

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i.e. where the development status for the drug(s) is one of the following: No Development Reported, Discontinued, or Withdrawn.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

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# **Marinus Pharmaceuticals Inc**

#### **COMPANY OVERVIEW**

Company Name	Marinus Pharmaceuticals Inc
Parent Company Name	Marinus Pharmaceuticals Inc
Website	http://www.marinuspharma.com/
Country	US
Number of Drugs in Active Development	3
Number of Inactive Drugs	1
Number of Patents as Owner	7
Number of Patents as Third Party	2
Number of Deals	7
Key Indications	Central nervous system disease, Epilepsy, Fragile X syndrome, Post traumatic stress disorder, Cancer, Allergic rhinitis, Attention deficit hyperactivity disorder, Bipolar disorder, Brain injury, Inflammatory disease, Migraine, Nasal polyps, Pain, Schizophrenia, Seasonal allergic rhinitis, Storage disease
Key Target-based Actions	GABA A receptor agonist,AKT1 protein kinase modulator,Alpha 1 antichymotrypsin modulator,Angiotensinogen ligand modulator,Clusterin modulator,Contactin 1 modulator,Contactin 2 modulator,Dickkopf-3 ligand modulator,Erbb2 tyrosine kinase receptor modulator,Extracellular signal related kinase-1 modulator,Extracellular signal related kinase-4 modulator,GABA A receptor modulator,MAP kinase modulator,Monocyte differentiation antigen CD14 modulator,Neuronal cell adhesion molecule modulator,Protein kinase C inhibitor,Serum amyloid P modulator,Topoisomerase I inhibitor,Topoisomerase II inhibitor,VEGF receptor modulator
Key Technologies	Small molecule therapeutic, Steroid, Oral formulation, Capsule formulation, Intravenous formulation, Nanoparticle formulation oral, Oral liquid formulation, Oral suspension formulation, Formulation preservation, Fluorescence, Formulation solid oral, Nucleophilic substitutional synthesis, Stereochemical synthesis, Steroid synthesis

## **COMPANY PROFILE**

#### **SUMMARY**

Marinus Pharmaceuticals focuses on the identification, development and commercialization of drugs to treat serious neurological, psychiatric and pain disorders.

#### **FINANCIAL**

In July 2014, Marinus priced its IPO of 5,625,000 shares at \$8 per share. Underwriters were granted a 30-day overallotment option to buy an additional 843,750 shares. The IPO was expected to close on August 05, 2014. In September 2014, the underwriters exercised their option to purchase an additional 133,000 shares at a price of \$8 each, which bought the total shares issued by the company in the offering to 5,758,000. Net proceeds were approximately \$41.3 million.

In January 2013, Marinus raised \$21 million from a series C financing.

In April 2009, Marinus raised \$20 million from a series B financing round.

In October 2005, Marinus raised \$29.4 million in a series A financing.

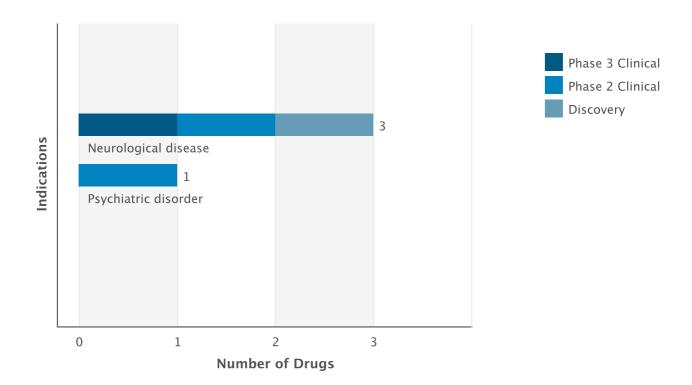


# PRODUCT PORTFOLIO SUMMARY

## **DRUGS**

# Drugs by Indication

Active Drugs by Indication Chart



# Drugs by Indication Table

Indication	Active	Inactive	Total
Neurological disease	3	0	3
Psychiatric disorder	1	1	2
Genetic disorder	0	1	1

# **Drugs by Highest Status**

Active Drugs by Highest Status Chart



Drugs by Highest Status Table

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

#### **DEALS**

Deal Type	Principal		Partner		Total
	Active	Inactive	Active	Inactive	
Drug - Funding	1	0	0	0	1
Drug - Early Research/Development	0	0	1	0	1
Drug - Development/Commercialization License	1	0	1	0	2
Drug - Development Services	0	0	2	0	2
Technology - Delivery/Formulation	0	0	1	0	1



