

# Cerulean Pharma 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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## ABOUT CORTELLIS COMPANY DETAILED PIPELINE REPORT

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### **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i.e. where the development status for the drug(s) is one of the following: No Development Reported, Discontinued, or Withdrawn.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.

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# **TABLE OF CONTENTS**

Company Overview	5
Company Profile	6
Product Portfolio Summary	7
Product Portfolio Drug Pipeline Detail	10
Phase 2 Clinical	11
Discovery	23



### Cerulean Pharma Inc

### **COMPANY OVERVIEW**

Company Name	Cerulean Pharma Inc
Parent Company Name	Cerulean Pharma Inc
Website	http://ceruleanrx.com/
Country	US
Number of Drugs in Active Development	4
Number of Inactive Drugs	1
Number of Patents as Owner	26
Number of Patents as Third Party	3
Number of Deals	2
Key Indications	Cancer,Breast tumor,Non-small-cell lung cancer,Ovary tumor,Stomach tumor,Renal tumor,Cardiovascular disease,Advanced solid tumor,Rectal tumor,Small-cell lung cancer
Key Target-based Actions	Topoisomerase I inhibitor, Hypoxia inducible factor-1 alpha inhibitor, Proteasome inhibitor, Topoisomerase II inhibitor, DHFR inhibitor, DNA polymerase inhibitor, Hemagglutinin inhibitor, Hemagglutinin modulator, JAK tyrosine kinase inhibitor, PLK1 gene inhibitor, Thymidylate synthase inhibitor, Transferase inhibitor, VEGF receptor antagonist
Key Technologies	Nanoparticle formulation, Small molecule therapeutic, PEGylated formulation, Intravenous formulation, Nanoparticle formulation injectable, Biological therapeutic, Oligonucleotide, Formulation preservation, Peptide, Controlled release formulation

### **COMPANY PROFILE**

#### **SUMMARY**

Cerulean Pharma (formerly Tempo Pharmaceuticals Inc) is a biopharmaceutical company specializing in the development of nanoparticle-based therapeutics for oncology, autoimmune and inflammatory diseases, based on its Nanocell technology that was exclusively licensed from the Massachusetts Institute of Technology. In October 2008, the company changed its name to Cerulean Pharma.

#### **FINANCIAL**

In January 2015, the company entered into a loan and security agreement with Hercules Technology Growth Capital for a term loan of up to \$26.0 million and completed a private placement for \$1.0 million of Cerulean common stock with Hercules. Cerulean issued Hercules a warrant to purchase 171,901 shares of Cerulean common stock at an exercise price of \$6.05 per share. At that time, Hercules purchased 135,501 shares of unregistered Cerulean common stock at \$7.38 per share for an aggregate purchase price of \$1.0 million.

In April 2014, Cerulean priced its IPO of 8,500,000 shares of its common stock US \$7.00 per share. Underwriters were granted a 30-day option to purchase an additional 1,275,000 shares. Stock to be listed on the NASDAQ Global Market under the ticker symbol 'CERU'. At that time, the offering was expected to close on April 15, 2014. Later that month, the offering was closed. In May 2014, underwriters for the IPO exercised their over-allotment option and purchased an additional 1,069,715 shares, bringing total number of shares sold to 9,569,715 shares and total gross proceeds to \$67 million.

In December 2011, Cerulean raised \$15 million from a series D financing.

In November 2010, Cerulean raised \$24 million from a series C financing.

In July 2009, Cerulean raised \$10 million from a series B-1 financing.

In January 2008, Tempo raised \$8.1 million from a series B financing.



In May 2007, Tempo raised \$12.1 million from a series A financing round.

