

## **NephroGenex Inc**

### **CORTELLIS COMPANY DETAILED PIPELINE REPORT**

A comprehensive coverage of the the company's drug pipeline portfolio including detailed product records.

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[Return to Table of Contents](#)



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[Return to Table of Contents](#)



## GLOSSARY

### Number of Drugs in Active Development

Number of drugs associated with the company or subsidiary that are currently in active development, i.e. the development status for the drug(s) is one of the following: Discovery, Clinical, Phase I, Phase II, Phase III, Pre-registration, Registered, Launched, or Suspended.

### Number of Inactive Drugs

Number of drugs associated with the company or subsidiary that are currently classified as inactive, i.e. where the development status for the drug(s) is one of the following: No Development Reported, Discontinued, or Withdrawn.

### Number of Patents as Owner

Number of patents associated with the company where the company is listed as owner; i.e. the relationship type (or way the patent refers to the company) is: Patent Assignee/Owner, Patent owner (not assignee), Licensee for development and marketing, Licensee – marketing only (Distributor), Patent assignee of family member, Inferred assignee.

### Number of Patents as Third Party

Number of patents associated with the company where the company is listed as third party; i.e. the relationship type (or way the patent refers to the company) is: Patent assignee (not owner), Ex-Licensee for development and marketing, Ex-Licensee marketing only (Distributor), Customer of technology, Ex-Customer of technology, Patent opponent or infringer, Affiliate organization of inventor, Owner of underlying technology.

### Patents summary table

This table represents a summary of the core patent coverage for this company covering Therapeutic EP, US and WO patents since 1990 only.

### Number of Deals

A count of deals where the company or one of its subsidiaries is the primary company.

### Key Indications

Displays top ten key indications for the company and its subsidiaries based on frequency (indications occurring with high and identical frequency are always included, and this may result in more than ten Key Indications being listed). Includes both indications associated with patents where the company is patent owner and indications associated with drugs in active development. A drug is classified as 'active' if it features on a row (or rows) in the current development status table where the status is one of the following: Discovery, Clinical, Phase I, Phase II, Phase III, Pre-registration, Registered, Launched, or Suspended.

### Key Target-based Actions

Displays top ten key target-based actions for the company and its subsidiaries based on frequency (actions occurring with high and identical frequency are always included, and this may result in more than ten Key Target-based Actions being listed). Includes both target-based actions associated with patents where the company patent owner and target-based actions associated with drugs in active development. A drug is classified as 'active' if it features on a row (or rows) in the current development status table where the status is one of the following: Discovery, Clinical, Phase I, Phase II, Phase III, Pre-registration, Registered, Launched, or Suspended. A target-based action is one that is associated with a target.

### Key Technologies

Displays top ten key technologies for the company and its subsidiaries based on frequency (technologies occurring with high and identical frequency are always included, and this may result in more than ten Key Technologies being listed). Includes both key technologies associated with patents where the company relationship is patent owner and key technologies associated with drugs in active development. A drug is classified as 'active' if it features on a row (or rows) in the current development status table where the status is one of the following: Discovery, Clinical, Phase I, Phase II, Phase III, Pre-registration, Registered, Launched, or Suspended.

[Return to Table of Contents](#)



TABLE OF CONTENTS

Company Overview..... 5

Company Profile..... 6

Product Portfolio Summary..... 6

Product Portfolio Drug Pipeline Detail..... 9

    Phase 3 Clinical..... 10

    Discovery..... 17

[Return to Table of Contents](#)

# NephroGenex Inc

## COMPANY OVERVIEW

Company Name	NephroGenex Inc
Parent Company Name	NephroGenex Inc
Website	<a href="http://www.nephrogenex.com/">http://www.nephrogenex.com/</a>
Country	US
Number of Drugs in Active Development	2
Number of Inactive Drugs	2
Number of Patents as Owner	3
Number of Patents as Third Party	0
Number of Deals	7
Key Indications	Diabetic nephropathy, Renal injury, Renal failure
Key Target-based Actions	
Key Technologies	Intravenous formulation, Small molecule therapeutic, Synthetic method

