NephroGenex, Inc.
Form 10-K
March 29, 2016

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K
(Mark One)

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

For the fiscal year ended December 31, 2015
OR

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

For the transition period from to

Commission file number: 001 36303
NephroGenex, Inc.
(Exact name of registrant as specified in its charter)

Delaware	20 1295171
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
3200 Beechleaf Court Suite 900 Raleigh, NC	27604
(Address of principal executive offices)	(Zip Code)

(609) 986 1780
Registrant's telephone number, including area code

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of each class	Name of each exchange on which registered
Common Stock, $0.001 Par Value Per Share	NASDAQ Capital Market

Securities registered pursuant to Section 12(g) of the Exchange Act: None
Indicate by check mark if the registrant is a well known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No x
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes o No x
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 x No o
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 during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10 K or any amendment to this Form 10 K. o
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 o	Accelerated filer o
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company x

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b 2 of the Exchange Act). Yes No x

The aggregate market value of the registrant's voting and non voting common stock held by non affiliates of the registrant (without admitting that any person whose shares are not included in such calculation is an affiliate) computed by reference to the price at which the common stock was last sold as of June 30, 2015, the last business day of the registrant's most recently completed second fiscal quarter, was $30,175,671.

As of March 28, 2016 the registrant had 12,947,518 shares of common stock outstanding.

TABLE OF CONTENTS

Forward Looking Statements

This Annual Report on Form 10 K contains forward looking statements. All statements other than statements of historical facts contained in this Annual Report on Form 10 K, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth are forward looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward looking statements.

The words “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “sh “will,” “would” and similar expressions are intended to identify forward looking statements, although not all forward looking statements contain these identifying words. These forward looking statements include, among other things, statements about:

- our ability to obtain additional financing;
- the accuracy of our estimates regarding expenses, future revenues and capital requirements;
- the success and timing of any preclinical studies and clinical trials;
- our ability to obtain and maintain regulatory approval of any product candidate we may develop, and the labeling under any approval we may obtain;
- regulatory developments in the United States and other countries;
- the performance of third party manufacturers;
- our plans to develop and commercialize our product candidates;
- our ability to obtain and maintain intellectual property protection for our product candidates;
- the successful development of our sales and marketing capabilities;
- the potential markets for our product candidates and our ability to serve those markets;
- the rate and degree of market acceptance of any future products;
- the success of competing drugs that are or become available; and
- the loss of key scientific or management personnel.

These forward looking statements are only predictions and we may not actually achieve the plans, intentions or expectations disclosed in our forward looking statements, so you should not place undue reliance on our forward looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward looking statements we make. We have based these forward looking statements largely on our current expectations and projections about future events and trends that we believe may affect our business, financial condition and operating results. We have included important factors in the cautionary statements included in this Annual Report on Form 10 K, particularly in Item 1.A. Risk Factors, that could cause actual future results or events to differ materially from the forward looking statements that we make. Our forward looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

You should read this Annual Report on Form 10 K and the documents that we have filed as exhibits to the Annual Report on Form 10 K with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward looking statements whether as a result of new information, future events or otherwise, except as required by applicable law.

PART 1

Item 1. BUSINESS

All brand names or trademarks appearing in this report are the property of their respective holders. Unless the context requires otherwise, references in this report to “NephroGenex,” the “Company,” “we,” “us,” and “our” refer to NephroGenex, Inc.

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.

In February 2016, due to the remaining trial costs, our cash position and condition of the capital markets, our Board of Directors made a decision to pause the clinical program of our product candidate oral Pyridorin® and retained MTS Health Partners, L.P. to act as our financial advisor in connection with our exploration of potential business alternatives. There can be no assurance that the process to identify and evaluate potential business alternatives will result in a successful alternative for our business. If no transactions with respect to potential business alternatives are identified and completed, our Board of Directors may decide to pursue a restructuring, which may include a reorganization or bankruptcy under Federal bankruptcy laws, or a dissolution, liquidation and/or winding up of our company.

In addition, in February 2016, we undertook plans to reorganize our operations as part of our efforts to focus resources on three principal activities as a result of the suspension of our clinical development activities: completion of the final closure of the clinical program of our product candidate oral Pyridorin, diligence activities associated with thoroughly exploring potential business alternatives, and our compliance activities associated with being a public company in good regulatory standing. As such, although we continue to describe our intellectual property assets and programs herein, we are no longer pursuing development of such assets or expending material resources on them.

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). Prior to the suspension of our clinical development activities, we were 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. (BioStratum) in May of 2006. We subsequently acquired the 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 five preclinical efficacy studies, 36 preclinical safety studies, four Phase 1 studies and five Phase 2 studies with Pyridorin. After the acquisition, we conducted a multi-center, randomized, placebo-controlled Phase 2b study, namely PYR-210 and completed the Phase 1 QT/QTc (TQT) cardiac safety study. In addition, we worked with the U.S. Food and Drug Administration (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. BioStratum subsequently dissolved in December 2015.

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 FDA, with fast track designation, under a Special Protocol Assessment (SPA). This Phase 3 program was using a novel, events-based endpoint based on end stage renal disease (ESRD) or a 50% increase in serum creatinine (SCr).

AKI is a serious medical problem that results in substantial morbidity, prolonged hospitalization, increased medical costs, and significant mortality. The major causes of hospital-acquired AKI are decreased renal perfusion during surgery, contrast nephropathy and cancer therapy with nephrotoxic drugs such as cisplatin. We were 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 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. Most recently, the FDA has cleared our Investigational New Drug (IND) application for clinical studies with intravenous Pyridorin for the treatment of AKI in December 2015. Our decision to further pursue this product candidate or any additional product candidates in the future other than Pyridorin will be based in part upon available funding and partnering opportunities.

Recent Developments

On February 24, 2016, we announced that our Board of Directors has made a determination to pause the clinical program of our product candidate oral Pyridorin for the treatment of diabetic nephropathy, effect a restructuring of our operations and implement a strategic transaction. Our Board of Directors made this determination in light of the remaining trial costs, our cash balance and condition of the capital markets. Concurrently, our Board of Directors retained MTS Health Partners, L.P. to act as our financial adviser in connection with our exploration of potential business alternatives. In connection with the exploration of potential business alternatives, we paid off all amounts outstanding under our term loan, accrued interest expense and an end-of-term fee, totaling approximately $6.3 million as of February 23, 2016.

Following these announcements, we implemented a workforce reduction plan which eliminated approximately five positions or approximately 50% of our workforce, impacting primarily positions within our research and development function. We anticipate recording approximately $175,000 of restructuring charges during the first quarter of 2016 covering severance, related benefits and other costs.

Corporate Objectives

Prior to the recent developments discussed above, our principal corporate objective was the maximization of shareholder value by advancing Pyridorin through Phase 3 development and approval. In order to maximize the market potential of Pyridorin, we had intended 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 intended 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. Prior to the recent developments, we have anticipated seeking corporate partners to aid us in development, commercialization and market entry.

Competition

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Although we believe that Pyridorin is one of the few drug candidates for diabetic kidney disease that targets an underlying cause of the disease, our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results.

Diabetic Nephropathy

As of 2014, the Center for Disease Control and U.S. Census data estimate the prevalence of diabetic nephropathy across all stages of disease to be approximately 11.6 million patients in the United States and this population is expected to grow. According to 2015 study commissioned by us, approximately 1.5 million diabetic patients have overt nephropathy, approximately 6.9 million patients have early stage diabetic nephropathy and approximately 3.2 million patients are at high risk of progressing to diabetic nephropathy.

While the market opportunity for drugs to treat diabetic nephropathy is large and growing, the availability of drugs to treat this condition is very limited. There are two classes of drugs currently approved to slow the progression of diabetic nephropathy: ACE Inhibitors and ARBs. These agents target the renin angiotensin system. Approved initially as anti hypertension drugs, these agents are now considered SOC for patients with diabetic nephropathy. The table below summarizes the competitive landscape.

4

COMPANIES WITH CLINICAL PROGRAMS IN DIABETIC NEPHROPATHY

Company	Agent	Phase	Program Status
AbbVie	Endothelin receptor antagonist	3	Active
Janssen Pharmaceuticals	INVOKANA SGLT2 Inhibitor	3	Active
Bayer Healthcare	Mineralcorticoid Receptor Antagonist	3	Active
Pfizer	Chemokine CCR2/5 Receptor Antagonist	2	Completed
	Phosphodiesterase type 5 inhibitor	2	Completed
Eli Lilly	Transforming Growth Factor B-Monoclonal Antibody (IV)	2	Terminated
	MR Antagonist	2	Active
BMS	BMS-813160 CCCR2 antagonist	2	Active
Eli Lilly & Incyte Corp.	Janus Kinase 1 Inhibitor, TKI	2	Completed
Gilead Sciences	GS-4997 Mitogen-activated Protein Kinase Inhibitor	2	Active
La Jolla Pharmaceuticals Co.	GCS-100 (injection) Angiogenesis Inhibitor, Apoptosis Stimulant	2	Planned
Concert Pharmaceuticals	CTP-499 Unidentified pharmacological activity	2	Completed
ChemoCentryx	Chemokine CCR2 Receptor Antagonist	2	Completed
Genkyotex Innovation SAS	NOX 1 Inhibitor	2	Active
Vascular Pharmaceuticals, Inc.	VPI-2690B injection targets Insulin-like growth factor 1	2	Active
Sanwa Kagaku Kenkyusho Co., Ltd	Topiroxostat Xanthine oxidase inhibitor	2	Planned
Yuhan Corporation	5-hydroxytryptamine 2A Receptor Antagonist	2	Completed
Daiichi Sankyo, Inc.	Mineralcorticoid-receptor antagonist	2	Active
Kyowa Hakko Kirin Co. Ltd	RTA-402 Bardoxolone Methy Activator of Nrf2	2	Active
Korea Otsuka Pharmaceutical Co., Ltd	Probucol Cholesterol inhibitor reducing agent	2	Completed
Yuhan Corporation	Anplag (Sarpogrelate) 5-hydroxytryptamine 2A receptor antagonist	2	Completed
Dong Wha Pharmaceutical Co., Ltd	DW1029 Botantical extract	2	Completed

Competition for Phase 3 Recruitment

We believe AbbVie's Phase 3 trial is actively recruiting over 4,100 patients worldwide, Janssen's Phase 3 trial is actively recruiting over 3,700 patients worldwide, and in the second half of 2015, Bayer initiated a 4,800 patient study in diabetic nephropathy and a 6,400 patient cardiovascular study in a population of type 2 diabetic patients with kidney disease. While the eligible patient population is not identical, it is similar enough to impact enrollment goals set by our Pyridorin Phase 3 program. Accordingly, we had increased our planned spending on investigator and CRO costs to minimize any enrollment impact prior to our announcement of the recent developments.

Acute Kidney Injury (AKI)

In the United States, the incidence of AKI varies from 20% to 40% in critical care patients. It is estimated that up to 7% of all patients who visit the hospital will experience AKI. Patients with uncomplicated AKI have a mortality rate of up to 10%. If RRT is required, the mortality rate rises to as high as 80%.

The current treatment for AKI is mainly supportive in nature; no therapeutic modalities to date have shown efficacy in treating the condition.

We believe the market opportunity for effective treatments for AKI is large. There are a small number of industry drug trials in later stage development. Companies with an active AKI agent or program in Phase 2 or beyond include AM-Pharma, Baxter International, Inc., Ischemix, Inc., LG Life Sciences, Ltd., NeuroVive Pharmaceuticals AB, Quark Pharmaceuticals Inc., Stealth Biotherapeutics, Inc. and Thrasos Therapeutics, Inc.

5

Intellectual Property

The proprietary nature of, and protection for, our product candidates and our discovery programs, processes and know how are important to our business. We have sought patent protection in the United States and internationally for Pyridorin and our discovery programs, and any other inventions to which we have rights, where available and when appropriate. Our policy is to pursue, maintain and defend patent rights, whether developed internally or licensed from third parties, and to protect the technology, inventions and improvements that are commercially important to the development of our business. We also rely on trade secrets that may be important to the development of our business. However, we do not have composition of matter patent protection for Pyridorin which may result in competitors being able to offer and sell products including pyridoxamine so long as these competitors do not infringe any other patents that we or third parties hold, including synthesis and method of use patents.

Our ability to stop third parties from making, using, selling, offering to sell or importing our products depends on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We cannot be sure that patents will be granted with respect to any of our pending patent applications, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting us. For this and more comprehensive risks related to our intellectual property, please see “Risk Factors-Risks Relating to Our Intellectual Property.”

Patents and Proprietary Rights Covering Our Drug Candidates

We strive to protect our product candidates and exclusivity rights, as well as both maintain and fortify our position in the field of kidney disease therapeutics. We believe our intellectual property portfolio consists of early and broad filings in the area. We have focused on patents and patent applications covering, where possible, use of our products in disease treatment. We have sought and continue to seek the strongest possible intellectual property protection available to us in order to prevent others from directly competing with us, as well as to exclude competition around our products where possible, their manufacture, and methods for use of the products in disease treatment. Our intellectual property portfolio contains 28 issued patents and at least six pending patent applications in the United States and worldwide of both in licensed and NephroGenex owned inventions. This portfolio includes patents and proprietary rights around:

(i) Methods for using Pyridorin (pyridoxamine dihydrochoride) as a therapeutic agent to treat diabetic nephropathy;

(ii) Methods for manufacture of Pyridorin;

(iii) Methods for using Pyridorin as a therapeutic agent to treat a variety of other kidney diseases and other disorders; and

(iv) Pyridorin analog drug candidates, and their use for treating kidney disease.

We own patents covering methods for using Pyridorin to treat diabetic nephropathy in patients with type 2 diabetes and elevated levels of SCr, and thus closely track the anticipated drug label for an approved Pyridorin drug. These patents consist of an issued U.S. patent (U.S. Patent 8067444) and corresponding issued patents in Canada and Europe, which will expire in 2024 absent any extension to the patent term.

We also have worldwide, exclusive licenses from Kansas University Medical Center and Vanderbilt University to patents covering methods for using Pyridorin to treat a variety of other disorders. These patents include patents for treating urinary stone disease (US Patent 6521645), proteinuria (U.S. Patent 6472400), retinopathy (U.S. Patent 6750209), neurodegenerative disease (U.S. Patent 6750209), diabetic neuropathy (U.S. Patent 7030146), oxidative protein modification (U.S. Patent No. 6730686), oxidative stress related disorders (U.S. Patent No. 6716858), diabetes-associated hypercholesterolemia (U.S. Patent No. 6740668) and some corresponding foreign patents. The term of these patents will expire at various times, but all would expire by 2021. These patents also include a pending application in the United States for treating symptoms of kidney disorders; if a patent is granted on this application, it would expire in 2026.

These patents further include pending US and foreign applications for limiting development of AKI. If granted, patents issuing from these patent applications would expire by 2035.

We also own patents covering Methods for manufacture of Pyridorin; these patents consist of two issued U.S. patents (U.S. Patents 7214799 and 8431712), which will expire in 2025.

6

We own pending patent applications in the United States and Europe covering Pyridorin analogs, and uses of such analogs as therapeutics to treat a variety of disorders, including kidney disorders such as nephropathy. Patent protection, to the extent it issues, would be expected to extend to 2027.

Intellectual Property Strategy

We do not know if patents will be issued for all of the patent applications in our portfolio. Furthermore, for patent claims now issued and for claims to be issued in the future, we do not know if such claims will provide significant proprietary protection to our drug candidates and proprietary technologies or if they will be challenged, circumvented, or invalidated.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the earliest date of filing for a non provisional patent application to which the patent claims priority. In the United States, a patent's term may be shortened if a patent is terminally disclaimed over another patent, and a patent's term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the U.S. Patent and Trademark Office in granting a patent.

The patent term of a patent that covers an FDA approved drug or biologic may also be eligible for patent term extension, as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug or biologic is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug or biologic may be extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug or biologic. For more information regarding U.S. patent laws, see "Business-Government Regulation."

In addition to the patent term extension rights described above, an FDA-approved drug or biologic that receives FDA approval may also be eligible for market exclusivity protection under the Federal Food, Drug and Cosmetic Act or the Biologics Price Competition and Innovation Act of 2009. For more information regarding market exclusivity laws, see "Business-Government Regulation."

Many pharmaceutical companies, biotechnology companies and academic institutions are competing with us in the field of diabetic nephropathy and filing patent applications potentially relevant to our business. In order to contend with the inevitable possibility of third-party intellectual property conflicts, from time to time, we review and assess the third party intellectual property landscape for competitive and other developments that may inform or impact our intellectual property development.

With respect to third-party intellectual property, it is impossible to establish with certainty that our product candidates will be free of claims by third-party intellectual property holders or whether we will require licenses from such third parties. Even with modern databases and on line search engines, literature searches are imperfect and may fail to identify relevant patents and published applications. Even when a third-party patent is identified, we may conclude upon a thorough analysis, that we do not infringe the patent or that the patent is invalid. If the third-party patent owner disagrees with our conclusion and we continue with the business activity in question, we might have patent litigation thrust upon us. Alternatively, we might decide to initiate litigation in an attempt to have a court declare the third-party patent invalid or not infringed by our activity. In either scenario, patent litigation typically is costly and time consuming, and the outcome is uncertain. The outcome of patent litigation is subject to uncertainties that cannot be quantified in advance, for example, the credibility of expert witnesses who may disagree on technical interpretation of scientific data.

To protect our competitive position, it may be necessary to enforce our patent rights through litigation against infringing third parties. Litigation to enforce our own patent rights is subject to the same uncertainties discussed above. In addition, however, litigation involving our patents carries the risk that one or more of our patents will be held invalid (in whole or in part, on a claim by claim basis) or held unenforceable. Such an adverse court ruling could allow third parties to commercialize our products, and then compete directly with us, without payment to us.

Trade Secrets

In addition to patents, we rely on trade secrets and know how to develop and maintain our competitive position. Trade secrets and know how can be difficult to protect. We seek to protect our proprietary processes, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and commercial partners. These agreements are designed to protect our proprietary information. We also seek to preserve the

integrity and confidentiality of our data, trade secrets and know how by maintaining physical security of our premises and physical and electronic security of our information technology systems.

License Agreements

Licensing Payments

Set forth below is a summary chart outlining various potential license payments due under our license agreements referenced below:

Indication	Diabetic Nephropathy Phase III	Acute Kidney Injury, Chemotherapy Protection, or Radiation Damage Pre clinical AKI	Diabetic Neuropathy or Hyperlipedemia Not in current pipeline
Institution	Kansas University Medical Center	Vanderbilt University	South Carolina Research Foundation
FDA approval of SPA for designated indication	$25,000	—	—
Submission of IND	—	$75,000	—
Commencement of first Phase 1	—	$100,000	—
Commencement of first Phase 2	—	$150,000	—
Commencement of first Phase 3	—	$250,000	—
Submit NDA or foreign equivalent	—	—	—
FDA approval of NDA	$200,000	$500,000 ($250,000 credited against royalty)	—
First commercial sale	—	—	—
Royalty on net sales	—	5% (minus $250,000 credit)	—
Licensing fee	—	—	$30,000 payable up to license termination
Upon execution of a sublicense	—	25% of any sublicense fees or milestone payments	—

License Agreements

Kansas University Medical Center (KUMC) Exclusive License Agreement

In May 2007, we entered into an amended license agreement with KUMC. Under the agreement, KUMC grants us an exclusive, royalty free, worldwide license, with a right to grant sublicenses, to make, have made, use, distribute, sell, have sold, have distributed, offer to sell, market, import, have imported or otherwise dispose of licensed products for diagnostic testing and palliative, prophylactic and therapeutic treatments which incorporate the use of the technology relating to the licensed patents and improvements. The patents licensed from KUMC include claims reciting methods for using Pyridorin to: (a) treat diabetic nephropathy (expires September 10, 2016 absent any extension); (b) treat proteinuria or albuminuria associated with elevated blood sugar levels (expires September 10, 2016 absent any extension); (c) treat retinopathy or neurodegenerative disease (expires September 10, 2016 absent any extension); (d) inhibiting oxidative modification of proteins or treating atherosclerosis in a non hyperglycemic mammal (expires September 10, 2016 in the United States and by 2019 outside the United States absent any extension); (e) treat a condition associated with oxidative stress in a hyperglycemic mammal (expires September 10, 2016 absent any extension); (f) treat diabetes associated increases in hypercholesterolemia or hypertriglyceridemia in a diabetic mammal; (expires September 10, 2016 in the United States and by 2019 outside the United States absent any extension); (g) treat diabetic neuropathy (expires September 30, 2016 in the United States and by 2019 outside the United States absent any extension); (h) decrease dialysis related amyloidosis or dialysis related increases in permeability of the peritoneal membrane in a dialysis patient (expires September 10, 2016 absent any extension); and (i) urinary stone disease (expires by 2021 absent any extension).

The patents licensed from KUMC also include patents with claims reciting novel Pyridorin analogues, and methods for using them to treat AGE related pathologies, diabetic nephropathy, proteinuria, albuminuria; diabetes associated

increases in hypercholesterolemia or hypertriglyceridemia in a diabetic mammal; and for inhibiting oxidative modification of proteins or treating atherosclerosis in a non hyperglycemic mammal (expire in September 10, 2016 in the United States and by 2019

outside the United States absent any extension). The granted license is subject to certain rights and license granted to the United States pursuant to U.S. government patent laws and regulations.

We must pay KUMC milestone payments related to milestones met in the FDA regulatory approval process. These milestone payments include $25,000 upon receipt of FDA approval of our SPA for our first licensed product and $200,000 upon receipt of FDA approval of our submitted NDA for our first licensed product in respect to the first primary indication. We must exercise commercially reasonable efforts to seek regulatory approval for the marketing of a licensed product for at least one primary indication, effect the introduction of a licensed product for at least one primary indication into the commercial market and maximize these sales. Primary indications are the diagnosis, treatment, palliation or prophylaxis of diabetic nephropathy, diabetic retinopathy and diabetic neuropathy.

The agreement survives until expiration of the last to expire licensed patent, or in November 2018, whichever occurs last. We may terminate the license for any reason upon 90 days written notice. If either we or KUMC breach a material obligation under the agreement the non breaching party may terminate the agreement upon an additional written notice.

The South Carolina Research Foundation (SCRF) Exclusive License Agreement

In April 2012, we entered into an amended license agreement with SCRF. Under the agreement, SCRF grants us an exclusive, royalty free, worldwide license, under certain patent rights and related technology (including know how) with a right to sub license to utilize the patent rights and the technology during the term of the agreement and to practice under the patent rights to make, have made, use, sell, have sold, offer to sell, market, import, lease, or otherwise dispose of licensed products for all uses covered under the patent rights. The licensed product is Pyridorin or any other pharmaceutical compound labeled for an FDA approved indication that would infringe a valid claim of the patent rights in the absence of the license.

The patents licensed from SCRF include claims reciting methods for using Pyridorin to: (a) inhibit oxidative modification of proteins or treating atherosclerosis in a non hyperglycemic mammal (expires in 2016 in the United States and by 2019 outside the United States absent any extension); (b) treat diabetes associated increases in hypercholesterolemia or hypertriglyceridemia in a diabetic mammal; (expires September 10, 2016 in the United States and by 2019 outside the United States absent any extension); and (c) treat diabetic neuropathy (expires September 10, 2016 in the United States and by 2019 outside the United States absent any extension). The patents licensed from SCRF also include patents with claims reciting novel Pyridorin analogues, and methods for using them to treat diabetes associated increases in hypercholesterolemia or hypertriglyceridemia in a diabetic mammal, and for inhibiting oxidative modification of proteins or treating atherosclerosis in a non hyperglycemic mammal; (expires September 10, 2016 in the United States and by 2019 outside the United States absent any extension).

Under the license, SCRF retains the right to practice under the patents in the field solely for non profit, educational, research, and academic purposes. The license also is subject to any U.S. government rights in the patent rights, if the technology or patent rights were developed with the support of the U.S. government or an agency thereof.

We must exercise commercially reasonable efforts to develop and commercialize one or more licensed products. If we fail to comply with our diligence obligations with respect to at least one licensed product, then SCRF may terminate the license. If we develop Pyridorin for the treatment of hyperlipidemia or diabetic neuropathy, we must pay SCRF milestone payments related to milestones met in the FDA regulatory approval process in the aggregate amount of $6,075,000. We must pay SCRF an annual license fee each year that we are actively marketing Pyridorin or have an active sublicense for Pyridorin for the treatment of hyperlipidemia or diabetic neuropathy, which are creditable only against Licensed Product Sublicense upfront fees and milestone payments earned and payable in the same calendar year. We must pay SCRF an annual fee of $120,000 for 2015 and the years thereafter. We must pay SCRF a one time fee of $35,000 upon execution of a sub license between NephroGenex and a third-party, and must pay to SCRF 25% of any non royalty sublicense payments made by such sub licensee to NephroGenex. The planned phase 3 program for Pyridorin is for the treatment of diabetic nephropathy. Hyperlipidemia and diabetic neuropathy are not being evaluated in the current trial.

The agreement survives until the expiration or other disposition of the licensed patent rights. We may terminate the license at any time on three months prior written notice to SCRF. If we breach a material obligation under the

agreement, and such obligation is not cured within 90 days after we receive written notice of the breach, then SCRF may terminate the agreement upon an additional written notice. SCRF may also terminate the license if (i) we cease operations and have not assigned the license to a third-party; (ii) we become insolvent or make a general assignment of substantially all of our assets for the benefit of creditors, or if a petition of bankruptcy or any reorganization shall be commenced by, against, or in respect of us; or (iii) we fail to make a payment due under the license and the default is not cured within 30 days after written notice of such default, and SCRF has provided additional written notice.

On February 26, 2016, we provided written notice to SCRF to terminate this license agreement in light of the suspension of the Phase 3 Development Plan for oral Pyridorin.

