

NephroGenex, Inc.
Form S-1/A
June 25, 2015

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As filed with the Securities and Exchange Commission on June 25, 2015

Registration No. 333-203530

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

Amendment No. 2
to

FORM S-1

REGISTRATION STATEMENT
UNDER THE SECURITIES ACT OF 1933

NephroGenex, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

2834
(Primary Standard Industrial
Classification Code Number)
3200 Beechleaf Court
Suite 900
Raleigh, NC 27604
(609) 986-1780

20-1295171
(IRS Employer
Identification No.)

(Address, including zip code, and telephone number,
including area code, of registrant's principal executive offices)

Pierre Legault
Chief Executive Officer
NephroGenex, Inc.
3200 Beechleaf Court
Suite 900
Raleigh, NC 27604
(609) 986-1780

(Name, address, including zip code, and telephone number,
including area code, of agent for service)

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Approximate date of commencement of proposed sale to public:

As soon as practicable after this Registration Statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box:

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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 12b2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed Maximum Aggregate Offering Price⁽¹⁾	Amount of Registration Fee⁽²⁾
Common Stock, \$.001 par value per share	\$17,250,000	\$2,004.45

(1) Estimated solely for the purpose of calculating the amount of registration fee pursuant to Rule 457(o) under the Securities Act, as amended.

(2) Previously paid.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell securities, and we are not soliciting offers to buy these securities, in any state where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS

SUBJECT TO COMPLETION

DATED JUNE 25, 2015

\$15,000,000
Common Stock

NephroGenex, Inc. is offering 2,008,032 shares of its common stock, assuming a public offering price of \$7.47 per share, the last reported sale price of our common stock on the NASDAQ Capital Market on June 24, 2015, with an aggregate market value of approximately \$15,000,000. Our common stock is listed on the NASDAQ Capital Market under the symbol "NRX."

We are an "emerging growth company" as that term is used in the Jumpstart Our Business Startups Act of 2012, and, as such, we have elected to take advantage of certain reduced public company reporting requirements for this prospectus and future filings.

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page 8 of this prospectus for a discussion of information that should be considered in connection with an investment in our common stock.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Share	Total
Public Offering Price	\$	\$
Underwriting discounts and commissions ⁽¹⁾	\$	\$
Offering proceeds to us, before expenses	\$	\$

⁽¹⁾ We have agreed to reimburse the underwriters for certain expenses. See "Underwriting" beginning on page 127 of this prospectus.

We have granted a 45-day option to the representatives of the underwriters to purchase up to 301,205 additional shares of common stock to cover over-allotments, if any.

The underwriters expect to deliver the shares to purchasers in this offering on or about _____, 2015.

Aegis Capital Corp

The date of this prospectus is _____, 2015

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You should rely only on the information contained in this prospectus. Neither we nor any of the underwriters have authorized anyone to provide you with information different from, or in addition to, that contained in this prospectus or any free writing prospectus prepared by or on behalf of us or to which we may have referred you in connection with this offering. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. Neither we nor any of the underwriters is making an offer to sell or seeking offers to buy these securities in any jurisdiction where, or to any person to whom, the offer or sale is not permitted. The information in this prospectus is accurate only as of the date on the front cover of this prospectus, regardless of the time of delivery of this prospectus or of any sale of shares of our common stock, and the information in any free writing prospectus that we may provide you in connection with this offering is accurate only as of the date of that free writing prospectus. Our business, financial condition, results of operations and future growth prospects may have changed since those dates.

This prospectus includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data.

For investors outside the United States: We have not and the underwriters have not done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities and the distribution of this prospectus outside the United States.

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PROSPECTUS SUMMARY

This summary provides an overview of selected information contained elsewhere in this prospectus and does not contain all of the information you should consider before investing in our common stock. You should carefully read this prospectus and the registration statement of which this prospectus is a part in their entirety before investing in our common stock, including the information discussed under "Risk Factors" and our financial statements and notes thereto that appear elsewhere in this prospectus. Unless otherwise indicated herein, the terms "we," "our," "us," or "the Company" refer to NephroGenex, Inc.

