

Eagle Pharmaceuticals 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



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.



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 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.

THOMSON REUTERS

TABLE OF CONTENTS

Company Overview	5
Company Profile	6
Product Portfolio Summary	6
Product Portfolio Drug Pipeline Detail	10
Registered	11
Pre-registration	16
Discovery	23



Eagle Pharmaceuticals Inc

COMPANY OVERVIEW

Company Name	Eagle Pharmaceuticals Inc
Parent Company Name	Eagle Pharmaceuticals Inc
Website	http://www.eagleus.com/
Country	US
Number of Drugs in Active Development	5
Number of Inactive Drugs	3
Number of Patents as Owner	11
Number of Patents as Third Party	0
Number of Deals	9
Key Indications	Cancer,Non-Hodgkin lymphoma,Chronic lymphocytic leukemia,Hyperthermia,Mesothelioma,Thrombosis,Malignant hyperthermia,Metastatic non small cell lung cancer,B-cell lymphoma,Acute myelogenous leukemia,Bacterial endocarditis,Bacterial infection,Bacterial skin infection,Congestive heart failure,Enterococcus faecalis infection,MRSA infection,Myelodysplastic syndrome,Non-small-cell lung cancer,Renal insufficiency,Sepsis,Staphylococcus aureus infection,Streptococcus agalactiae infection,Streptococcus infection,Streptococcus pyogenes infection
Key Target-based Actions	Factor IIa antagonist,PARP modulator,DHFR inhibitor,Thymidylate synthase inhibitor,Transferase inhibitor,DNA methyltransferase inhibitor,Ryanodine receptor antagonist
Key Technologies	Intravenous formulation, Small molecule therapeutic, Infusion, Peptide, Biological therapeutic, Nanoparticle formulation injectable, Suspension, Formulation preservation, Liquid formulation, Injectable formulation

COMPANY PROFILE

SUMMARY

Eagle Pharmaceuticals Inc is a specialty pharmaceutical company, founded in 2007, which develops improved formulations of injectable products.

LICENSING AGREEMENTS

In September 2009, The Medicines Company licensed rights in the US and Canada to a ready-to-use formulation of argatroban from Eagle Pharmaceuticals. The formulation was under review by the FDA. Eagle would receive \$5 million up front in cash, and The Medicines Company would make a \$2 million equity investment in Eagle. Eagle could also receive milestones and royalties.

FINANCIAL

By May 2014, a one-for-6.41 reverse stock split of the company's common stock, and all outstanding shares of preferred stock converted into 7,487,928 million shares of common stock, had been approved by the company's board of directors. And also, all series C preferred stock warrants outstanding have been exercised for 34,074 shares of common stock.

In February 2014, the company planned to issue 3.35 million shares of common stock through an initial public offering at a price of \$15 per share and underwriters were granted 30-day option to purchase additional 502,500 shares of common stock. The Offering was expected to close on February 18, 2014. At that time, the shares were expected to be traded undet the ticker symbol "EGRX".