## COMPANY PROFILE

### SUMMARY

NephroGenex is a biotechnology company based in Cary, NC. The company is applying the latest advances in molecular profiling technologies with regard to developing drugs for the potential treatment of kidney disease, and is acquiring commercial rights to clinical-stage candidates that exhibit activity toward established renal pathology, as well as identifying renal molecular profiles and biomarkers that identify patients that are more likely to respond to therapy.

### LICENSING AGREEMENTS

In May 2005, NephroGenex acquired exclusive commercial rights to glomerular transcriptome profiling technology developed by Drs. Karl Tryggvason and Christer Betsholtz of the Department of Medical Biochemistry and Biophysics at the Karolinska Institute. The technology utilizes GlomChip, a DNA chip developed to measure expressed genes in the glomerulus.

### FINANCIAL

In February 2014, the company expected to raise gross proceeds of \$37,200,000 from an IPO of 3,100,000 shares of its common stock, priced at \$12.00 per share. The underwriters were granted a 45-day option to buy up to an additional 465,000 shares of common stock to cover any over-allotments. At that time, the offering was expected to close on February 14, 2014. Also at that time, the company's common stock was approved for listing on the NASDAQ Capital Market and trading was expected to begin under the ticker symbol "NRX" on February 11, 2014. Later that month, trading of shares began; and the IPO was closed and the company raised net proceeds of \$33.4 million.

[Return to Table of Contents](#)

