

NephroGenex Inc

CORTELLIS COMPANY DETAILED PIPELINE REPORT

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

Publication Date: 15-Dec-2014

THOMSON REUTERS

3 Times Square
New York, New York 10036
United States

Tel: +1 646 223 4000

thomsonreuters.com

[Return to Table of Contents](#)

ABOUT CORTELLIS COMPANY DETAILED PIPELINE REPORT

Thomson Reuters provides the knowledge, tools, and expertise to help support drug discovery and development activities, IP portfolio optimization, identification of licensing and partnering opportunities, delivery of successful regulatory submissions, and the ability to keep current with the rapidly-changing pharmaceutical and chemical markets, supporting informed, early decisions.

This report was created by Thomson Reuters, using information from *Thomson Reuters Cortellis™ for Competitive Intelligence*; a comprehensive, proven intelligence solution that leverages the most accurate, complete, and widely respected drug pipeline information. From drug discovery and development activities to patent reports, the latest deals, and partnering opportunities, *Cortellis* can provide the confidence to make the most informed business decisions, faster. *Cortellis for Competitive Intelligence* provides accurate and validated information on pharmaceutical and biotechnology companies globally, their drug pipelines, deals, patents, and clinical trials, plus breaking industry news and conference coverage. All contained in one simple, highly intuitive research platform.

Cortellis Company Detailed Pipeline reports are the second in a series of that track pharmaceutical and biotechnology companies worldwide. All *Cortellis for Competitive Intelligence* content is subject to the most comprehensive editorial review process available, conducted by scientists, pharma professionals, regulatory experts, and generics specialists. Featuring timely drug pipeline information expertly uncovered and integrated from over 400 global meetings each year, you'll always be on top of the latest developments.

Chosen by leading life sciences companies, their executives and investors, *Cortellis for Competitive Intelligence* accelerates your deal-making and gives you timely insights on the development landscape.

Discover undiscovered opportunities in drug development and licensing faster with *Thomson Reuters Cortellis™ for Competitive Intelligence*

DISCLAIMER

The information contained in this report is based on sources believed to be correct but Thomson Reuters does not guarantee the accuracy, timeliness, or completeness of this information. Opinions, if any, are those held by the author of any individual report or article at the time of initial publication and do not necessarily reflect the views of Thomson Reuters.

Information in this report on companies is intended for reference use only, and does not constitute a recommendation to buy or sell any particular security or other investment and does not constitute an offer to buy from or sell to any particular investor. Any company or securities mentioned in this report may not be suitable for any particular investor, depending on that investor's financial position and needs.

[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	http://www.nephrogenex.com/
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 November 2014, NephroGenex closed a \$12 million term loan facility with East West Bank, which includes an immediate \$7 million draw, with the additional \$5 million available upon the achievement of certain milestones before the end of May 2015. The bank facility was to mature in 2018.

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](#)