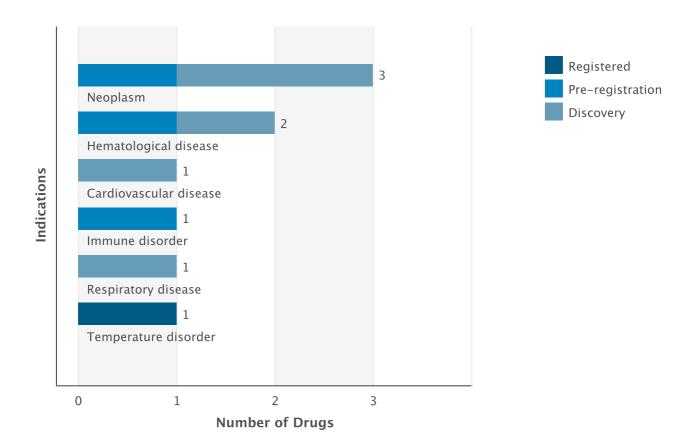


PRODUCT PORTFOLIO SUMMARY

DRUGS

Drugs by Indication

Active Drugs by Indication Chart



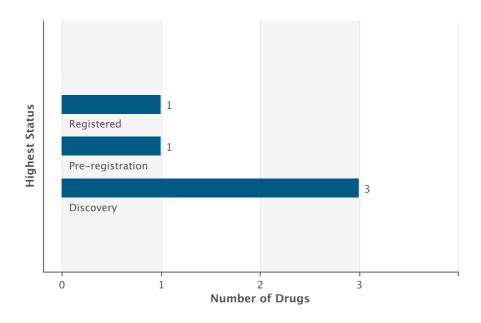
Drugs by Indication Table

Indication	Active	Inactive	Total
Neoplasm	3	1	4
Hematological disease	2	1	3
Respiratory disease	1	1	2
Immune disorder	1	0	1
Infectious disease	0	1	1
Cardiovascular disease	1	0	1
Temperature disorder	1	0	1



Drugs by Highest Status

Active Drugs by Highest Status Chart



Drugs by Highest Status Table

Development Status	Number of Drugs
Registered	1
Pre-registration	1
Discovery	3
Discontinued	1
No Development Reported	2

DEALS

Deal Type	Prin	cipal	Pai	tner	Total
	Active	Inactive	Active	Inactive	
Patent - Exclusive Rights	0	0	3	0	3
Drug - Development/Commercialization License	1	0	2	0	3
Drug - Manufacturing/Supply	0	0	1	0	1
Technology - Delivery/Formulation	0	0	1	0	1



CLINICAL TRIALS

Trials by Condition Studied

Condition Studied	Ongoing	All
Gastrointestinal disease	0	1
Hematological disease	0	1
Neoplasm	0	1
Immune disorder	0	1
Inflammatory disease	0	1

Trials by Phase

Phase	Ongoing	All
Phase 3	0	1
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	5	0	5
Endocrine disease	1	0	1
Gastrointestinal disease	1	0	1
Genitourinary disease	2	0	2
Hematological disease	5	0	5
Immune disorder	2	0	2
Neoplasm	6	0	6
Neurological disease	2	0	2
Respiratory disease	2	0	2
Infectious disease	1	0	1



Injury	2	0	2
Inflammatory disease	1	0	1
Gynecology and obstetrics	1	0	1
Temperature disorder	2	0	2
Dermatological 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.

PRODUCT PORTFOLIO DRUG PIPELINE DETAIL

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

dantrolene sodium (heat stroke/malignant hyperthermia), Eagle Pharmaceuticals

dantrolene sodium (heat stroke/malignant hyperthermia), Eagle Pharmaceuticals SNAPSHOT

Drug Name	dantrolene sodium (heat stroke/malignant hyperthermia), Eagle Pharmaceuticals
Key Synonyms	dantrolene;dantrolene sodium;Ryanodex
Originator Company	Eagle Pharmaceuticals Inc
Active Companies	Eagle Pharmaceuticals Inc
Inactive Companies	
Highest Status	Registered
Active Indications	Malignant hyperthermia;Hyperthermia
Target-based Actions	
Other Actions	Unspecified drug target
Technologies	Nanoparticle formulation injectable;Intravenous formulation;Suspension;Small molecule therapeutic
Last Change Date	24-Oct-2014

dantrolene sodium (heat stroke/malignant hyperthermia), Eagle Pharmaceuticals DEVELOPMENT PROFILE

SUMMARY

Eagle Pharmaceuticals has developed Ryanodex, dantrolene sodium, as a nanoparticle suspension for iv injection, for the potential treatment of malignant hyperthermia and also developing the drug as EP-4104, for the potential treatment of heat stroke,.. In July 2014, the FDA had approved the drug for malignant hyperthermia; at that time, the drug was expected to be available in August 2014 and the company was planning to ship the drug in the very 'near future'. By March 2014, a phase I study for EP-4104 had been completed and a pivotal study was expected to begin in the fourth quarter of that year. In August 2014, the company was planning to file for approval of Ryanodex with the EMA by mid-2015.