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.

Pathogenic oxidative chemistries are collectively a group of oxygen-based chemical reactions that occur in the body during stress, injury, or disease, to form compounds that can induce pathological changes in tissues that effect normal physiological function. These include (i) advanced glycation end-products (AGE's), which are oxidative end products of glucose-modified biomolecules which adversely affect their function; (ii) reactive oxygen species (ROS), which are chemically reactive molecules containing oxygen such as oxygen ions and peroxides that when elevated in the body can induce pathology; and (iii) toxic carbonyls which are reactive compounds that can modify biomolecules and affect their function. These chemistries are generally agreed to be involved in the etiology of diabetic nephropathy, a common complication of diabetes, and in cases of acute kidney injury (AKI). We are developing Pyridorin (Pyridorin), a small molecule drug that is a unique and broadly acting inhibitor of the pathogenic oxidative chemistries which are elevated in diabetic patients.

We licensed patents covering methods of use and synthesis of Pyridorin from BioStratum, Inc. in May of 2006. We subsequently acquired Pyridorin-related patents from BioStratum through a Series A financing completed in May of 2007. At the time of acquisition, BioStratum, through its contracted investigators, contract research organizations, and collaborators had completed 5 preclinical efficacy studies, 36 preclinical safety studies, 4 Phase 1 studies and 5 Phase 2 studies with Pyridorin. After the acquisition, we conducted a multi-center, randomized, placebo-controlled Phase 2b study, namely PYR-210 and recently completed the Phase 1 QT/QTc (TQT) cardiac safety study. In addition, we worked with the FDA to establish a new regulatory pathway for Pyridorin approval, as well as received support from the European Medicines Agency (EMA) regarding the pivotal Phase 3 program with Pyridorin in diabetic nephropathy.

Pyridorin has demonstrated preliminary evidence of efficacy in slowing the progression of diabetic nephropathy in relevant patient populations in three Phase 2 clinical studies. Based on these results, Pyridorin entered into a Phase 3 program in 2014 termed the PIONEER trial which was agreed to by the U.S. Food and Drug Administration (FDA), with fast track designation, under a Special Protocol Assessment (SPA). This Phase 3 program is using an events-based endpoint based on end stage renal disease (ESRD) or a 50% increase in serum creatinine (SCr). We believe this change will significantly reduce the cost and time for completion of our Phase 3 program compared to the traditional endpoint used in previous pivotal trials for diabetic nephropathy which is a 100% increase in SCr from baseline or end stage renal disease (ESRD). Based on an analysis of the Irbesartan Type II Diabetic Nephropathy Trial (IDNT) used for the approval of the drug irbesartan, the follow-up time required to reach the new endpoint of a 50% SCr increase would be approximately 50% less than the follow-up time required to reach the traditional endpoint in a similar patient population.

We are also studying the application of an intravenous formulation of Pyridorin to specific types of AKI in patients at increased risk and where pathogenic oxidative chemistries have been identified as a

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possible contributing factor to the severity of this condition. Our preclinical program has shown encouraging results in animal models of ischemia-reperfusion AKI including an observed treatment effect on post injury fibrosis. We expect to complete our preclinical program for an intravenous formulation of AKI in the third quarter of 2015.

Corporate Objectives

There is a large medical need and market opportunity for treatments that can (1) slow the progression of renal disease and thus delay or avoid the onset of ESRD; or (2) reduce the severity of AKI and its associated potential treatment costs and long term complications.

Our principal corporate objective is the maximization of shareholder value by advancing Pyridorin through Phase 3 development and approval. In order to maximize the market potential of Pyridorin, we intend to consider entering into a partnership for the launch and marketing of the product at the end of Phase 3 or possibly earlier, based on interim clinical data. We also intend to consider acquisitions and the development of other clinical candidates as we see appropriate.

