

## **Corium International Inc**

## **CORTELLIS COMPANY DETAILED PIPELINE REPORT**

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

Publication Date: 07-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.



## **TABLE OF CONTENTS**

Company Overview	5
Company Profile	6
Product Portfolio Summary	6
Product Portfolio Drug Pipeline Detail	10
Phase 2 Clinical	11
Phase 1 Clinical	12
Discovery	15



## **Corium International Inc**

#### **COMPANY OVERVIEW**

Company Name	Corium International Inc
Parent Company Name	Corium International Inc
Website	http://www.coriumgroup.com/
Country	US
Number of Drugs in Active Development	5
Number of Inactive Drugs	0
Number of Patents as Owner	5
Number of Patents as Third Party	0
Number of Deals	3
Key Indications	Osteoporosis,Prostate hyperplasia,Alzheimers disease,Poliovirus infection,Psychiatric disorder,Urinary dysfunction,Urinary tract disease
Key Target-based Actions	Parathyroid hormone receptor agonist, Acetylcholinesterase inhibitor, Alpha adrenoceptor antagonist, Parathyroid hormone ligand, Alpha 1A adrenoceptor antagonist
Key Technologies	Transdermal formulation,Patch formulation,Biological therapeutic,Small molecule therapeutic,Peptide,Absorption enhancer transdermal,Formulation preservation,Sustained release formulation,Dermatological formulation,Matrix formulation

## **COMPANY PROFILE**

#### **SUMMARY**

Corium International Inc specializes in the R&D and manufacture of transdermal drug delivery platforms and products.

#### **FINANCIAL**

In December 2014, the company revised and closed an expanded term loan facility with CRG (previously known as Capital Royalty L.P.). Under the revised term, the company would get additional \$10 million from CRG cumulating the total loan amount to \$45 million and the maturity date of the all the debt to CRG was changed from June 2017 to June 2019.

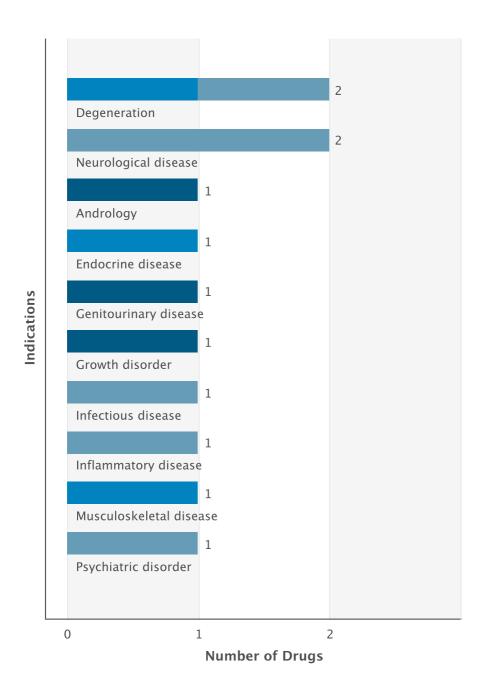
In March 2014, Corium filed a registration statement Form S-1 with the US SEC for a proposed initial public offering of common stock. At that time, the company planned to list on the NASDAQ Global Market under the ticker symbol 'CORI'. In April 2014, the company priced its initial public offering of 6,500,000 shares of common stock priced at \$8.00 each and the underwriters were granted a 30-day option to purchase up to 975,000 additional shares of common stock. At that time, the shares began trading on the NASDAQ Stock Market. By May 2014, the initial public offering was completed and the company raised \$48.5 million net proceeds through the offering.

## PRODUCT PORTFOLIO SUMMARY

#### **DRUGS**

## **Drugs by Indication**

Active Drugs by Indication Chart



Phase 2 Clinical
Phase 1 Clinical
Discovery

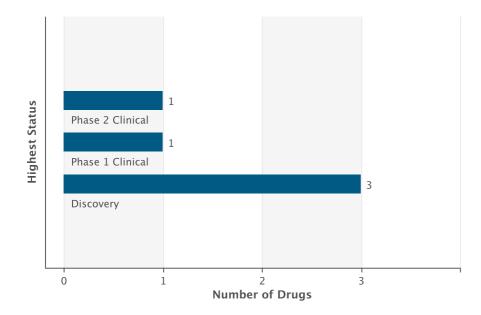


## Drugs by Indication Table

Indication	Active	Inactive	Total
Degeneration	2	0	2
Neurological disease	2	0	2
Andrology	1	0	1
Inflammatory disease	1	0	1
Musculoskeletal disease	1	0	1
Genitourinary disease	1	0	1
Infectious disease	1	0	1
Growth disorder	1	0	1
Endocrine disease	1	0	1
Psychiatric disorder	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	1
Phase 1 Clinical	1
Discovery	3

