office lease agreement in Research Triangle Park, North Carolina expired in December 2013, and the Company is currently leasing the space on a month-to-month basis.

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

Provisions of the September 12, 2014 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. The following is a schedule of future non-cancellable minimum lease payments for operating leases at September 30, 2014 (in thousands):

2014	\$9
2015	105
2016	118
2017	122
2018	125
Thereafter	184
	\$663

Rent expense was approximately \$26,000 and \$39,000 for each of the three and nine month periods ended September 30, 2014 and 2013, respectively.

9. 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 reimburses 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 and the three and nine month periods ended September 30, 2013 in connection with services provided by Care was \$0, \$70,000, \$45,000 and \$93,000, respectively.

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 our initial public offering, or IPO, and the private placement of preferred stock, common stock and convertible notes. In February 2014, we completed our IPO pursuant to a registration statement on Form S-1, and raising approximately \$33.4 million, after deducting underwriting discounts, commissions and offering expenses.

We have incurred net losses in each year since our inception in 2004. Our net losses for the three and nine months ended September 30, 2014 were \$4.4 million and \$11.5 million, respectively. As of September 30, 2014, we had an accumulated deficit of approximately \$52.5 million. Our net losses for the period 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 Phase 3 clinical trial activities ;
- complete the development of an intravenous formulation of Pyridorin for the treatment of acute kidney injury (AKI);
- 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 anticipate that we will need to raise additional capital prior to the 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 develop our 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 clinical research organizations (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 our 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 and other indications, subject to the availability of additional funding.

The table below summarizes our direct research and development expenses for Pyridorin for the periods indicated. Our direct 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. Those expenses are included in "Indirect research

and development expense” in the table below.

17

(in thousands)	Three Months Ended September		Nine Months Ended September	
	30, 2014	2013	30, 2014	2013
Direct research and development expense	\$2,494	\$54	\$5,987	\$54
Personnel costs	485	175	1,255	513
Indirect research and development expense	98	220	167	368
Total research and development expense	\$3,077	\$449	\$7,409	\$935

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 currently focused on the Phase 3 Pyridorin program and our other planned clinical and nonclinical studies 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 program and other contemplated trials;

- working with our CROs to conduct a Phase 1 QT interval (TQT) trial; and

- working with our academic research groups.

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

18

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 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, 2013. 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, 2014 and the Three Months Ended September 30, 2013

19

The following table summarizes our results of operations for each of the three months ended September 30, 2014 and 2013, together with the changes in those items in dollars and as a percentage:

(in thousands)	Three Months Ended September 30,		Dollar		
	2014	2013	Change	% Change	
Expenses:					
Research and development	\$3,077	\$449	\$2,628	585.3	%
General and administrative	1,350	230	1,120	487.0	%
Loss from operations	(4,427) (679) 3,748	(552.0)%
Other income (expense):					
Change in value of preferred stock warrants	—	(95) 95	(100.0)%
Interest expense	—	(100) 100	(100.0)%
Interest income	12	—	12	—	%
Net loss	\$ (4,415) \$ (874) \$ 3,541	(405.1)%

Research and Development Expenses

Research and development expenses were approximately \$3.1 million and \$449,000 for the three months ended September 30, 2014 and 2013, respectively. The increase in research and development expense is primarily due to our Phase 3 clinical development activities for Pyridorin and an increase in personnel-related expenses as a result of an increase in headcount.

General and Administrative Expenses

General and administrative expenses were approximately \$1.4 million and \$230,000 for the three months ended September 30, 2014 and 2013, respectively. The increase in general and administrative expenses was primarily a result of an increase in personnel-related expenses including non-cash stock based compensation expense and an increase in our corporate governance expenses including our director and officer liability insurance and other professional fees incurred for operating as a public company.

Other Income (Expense)

Interest income for the three months ended September 30, 2014 was approximately \$12,000 from interest received on our cash, cash equivalents and investments. Interest expense for the three months ended September 30, 2013 was for interest accrued on our convertible promissory notes, which were converted into common stock upon closing of the IPO in February 2014. The change in FV of our preferred stock warrant liability for the three months ended September 30, 2013 was \$95,000. The preferred stock warrant liability was settled upon the closing of the IPO.