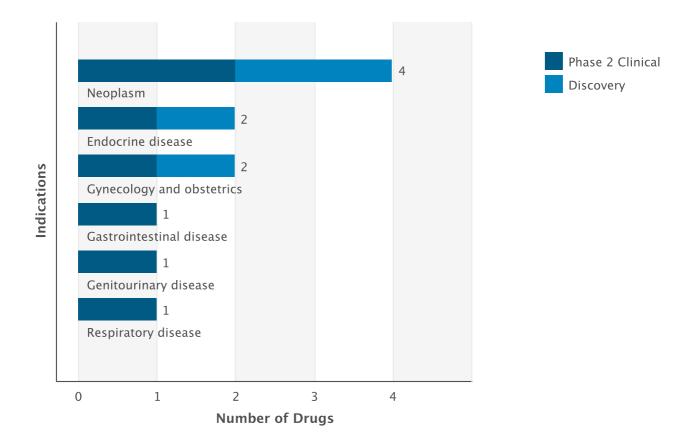
In December 2006, Tempo raised \$2 million from a seed round.

# PRODUCT PORTFOLIO SUMMARY

## **DRUGS**

## Drugs by Indication

Active Drugs by Indication Chart



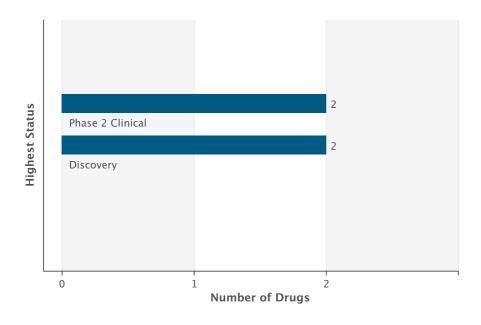


# Drugs by Indication Table

Indication	Active	Inactive	Total
Neoplasm	4	1	5
Endocrine disease	2	0	2
Gynecology and obstetrics	2	0	2
Gastrointestinal disease	1	0	1
Respiratory disease	1	0	1
Genitourinary disease	1	0	1

# **Drugs by Highest Status**

Active Drugs by Highest Status Chart



# Drugs by Highest Status Table

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



#### **DEALS**

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

### **CLINICAL TRIALS**

### Trials by Condition Studied

Condition Studied	Ongoing	All
Neoplasm	3	6
Genitourinary disease	1	2
Gastrointestinal disease	1	1
Gynecology and obstetrics	0	1
Respiratory disease	0	1
Endocrine disease	0	1

### Trials by Phase

Phase	Ongoing	All
Phase 2	1	3
Phase 1	2	3

#### **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	10	1	11
Endocrine disease	12	0	12
Gastrointestinal disease	12	0	12
Genitourinary disease	8	0	8



Growth disorder	1	0	1
Hematological disease	4	0	4
Degeneration	2	0	2
Andrology	2	0	2
Immune disorder	15	1	16
Psychiatric disorder	1	0	1
Musculoskeletal disease	6	0	6
Neoplasm	24	1	25
Ocular disease	2	0	2
Genetic disorder	2	0	2
Metabolic disorder	11	0	11
Neurological disease	6	0	6
Nutritional disorder	3	0	3
Respiratory disease	6	2	8
Infectious disease	5	2	7
Inflammatory disease	14	1	15
Otorhinolaryngological disease	1	0	1
Gynecology and obstetrics	8	0	8
Dermatological disease	6	0	6

<sup>\*</sup> 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

## camptothecin nanoparticle (cancer), Cerulean Pharma

#### camptothecin nanoparticle (cancer), Cerulean Pharma SNAPSHOT

Drug Name	camptothecin nanoparticle (cancer), Cerulean Pharma
Key Synonyms	
Originator Company	Calando Pharmaceuticals Inc
Active Companies	Cerulean Pharma Inc
Inactive Companies	Calando Pharmaceuticals Inc
Highest Status	Phase 2 Clinical
Active Indications	Small-cell lung cancer;Non-small-cell lung cancer;Breast tumor;Renal tumor;Ovary tumor;Stomach tumor;Rectal tumor
Target-based Actions	Topoisomerase I inhibitor; Hypoxia inducible factor-1 alpha inhibitor
Other Actions	Synergist;Anticancer
Technologies	Nanoparticle formulation injectable; Controlled release formulation; Small molecule therapeutic; Intravenous formulation
Last Change Date	04-Mar-2015