#### **DEALS**

Deal Type	Prin	cipal	Par	tner	Total
	Active	Inactive	Active	Inactive	
Drug - Funding	1	0	0	0	1
Drug - Development/Commercialization License	0	0	1	0	1
Drug - Manufacturing/Supply	1	0	0	0	1

#### **CLINICAL TRIALS**

## Trials by Phase

Phase	Ongoing	All
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	6	0	6
Gastrointestinal disease	2	0	2
Genitourinary disease	1	0	1
Growth disorder	1	0	1
Degeneration	5	0	5



Andrology	1	0	1
Psychiatric disorder	1	0	1
Musculoskeletal disease	5	0	5
Neoplasm	1	0	1
Metabolic disorder	1	0	1
Neurological disease	3	0	3
Respiratory disease	1	0	1
Infectious disease	3	0	3
Injury	1	0	1
Inflammatory disease	2	0	2
Ulcer	1	0	1

<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

## tamsulosin (transdermal/Corplex, benign prostatic hyperplasia), Corium

#### tamsulosin (transdermal/Corplex, benign prostatic hyperplasia), Corium SNAPSHOT

Drug Name	tamsulosin (transdermal/Corplex, benign prostatic hyperplasia), Corium
Key Synonyms	tamsulosin
Originator Company	Corium International Inc
Active Companies	Corium International Inc
Inactive Companies	
Highest Status	Phase 2 Clinical
Active Indications	Prostate hyperplasia
Target-based Actions	Alpha adrenoceptor antagonist
Other Actions	
Technologies	Transdermal formulation;Small molecule therapeutic
Last Change Date	20-Nov-2013

tamsulosin (transdermal/Corplex, benign prostatic hyperplasia), Corium DEVELOPMENT PROFILE

#### **SUMMARY**

Corium International is developing a transdermal formulation of tamsulosin, an FDA-approved urological product as alpha adrenoceptor antagonistic activity, using Corplex transdermal technology, for the potential treatment of benign prostatic hyperplasia. In November 2013, the drug was listed as being in phase II development, and at that time, the company was seeking to outlicense the drug.

tamsulosin (transdermal/Corplex, benign prostatic hyperplasia), Corium DEVELOPMENT STATUS

#### **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	<b>Development Status</b>	Date
Corium International Inc	Prostate hyperplasia	US	Phase 2 Clinical	06-Nov-2013

tamsulosin (transdermal/Corplex, benign prostatic hyperplasia), Corium CHEMICAL STRUCTURES

CAS Registry Number:	Confidence Level:
106133-20-4	1
H <sub>2</sub> N S	H O O
Name	Туре
tamsulosin	INN
GLC-2-TA	Research Code
GL-2702	Research Code
NAL-0637	Research Code

## tamsulosin (transdermal/Corplex, benign prostatic hyperplasia), Corium DRUG NAMES

Names	Туре
tamsulosin (transdermal/Corplex, benign prostatic hyperplasia), Corium	
apha adrenoceptor antagonist (transdermal, benign prostatic hyperplasia), Corium	
urological therapeutic (transdermal, benign prostatic hyperplasia), Corium	
tamsulosin	INN