Vanderbilt University (VU) Exclusive License Agreement

In connection with our additional pipeline opportunities for specific types of acute kidney injury, in July 2012, we entered into a license agreement with VU, which was amended on November 6, 2013 and again on March 16, 2015. Under the agreement, VU grants us an exclusive, royalty bearing, worldwide license, under certain patent rights, and a corresponding nonexclusive license under related know how, with a right to sub license, to make, have made, use, offer to sell, sell, and import licensed products incorporating the technology embodied in the licensed VU patent rights for use of pyridoxamine in the field of use, which is defined as treatment of acute renal failure or acute renal injury, use for radiation protection, and use for chemotherapy protection. The patent applications licensed from VU include claims reciting methods for using Pyridorin to: (a) ameliorate at least one symptom of a kidney disorder associated with oxidative stress, carbonyl stress, or combinations thereof (if issued, would expire by 2026); and (b) treat or prevent acute renal injury or acute renal failure (if issued, would expire by 2026), and (c) limiting development of acute kidney injury (if issued, would expire by 2035).

The patent applications licensed from VU also include claims reciting intravenous formulations of Pyridorin (if issued, would expire by 2026). Federal government rights in the licensed patents are reserved, as are VU's right to use the subject matter of the licensed patents for academic research or other not for profit scholarly purposes, and to grant to other academic, governmental, or not for profit organizations a non exclusive right, non transferable, non sublicensable right to practice the licensed patent rights for academic research or other not for profit scholarly research purposes, expressly excluding any human use.

We must pay VU milestone payments related to milestones met in the FDA regulatory approval process in the aggregate amount of $1,075,000. We must also pay VU a 5% royalty on net sales of licensed products in the field of use. We must also pay VU 25% of non royalty sublicense payments to us such as milestone payments we recoup from sub licensees. We must exercise commercially reasonable efforts to develop and commercialize a licensed product for at least one indication. Our diligence obligations include a series of patent prosecution and clinical trial milestones. If we fail to comply with our diligence obligations with respect to at least one licensed product, then VU may terminate the license.

The agreement survives until the last to expire of the licensed patent rights. We may terminate the agreement upon 60 days written notice to VU. If either we or VU breach a material obligation under the agreement, and such obligation, then the non breaching party may terminate the agreement upon an additional written notice. VU may also terminate the license if we become insolvent or suspend business, or file a voluntary petition or an answer admitting the jurisdiction of the court, or consent to an involuntary petition pursuant to any reorganization or insolvency law of any jurisdiction, or make an assignment for the benefit of creditors, or apply for or consent to the appointment of a receiver or trustee of a substantial part of our property.

BioStratum Grant Back License Agreement

In May 2007, we entered into a grant back license agreement with BioStratum as part of our acquisition of certain of BioStratum's assets, including certain patent rights. The licensed patent rights include all patents and patent applications licensed by NephroGenex from BioStratum under an earlier, terminated license agreement between the parties. These rights include all patents owned or licensed by us with the exception of the patent applications that we license from VU. Under this agreement, we granted BioStratum an exclusive, sublicensable license and sublicense under those patent rights to make, have made, use, sell, offer for sale and import licensed products solely in Japan, Taiwan, Korea and China. The licensed products are Pyridorin or AGE inhibitor products that are covered by the licensed patents. As this license has been fully paid, there are no milestone payments under this agreement. In this agreement, we also agreed not to modify the Kansas or USC license agreements in a manner that would adversely affect BioStratum's rights.

The license grant to BioStratum was made solely to enable BioStratum to exercise its rights and perform its obligations pursuant to a license agreement with Kowa Company, Ltd. (Kowa) pursuant to which BioStratum granted

Kowa an exclusive license (the Kowa Agreement) to manufacture and use licensed products in Japan, Taiwan, Korea, and China. The Kowa Agreement was terminated by Kowa on December 5, 2007. We terminated this grant-back license as of June 22, 2015.

Manufacturing

We do not own or operate manufacturing facilities for the production of any of our product candidates, nor do we have plans to develop our own manufacturing operations in the foreseeable future. Prior to the recent developments, we relied on

third party contract manufacturers for all of our required raw materials, active pharmaceutical ingredient (API) and finished product for our preclinical research and clinical trials, including the Phase 3 trials for Pyridorin for the treatment of diabetic nephropathy in patients with type 2 diabetes. In March 2015, we successfully negotiated a new manufacturing agreement with DPx Fine Chemical Regensburg GmbH, a German subsidiary of Patheon, to manufacture pyridoxamine dihydrochloride, the API in Pyridorin. Furthermore, Patheon manufactures clinical trial drug supply of pyridoxamine dihydrochloride capsules and placebo for our clinical supply. We do not have any current contractual relationships for the manufacture of commercial supplies of any of our product candidates. If any of our products are approved by any regulatory agency, we intend to enter into agreements with a third party contract manufacturer and one or more back up manufacturers for the commercial production of those products. Development and commercial quantities of any products that we develop will need to be manufactured in facilities, and by processes, that comply with the current Good Manufacturing Practice regulations, or cGMPs, and other requirements of the FDA and the regulatory agencies of other jurisdictions in which we are seeking approval. We employed internal resources to manage our manufacturing contractors prior to the recent workforce reduction.

Government Regulation and Product Approval

Governmental authorities in the United States, at the federal, state and local level, and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, packaging, promotion, storage, advertising, distribution, marketing and export and import of products such as those we are developing. Our product candidates must be approved by the FDA through the NDA process before they may be legally marketed in the United States and by the EMA through the MAA process before they may be legally marketed in most countries in Europe. Our product candidates will be subject to similar requirements in other countries prior to marketing in those countries. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

United States Government Regulation

NDA Approval Processes

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (the FDCA) and implementing regulations. Failure to comply with the applicable U.S. requirements at any time during the product development process or approval process, or after approval, may subject an applicant to administrative or judicial sanctions, any of which could have a material adverse effect on us. These sanctions could include:

- refusal to approve pending applications;
- withdrawal of an approval;
- imposition of a clinical hold;
- warning letters;
- product seizures;
- total or partial suspension of production or distribution; or
- injunctions, fines, disgorgement of profits, or civil or criminal penalties.

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests, animal studies and formulation studies conducted according to Good Laboratory Practices (GLPs) or other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- performance of adequate and well controlled human clinical trials according to Good Clinical Practices (GCPs) to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of a NDA;

- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with cGMPs to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and
- FDA review and approval of the NDA.

Once a pharmaceutical candidate is identified for development, it enters the preclinical or nonclinical testing stage. Nonclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. An IND sponsor must submit the results of the nonclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND. Some nonclinical testing may continue even after the IND is submitted. In addition to including the results of the nonclinical studies, the IND will also include a protocol detailing, among other things, the objectives of the initial clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the first phase lends itself to an efficacy determination. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30 day time period, places the IND on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. A clinical hold may occur at any time during the life of an IND, and may affect one or more specific studies or all studies conducted under the IND.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCPs. They must be conducted under protocols detailing, among other things, the objectives of the trial, dosing procedures, research subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND, and progress reports detailing the status of the clinical trials must be submitted to the FDA annually. Sponsors also must timely report to the FDA serious and unexpected adverse reactions, any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigation brochure, or any findings from other studies or animal or in vitro testing that suggest a significant risk in humans exposed to the drug. An institutional review board, or IRB, at each institution participating in the clinical trial must review and approve the protocol before a clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each research subject or the subject's legal representative, monitor the study until completed and otherwise comply with IRB regulations.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

Phase 1. The drug is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and elimination. In the case of some products for severe or life threatening diseases, such as cancer, especially when the product may be inherently too toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.

Phase 2. Clinical trials are performed on a limited patient population intended to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage.

Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These studies are intended to establish the overall risk benefit ratio of the product and provide an adequate basis for product labeling.

Human clinical trials are inherently uncertain and Phase 1, Phase 2 and Phase 3 testing may not be successfully completed. The FDA or the sponsor may suspend a clinical trial at any time for a variety of reasons, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to the submission of an IND, at the end of Phase 2 and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date and for the FDA to provide advice on the next phase of development. Sponsors typically use the meeting at the end of Phase 2 to discuss their Phase 2 clinical results and present their plans for the pivotal Phase 3 clinical trials that they believe will support the approval of the new drug. If a Phase 2 clinical trial is the subject of

discussion at the end of Phase 2 meeting with the FDA, a sponsor may be able to request an SPA, the purpose of which is to reach agreement with the FDA on the Phase 3 clinical trial protocol design and analysis that will form the primary basis of an efficacy claim.

According to published guidance on the SPA process, a sponsor that meets the prerequisites may make a specific request for an SPA and provide information regarding the design and size of the proposed clinical trial. The FDA is supposed to evaluate the protocol within 45 days of the request to assess whether the proposed trial is adequate, and that evaluation may result in discussions and a request for additional information. An SPA request must be made before the proposed trial begins, and all open issues must be resolved before the trial begins. If a written agreement is reached, it will be documented and made part of the record. The agreement will be binding on the FDA and may not be changed by the sponsor or the FDA after the trial begins except with the written agreement of the sponsor and the FDA or if the FDA determines that a substantial scientific issue essential to determining the safety or efficacy of the drug was identified after the testing began.

Concurrent with clinical trials, sponsors usually complete additional animal safety studies and also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing commercial quantities of the product in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug and the manufacturer must develop methods for testing the quality, purity and potency of the drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its proposed shelf life.

The results of product development, nonclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests and other control mechanisms, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of user fees, but a waiver of such fees may be obtained under specified circumstances. The FDA reviews all NDAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. It may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing.

Once the submission is accepted for filing, the FDA begins an in depth review. NDAs receive either standard or priority review. A drug representing a significant improvement in treatment, prevention or diagnosis of disease may receive priority review. The FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical or other data. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP compliant. The FDA may refer the NDA to an advisory committee for review and recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured and tested.

Expedited Review and Approval

The FDA has various programs, including Fast Track, priority review, and accelerated approval, which are intended to expedite or simplify the process for reviewing drugs, and/or provide for the approval of a drug on the basis of a surrogate endpoint. Even if a drug qualifies for one or more of these programs, the FDA may later decide that the drug no longer meets the conditions for qualification or that the time period for FDA review or approval will be shortened. Generally, drugs that are eligible for these programs are those for serious or life threatening conditions, those with the potential to address unmet medical needs and those that offer meaningful benefits over existing treatments. For example, Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious or life threatening diseases or conditions and fill unmet medical needs. Priority review is designed to give drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists an initial review within six months as compared to a standard review time of ten months.

Although Fast Track and priority review do not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast Track designated drug and expedite review of the application for a drug designated for priority review. Accelerated approval, which is described in Subpart H of 21 CFR Part 314,

provides for an earlier approval for a new drug that is intended to treat a serious or life threatening disease or condition and that fills an unmet medical need based on a surrogate endpoint. A surrogate endpoint is a laboratory measurement or physical sign used as an indirect or substitute measurement representing a clinically meaningful outcome. As a condition of approval, the FDA may require that a sponsor of a product candidate receiving accelerated approval perform post marketing clinical trials.

In the Food and Drug Administration Safety and Innovation Act, or FDASIA, which was signed into law in July 2012, Congress encouraged the FDA to utilize innovative and flexible approaches to the assessment of products under accelerated approval. The law required the FDA to issue related draft guidance within a year after the law's enactment and also promulgate confirming regulatory changes. In June 2013, the FDA published a draft Guidance for Industry entitled, "Expedited Programs for Serious Conditions-Drugs and Biologics" which provides guidance on FDA programs that are intended to facilitate and

expedite development and review of new drugs as well as threshold criteria generally applicable to concluding that a drug is a candidate for these expedited development and review programs. In addition to the Fast Track, accelerated approval and priority review programs discussed above, the FDA also provided guidance on a new program for Breakthrough Therapy designation. A request for Breakthrough Therapy designation should be submitted concurrently with, or as an amendment to an IND. FDA has already granted this designation to over 70 new drugs and has approved almost 20 Breakthrough Therapy designated drugs.

Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of FDA approval of the use of our drug candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch Waxman Act. The Hatch Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one half the time between the effective date of an IND, and the submission date of an NDA, plus the time between the submission date of a NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for extension must be made prior to expiration of the patent. The United States Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restorations of patent term for some of our currently owned or licensed patents to add patent life beyond their current expiration date, depending on the expected length of clinical trials and other factors involved in the submission of the relevant NDA.

Market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five year period of non patent marketing exclusivity within the United States to the first applicant to gain approval of a NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non infringement. The FDCA also provides three years of marketing exclusivity for a NDA, 505(b)(2) NDA or supplement to an approved NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, for new indications, dosages or strengths of an existing drug. This three year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five year and three year exclusivity will not delay the submission or approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric Exclusivity and Pediatric Use

Under the Best Pharmaceuticals for Children Act (BPCA) certain drugs may obtain an additional six months of exclusivity, if the sponsor submits information requested in writing by the FDA (a Written Request) relating to the use of the active moiety of the drug in children. The FDA may not issue a Written Request for studies on unapproved or approved indications or where it determines that information relating to the use of a drug in a pediatric population, or part of the pediatric population, may not produce health benefits in that population.

We have not received a Written Request for such pediatric studies, although we may ask the FDA to issue a Written Request for such studies in the future. To receive the six month pediatric market exclusivity, we would have to receive a Written Request from the FDA, conduct the requested studies in accordance with a written agreement with the FDA or, if there is no written agreement, in accordance with commonly accepted scientific principles, and submit reports of the studies. A Written Request may include studies for indications that are not currently in the labeling if the FDA determines that such information will benefit the public health. The FDA will accept the reports upon its

determination that the studies were conducted in accordance with and are responsive to the original Written Request or commonly accepted scientific principles, as appropriate, and that the reports comply with the FDA's filing requirements.

In addition, the Pediatric Research Equity Act (PREA) requires all applications (or supplements to an application) submitted under section 505 of the FDCA (21 U.S.C. Section 355) for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration to contain a pediatric assessment unless the applicant has obtained a waiver or deferral. It also authorizes the FDA to require holders of approved NDAs for marketed drugs to conduct pediatric studies under certain circumstances. In general, PREA applies only to those drugs developed for diseases and/or conditions that

occur in both the adult and pediatric populations. Products intended for pediatric specific indications will be subject to the requirements of PREA only if they are initially developed for a subset of the relevant pediatric population.

As part of the FDASIA, Congress reauthorized both BPCA and PREA, which were slated to expire on September 30, 2012, and made both laws permanent.

Post approval Requirements

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval. In addition, the FDA may require testing and surveillance programs to monitor the effect of approved products that have been commercialized, and the FDA has the power to prevent or limit further marketing of a product based on the results of these post marketing programs.

Any drug products manufactured or distributed by us pursuant to FDA approvals are subject to continuing regulation by the FDA, including, among other things:

- record keeping requirements;
- reporting of adverse experiences with the drug;
- providing the FDA with updated safety and efficacy information;
- drug sampling and distribution requirements;
- notifying the FDA and gaining its approval of specified manufacturing or labeling changes; and
- complying with FDA promotion and advertising requirements.

Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and some state agencies for compliance with cGMP and other laws.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products. Future FDA and state inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition, FDA regulations and guidance are often revised or reinterpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether legislative changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

Regulation Outside of the United States

In addition to regulations in the United States, we will be subject to regulations of other countries governing clinical trials and commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain approval by the comparable regulatory authorities of countries outside of the United States before we can commence clinical trials in such countries and approval of the regulators of such countries or economic areas, such as the European Union, before we may market products in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

Under European Union regulatory systems, a company may submit marketing authorization applications either under a centralized or decentralized procedure. The centralized procedure, which is compulsory for medicines produced by biotechnology or those medicines intended to treat AIDS, cancer, neurodegenerative disorders or diabetes and optional for those medicines which are highly innovative, provides for the grant of a single marketing authorization that is valid for all European Union member states. The decentralized procedure provides for mutual recognition of national approval decisions.

15

Under this procedure, the holder of a national marketing authorization may submit an application to the remaining member states. Within 90 days of receiving the applications and assessments report, each member state must decide whether to recognize approval. If a member state does not recognize the marketing authorization, the disputed points are eventually referred to the European Commission, whose decision is binding on all member states.

Reimbursement

Sales of our products will depend, in part, on the extent to which the costs of our products will be covered by third party payors, such as government health programs, commercial insurance and managed healthcare organizations. These third party payors are increasingly challenging the prices charged for medical products and services. Additionally, the containment of healthcare costs has become a priority of federal and state governments and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. If these third party payors do not consider our products to be cost effective compared to other therapies, they may not cover our products after approved as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the MMA) imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which will provide coverage of outpatient prescription drugs. Part D plans include both stand alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for our products for which we receive marketing approval. However, any negotiated prices for our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non governmental payors.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research will be developed by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of any product, if any such product or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor’s product could adversely affect the sales of our product candidates. If third party payors do not consider our products to be cost effective compared to other available therapies, they may not cover our products as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 (collectively, the ACA), enacted in March 2010, is expected to have a significant impact on the health care industry. The ACA is expected to expand coverage for the uninsured while at the same time containing overall healthcare costs. With regard to pharmaceutical products, among other things, the ACA is expected to expand and increase industry rebates for drugs covered under Medicaid programs and make changes to the

coverage requirements under the Medicare Part D program. We cannot predict the impact of the ACA on pharmaceutical companies, as many of the ACA reforms require the promulgation of detailed regulations implementing the statutory provisions which has not yet occurred. In addition, although the United States Supreme Court upheld the constitutionality of much of the law, some members of the U.S. Congress continue to try to overturn at least portions of the legislation, and we expect they will continue to review and assess this legislation and alternative health care reform proposals. Any legal challenges to the ACA, as well as Congressional efforts to repeal the ACA, add to the uncertainty of the legislative changes enacted as part of the ACA.

In addition, in some non U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may

approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally tend to be significantly lower.

Corporate Information

We are subject to the information requirements of the Exchange Act. Therefore, we file public reports, proxy statements and other information with the Securities and Exchange Commission (SEC), which may be obtained by visiting the Public Reference Room of the SEC at 100 F Street, NE, Washington, DC 20549 or by calling the SEC at 1-(800)-SEC-0330. The SEC also maintains a website (www.sec.gov) that contains reports, proxy information statements, and other information that issuers file electronically.

In addition, we maintain a website at www.nephrogenex.com and make available free of charge through this website our Annual Reports on Form 10-K, our Quarterly Reports on Form 10-Q, our Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Sections 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. We also similarly make available, free of charge on our website, the reports filed with the SEC by our executive officers, directors and 10% stockholders pursuant to Section 16 under the Exchange Act as soon as reasonably practicable after copies of those filings are provided to us by those persons. We also make available on our website (i) the charters for the committees of our Board of Directors, including the Audit Committee, Compensation Committee and Nominating and Governance Committee, and (ii) our Corporate Code of Conduct and Ethics and Whisleblower Policy governing our directors, officers and employees. We intend to disclose on our website any amendments to, or waivers from, our Code of Business Conduct and Ethics that are required to be disclosed pursuant to the rules of the SEC. We are not including the information contained at www.nephrogenex.com, or at any other Internet address as part of, or incorporating it by reference into, this Annual Report on Form 10-K.

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012. 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 SEC. We refer to the Jumpstart Our Business Startups Act of 2012 herein as the “JOBS Act,” and references herein to “emerging growth company” shall have the meaning associated with it in the JOBS Act.

Employees

As of March 28, 2016, we had five full-time employees, of which all are involved in our clinical development close-down operations or in general and administrative functions.

Item 1A. RISK FACTORS

Except for the historical information contained herein or incorporated by reference, this report and the information incorporated by reference contain forward looking statements that involve risks and uncertainties. These statements include projections about our accounting and finances, plans and objectives for the future, future operating and economic performance and other statements regarding future performance. These statements are not guarantees of future performance or events. Our actual results could differ materially from those discussed in this report. Factors that could cause or contribute to these differences include, but are not limited to, those discussed in the following section, as well as those discussed in Part II, Item 7 entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere throughout this report and in any documents incorporated in this report by reference.

You should consider carefully the following risk factors, together with all of the other information included or incorporated in this report. If any of the following risks, either alone or taken together, or other risks not presently known to us or that we currently believe to not be significant, develop into actual events, then our business, financial condition, results of operations or prospects could be materially adversely affected. If that happens, the market price of our common stock could decline, and stockholders may lose all or part of their investment.

RISK FACTORS

An investment in our securities involves a high degree of risk. The risks described below may not be the only ones relating to our company. Additional risks that we currently believe are immaterial may also impair our business operations. Our business, financial condition and future prospects and the trading price of our common stock could be harmed as a result of any of these risks. Investors should also refer to the other information contained in this prospectus, and our other filings from time to time with the SEC.

Risks Related To Our Financial Position and Need for Additional Capital

If our process to identify and evaluate potential business alternatives is not successful, our Board of Directors may decide to pursue a restructuring, which may include a reorganization or bankruptcy under Federal bankruptcy laws, or a dissolution, liquidation and/or winding up of our company.

There can be no assurance that the process to identify and evaluate potential business alternatives will result in a successful alternative for our business. If no transactions with respect to potential business alternatives are identified and completed, our Board of Directors may decide to pursue a restructuring, which may include a reorganization or bankruptcy under Federal bankruptcy laws, or a dissolution, liquidation and/or winding up of our company. If our Board of Directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation of our company, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. Our commitments and contingent liabilities may include (i) obligations under our employment and separation agreements with certain members of its management that provide for severance and other payments following a termination of employment occurring for various reasons, including a change in control of our company, (ii) various claims and legal actions arising in the ordinary course of business and (iii) non-cancelable lease obligations. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation of our company. If a dissolution and liquidation were pursued, our Board of Directors, in consultation with its advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock may lose their entire investment in the event of a reorganization, bankruptcy, liquidation, dissolution or winding up of our company.

We will require substantial additional funding, which may not be available to us on acceptable terms, or at all, and, if not so available, may require us to delay, limit, reduce or cease our operations.

Prior to our Board of Directors' decision to pause our clinical trials, we were advancing Pyridorin through clinical development for diabetic nephropathy and an intravenous formulation of Pyridorin for AKI through preclinical development. Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We will require substantial additional future capital in order to complete clinical development and commercialize any product candidate.

We will continue to require substantial additional capital to conduct any clinical development or commercialization activities. Because successful development of any product candidate is uncertain, we are unable to estimate the actual funds we may require to complete research and development and commercialize any product candidate.

We do not expect our existing capital resources to be sufficient to enable us to initiate any clinical trials or additional development work needed for any product candidate. Accordingly, we will need to raise additional funds in the future.

We may seek additional funding through a combination of equity offerings, debt financings, government or other third-party funding, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. Additional funding may not be available to us on acceptable terms or at all. In addition, the terms of any financing may adversely affect the holdings or the rights of our stockholders. In addition, the issuance of additional shares by us, or the possibility of such issuance, may cause the market price of our shares to decline.

We have paused our clinical development program and our exploration of potential business alternatives is uncertain

In February 2016, we announced plans to pause our clinical development program and explore potential business alternatives. Consistent with this announcement, we have substantially suspended all clinical development activities with a goal of conserving capital and maximizing value returned to our stockholders. As a result of our February 2016 announcement, we expect recording approximately $175,000 of restructuring charges during the first quarter of 2016 covering severance, related benefits and other costs. Our process to identify and evaluate potential business alternatives includes a review of the possible sale or disposition of one or more of our clinical candidates or other assets. There can be no assurance that our process to identify and evaluate potential business alternatives will result in any definitive offer to acquire us, or if made what the terms thereof will be or that any other transaction will be approved or consummated. If any definitive offer to acquire us is made, there can be no assurance that a definitive agreement will be executed or that, if a definitive agreement is executed, the transaction will be consummated. In addition, there can be no assurance that any transaction, involving our product candidates and/or other assets, that is consummated would deliver that anticipated benefits or enhance stockholder value. If no transactions with respect to potential business alternatives are identified and completed, our Board of Directors may decide to pursue a restructuring, which may include a reorganization or bankruptcy under Federal bankruptcy laws, or a dissolution, liquidation and/or winding up of our company.

We have never been profitable. Currently, we have no products approved for commercial sale, and to date we have not generated any revenue from product sales. As a result, our ability to reduce our losses and reach profitability is unproven, and we may never achieve or sustain profitability.

We have never been profitable and do not expect to be profitable in the foreseeable future. We have not yet submitted any product candidates for approval by regulatory authorities in the United States or elsewhere any indication. We have incurred net losses in each year since our inception, including net losses of $22.9 million and $16.8 million for the years ended December 31, 2015 and 2014, respectively. We had an accumulated deficit of approximately $80.7 million as of December 31, 2015.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues.

In connection with our decision to pause the clinical program of our lead product candidate, we retained MTS Health Partners, L.P. to act as our financial advisor in connection with our exploration of business alternatives. If this process is not successful, we may never achieve or sustain profitability on a quarterly or annual basis or return value to our stockholders. Our failure to become and remain profitable would depress the market price of our common stock and could impair our ability to raise capital or continue our operations. If we continue to suffer losses as we have in the past, investors may not receive any return on their investment and may lose their entire investment.

We have a limited operating history and we expect a number of factors to cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance.

We are a development stage pharmaceutical company with a limited operating history. Our operations to date, prior to our decision to pause the clinical trial program of our lead product candidate, have been limited to developing our technology and undertaking preclinical studies and clinical trials of our product candidates. We have not yet obtained regulatory approvals for any product candidate and have suspended their development. In addition, we have

initiated a process to identify and evaluate potential business alternatives. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or approved products on the market. Our financial condition and operating results have varied significantly in the past and are expected to continue to significantly fluctuate from quarter-to-quarter or year-to-year due to a variety of factors, many of which are beyond our control.

Accordingly, the results of any quarterly or annual periods should not be relied upon as indications of future operating performance.

Our recurring losses from operations may raise substantial doubt regarding our ability to continue as a going concern.

Our recurring losses from operations may raise substantial doubt about our ability to continue as a going concern. There is no assurance that sufficient financing will be available when needed to allow us to continue as a going concern. The

perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations.