#### camptothecin nanoparticle (cancer), Cerulean Pharma DEVELOPMENT PROFILE

#### **SUMMARY**

Cerulean Pharma, under license from Calando, following its merger with Insert in April 2008, is developing a nanoparticle-drug conjugate, CRLX-101 (formerly IT-101), an iv Cyclosert formulation of camptothecin (structure shown), a topoisomerase and hypoxia inducible factor-1 alpha inhibitor, for the potential treatment of cancer, including gastric, ovarian, renal, rectal, prostate and non-small cell lung cancer (NSCLC),... Cerulean Pharma, is also investigating CRLX-101, for the potential treatment of breast cancer. In June 2011, a phase II trial in NSCLC was initiated. In June 2012, a phase lb/lla trial in relapsed renal cell carcinoma was initiated. In October 2014, a phase II trial for advanced renal cell carcinoma was initiated in the US and at that time, the trial was expected to be completed in February 2016. In July 2012, the first patient was dosed in a phase II trial for ovarian cancer. In January 2013, the first patient was dosed in a phase II trial for gastric cancer. In January 2013, a phase II trial in extensive-stage small-cell-lung cancer (SCLC) was initiated. In October 2013, a phase Ib/II study was ongoing to assess the activity of neoadjuvant CRLX-101 in combination with capecitabine and radiotherapy for rectal cancer; in January 2015, initiate data from the trial were presented. In February 2014, a phase II ovarian cancer study of CRLX-101 in combination with Avastin was initiated in the US; in August 2014, proof-of-principle data were expected in the in the first quarter of 2015. In October 2011, the company was seeking to outlicense the drug.

Calando was previously developing CRLX-10; in September 2008, Calando began a phase II ovarian cancer trial; however, in June 2009, the trial was terminated due to poor recruitment.



## camptothecin nanoparticle (cancer), Cerulean Pharma DEVELOPMENT STATUS

## **CURRENT DEVELOPMENT STATUS**

CORRENT DEVELOP	VIENT STATUS			
Company	Indication	Country	<b>Development Status</b>	Date
Cerulean Pharma Inc	Non-small-cell lung cancer	Russian Federation	Phase 2 Clinical	29-Jun-2011
Cerulean Pharma Inc	Non-small-cell lung cancer	Ukraine	Phase 2 Clinical	29-Jun-2011
Cerulean Pharma Inc	Ovary tumor	US	Phase 2 Clinical	23-Jun-2009
Cerulean Pharma Inc	Rectal tumor	US	Phase 2 Clinical	21-Oct-2013
Cerulean Pharma Inc	Renal tumor	US	Phase 2 Clinical	21-Jun-2012
Cerulean Pharma Inc	Small-cell lung cancer	US	Phase 2 Clinical	31-Jan-2013
Cerulean Pharma Inc	Stomach tumor	US	Phase 2 Clinical	30-Nov-2012
Cerulean Pharma Inc	Breast tumor	US	Discovery	19-Feb-2015
Calando Pharmaceuticals Inc	Ovary tumor	US	Discontinued	03-Jun-2009

# camptothecin nanoparticle (cancer), Cerulean Pharma CHEMICAL STRUCTURES

CAS Registry Number:	Confidence Level:
7689-03-4	1
	N OH O
Name	Туре
Camposomes	Trade Name
camptothecin	



## camptothecin nanoparticle (cancer), Cerulean Pharma DRUG NAMES

Names	Туре
Cyclosert-camptothecin, Calando	
CRLX-101	Research Code
Cyclosert-camptothecin, Cerulean Pharma	
IT-101	Research Code
camptothecin nanoparticle (cancer), Cerulean Pharma	
Cyclosert-camptothecin, Insert Therapeutics	
CRLX-101-202	Research Code
camptothecin	