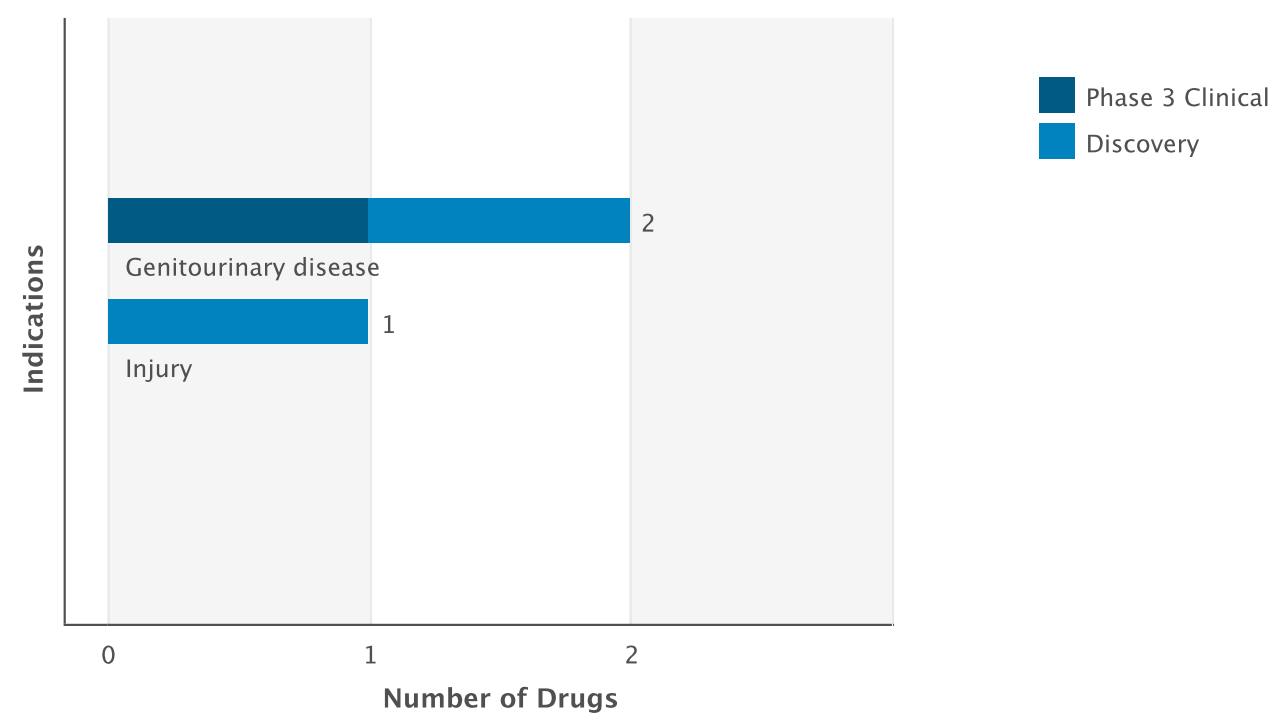


PRODUCT PORTFOLIO SUMMARY

DRUGS

Drugs by Indication

Active Drugs by Indication Chart



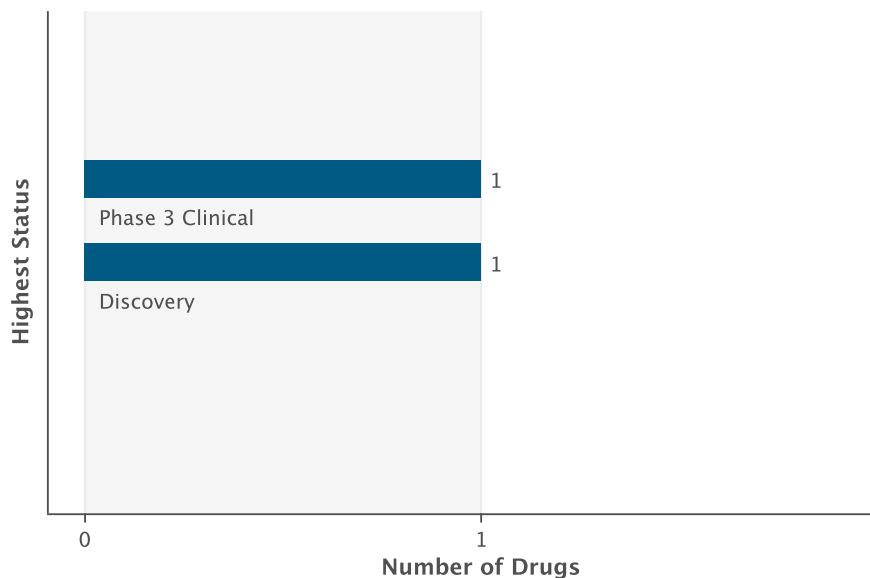
Drugs by Indication Table

Indication	Active	Inactive	Total
Genitourinary disease	2	1	3
Metabolic disorder	0	1	1
Endocrine disease	0	1	1
Injury	1	0	1
Gastrointestinal disease	0	1	1

[Return to Table of Contents](#)

## Drugs by Highest Status

Active Drugs by Highest Status Chart



Drugs by Highest Status Table

Development Status	Number of Drugs
Phase 3 Clinical	1
Discovery	1
No Development Reported	2

## DEALS

Deal Type	Principal		Partner		Total
	Active	Inactive	Active	Inactive	
Technology - Other Proprietary	0	0	1	0	1
Drug - Development/Commercialization License	0	0	2	0	2
Drug - Commercialization License	0	0	1	0	1
Drug - Manufacturing/Supply	0	0	1	0	1
Drug - Development Services	0	0	2	0	2

[Return to Table of Contents](#)

## CLINICAL TRIALS

### Trials by Condition Studied

Condition Studied	Ongoing	All
Genitourinary disease	1	4

### Trials by Phase

Phase	Ongoing	All
Phase 3	1	1
Phase 2	0	2
Phase 1	0	1

### Phase Definitions

#### Phase 3 Clinical

Includes Phase 3, Phase 3b, Phase 3a, Phase 2/3 (where enrolment count is 300 or over)