Risks Relating to Our Intellectual Property

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection. If our patent position does not adequately protect our product candidates, others could compete against us more directly, which would harm our business, possibly materially.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our product candidates and the methods used to develop and manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell or importing our products depends on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our product candidates, discovery programs and processes.

The patent positions of biotechnology and pharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved.

No consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the United States or in many jurisdictions outside of the United States. Changes in either the patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be enforced in the patents that may be issued from the applications we currently or, may in the future, own or license from third parties. Further, if any patents we obtain or license are deemed invalid and unenforceable, our ability to commercialize or license our technology could be adversely affected.

In the future others may file patent applications covering products and technologies that are similar, identical or competitive to ours or important to our business. We cannot be certain that any patent application owned by a third-party will not have priority over patent applications filed or in-licensed by us, or that we or our licensors will not be involved in interference, opposition or invalidity proceedings before U.S. or non-U.S. patent offices.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to develop a platform similar to, or better than, ours in a way that is not covered by the claims of our patents;
- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of our patents;
- we might not have been the first to make the inventions covered by our pending patent applications;
- we might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- any patents that we obtain may not provide us with any competitive advantages;
- we may not develop additional proprietary technologies that are patentable; or
- the patents of others may have an adverse effect on our business.

As of December 31, 2015, we were the owner of record or the licensee of 26 issued or granted U.S. and non-U.S. patents relating to Pyridorin with claims directed to methods of making Pyridorin, and methods of using Pyridorin in various indications. We were also the owner of record or licensee of four pending U.S. and non-U.S. patent applications relating to Pyridorin in these areas. In addition, as of December 31, 2015, we were the owner of record of two issued US patents and two pending U.S. and non-U.S. applications relating to our product candidates other than Pyridorin, with claims directed to pharmaceutical compounds, pharmaceutical compositions and methods of using these compounds in various indications.

Patents covering methods of using Pyridorin expire in 2024 if the appropriate maintenance fee renewal, annuity, or other government fees are paid, unless a patent term extension based on regulatory delay is obtained. We expect that expiration in 2016 of some of our method-of-use patents, or their foreign equivalents, covering use of Pyridorin for treating diabetic nephropathy will have a limited impact on our ability to protect our intellectual property in the United States, Europe, and Canada, where we have additional issued patents covering this use that extend until 2024. In other countries, our patent protection covering use of Pyridorin for treating diabetic nephropathy will expire in 2016. We will attempt to mitigate the effect of patent expiration by

seeking data exclusivity, or the foreign equivalent thereof, in conjunction with product approval, as well as by filing additional patent applications covering improvements in our intellectual property.

We expect that the other patents and patent applications for the Pyridorin portfolio, if issued, and if the appropriate maintenance, renewal, annuity or other governmental fees are paid, would expire from 2016 to 2035. We own pending applications in the United States and Europe covering Pyridorin analogs, and uses of such analogs as therapeutics to treat a variety of disorders, including kidney disorders such as nephropathy. Patent protection, to the extent it issues, would be expected to extend to 2027, unless a patent term extension based on regulatory delay is obtained.

Due to the patent laws of a country, or the decisions of a patent examiner in a country, or our own filing strategies, we may not obtain patent coverage for all of our product candidates or methods involving these candidates in the parent patent application. We plan to pursue divisional patent applications or continuation patent applications in the United States and other countries to obtain claim coverage for inventions which were disclosed but not claimed in the parent patent application.

We may also rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or feasible. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third-party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

Pyridorin does not have composition of matter patent protection.

Although we own and exclusively license patents and patent applications with claims directed to the methods of use of Pyridorin (pyridoxamine) to treat diabetic nephropathy and other conditions, and methods for its synthesis, we are unaware of any composition of matter patent protection for Pyridorin in the United States or elsewhere. As a result, competitors may be able to offer and sell products including pyridoxamine so long as these competitors do not infringe any other patents that we or third parties hold, including synthesis and method of use patents. However, method of use patents, in particular, are more difficult to enforce than composition of matter patents because of the risk of off-label sale or use of the subject compounds. Physicians are permitted to prescribe an approved product for uses that are not described in the product's labeling. Although off-label prescriptions may infringe our method of use patents, the practice is common across medical specialties and such infringement is difficult to prevent or prosecute. Off-label sales would limit our ability to generate revenue from the sale of Pyridorin, if approved for commercial sale.

In addition, other third parties have obtained patents in the United States and elsewhere relating to methods of use of pyridoxamine for the treatment of certain diseases. As a result, it is possible that we could face competition from third-party products that have pyridoxamine as the active pharmaceutical ingredient. If a third-party were to obtain FDA approval in the United States for the use of pyridoxamine, or regulatory approval in another jurisdiction, for an indication before we did, such third-party would be first to market and could establish the price for pyridoxamine in these jurisdictions. This could adversely impact our ability to implement our pricing strategy for the product and may limit our ability to maximize the commercial potential of Pyridorin in the United States and elsewhere. The presence of a lower priced competitive product with the same active pharmaceutical ingredients as our product could lead to use of the competitive product for our diabetic nephropathy indication. This could lead to pricing pressure for Pyridorin, which would adversely affect our ability to generate revenue from the sale of Pyridorin for treating diabetic nephropathy. This would also limit the length of data exclusivity and patent term extension available if we later obtain approval to market Pyridorin for treating diabetic nephropathy.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

If we choose to go to court to stop another party from using the inventions claimed in any patents we obtain, that individual or company has the right to ask the court to rule that such patents are invalid or should not be enforced against that third party. These lawsuits are expensive and would consume time and resources and divert the attention

of managerial and scientific personnel even if we were successful in stopping the infringement of such patents. In addition, there is a risk that the court will decide that such patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of such patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our rights to such patents. In addition, in recent years the U.S. Supreme Court modified some tests used by the U.S. Patent and Trademark Office (USPTO) in granting patents over the past 20 years, which may decrease the likelihood that we will be able to obtain patents and increase the likelihood of challenge of any patents we obtain or license.

We may infringe the intellectual property rights of others, which may prevent or delay our product development efforts and stop us from commercializing or increase the costs of commercializing our product candidates.

Our success will depend in part on our ability to operate without infringing the proprietary rights of third parties. We cannot guarantee that our products, or manufacture or use of our product candidates, will not infringe third-party patents. Furthermore, a third party may claim that we or our manufacturing or commercialization collaborators are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and scientific personnel. There is a risk that a court would decide that we or our commercialization collaborators are infringing the third party's patents and would order us or our collaborators to stop the activities covered by the patents. In that event, we or our commercialization collaborators may not have a viable way around the patent and may need to halt commercialization of the relevant product. In addition, there is a risk that a court will order us or our collaborators to pay the other party damages for having violated the other party's patents. In the future, we may agree to indemnify our commercial collaborators against certain intellectual property infringement claims brought by third parties. The pharmaceutical and biotechnology industries have produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, which may not be available, defend an infringement action or challenge the validity of the patents in court. Patent litigation is costly and time consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid, we may incur substantial monetary damages, encounter significant delays in bringing our product candidates to market and be precluded from manufacturing or selling our product candidates.

We cannot be certain that others have not filed patent applications for technology covered by our pending applications, or that we were the first to invent the technology, because:

- some patent applications in the United States may be maintained in secrecy until the patents are issued;
- patent applications in the United States are typically not published until 18 months after the priority date; and
- publications in the scientific literature often lag behind actual discoveries.

Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our patent applications, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions. Other countries have similar laws that permit secrecy of patent applications, and may be entitled to priority over our applications in such jurisdictions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We employ an outside firm and rely on our outside counsel to pay these fees due to non-U.S. patent agencies and this outside firm has systems in place to ensure compliance on payment of fees. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

If any of our license agreements are terminated, we may lose the right to develop or market that product.

We have acquired or licensed intellectual property from third parties, including patent applications and patents relating to intellectual property for Pyridorin. Our product development of Pyridorin depends on our ability to maintain rights under these agreements. Each licensor has the power to terminate its agreement with us if we fail to meet our obligations under these licenses. Due to our decision to pause our clinical program for the development of Pyridorin, we may not be able to meet our obligations under these licenses. If we default under any license agreement, we may lose our right to market and sell any products based on the licensed technology and may be forced to cease operations, liquidate our assets and possibly seek bankruptcy protection. Bankruptcy may result in the termination of agreements pursuant to which we license certain intellectual property rights.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers. If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and products could be significantly diminished.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

Failure to secure trademark registrations could adversely affect our business.

If we seek to register additional trademarks, our trademark applications may not be allowed for registration or our registered trademarks may not be maintained or enforced. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many other jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we do not secure registrations for our trademarks, we may encounter more difficulty in enforcing them against third parties than we otherwise would.

If the FDA, EMA or other regulatory agencies fail to monitor and enforce the illegal sale of pyridoxamine as a dietary supplement, the commercial success of Pyridorin may be limited.

Following the publication of the initial Phase 2 studies that evaluated pyridoxamine therapy in diabetic nephropathy patients, a number of dietary supplement companies began selling pyridoxamine over the internet. In January 2009, the FDA ruled that pyridoxamine is an investigational drug candidate not eligible for sale as a dietary supplement. A significant decline in product availability occurred after the issuance of the above mentioned FDA ruling. However, approximately five sites on the internet can be found that continue to illegally sell pyridoxamine. In at least one example, the FDA has taken action against a dietary supplement company and prohibited such company from selling an FDA approved active drug ingredient in a dietary supplement. However, there is no guarantee that the

FDA will take action against other companies that illegally sell pyridoxamine after its approval. Food and dietary supplements in Europe are regulated by Directive 2002/46/EC, European Commission, Health and Consumers Directorate-General. Those approved are listed in Annex I and II of Directive 2002/46/EC. Pyridoxamine is not included on either list, and therefore the sale of pyridoxamine in foods and supplements in Europe is not permitted. The European Commission, Health and Consumers Directorate-General has indicated to us in April of 2013 that no applications for pyridoxamine have been received and that any new product intended for preventing, curing or treating diseases, would fall under the scope of medicinal products and not dietary supplements products. We are not aware of any direct action that this agency has taken against a company illegally selling an EMA approved drug for preventing, curing or treating disease, in the European Union. It is possible that this agency would not be successful in prohibiting such sales. We will rely on the FDA, EMA and other regulatory agencies to enforce laws and rulings that prohibit the illegal sale of pyridoxamine as a dietary supplement. If these agencies fail to enforce such laws and rulings, the commercial success of Pyridorin may be limited.

Risks Relating to Owning Our Common Stock

The trading market in our common stock has been extremely limited and substantially less liquid than the average trading market for a stock quoted on the NASDAQ Capital Market.

Since our initial listing on the NASDAQ Capital Market on February 11, 2014, the trading market in our common stock has been limited. The quotation of our common stock on the NASDAQ Capital Market does not assure that a meaningful, consistent and liquid trading market currently exists. We cannot predict whether a more active market for our common stock will develop in the future. An absence of an active trading market could adversely affect our stockholders' ability to sell our common stock at current market prices in short time periods, or possibly at all. Additionally, market visibility for our common stock may be limited and such lack of visibility may have a depressive effect on the market price for our common stock. As of March 15, 2016, 48.1% of our outstanding shares of common stock were held by our officers, directors, beneficial owners of 5% or more of our securities and their respective affiliates, which adversely affects the liquidity of the trading market for our common stock, in as much as federal securities laws restrict sales of our shares by these stockholders. If our affiliates continue to hold their shares of common stock, there will be limited trading volume in our common stock, which may make it more difficult for investors to sell their shares or increase the volatility of our stock price.

If we fail to comply with the continued listing requirements of the NASDAQ Capital Market, our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

Our common stock is listed for trading on the NASDAQ Capital Market. We must satisfy NASDAQ's continued listing requirements, including, among other things, a minimum closing bid price requirement of $1.00 per share for 30 consecutive business days. If a company trades for 30 consecutive business days below the $1.00 minimum closing bid price requirement, NASDAQ will send a deficiency notice to the company, advising that it has been afforded a "compliance period" of 180 calendar days to regain compliance with the applicable requirements. Thereafter, if such a company does not regain compliance with the bid price requirement, a second 180-day compliance period may be available.

A delisting of our common stock from NASDAQ could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, employees and fewer business development opportunities.

Our share price may be volatile, which could subject us to securities class action litigation and result in substantial losses to our stockholders.

The trading price of our common stock is highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. Our stock price is likely to remain volatile. The stock market in general and the market for pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price at which it was purchased.

Furthermore, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations often have been unrelated or disproportionate to the operating performance of those companies. These broad market and industry fluctuations, as well as general economic, political and market conditions such as recessions, interest rate changes or international currency fluctuations, may negatively impact the market price of shares of our common stock, regardless of our actual operating performance. In addition, such fluctuations could subject us to securities class action litigation, which could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business. As a result of this volatility, our stockholders could incur substantial losses.

We have a significant stockholder, which will limit your ability to influence corporate matters and may give rise to conflicts of interest.

Care Capital III LLC, together with its affiliates (collectively, Care Capital) is our largest stockholder. As of March 15, 2016, Care Capital beneficially owned 4,241,097 shares of our common stock. The shares of common

stock beneficially owned by Care Capital represent approximately 32.8% of our outstanding shares of common stock. Accordingly, Care Capital exerts significant influence over us and any action requiring the approval of the holders of our common stock, including the election of directors and approval of significant corporate transactions. This concentration of voting power makes it less likely that any other holder of common stock or directors of our business will be able to affect the way we are managed and could delay or prevent an acquisition of us on terms that other stockholders may desire. In addition, if Care Capital obtains a majority of our common stock, Care Capital would be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, Care Capital would be able to control the election of directors, amendments to our organizational documents and approval of any merger, consolidation, sale of all or substantially all of our assets or other business combination or reorganization. In addition, if Care Capital obtains a majority of our common stock, we would be deemed a "controlled company" for purposes of NASDAQ

listing requirements. Under NASDAQ rules, a "controlled company" may elect not to comply with certain NASDAQ corporate governance requirements, including (i) the requirement that a majority of our board of directors consist of independent directors, (ii) the requirement that the compensation of our officers be determined or recommended to the board by a majority of independent directors or a compensation committee that is composed entirely of independent directors and (iii) the requirement that director nominees be selected or recommended to the board by a majority of independent directors or a nominating committee that is composed of entirely independent directors.

Furthermore, the interests of Care Capital may not always coincide with your interests or the interests of other stockholders and Care Capital may act in a manner that advances its best interests and not necessarily those of other stockholders, including seeking a premium value for its common stock, and might affect the prevailing market price for our common stock. Our board of directors, which currently consists of six directors, including one designated by Care Capital, has the power to set the number of directors on our board from time to time. Richard J. Markham, a partners at Care Capital, is a member of our board of directors and some of its committees.

Being a public company has increased our expenses and administrative burden.

As a public company, we are incurring, and will continue to incur significant legal, insurance, accounting and other expenses. In addition, we are required to bear all of the internal and external costs of preparing and distributing periodic public reports in compliance with our obligations under the securities laws.

In addition, laws, regulations and standards applicable to public companies relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act and related regulations implemented by the SEC and the NASDAQ Stock Market, are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment will result in increased general and administrative expenses and may divert management's time and attention from product development activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed. In connection with our initial public offering, we increased our directors' and officers' insurance coverage, which increased our insurance cost. In the future, it will be more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

We are an "emerging growth company" and we will continue to avail ourselves of the reduced disclosure requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act and we have and intend to continue to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies" including not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we have and may continue to rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We may take advantage of these reporting exemptions until we are no longer an "emerging growth company." 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 SEC.

If we fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately report our financial condition, results of operations or cash flows, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. Commencing with our annual report on Form 10-K for the year ending December 31, 2014, we will be required, under Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a control deficiency, or combination of control deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely

basis. Section 404 of the Sarbanes-Oxley Act also generally requires an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. However, for as long as we remain an emerging growth company, as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the independent registered public accounting firm's requirement to attest to the effectiveness of our internal controls over financial reporting.

Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge, and compile the system and process documentation necessary to perform the evaluation needed to comply with Section 404. We may not be able to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begin its Section 404 reviews, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the NASDAQ stock market, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosure due to error or fraud may occur and not be detected.

Future sales of our common stock, or the perception that future sales may occur, may cause the market price of our common stock to decline, even if our business is doing well.

Sales of substantial amounts of our common stock, or the perception that these sales may occur, could materially and adversely affect the price of our common stock and could impair our ability to raise capital through the sale of additional equity securities.

We had outstanding 12,947,518 shares of common stock as of March 15, 2016, 4,255,597 of which are restricted securities that may be sold only in accordance with the resale restrictions under Rule 144 of the Securities Act of 1933, as amended. In addition, as of March 15, 2016, we had outstanding options to purchase 1,542,732 shares of our common stock, 890,117 shares of common stock were issuable upon the settlement of outstanding restricted stock units and we had outstanding warrants to purchase 10,039,682 shares of our common stock. Shares issued upon the exercise of stock options or upon the settlement of outstanding restricted stock units generally will be eligible for sale in the public market, except that affiliates will continue to be subject to volume limitations and other requirements of Rule 144 under the Securities Act. The issuance or sale of such shares could depress the market price of our common

stock.

In the future, we also may issue our securities if we need to raise additional capital. The number of new shares of our common stock issued in connection with raising additional capital could constitute a material portion of the then-outstanding shares of our common stock. We are unable to predict the effect that transactions on our stock may have on the prevailing market price of our common stock.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline.

The trading market for our common stock will depend on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. There can be no assurance that analysts will continue to cover us or provide favorable coverage. If one or more of the analysts who cover us downgrade our stock or change their opinion

of our stock, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

NASDAQ may delist our securities from its exchange, which could limit investors' ability to make transactions in our securities and subject us to additional trading restrictions.

If we fail to maintain the listing of our common stock on the NASDAQ Capital Market, the liquidity for our common stock would be significantly impaired, which may substantially decrease the trading price of our common stock. We cannot assure you that, in the future, our securities will meet the continued listing requirements to be listed on NASDAQ. If NASDAQ delists our common stock from trading on its exchange, we could face significant material adverse consequences, including:

- a limited availability of market quotations for our securities;
- a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly resulting in a reduced level of trading activity in the secondary trading market for our common stock;
- a limited amount of news and analyst coverage for our company; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

If our shares become subject to the penny stock rules, it would become more difficult to trade our shares.

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $5.00, other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. If we do not obtain or retain a listing on The NASDAQ Capital Market and if the price of our common stock is less than $5.00, our common stock will be deemed a penny stock. The penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that before effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser's written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our common stock, and therefore stockholders may have difficulty selling their shares.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our restated certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third-party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders. These provisions include:

- authorizing the issuance of "blank check" convertible preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- creating a staggered board of directors;
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prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;

- eliminating the ability of stockholders to call a special meeting of stockholders;

- permitting our board of directors to accelerate the vesting of outstanding equity awards upon certain transactions that result in a change of control; and

- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may also frustrate or prevent any attempts by our stockholders to replace or remove our current management or members of our board of directors. In addition, we are subject to Section 203 of the Delaware General Corporation Law (DGCL), which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful stockholder claims against us and may reduce the amount of money available to us.

As permitted by Section 102(b)(7) of the DGCL, our restated certificate of incorporation limits the liability of our directors to the fullest extent permitted by law. In addition, as permitted by Section 145 of the DGCL, our restated certificate of incorporation and restated bylaws provide that we shall indemnify, to the fullest extent authorized by the DGCL, each person who is involved in any litigation or other proceeding because such person is or was a director or officer of our company or is or was serving as an officer or director of another entity at our request, against all expense, loss or liability reasonably incurred or suffered in connection therewith. Our restated certificate of incorporation provides that the right to indemnification includes the right to be paid expenses incurred in defending any proceeding in advance of its final disposition, provided, however, that such advance payment will only be made upon delivery to us of an undertaking, by or on behalf of the director or officer, to repay all amounts so advanced if it is ultimately determined that such director is not entitled to indemnification. If we do not pay a proper claim for indemnification in full within 60 days after we receive a written claim for such indemnification, except in the case of a claim for an advancement of expenses, in which case such period is 20 days, our restated certificate of incorporation and our restated bylaws authorize the claimant to bring an action against us and prescribe what constitutes a defense to such action.

Section 145 of the DGCL permits a corporation to indemnify any director or officer of the corporation against expenses (including attorney's fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with any action, suit or proceeding brought by reason of the fact that such person is or was a director or officer of the corporation, if such person acted in good faith and in a manner that he reasonably believed to be in, or not opposed to, the best interests of the corporation, and, with respect to any criminal action or proceeding, if he or she had no reason to believe his or her conduct was unlawful. In a derivative action, (i.e., one brought by or on behalf of the corporation), indemnification may be provided only for expenses actually and reasonably incurred by any director or officer in connection with the defense or settlement of such an action or suit if such person acted in good faith and in a manner that he or she reasonably believed to be in, or not opposed to, the best interests of the corporation, except that no indemnification shall be provided if such person shall have been adjudged to be liable to the corporation, unless and only to the extent that the court in which the action or suit was brought shall determine that the defendant is fairly and reasonably entitled to indemnity for such expenses despite such adjudication of liability.

The rights conferred in the restated certificate of incorporation and the restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons. We have entered into or plan to enter into indemnification agreements with each of our officers and directors.

The above limitations on liability and our indemnification obligations limit the personal liability of our directors and officers for monetary damages for breach of their fiduciary duty as directors by shifting the burden of such losses and expenses to us. Although we have increased the coverage under our directors' and officers' liability insurance, certain liabilities or expenses covered by our indemnification obligations may not be covered by such insurance or the coverage limitation amounts may be exceeded. As a result, we may need to use a significant amount of our funds to satisfy our indemnification obligations, which could severely harm our business and financial condition and limit the funds available to stockholders who may choose to bring a claim against our company.

We do not anticipate paying cash dividends, and accordingly, stockholders must rely on stock appreciation for any return on their investment.

We do not anticipate paying cash dividends in the future. As a result, only appreciation of the market price of our common stock, which may never occur, will provide a return to stockholders. Investors seeking cash dividends should not invest in our common stock.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2015, we had federal net operating loss carryforwards (NOLs) of $41.9 million, which expire from 2024 through 2035. Our ability to utilize our NOLs may be limited under Section 382 of the Internal Revenue Code. The limitations apply if an ownership change, as defined by Section 382, occurs. Generally, an ownership change occurs when certain shareholders increase their aggregate ownership by more than 50 percentage points over their lowest ownership percentage in a testing period (typically three years). Although we have not undergone a Section 382 analysis, it is possible that the utilization of the NOLs, could be substantially limited. Additionally, U.S. tax laws limit the time during which these carryforwards may be utilized against

future taxes. As a result, we may not be able to take full advantage of these carryforwards for federal and state tax purposes. Future changes in stock ownership may also trigger an ownership change and, consequently, a Section 382 limitation.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

Facilities

Since November 24, 2014, our corporate headquarters and clinical development operations have been located in 5,514 square feet of office space located at 3200 Beechleaf Court, Raleigh, North Carolina, pursuant to a lease agreement that commenced on December 1, 2014 and terminates on May 31, 2020. The lease agreement gives us the right and option to extend the lease term for an additional 36 months contingent upon certain conditions set forth in the lease agreement.

We believe that our facility is suitable and adequate for our current needs.

Item 3. LEGAL PROEEDINGS

We are not a party to any legal proceedings and we are not aware of any claims or actions pending or threatened against us. In the future, we might from time to time become involved in litigation relating to claims arising from our ordinary course of business.

Item 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

Item 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock began trading on the NASDAQ Capital Market on February 11, 2014, under the symbol “NRX”. Prior to that there was no public market for our common stock. Shares sold in our initial public offering on February 10, 2014, were priced at $12.00 per share.

The following table sets forth the high and low sales prices for our common stock, as reported on the NASDAQ Capital Market:

	2014*		2015	
	High	Low	High	Low
First quarter	$13.00	$7.26	$12.94	$6.01
Second Quarter	8.98	5.00	9.01	6.27
Third Quarter	6.09	3.96	6.78	3.34
Fourth Quarter	17.98	4.00	3.91	1.44

*Beginning on February 11, 2014

On March 14, 2016, the closing price for our common stock as reported on the NASDAQ Capital Market was $0.49.

Holders of Record

As of March 14, 2016, there were approximately 36 stockholders of record of the 12,947,518 outstanding shares of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividends

We have never declared or paid dividends to our stockholders and we do not plan to pay cash dividends in the foreseeable future. We currently intend to retain earnings, if any, to finance the growth of our Company.

30

Securities Authorized for issuance under Equity Compensation Plans

The information required by Item 5 of Form 10 K regarding equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report on Form 10-K.

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

We did not purchase any of our registered equity securities during the period covered by this Annual Report on Form 10 K.

Use of Proceeds from Registered Securities

None.

Item 6. SELECTED FINANCIAL DATA

Not required as we are a smaller reporting company.

Item 7. 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 Annual Report on Form 10-K. 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 report including those set forth under Item 1.A. "Risk Factors" in this 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.

On February 24, 2016, we announced that our Board of Directors has made a determination to pause the clinical program of our product candidate oral Pyridorin for the treatment of diabetic nephropathy, effect a restructuring of our operations and implement a strategic transaction. Our Board of Directors made this determination in light of the remaining trial costs, our cash balance and condition of the capital markets. Concurrently, our Board of Directors retained MTS Health Partners, L.P. to act as financial adviser in connection with our exploration of potential business alternatives. In connection with the exploration of potential business alternatives, we paid off all amounts outstanding under our term loan, accrued interest expense and an end-of-term fee, totaling approximately $6.3 million as of February 23, 2016.