## teriparatide (transdermal, MicroCor, osteoporosis), Corium International

#### teriparatide (transdermal, MicroCor, osteoporosis), Corium International SNAPSHOT

Drug Name	teriparatide (transdermal, MicroCor, osteoporosis), Corium International
Key Synonyms	teriparatide;MicroCor PTH(1-34)
Originator Company	Corium International Inc
Active Companies	Corium International Inc
Inactive Companies	
Highest Status	Phase 1 Clinical
Active Indications	Osteoporosis
Target-based Actions	Parathyroid hormone ligand;Parathyroid hormone receptor agonist
Other Actions	Osteoblast stimulator;Bone synthesis stimulator
Technologies	Transdermal formulation;Patch formulation;Biological therapeutic;Peptide
Last Change Date	16-May-2014

teriparatide (transdermal, MicroCor, osteoporosis), Corium International DEVELOPMENT PROFILE

#### **SUMMARY**

Corium International is developing transdermal delivery of teriparatide (human PTH(1-34); MicroCor PTH(1-34)) using its MicroCor technology, for the potential treatment of osteoporosis. In June 2011, the drug was listed as being in phase II development. However, in November 2013, the drug was listed as being in phase I development. In May 2014, phase II trials for osteoporosis were planned for 2015.

teriparatide (transdermal, MicroCor, osteoporosis), Corium International DEVELOPMENT STATUS

#### **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	<b>Development Status</b>	Date
Corium International Inc	Osteoporosis	US	Phase 1 Clinical	06-Nov-2013

## teriparatide (transdermal, MicroCor, osteoporosis), Corium International DRUG NAMES

Names	Туре
teriparatide	USAN, INN
PTH (1-34) (transdermal, MicroCor, osteoporosis), Corium International	
MicroCor PTH(1-34)	Trade Name
teriparatide (transdermal, MicroCor, osteoporosis), Corium International	

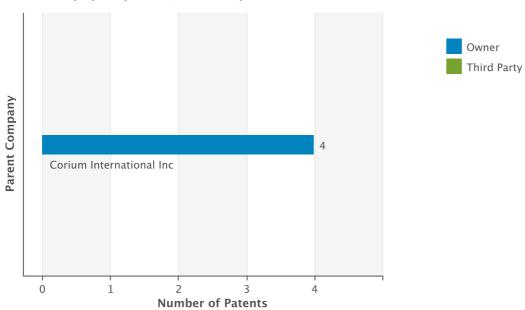


## teriparatide (transdermal, MicroCor, osteoporosis), Corium International DEALS AND PATENTS

#### **PATENTS**

## **Patents by Parent Company Chart**

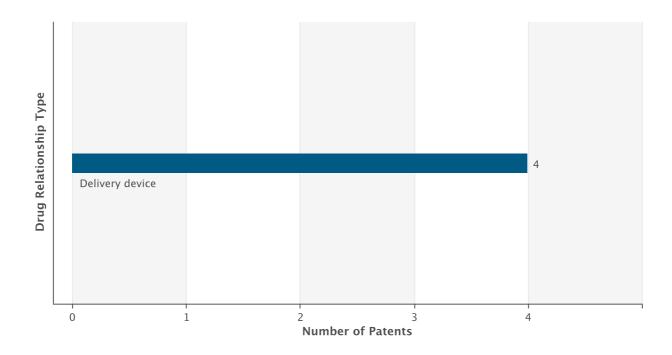
Chart displayed by Owner/Third Party



## **Patents by Parent Company Table**

Company Name	As Owner	As Third Party	Total
Corium International Inc	4	0	4

## **Patents by Drug Relationship Type Chart**



## **Patents by Drug Relationship Type Table**

Drug Relationship	Total
Delivery device	4

## polio vaccine (transdermal), Corium

#### polio vaccine (transdermal), Corium SNAPSHOT

Drug Name	polio vaccine (transdermal), Corium
Key Synonyms	
Originator Company	Corium International Inc
Active Companies	Corium International Inc
Inactive Companies	
Highest Status	Discovery
Active Indications	Poliovirus infection
Target-based Actions	
Other Actions	Vaccine;Anti-inflammatory
Technologies	Transdermal formulation;Patch formulation;Biological therapeutic
Last Change Date	19-Nov-2014

#### polio vaccine (transdermal), Corium DEVELOPMENT PROFILE

#### **SUMMARY**

Corium International is investigating a transdermal formulation of polio vaccine using its MicroCor technology, for the potential prevention or treatment of polio.