REGULATORY INFORMATIONTHE US

In January 2014, an NDA was filed to the US FDA for the treatment of malignant hyperthermia. In March 2014, the US FDA accepted the NDA and granted a Priority Review classification. At that time, the PDUFA date was given as July 22, 2014 and the company intended to commercialize dantrolene after approval and retain exclusive marketing rights in the US. In July 2014, the FDA had approved the drug for malignant hyperthermia; at that time, the drug was expected to be available in August 2014 and the company was planning to ship the drug in the very 'near future'.

In September 2012, the US FDA granted dantrolene sodium Orphan Drug designation for the treatment of heat stroke. In August 2013, the FDA granted dantrolene sodium suspension for injection Orphan designation for the treatment of malignant hyperthermia syndrome. In July 2014, the drug was expected to receive the seven year Orphan Drug market exclusivity in 4 to 6 weeks.



EUROPE

In October 2014, the EMA's COMP recommended granting dantrolene sodium Orphan designation for the treatment of malignant hyperthermia.

In August 2014, the company was planning to file for approval of Ryanodex with the EMA by mid-2015.

dantrolene sodium (heat stroke/malignant hyperthermia), Eagle Pharmaceuticals DEVELOPMENT STATUS

CURRENT DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
Eagle Pharmaceuticals Inc	Malignant hyperthermia	US	Registered	23-Jul-2014
Eagle Pharmaceuticals Inc	Hyperthermia	US	Discovery	25-Sep-2012
Eagle Pharmaceuticals Inc	Malignant hyperthermia	Europe	Discovery	11-Aug-2014

dantrolene sodium (heat stroke/malignant hyperthermia), Eagle Pharmaceuticals CHEMICAL STRUCTURES

OTHOOTOTIES	
CAS Registry Number:	Confidence Level:
24868-20-0	2
0 = N	$N \longrightarrow N^{N^{-}} Na^{+} H \longrightarrow H$
Name	Туре
dantrolene sodium	USAN

CAS Registry Number:	Confidence Level:
7261-97-4	1
	√ N Å
	NH NH



Name	Туре
dantrolene	BANN; INN; USAN
Ryanodex	Trade Name

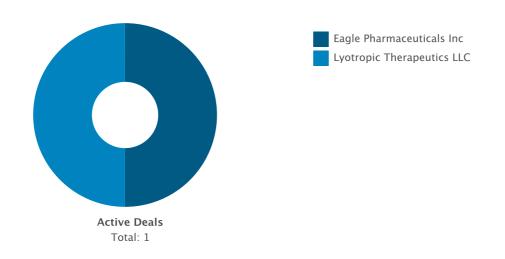
dantrolene sodium (heat stroke/malignant hyperthermia), Eagle Pharmaceuticals DRUG NAMES

Names	Туре
dantrolene	USAN, BANN, INN
EP-4104	Research Code
dantrolene sodium	USAN
dantrolene sodium (heat stroke/malignant hyperthermia), Eagle Pharmaceuticals	
Ryanodex	Trade Name

dantrolene sodium (heat stroke/malignant hyperthermia), Eagle Pharmaceuticals DEALS AND PATENTS

DEALS

Deals by Parent Company Chart

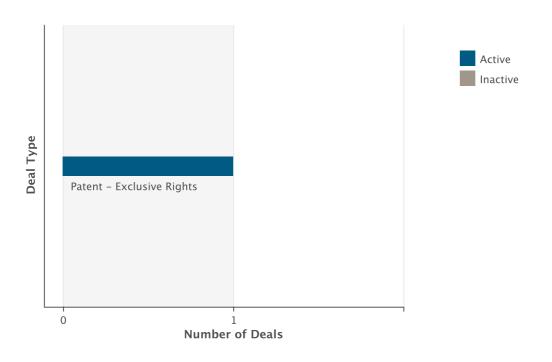




Deals by Parent Company Table

Company Name	Prin Active	i cipal Inactive	Par Active	tner Inactive	Total
Lyotropic Therapeutics LLC	1	0	0	0	1
Eagle Pharmaceuticals Inc	0	0	1	0	1