#### Phase 2 Clinical

Includes Phase 2, Phase 2a, Phase 2b, Phase 1/2 (where enrolment count is 100 or over), Phase 2/3 (where enrolment count is under 300 or not specified)

#### Phase 1 Clinical

Includes Phase 1, Phase 1a, Phase 1, Phase 1/2 (where enrolment count is under 100 or not specified), Phase 0

## PATENTS \*

Indication	As Owner	As Third Party	Total
Cardiovascular disease	1	0	1
Endocrine disease	2	0	2
Gastrointestinal disease	2	0	2
Genitourinary disease	4	0	4
Musculoskeletal disease	1	0	1
Ocular disease	1	0	1
Metabolic disorder	3	0	3
Neurological disease	1	0	1
Inflammatory disease	1	0	1

\* This table represents a summary of the core patent coverage for this company covering Therapeutic EP, US and WO patents since 1990 only.

[Return to Table of Contents](#)





## PRODUCT PORTFOLIO DRUG PIPELINE DETAIL

**PLEASE NOTE:** Highest status refers to highest development of that drug for one of the active companies

### pyridoxamine dihydrochloride

#### pyridoxamine dihydrochloride SNAPSHOT

<b>Drug Name</b>	pyridoxamine dihydrochloride
<b>Key Synonyms</b>	Pyridorin
<b>Originator Company</b>	BioStratum Inc
<b>Active Companies</b>	NephroGenex Inc;Kowa Co Ltd
<b>Inactive Companies</b>	BioStratum Inc
<b>Highest Status</b>	Phase 3 Clinical
<b>Active Indications</b>	Psychiatric disorder;Diabetic nephropathy
<b>Target-based Actions</b>	
<b>Other Actions</b>	Glycosylation inhibitor;Antioxidant agent;Protectant
<b>Technologies</b>	Oral formulation;Small molecule therapeutic
<b>Last Change Date</b>	13-Nov-2014

#### pyridoxamine dihydrochloride DEVELOPMENT PROFILE

##### SUMMARY

NephroGenex, under license from BioStratum, is developing pyridoxamine dihydrochloride (Pyridorin,

In February 2001, Kowa licensed rights from Biostratum to develop, manufacture and market pyridoxamine in Asian markets for diabetic kidney disease . In July 2014, preparation was underway by Kowa to evaluate the drug for the treatment of mental disorder.

Previously kowa was developing the drug for diabetic nephropathy. By February 2006, Kowa had initiated a phase II trial in Japan for diabetic nephropathy ; by December 2007, this trial was ongoing . However, by November 2008, the program was no longer listed on Kowa's pipeline.

[Return to Table of Contents](#)

NephroGenex, utilizing certain rights from Vanderbilt University, was also investigating the drug for the potential treatment of acute renal failure. In May 2006, NephroGenex was planning a phase IIa/IIb study in patients with acute renal failure ; however, by December 2013, the program was no longer listed on the company's pipeline.

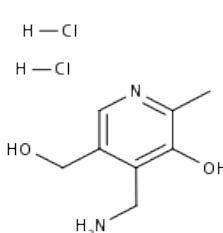
NephroGenex is also investigating a series of second generation AGE inhibitors.

## pyridoxamine dihydrochloride DEVELOPMENT STATUS

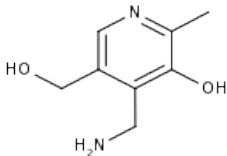
### CURRENT DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
NephroGenex Inc	Diabetic nephropathy	US	Phase 3 Clinical	13-Jun-2014
Kowa Co Ltd	Psychiatric disorder	Japan	Discovery	31-Jul-2014
NephroGenex Inc	Diabetic nephropathy	Europe	Discovery	31-Mar-2014
BioStratum Inc	Diabetic nephropathy	US	Discontinued	10-May-2006
Kowa Co Ltd	Diabetic nephropathy	Japan	No Development Reported	30-Nov-2008
NephroGenex Inc	Renal failure	US	No Development Reported	02-Dec-2013