# camptothecin nanoparticle (cancer), Cerulean Pharma CLINICAL TRIALS

# Trials by Phase and Condition Studied

	se 4 nical		se 3 nical		se 2 lical		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
Ovary tur	mor										
0	0	0	0	0	2	0	0	0	0	0	2
Renal ce	II carcinom	na									
0	0	0	0	1	1	0	0	0	0	1	1
Metastatic esophageal cancer											
0	0	0	0	1	1	0	0	0	0	1	1
Rectal tu	mor										
0	0	0	0	0	0	1	1	0	0	1	1
Metastati	c stomach	cancer									
0	0	0	0	1	1	0	0	0	0	1	1
Advanced solid tumor											
0	0	0	0	0	0	0	1	0	0	0	1
Small-cell lung cancer											
0	0	0	0	0	1	0	0	0	0	0	1



Metastatic non small cell lung cancer											
0	0	0	0	0	1	0	0	0	0	0	1
Fallopian	Fallopian tube cancer										
0	0	0	0	0	1	0	0	0	0	0	1
Metastati	c renal ca	ncer									
0	0	0	0	0	0	0	1	0	0	0	1
Peritoneal tumor											
0	0	0	0	0	1	0	0	0	0	0	1

## Total Trials by Phase and Status

	se 4 nical		ise 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	2	6	1	3	0	0	3	9

#### **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

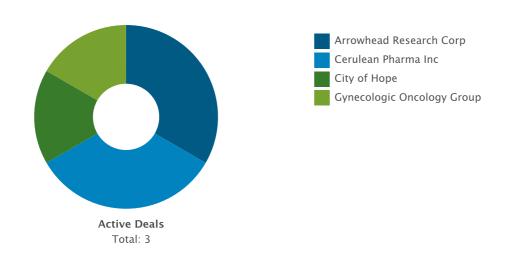
Includes Phase 2, Phase 2a, Phase 2b, Phase 1/2 (where enrolment count is 100 or over), Phase 2/3 (where enrolment count is under 300 or not specified)

#### Phase 1 Clinical

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

DEALS

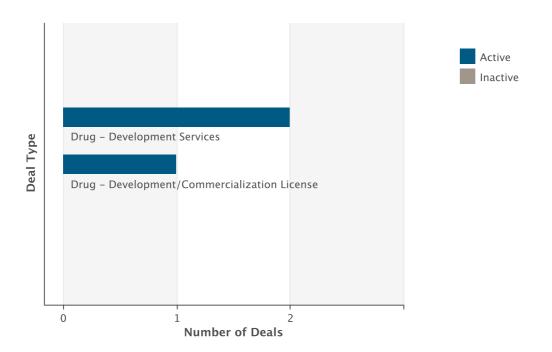
Deals by Parent Company Chart



## **Deals by Parent Company Table**

Company Name		cipal Inactive		tner Inactive	Total
Arrowhead Research Corp	1	0	1	0	2
Cerulean Pharma Inc	0	0	2	0	2
City of Hope	1	0	0	0	1
Gynecologic Oncology Group	1	0	0	0	1

# **Deals by Type Chart**



# **Deals by Type Table**

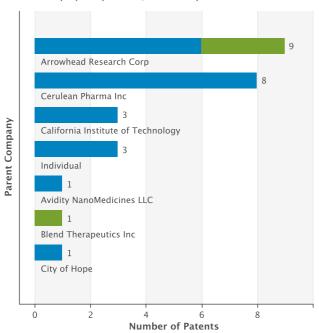
Deal Type	Active	Inactive	Total
Drug - Development Services	2	0	2
Drug - Development/Commercialization License	1	0	1



#### **PATENTS**

## **Patents by Parent Company Chart**

Chart displayed by Owner/Third Party

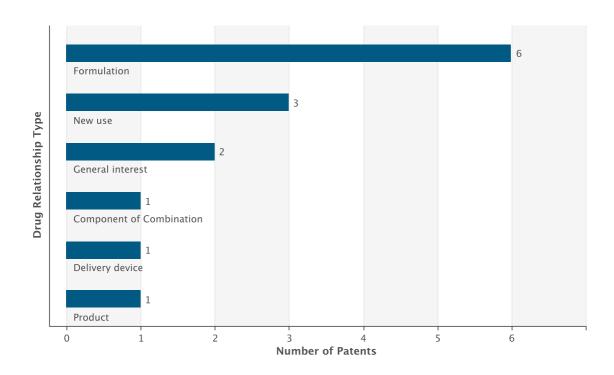




# **Patents by Parent Company Table**

Company Name	As Owner	As Third Party	Total
Arrowhead Research Corp	6	3	9
Cerulean Pharma Inc	8	0	8
California Institute of Technology	3	0	3
Individual	3	0	3
Blend Therapeutics Inc	0	1	1
Avidity NanoMedicines LLC	1	0	1
City of Hope	1	0	1