We have devoted substantially all of our resources to development efforts relating to our product candidates, including conducting clinical trials of our product candidates, 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, the private placement of preferred stock, common stock, convertible notes and a term loan. In February 2014, we completed our IPO pursuant to a registration statement on Form S-1, and raised approximately $33.4 million in net proceeds, after deducting underwriting discounts, commissions and offering expenses. On July 22, 2015, we completed a public offering of common stock and accompanying warrants pursuant to a registration statement on Form S-1, and raised approximately $7.1 million in net proceeds, after deducting underwriting discounts, commissions and offering expenses. On November 6, 2015, we raised approximately $5.0 million in net proceeds, after deducting commissions and other fees, from a private placement of our common stock and accompanying warrants. In addition, during the second half of 2015, we raised approximately $1.1 million in net proceeds, after deducting commissions and other fees, from an at-the-market equity offering of common stock.

We have incurred net losses in each year since our inception in 2004. Our net losses for the years ended December 31, 2015 and 2014 were $22.9 million and $16.8 million, respectively. As of December 31, 2015, we had an accumulated deficit of approximately $80.7 million. Our net losses have resulted primarily from costs incurred in connection with

our research and development programs and from general and administrative costs associated with our operations and from changes in the value of our preferred stock warrant liability which was settled in February 2014 upon completion of our IPO.

Recent Developments

On February 24, 2016, we announced that our Board of Directors made a determination to pause the clinical program of our product candidate oral Pyridorin for the treatment of diabetic nephropathy, effect a restructuring of our operations and implement a strategic transaction. In addition, we announced that we paid off our term loan as of February 23, 2016. Concurrently, our Board of Directors retained MTS Health Partners, L.P. to act as financial adviser in connection with the Company's exploration of potential business alternatives. The Company's evaluation of potential business alternatives entails numerous significant risks and uncertainties, including the risks and uncertainties set forth in Item 1A under the heading "Risk Factors" of this Annual Report on Form 10-K. There can be no assurance that the Company's evaluation of potential business alternatives will result in any transaction.

Financial Overview

Revenue

We have not generated any revenue since our inception on May 25, 2004.

Research and Development Expenses

Prior to the suspension of our clinical development activities, 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:

- fees paid to CROs and consultants 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;
- salaries and related overhead expenses for personnel in research and development functions, including costs related to stock options or other stock-based compensation;
- costs related to acquiring and manufacturing clinical trial materials; and
- costs related to compliance with regulatory requirements.

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.

	Year Ended December 31,	
(in thousands)	2015	2014
Direct research and development expense	$12,708	$8,417
Personnel costs	2,098	1,676
Indirect research and development expense	500	1,171
Total research and development expense	$15,306	$11,264

Pyridorin

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

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

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

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

In addition, prior to the suspension of our clinical development activities, we were 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 significant expenses relating to:

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

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

We have suspended our research and development activities and are in the process of completing necessary wind-down and regulatory activities. As a result, we expect our research and development expenses to decrease in future periods for the forseeable future.

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 insurance, accounting and legal services, facilities costs and other consulting services related to our corporate governance activities.

We expect that our general and administrative expenses may increase in the future as a result of the increased spending in support of the identification and evaluation of potential business alternatives partially offset by the workforce reduction plan implemented in February 2016 (see Note 13 to financial statements).

Other Income (expense)

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

Critical Accounting Policies and Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with generally accepted accounting principles in the United States (GAAP). The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. We evaluate these estimates and judgments on an ongoing basis. 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 readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2 to our financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

Accrued Expenses

As part of the process of preparing financial statements, we are required to estimate accrued expenses. This process involves communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us. We periodically confirm the accuracy of our estimates with selected service providers and make adjustments, if necessary. To date, we have not adjusted our estimate at any particular balance sheet date by any material amount. Examples of estimated accrued expenses include:

- fees paid to CROs for management of our clinical trial activities;
- fess paid to investigative sites in connection with clinical trials;
- fess paid to contract manufacturers in connection with the production of clinical trial supplies; and
- professional services and fees.

We base our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple research institutions and CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If we do not accurately identify costs that we have begun to incur or if we underestimate or overestimate the level of services performed or the costs of these services, our actual expenses could differ from our estimates.

Fair Value Measurements

The carrying amounts of certain of our financial instruments, including cash and cash equivalents and short-term investments are stated at fair value. We account for the fair value of our financial instruments in accordance with the provisions of the Fair Value Measurement topic of the Financial Accounting Standards Board Codification (the Codification).

Fair value is the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the measurement date. We apply the market approach valuation technique for fair value measurements on a recurring basis and attempt to maximize the use of observable inputs and minimize the use of unobservable inputs. The fair value hierarchy prioritizes the inputs to valuation techniques used to measure fair value into three broad levels. All of our cash equivalents and short-term investments are measured using inputs classified at Level 1 or Level 2 within the fair value hierarchy. Level 1 inputs are quoted prices in active markets for identical assets. Level 2 inputs are based upon quoted prices for similar instruments in active markets, quoted prices for identical or similar instruments in markets that are not active and model-based valuation techniques for which all significant inputs are observable in the market or can be corroborated by observable market data for substantially the full term of the assets. Level 3 inputs are unobservable inputs that are supported by little or no market activity and are significant to the fair value of the assets or liabilities. Where applicable, these models project future cash flows and discount the future amounts to a present value using market-based observable inputs obtained from various third-party data providers, including but not limited to, benchmark yields, interest rate curves, reported trades, broker/dealer quotes and market reference data.

Stock-Based Compensation

The provisions of the Compensation - Stock Compensation topic of the Codification establish accounting for stock-based awards exchanged for employee services. In accordance with this topic stock-based compensation cost is measured on the grant date, based on the fair value of the award, and is recognized as expense over the requisite employee service period.

We estimate the fair value of stock options and stock purchase rights using a Black-Scholes valuation model which requires the input of highly subjective assumptions, including the option’s expected life and the price volatility of the underlying stock. We have opted to use the simplified method for estimating the expected term as provided by the SEC's Staff Accounting Bulletin No.107. The simplified method calculates the expected term as the average time-to-vesting and the contractual life of the options. The expected stock price volatility assumption was determined by examining the historical volatilities of a group of industry peers. The fair value of each option grant is estimated on the date of grant using the Black-Scholes option valuation model, and the resulting charge is expensed using the straight-line attribution method over the vesting period. Restricted stock units are measured at the fair value of our common stock on the date of grant and expensed over the period of vesting using the straight-line attribution approach. The Black-Scholes option-pricing model was developed for use in estimating the fair value of short-lived, exchange-traded options that have no vesting restrictions and are fully transferable.

Research and Development Expenses

Research and development expenses consist of costs associated with external research and development expenses incurred (i) under agreements with third-party investigative sites, where a substantial portion of our preclinical studies and all of our clinical trials are conducted, (ii) under the agreements with third-party manufacturing organizations, where a substantial portion of our clinical supplies are produced, and (iii) related to consultants and employee-related expenses.

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 SEC.

Results of Operations

Comparison of the Year Ended December 31, 2015 and the Year Ended December 31, 2014

The following table summarizes our results of operations for each of the years ended December 31, 2015 and 2014, together with the changes in those items in dollars and as a percentage:

	Years Ended December 31,		$	
(in thousands)	2015	2014	Change	% Change
Expenses:				
Research and development	$15,306	$11,264	$4,042	35.9 %
General and administrative	7,016	5,323	1,693	31.8 %
Loss from operations	(22,322)	(16,587)	5,735	(34.6)%
Other income (expense):				
Change in value of preferred stock warrants	—	(140)	140	(100.0)%
Interest expense	(565)	(140)	(425)	303.6 %
Interest income	23	47	(24)	(51.1)%
Net loss	$(22,864)	$(16,820)	$6,044	(35.9)%

Research and Development Expenses

Research and development expenses were approximately $15.3 million and $11.3 million for the years ended December 31, 2015 and 2014, respectively. The increase in research and development expense of $4.0 million, or 35.9%, is primarily due to our Phase 3 clinical development activities for Pyridorin which began in mid-2014,

pre-clinical development activities for Pyridorin for the treatment of AKI and an increase in personnel-related expenses for employees involved in our research and development activities.

General and Administrative Expenses

General and administrative expenses were approximately $7.0 million and $5.3 million for the years ended December 31, 2015 and 2014, respectively. The increase in general and administrative expenses of $1.7 million, or 31.8%, was primarily a result of 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 and an increase in personnel-related expenses, including non-cash stock based compensation expense.

Other Income (Expense)

Interest income for the years ended December 31, 2015 and 2014, was approximately $23,000 and $47,000, respectively, from interest received on our cash, cash equivalents and investments. Interest expense for the year ended December 31, 2015 was for interest on our term loan. Interest expense for the year ended December 31, 2014 was for interest on our convertible notes payable and term loan. The change in fair value of our preferred stock warrant liability for the year ended December 31, 2014 was $140,000. 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 December 31, 2015, we had an accumulated deficit of $80.7 million. We anticipate that we will continue to incur losses for at least the next several years. 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, 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 and debt. As of December 31, 2015, we had cash and cash equivalents and short-term investments of approximately $21.7 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 deposit held at various banks that do not exceed the Federal Deposit Insurance Corporation insurance limit.

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

Sale of common stock in public offering

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

At Market Issuance Sales Agreement

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

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

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

As of December 31, 2015, we had sold 308,541 ATM Shares of common stock at an average sales price of $3.92 per ATM Share for total net proceeds of approximately $1.1 million after deducting discounts and commissions and estimated offering expenses of approximately $98,000. In connection with the Securities Purchase Agreement entered into in November 2015 (as further described below), we agreed to a period of 18 months from the date of the Securities Purchase Agreement not to make sales of ATM shares during such period.

Securities Purchase Agreement

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

Description	Warrants	Exercise Price	Date Exercisable	Expiration	Term
Series A Warrants	1,617,647	$3.56	May 6, 2016	November 6, 2020	5 years
Series B Warrants	2,156,863	$3.56	May 6, 2016	November 7, 2016	12 months + 1 day
Series C Warrants	2,156,863	$3.56	May 6, 2016	May 6, 2017	18 months
Series D Warrants	2,156,863	$3.56	May 6, 2016	July 6, 2016	8 months
Total	8,088,236				

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

In connection with the transactions described above, we also entered into a registration rights agreement with the investors pursuant to which we agreed to register the shares of common stock acquired from us (including upon any exercise of the warrants). The registration statement for these shares was declared effective by the SEC on December 15, 2015.

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

Cash Flows

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

	Years Ended December 31,	
(in thousands)	2015	2014
Net cash provided by (used in):		
Operating activities	$(19,635)	$(13,638)
Investing activities	11,680	(14,809)
Financing activities	12,807	40,293
Net increase in cash and cash equivalents	$4,852	$11,846

Operating Activities.

Net cash used in operating activities for the year ended December 31, 2015 was $19.6 million primarily due to our net loss from the operation of our business of $22.9 million, partially offset by changes in working capital, including an increase in our accrued liabilities and non-cash charges, including non-cash interest expense for our term loan and

stock based compensation expense. Net cash used in operating activities for the year ended December 31, 2014 was $13.6 million primarily related to our net loss from the operation of our business of $16.8 million, 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.

Investing Activities. Net cash provided by investing activities during the year ended December 31, 2015 was $11.7 million primarily related to the proceeds received from the sales of available-for-sale investments of $25.0 million, partially offset by the purchase of available-for-sale investments of $13.2 million. Net cash used in investing activities during the year ended December 31, 2014 was $14.8 million primarily related to the purchase of available-for-sale investments of $26.4 million, partially offset by the sales of available-for-sale investments of $11.6 million.

Financing Activities. Net cash provided by financing activities in the amount of $12.8 million for the year ended December 31, 2015 consisted of approximately $13.2 million in net proceeds received from the sales of our common stock, partially offset by the $0.4 million in repayment of our term loan. Net cash provided by financing activities in the amount of $40.3 million for the year ended December 31, 2014 consisted of approximately $33.4 million in net proceeds received from the issuance of common stock in our IPO and $6.9 million, net of issuance costs, from borrowing under our term loan.

Credit Facilities

On November 20, 2014, we entered into a Loan Agreement with East West Bank, or East West, pursuant to which East West agreed to extend an Initial Term Loan to us with an aggregate principal amount of $7.0 million and, subject to the terms and conditions set forth in the Loan Agreement, a Second Term Loan with an aggregate principal amount of $5.0 million. Each term loan shall accrue interest at a rate of 2.25% per annum plus the greater of 3.25% or the current prime rate. As of December 31, 2015, the interest rate on the loan was 5.75%. As security for our obligations under the Loan Agreement, we granted East West a lien on substantially all of our assets, including owned and licensed intellectual property.

On November 20, 2014, East West funded the Initial Term Loan which provided us with approximately $6.9 million of net loan proceeds. The Loan Facility matures on October 1, 2018. Interest only payments were due during the first twelve months of the Initial Term Loan and beginning on November 1, 2015, we are required to make 36 equal monthly payments of principal and interest. Upon payment of the final monthly installment under the Loan Agreement, or the remaining balance in the case of a prepayment, we would pay an end-of-term fee of approximately $60,000. We may prepay each term loan in full with no prepayment penalty.

As of December 31, 2015, $6.6 million of principal remains outstanding on the loan.

At our option, we were permitted to borrow the Second Term Loan on or before May 29, 2015, if we had met certain milestones for enrollment and recruitment of Phase 3 Pyridorin trial patients and achieved positive TQT cardiac safety study results. We may prepay each term loan in full with no prepayment penalty. In January 2015, we made a proposal to East West requesting additional borrowing under the Second Term Loan. As of the date hereof, we have not met the clinical milestones for the Second Term Loan and no additional borrowing has been granted under the Second Term Loan.

The Loan Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among others, covenants that limit or restrict the our ability to incur indebtedness, grant liens, merge or consolidate, dispose of assets, make investments, make acquisitions, enter into certain transactions with affiliates, pay dividends or make distributions, or repurchase stock, in each case subject to customary exceptions for a loan facility of this size and type. In addition, the Loan Agreement contains customary events of default that entitle East West to cause any or all of our indebtedness under the Loan Agreement to become immediately due and payable. The events of default include, among others, non-payment, inaccuracy of representations and warranties, covenant defaults, the occurrence of a material adverse effect (as defined in the Loan Agreement), cross-default to material agreements, cross-default to material indebtedness, bankruptcy and insolvency, material judgment defaults, discontinuation of the Phase 3 Pyridorin trial and defaults related to certain actions taken against the us by the FDA or other equivalent governmental authority.
As of December 31, 2015, we were in compliance with all covenants under the Loan Agreement.
Pursuant to the terms of the Loan Agreement, we issued to East West warrants to purchase up to 56,603 shares of our common stock at an exercise price equal to $4.24 per share. The warrants are immediately exercisable and expire on November 20, 2021.

On February 23, 2016, we paid off all amounts outstanding under the loan, accrued interest expense and an end-of-term fee, totaling approximately $6.3 million.

Future Funding Requirements

We have not completed development of our product candidates. In February 2016, we suspended all development and clinical trials activities. We also repaid our outstanding term loan in full. In addition, we reduced our workforce and terminated all but critical contracts and our office lease. As a result, our on-going expense rate has declined substantially. However, our expenses may increase if we enter into a transaction involving a potential business alternative. We believe that our existing cash and cash equivalents will be sufficient to fund the company’s operation through mid-2016.

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, 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 Commitments and Obligations

We are a party to license agreements with universities and other third parties, as well as patent assignment agreements, under which we have obtained rights to patents, patent applications and know how. These license agreements are subject to various milestone payments related to milestones met in the FDA regulatory approval process. The commitments under our licensing agreement with The South Carolina Research Foundation (USCRF) are payable quarterly until the expiration of certain patent rights and related technology. We can terminate the license at any time upon three months prior written notice to USCRF. On February 26, 2016, we provided written notice to USCRF to terminate the license agreement in light of our Board of Directors determination to pause the clinical program of our oral Pyridorin for the treatment of diabetic nephropathy.

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 serve as our 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.

We have employment agreements with certain employees which require the funding of specific levels of payments, if certain events, such as a change in control or termination without cause, occur. We enter into contracts in the normal course of business with CROs for clinical trials and clinical supply manufacturing and with vendors for preclinical research studies and other services and products for operating purposes, which generally provide for termination within 30 days of notice or less, and therefore are cancelable contracts and not included as contractual obligations and commitments.

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 SEC.

Recent Accounting Pronouncements

In August 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2014-15, “Presentation of Financial Statements - Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern.” The amendments in this ASU are intended to define management’s responsibility to evaluate whether there is substantial doubt about an entity’s ability to continue as a going concern and to provide related footnote disclosures. Specifically, this ASU provides a definition of the term substantial doubt and requires an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). It also requires certain disclosures when substantial doubt is alleviated as a result of consideration of management’s plans and requires an express statement and other disclosures when substantial doubt is not alleviated. The new standard will be effective for reporting periods beginning after December 15, 2016, with early adoption permitted. We are currently evaluating the impact the adoption of this standard will have on our financial statements

and disclosures.

In April 2015, the FASB issued ASU No. 2015-03, "Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs." The amendments in this ASU require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by the amendments in this ASU. The new standard will be effective for reporting periods beginning after December 15, 2015, with early adoption permitted. The amendments should be applied on a retrospective basis, wherein the balance sheet of each individual period presented should be adjusted to reflect the period-specific effects of applying the new standard. We have not adopted this ASU as of December 31, 2015, but believe that the adoption of this ASU will not have a material impact on our financial statements and related disclosures.

In April 2015, the FASB issued ASU No. 2015-05, "Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40): Customer's Accounting for Fees Paid in a Cloud Computing Arrangement." The amendments in this ASU provide guidance to customers about whether a cloud computing arrangement includes a software license. If a cloud computing arrangement includes a software license, then the customer should account for the software license element of the arrangement consistent with the acquisition of other software licenses. If a cloud computing arrangement does not include a software license, the customer should account for the arrangement as a service contract. The amendments do not change the accounting for a customer's accounting for service contracts. The new standard will be effective for annual periods ending after December 15, 2015, and interim periods thereafter, with early adoption permitted. We have not adopted this ASU as of December 31, 2015, but believe that the adoption of this ASU will not have a material impact on our financial statements and related disclosures.

In November 2015, the FASB issued ASU No. 2015-17, "Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes." This amendment requires deferred tax liabilities and assets to be classified as non-current in a classified statement of financial position, as opposed to separating the deferred tax liability and asset amounts into current and non-current amounts. The new standard will be effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods, with early adoption permitted. We are currently evaluating the impact the adoption of this standard will have on our financial statements and disclosures.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Market Risk

Our cash and cash equivalents and short-term investments as of December 31, 2015, consisted primarily of cash, cash equivalents, money market funds and certificates of deposits. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of United States interest rates. However, because of the short-term nature of the instruments in our portfolio, a sudden change in market interest rates would not be expected to have a material impact on our financial condition and/or results of operations.

Item 8. Financial Statements and Supplementary Data

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of
NephroGenex, Inc.

We have audited the accompanying balance sheets of NephroGenex, Inc. (the “Company”) as of December 31, 2015 and 2014, and the related statements of comprehensive loss, stockholders’ equity (deficit), and cash flows for each of the years then ended. The financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of NephroGenex, Inc. as of December 31, 2015 and 2014, and the results of its operations and its cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred losses since its inception and has a significant accumulated deficit, which raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ EisnerAmper LLP

Philadelphia, PA
March 28, 2016

NephroGenex, Inc.
Balance Sheets
(in thousands except share and per share information)

	December 31, 2015	2014
Assets		
Current assets		
Cash and cash equivalents	$18,830	$13,978
Restricted cash	25	—
Short-term investments	2,894	14,698
Prepaid expenses and other assets	965	309
Total current assets	22,714	28,985
Property and equipment, net	38	36
Other assets	294	210
Total assets	$23,046	$29,231
Liabilities and Stockholders' Equity		
Current liabilities		
Accounts payable	$1,974	$1,750
Accrued and other liabilities	3,403	1,405
Current portion of note payable	2,264	293
Total current liabilities	7,641	3,448
Note payable, less current portion	4,238	6,442
Other long-term liabilities	24	10
Total liabilities	11,903	9,900
Commitments and contingencies (notes 5 and 12)	0	0
Stockholders' equity		
Preferred stock; $.001 par value; 5,000,000 shares authorized; no shares issued and outstanding	—	—
Common stock; $.001 par value; 100,000,000 shares authorized; 12,946,018 and 8,862,114 shares issued and outstanding at December 31, 2015 and 2014, respectively	13	9
Additional paid-in capital	91,816	77,149
Accumulated other comprehensive loss	(3)	(8)
Accumulated deficit	(80,683)	(57,819)
Total stockholders' equity	11,143	19,331
Total liabilities and stockholders' equity	$23,046	$29,231

(See accompanying Notes to Financial Statements)

NephroGenex, Inc.
Statements of Comprehensive Loss
(in thousands except share and per share information)

	Year Ended December 31,	
	2015	2014
Expenses:		
Research and development	$15,306	$11,264
General and administrative	7,016	5,323
Total expenses	22,322	16,587
Loss from operations	(22,322)	(16,587)
Other income (expense):		
Change in value of preferred stock warrants	—	(140)
Interest expense	(565)	(140)
Interest income	23	47
Net loss	$(22,864)	$(16,820)
Net loss per share – basic and diluted	$(2.29)	$(2.15)
Weighted average shares outstanding – basic and diluted	10,005,451	7,827,519
Other comprehensive loss:		
Net loss	$(22,864)	$(16,820)
Unrealized income (loss) on short-term investments	5	(8)
Comprehensive loss	$(22,859)	$(16,828)

(See accompanying Notes to Financial Statements)

NephroGenex, Inc.
Statement of Stockholders' Equity (Deficit)
(in thousands except share information)

	Common Stock		Additional	Accumulated		
	Shares	Amount	Paid-In Capital	Other Comprehensive Loss	Accumulated Deficit	Total
Balance at December 31, 2013	319,882	$—	$ 26,789	$ —	$ (40,999)	$(14,186)
Issuance of common stock at IPO, net of expenses of $3,767	3,100,000	3	33,430	—	—	33,433
Issuance of common stock for preferred stock warrant	593,589	1	7,123	—	—	7,124
Issuance of common stock for convertible notes and accrued interest	1,197,289	1	8,644	—	—	8,645
Issuance of common stock for preferred stock	3,644,354	4	20	—	—	—
Issuance of common stock for restricted stock units	7,000	—	—	—	—	—
Issuance of warrants with term loan	—	—	192	—	—	192
Stock based compensation	—	—	951	—	—	951
Other comprehensive loss	—	—	—	(8)	—	(8)
Net loss	—	—	—	—	(16,820)	(16,820)
Balance at December 31, 2014	8,862,114	9	77,149	(8)	(57,819)	19,331
Issuance of common stock for restricted stock units	6,000	—	—	—	—	—
Issuance of common stock in public offering, including warrants, net of offering expenses of $964	1,612,500	2	7,098	—	—	7,100
Issuance of common stock in at-the-market public offering, net of offering expenses of $98	308,541	—	1,112	—	—	1,112
Issuance of common stock in PIPE offering, including warrants, net of offering expenses of $516	2,156,863	2	4,982	—	—	4,984
Stock-based compensation	—	—	1,475	—	—	1,475
Other comprehensive income	—	—	—	5	—	5
Net loss	—	—	—	—	(22,864)	(22,864)
Balance at December 31, 2015	12,946,018	$13	$ 91,816	$ (3)	$ (80,683)	$11,143

(See accompanying Notes to Financial Statements)

NephroGenex, Inc.
Statements of Cash Flows
(in thousands)

	Year Ended December 31,	
	2015	2014
Operating activities		
Net loss	$(22,864)	$(16,820)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities		
Depreciation and amortization	11	4
Loss on disposal of fixed assets	3	—
Change in fair value of preferred stock warrants	—	140
Non-cash interest expense	176	95
Accretion of premium on investment activities	37	71
Accrued interest receivable	51	4
Stock based compensation expense	1,475	951
Changes in operating assets and liabilities		
Prepaid expenses and other assets	(760)	(455)
Accounts payable, accrued and other liabilities	2,236	2,372
Net cash and cash equivalents used in operating activities	(19,635)	(13,638)
Investing activities		
Change in restricted cash	(25)	—
Purchases of investments	(13,232)	(26,383)
Sales of investments	24,953	11,603
Property and equipment purchases	(16)	(29)
Net cash and cash equivalents provided by (used in) investing activities	11,680	(14,809)
Financing activities		
Proceeds from issuance of note payable	—	6,880
Payments on term loan	(389)	—
Payment of debt issuance costs	—	(50)
Payment of offering costs	(1,579)	(3,737)
Proceeds from issuance of common stock and warrants	14,775	37,200
Net cash and cash equivalents provided by financing activities	12,807	40,293
Net increase in cash and cash equivalents	4,852	11,846
Cash and cash equivalents at beginning of year	13,978	2,132
Cash and cash equivalents at end of year	$18,830	$13,978
Supplemental disclosure of cash flow information		
Cash paid for interest	$390	$12
Supplemental disclosure of non-cash financing activities		
Unrealized gain (loss) on investments	$5	$(8)
Issuance of warrants	$3,257	$—
Conversion of convertible notes payable, accrued interest, preferred stock and warrants into common stock	$—	$15,793

(See accompanying Notes to Financial Statements)

NephroGenex, Inc.
Notes to Financial Statements

1. Description of Business and Basis of Presentation

Description of Business

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

The Company’s primary efforts to date have been devoted to raising capital, recruiting senior management and staff and conducting research and development activities. The Company has experienced net losses since its inception and, as of December 31, 2015, has an accumulated deficit of $80.7 million.

The Company currently has no commercially approved products and has recognized no revenue since its inception in 2004. The Company does not expect to generate revenue from product sales unless and until it successfully completes development and obtains marketing approval for one or more of its product candidates, which it 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. In September 2014, the Company registered to form NephroGenex International Limited, a wholly-owned subsidiary, in Dublin, Ireland. From inception to date, there have been no activities transacted in this wholly-owned subsidiary and thus has no results to be consolidated into the Company's financial statements.

Recent Developments

As further discussed in Note 13 - Subsequent Event, on February 24, 2016, the Company announced its plan to pause the clinical program of the Company's product candidate oral Pyridorin for the treatment of diabetic nephropathy, effect a restructuring of its operations and implement a strategic transaction. In addition, the Company announced that it has paid off its outstanding term loan as of February 23, 2016.