#### **CLINICAL TRIALS**

#### Trials by Condition Studied

Condition Studied	Ongoing	All
Neurological disease	2	8
Psychiatric disorder	1	2

## Trials by Phase

Phase	Ongoing	All
Phase 3	1	1
Phase 2	2	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 1, Phase 1, Phase 1/2 (where enrolment count is under 100 or not specified), Phase 0

## **PATENTS** \*

Indication	As Owner	As Third Party	Total
Immune disorder	1	0	1
Psychiatric disorder	2	0	2
Musculoskeletal disease	1	0	1
Neoplasm	2	1	3
Genetic disorder	1	0	1
Metabolic disorder	1	0	1
Neurological disease	4	1	5
Respiratory disease	1	0	1
Infectious disease	2	0	2
Injury	0	1	1
Inflammatory disease	2	0	2
Otorhinolaryngological disease	1	0	1



Debugging Table of Connects	* This table represents a summary of the core patent coverage for this company covering Therapeutic 1990 only.	EP, US and WO patents since
Polytre to Table of Contents		
Deturn to Table of Contents		
Polytra for Tables of Contents		
Deture to Table of Contests		
Pature to Table of Contents		
Potent to Table of Contracts		
Detugs to Table of Contacts		
Deliver to Table of Contacts		
Deturn to Table of Contents		
Dollura to Table of Contents		
Pature to Table of Contents		
Datum to Table of Contents		
Paturn to Table of Contents		
Poture to Table of Contents		
Return to Table of Contents		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

# ganaxolone (oral capsule/nanoparticle, PTSD/CNS disorders), Marinus/NovaMedica

ganaxolone (oral capsule/nanoparticle, PTSD/CNS disorders), Marinus/NovaMedica SNAPSHOT

Drug Name	ganaxolone (oral capsule/nanoparticle, PTSD/CNS disorders), Marinus/NovaMedica
Key Synonyms	ganaxolone
Originator Company	Marinus Pharmaceuticals Inc
Active Companies	Marinus Pharmaceuticals Inc;NovaMedica
Inactive Companies	
Highest Status	Phase 3 Clinical
Active Indications	Post traumatic stress disorder;Epilepsy;Central nervous system disease
Target-based Actions	GABA A receptor agonist
Other Actions	CNS modulator;Anticonvulsant agent
Technologies	Nanoparticle formulation oral;Oral formulation;Capsule formulation;Small molecule therapeutic;Steroid
Last Change Date	14-May-2015

# ganaxolone (oral capsule/nanoparticle, PTSD/CNS disorders), Marinus/NovaMedica DEVELOPMENT PROFILE

#### **SUMMARY**

Marinus Pharmaceuticals is developing a solid nanoparticle capsule formulation of ganaxolone, for the potential oral treatment of post-traumatic stress disorder (PTSD) and epilepsy,. Presumably, the company is also investigating the drug for the potential treatment of other central nervous system disorders, including fragile X syndrome (FXS). In November 2013, a phase IIb/III study for epilepsy was initiated and at that time, the study was expected to complete in July 2016, ; in November 2014, data was expected in the second half of 2015. In April 2011, a phase II study was initiated in PTSD patients in the US; in April 2012, the trial was ongoing. In December 2012, it was reported that NovaMedica would commercialize ganaxolone in Russia and CIS countries. At that time, Marinus was planning to conduct phase II studies in Russia.

Marinus is also developing an oral liquid suspension formulation of ganaxolone.