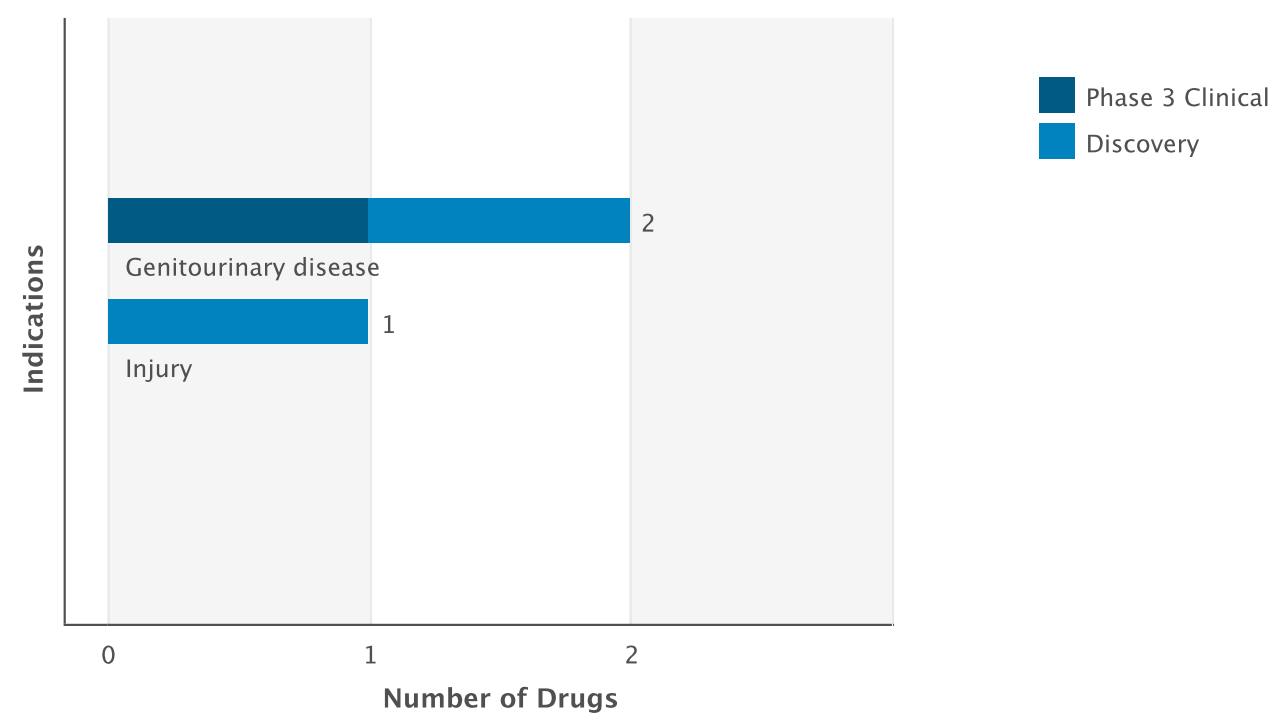


PRODUCT PORTFOLIO SUMMARY

DRUGS

Drugs by Indication

Active Drugs by Indication Chart



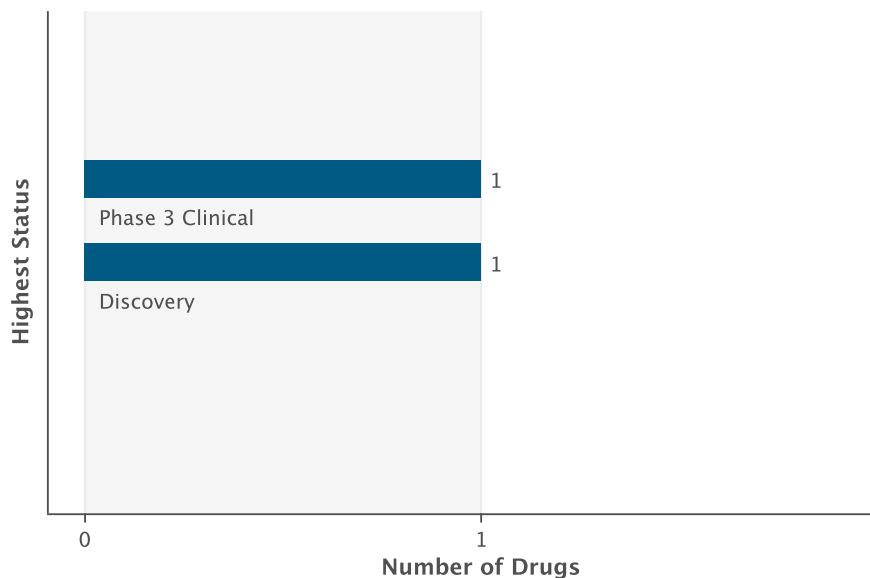
Drugs by Indication Table

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

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

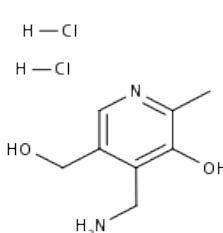
NephroGenex is also investigating a series of second generation AGE inhibitors.

pyridoxamine dihydrochloride DEVELOPMENT STATUS

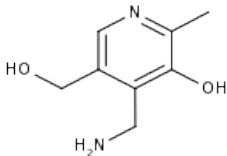
CURRENT DEVELOPMENT STATUS

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)