## polio vaccine (transdermal), Corium DEVELOPMENT STATUS

#### **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	<b>Development Status</b>	Date
Corium International Inc	Poliovirus infection	US	Discovery	18-Nov-2014

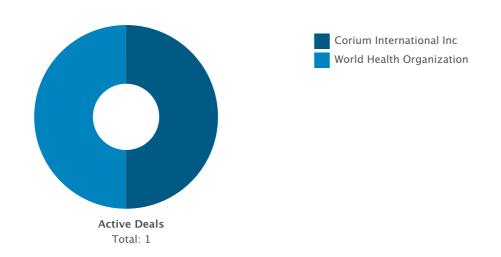
## polio vaccine (transdermal), Corium DRUG NAMES

Names	Туре
polio vaccine (transdermal), Corium	

## polio vaccine (transdermal), Corium DEALS AND PATENTS

DEALS

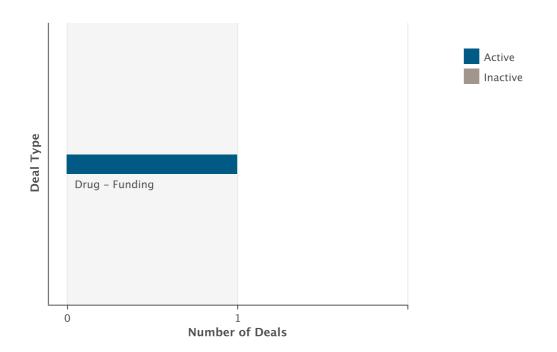
Deals by Parent Company Chart



## **Deals by Parent Company Table**

Company Name		<b>cipal</b> Inactive		tner Inactive	Total
Corium International Inc	1	0	0	0	1
World Health Organization	0	0	1	0	1

## **Deals by Type Chart**



## **Deals by Type Table**

Deal Type	Active	Inactive	Total
Drug - Funding	1	0	1



## donepezil (transdermal patch, Alzheimers disease), Corium

#### donepezil (transdermal patch, Alzheimers disease), Corium SNAPSHOT

Drug Name	donepezil (transdermal patch, Alzheimers disease), Corium
Key Synonyms	
Originator Company	Corium International Inc
Active Companies	Corium International Inc
Inactive Companies	
Highest Status	Discovery
Active Indications	Alzheimers disease
Target-based Actions	Acetylcholinesterase inhibitor
Other Actions	Nootropic agent;Neuroprotectant
Technologies	Transdermal formulation;Patch formulation;Small molecule therapeutic
Last Change Date	25-Nov-2014

donepezil (transdermal patch, Alzheimers disease), Corium DEVELOPMENT PROFILE

#### **SUMMARY**

Corium is investigating a transdermal patch formulation of the acetylcholinesterase inhibitor donepezil for the potential treatment of Alzheimer's disease. In November 2014, the company was planning to initiate phase I trials in the first half of 2015.

donepezil (transdermal patch, Alzheimers disease), Corium DEVELOPMENT STATUS

#### **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	<b>Development Status</b>	Date
Corium International Inc	Alzheimers disease	US	Discovery	03-Mar-2014

donepezil (transdermal patch, Alzheimers disease), Corium CHEMICAL STRUCTURES

CAS Registry Number: Confidence Level:		
120014-06-4	1	
Name	Туре	
donepezil	BAN; INN	
NAL-8817	Research Code	
NAL-8812	Research Code	

## donepezil (transdermal patch, Alzheimers disease), Corium DRUG NAMES

Names	Туре
donepezil (transdermal patch, Alzheimers disease), Corium	

## aripiprazole (transdermal patch, psychiatric disorder), Aequus Pharmaceuticals/Corium

## aripiprazole (transdermal patch, psychiatric disorder), Aequus Pharmaceuticals/Corium SNAPSHOT

Drug Name	aripiprazole (transdermal patch, psychiatric disorder), Aequus Pharmaceuticals/Corium
Key Synonyms	aripiprazole
Originator Company	Transdermal Research Pharm Laboratories LLC
Active Companies	Aequus Pharmaceuticals Inc;Corium International Inc
Inactive Companies	Transdermal Research Pharm Laboratories LLC
Highest Status	Discovery
Active Indications	Psychiatric disorder
Target-based Actions	5-HT 2a receptor antagonist
Other Actions	Antipsychotic;Dopamine D2 receptor partial agonist;5-HT 1a receptor partial agonist
Technologies	Transdermal formulation;Patch formulation;Small molecule therapeutic
Last Change Date	24-Nov-2014