# **Patents by Drug Relationship Type Chart**



# **Patents by Drug Relationship Type Table**

Drug Relationship	Total
Formulation	6
New use	3
General interest	2
Product	1
Component of Combination	1
Delivery device	1



# docetaxel (Cyclodextrin Nanoparticle Technology), Cerulean

### docetaxel (Cyclodextrin Nanoparticle Technology), Cerulean SNAPSHOT

Drug Name	docetaxel (Cyclodextrin Nanoparticle Technology), Cerulean
Key Synonyms	
Originator Company	Cerulean Pharma Inc
Active Companies	Cerulean Pharma Inc
Inactive Companies	
Highest Status	Phase 2 Clinical
Active Indications	Advanced solid tumor;Cancer
Target-based Actions	
Other Actions	Microtubule inhibitor;Anticancer;Cell cycle inhibitor
Technologies	Nanoparticle formulation injectable;Small molecule therapeutic;Intravenous formulation
Last Change Date	30-Jan-2015

### docetaxel (Cyclodextrin Nanoparticle Technology), Cerulean DEVELOPMENT PROFILE

#### **SUMMARY**

Cerulean is developing CRLX-301, a cyclodextrin nanoparticle formulation of docetaxel, developed using its dynamic tumor targeting platform, for the potential iv treatment of cancer including advanced solid tumors. In December 2014, a phase I/IIa trial was initiated in Australia, in patients with solid tumors.

The company is also investigating CRLX-288, a PEGylated polymeric nanoparticle technology docetaxel.

#### docetaxel (Cyclodextrin Nanoparticle Technology), Cerulean DEVELOPMENT STATUS

#### **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	<b>Development Status</b>	Date
Cerulean Pharma Inc	Advanced solid tumor	Australia	Phase 2 Clinical	17-Dec-2014
Cerulean Pharma Inc	Cancer	US	Discovery	10-Mar-2012

docetaxel (Cyclodextrin Nanoparticle Technology), Cerulean CHEMICAL STRUCTURES

CAS Registry Number: 114977-28-5	Confidence Level: 1
<b>&gt;</b>	OH OH OH OH

Name	Туре
docetaxel	INN; USAN
Tyxan	Trade Name
Taxotere	Trade Name
Monotaxel	Trade Name
PEG-TX1	Trade Name
MBP-Y004	Research Code
SP-1012C	Research Code
NKTR-105	Research Code
CRLX-288	Research Code
SD-009	Research Code
ML-061	Research Code
BIND-014	Research Code
SYP-0704A	Research Code
NMR-1827	Research Code
RP-56976	Research Code
ATI-1123	Research Code
docetaxel-PNP	
docetaxel-PM	



### docetaxel (Cyclodextrin Nanoparticle Technology), Cerulean DRUG NAMES

Names	Туре
CRLX-301	Research Code
docetaxel (Cyclodextrin Nanoparticle Technology), Cerulean	

# docetaxel (Cyclodextrin Nanoparticle Technology), Cerulean 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
Advanced solid tumor											
0	0	0	0	0	0	1	1	0	0	1	1

### Total Trials by Phase and Status

	se 4 nical		ise 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	1	1	0	0	1	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

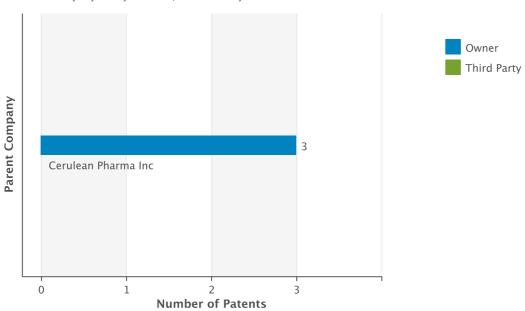
Includes Phase 1, Phase 1, Phase 1, Phase 1/2 (where enrolment count is under 100 or not specified), Phase 0