Deals by Type Chart



Deals by Type Table

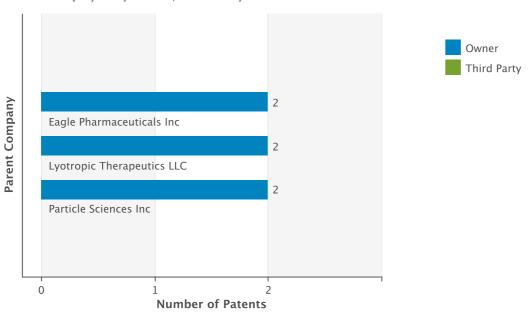
Deal Type	Active	Inactive	Total
Patent - Exclusive Rights	1	0	1



PATENTS

Patents by Parent Company Chart

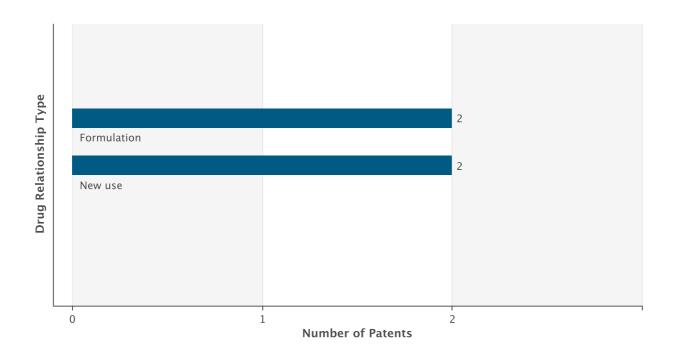
Chart displayed by Owner/Third Party



Patents by Parent Company Table

Company Name	As Owner	As Third Party	Total
Particle Sciences Inc	2	0	2
Lyotropic Therapeutics LLC	2	0	2
Eagle Pharmaceuticals Inc	2	0	2

Patents by Drug Relationship Type Chart



Patents by Drug Relationship Type Table

Drug Relationship	Total
Formulation	2
New use	2

ready-to-dilute bendamustine hydrochloride (iv, chronic lymphocytic leukemia/non-Hodgkin's lymphoma), Eagle Pharmaceuticals

ready-to-dilute bendamustine hydrochloride (iv, chronic lymphocytic leukemia/non-Hodgkin's lymphoma), Eagle Pharmaceuticals SNAPSHOT

Drug Name	ready-to-dilute bendamustine hydrochloride (iv, chronic lymphocytic leukemia/non-Hodgkin's lymphoma), Eagle Pharmaceuticals
Key Synonyms	bendamustine
Originator Company	Eagle Pharmaceuticals Inc
Active Companies	Eagle Pharmaceuticals Inc
Inactive Companies	
Highest Status	Pre-registration
Active Indications	Chronic lymphocytic leukemia;Non-Hodgkin lymphoma
Target-based Actions	PARP modulator
Other Actions	Anticancer alkylating agent
Technologies	Intravenous formulation;Infusion;Small molecule therapeutic
Last Change Date	11-Nov-2014

ready-to-dilute bendamustine hydrochloride (iv, chronic lymphocytic leukemia/non-Hodgkin's lymphoma), Eagle Pharmaceuticals DEVELOPMENT PROFILE

SUMMARY

Eagle Pharmaceuticals has developed a ready-to-dilute (RTD) 500-ml iv formulation of bendamustine hydrochloride, an alkylating agent and PARP modulator, as EP-3101, for the potential treatment of chronic lymphocytic leukemia (CLL) and non-Hodgkin's lymphoma (NHL). In September 2013, an NDA was submitted to the US FDA for EP-3101; in July 2014, the FDA granted tentative approval for the RTD formulation of bendamustine for indolent B-cell NHL; final approval is subject to the resolution of ongoing patent litigation between Eagle and Teva and the resolution or expiry of certain Orphan Drug exclusivities held by Teva .