# ganaxolone (oral capsule/nanoparticle, PTSD/CNS disorders), Marinus/NovaMedica DEVELOPMENT STATUS

#### **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	<b>Development Status</b>	Date
Marinus Pharmaceuticals Inc	Epilepsy	US	Phase 3 Clinical	06-Nov-2013
Marinus Pharmaceuticals Inc	Post traumatic stress disorder	US	Phase 2 Clinical	19-Apr-2011



Company	Indication	Country	<b>Development Status</b>	Date
Marinus Pharmaceuticals Inc	Central nervous system disease	US	Discovery	07-Apr-2011
NovaMedica	Central nervous system disease	Russian Federation	Discovery	19-Dec-2012
NovaMedica	Epilepsy	Russian Federation	Discovery	19-Dec-2012
NovaMedica	Post traumatic stress disorder	Russian Federation	Discovery	19-Dec-2012

# ganaxolone (oral capsule/nanoparticle, PTSD/CNS disorders), Marinus/NovaMedica CHEMICAL STRUCTURES

CAS Registry Number:	Confidence Level:		
38398-32-2	1		
H IIII			
Name	Туре		
ganaxolone	INN		
CCD-1042	Research Code		

# ganaxolone (oral capsule/nanoparticle, PTSD/CNS disorders), Marinus/NovaMedica DRUG NAMES

Names	Туре
ganaxolone (oral capsule/nanoparticle, PTSD/CNS disorders), Marinus/NovaMedica	
ganaxolone	INN
ganaxolone (oral solid nanoparticle/capsule, PTSD/epilepsy/CNS disorders), Marinus	

# ganaxolone (oral capsule/nanoparticle, PTSD/CNS disorders), Marinus/NovaMedica CLINICAL TRIALS

# Trials by Phase and Condition Studied

	ise 4 nical		ise 3 nical		se 2 nical	Pha Clir	se 1 lical		ase ecified	То	tal
On- going	All	On- going	All	On- going	All	On- going	All	On- going	All	On- going	All



Epilepsy											
0	0	1	1	0	0	0	0	0	0	1	1
Post traumatic stress disorder											
0	0	0	0	0	1	0	0	0	0	0	1

#### Total Trials by Phase and Status

Phase 4 Clinical			se 3 nical	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	1	0	0	0	0	1	2

#### **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)

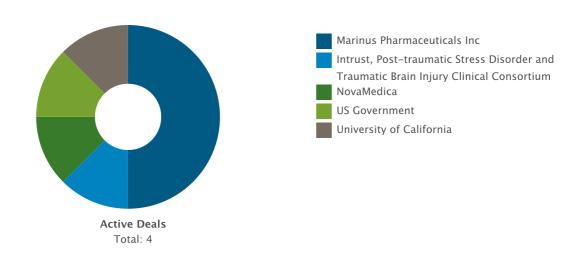
#### Phase 1 Clinical

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

# ganaxolone (oral capsule/nanoparticle, PTSD/CNS disorders), Marinus/NovaMedica DEALS AND PATENTS

#### **DEALS**

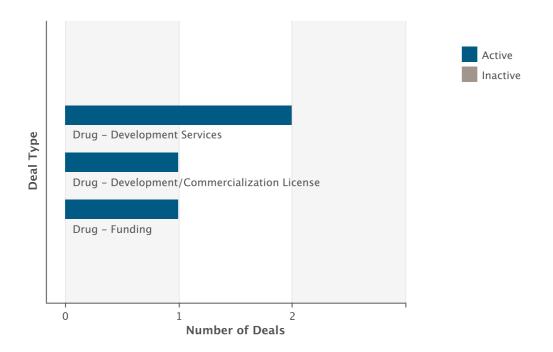
#### **Deals by Parent Company Chart**



#### **Deals by Parent Company Table**

Company Name	Prin Active	cipal Inactive	Par Active	tner Inactive	Total
Marinus Pharmaceuticals Inc	2	0	2	0	4
NovaMedica	0	0	1	0	1
Intrust, Post-traumatic Stress Disorder and Traumatic Brain Injury Clinical Consortium	1	0	0	0	1
US Government	0	0	1	0	1
University of California	1	0	0	0	1