# docetaxel (Cyclodextrin Nanoparticle Technology), Cerulean DEALS AND PATENTS

#### **PATENTS**

## **Patents by Parent Company Chart**

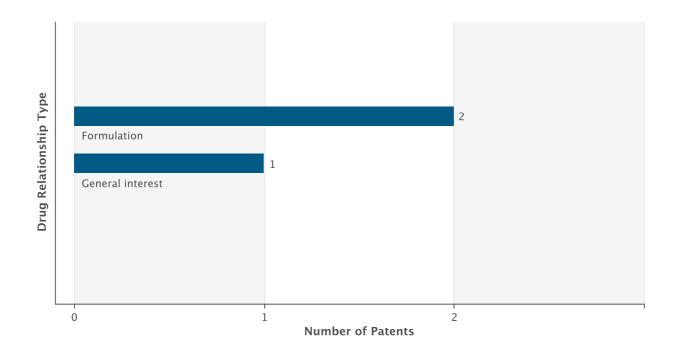
Chart displayed by Owner/Third Party



## **Patents by Parent Company Table**

Company Name	As Owner	As Third Party	Total
Cerulean Pharma Inc	3	0	3

# **Patents by Drug Relationship Type Chart**



# **Patents by Drug Relationship Type Table**

Drug Relationship	Total
Formulation	2
General interest	1

# siRNA-containing polymeric nanoparticle technology (cancer), Cerulean

### siRNA-containing polymeric nanoparticle technology (cancer), Cerulean SNAPSHOT

Drug Name	siRNA-containing polymeric nanoparticle technology (cancer), Cerulean
Key Synonyms	
Originator Company	Cerulean Pharma Inc
Active Companies	Cerulean Pharma Inc
Inactive Companies	
Highest Status	Discovery
Active Indications	Breast tumor
Target-based Actions	
Other Actions	Anticancer;siRNA agent
Technologies	Nanoparticle formulation;Biological therapeutic;Oligonucleotide
Last Change Date	24-Sep-2014

### siRNA-containing polymeric nanoparticle technology (cancer), Cerulean DEVELOPMENT PROFILE

#### **SUMMARY**

Cerulean is investigating a siRNA-containing polymeric nanoparticle technology formulation for the potential treatment of cancer. By March 2012, preclinical studies were ongoing; in September 2014, development was ongoing.

### siRNA-containing polymeric nanoparticle technology (cancer), Cerulean DEVELOPMENT STATUS

#### **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	<b>Development Status</b>	Date
Cerulean Pharma Inc	Breast tumor	US	Discovery	10-Mar-2012

### siRNA-containing polymeric nanoparticle technology (cancer), Cerulean DRUG NAMES

Names	Туре
siRNA-containing polymeric nanoparticle technology (cancer), Cerulean	



# **CRLX-522**

#### **CRLX-522 SNAPSHOT**

Drug Name	CRLX-522
Key Synonyms	
Originator Company	Cerulean Pharma Inc
Active Companies	Cerulean Pharma Inc
Inactive Companies	
Highest Status	Discovery
Active Indications	Cancer
Target-based Actions	
Other Actions	Anticancer
Technologies	Nanoparticle formulation;Small molecule therapeutic
Last Change Date	17-Apr-2014

### **CRLX-522 DEVELOPMENT PROFILE**

### **SUMMARY**

Cerulean is investigating CRLX-522, a cabazitaxel nanoparticle formulation, for the potential treatment of cancer. In April 2014, preclinical data were presented.

### **CRLX-522 DEVELOPMENT STATUS**

### **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	<b>Development Status</b>	Date
Cerulean Pharma Inc	Cancer	US	Discovery	08-Apr-2014

### **CRLX-522 DRUG NAMES**

Names	Туре
CRLX-522	Research Code
cabazitaxel nanoparticle (cancer), Cerulean	



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