## pyridoxamine dihydrochloride CHEMICAL STRUCTURES

CAS Registry Number:	Confidence Level:
	1
	
Name	Type
Pyridorin	Trade Name
pyridoxamine dihydrochloride	
Pyridorin-XR	

[Return to Table of Contents](#)

CAS Registry Number:	Confidence Level:
85-87-0	1
	
Name	Type
K-163	Research Code
pyridoxamine	

### pyridoxamine dihydrochloride DRUG NAMES

Names	Type
pyridoxamine	
BST-4001	Research Code
pyridoxamine dihydrochloride	
K-163	Research Code
Pyridorin-XR	
Pyridorin	Trade Name
K-163-SZ	Research Code

### pyridoxamine dihydrochloride CLINICAL TRIALS

#### Trials by Phase and Condition Studied

Phase 4 Clinical		Phase 3 Clinical		Phase 2 Clinical		Phase 1 Clinical		Phase Unspecified		Total	
On-going	All	On-going	All	On-going	All	On-going	All	On-going	All	On-going	All
Diabetic nephropathy											
0	0	1	1	0	4	0	3	0	0	1	8
Urolithiasis											
0	0	0	0	0	1	0	0	0	0	0	1

[Return to Table of Contents](#)

Renal failure											
0	0	0	0	0	0	0	1	0	0	0	1
Proteinuria											
0	0	0	0	0	0	0	0	0	1	0	1
Insulin dependent diabetes											
0	0	0	0	0	0	0	1	0	0	0	1

### Total Trials by Phase and Status

Phase 4 Clinical		Phase 3 Clinical		Phase 2 Clinical		Phase 1 Clinical		Phase Unspecified		Total	
On-going	All	On-going	All	On-going	All	On-going	All	On-going	All	On-going	All
Total by Phase and Status											
0	0	1	1	0	5	0	3	0	1	1	10

### Phase Definitions

#### Phase 3 Clinical

Includes Phase 3, Phase 3b, Phase 3a, Phase 2/3 (where enrolment count is 300 or over)

#### Phase 2 Clinical

Includes Phase 2, Phase 2a, Phase 2b, Phase 1/2 (where enrolment count is 100 or over), Phase 2/3 (where enrolment count is under 300 or not specified)

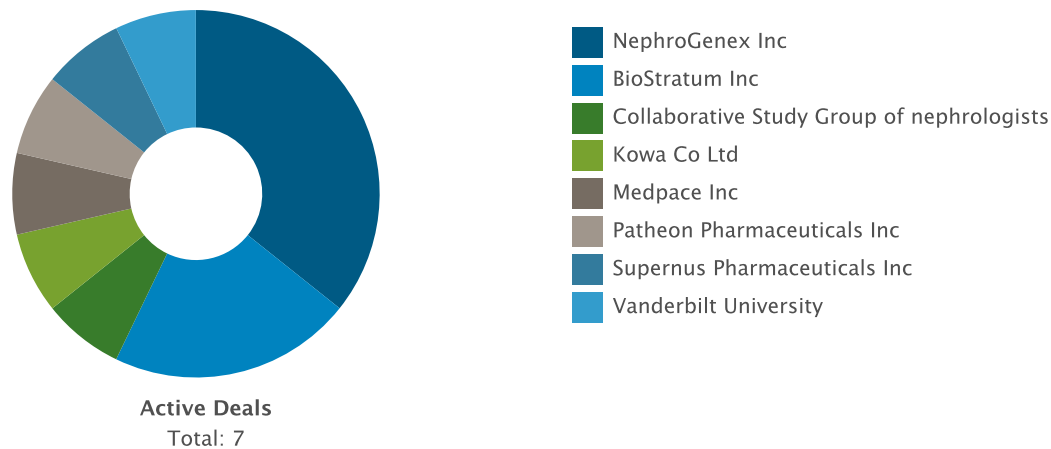
#### Phase 1 Clinical

Includes Phase 1, Phase 1a, Phase 1, Phase 1/2 (where enrolment count is under 100 or not specified), Phase 0