The Company's evaluation of potential business alternatives entails numerous significant risks and uncertainties, including the risks and uncertainties set forth in Item 1A under the heading "Risk Factors" of this Annual Report on Form 10-K. There can be no assurance that the Company's evaluation of potential business alternatives will result in any transaction.

Going Concern

The Company's financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The Company has incurred losses since its inception, expects to incur additional costs and requires additional capital to continue as a going concern. As a result, the Company will require additional funds and will continue to seek private or public equity to meet its capital requirements. Even if the Company does not have an immediate need for additional cash, it may seek access to the private or public equity markets if and when conditions are favorable. If such funds are not available, management may need to reassess its business plans. There is no assurance that such additional funds will be available for the Company to finance its operations on acceptable terms, if at all. As a result of the announcement in February 2016, the Company determined to suspend all development and clinical trials activities due to the lack of financial resources and to seek other potential business

alternatives that may be available.

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”).

Use of Estimates

NephroGenex, Inc.
Notes to Financial Statements

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Reverse Stock Split

On February 6, 2014, the Company effected a 1-for-6.5 reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the conversion ratio for the Company's outstanding Series A Preferred Stock. All share and per share amounts for the twelve month period ended December 31, 2014 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.

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 received 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 Company recorded $140,000 as other expense as as a result of the change in fair value of the preferred stock warrant liability for the years ended December 31, 2014. The preferred stock warrant liability was settled upon the closing of the IPO.

Segment Reporting

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker in making decisions regarding resource allocation and assessing performance. The Company views its operations and manages its business in one operating segment.

Cash and Cash Equivalents

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

Restricted Cash

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

The Company invests in money market funds and certificates of deposits and considers all investments purchased with original maturity dates greater than three months and less than one year to be short-term investments. Those investments with original maturity dates greater than one year at each balance sheet date are considered to be long-term investments. As of December 31, 2015, all investments were classified as available-for-sale and had original maturity dates less than one year. These investments are carried at estimated fair value with unrealized gains and losses included in stockholders' equity. The

NephroGenex, Inc.
Notes to Financial Statements

amortized cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity, which is included in interest income.

Concentration of Credit Risk

The Company invests its available cash balances in bank deposits, money market funds and certificates of deposit. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. Management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held. Additionally, the Company has established guidelines regarding approved investments and maturities of investments, which are designed to maintain safety and liquidity.

Property and Equipment

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

Fair Value of Financial Instruments

As of December 31, 2015, financial instruments consist of cash and cash equivalents, short-term investments, a term loan, 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 in active markets; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities; and
- Level 3: Unobservable inputs that are supported by little or no market activity, which require the reporting entity to develop its own assumptions.

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

The Company targets investments principally in Level 1 and Level 2 cash equivalents and financial instruments and records them at FV. The Company did not rely on Level 3 inputs for the valuation of any investments at December 31,

2015 or December 31, 2014. The Company expects that the carrying values of cash equivalents will approximate FV because of their short maturities.

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

The following table sets forth our financial instruments carried at FV within the ASC 820 hierarchy and using the lowest level of input as of December 31, 2015:

NephroGenex, Inc.
Notes to Financial Statements

(in thousands)	Balance	Quoted Prices in Active Markets For Identical Assets	Significant Other Observable Inputs	Significant Unobservable Inputs
Assets:	December 31, 2015	Level 1	Level 2	Level 3
Certificates of Deposit	$7,142	$—	$7,142	$—
	$7,142	$—	$7,142	$—

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

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

The Company recorded $140,000 as other expense as as a result of the change in fair value of the preferred stock warrant liability for the year ended December 31, 2014.

Debt Issuance Costs

Debt issuance costs represent legal and other direct costs related to the Company's outstanding loan. These costs are recorded as an asset on the accompanying balance sheets and are being amortized to interest expense utilizing the effective interest method through the earliest date at which the Company can be required to repay the notes. The balance of debt issuance costs was $27,000 and $48,000 for the years ended December 31, 2015 and 2014, respectively.

Research and Development Costs

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

Stock-Based Compensation

The Company estimates the FV of stock options and stock purchase rights using a Black-Scholes option valuation model which requires the input of highly subjective assumptions, including the option’s expected life and the price volatility of the underlying stock. The Company uses the simplified method for estimating the expected term as provided by the Securities and Exchange Commission's Staff Accounting Bulletin No. 107. The simplified method calculates the expected term as the average time-to-vesting and the contractual life of the options. The expected stock

price volatility assumption was determined by examining the historical volatilities of a group of industry peers. The FV of each option grant is estimated on the date of grant using the Black-Scholes option valuation model, and the resulting FV is expensed using the straight-line attribution method over the vesting period, which is the same as the requisite service period. Restricted stock units are measured at the FV of the Company's common stock on the date of grant and expensed over the period of vesting, which is the same as the requisite service period using the straight-line attribution method.

NephroGenex, Inc.
Notes to Financial Statements

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

Recently Issued Accounting Pronouncements

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

In August 2014, FASB issued Accounting Standards Update ("ASU") No. 2014-15, "Presentation of Financial Statements - Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern." The amendments in this ASU are intended to define management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. Specifically, this ASU provides a definition of the term substantial doubt and requires an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). It also requires certain disclosures when substantial doubt is alleviated as a result of consideration of management's plans and requires an express statement and other disclosures when substantial doubt is not alleviated. The new standard will be effective for annual periods ending after December 15, 2016, and interim periods thereafter, with early adoption permitted. We are currently evaluating the impact the adoption of this standard will have on the Company's financial statements and disclosures.

In April 2015, the FASB issued ASU No. 2015-03, "Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs." The amendments in this ASU require that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by the amendments in this ASU. The new standard will be effective for reporting periods beginning after December 15, 2015, with early adoption permitted. The amendments should be applied on a retrospective basis, wherein the balance sheet of each individual period presented should be adjusted to reflect the period-specific effects of applying the new standard. We have not adopted this ASU as of December 31, 2015, but believe that the adoption of this ASU will not have a material impact on the Company's financial statements and related disclosures.

In April 2015, the FASB issued ASU No. 2015-05, "Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40): Customer's Accounting for Fees Paid in a Cloud Computing Arrangement." The amendments in this ASU provide guidance to customers about whether a cloud computing arrangement includes a software license. If a cloud computing arrangement includes a software license, then the customer should account for the software license element of the arrangement consistent with the acquisition of other software licenses. If a cloud computing arrangement does not include a software license, the customer should account for the arrangement as a service contract. The amendments do not change the accounting for a customer's accounting for service contracts. The new standard will be effective for annual periods ending after December 15, 2015, and interim periods thereafter, with early adoption permitted. We have not adopted this ASU as of December 31, 2015, but believe that the adoption of this ASU will not have a material impact on the Company's financial statements and related disclosures.

In November 2015, the FASB issued ASU No. 2015-17, "Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes." This amendment requires deferred tax liabilities and assets to be classified as non-current in a classified statement of financial position, as opposed to separating the deferred tax liability and asset amounts into current and non-current amounts. The new standard will be effective for annual periods beginning after December 15, 2016, and interim periods within those annual periods, with early adoption permitted. We are currently evaluating the impact the adoption of this standard will have on the Company's financial statements and disclosures.

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

NephroGenex, Inc.
Notes to Financial Statements

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:

	Year Ended December 31,	
	2015	2014
Numerator:		
Net loss	$(22,864)	$(16,820)
Denominator:		
Weighted average common shares outstanding	10,005,451	7,827,519
Net loss per share-basic and diluted	$(2.29)	$(2.15)

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:

	2015	2014
Common stock options	1,542,732	848,025
Restricted stock units	891,617	24,000
Common stock warrants	10,039,682	61,039

4. Balance Sheet Items

Investments

The following table summarizes the Company's available for sale investments as of December 31, 2015 (in thousands):

Short-term Investments	Maturity (in years)	Amortized Cost	Unrealized Gains	Unrealized Loss	Estimated Fair Value
Certificates of Deposit	1 or less	$2,897	$—	$(3)	$2,894
Total Investments		$2,897	$—	$(3)	$2,894

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

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

At each reporting date, the Company performs an evaluation of impairment to determine if the unrealized losses are other-than-temporary. For debt securities, management determines whether it intends to sell the impaired securities, and if there is no intent or expected requirement to sell, management considers whether it is likely that the amortized cost will be

53

NephroGenex, Inc.
Notes to Financial Statements

recovered. The Company does not consider unrealized losses on its debt investment securities to be credit-related. These unrealized losses relate to changes in interest rates and market spreads subsequent to purchase. The Company has not made a decision to sell securities with unrealized losses and believes it is more likely than not it would not be required to sell such securities before recovery of its amortized cost. There have been no other than temporary losses recognized in earnings.

Property and Equipment
As of December 31, 2015 and 2014 property and equipment were as follows (in thousands):

	Useful Life	2015	2014
Computer equipment	3-5 years	$67	$54
Furniture and fixtures	7 years	66	66
Leasehold improvements	5.5 years	18	18
		151	138
Less accumulated depreciation and amortization		(113)	(102)
Property and equipment, net		$38	$36

For the years ended December 31, 2015 and 2014, depreciation and amortization expense was approximately $11,000 and $4,000, respectively.
Accrued Liabilities

As of December 31, 2015 and 2014 accrued liabilities were as follows (in thousands):

	2015	2014
Accrued clinical trial expenses	$2,432	$393
Accrued compensation	964	909
Other accruals	7	103
Total	$3,403	$1,405

5. License Agreements

The University of South Carolina Research Foundation, Corp.

During 2007, the Company licensed certain technology from the University of South Carolina Research Foundation, Corp. (“USCRF”). 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 as long as the agreement remains in effect. Upon the achievement of certain defined product development milestones for diabetic neuropathy or hyperlipidemia, the Company would be obligated to make up to $6.1 million of payments to USCRF. The Company will be obligated to pay USCRF a one-time fee of $35,000 upon execution of a sublicense and would pay to USCRF 25% of any non-royalty sublicense payments received from a sub-licensee. The term of the agreement expires on the expiration of the underlying USCRF patents. The Company can terminate the license at any time upon three months prior written notice to USCRF. As of December 31, 2015, 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 $120,000 for each of the years ended December 31, 2015 and 2014, respectively, for annual licensing fees due under this agreement.
In connection with the Company's plan to pause the clinical program of oral Pyridorin for the treatment of diabetic nephropathy (See note 13), the Company has provided written notice to USCRF to terminate this license agreement on February 26, 2016.

54

NephroGenex, Inc.
Notes to Financial Statements

Vanderbilt University
During 2006, the Company entered into a licensing agreement with Vanderbilt University (“Vanderbilt”) for the rights to use certain technology. The agreement, as amended, requires the Company to make milestone payments totaling approximately $1.1 million in the event certain defined events occur. Should the Company successfully develop a product using the licensed technology, Vanderbilt will be due royalties based on net sales at a rate of 5%. The Company must also pay Vanderbilt 25% of non royalty sub licensee payments received from a sub licensee. Annual minimum royalties due under the licensing agreement are $10,000 and will increase to $25,000 when a claim in the licensed patent rights is issued in a major market country, as defined. The licensing agreement expires when the underlying patents to the licensed technology expire. The Company may terminate the agreement upon sixty days written notice to Vanderbilt.
Certain milestones can be paid in stock or are creditable against future royalties due based on net sales. The Company paid $75,000 and $0 for the years ended December 31, 2015 and 2014, respectively, for milestone payments due under this agreement.
The University of Kansas Medical Center Research Institute, Inc.
During 2007, the Company received rights to certain technology licensed from the University of Kansas Medical Center Research Institute, Inc. ("KUMC") to the Company. The license gives the Company worldwide royalty-free rights to use certain technology. Upon the achievement of certain defined product development milestones, the Company would be obligated to make up to $225,000 of payments to KUMC. As of December 31, 2015 and 2014, no milestones have been paid or accrued. The term of the agreement expires on the expiration of the underlying KUMC patents or November 2018, whichever occurs last. The Company can terminate the agreement with 90 days notice.
BioStratum, Inc.
During 2007, the Company entered into a grant back license agreement with BioStratum, Inc. ("BioStratum"), as part of our acquisition of certain of BioStratum’s assets, including certain patent rights. The license grant to BioStratum was made solely to enable BioStratum to exercise its rights and perform its obligations pursuant to a license agreement with Kowa Company, Ltd. ("Kowa") pursuant to which BioStratum granted Kowa an exclusive license (the "Kowa Agreement") to manufacture and use licensed products in Japan, Taiwan, Korea, and China. The Kowa Agreement was terminated by Kowa on December 5, 2007. BioStratum did not exercise its option to assume Kowa's rights under the Kowa agreement. Therefore, the grant-back license agreement automatically terminated on January 15, 2008. However, the grant-back license agreement expressly states that the Company must have the written consent of BioStratum to grant licenses to the manufacture and use licensed products in Japan, Taiwan, Korea and China (the "Surviving Provision"). On June 22, 2015, the Company entered into a termination agreement with BioStratum ("Termination Agreement") to terminate this Surviving Provision under the grant-back license agreement. The Company paid $35,000 in connection with the execution of this Termination Agreement.
6. Convertible Notes Payable

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

Interest expense for the years ended December 31, 2015 and 2014 relating to the notes was approximately $0 and $78,000, respectively.

7. Term Loan
On November 20, 2014, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with East West Bank ("East West") for a term loan (the “Initial Term Loan”) with an aggregate principal amount of $7.0 million and, subject to the terms and conditions set forth in the agreement, a second term loan (the “Second Term Loan”) with an aggregate principal amount of $5.0 million. Each term loan shall accrue interest at a rate of 2.25% per annum plus the greater of 3.25% or the current prime rate. As of December 31, 2015 the interest rate on the loan was 5.75%. As security for its obligations under the Loan Agreement, the Company granted the East West a lien on substantially all

of its assets, including owned and licensed intellectual property.

The Loan Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among others, covenants that limit or restrict the Company's ability to incur indebtedness, grant liens, merge or consolidate, dispose of assets, make investments, make acquisitions, enter into certain transactions with affiliates, pay dividends or make distributions, or repurchase stock, in each case subject to customary exceptions for a loan facility of this size

NephroGenex, Inc.
Notes to Financial Statements

and type. In addition, the Loan Agreement contains customary events of default that entitle East West to cause any or all of our indebtedness under the Loan Agreement to become immediately due and payable. The events of default include, among others, non-payment, inaccuracy of representations and warranties, covenant defaults, the occurrence of a material adverse effect (as defined in the Loan Agreement), cross-default to material agreements, cross-default to material indebtedness, bankruptcy and insolvency, material judgment defaults, discontinuation of the Phase 3 Pyridorin trial and defaults related to certain actions taken against the us by the FDA or other equivalent governmental authority.

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

At the Company’s option, the Company could have borrowed the Second Term Loan on or before May 29, 2015, if the Company had met certain clinical milestones. In January 2015, the Company made a proposal to East West requesting additional borrowing under the Second Term Loan. As of the date hereof, the Company has not met the clinical milestones for the Second Term Loan and no additional borrowing was granted under the Second Term Loan. The Company may prepay each term loan in full with no prepayment penalty. Upon payment of the final monthly installment of the loan, or the remaining balance in the case of a prepayment, the Company would pay an end-of-term fee of approximately $60,000.

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

The Company recognized $0.6 million and $62,000 in interest expense related to the term loan, including the amortization of the warrants, for the years ended December 31, 2015 and 2014, respectively. As of December 31, 2015 and 2014, the Company was in compliance with all financial and non-financial covenants under this Loan Agreement.

The following represents the outstanding principal balances, carrying amounts and maturities of notes payable as of December 31, 2015 (in thousands):

	Principal Value	Amortization of Debt Discount	Accrued Interest	Carrying Value of Note Payable
2016	$2,333	$(101)	$32	$2,264
2017	2,334	(57)	21	2,298
2018	1,944	(14)	10	1,940
	$6,611	$(172)	$63	$6,502
Less current portion				2,264
Long-term note payable, net of discount				$4,238

On February 23, 2016, the Company paid off all amounts outstanding under the term loan, accrued interest expense and an end-of-term fee, totaling approximately $6.3 million.

8. 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

NephroGenex, Inc.
Notes to Financial Statements

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.

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

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

On November 6, 2015, the Company, in connection with the sale of common stock, issued the following warrants to purchase common stock:

Description	Warrants	Exercise Price	Date Exercisable	Expiration	Term
Series A Warrants	1,617,647	$3.56	May 6, 2016	November 6, 2020	5 years
Series B Warrants	2,156,863	$3.56	May 6, 2016	November 7, 2016	12 months + 1 day
Series C Warrants	2,156,863	$3.56	May 6, 2016	May 6, 2017	18 months
Series D Warrants	2,156,863	$3.56	May 6, 2016	July 6, 2016	8 months
Total	8,088,236				

In addition, the Company issued warrants to purchase up to an aggregate of 107,843 share of common stock with the same terms as the Series A Warrants to the placement agent for the transaction.
As of December 31, 2015, the following warrants to purchase common stock were outstanding:

Issuance Date	Shares	Exercise Price	Expiration
2/10/2014	62,000	$15.00	2/10/2018
11/20/2014	56,603	$4.24	11/20/2021
7/22/2015	1,725,000	$6.25	7/22/2020
11/6/2015	2,156,863	$3.56	7/6/2016
11/6/2015	2,156,863	$3.56	11/7/2016
11/6/2015	2,156,863	$3.56	5/6/2017
11/6/2015	1,725,490	$3.56	11/6/2021
Total warrants outstanding	10,039,682		

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.

Public Offering

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

NephroGenex, Inc.
Notes to Financial Statements

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

At Market Issuance Sales Agreement

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

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

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

As of December 31, 2015, the Company had sold 308,541 ATM Shares of common stock at an average sales price of $3.92 per ATM Share for total net proceeds of approximately $1.1 million after deducting discounts and commissions and estimated offering expenses of approximately $98,000.

PIPE Offering

On November 6, 2015, the Company sold 2,156,863 shares of common stock pursuant to a securities purchase agreement to certain institutional investors ("PIPE offering") at a purchase price of $2.55 per share for total gross proceeds of approximately $5.5 million. As part of this PIPE offering, the Company issued warrants to purchase 8.1 million shares of its common stock at $3.56 per share.

Other Common Stock Issuances

During 2015, the Company issued 6,000 shares of common stock to its chief executive officer for restricted stock units that vested during the year.

Shares Reserved for Future Issuance

As of December 31, 2015, the Company had 12,946,018 shares of common stock outstanding. The Company has reserved shares of common stock for future issuance as of December 31, 2015 as follows:

Stock options outstanding	1,542,732
Shares available for grant under stock option plans	49,401
Restricted stock units	891,617
Common stock warrants	10,039,682
Total shares reserved for future issuance	12,523,432

Stock Based Compensation

NephroGenex, Inc.
Notes to Financial Statements

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

On March 24, 2015, the Company's Board of Directors adopted, and stockholders subsequently approved, an amendment to the Company's Amended and Restated 2007 Equity Incentive Plan, as amended (the "Stock Plan") to increase the number of shares authorized for issuance of awards under the Stock Plan from 1,283,226 to an aggregate of 2,483,226 shares of common stock. As of December 31, 2015, there were 49,401 shares available for issuance from the Stock Plan.

Stock Options

The table below summarizes stock option activity for the years ended December 31, 2015 and 2014.

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)
Outstanding as of December 31, 2013	563,453	$1.18	
Granted	712,204	6.60	
Exercised	—	—	
Expired	—	—	
Forfeited	(3,076)	11.90	
Outstanding as of December 31, 2014	1,272,581	4.19	
Granted	467,183	5.04	
Exercised	—	—	
Expired	(4,865)	15.20	
Forfeited	(192,167)	5.23	
Outstanding as of December 31, 2015	1,542,732	$4.28	7.5
Exercisable as of December 31, 2015	817,002	$3.23	5.3

During the years ended December 31, 2015 and 2014, the Company's Board of Directors granted stock options of 467,183 and 712,204, respectively to employees, a non-employee consultant and Directors of the Company with a weighted average fair value of $3.54 and $5.40 per share, respectively. The stock options vest based on terms in the stock option agreements (generally over four years) and are exercisable after they have been granted for up to ten years from the date of grant.

The weighted-average assumptions used in the Black-Scholes valuation model for stock option awards granted during the years ended December 31, 2015 and 2014 are shown in the table below.

	2015		2014	
Expected volatility	99.69	%	88.29	%
Expected dividends	—		—	
Expected life in years	6.0		6.5	
Risk-free interest rate	1.75	%	1.98	%

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 accounting for stock options to non-employees, the fair value of services related to the options granted are generally recorded as an expense as these services are provided to the Company over the relating service periods. The Company re-

NephroGenex, Inc.
Notes to Financial Statements

measures any unvested, non-employee options to fair value at the end of each reporting period using the Black-Scholes pricing model.

At December 31, 2015, the aggregate intrinsic value of options outstanding was $0.4 million. The aggregate intrinsic value of options outstanding as of December 31, 2015 represents the pretax value (the Company's closing market price of $1.60 per share on December 31, 2015, less the exercise price per share, times the number of in-the-money options) that would have been received by all option holders had they exercised their options at the end of the period. No options were exercised during the years ended December 31, 2015 or 2014.

Restricted Stock Units (RSU)

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% are vesting in equal monthly installments on the 1st day of each calendar month beginning November 1, 2014. As of December 31, 2015, the Company had issued 13,000 shares of common stock for RSU's that had vested.

In November 2015, the Company issued Restricted Stock Units (RSU) to its named executive officers. The RSU represent the right to receive shares of common stock, subject to the terms and conditions of a restricted stock unit agreement (the "agreement") and the Plan. The RSUs are subject to time based vesting in equal quarterly installments on the first day of each calendar quarter, beginning on January 1, 2016 and continuing for 11 additional quarters thereafter, provided that the applicable officers continues to provide services to the Company. Subsequently, these named executive officers elected to defer the receipt of shares of common stock in connection with the issuance of these RSUs until the separation from services from the Company or change in control defined in the agreement.

Restricted stock units will be settled through the issuance of an equivalent number of shares of our common stock and are equity classified. The Company measures the fair value of grants of restricted stock units based on the closing market price of a share of its common stock on the date of grant.

The following table summarizes the activity related to restricted stock units during 2015:

	Units	Weighted Average Grant Date Fair Value
Unvested at January 1	17,000	$4.55
Units granted	880,617	$2.31
Units vested	(6,000)	$4.55
Units forfeited	—	
Unvested at December 31	891,617	$2.34

As of December 31, 2015, there was $4.6 million of unrecognized compensation expense related to unvested stock options and RSUs, which is expected to be recognized over a weighted average period of 1.42 years.

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

	Year Ended December 31,	
(in thousands)	2015	2014
Research and development	$335	$130

General and administrative	1,140	821
Total	$1,475	$951

9. Retirement Savings Plan

The Company provides a qualified 401(k) savings plan for its employees. All employees are eligible to participate, provided they meet the requirements of the plan. The Company provides a contribution on the first 3% of an employee's

NephroGenex, Inc.
Notes to Financial Statements

eligible salary subject to statutory limitations as prescribed by law. For the years ended December 31, 2015 and 2014, the Company recorded $50,000 and $48,000 of expense for 401(k) contributions, respectively.

10. Related Party Transactions

Prior to June 30, 2014, the Company reimbursed Care Capital, LLC ("Care"), an affiliate of the majority shareholder of the Company, for services of a Care employee and reimbursed Care for such personnel services incurred by Care on behalf of the Company. Total expense recognized in operating results for the years ended December 31, 2015 and 2014 in connection with services provided by Care was $0 and $70,000, respectively.

11. Income Taxes

The Company recognized deferred tax liabilities and assets for the expected future tax consequences of events that have been recognized differently between the financial statements and tax returns. Under this method, deferred tax liabilities and assets are determined based on the difference between the financial statement carrying amounts and tax basis of liabilities and assets using enacted tax rates and laws in effect in the years in which the differences are expected to reverse. Deferred tax assets are evaluated for realization based on a more likely than not criteria in determining if a valuation allowance should be provided.

There was no income tax provision for the years ended December 31, 2015 and 2014.

The components of the Company's deferred tax assets at December 31, 2015 and 2014 are as follows:

(in thousands)	2015	2014
Net operating loss carry forwards	$14,841	$11,044
Stock based compensation	749	357
Tax credits	1,720	1,516
Depreciation	(2)	1
Amortization	10,388	6,392
Accrued compensation	28	—
Accrued expenses	9	4
Accrued interest	—	12
Deferred tax assets	27,733	19,326
Less: valuation allowance	(27,733)	(19,326)
Net deferred tax asset	$—	$—

The Company's valuation allowance increased by $8.4 million and $5.2 million during the years ended December 31, 2015 and 2014, respectively. The reconciliation between the Company's effective tax rate and the federal statutory rate for the years ended December 31, 2015 and 2014 are as follows:

	2015	2014
Federal statutory rate	(34.00)%	(34.00)%
State income taxes	(2.80)%	0.73 %
Valuation allowance	(36.80)%	33.27 %
Effective tax rate	— %	— %

As of December 31, 2015, the Company had approximately $41.9 million of Federal net operating losses that will begin to expire in 2024 and approximately $22.4 million of State net operating losses that will begin to expire in 2026. As of December 31, 2015, the Company has research and development credit carryovers for Federal and New Jersey of approximately $1.5 million and $189,000, respectively; these will begin to expire in 2024 for federal and 2016 for New Jersey tax purposes. The Internal Revenue Code ("IRC") limits the amounts of net operating loss carryforwards that a company may use in any one year in the event of certain cumulative changes in ownership over a three year period as described in Section 382 of the IRC. The Company has not performed a detailed analysis to determine whether an ownership change has occurred. Such a change of ownership could limit the utilization of the net operating

losses, and could be triggered by subsequent sales of securities by the Company or its stockholders.