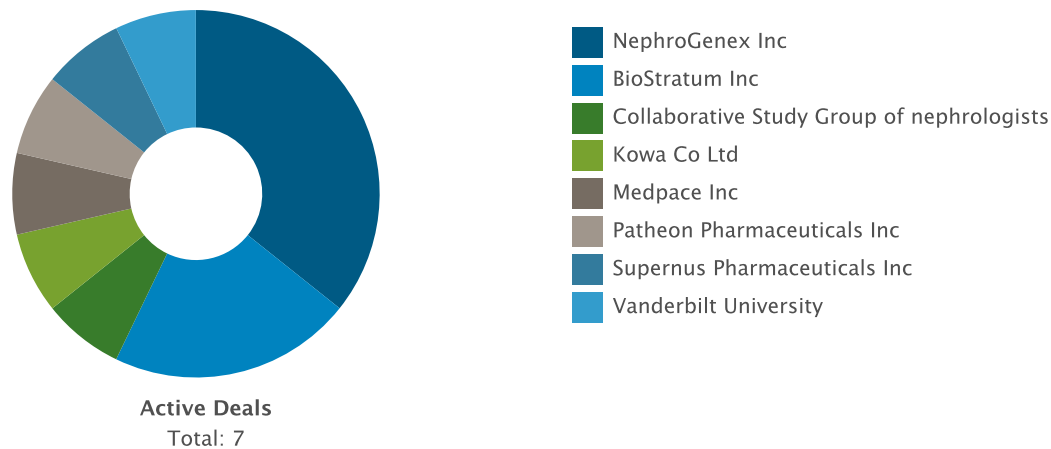
Phase 1 Clinical

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

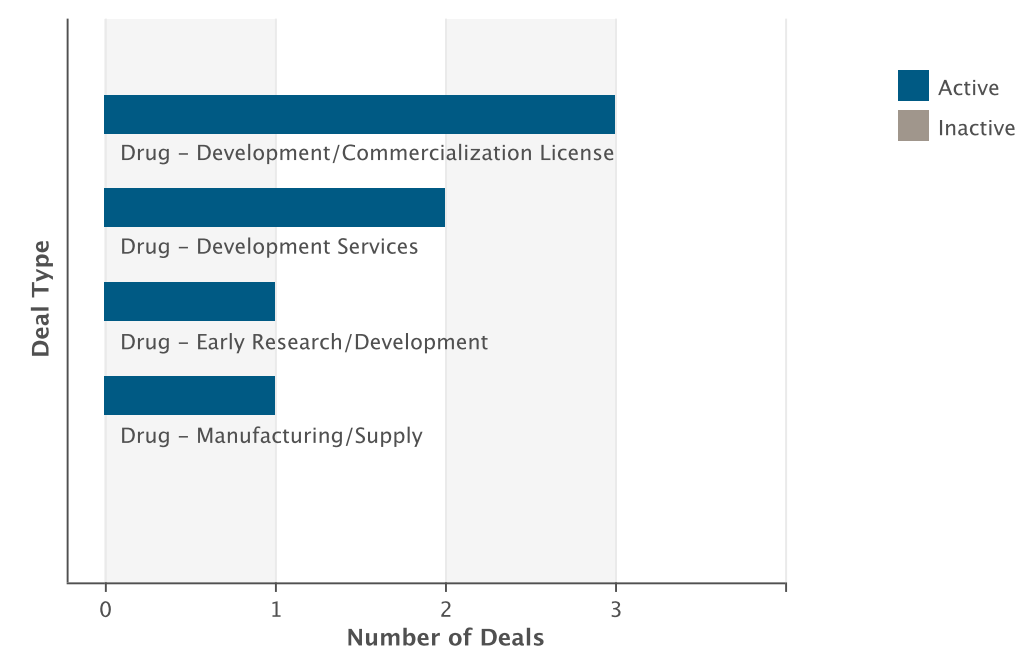


Deals by Parent Company Table

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



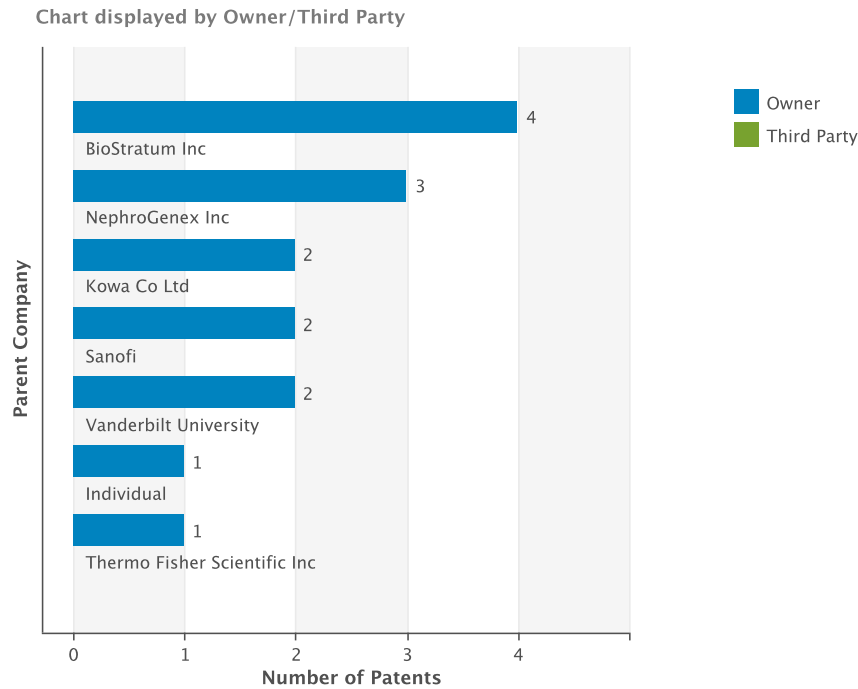
Deals by Type Table

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

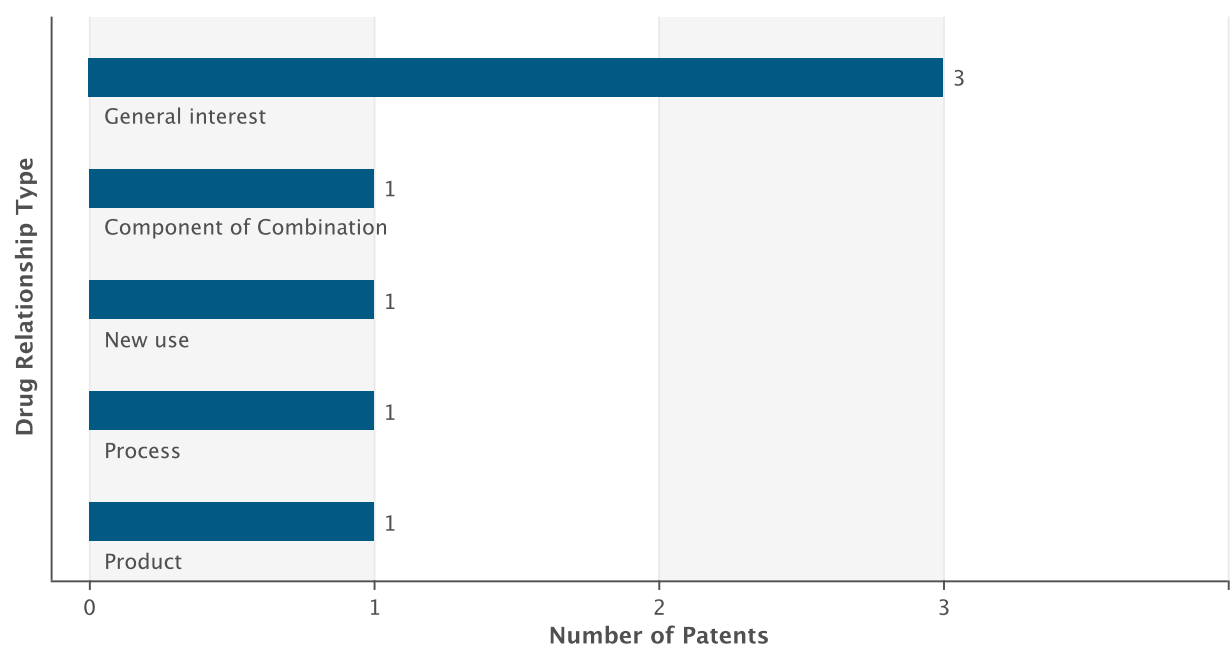


Patents by Parent Company Table

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.

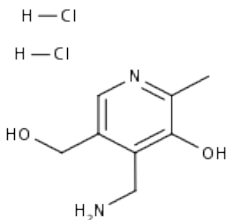
pyridoxamine dihydrochloride (intravenous, acute kidney injury), NephroGenex DEVELOPMENT STATUS

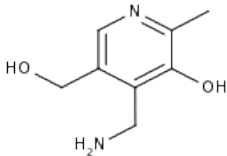
CURRENT DEVELOPMENT STATUS

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](#)

This report was created by Thomson Reuters, using information from *Thomson Reuters Cortellis™ for Competitive Intelligence*; a comprehensive, proven intelligence solution that leverages the most accurate, complete, and widely respected drug pipeline information.

For more information about *Cortellis for Competitive Intelligence*, visit:

http://cortellis.thomsonreuters.com/cortellis_for_you/?cid=thomsonone.

For subscription information, e-mail scientific.lifesciences@thomsonreuters.com.

© 2012 Thomson Reuters. All rights reserved.
Republication or redistribution of Thomson Reuters content, including by framing or similar means, is prohibited without the prior written consent of Thomson Reuters. 'Thomson Reuters' and the Thomson Reuters logo are registered trademarks and trademarks of Thomson Reuters and its affiliated companies.

[Return to Table of Contents](#)