We acquired commercial rights to Pyridorin in 2007 and, since then, have been investigating the safety and efficacy of Pyridorin therapy for diseases in which pathogenic oxidative chemistries are an established and/or causative and contributing factor in kidney disease. These include diabetic nephropathy and AKI.

We anticipate seeking corporate partners to aid us in commercialization and market entry.

Our Strategy

We are committed to applying our leadership position in the field of kidney disease to transform the lives of patients with debilitating, costly diseases or conditions. Each of our ongoing and planned development projects addresses kidney diseases or conditions with high unmet medical need that presents a significant market opportunity. The core elements of our strategy include:

advancing Pyridorin through Phase 3 development for the treatment of diabetic nephropathy in patients with type 2 diabetes;

submission and approval of a new drug application (NDA) in the United States and a Market Authorization Application (MAA) in Europe;

commercializing Pyridorin using a highly targeted sales force in the United States and the rest of the world;

continued development of an intravenous formulation of Pyridorin for AKI, with an investigational new drug application (IND) filing and launch of the initial clinical study during the second half of 2015; and

deploying capital strategically to develop our portfolio of product candidates and create shareholder value.

Risks Relating to Our Business

We are a biopharmaceutical company, and our business and ability to execute our business strategy are subject to a number of risks of which you should be aware before you decide to buy our common stock. In particular, you should consider the risks discussed in the "Risk Factors" section of this prospectus and in the documents incorporated by reference, including, but not limited to, the following:

we have never been profitable, have no products approved for commercial sale and to date have not generated any revenue from product sales;

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we will require substantial additional funding beyond this contemplated offering to complete the development and commercialization of Pyridorin and to continue to advance the development of the intravenous formulation of Pyridorin, and such funding may not be available on acceptable terms or at all;

Pyridorin may not receive regulatory approval in a timely manner or at all;

we face competition from other biotechnological and pharmaceutical companies and our operating results will suffer if we fail to compete effectively;

we depend on third-party contractors for a substantial portion of our operations and may not be able to control their work as effectively as if we performed the function ourselves

we may be subject to delays in our clinical trials, which could result in increased costs and delays or limit our ability to obtain regulatory approval for our product candidates;

because the results of earlier studies and clinical trials of our product candidates may not be predictive of future clinical trial results, our product candidates may not have favorable results in future clinical trials, which would delay or limit their future development; and

we may be unable to maintain and protect our intellectual property assets, which could impair the advancement of our pipeline and commercial opportunities.

Implications of Being an Emerging Growth Company

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. See "Risk Factors - Risks Relating to Our Common Stock and this Offering - We are an 'emerging growth company' and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our common stock less attractive to investors." These provisions include:

only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;

reduced disclosure about our executive compensation arrangements;

no non-binding advisory votes on executive compensation or golden parachute arrangements; and

exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these provisions until December 31, 2019. However, if certain events occur prior to December 31, 2019, including if we become a "large accelerated filer," our annual gross revenues exceed \$1.0 billion or we issue more than \$1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company before such date.

We have elected to take advantage of certain of the reduced disclosure obligations and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than the information

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you might receive from other public reporting companies in which you hold equity interests.

We refer to the Jumpstart Our Business Startups Act of 2012 in this prospectus as the "JOBS Act," and references in this prospectus to "emerging growth company" have the meaning associated with it in the JOBS Act.

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Notwithstanding the above, we are also currently a "smaller reporting company" meaning that we are not an investment company, an asset-backed issuer, or a majority-owned subsidiary of a parent company that is not a smaller reporting company and have a public float of less than \$75 million and annual revenues of less than \$50 million during the most recently completed fiscal year. In the event that we are still considered a smaller reporting company, at such time as we cease being an emerging growth company, the disclosure we will be required to provide in our SEC filings will increase, but will still be less than it would be if we were not considered either an emerging growth company or a smaller reporting company. Specifically, similar to emerging growth companies, smaller reporting companies are able to provide simplified executive compensation disclosures in their filings; are exempt from the provisions of Section 404(b) of the Sarbanes-Oxley Act requiring that independent registered public accounting firms provide an attestation report on the effectiveness of internal control over financial reporting; and have certain other decreased disclosure obligations in their SEC filings, including, among other things, only being required to provide two years of audited financial statements in annual reports.