# **Deals by Type Chart**



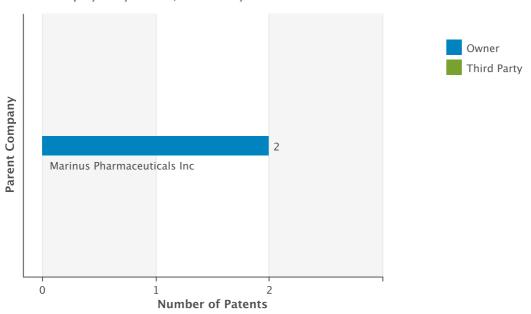
# **Deals by Type Table**

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

#### **PATENTS**

# **Patents by Parent Company Chart**

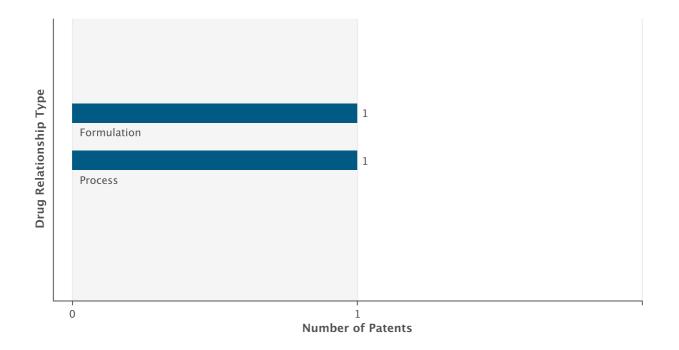
Chart displayed by Owner/Third Party



# **Patents by Parent Company Table**

Company Name	As Owner	As Third Party	Total
Marinus Pharmaceuticals Inc	2	0	2

# **Patents by Drug Relationship Type Chart**





# **Patents by Drug Relationship Type Table**

Drug Relationship	Total
Process	1
Formulation	1



# ganaxolone (oral liquid suspension, epilepsy/fragile X syndrome), Marinus/NovaMedica

# ganaxolone (oral liquid suspension, epilepsy/fragile X syndrome), Marinus/NovaMedica SNAPSHOT

Drug Name	ganaxolone (oral liquid suspension, epilepsy/fragile X syndrome), Marinus/NovaMedica
Key Synonyms	ganaxolone
Originator Company	Marinus Pharmaceuticals Inc
Active Companies	Marinus Pharmaceuticals Inc;NovaMedica
Inactive Companies	
Highest Status	Phase 2 Clinical
Active Indications	Fragile X syndrome;Epilepsy;Central nervous system disease
Target-based Actions	GABA A receptor agonist
Other Actions	CNS modulator;Anticonvulsant agent
Technologies	Oral liquid formulation;Oral suspension formulation;Oral formulation;Small molecule therapeutic;Steroid
Last Change Date	19-May-2015

# ganaxolone (oral liquid suspension, epilepsy/fragile X syndrome), Marinus/NovaMedica DEVELOPMENT PROFILE

#### **SUMMARY**

Marinus is developing an oral liquid suspension formulation of ganaxolone, a synthetic analog of allopregnanolone and positive allosteric modulator of the GABA A receptor, for the potential treatment of epilepsy and fragile X syndrome (FXS),. In January 2007, a phase IIb trial for pediatric spasms was initiated. A second phase II trial for adult partial seizures began in February 2007; positive data were reported in March 2009; at that time, a dose-ranging phase IIb trial was planned. In November 2012, a phase II trial in children with FXS was initiated ; in November 2014, top-line data were expected in mid-2015. In March 2009, Marinus intended to explore the use of the drug in other CNS indications such as post-traumatic stress disorder (PTSD) and postpartum depression. In December 2012, it was reported that NovaMedica would commercialize the drug in Russia and CIS countries. At that time, Marinus was planning to conduct phase II studies in Russia.

Marinus is also developing an oral capsule formulation of ganaxolone.

Ganaxolone was previously being developed by Purdue, but development was discontinued by July 2002.

# ganaxolone (oral liquid suspension, epilepsy/fragile X syndrome), Marinus/NovaMedica DEVELOPMENT STATUS

#### **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	<b>Development Status</b>	Date
Marinus Pharmaceuticals Inc	Epilepsy	Europe	Phase 2 Clinical	28-Feb-2007



Company	Indication	Country	<b>Development Status</b>	Date
Marinus Pharmaceuticals Inc	Epilepsy	US	Phase 2 Clinical	31-Jan-2007
Marinus Pharmaceuticals Inc	Fragile X syndrome	US	Phase 2 Clinical	30-Nov-2012
Marinus Pharmaceuticals Inc	Central nervous system disease	US	Discovery	03-Mar-2009
NovaMedica	Epilepsy	Russian Federation	Discovery	19-Dec-2012
NovaMedica	Fragile X syndrome	Russian Federation	Discovery	19-Dec-2012

# ganaxolone (oral liquid suspension, epilepsy/fragile X syndrome), Marinus/NovaMedica CHEMICAL STRUCTURES

CAS Registry Number:	Confidence Level:
38398-32-2	1
HO	
Name	Туре
ganaxolone	INN
CCD-1042	Research Code