[Return to Table of Contents](#)

DEALS

Deals by Parent Company Chart

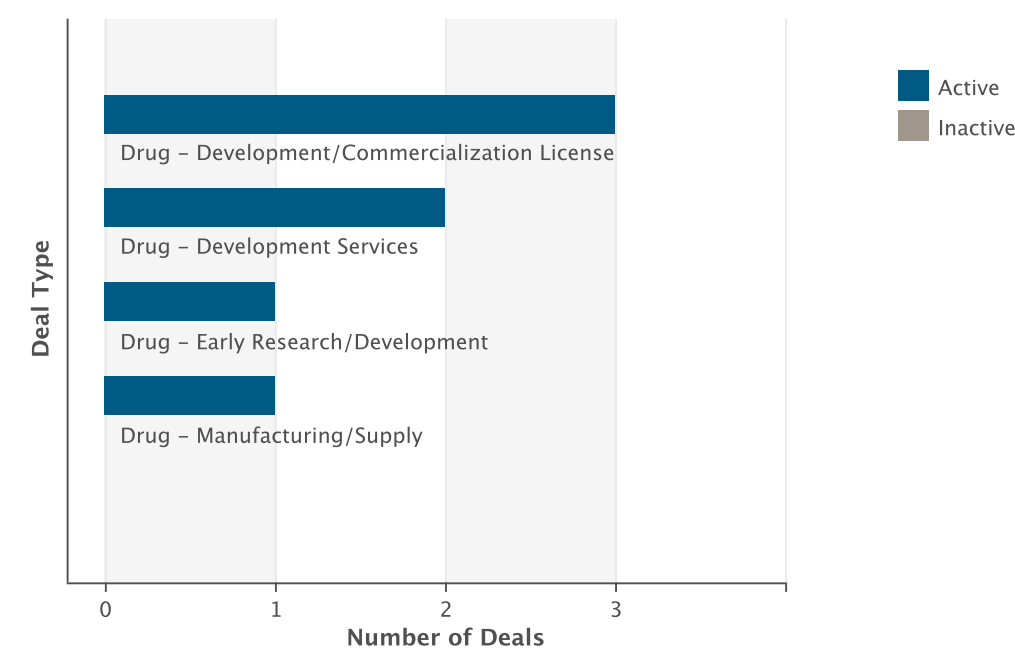


Deals by Parent Company Table

Company Name	Principal		Partner		Total
	Active	Inactive	Active	Inactive	
NephroGenex Inc	0	0	5	0	5
BioStratum Inc	3	0	0	0	3
Patheon Pharmaceuticals Inc	1	0	0	0	1
Collaborative Study Group of nephrologists	1	0	0	0	1
Kowa Co Ltd	0	0	1	0	1
Medpace Inc	1	0	0	0	1
Vanderbilt University	1	0	0	0	1
Supernus Pharmaceuticals Inc	0	0	1	0	1

[Return to Table of Contents](#)