Corporate Information

We were incorporated in the State of Delaware on May 25, 2004. Our principal executive offices are located at 3200 Beechleaf Court, Suite 900, Raleigh, NC 27604 and our telephone number is (609) 986-1780. Our website address is www.nephrogenex.com. The information contained on, or that can be accessed through, our website is not part of this prospectus.

We have obtained a registered trademark for Pyridorin in the United States. This prospectus contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other company.

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THE OFFERING

Common stock offered by us	2,008,032 shares
Common stock to be outstanding after this offering	10,871,646 shares
Over-allotment option	We have granted the underwriters a 45-day option to purchase up to 301,205 additional shares of our common stock from us at the public offering price less underwriting discounts and commissions.
Use of proceeds	We intend to use the net proceeds received from this offering for working capital and general corporate purposes. See "Use of Proceeds."
Risk Factors	See the section entitled "Risk Factors" beginning on page 7 of this prospectus for a discussion of factors you should carefully consider before deciding to invest in our common stock.
Nasdaq Capital Market symbol	NRX

The number of shares of our common stock to be outstanding after this offering is based on 8,863,614 shares of our common stock outstanding as of March 31, 2015 and excludes as of such date:

1,271,321 shares of our common stock issuable upon the exercise of stock options, with a weighted average exercise price of \$4.16 per share;

15,500 shares of our common stock issuable upon the settlement of outstanding restricted stock units;

118,603 shares of our common stock issuable upon the exercise of outstanding warrants, with a weighted average exercise price of \$9.86 per share;

any shares of our common stock issuable upon exercise of the underwriters' over-allotment option; and

other shares of our common stock reserved for future issuance under our Amended and Restated 2007 Equity Incentive Plan, as amended.

Unless otherwise indicated, all information contained in this prospectus assumes no exercise by the underwriters of their over-allotment option to purchase up to an additional 301,205 shares of our common stock.

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The following tables set forth a summary of our historical financial data as of, and for the periods ended on, the dates indicated. We have derived the statement of operations data for the years ended December 31, 2014 and 2013 from our audited financial statements incorporated by reference in this prospectus. We have derived the statement of operations data for the three months ended March 31, 2015 and 2014 and the balance sheet data as of March 31, 2015 from our unaudited financial statements incorporated by reference in this prospectus. The unaudited financial statements have been prepared on the same basis as our audited financial statements and include, in the opinion of management, all adjustments necessary for a fair presentation of the financial information set forth in those statements. You should read this data together with our financial statements and related notes appearing elsewhere in this prospectus and the sections in this prospectus entitled "Risk Factors," "Capitalization," "Selected Financial Data," and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Our historical results for any prior period are not necessarily indicative of our future results.

	Years ended December 31,		Three months ended March 31,	
	2014	2013	2015 (unaudited)	2014 (unaudited)
(in thousands, except share and per share data)				
Statement of Operations Data:				
Expenses:				
Research and development	\$ 11,264	\$ 1,480	\$ 3,369	\$ 457
General and administrative	5,323	1,026	1,670	1,035
Total expenses	16,587	2,506	5,039	1,492
Loss from operations	(16,587)	(2,506)	(5,039)	(1,492)
Other income (expense):				
Change in value of preferred stock warrants	(140)	(3,417)		(140)
Interest expense	(140)	(383)	(143)	(78)
Interest income	47	1	9	10
Net loss	\$ (16,820)	\$ (6,305)	\$ (5,173)	\$ (1,700)
Net loss per share, basic and diluted	\$ (2.15)	\$ (19.71)	(0.58)	(0.37)
Weighted average shares outstanding, basic and diluted	7,827,519	319,882	8,863,103	4,587,498

As of March 31, 2015	As Adjusted(1)
(Unaudited)	(Unaudited)
(in thousands)	

Balance Sheet Data