NephroGenex, Inc.
Notes to Financial Statements

The Company did not have a liability related to unrecognized tax benefits as of December 31, 2015 or 2014. The Company records interest accrued and penalties related to unrecognized tax benefits within the income tax expense. The Company had not accrued any interest or penalties related to unrecognized benefits. The Company is no longer subject to federal income tax assessment for years before 2012 and for years before 2011 for New Jersey income tax purposes. However, since the Company has incurred net operating losses in every year since inception, all of its income tax returns are subject to examination and adjustments by the Internal Revenue Service for at least three years following the year in which the tax attributes are utilized. The Company does not believe that there will be a material change in its unrecognized tax positions over the next twelve months. There is no amount of unrecognized tax benefit that, if recognized, would affect the effective tax rate.

12. Commitments

Lease

On September 12, 2014, the Company entered into an agreement to lease office space at 3200 Beechleaf Court, Raleigh, North Carolina for the period December 1, 2014 through May 31, 2020. These premises will serve as the Company's corporate headquarters. The lease provides for abatement of rent during certain periods and escalating rent payments during the lease term. The Company records rent expense on a straight-line basis over the life of the lease. The following is a schedule of future non-cancellable minimum lease payments for operating leases at December 31, 2015 (in thousands):

Year	
2016	$118
2017	122
2018	125
2019	129
2020	55
	$549

Rent expense was approximately $115,000 and $62,000 for the years ended December 31, 2015 and 2014, respectively.

Legal Contingencies

The Company is subject to claims and assessments from time to time in the ordinary course of business. The Company's management does not believe that any such matters, individually or in the aggregate, will have a material adverse effect on the Company's business, financial conditions, results of operations or cash flows.

Indemnification

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnification. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future, but that have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. The Company may, however, record charges in the future as a result of these indemnification obligations.

In accordance with its Amended and Restated Certificate of Incorporation and Bylaws, the Company has indemnification obligations to its directors, and has the authority to indemnify its officers and employees, for certain events or occurrences, subject to certain limits, while they are serving at the Company's request in such capacity. There have been no claims to date, and the Company has director and officer insurance that enables it to recover a portion of any amounts paid for future potential claims.

NephroGenex, Inc.
Notes to Financial Statements

In addition to the indemnification provided for in its Certificate of Incorporation and Bylaws, the Company has also entered into separate indemnification agreements with each of its directors, which agreements provide such directors with indemnification rights under certain circumstances.

13. Subsequent Events

Recent Developments

On February 24, 2016, the Company announced that its Board of Directors (the "BOD") has made a determination to pause the clinical program of the Company's product candidate oral Pyridorin for the treatment of diabetic nephropathy, effect a restructuring of its operations and implement a strategic transaction. The BOD made this determination in light of the remaining trial costs, the Company's cash balance and condition of the capital markets. Concurrently, the BOD retained MTS Health Partners, L.P. to act as financial adviser in connection with the Company's exploration of potential business alternatives and the Company implemented a workforce reduction plan.

The workforce reduction eliminated approximately five positions throughout the Company, impacting primarily positions within its research and development function. The Company anticipates recording approximately $175,000 of restructuring charges during the first quarter of 2016 covering severance, related benefits and other costs.

In connection with the exploration of potential business alternatives, the Company also paid off all amounts outstanding under the term loan, accrued interest expense and an end-of-term fee, totaling approximately $6.3 million.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.
None.

Item 9A. Controls and Procedures
Management’s Evaluation of our Disclosure Controls and Procedures
Our management, with the participation of our principal executive officer and principal financial and accounting 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, as amended, or the Exchange Act) as of December 31, 2015. Based on that evaluation, our principal executive officer and principal financial and accounting officer concluded that our disclosure controls and procedures as of December 31, 2015 are functioning effectively to provide reasonable assurance that the information required to be disclosed by us in reports filed under the Exchange Act is (i) recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and (ii) accumulated and communicated to our management, including our principal executive officer and principal financial and accounting officer, as appropriate to allow timely decisions regarding disclosures. A controls system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

Changes in Internal Control Over Financial Reporting
During the year ended December 31, 2015, there have been no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Securities Exchange Act of 1934, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Management’s Report on Internal Control Over Financial Reporting
Management is responsible for establishing and maintaining adequate internal control over financial reporting. Management has used the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework),

or the COSO framework, to evaluate the effectiveness of internal control over financial reporting. Management believes that the COSO framework is a suitable framework for its evaluation of financial reporting because it is free from bias, permits reasonably consistent qualitative and quantitative measurements of our internal control over financial reporting, is sufficiently complete so that those relevant factors that would alter a conclusion about the effectiveness of our internal control over financial reporting are not omitted and is relevant to an evaluation of internal control over financial reporting. Management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2015 and has concluded that such internal control over financial reporting was effective.

An attestation report of control over financial reporting by our registered public accounting firm is not required for the year ended December 31, 2015.

Item 9B. Other Information
Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance
Our restated certificate of incorporation and restated bylaws provide that our business is to be managed by or under the direction of our Board of Directors. Our Board of Directors is divided into three classes for purposes of election. One class is elected at each annual meeting of stockholders to serve for a three-year term. Our Board of Directors currently consists of six members, classified into three classes as follows: (1) Richard Markham and Pierre Legault constitute a class with a term ending at the 2016 annual meeting; (2) Eugen Steiner, M.D., Ph.D. and Marco Taglietti, M.D. constitute a class with a term ending at the 2017 annual meeting and (3) James Mitchum and Robert Seltzer constitute a class with a term ending at the 2018 annual meeting.
Set forth below are our directors as of March 28, 2016, their ages, their offices in the Company, if any, their principal occupations or employment for at least the past five years, the length of their tenure as directors and the names of other public companies in which such persons hold or have held directorships during the past five years. Additionally, information about the specific experience, qualifications, attributes or skills that led to our Board of Directors' conclusion at the time of filing of this Annual Report on Form 10-K that each person listed below should serve as a director is set forth below:

Name	Age	Position with the Company
Richard J, Markham(2)(3)	65	Chairman of the Board
Pierre Legault	55	Chief Executive Officer and President
James Mitchum(1)(2)	63	Director
Robert R. Seltzer(3)	40	Director
Eugen Steiner, M.D., Ph.D(1)	61	Director
Marco Taglietti, M.D. (1)(2)	56	Director

(1) Member of our Audit Committee.
(2) Member of our Compensation Committee.
(3) Member of our Nominating and Governance Committee.
Our Board of Directors has reviewed the materiality of any relationship that each of our directors has with us, either directly or indirectly. Based upon this review, our Board of Directors has determined that the following members of the Board of Directors are "independent directors" as defined by The NASDAQ Stock Market: Richard Markham, James Mitchum, Robert R. Seltzer, Eugen Steiner, M.D. Ph.D., and Marco Taglietti, M.D.
Richard J. Markham has served as a member of our Board of Directors since 2007 and as the chairman of our Board of Directors since October 2013. Mr. Markham has been a partner in the venture capital firm Care Capital, LLC, an affiliate of one of our principal stockholders, since November 2004 and continues in that role. Prior to joining Care Capital, he was the Vice Chairman of the Management Board and COO of Aventis. Previously, he was the CEO of Aventis Pharma and Hoechst Marion Roussel and the President and COO of Marion Merrell Dow, Inc. and a member of its board of directors. From 1973 to 1993, Mr. Markham was associated with Merck & Co., Inc., culminating in his position as President and COO. Prior to this role Richard held a number of positions, starting as a professional representative and then becoming district manager, product manager and director, executive director and then Vice President Marketing for the Merck Sharp & Dohme Division. He later was responsible for Merck's European pharmaceutical business before being named senior vice president of Merck & Co. and president of the Merck Human Health Division, responsible for worldwide marketing and sales of Merck's pharmaceutical products. Mr. Markham received a B.S. in Pharmacy and Pharmacal Sciences from Purdue University and has served as a member of the Dean's Advisory Council of the university. He has also been awarded an honorary Doctor of Science degree, the university's highest honor for achievement. Mr. Markham previously served as a member of the board of directors of

Acura Pharmaceuticals, Inc. and Anacor Pharmaceuticals, Inc. In addition, Mr. Markham has been a member of the board of directors and executive committee of the Pharmaceutical Research and Manufacturers Association, a member of the Board of Trustees of the HealthCare Institute of New Jersey and a member of the board of directors of Aventis Pasteur and of Commerce Bank of Kansas City.

We believe that Mr. Markham's extensive experience within the life sciences industry, the experience he brings as a Board member of life sciences companies, his knowledge of finance and transactions, and his historic knowledge of our company and our product candidates qualify him to serve as a member of our Board of Directors.

Pierre Legault was named our Chief Executive Officer on October 18, 2013, has been a member of our Board of Directors since November 2012 and been President since December 2015. Mr. Legault is also the Chief Executive Officer of Prosidion Ltd., a U.K. mid-size biotechnology firm discovering, developing and commercializing products in the therapeutic areas of diabetes and obesity since January 2009. From April 2012 until October 2013, Mr. Legault was the Chief Executive Officer of Stone Mgmt L.L.C., a consulting company. From January 2009 to September 2010, he served as Executive VP, Chief Financial Officer and Treasurer with OSI Pharmaceuticals, a mid-size biotechnology company focused on oncology. He was also Senior Executive VP and Chief Administrative Officer of Rite Aid Corporation, a fortune 500 pharmaceutical retail company, from July 2007 to December 2008. From January 2006 to July 2007, Mr. Legault served as Executive VP of The Jean Coutu Group (PJC) Inc. and President of the Eckerd group, with overall management responsibilities for the Brooks Eckerd operations in the US.

Previously Mr. Legault held several senior positions for a period of 16 years with Sanofi-Aventis and predecessor companies, last serving as Worldwide President of Sanofi-Aventis Dermatology/Dermik (2003 to 2005). Prior positions included the Senior VP and Chief Financial Officer of Aventis Pharmaceuticals Inc. (2000 to 2003), Global Senior VP Finance and Treasury of Hoechst Marion Roussel, Inc. (1998 to 2000), VP and Chief Financial Officer, North America Finance, IT and Administration of Marion Merrell Dow, Inc. (1997 to 1998), and VP and Chief Financial Officer of Marion Merrell Dow Pharmaceutical Canada (1989 to 1996). Mr. Legault has served on several public, private and nonprofit company boards and audit committees, as well as on several advisory boards, including the following: Cyclacel Pharmaceutical Inc., a publicly traded biotech company (2006-2008), Forest Laboratories, Inc. (2012-2014), NPS Pharmaceuticals, Inc. (2014-2015) and Regado Biosciences, Inc. (2013-2015), Tobira Biosciences (2015 to present), Iroko Pharmaceuticals, LLC (2015 to present) and Poxel SA (2016 to present). Mr. Legault also belongs to several professional associations and he studied at McGill University, University of Montreal (HEC) and the Harvard Business School. He has a Six Sigma Green Belt, a BAA, MBA, CA and CPA diploma.

We believe that Mr. Legault's perspective and the experience he brings as our chief executive officer, together with his historic knowledge of our company and our product candidates, operational expertise and continuity to our Board of Directors, and his experience in managing and investing in companies within the life sciences industry, qualify him to serve as a member of our Board of Directors.

James Mitchum has served as a member of our Board of Directors since February 2014. Mr. Mitchum is currently the Chief Executive Officer of Heart to Heart International a non-profit humanitarian organization. From 2009 to July 2012, Mr. Mitchum served as President of the Americas for EUSA Pharma (USA), Inc., where he oversaw the streamlining of that business as well as the development, FDA approval and successful launch of a pediatric oncology drug in 2011. From 2005 to 2008, Mr. Mitchum served as President and Chief Executive Officer of Enturia, Inc., a privately owned drug-device company, based in Kansas City, Missouri. From 2004 to 2005, Mr. Mitchum served as the President and Chief Executive Officer of Sanofi-Aventis Group Japan. Mr. Mitchum has also served as a director on numerous private company and organization boards. Mr. Mitchum earned an MBA in Business from the University of Tennessee in Knoxville, Tennessee and a Bachelor of Science degree in Business and Math from Milligan College in Johnson City, Tennessee.

We believe that Mr. Mitchum's experience in managing companies in the life sciences industry, as well as his financial and operational expertise, qualify him to serve on our Board of Directors.

Robert R. Seltzer has served as a member of our Board of Directors since October 2013. Mr. Seltzer is a Managing Partner at at Amzak Health, an investment firm focused on venture capital and growth equity opportunities in healthcare. Prior to joining Amzak Health in 2015, Mr. Seltzer was a Partner at Care Capital, LLC, a life sciences venture capital firm and an affiliate of one of our principal stockholders, which he joined in July 2005. He was previously a management consultant at the Boston Consulting Group (1997 to 2000 and 2004 to 2005), and he was the Co-Founder and President of Trenza Corp (2000 to 2001). He has served on the board of directors of Minerva Neurosciences, Inc. and a number of private biopharmaceutical and drug development companies. Mr. Seltzer

received his MBA from The Wharton School, a Master of Biotechnology from the University of Pennsylvania, and a B.S. in Molecular Biophysics and Biochemistry from Yale University.

We believe that Mr. Seltzer's perspective and the experience he brings as a Board member of life sciences companies, his knowledge of finance and transactions, and his historic knowledge of our company and our product candidates qualify him to serve as a member of our Board of Directors.

Eugen Steiner, M.D., Ph.D., has served as a member of our Board of Directors since 2007. Dr. Steiner is a venture partner of HealthCap, a group of multistage venture capital funds, investing globally in the life sciences. He is currently the Chief Executive Officer of Glionova AB, an early-stage Swedish biopharmaceutical company a portfolio company of HealthCap. He has more than 25 years of executive management experience, and since 1997 has served as CEO of certain

companies in which HealthCap has invested, leading these companies mostly in start-up and early stages of development. He has been CEO of Affibody AB, Biostratum Inc., Calab Medical AB, Creative Peptides AB, Eurona Medical AB, Melacure Therapeutics AB, Nordic Vision Clincs AS, PyroSequencing AB and Visual Bioinformatics AB. Dr. Steiner has served on several public, private and nonprofit company boards, including Alba Therapeutics, APL, Biolipox (chairman), BioPhausia, Biostratum (chairman), Biotage, Praktikertjänst, and Stockholm School of Entrepreneurship, and also belongs to several professional medical, industry and investor associations. He studied medicine and earned his MD as well as PhD degrees at the Karolinska Institute. Until 1987 Dr. Steiner practiced medicine and was active in medical research at the Karolinska Hospital, Stockholm, Sweden.

We believe that Dr. Steiner's experience, together with his historic knowledge of our company and our product candidates, and continuity to our Board of directors, and his experience in managing and investing in companies within the life sciences industry, qualify him to serve as a member of our Board of directors.

Marco Taglietti, M.D. has served on our Board of Directors since October 2014. Dr. Taglietti is the Chief Executive Officer of Scynexis, Inc., effective as of April 1, 2015. Dr. Taglietti also serves as a member of the Board of Directors of Delcath Systems, Inc. Prior to its recent acquisition, Dr. Taglietti served as Executive Vice President, Research and Development, and Chief Medical Officer of Forest Laboratories, Inc. He also served as President, Chief Medical Officer of the Forest Research Institute. Prior to joining Forest Labs in 2007, Dr. Taglietti held the position of Senior Vice President, Head of Global Research and Development, at Stiefel Laboratories, Inc. for three years. He joined Stiefel after 12 years at Schering-Plough Corporation where he last held the position of Vice President, Worldwide Clinical Research for Anti-Infectives, Oncology, CNS, Endocrinology and Dermatology. Dr. Taglietti began his career at Marion Merrell Dow Research Institute. Over the course of his career, he has brought to market 35 different products in the U.S. and internationally. He received his medical degree and board certifications from the University of Pavia in Italy.

We believe that Dr. Taglietti’s experience in managing companies in the life sciences industry, as well as his financial and operational expertise, qualify him to serve on our Board of Directors.

There are no family relationships between or among any of our directors or nominees. The principal occupation and employment during the past five years of each of our directors and nominees was carried on, in each case except as specifically identified above, with a corporation or organization that is not a parent, subsidiary or other affiliate of us. There is no arrangement or understanding between any of our directors or nominees and any other person or persons pursuant to which he or she is to be selected as a director or nominee.

There are no legal proceedings to which any of our directors is a party adverse to us or any of our subsidiaries or in which any such person has a material interest adverse to us or any of our subsidiaries.

Director Independence

Based upon information requested from and provided by each director concerning their background, employment and affiliations, including family relationships, our Board of Directors has determined that Messrs. Markham, Mitchum and Seltzer and Drs. Steiner and Taglietti are independent under the applicable rules and regulations of the NASDAQ Stock Market. Our Board of Directors also determined that Messrs. Markham and Mitchum and Dr. Taglietti, who comprise our Compensation Committee; and Messrs. Seltzer and Markham, who comprise our Nominating and Governance Committee, all satisfy the independence standards for such committees established by the SEC and the NASDAQ Marketplace Rules, as applicable. With respect to our Audit Committee, our Board of Directors has determined that Mr. Mitchum and Drs. Steiner and Taglietti satisfy the independence standards for such committee established by Rule 10A-3 under the Exchange Act, the Securities and Exchange Commission and the NASDAQ Marketplace Rules, as applicable. In making such determinations, our Board of Directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances the Board of Directors deemed relevant in determining their independence.

Committees of the Board of Directors and Meetings

The following table sets forth the number of meetings held during calendar year 2015 by the Board of Directors and by each committee thereof. Each of the directors, who were serving on our Board of Directors during 2015, attended at least 75% of the total number of meetings of the Board of Directors and of the committees of which he was a

member during the time each such individual was a member of the Board of Directors.

	Number of Meetings Held
Board of Directors	9
Audit Committee	5
Compensation Committee	6
Nominating and Corporate Governance	4

Audit Committee. Our Audit Committee has three members: James Mitchum, Eugen Steiner, M.D., Ph.D. and Marco Taglietti, M.D. Mr. Mitchum is the chairperson of the committee. Our Board of Directors has determined that Mr. Mitchum is an audit committee financial expert, as defined by the rules of the SEC, and satisfies the financial sophistication requirements of applicable NASDAQ rules.

Our Board of Directors has determined that each of Mr. Mitchum and Drs. Steiner and Taglietti are independent directors under the NASDAQ Marketplace Rules and Rule 10A-3 of the Exchange Act.

Our Audit Committee is authorized to:

- approve and retain the independent auditors to conduct the annual audit of our financial statements;
- review the proposed scope and results of the audit;
- review and pre-approve audit and non-audit fees and services;
- review accounting and financial controls with the independent auditors and our financial and accounting staff;
- review and approve transactions between us and our directors, officers and affiliates;
- recognize and prevent prohibited non-audit services;
- establish procedures for complaints received by us regarding accounting matters;
- oversee internal audit functions, if any; and
- prepare the report of the Audit Committee that the rules of the SEC require to be included in our annual meeting proxy statement.

A copy of the Audit Committee's written charter is publicly available in the "Investors & Media" section on our website at www.nephrogenex.com.

Compensation Committee. Our Compensation Committee has three members: Richard J. Markham, James Mitchum, and Marco Taglietti, M.D. Mr. Markham is the chairperson of the committee. Our Compensation Committee's role and responsibilities are set forth in the Compensation Committee's written charter and includes reviewing, approving and making recommendations regarding our compensation policies, practices and procedures to ensure that legal and fiduciary responsibilities of the Board of Directors are carried out and that such policies, practices and procedures contribute to our success. Our Compensation Committee also administers the Stock Plan. The Compensation Committee is responsible for the determination of the compensation of our chief executive officer, and shall conduct its decision making process with respect to that issue without the chief executive officer present. All members of the Compensation Committee qualify as independent under the definition promulgated by The NASDAQ Stock Market.

Our Compensation Committee's role and responsibilities are set forth in the Compensation Committee's written charter and include:

- reviewing and recommending the compensation arrangements with management, including the compensation of our chief executive officer
- establishing and reviewing general compensation policies with the objective of aligning, where appropriate, the long-term interests of executive officers and other key employees with those of our stockholders and otherwise encouraging the achievement of superior results over an extended time period; and
- overseeing any of our equity incentive plans, as applicable.

The Compensation Committee’s independent compensation consultant during fiscal year 2015 was the Hay Group (“Hay Group”). Hay Group is engaged by, and reports directly to, the Compensation Committee, which has the sole authority to hire or fire them and to approve fee arrangements for work performed. Hay Group assists the Compensation Committee in fulfilling its responsibilities under its charter, including advising on proposed compensation packages for executive officers, compensation program design and market practices generally. The Compensation Committee has authorized Hay Group to interact with management on behalf of the Compensation Committee, as needed in connection with advising the Compensation

Committee, and Hay Group is included in discussions with management and, when applicable, the Compensation Committee's outside legal counsel on matters being brought to the Compensation Committee for consideration.

The Compensation Committee has assessed the independence of Hay Group pursuant to SEC rules and concluded that Hay Group's work for the Compensation Committee does not raise any conflict of interest.

A copy of the Compensation Committee's written charter is publicly available in the "Investors & Media" section on our website at www.nephrogenex.com.

Nominating and Governance Committee. Our Nominating and Governance Committee is comprised of Richard J. Markham and Robert R. Seltzer. Mr. Seltzer is the chairperson of the committee. The Nominating and Governance Committee's role and responsibilities are set forth in the Nominating and Governance Committee's written charter and include evaluating and making recommendations to the full Board as to the size and composition of the Board of Directors and its committees, evaluating and making recommendations as to potential candidates, and evaluating the performance of current members of the Board of Directors. All members of the Nominating and Governance Committee qualify as independent under the definition promulgated by The NASDAQ Stock Market.

If a stockholder wishes to nominate a candidate for director who is not to be included in our proxy statement, it must follow the procedures described in our bylaws.

In addition, under our current corporate governance policies, the Nominating and Governance Committee may consider candidates recommended by stockholders as well as from other sources such as other directors or officers, third party search firms or other appropriate sources. For all potential candidates, the Nominating and Governance Committee may consider all factors it deems relevant, such as a candidate's personal integrity and sound judgment, business and professional skills and experience, independence, knowledge of the industry in which we operate, possible conflicts of interest, diversity, the extent to which the candidate would fill a present need on the Board of Directors, and concern for the long-term interests of the stockholders. In general, persons recommended by stockholders will be considered on the same basis as candidates from other sources. If a stockholder wishes to propose a candidate for consideration as a nominee by the Nominating and Governance Committee under our corporate governance policies, it should submit such recommendation in writing c/o Secretary, NephroGenex, Inc., 3200 Beechleaf Court, Suite 900, Raleigh, North Carolina, 27604.

Our Nominating and Governance committee has not adopted a formal diversity policy in connection with the consideration of director nominations or the selection of nominees. However, the Nominating and Governance Committee will consider issues of diversity among its members in identifying and considering nominees for director, and will strive where appropriate to achieve a diverse balance of backgrounds, perspectives, experience, age, gender, ethnicity and energy industry experience on our Board of Directors and its committees.

A copy of the Nominating and Governance Committee's written charter is publicly available on the Company's website at www.nephrogenex.com.

Board Leadership Structure and Role in Risk Oversight

The positions of chairman of the board and chief executive officer are presently separated at our company. We believe that separating these positions allows our chief executive officer to focus on our day-to-day business, while allowing our chairman of the board to lead the Board of Directors in its fundamental role of providing advice to, and independent oversight of, management. Our Board of Directors recognizes the time, effort and energy that the chief executive officer is required to devote to his position in the current business environment, as well as the commitment required to serve as our chairman, particularly as the Board of Directors' oversight responsibilities continue to grow. Our Board of Directors also believes that this structure ensures a greater role for the independent directors in the oversight of our company and active participation of the independent directors in setting agendas and establishing priorities and procedures for the work of our Board of Directors. This leadership structure also is preferred by a significant number of our stockholders. Our Board of Directors believes its administration of its risk oversight function has not affected its leadership structure.

While our restated bylaws and corporate governance guidelines do not require that our chairman and chief executive officer positions be separate, our Board of Directors believes that having separate positions is the appropriate leadership structure for us at this time and demonstrates our commitment to good corporate governance.

Risk is inherent with every business, and how well a business manages risk can ultimately determine its success. We face a number of risks, including risks relating to product candidate development, having no commercial manufacturing experience, marketing or sales capability or experience and dependence on key personnel, as more fully discussed under Item 1.A. "Risk Factors" in our annual report on this Annual Report on Form 10-K. Management is responsible for the day-to-day

management of risks we face, while our Board of Directors, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, our Board of Directors has the responsibility to satisfy itself that the risk management processes designed and implemented by management are adequate and functioning as designed.

Our Board of Directors is actively involved in oversight of risks that could affect us. This oversight is conducted primarily through committees of the Board of Directors, but the full board of directors has retained responsibility for general oversight of risks. Our Board of Directors satisfies this responsibility through full reports by each committee chair regarding the committee's considerations and actions, as well as through regular reports directly from officers responsible for oversight of particular risks within our company as our Board of Directors believes that full and open communication between management and the Board of Directors is essential for effective risk management and oversight.

Stockholder Communications to the Board

Generally, stockholders who have questions or concerns should contact us at http://investors.nephrogenex.com/contactus.cfm. However, any stockholders who wish to address questions regarding our business directly with the Board of Directors, or any individual director, should direct his or her questions in writing to our Secretary, John P. Hamill, NephroGenex, Inc., 3200 Beechleaf Court, Suite 900, Raleigh, North Carolina, 27604. Communications will be distributed to the Board, or to any individual director or directors as appropriate, depending on the facts and circumstances outlined in the communications. Items that are unrelated to the duties and responsibilities of the Board of Directors may be excluded, such as:

• junk mail and mass mailings
• resumes and other forms of job inquiries
• surveys
• solicitations or advertisements.

In addition, any material that is unduly hostile, threatening, or illegal in nature may be excluded, provided that any communication that is filtered out will be made available to any outside director upon request.

Executive Officers

The following table sets forth certain information regarding our executive officers who are not also directors.