# ganaxolone (oral liquid suspension, epilepsy/fragile X syndrome), Marinus/NovaMedica DRUG NAMES

Names	Туре
ganaxolone (oral liquid suspension, epilepsy/fragile X syndrome), Marinus/NovaMedica	
ganaxolone (oral liquid suspension, epilepsy/fragile X syndrome), Marinus	
ganaxolone	INN
ganaxolone (liquid-suspension, epilepsy), Marinus	

# ganaxolone (oral liquid suspension, epilepsy/fragile X syndrome), Marinus/NovaMedica CLINICAL TRIALS

Trials by Phase and Condition Studied

	se 4 lical		se 3 nical		se 2 nical		se 1 nical		ase ecified	То	tal
On- going	All	On- going	All								
Epilepsy											
0	0	0	0	0	4	0	0	0	0	0	4
Seizure d	lisorder										
0	0	0	0	0	3	0	0	0	0	0	3
Attention	deficit hyp	peractivity	disorder								
0	0	0	0	1	1	0	0	0	0	1	1
Anxiety d	isorder										
0	0	0	0	1	1	0	0	0	0	1	1
Infantile s	spasms										
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 an	d Status									
0	0	0	0	1	7	0	0	0	0	1	7

#### **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)

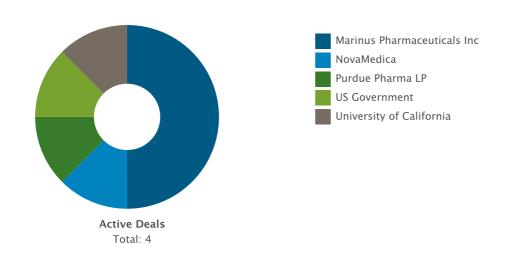
#### Phase 1 Clinical

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

# ganaxolone (oral liquid suspension, epilepsy/fragile X syndrome), Marinus/NovaMedica DEALS AND PATENTS

#### **DEALS**

## **Deals by Parent Company Chart**

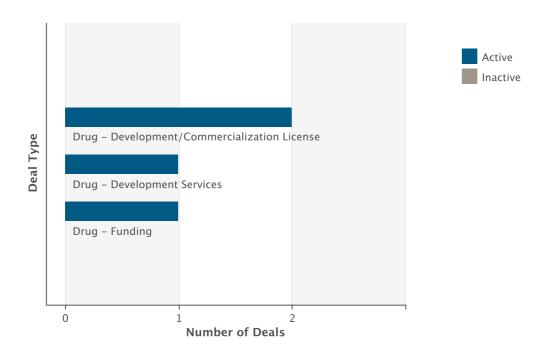


#### **Deals by Parent Company Table**

Company Name	Prin Active	cipal Inactive		tner Inactive	Total
Marinus Pharmaceuticals Inc	2	0	2	0	4
NovaMedica	0	0	1	0	1
University of California	1	0	0	0	1
Purdue Pharma LP	1	0	0	0	1
US Government	0	0	1	0	1