Comparison of the Nine Months Ended September 30, 2014 and the Nine Months Ended September 30, 2013

The following table summarizes our results of operations for each of the nine months ended September 30, 2014 and 2013, together with the changes in those items in dollars and as a percentage:

(in thousands)	Nine Months Ended September 30,		Dollar Change	% Change	
	2014	2013			
Expenses:					
Research and development	\$7,409	\$935	\$6,474	692.4	%
General and administrative	3,945	522	3,423	655.7	%
Loss from operations	(11,354) (1,457) 9,897	(679.3)%
Other income (expense):					
Change in value of preferred stock warrants	(140) (436) 296	(67.9)%
Interest expense	(78) (258) 180	(69.8)%
Interest income	34	—	34	—	%
Net loss	\$(11,538) \$(2,151) \$9,387	(436.4)%

Research and Development Expenses

Research and development expenses were approximately \$7.4 million and \$935,000 for the nine months ended September 30, 2014 and 2013, respectively. The increase in research and development expense is primarily due to our Phase 3 clinical development activities for Pyridorin and an increase in personnel-related expenses as a result of an increase in headcount.

General and Administrative Expenses

General and administrative expenses were approximately \$3.9 million and \$522,000 for the nine months ended September 30, 2014 and 2013, respectively. The increase in general and administrative expenses was primarily a result of an increase in personnel-related expenses including non-cash stock based compensation expense and an increase in our corporate governance expenses including our director and officer liability insurance and other professional fees incurred for operating as a public company.

Other Income (Expense)

Interest income for the nine months ended September 30, 2014 was approximately \$34,000 from interest received on our cash, cash equivalents and investments. Interest expense for the nine months ended September 30, 2014 and 2013 was for interest accrued on our convertible promissory notes, which were converted into common stock upon closing of the IPO in February 2014. The change in FV of our preferred stock warrant liability for the nine months ended September 30, 2014 and 2013 was \$140,000 and \$436,000, respectively. The preferred stock warrant liability was settled upon the closing of the 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, 2014, we had an accumulated deficit of \$52.5 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 convertible notes. As of September 30, 2014, we had cash and cash equivalents and short-term investments of approximately \$26.6 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.

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,	
	2014	2013
Net cash provided by (used in):		
Operating activities	\$(8,912) \$(2,022
Investing activities	(18,667) (12
Financing activities	33,463	1,912
Net increase (decrease) in cash and cash equivalents	\$5,884	\$(122

Operating Activities.

Net cash used in operating activities for the nine months ended September 30, 2014 was primarily due to our net losses from the operation of our business of \$11.5 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 convertible notes, stock based compensation expense and changes in our preferred stock warrant liability. Cash used in operating activities for the nine months ended September 30, 2013 was primarily related to our net loss of \$2.1 million during such period, changes in working capital, including a decrease in our accrued liabilities, 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 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. Net cash provided by financing activities for the nine months ended September 30, 2014 and 2013 consisted of approximately \$33.4 million in net proceeds received from the issuance of common stock in our IPO and \$1.3 million of net proceeds from the sale of convertible notes, respectively.

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 \$33.4 million of net proceeds received from our IPO completed in February 2014, 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 early 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 further preclinical and Phase 1 & 2 development work on an intravenous formulation of Pyridorin for AKI in which pathogenic oxidative chemistries have been identified as a possible contributing factor in the severity of this condition; 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 Phase 3 Pyridorin program for the treatment of diabetic nephropathy in patients with type 2 diabetes, and the clinical development of an intravenous formulation of Pyridorin for AKI;

- the willingness of the EMA or other regulatory agencies outside the U.S. 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

On September 12, 2014, we entered into an office lease for approximately 5,514 square feet of office space located at 3200 Beechleaf Court, Raleigh, North Carolina. These premises will serve as our new corporate headquarters. Under the terms of the lease agreement, the lease term is 66 months, commencing on December 1, 2014 and terminating on May 31, 2020. Our monthly base rent, commencing on February 1, 2015, is approximately \$9,500 per month and will increase at a rate of approximately 3.0% per year during the term of the lease.

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, 2013, 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, 2014, 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, 2014, 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, 2014, 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, 2014, 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.

24

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

There have been no material changes in the risk factors described in "Item 1A. Risk Factors" of our Annual Report on Form 10-K for the year ended December 31, 2013.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibits required by Item 601 of Regulation S-K.

EXHIBIT INDEX

Exhibit No.	Description
10.1	Office Lease, dated September 12, 2014, by and between the Company and Highwoods Realty Limited Partnership (Incorporated by reference to Exhibit 10.1 of the Company's Current Report on 8-K filed on September 15, 2014).
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

*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, 2014, 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, 2014

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

Date: November 12, 2014

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