Name	Age	Position
John P. Hamill	51	Chief Financial Officer, Treasurer and Secretary
Jaikrishna Patel	54	Chief Scientific Officer

We have employment agreements with all of our executive officers.

John P. Hamill has served as our Chief Financial Officer since January 2014. From June 2013 until January 2014, Mr. Hamill served as Co-President and Chief Financial Officer of Savient Pharmaceuticals, Inc. ("Savient") and as Senior Vice President and Chief Financial Officer of Savient since September 2012. Savient filed for bankruptcy on October 14, 2013, while Mr. Hamill was Savient's Co-President and Chief Financial Officer and, shortly thereafter, Savient sold its assets in bankruptcy. From 2010 to 2012, Mr. Hamill served as a financial consultant for various private companies. From 2001 until 2009, Mr. Hamill worked for PharmaNet Development Group, Inc., where he served as Executive Vice President and Chief Financial Officer from 2006 until 2009. During the period in which Mr. Hamill served as Executive Vice President and Chief Financial Officer, he also maintained responsibilities as the Chief Financial Officer of PharmaNet Development Group, Inc.'s wholly-owned subsidiary, PharmaNet, Inc. Mr. Hamill earned his B.S. with a dual major in Accounting/Business and Computer Science from DeSales University (formerly Allentown College of St. Francis de Sales) in 1986. Mr. Hamill is a Certified Public Accountant and is a member of the Pennsylvania Institute of Certified Public Accountants and the American Institute of Certified Public Accountants.

Jaikrishna Patel has served as our Chief Medical Officer since July 2015 and Chief Scientific Officer since December 2015. Dr. Patel has a significant role in our PIONEER clinical trial program. He also focuses on new areas and has taken over the activities recently performed by contractors and consultants. Dr. Patel has held numerous positions at GlaxoSmithKline, including his most recent position as Vice President, Metabolic Pathways and Cardiovascular, Global Regulatory Affairs, which he held since April 2012. Prior to that, Dr. Patel served as Vice President, U.S.

Regional Regulatory Affairs from September 2010 to April 2012. He has served at GlaxoSmithKline and its predecessor companies in varying roles since 1991. Dr. Patel graduated from the University of London with a BSc (Hons), 1st class, in Experimental Pathology in 1983. He received an MBBS with distinction from St. Bartholomew's Hospital in 1986, and an MRCP in 1989. Dr. Patel completed his post-graduate medical training at St. Bartholomew's Hospital and Kings College Hospital in London and is licensed with the UK General Medical Council.

Item 11. Executive Compensation

Summary Compensation Table

The following table sets forth the compensation paid or accrued during the last two fiscal years to our named executive officers.

Name and Principal Position		Salary	Bonus (1)	Stock Awards (2)	Option Awards (3)	All Other Compensation (4)	Total Compensation
		$	$	$	$	$	$
Pierre Legault(5)	2015	502,083	386,720	1,494,408	288,170	67,088	2,738,469
Chief Executive Officer and President	2014	395,000	409,090	30,395	1,932,321	40,935	2,807,741
John P. Hamill	2015	333,025	150,000	315,040	86,451	58,634	943,150
Chief Financial Officer	2014	291,875	140,100	—	512,728	40,793	985,496
Jaikrishna Patel (6)	2015	154,022	60,959	224,777	175,215	7,125	622,098
Chief Scientific Officer	2014	—	—	—	—	—	—
J. Wesley Fox(7)	2015	280,950	—	—	300,570	47,368	628,888
Former President and Chief Scientific Officer	2014	352,504	147,170	—	392,693	43,972	936,339

(1) Bonus payments to our named executive officer are subject to the discretion of the Board of Directors and Compensation Committee. Amounts represent cash bonuses earned in 2015, which were paid during 2016, and cash bonuses earned in 2014, which were paid in 2015, based on achievement of performance goals and other factors deemed relevant by our Board of Directors and the Compensation Committee. The corporate performance goals for 2015 including site openings and patient recruitment for the PIONEER trial, securing additional financing, adequate investor relations activities, advancement of the IV Pyridorin development program, EMA acceptance of the new end point and ensuring adequate and high quality clinical trial supplies. The corporate performance goals for 2014 included key strategic and financial goals that related to development programs, obtaining approval from the FDA for Pyridorin, securing new sources of capital/financing and achieving the budgeted financial targets. In addition, Mr. Legault's bonus included cash compensation earned under a restricted stock unit agreement in the amount of $96,720 and $112,840 in 2015 and 2014, respectively.

(2) These amounts for the fiscal years ended December 31, 2015 and 2014, respectively, represent the fair market value of common stock issued to our named executive officers under their respective restricted stock agreements.

(3) These amounts represent the aggregate grant date fair value of options granted in fiscal years ended December 31, 2015 and 2014, respectively computed in accordance with FASB ASC Topic 718. A discussion of the assumptions used in determining grant date fair value may be found in Note 2 to our Financial Statements, incorporated by reference herein.

(4) Amount represents 401(k) match, medical, dental, vision, life and long-term disability benefits paid by us on behalf of each employee. In addition, amounts include payment for unused vacation for Mr. Legault, Mr. Hamill and Dr. Fox.

(5) Mr. Legault was appointed as our Chief Executive Officer on October 18, 2013 and President on September 1, 2015. Prior to October 18, 2013, Mr. Legault served as the chairman of our Board of Directors.

(6) Dr. Patel was appointed as our Chief Medical Officer on July 27, 2015 and Chief Scientific officer on December 17, 2015.

(7) Dr. Fox was our President and Chief Scientific Officer from October 18, 2013 to September 1, 2015 and has served as a consultant from September 1, 2015 through February 29, 2016.

71

Employment Arrangements with Our Named Executive Officers

Pierre Legault. On November 7, 2013, we entered into an employment agreement with Pierre Legault to reflect his role and responsibilities as Chief Executive Officer. Mr. Legault's service as Chief Executive Officer commenced on October 18, 2013 (the "Commencement Date"). The employment agreement will continue until Mr. Legault's employment is terminated by either party pursuant to the terms and provisions of the employment agreement. The employment agreement provides Mr. Legault an annual base salary of $400,000. Mr. Legault’s annual base salary was increased by our Board of Directors on December 12, 2014 to $500,000, effective as of January 1, 2015 and further increased on November 10, 2015 to $550,000, effective as of December 16, 2015. For each completed fiscal year during Mr. Legault's service to us, Mr. Legault is eligible to earn a bonus based on achievement of reasonable individual and corporate performance objectives established by our Board of Directors and communicated to Mr. Legault. The target amount of Mr. Legault's annual bonus for each fiscal year will be 50% of the base salary paid or payable to Mr. Legault for his service in that year. To receive any annual bonus otherwise earned for a given year, Mr. Legault must remain employed with us through the last business day of that year.

Pursuant to his employment agreement, Mr. Legault received a grant of restricted stock units (“RSUs”) which represent the right to receive 24,000 shares of our common stock, subject to the terms and conditions of a restricted stock unit agreement and grant notice (the "RSU Award"). 25% of the RSUs granted to Mr. Legault vested on October 21, 2014, and the remaining 75% of the RSUs granted to Mr. Legault vest in equal monthly installments, on the first day of each calendar month, beginning on November 1, 2014 and continuing for 36 months thereafter, provided that Mr. Legault remains in service with us. The RSUs will vest in full upon a change in control of the Company, provided that Mr. Legault remains employed with the Company through the date of the change in control. A “change in control” generally means the occurrence of one or more of the following: (i) any person becomes owner, directly or indirectly, of Company securities representing more than 50% of the combined voting power of the Company other than by virtue of a merger, consolidation or similar transaction; (ii) the consummation of a merger, consolidation or similar transaction where immediately after the consummation of such transaction the stockholders of the Company immediately prior to the transaction do not own, directly or indirectly, either 50% or more of the combined voting power of the surviving entity or the parent of the surviving entity; or (iii) the disposition of all or substantially all of the consolidated assets of the Company and its subsidiaries during any 12 month period. We also make special cash bonus payments to Mr. Legault on each date that shares are delivered to Mr. Legault upon vesting of RSUs in an amount equal to the product of the number of shares of common stock delivered on such date and $16.12, less applicable taxes and withholdings; but in no event shall this bonus amount exceed $387,000 in the aggregate, before adjustment for applicable taxes and withholdings. The per share bonus amount shall be equitably adjusted in the event of any capitalization adjustment of the Company.

The employment agreement further provides that during Mr. Legault's continuing service to us, if the number of issued and outstanding shares of our capital stock increases, without limitation, in connection with an initial public offering of our common stock or a stock dividend with respect to our preferred stock, but not including the conversion of convertible debt or convertible promissory notes issued prior to the one year anniversary of the Commencement Date (the "Additional Shares"), we shall grant Mr. Legault an option under the Stock Plan or any successor plan of ours (the "True Up Option") covering the number of shares of common stock equal to three ninety-sevenths of the Additional Shares, rounded to the nearest whole share.

In connection with the completion of our initial public offering, on February 14, 2014, we granted Mr. Legault, a True Up Option to purchase 114,234 shares of our common stock with an exercise price of $12.00 per share. With respect to 76,156 of the shares subject to the True Up Option, 1/48th of the shares vest when Mr. Legault completes each month of continuous service to us, with 23,799 shares vested as of the date of grant. With respect to the 38,078 remaining shares subject to the True Up Option, 25% of the shares vested on October 21, 2014 and 75% of the shares vest in equal monthly installments on the first day of each calendar month for 36 months, beginning November 1, 2014, provided however, that Mr. Legault must remain in service to us on each applicable vesting date. The True Up Option shall vest in full upon the earlier of a change in control, or upon a termination due to death, disability or involuntary termination, provided that Mr. Legault remains employed with the Company through the date of the

change in control, death, disability or an involuntary termination. For purposes of the True Up Option, a change in control generally means the (i) consummation of a merger or consolidation with or into another entity or (ii) the dissolution, liquidation or winding up of the Company.

Further, in connection with the completion of our initial public offering, on February 14, 2014 and the conversion of all of our convertible notes into common stock, we granted Mr. Legault an additional option to purchase 37,029 shares of our common stock with an exercise price of $2.02 per share (the “Additional Option”), subject to the terms discussed below in order for such option to comply with Section 409A of the Internal Revenue Code (“Section 409A”). With respect to 24,686 of the shares subject to the Additional Option, 1/48th of the shares vest upon each completed month of continuous service from November 26, 2012, with 7,714 shares vested as of the date of grant. With respect to the 12,343 remaining shares subject to the Additional Option, 25% of the shares vested on October 21, 2014; and 75% of the shares vest in equal monthly installments on the first day of each calendar month for 36 months, beginning November 1, 2014, and based on Mr. Legault’s continued service. The Additional Option shall vest in full upon the earlier of a change in control or upon a termination due to death, disability or involuntary termination, provided that Mr. Legault remains employed with the Company through the date of the

change in control, death, disability or an involuntary termination. The Additional Option may only be exercised, to the extent vested, during the period beginning on the earliest of the following: (i) Mr. Legault's "separation from service" (as defined under Section 409A), including any applicable six-month delay required under Section 409A; (ii) the time immediately preceding a change in control, but only if such change in control constitutes a "change in control event" (as defined under Section 409A); or (iii) January 1, 2023. Once exercisable, each Additional Option will continue to be exercisable until, as applicable, (x) the last day of the calendar year in which the option became exercisable, (y) the closing of a change in control, or (z) the expiration date of the Additional Option. For purposes of the Additional Option, a change in control generally means the (i) consummation of a merger or consolidation with or into another entity or (ii) the dissolution, liquation or winding up of the Company.

On November 10, 2015 Mr. Legault received an award of 646,930 RSUs under the 2007 Equity Incentive Plan, pursuant to an RSU agreement. The RSUs will vest, provided that Mr. Legault continues to provide services to us, in equal quarterly installments on the first day of each calendar quarter, beginning on January 1, 2016 and continuing for 11 additional quarters thereafter, provided that the number of shares vesting on each date shall be rounded down to the nearest whole number, whilst the number of shares vesting on the final date shall be the remaining unvested balance of the RSUs. The RSUs will vest in full upon a change in control of the Company, provided that Mr. Legault remains employed with the Company through the date of the change in control. A change in control is defined in the same manner as Mr. Legault's RSU Award described above.

Mr. Legault also received a stock option grant covering 593,202 shares of the Company's common stock on May 2, 2013 while he was a consultant to the Company. This option shall become vested in full if the Company is subject to a change in control prior to Mr. Legault's termination of service. For purposes of this stock option grant, a change in control is defined by reference to Mr. Legault's RSU Award described above.

Upon the termination of Mr. Legault's employment, he will receive payment for any accrued but unpaid wages, accrued but unused vacation and for any incurred but unreimbursed expenses, subject to our policies for expense reimbursements. If Mr. Legault's employment is terminated by us upon 53 days prior written notice or is terminated by Mr. Legault for "Good Reason," we will (a) make a cash lump sum payment to Mr. Legault equal to 150% of his base salary (at the rate in effect immediately prior to such termination), less applicable taxes and withholdings, and (b) for a period of twelve (12) months (or by lump sum covering twelve (12) months if allowed by applicable law) pay Mr. Legault the monthly benefit stipend equal to Mr. Legault's premiums for continuation of medical and dental benefits pursuant to Mr. Legault's COBRA election, including payments to account for applicable taxes and withholdings. Such payments will be conditioned on Mr. Legault's execution of a general release of claims against us and our affiliates (excluding Mr. Legault's rights as a stockholder, rights with respect to equity incentive awards and rights to indemnification for acts performed in Mr. Legault's capacity as an director, officer or employee) in a mutually acceptable form and on such release becoming effective no later than 53 days following such termination. Notwithstanding the foregoing, if Mr. Legault is terminated with appropriate notice or resigns for Good Reason during the twenty-four (24) month period following any change in control (as defined in Mr. Legault's RSU Award described above): we will (a) make a cash lump sum payment to Mr. Legault equal to 225% of his base salary (at the rate in effect immediately prior to such termination) and (b) continue to pay Mr. Legault the monthly benefit stipend described above for eighteen (18) months following such termination.

"Good Reason" is defined under the employment agreement as (i) any adverse change in Mr. Legault's title, authority or duties (including, without limitation, the assignment to Mr. Legault of duties materially inconsistent with his position) or (ii) any other material breach by us of any term or condition of the employment agreement.

Mr. Legault also participates in the employee benefit plans, policies or arrangements maintained by us for our management-level employees. Further, we have agreed to pay directly, or reimburse, Mr. Legault for travel and business expenses in accordance with our generally applicable policies relating to such expenses.

Receipt of the severance benefits described above may be modified by us to comply with Section 409A of the Internal Revenue Code of 1986, as amended, or the Code.

John P. Hamill. On December 12, 2013, we entered into an employment agreement with John P. Hamill to reflect his role and responsibilities as Chief Financial Officer. Mr. Hamill's service as Chief Financial Officer commenced on

January 21, 2014. The employment agreement will continue until Mr. Hamill’s employment is terminated by either party pursuant to the terms and provisions of the employment agreement. The employment agreement provides Mr. Hamill an annual base salary of $300,000. Mr. Hamill’s annual base salary was increased by our Board of Directors on December 12, 2014 to $331,200, effective as of January 1, 2015 and further increased on November 10, 2015 to $375,200, effective as of December 16, 2015. For each completed fiscal year during Mr. Hamill’s service to us, Mr. Hamill is eligible to earn a bonus based on achievement of reasonable individual and corporate performance objectives established by our Board of Directors and communicated to Mr. Hamill. The target amount of Mr. Hamill's annual bonus for each fiscal year will be 40% of the base salary paid or payable to Mr. Hamill for his service in that year. To receive any annual bonus otherwise earned for a given year, Mr. Hamill must remain employed with us through the last business day of that year.

In connection with the commencement of his employment, Mr. Hamill received a stock option grant covering 30,769 shares of the Company's common stock on February 14, 2014. 25% of the shares vested on January 21, 2015 with 1/48th vesting monthly on the anniversary of January 21, 2015 in each of the following 36 months. This option shall become vested in full if the Company is subject to a change in control prior to Mr. Hamill's termination of service. For purposes of this option, a change in control generally means the (i) consummation of a merger or consolidation with or into another entity or (ii) the dissolution, liquidation or winding up of the Company.

On November 10, 2015, Mr. Hamill received an award of 136,381 RSUs under the 2007 Equity Incentive Plan, pursuant to an RSU agreement. The RSUs will vest, provided that Mr. Hamill continues to provide services to us, in equal quarterly installments on the first day of each calendar quarter, beginning on January 1, 2016 and continuing for 11 additional quarters thereafter, provided that the number of shares vesting on each date shall be rounded down to the nearest whole number, whilst the number of shares vesting on the final date shall be the remaining unvested balance of the RSUs. The RSUs will vest in full upon a change in control of the Company, provided that Mr. Hamill remains employed with the Company through the date of the change in control. A change in control is defined in the same manner as Mr. Legault's RSU Award described above.

Upon the termination of Mr. Hamill's employment, he will receive payment for any accrued but unpaid wages, accrued but unused vacation and for any incurred but unreimbursed expenses, subject to our policies for expense reimbursements. If Mr. Hamill's employment is terminated by us upon 30 days prior written notice or is terminated by Mr. Hamill for "Good Reason," we will (a) make a cash lump sum payment to Mr. Hamill equal to 140% of his base salary (at the rate in effect immediately prior to such termination), less applicable taxes and withholdings, and (b) for a period of twelve (12) months (or by lump sum covering twelve (12) months if allowed by applicable law) pay Mr. Hamill the monthly benefit stipend equal to Mr. Hamill's premiums for continuation of medical and dental benefits pursuant to Mr. Hamill's COBRA election, including payments to account for applicable taxes and withholdings. Such payments will be conditioned on Mr. Hamill's execution of a general release of claims against us and our affiliates (excluding Mr. Hamill's rights as a stockholder, rights with respect to equity incentive awards and rights to indemnification for acts performed in Mr. Hamill's capacity as an director, officer or employee) in a mutually acceptable form and on such release becoming effective no later than 60 days following such termination. Notwithstanding the foregoing, if Mr. Hamill resigns within 30 days following a change in control we will make a cash lump sum payment to Mr. Hamill equal to 210% of his base salary (at the rate in effect immediately prior to such termination). A change in control is defined in generally the same manner as is defined in Mr. Legault's RSU Award described above.

"Good Reason" is defined under the employment agreement as (i) any material adverse change in Mr. Hamill's title, authority or duties (including, without limitation, the assignment to Mr. Hamill of duties materially inconsistent with his position) or (ii) any other material breach by us of any term or condition of the employment agreement.

Mr. Hamill also participates in the employee benefit plans, policies or arrangements maintained by us for our management-level employees, subject to the terms and conditions of such plans, policies or arrangements. Further, we have agreed to pay directly, or reimburse, Mr. Hamill for travel and business expenses in accordance with our generally applicable policies relating to such expenses.

Receipt of the severance benefits described above may be modified by us to comply with Section 409A of the Internal Revenue Code of 1986, as amended, or the Code.

Jaikrishna Patel. On July 2, 2015, we entered into an employment agreement with Jaikrishna Patel, pursuant to which Dr. Patel was appointed as our Chief Medical Officer. Dr. Patel's service commenced on July 27, 2015. Subsequently on December 16, 2015, Dr. Patel's title was changed from Chief Medical Officer to Chief Scientific Officer based on his expanded roles and responsibilities on strategy, strategic products, in our PIONEER clinical trial program, the Scientific Advisory Board, investor relations and other activities. The employment agreement will continue until Dr. Patel's employment is terminated by either party pursuant to the terms and provisions of the employment agreement. The employment agreement provides Dr. Patel an annual base salary of $350,000. Mr. Patel's annual base salary was increased by our Board of Directors on November 10, 2015 to $385,000, effective as of December 16, 2015. For each completed fiscal year during Dr. Patel's service to us, Dr. Patel is eligible to earn a bonus based on achievement of reasonable individual and corporate performance objectives established by our Board of Directors and communicated to Dr. Patel. The target amount of Dr. Patel's annual bonus for each fiscal year will be 35% of the base salary paid or payable to Dr. Patel for his service in that year. To receive any annual bonus otherwise earned for a given year, Dr. Patel must remain employed with us through the last business day of that year.

On November 10, 2015, Dr. Patel received an award of 97,306 RSUs under the 2007 Equity Incentive Plan. The RSUs will vest, provided that Dr. Patel continues to provide services to us, in equal quarterly installments on the first day of each calendar quarter, beginning on January 1, 2016 and continuing for 11 additional quarters thereafter, provided that the number of shares vesting on each date shall be rounded down to the nearest whole number, whilst the number of shares vesting on the final date shall be the remaining unvested balance of the RSUs. The RSUs will vest in full upon a change in control of the Company, provided that Dr. Patel remains employed with the Company through the date of the change in control. A change in control is defined in the same manner as Mr. Legault's RSU Award described above.

Upon the termination of Dr. Patel's employment, he will receive payment for any accrued but unpaid wages, accrued but unused vacation and for any incurred but unreimbursed expenses, subject to our policies for expense reimbursements. If Dr. Patel's employment is terminated by us upon 30 days prior written notice or is terminated by Dr. Patel for "Good Reason," we will (a) make a cash lump sum payment to Dr. Patel equal to 135% of his base salary (at the rate in effect immediately prior to such termination), less applicable taxes and withholdings, and (b) for a period of twelve (12) months (or by lump sum covering twelve (12) months if allowed by applicable law) pay Dr. Patel the monthly benefit stipend equal to Dr. Patel's premiums for continuation of medical and dental benefits pursuant to Dr. Patel's COBRA election, including payments to account for applicable taxes and withholdings. Such payments will be conditioned on Dr. Patel's execution of a general release of claims against us and our affiliates (excluding Dr. Patel's rights as a stockholder, rights with respect to equity incentive awards and rights to indemnification for acts performed in Dr. Patel's capacity as an director, officer or employee) in a mutually acceptable form and on such release becoming effective no later than 60 days following such termination. Notwithstanding the foregoing, if Dr. Patel resigns for Good Reason or the Company terminates Dr. Patel's employment without Cause more than 12 months following a Change in Control, then Dr. Patel will not be entitled to any severance benefits described above. A change in control is defined in generally the same manner as is defined in Mr. Legault's RSU Award described above.

"Good Reason" is defined under the employment agreement as (i) any material adverse change in Dr. Patel's title, authority or duties (including, without limitation, the assignment to Dr. Patel of duties materially inconsistent with his position) or (ii) any other material breach by us of any term or condition of the employment agreement.

Dr. Patel will also participate in the employee benefit plans, policies or arrangements maintained by us for our management-level employees, subject to the terms and conditions of such plans, policies or arrangements. Further, we have agreed to pay directly, or reimburse, Dr. Patel for travel and business expenses in accordance with our generally applicable policies relating to such expenses.

Receipt of the severance benefits described above may be modified by us to comply with Section 409A of the Internal Revenue Code of 1986, as amended, or the Code.

J. Wesley Fox, Ph.D. Effective as of September 1, 2015, Dr. Fox resigned from his positions as our President and Chief Scientific Officer and became a consultant. On August 6, 2015, the Board approved and entered into the consulting agreement by and between the Company and Dr. Fox. The term of the consulting agreement commences on September 1, 2015 and is effective until terminated by either party upon 30 days advance written notice to the other party. Pursuant to the terms of the consulting agreement, Dr. Fox will be entitled to receive a fee of $12,000 per month in exchange for services to the Company. Additionally, provided Dr. Fox successfully leads a scientific advisory board on behalf of the Company, the Company agrees to pay him an annual $35,000 advisory fee, subject to adjustment by the Board, such amounts to be paid following the termination of the consulting agreement; provided, however, that such termination must be by the Company and not Dr. Fox. Notwithstanding the above, if the Company terminates the consulting agreement on or prior to February 29th, 2016 for reasons unrelated to Consultant's performance, the Company shall pay Dr. Fox a lump sum amount of $72,000 minus consulting fees previously paid up to the date of termination. Dr. Fox is obligated to comply with various restrictive covenants, including a non-compete, non-solicit and protection of the Company's confidential information and inventions. In connection with the recent developments in February 2016, the Company terminated the consulting agreement with Dr. Fox effective on

February 29, 2016 and, as a result, no additional amounts are owed to Dr. Fox as part of this termination.

Pension Benefits

None of our named executive officers participates in or has account balances in qualified or non-qualified defined benefit plans sponsored by us.

Outstanding Equity Awards at 2015 Fiscal Year-End

The following table shows grants of stock options and grants of restricted stock unit awards outstanding on the last day of the fiscal year ended December 31, 2015, including both awards subject to performance conditions and non-performance-based awards, to each of the executive officers named in the Summary Compensation Table.

	Option Awards					Restricted Stock Units		
Name	Number of Securities Underlying Underlying Unexercised Options Exercisable	Number of Securities Underlying Underlying Unexercised Options Unexercisable		Option Exercise Price ($)	Option Expiration Date	Number of Unvested Securities		Market Value of Units that are Unvested ($)
Pierre Legault	70,347	20,914	(1)	2.02	5/1/2023	11,000	(2)	17,600
	19,028	5,658	(1)	2.02	11/6/2023	646,930	(3)	1,035,088
	6,685	5,658	(4)	2.02	5/1/2023	—		—
	58,703	17,453	(1)	12.00	11/6/2023	—		—
	20,625	17,453	(4)	12.00	5/1/2023	—		—
	21,413	64,239	(5)	4.67	12/12/2024	—		—
	16,087	48,261	(5)	4.67	12/12/2024	—		—
	—	50,000	(6)	7.31	4/30/2025			
J. Wesley Fox, Ph.D.	27,227	—		0.39	4/30/2017	—		—
	27,502	—		0.39	4/17/2018	—		—
	75,765	—		0.39	4/17/2018	—		—
	32,538	—		1.95	6/5/2019	—		—
	20,812	—		1.95	12/11/2019	—		—
	38,769	—		1.82	12/8/2021	—		—
	13,397	—		1.82	12/8/2021	—		—
	7,051	8,333	(5)	11.90	2/14/2024	—		—
	4,436	18,667	(5)	4.49	8/14/2024	—		—
	4,897	—		4.67	8/14/2024			
	11,250	33,750	(5)	4.67	12/12/2024	—		—
		15,000	(6)	7.31	4/30/2025			
John. P. Hamill	14,102	16,667	(5)	11.90	2/14/2024	136,381	(3)	218,210
	8,000	16,000	(5)	4.49	8/14/2024	—		—
	11,250	33,750	(5)	4.67	12/12/2024	—		—
	—	15,000	(6)	7.31	4/30/2025			
Jaikrishna Patel	—	54,347	(7)	4.12	8/6/2025	97,306	(3)	155,690

(1) 1/48th of the option covered by these grants vest monthly commencing November 26, 2012. The option covered by the grants will vest in full upon a change in control of the Company.