The company is also developing a 50-ml iv formulation of bendamustine hydrochloride with short infusion time, as EP-3102, for the potential treatment of CLL and NHL. In November 2013, a phase I trial began; in November 2014, data were reported. At that time, the company planned a pre-NDA meeting with the FDA in mid-December 2014.

ready-to-dilute bendamustine hydrochloride (iv, chronic lymphocytic leukemia/non-Hodgkin's lymphoma), Eagle Pharmaceuticals DEVELOPMENT STATUS

CURRENT DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
Eagle Pharmaceuticals Inc	Chronic lymphocytic leukemia	US	Pre-registration	06-Sep-2013
Eagle Pharmaceuticals Inc	Non-Hodgkin lymphoma	US	Pre-registration	06-Sep-2013



ready-to-dilute bendamustine hydrochloride (iv, chronic lymphocytic leukemia/non-Hodgkin's lymphoma), Eagle Pharmaceuticals CHEMICAL STRUCTURES

CAS Registry Number:	Confidence Level:
3543-75-7	2
CI	N
	о он
Name	Туре
Name Treakisym	,//
	Type
Treakisym	Type Trade Name

CAS Registry Number:	Confidence Level:
16506-27-7	1
CI	N OH
Name	Туре
bendamustine	INN
Treanda	Trade Name
Levact	Trade Name
SP-1031C	Research Code
SDX-105	Research Code

ready-to-dilute bendamustine hydrochloride (iv, chronic lymphocytic leukemia/non-Hodgkin's lymphoma), Eagle Pharmaceuticals DRUG NAMES

Names	Туре
bendamustine	INN
EP-3101	Research Code
EP-3102	Research Code
bendamustine hydrochloride	
ready-to-dilute bendamustine hydrochloride (iv, chronic lymphocytic leukemia/non-Hodgkin's lymphoma), Eagle Pharmaceuticals	

ready-to-dilute bendamustine hydrochloride (iv, chronic lymphocytic leukemia/non-Hodgkin's lymphoma), Eagle Pharmaceuticals CLINICAL TRIALS

Trials by Phase and Condition Studied

	se 4 nical		se 3 nical		se 2 nical		se 1 nical		ase ecified	То	tal
On- going	All	On- going	All	On- going	All	On- going	All	On- going	All	On- going	All
Solid tum	Solid tumor										
0	0	0	0	0	0	0	1	0	0	0	1
Hematological neoplasm											
0	0	0	0	0	0	0	1	0	0	0	1

Total Trials by Phase and Status

	se 4 nical		se 3 nical		se 2 nical		se 1 nical		ase ecified	То	tal
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	0	0	0	0	0	1	0	0	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

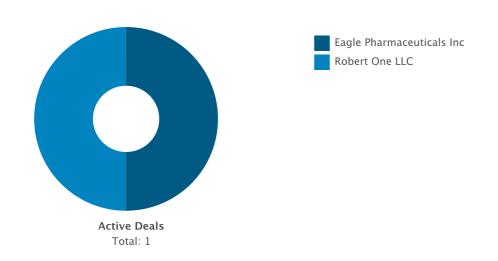
Includes Phase 1, Phase 1a, Phase 1, Phase 1/2 (where enrolment count is under 100 or not specified), Phase 0



ready-to-dilute bendamustine hydrochloride (iv, chronic lymphocytic leukemia/non-Hodgkin's lymphoma), Eagle Pharmaceuticals DEALS AND PATENTS