Deals by Type Chart



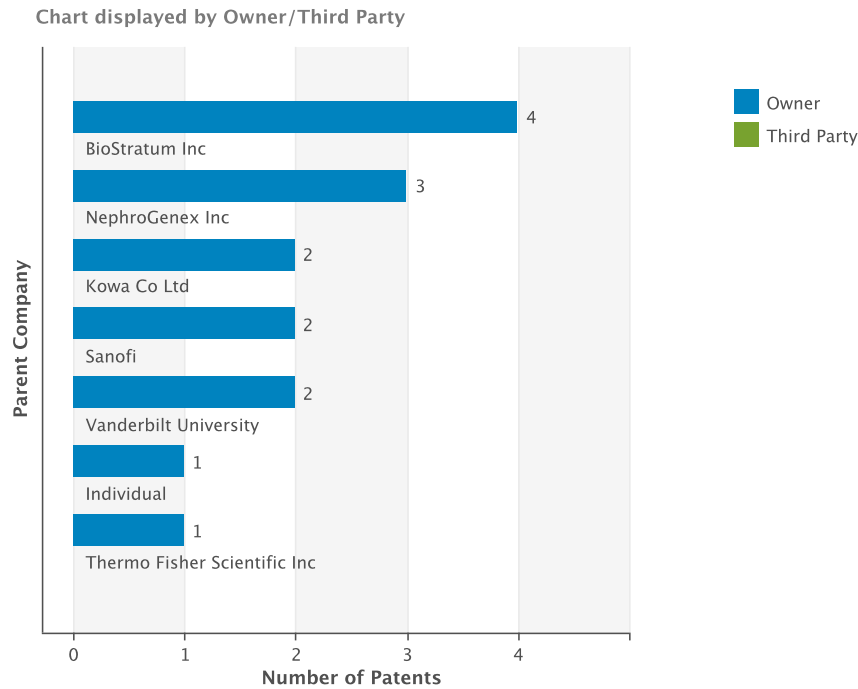
Deals by Type Table

Deal Type	Active	Inactive	Total
Drug - Development/Commercialization License	3	0	3
Drug - Development Services	2	0	2
Drug - Early Research/Development	1	0	1
Drug - Manufacturing/Supply	1	0	1

[Return to Table of Contents](#)