(2) 25% of the restricted stock units granted to Mr. Legault vested on October 21, 2014, and the remaining 75% of the restricted stock units granted to Mr. Legault vest in 36 equal monthly installments, on the first day of each calendar month, beginning on November 1, 2014. The restricted stock units will vest in full upon a change in control of the Company.

(3) All of the restricted stock units will vest in 36 equal monthly installments, on the first day of each calendar month, beginning on January 1, 2016. The restricted stock units will vest in full upon a change in control of the Company.

(4) 25% of the options covered by these grants vested on October 21, 2014 and the remaining 75% vest in 36 equal monthly installments beginning November 1, 2014. The options covered by these grants will vest in full upon a change in control of the Company.

(5) The options covered by these grants vest and become exercisable at a rate of 25% of the total grant on the first anniversary of the vesting start date and the remaining 75% vesting in 36 equal monthly installments over the first 36 months following the first anniversary of the vesting start date. The option granted to Mr. Hamill which expires on February 14, 2024 will vest in full upon a change in control of the Company.

(6) 25% of the shares underlying the options granted will vest on April 30, 2016 and the remaining 75% of the shares underlying the options will vest in 36 equal monthly installments.

(7) 25% of the shares underlying the options granted will vest on August 6, 2016 and the remaining 75% of the shares underlying the options will vest in 36 equal monthly installments.

Director Compensation

2015 Non-Employee Director Compensation Policy

Set forth below is our 2015 Non-Employee Director Compensation Policy which became effective on October 1, 2014.

	Annual Amount
Annual Retainer for each Board Member:	$40,000
Additional Retainer for the Chairman of the Board:	25,000
Audit Committee Chair:	15,000
Compensation Committee Chair:	10,000
Nominating and Corporate Governance Committee Chair:	7,500

In addition, each member will receive the value of an annual stock option award of $37,500 with the number of stock options to be determined based on a Black-Scholes calculation on the date of the grant. All options will vest on the first anniversary of the grant date. Newly elected or appointed directors will receive two times the regular annual option grant or $75,000 of fair value, at the time of their election. It is contemplated that non-employee directors grants will be made annually at the time of the Registrant’s annual meeting. At that time, consideration may also be given to adjust the compensation of the most recently elected director to reflect the new policy.

2015 Non-Employee Director Compensation

The following table presents information regarding the compensation of our non-employee directors in 2015.

Name	Fees Earned or Paid in Cash ($)(1)	Option Awards ($)(2)	Total ($)
Richard J. Markham (3)	75,000	37,510	112,510
James Mitchum	55,000	75,020	130,020
Robert R. Seltzer (4)	47,500	37,510	85,010
Eugen Steiner, M.D., Ph.D. (5)	40,000	37,510	77,510
Marco Taglietti, M.D.	40,000	37,510	77,510

77

(1) Amounts in this column represent fees earned under all 2015 Non-Employee Director Compensation Policies.

(2) Amounts in this column represent the grant date fair value of option awards granted to non-employee directors during 2015, computed in accordance with FASB ASC Topic 718. These amounts do not necessarily correspond to the actual value that may be realized by non-employee directors. The assumptions made in valuing the option awards reported in this column are discussed in the Company's audited financial statements (Note 2), Summary of Significant Accounting Policies under subsection "Stock-Based Compensation," in this Annual Report on Form 10-K.

(3) All directors fees paid to Mr. Markham are remitted by Mr. Markham to Care Capital. In addition, any proceeds received upon the exercises of option awards will be remitted by Mr. Markham to Care Capital.

(4) All directors fees paid to Mr. Seltzer from January 1, 2015 to August 31, 2015 are remitted by Mr. Seltzer to Care Capital.

(5) Pursuant to an agreement between Dr. Steiner and the Company, all of these director fees were paid directly to Setraco EHF.

The aggregate number of shares subject to outstanding option awards held by our non-employee directors as of December 31, 2015 was as follows:

	Number of Options Outstanding at December 31, 2015
Richard J. Markham	9,946
James Mitchum	16,816
Robert R. Seltzer	9,946
Eugen Steiner, M.D., Ph.D.	9,946
Marco Taglietti, M.D.	29,526

EQUITY COMPENSATION PLAN INFORMATION

The following table provides certain aggregate information with respect to all of the Company's equity compensation plans in effect as of December 31, 2015.

	a	b	c
Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by security holders(1)	2,434,349	$3.62	49,401
Equity compensation plans not approved by security holders	—	—	—
Total	2,434,349	$3.62	49,401

(1) Consists of options to purchase 1,542,732 shares and restricted stock units to purchase 880,617 shares of our common stock granted under the 2007 Equity Incentive Plan. Also consists of unvested restricted stock units for up to 11,000 shares granted to Mr. Legault in November 2013, outside of the Stock Plan but with the approval of the stockholders.

78

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of March 15, 2016, for (a) the executive officers named in Item 11 of this Annual Report on Form 10-K, (b) each of our directors and director nominees, (c) all of our current directors and executive officers as a group and (d) each stockholder known by us to own beneficially more than 5% of our common stock. Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the securities. We deem shares of common stock that may be acquired by an individual or group within 60 days of March 15, 2016 pursuant to the exercise of options or warrants to be outstanding for the purpose of computing the percentage ownership of such individual or group, but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person shown in the table. Except as indicated in footnotes to this table, we believe that the stockholders named in this table have sole voting and investment power with respect to all shares of common stock shown to be beneficially owned by them based on information provided to us by these stockholders. Percentage of ownership is based on 12,947,518 shares of common stock outstanding on March 15, 2016.

Unless otherwise indicated, the address for each director and executive officer listed is: c/o NephroGenex, Inc., 3200 Beechleaf Ct., Suite 900, Raleigh, NC 27604.

	Shares Beneficially Owned		
Name and Address	Number	Percent	
Directors and Executive Officers			
Pierre Legault (1)	385,593	2.98	%
J. Wesley Fox, Ph.D. (2)	278,587	2.15	%
John P. Hamill (3)	70,224	*	
Richard J. Markham (4)	8,600	*	
James Mitchum (5)	15,470	*	
Robert R. Seltzer (6)	8,600	*	
Eugen Steiner M.D., Ph.D. (7)	84,645	*	
Marco Taglietti, M.D. (8)	29,526	*	
Jaikrishna Patel (9)	16,216	*	
All directors and current executive officers as a group (8 persons) (10)	617,874	4.77	%
Five Percent Stockholders			
Funds affiliated with Care Capital, LLC (11)	4,241,097	32.8	%
Funds affiliated with Rho Ventures (12)	1,052,966	8.1	%
Funds affiliated with Visium Asset Management (13)	920,000	7.1	%

*Represents beneficial ownership of less than 1% of the shares of Common Stock.

(1) Includes (a) options to purchase 262,273 shares of common stock that are exercisable within 60 days of March 15, 2016; (b) restricted stock units to purchase 107,820 shares of common stock that are exercisable within 60 days of March 15, 2016; (c) 1,000 shares of common stock issuable under a Restricted Stock Unit Grant within 60 days of March 15, 2016 and (d) 14,500 shares of common stock.

(2) Consists of options to purchase 278,587 shares of common stock that are exercisable within 60 days of March 15, 2016.

(3) Includes (a) options to purchase 47,494 shares of common stock that are exercisable within 60 days of March 15, 2016 and (b) restricted stock units to purchase 22,730 shares of common stock that are exercisable within 60 days of March 15, 2016.

(4) Consists of options to purchase 8,600 shares of common stock that are exercisable within 60 days of March 15, 2016. Mr. Markham is one of four managing members at Care Capital III, LLC. Care Capital III, LLC is the general partner of Care Capital Investments III, LP and Care Capital Offshore Investments III, LP (collectively referred to herein as "Care Capital"). Mr. Markham disclaims beneficial ownership of the shares held by Care Capital.

(5) Consists of options to purchase 8,600 shares of common stock that are exercisable within 60 days of March 15, 2016.

(6) Consists of options to purchase 8,600 shares of common stock that are exercisable within 60 days of March 15, 2016.

(7) Consists of options to purchase 8,600 shares of common stock that are exercisable within 60 days of March 15, 2016 and 76,045 shares of common stock, which were acquired upon the pro rata distribution of shares from the dissolution of Biostratum, Inc., beneficially owned by Mr. Steiner and indirectly held through Setraco EHF.

(8) Consists of options to purchase 29,526 shares of common stock that are exercisable within 60 days of March 15, 2016.

(9) Consists of restricted stock units to purchase 16,216 shares of common stock that are exercisable within 60 days of March 15, 2016.

(10) Includes (a) options to purchase 456,608 shares of common stock beneficially owned by our officers and directors that are exercisable within 60 days of March 15, 2016; (b) restricted stock units to purchase 146,766 shares of common stock beneficially owned by our officers that are exercisable within 60 days of March 15, 2016 and (c) 1,000 share of commons stock issuable to Mr. Legault under a Restricted Stock Unit Grant within 60 days of March 15, 2016.

(11) This information is based on the Schedule 13D filed with the SEC on February 24, 2014, by Care Capital III LLC, a Delaware limited liability company ("Care Capital III LLC"), Care Capital Investments III LP, a Delaware limited partnership ("Care Capital Investments III LP"), and Care Capital Offshore Investments III LP, a Cayman Islands exempted limited partnership ("Care Capital Offshore Investments III LP"). Mr. Markham, Jan Leschly, Jerry N. Karabelas and David R. Ramsay are the four managing members at Care Capital III, LLC, and in their capacity as such, may be deemed to exercise shared voting and investment power over the shares held by Care Capital. The address of Care Capital is 47 Hulfish Street, Princeton, New Jersey 08542.

(12) This information is based on the Schedule 13D filed with the SEC on January 7, 2015, by Rho Ventures V, L.P. ("RV V"), Rho Ventures V Affiliates, L.L.C. ("RV V Affiliates"), RMV V, L.L.C. ("RMV") and Rho Capital Partners LLC ("RCP," and together with RV V, RV V Affiliates, RMV, collectively, the "Rho Entities") (the "Rho 13D"). The address for the Rho Ventures group is Carnegie Hall Tower, 152 West 57th Street, 23rd Floor, New York, New York 10019.

(13) This information is based on the Schedule 13G/A filed with the SEC on February 12, 2016 by Visium Balanced Master Fund, Ltd. ("VBMF"), Visium Asset Management, LP ("VAM"), JG Asset, LLC ("JG Asset"), and Jacob Gottlieb (the "Visium 13G/A"). VAM, JG Asset and Mr. Gottlieb disclaim beneficial ownership of the securities, except to the extent of his or its pecuniary interest therein. The mailing address of the beneficial

owner is 888 Seventh Avenue, New York, NY 10019.

Item 13. Certain Relationships and Related Transactions, and Director Independence

In addition to the director and executive officer compensation arrangements discussed above in "Executive and Director Compensation," during the past two years, we have been a party to the following transactions in which the amount involved exceeded $120,000 and in which any director, executive officer or holder of more than 5% of our voting securities, whom we refer to as our principal stockholders, or affiliates or immediate family members of our directors, executive officers and principal stockholders had or will have a material interest. We believe that all of these transactions were on terms as favorable as could have been obtained from unrelated third parties.

Director and Executive Officer Compensation

Please see "Executive and Director Compensation" for information regarding compensation of directors and executive officers.

Payments for Services

During 2013, 2014 and 2015, we paid Care Capital, LLC, an affiliate of our largest shareholder, $124,000, $70,000 and $0, respectively, for accounting services provided to us by a Care Capital, LLC employee.

Participation in our Initial Public Offering

Entities affiliated with Care Capital, LLC purchased an aggregate of 790,000 shares of our common stock in our initial public offering at the initial public offering price for an aggregate purchase price of approximately $9.5 million.

Indemnification Agreements

We enter into indemnification agreements with each of our directors and officers. The indemnification agreements and our restated certificate of incorporation and restated bylaws require us to indemnify our directors and officers to the fullest extent permitted by Delaware law.

Policy for Approval of Related Person Transactions

Pursuant to the written charter of our Audit Committee, the Audit Committee is responsible for reviewing and approving, prior to our entry into any such transaction, all transactions in which we are a participant and in which any parties related to us, including our executive officers, our directors, beneficial owners of more than 5% of our securities, immediate family members of the foregoing persons and any other persons whom our Board of Directors determines may be considered related parties under Item 404 of Regulation S-K, has or will have a direct or indirect material interest.

In reviewing and approving such transactions, the Audit Committee shall obtain, or shall direct our management to obtain on its behalf, all information that the committee believes to be relevant and important to a review of the transaction prior to its approval. Following receipt of the necessary information, a discussion shall be held of the relevant factors if deemed to be necessary by the committee prior to approval. If a discussion is not deemed to be necessary, approval may be given by written consent of the committee. This approval authority may also be delegated to the chair of the Audit Committee in some circumstances. No related party transaction shall be entered into prior to the completion of these procedures.

The Audit Committee or its chair, as the case may be, shall approve only those related party transactions that are determined to be in, or not inconsistent with, the best interests of us and our stockholders, taking into account all available facts and circumstances as the committee or the chair determines in good faith to be necessary in accordance with principles of Delaware law generally applicable to directors of a Delaware corporation. These facts and circumstances will typically include, but not be limited to, the benefits of the transaction to us; the impact on a director's independence in the event the related party is a director, an immediate family member of a director or an entity in which a director is a partner, stockholder or executive officer; the availability of other sources for comparable products or services; the terms of the transaction; and the terms of comparable transactions that would be available to unrelated third parties or to employees generally. No member of the Audit Committee shall participate in any review, consideration or approval of any related party transaction with respect to which the member or any of his or her immediate family members has an interest.

Item 14. Principal Accounting Fees and Services

The Audit Committee has appointed EisnerAmper LLP ("EisnerAmper"), as our independent registered public accounting firm, to audit our financial statements for the fiscal year ending December 31, 2015. Accordingly, EisnerAmper audited our financial statements for the fiscal year ended December 31, 2015.

In deciding to appoint EisnerAmper, the Audit Committee reviewed auditor independence issues and existing commercial relationships with EisnerAmper and concluded that EisnerAmper had no commercial relationship with the Company that would impair its independence for the fiscal year ending December 31, 2015.

81

Audit Fees

The following table presents fees for professional audit services and fees billed for other services rendered by EisnerAmper for the audit of the Company's annual financial statements for the years ended December 31, 2015 and 2014.

	2015	2014
Audit fees	$238,113	$275,875
Audit related fees	—	—
Tax fees	7,500	8,800
All other fees	—	—
Total	$245,613	$284,675

Audit Fees. Audit fees for 2015 consisted of fees incurred for professional services rendered for the audit of our annual financial statements, review of our quarterly reports on Form 10-Q, review of our registration statement on Form S-1, Form S-3 and other regulatory filings. Audit fees for 2014 consisted of fees for audit services related to the review of our registration statement on Form S-1 and fees associated with our annual audit and the review of our quarterly reports on Form 10-Q and other regulatory filings.

Audit-Related Fees. There were no fees for the category “Audit-Related Fees” in 2015 and 2014.

Tax Fees. Tax fees for 2015 and 2014 were for the preparation of our corporate income tax returns.

All Other Fees. There were no fees for the category “All Other Services” in 2015 and 2014.

Pre-Approval Policies and Procedures

Our Audit Committee has established a policy that requires it to pre-approve all services provided by the Company’s independent registered public accounting firm and the fees for such services. The prior approval of our Audit Committee was obtained for all services provided by EisnerAmper after completing the initial public offering in February 2014 and the fees for such services. Audit fees prior to the IPO, consisted of audit work performed in the preparation of our 2013 financial statements as well as work generally only the independent registered public accounting firm can reasonably be expected to provide. Audit fees for 2013 and 2014 also consisted of audit and tax services and other fees related to the review of our registration statement on Form S-1.

PART IV

Item 15. Exhibits

Exhibits required by Item 601 of Regulation S-K.

EXHIBIT INDEX

Exhibit Number	Exhibit Description	Incorporated by Reference	Filing Date	SEC File/Reg. Number
3.1	Restated Certificate of Incorporation of the Registrant.	Form 8-K (Exhibit 3.1)	2/14/2014	001-36303
3.2	Restated Bylaws of the Registrant.	Form 8-K (Exhibit 3.2)	2/14/2014	001-36303
4.1	Form of Common Stock Certificate.	Form S-1 (Exhibit 4.1)	1/10/2014	333-193023
4.2	Form of Representative's Warrant.	Form S-1 (Exhibit 4.2)	1/29/2014	333-193023
4.3	Amended and Restated Investors' Rights Agreement, dated February 28, 2008, as amended February 14, 2014.	Form 10-K (Exhibit 4.3)	3/31/2014	001-36303
4.4	Form of Common Stock Purchase Warrant.	Form 8-K (Exhibit 4.1)	7/22/2015	001-36303
4.5	Form of Warrant.	Form 8-K (Exhibit 4.1)	11/09/2015	001-36303
10.1*	Executive Employment Agreement by and between the Registrant and Pierre Legault, dated November 7, 2013.	Form S-1 (Exhibit 10.1)	12/23/2013	333-193023
10.1.1*	Restricted Stock Unit Grant Notice and Agreement by and between the Registrant and Pierre Legault, dated November 7, 2013.	Form 10-K (Exhibit 10.1.1)	9/15/2014	001-36303
10.2*	Offer of Employment Letter by and between the Registrant and Bob Peterson, dated August 8, 2009.	Form S-1 (Exhibit 10.2)	12/23/2013	333-193023
10.3*	Employment Agreement by and between J. Wesley Fox and the Registrant, dated April 30, 2007.	Form S-1 (Exhibit 10.3)	12/23/2013	333-193023
10.4*	Form of Indemnification Agreement by and between the Registrant and its directors and officers.	Form S-1 (Exhibit 10.4)	12/23/2013	333-193023
10.5	Office Lease, dated September 12, 2014 by and between NephroGenex, Inc. and Highwoods Realty Limited Partnership.	Form 8-K (Exhibit 10.2)	9/15/2014	001-36303
10.6.1	Amended and Restated License Agreement between University of Kansas Medical Center Research Institute, Inc. and BioStratum Incorporated (assigned to the Registrant), effective as of November 19, 1998.	Form S-1 (Exhibit 10.6.1)	12/23/2013	333-193023
10.6.2	First Amendment to Amended and Restated License Agreement between University of Kansas Medical Center Research Institute, Inc. and the Registrant, effective as of May 4, 2007.	Form S-1 (Exhibit 10.6.2)	12/23/2013	333-193023

10.6.3	Second Amendment to Amended and Restated License Agreement between University of Kansas Medical Center Research Institute, Inc. and the Registrant, effective as of June 25, 2008.	Form S-1 (Exhibit 10.6.3)	12/23/2013 333-193023
10.7.1	License Agreement between the University of South Carolina Research Foundation and BioStratum Incorporated (assigned to the Registrant), dated August 27, 2004.	Form S-1 (Exhibit 10.7.1)	12/23/2013 333-193023
10.7.2	Amendment to License Agreement between The South Carolina Research Foundation and the Registrant, effective as of June 20, 2011.	Form S-1 (Exhibit 10.7.2)	12/23/2013 333-193023

10.7.3	Second Amendment to License Agreement between The South Carolina Research Foundation and the Registrant, effective as of April 2, 2012.	Form S-1 (Exhibit 10.7.3)	12/23/2013	333-193023
10.7.4	Third Amendment to License Agreement between The South Carolina Research Foundation and the Registrant, effective as of August 9, 2013.	Form S-1 (Exhibit 10.7.4)	12/23/2013	333-193023
10.7.5	Fourth Amendment to License Agreement between The University of South Carolina Research Foundation and the Registrant, effective as of January 14, 2014.	Form S-1 (Exhibit 10.7.5)	01/17/2014	333-193023
10.8.1	License Agreement between Vanderbilt University and the Registrant, effective as of January 11, 2006.	Form S-1 (Exhibit 10.8.1)	12/23/2013	333-193023
10.8.2	First Amendment to License Agreement between Vanderbilt University and the Registrant, effective as of April 30, 2007.	Form S-1 (Exhibit 10.8.2)	12/23/2013	333-193023
10.8.3	Restated and Amended License Agreement between Vanderbilt University and the Registrant, effective as of July 1, 2012.	Form S-1 (Exhibit 10.8.3)	12/23/2013	333-193023
10.8.4	First Amendment to Restated and Amended License Agreement between Vanderbilt University and the Registrant, effective as of November 6, 2013.	Form S-1 (Exhibit 10.8.4)	12/23/2013	333-193023
10.8.5	Second Amendment to Restated and Amended License Agreement between Vanderbilt University and the Registrant, effective as of March 16, 2015.	Form S-1 (Exhibit 10.8.5)	04/30/2015	333-203530
10.9.1	License Agreement between BioStratum, Incorporated and the Registrant, effective as of May 8, 2006.	Form S-1 (Exhibit 10.9.1)	12/23/2013	333-193023
10.9.2	Amendment to License Agreement between BioStratum, Incorporated and the Registrant, effective September 13, 2006.	Form S-1 (Exhibit 10.9.2)	12/23/2013	333-193023
10.9.3	Grant Back License Agreement by and between the Registrant and BioStratum, Incorporated, dated May 4, 2007.	Form S-1 (Exhibit 10.9.3)	12/23/2013	333-193023
10.10*	NephroGenex, Inc. Amended and Restated 2007 Equity Incentive Plan.	Form 8-K (Exhibit 10.1)	05/15/2014	001-36303
10.10.1*	Amendment 2015-1 to the NephroGenex, Inc. Amended and Restated 2007 Equity Incentive Plan.	Form 8-K (Exhibit 3.2)	02/05/2015	001-36303
10.10.2**	NephroGenex, Inc. Amended and Restated 2007 Equity Incentive Plan, as amended.			
10.11*	Executive Employment Agreement between the Registrant and John P. Hamill, dated December 12, 2013.	Form 8-K (Exhibit 10.11)	12/23/2013	333-193023
10.12	Form of Omnibus Agreement and Consent among the Registrant, Care Capital Investments III, LP, Care Capital Offshore Investments III, LP, Rho Ventures V, L.P., Rho Ventures V Affiliates, L.L.C., Biostratum, Incorporated, Vanderbilt University, Vanderbilt University Medical Center, Vanderbilt University, by and through its Medical Center and	Form 8-K (Exhibit 10.12)	01/10/2014	333-193023

	John B. Mazur.			
10.13	Loan and Securities Agreement, dated November 20, 2014, by and between the Company and East West Bank.	Form 8-K (Exhibit 10.1)	11/20/2014	001-36303
10.14	Intellectual Property Security Agreement, dated November 20, 2014, by and between the Company and East West Bank.	Form 8-K (Exhibit 10.2)	11/20/2014	001-36303
10.15	Warrants, dated November 20, 2014, issued by the Company to East West Bank.	Form 8-K (Exhibit 10.3)	11/20/2014	001-36303
10.16*	Executive Employment Agreement, dated as of July 2, 2015, by and between NephroGenex, Inc. and Jaikrishna Patel.	Form S-1 (Exhibit 10.16)	07/07/2015	333-203530
10.17*	Consulting Agreement by and between NephroGenex, Inc. and J. Wesley Fox, Ph.D.	Form 8-K (Exhibit 10.1)	08/06/2015	001-36303

10.18	At Market Issuance Sales Agreement, dated as of August 7, 2015, between the Registrant and MLV & Co., LLC.	Form S-3 (Exhibit 1.2)	08/07/2015	333-206229
10.19	Form of Securities Purchase Agreement.	Form 8-K (Exhibit 10.1)	11/09/2015	001-36303
10.20	Form of Registration Rights Agreement.	Form 8-K (Exhibit 10.2)	11/09/2015	001-36303
10.21*	Form of Restricted Stock Unit Agreement under the Registrant's Amended and Restated 2007 Equity Incentive Plan, as amended.	Form 8-K (Exhibit 10.1)	11/13/2015	001-36303
23.1**	Consent of Independent Auditor			
31.1**	Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002			
31.2**	Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002			
32**	Certifications of the Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002			
101***	Financials in XBRL			

* Management contract or compensatory plan
** Filed herewith
*** Furnished herewith

Attached as Exhibits 101 to this report are the following financial statements from our Annual Report on Form 10-K for the year ended December 31, 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 Annual Report on Form 10-K 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 Section 13 or 15(d) 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: March 28, 2016

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities indicated below and on the dates indicated.

Signature	Title	Date
/s/ PIERRE LEGAULT Pierre Legault	Chief Executive Officer and Director (Principal Executive Officer)	March 28, 2016
/s/ JOHN P. HAMILL John P. Hamill	Chief Financial Officer (Principal Financial and Accounting Officer)	March 28, 2016
/s/ RICHARD MARKHAM Richard Markham	Director	March 28, 2016
/s/ JAMES MITCHUM James Mitchum	Director	March 28, 2016
/s/ ROBERT R. SELTZER Robert R. Seltzer	Director	March 28, 2016
/s/ EUGEN STEINER Eugene Steiner, M.D., PhD.	Director	March 28, 2016
/s/ MARCO TAGLIETTI Marco Taglietti, M.D.	Director	March 28, 2016