DEALS

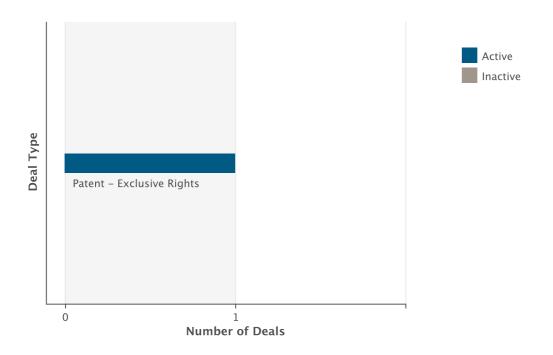
Deals by Parent Company Chart



Deals by Parent Company Table

Company Name		cipal Inactive		tner Inactive	Total
Eagle Pharmaceuticals Inc	0	0	1	0	1
Robert One LLC	1	0	0	0	1

Deals by Type Chart



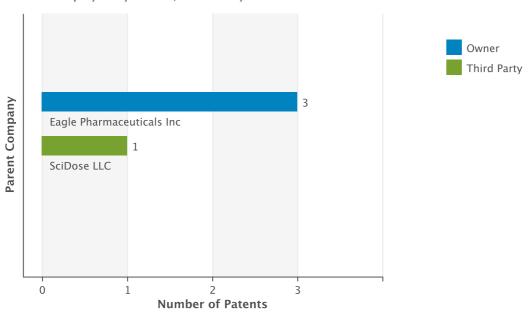
Deals by Type Table

Deal Type	Active	Inactive	Total
Patent - Exclusive Rights	1	0	1

PATENTS

Patents by Parent Company Chart

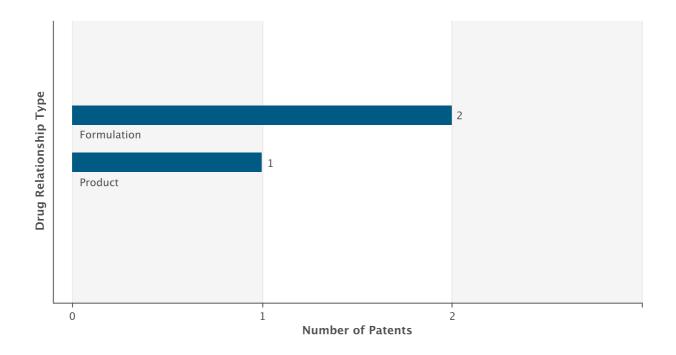
Chart displayed by Owner/Third Party



Patents by Parent Company Table

Company Name	As Owner	As Third Party	Total
Eagle Pharmaceuticals Inc	3	0	3
SciDose LLC	0	1	1

Patents by Drug Relationship Type Chart



Patents by Drug Relationship Type Table

Drug Relationship	Total
Formulation	2
Product	1

undisclosed compounds (cancer), SciDose/Eagle Pharmaceuticals

undisclosed compounds (cancer), SciDose/Eagle Pharmaceuticals SNAPSHOT

Drug Name	undisclosed compounds (cancer), SciDose/Eagle Pharmaceuticals
Key Synonyms	
Originator Company	SciDose LLC
Active Companies	Eagle Pharmaceuticals Inc;SciDose LLC
Inactive Companies	
Highest Status	Discovery
Active Indications	Cancer
Target-based Actions	
Other Actions	Anticancer;Unspecified drug target
Technologies	Small molecule therapeutic
Last Change Date	04-Jul-2014

undisclosed compounds (cancer), SciDose/Eagle Pharmaceuticals DEVELOPMENT PROFILE

SUMMARY

SciDose in collaboration with Eagle Pharmaceuticals, is investigating undisclosed compounds, for the potential treatment of cancer. In March 2011, development of nine drugs was underway. In July 2014, development of the program was presumed to be ongoing.

undisclosed compounds (cancer), SciDose/Eagle Pharmaceuticals DEVELOPMENT STATUS

CURRENT DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
Eagle Pharmaceuticals Inc	Cancer	US	Discovery	04-Mar-2011
SciDose LLC	Cancer	US	Discovery	04-Mar-2011