PATENTS

Patents by Parent Company Chart

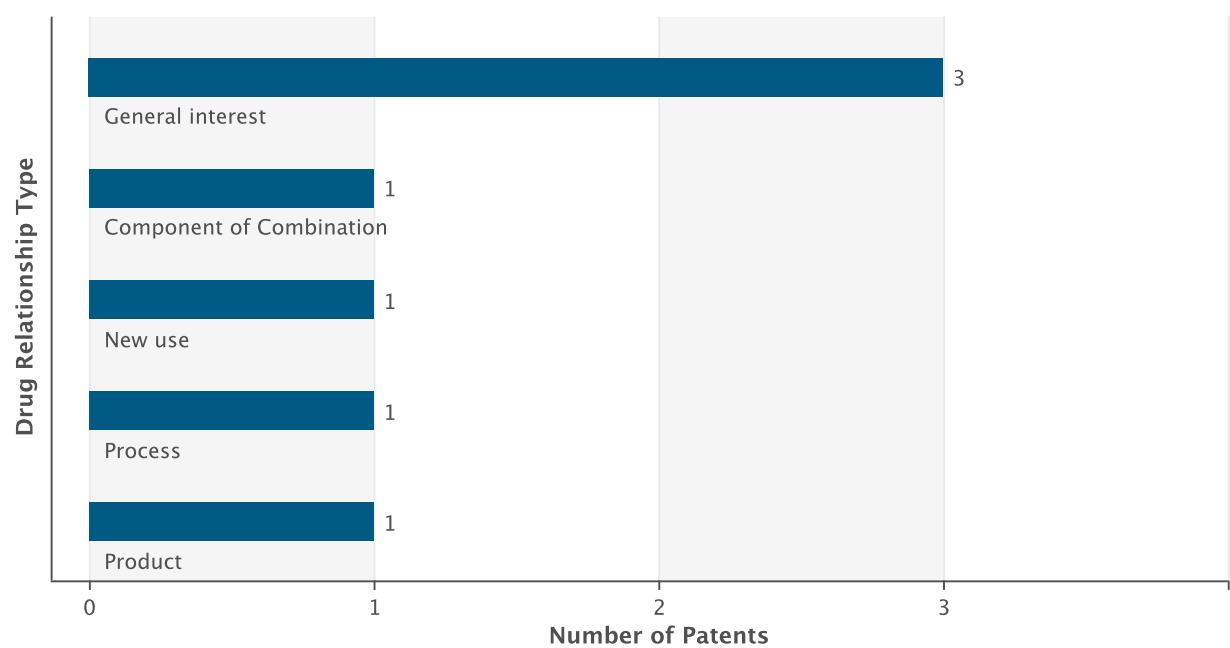


Patents by Parent Company Table

Company Name	As Owner	As Third Party	Total
BioStratum Inc	4	0	4
NephroGenex Inc	3	0	3
Vanderbilt University	2	0	2
Sanofi	2	0	2
Kowa Co Ltd	2	0	2
Individual	1	0	1
Thermo Fisher Scientific Inc	1	0	1

[Return to Table of Contents](#)

Patents by Drug Relationship Type Chart



Patents by Drug Relationship Type Table

Drug Relationship	Total
General interest	3
Product	1
Process	1
New use	1
Component of Combination	1



## pyridoxamine dihydrochloride (intravenous, acute kidney injury), NephroGenex

### pyridoxamine dihydrochloride (intravenous, acute kidney injury), NephroGenex SNAPSHOT

Drug Name	pyridoxamine dihydrochloride (intravenous, acute kidney injury), NephroGenex
Key Synonyms	Pyridorin
Originator Company	NephroGenex Inc
Active Companies	NephroGenex Inc
Inactive Companies	
Highest Status	Discovery
Active Indications	Renal injury
Target-based Actions	
Other Actions	Antioxidant agent;Protectant;Glycosylation inhibitor
Technologies	Intravenous formulation;Small molecule therapeutic
Last Change Date	13-Nov-2014

### pyridoxamine dihydrochloride (intravenous, acute kidney injury), NephroGenex DEVELOPMENT PROFILE

#### SUMMARY

NephroGenex is investigating an intravenous formulation of pyridoxamine dihydrochloride (Pyridorin) for the potential treatment of acute kidney injury. In December 2013, development was ongoing. In March 2014, the company planned to initiate pre-clinical program, later that year ; in October 2014, the company expected to complete preclinical studies. By November 2014, preclinical study in ischemic reperfusion induced acute kidney injury was completed. In October 2014filing an IND application and to initiate phase I/II trials by 2015.

### pyridoxamine dihydrochloride (intravenous, acute kidney injury), NephroGenex DEVELOPMENT STATUS

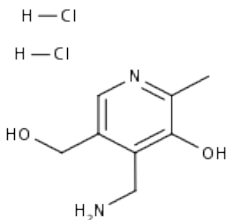
#### CURRENT DEVELOPMENT STATUS

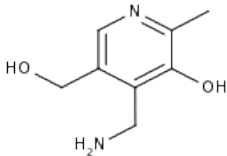
Company	Indication	Country	Development Status	Date
NephroGenex Inc	Renal injury	US	Discovery	02-Dec-2013

### pyridoxamine dihydrochloride (intravenous, acute kidney injury), NephroGenex CHEMICAL STRUCTURES

[Return to Table of Contents](#)



CAS Registry Number:	Confidence Level:
	1
	
Name	Type
Pyridorin	Trade Name
Pyridorin-XR	
pyridoxamine dihydrochloride	

CAS Registry Number:	Confidence Level:
85-87-0	1
	
Name	Type
K-163	Research Code
pyridoxamine	

### pyridoxamine dihydrochloride (intravenous, acute kidney injury), NephroGenex DRUG NAMES

Names	Type
pyridoxamine	
Pyridorin	Trade Name
pyridoxamine dihydrochloride (intravenous, acute kidney injury), NephroGenex	
pyridoxamine dihydrochloride	

[Return to Table of Contents](#)

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[Return to Table of Contents](#)