## aripiprazole (transdermal patch, psychiatric disorder), Aequus Pharmaceuticals/Corium DEVELOPMENT PROFILE

#### **SUMMARY**

Aequus Pharmaceuticals, (under license from Transdermal Research) in collaboration with Corium is investigating a transdermal formulation of aripiprazole (AQS-1301), a partial dopamine D2 and 5-HT 1A receptor agonist and 5-HT 2A receptor antagonist, for the potential treatment of psychiatric disorders, including schizophrenia, bipolar disorder and, major depressive disorder,. In September 2013, the drug was in preclinical development. In May 2014, the company planned to initiate clinical trials in 2014.

## aripiprazole (transdermal patch, psychiatric disorder), Aequus Pharmaceuticals/Corium DEVELOPMENT STATUS

#### **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	Development Status	Date
Aequus Pharmaceuticals Inc	Psychiatric disorder	US	Discovery	26-Sep-2013
Corium International Inc	Psychiatric disorder	US	Discovery	27-May-2014
Transdermal Research Pharm Laboratories LLC	Psychiatric disorder	US	Discontinued	26-Sep-2013

aripiprazole (transdermal patch, psychiatric disorder), Aequus Pharmaceuticals/Corium CHEMICAL STRUCTURES



CAS Registry Number:	Confidence Level:		
129722-12-9	1		
	O H H O		
Name	Туре		
aripiprazole	BANN; INN; USAN		
Abilify Maintena	Trade Name		
Abilitat	Trade Name		
Abilify	Trade Name		
ZY-102	Research Code		
ALKS-9070	Research Code		
OPC-31	Research Code		
OPC-14597	Research Code		
BMS-337039	Research Code		
ALKS-9072	Research Code		

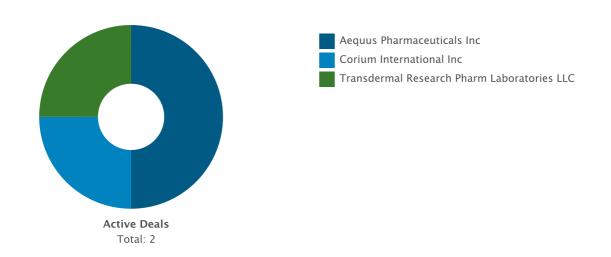
# aripiprazole (transdermal patch, psychiatric disorder), Aequus Pharmaceuticals/Corium DRUG NAMES

Names	Туре
aripiprazole (transdermal patch, psychiatric disorder), Aequus Pharmaceuticals/Corium	
aripiprazole	USAN, BANN, INN
AQS-1301	Research Code
aripiprazole (transdermal, psychiatric disorder), Aequus Pharmaceuticals/Corium	
aripiprazole (transdermal, psychiatric disorder), Transdermal Research	

## aripiprazole (transdermal patch, psychiatric disorder), Aequus Pharmaceuticals/Corium DEALS AND PATENTS

#### **DEALS**

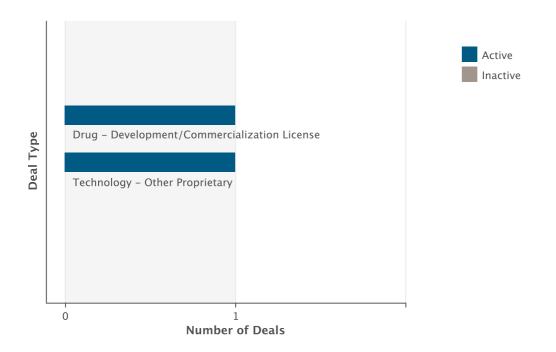
#### **Deals by Parent Company Chart**



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

Company Name		<b>cipal</b> Inactive		tner Inactive	Total
Aequus Pharmaceuticals Inc	1	0	1	0	2
Transdermal Research Pharm Laboratories LLC	1	0	0	0	1
Corium International Inc	0	0	1	0	1

## **Deals by Type Chart**



## **Deals by Type Table**

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