# **Deals by Type Chart**



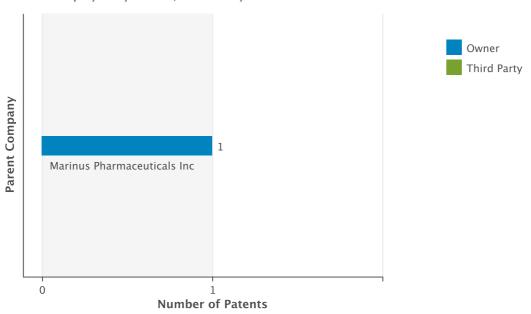
# **Deals by Type Table**

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

#### **PATENTS**

# **Patents by Parent Company Chart**

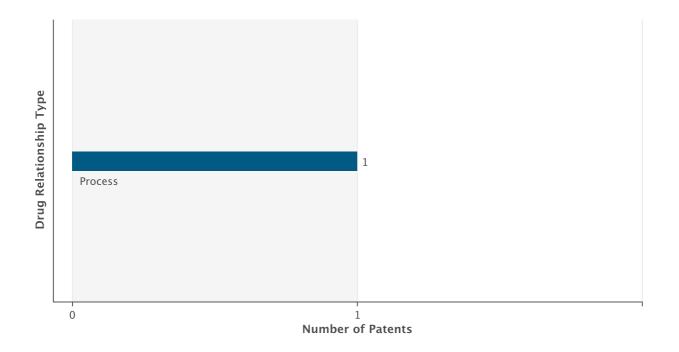
Chart displayed by Owner/Third Party



# **Patents by Parent Company Table**

Company Name	As Owner	As Third Party	Total
Marinus Pharmaceuticals Inc	1	0	1

# **Patents by Drug Relationship Type Chart**





# **Patents by Drug Relationship Type Table**

Drug Relationship	Total
Process	1



# ganaxolone (intravenous/Captisol, central nervous system diseases), Marinus

ganaxolone (intravenous/Captisol, central nervous system diseases), Marinus SNAPSHOT

Drug Name	ganaxolone (intravenous/Captisol, central nervous system diseases), Marinus
Key Synonyms	ganaxolone
Originator Company	Marinus Pharmaceuticals Inc
Active Companies	Marinus Pharmaceuticals Inc
Inactive Companies	
Highest Status	Discovery
Active Indications	Central nervous system disease
Target-based Actions	GABA A receptor agonist
Other Actions	CNS modulator
Technologies	Small molecule therapeutic;Intravenous formulation;Steroid
Last Change Date	12-May-2015

# ganaxolone (intravenous/Captisol, central nervous system diseases), Marinus DEVELOPMENT PROFILE

#### **SUMMARY**

Marinus Pharmaceuticals is investigating an iv formulation of ganaxolone, using CyDex's Captisol technology, presumably for the potential treatment of central nervous system (CNS) disorders including epileptic seizures. In May 2015, the drug was planned to enter into clinic in 2015.

Marinus is also developing oral liquid and oral capsule formulations for CNS disorders.

# ganaxolone (intravenous/Captisol, central nervous system diseases), Marinus DEVELOPMENT STATUS

#### **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	<b>Development Status</b>	Date
Marinus Pharmaceuticals Inc	Central nervous system disease	US	Discovery	12-Aug-2014

ganaxolone (intravenous/Captisol, central nervous system diseases), Marinus CHEMICAL STRUCTURES

CAS Registry Number:	Confidence Level:
38398-32-2	1
HO	
Name	Туре
ganaxolone	INN
CCD-1042	Research Code

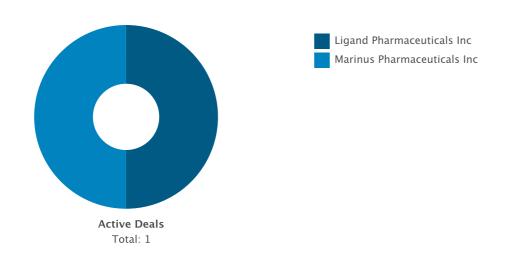
# ganaxolone (intravenous/Captisol, central nervous system diseases), Marinus DRUG NAMES

Names	Туре
ganaxolone	INN
ganaxolone (intravenous/Captisol, central nervous system diseases), Marinus	

# ganaxolone (intravenous/Captisol, central nervous system diseases), Marinus DEALS AND PATENTS

#### **DEALS**

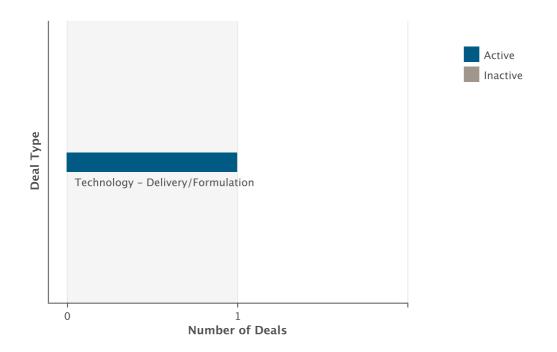
## **Deals by Parent Company Chart**



#### **Deals by Parent Company Table**

Company Name		cipal Inactive		tner Inactive	Total
Marinus Pharmaceuticals Inc	0	0	1	0	1
Ligand Pharmaceuticals Inc	1	0	0	0	1

# **Deals by Type Chart**



# **Deals by Type Table**

Deal Type	Active	Inactive	Total
Technology - Delivery/Formulation	1	0	1

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