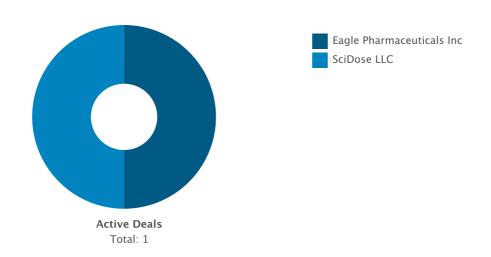
undisclosed compounds (cancer), SciDose/Eagle Pharmaceuticals DRUG NAMES

Names	Type
undisclosed compounds (cancer), SciDose/Eagle Pharmaceuticals	



DEALS

Deals by Parent Company Chart



Deals by Parent Company Table

Company Name		cipal Inactive		tner Inactive	Total
Eagle Pharmaceuticals Inc	0	0	1	0	1
SciDose LLC	1	0	0	0	1

Deals by Type Chart



Deals by Type Table

Deal Type	Active	Inactive	Total
Drug - Development/Commercialization License	1	0	1

ready-to-use bivalirudin (iv, thrombosis in percutaneous transluminal angioplasty), Eagle Pharmaceuticals

ready-to-use bivalirudin (iv, thrombosis in percutaneous transluminal angioplasty), Eagle Pharmaceuticals SNAPSHOT

Drug Name	ready-to-use bivalirudin (iv, thrombosis in percutaneous transluminal angioplasty), Eagle Pharmaceuticals
Key Synonyms	bivalirudin
Originator Company	Eagle Pharmaceuticals Inc
Active Companies	Eagle Pharmaceuticals Inc
Inactive Companies	
Highest Status	Discovery
Active Indications	Thrombosis
Target-based Actions	Factor IIa antagonist
Other Actions	Hirudin modulator;Coagulation inhibitor
Technologies	Intravenous formulation;Biological therapeutic;Peptide
Last Change Date	12-Aug-2014

ready-to-use bivalirudin (iv, thrombosis in percutaneous transluminal angioplasty), Eagle Pharmaceuticals DEVELOPMENT PROFILE

SUMMARY

Eagle Pharmaceuticals is investigating EP-6101, a ready-to-use (RTU) formulation of bivalirudin, an iv anticoagulant thrombin inhibitor and synthetic 20 amino acid hirudin derivative, for the potential prevention of thrombosis in percutaneous transluminal angioplasty. In March 2014, the program was listed as being in formulation and toxicology studies. In August 2014, the company was planning to submit the NDA in the first half of 2015.

ready-to-use bivalirudin (iv, thrombosis in percutaneous transluminal angioplasty), Eagle Pharmaceuticals DEVELOPMENT STATUS

CURRENT DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
Eagle Pharmaceuticals Inc	Thrombosis	US	Discovery	30-Nov-2013

ready-to-use bivalirudin (iv, thrombosis in percutaneous transluminal angioplasty), Eagle Pharmaceuticals CHEMICAL STRUCTURES

CAS Registry Number:	Confidence Level:
128270-60-0	1
Name	Туре
bivalirudin	INN; USAN
Hirulog	Trade Name
Angiomax	Trade Name
EP-6101	Research Code
Hirulog-8	

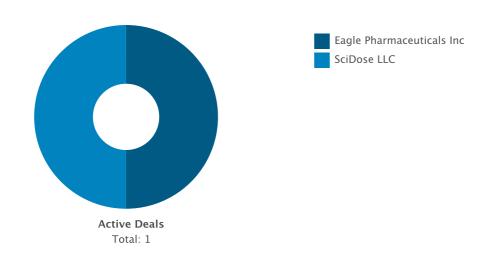
ready-to-use bivalirudin (iv, thrombosis in percutaneous transluminal angioplasty), Eagle Pharmaceuticals DRUG NAMES

Names	Туре
EP-6101	Research Code
ready-to-use bivalirudin (iv, thrombosis in percutaneous transluminal angioplasty), Eagle Pharmaceuticals	
bivalirudin	USAN, INN

ready-to-use bivalirudin (iv, thrombosis in percutaneous transluminal angioplasty), Eagle Pharmaceuticals DEALS AND PATENTS

DEALS

Deals by Parent Company Chart



Deals by Parent Company Table

Company Name		cipal Inactive		tner Inactive	Total
Eagle Pharmaceuticals Inc	0	0	1	0	1
SciDose LLC	1	0	0	0	1

Deals by Type Chart



Deals by Type Table

Deal Type	Active	Inactive	Total
Patent - Exclusive Rights	1	0	1



ready-to-dilute pemetrexed (iv, non-small cell lung cancer/mesothelioma), Eagle Pharmaceuticals

ready-to-dilute pemetrexed (iv, non-small cell lung cancer/mesothelioma), Eagle Pharmaceuticals SNAPSHOT

Drug Name	ready-to-dilute pemetrexed (iv, non-small cell lung cancer/mesothelioma), Eagle Pharmaceuticals
Key Synonyms	pemetrexed
Originator Company	Eagle Pharmaceuticals Inc
Active Companies	Eagle Pharmaceuticals Inc
Inactive Companies	
Highest Status	Discovery
Active Indications	Metastatic non small cell lung cancer;Mesothelioma
Target-based Actions	DHFR inhibitor;Thymidylate synthase inhibitor;Transferase inhibitor
Other Actions	Anticancer antimetabolite
Technologies	Intravenous formulation;Infusion;Small molecule therapeutic
Last Change Date	09-Apr-2014

ready-to-dilute pemetrexed (iv, non-small cell lung cancer/mesothelioma), Eagle Pharmaceuticals DEVELOPMENT PROFILE

SUMMARY

Eagle Pharmaceuticals is investigating EP-5101, a ready-to-dilute (RTD) formulation of pemetrexed, an antifolate antineoplastic agent that exerts its action by disrupting folate-dependent metabolic processes essential for cell replication, for the potential treatment of locally advanced or metastatic non-small cell lung cancer and mesothelioma. By December 2013, formulation studies had been completed. In March 2014, the program was listed as being in preclinical formulation and toxicology studies.

ready-to-dilute pemetrexed (iv, non-small cell lung cancer/mesothelioma), Eagle Pharmaceuticals DEVELOPMENT STATUS

CURRENT DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
Eagle Pharmaceuticals Inc	Mesothelioma	US	Discovery	20-Dec-2013
Eagle Pharmaceuticals Inc	Metastatic non small cell lung cancer	US	Discovery	20-Dec-2013

ready-to-dilute pemetrexed (iv, non-small cell lung cancer/mesothelioma), Eagle Pharmaceuticals CHEMICAL STRUCTURES

CAS Registry Number:	Confidence Level:
137281-23-3	1
HO NH	HN NH ₂
Name	Туре
pemetrexed	INN
EP-5101	Research Code

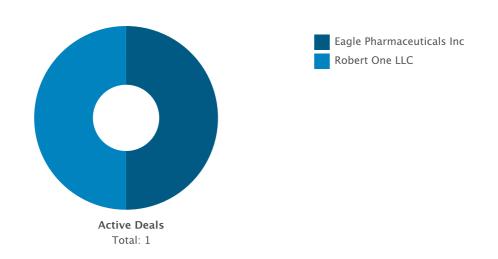
ready-to-dilute pemetrexed (iv, non-small cell lung cancer/mesothelioma), Eagle Pharmaceuticals DRUG NAMES

Names	Туре
pemetrexed	INN
ready-to-dilute pemetrexed (iv, non-small cell lung cancer/mesothelioma), Eagle Pharmaceuticals	
EP-5101	Research Code

ready-to-dilute pemetrexed (iv, non-small cell lung cancer/mesothelioma), Eagle Pharmaceuticals DEALS AND PATENTS

DEALS

Deals by Parent Company Chart



Deals by Parent Company Table

Company Name		i cipal Inactive		tner Inactive	Total
Eagle Pharmaceuticals Inc	0	0	1	0	1
Robert One LLC	1	0	0	0	1

Deals by Type Chart



Deals by Type Table

Deal Type	Active	Inactive	Total
Patent - Exclusive Rights	1	0	1

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.

THOMSON REUTERS