

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i.e. where the development status for the drug(s) is one of the following: No Development Reported, Discontinued, or Withdrawn.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

#### COMPANY OVERVIEW

Company Name	Flexion Therapeutics Inc
Parent Company Name	Flexion Therapeutics Inc
Website	http://flexiontherapeutics.com/
Country	US
Number of Drugs in Active Development	3
Number of Inactive Drugs	3
Number of Patents as Owner	2
Number of Patents as Third Party	0
Number of Deals	4
Key Indications	Pain,Inflammatory disease
Key Target-based Actions	Glucocorticoid agonist, TrkA receptor antagonist
Key Technologies	Small molecule therapeutic, Sustained release formulation, Intra-articular formulation, Systemic formulation unspecified, Steroid, Controlled release formulation, Matrix formulation, Emulsion formulation, Injectable formulation, Microparticle formulation

#### **COMPANY PROFILE**

#### **SUMMARY**

Flexion Therapeutics, a private US company founded in 2007, is focused on the development of therapeutics designed to target inflammatory and analgesic pathways.

#### LICENSING AGREEMENTS

In January 2010, Flexion licensed four undisclosed, late-stage, high-value, anti-inflammatory clinical compounds; one each from Merck Serono and AstraZeneca, and two further compounds from an undisclosed partner. The compounds would potentially be developed for inflammatory conditions, including intra-articular treatment of osteoarthritis, and tinnitus. Flexion would make milestone and royalty payments to all its partners.

In October 2009, Flexion expected to announce deals with three major pharmaceutical companies in the near future.

#### **FINANCIAL**

In January 2014, Flexion filed a registration statement on Form S-1 for a proposed initial public offering of shares of its common stock. In February 2014, the company announced the pricing of its initial public offering of 5,000,000 shares of common stock at a price of \$13 per share. Trading of shares was expected to begin on February 12, 2014, on the NASDAQ Global Market, under the ticker symbol "FLXN". The underwriters were granted a 30-day option to buy up to an additional 750,000 shares of common stock. The offering was expected to close on February 18, 2014; later that month, the offering was closed and net proceeds of \$67.3 million was expected; in March 2014, the offering was closed and the company raised gross proceeds of approximately \$75 million.

In December 2012, Flexion raised \$20 million in a series B financing round.

In January 2010, Flexion raised \$42 million from a series A financing round, from Pfizer Venture Capital group.

In October 2009, Flexion raised \$33 million from a series A financing round.

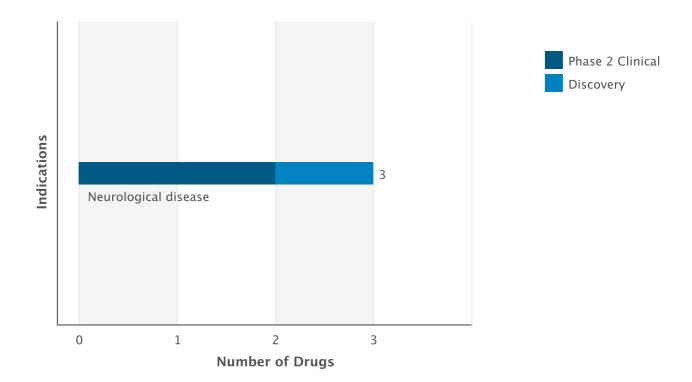


# PRODUCT PORTFOLIO SUMMARY

# **DRUGS**

# Drugs by Indication

Active Drugs by Indication Chart

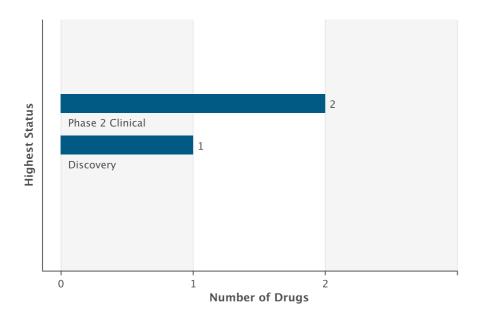


# Drugs by Indication Table

Indication	Active	Inactive	Total
Neurological disease	3	0	3
Neoplasm	0	2	2
Immune disorder	0	2	2
Otorhinolaryngological disease	0	1	1
Inflammatory disease	0	1	1
Gastrointestinal disease	0	1	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	1
No Development Reported	3

## **DEALS**

Deal Type	Principal		Pai	Total	
	Active	Inactive	Active	Inactive	
Technology - Other Proprietary	0	0	1	0	1
Drug - Development/Commercialization License	0	0	3	0	3

# **CLINICAL TRIALS**

# Trials by Condition Studied

Condition Studied	Ongoing	All
Neurological disease	1	5
Inflammatory disease	0	2
Musculoskeletal disease	0	2



## Trials by Phase

Phase	Ongoing	All
Phase 3	1	1
Phase 2	0	4

#### **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
Neurological disease	2	0	2
Inflammatory disease	2	0	2

<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

#### **FX-005**

## **FX-005 SNAPSHOT**

Drug Name	FX-005
Key Synonyms	
Originator Company	AstraZeneca plc
Active Companies	Flexion Therapeutics Inc
Inactive Companies	AstraZeneca plc
Highest Status	Phase 2 Clinical
Active Indications	Pain
Target-based Actions	p38 MAP kinase inhibitor
Other Actions	Analgesic;Anti-inflammatory
Technologies	Sustained release formulation;Intra-articular formulation;Small molecule therapeutic
Last Change Date	04-Mar-2014

## **FX-005 DEVELOPMENT PROFILE**

#### **SUMMARY**

Flexion, presumed to be under license from AstraZeneca, is developing a sustained-release formulation of p38 MAP kinase inhibitor FX-005, for the potential intra-articular treatment of pain in patients with osteoarthritis,. In May 2012, a phase IIb dose-ranging trial was planned to begin in the first half of 2013. In December 2010, a phase I/II trial in patients with osteoarthritis of the knee was initiated. In April 2012, the trial was completed and in May 2012, top-line results were reported. In March 2013, the drug was listed as being in phase II studies.

## **FX-005 DEVELOPMENT STATUS**

# **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	<b>Development Status</b>	Date
Flexion Therapeutics Inc	Pain	Canada	Phase 2 Clinical	31-Dec-2010
Flexion Therapeutics Inc	Pain	Spain	Phase 2 Clinical	31-Dec-2010
AstraZeneca plc	Pain	UK	Discontinued	29-Jan-2010



#### **FX-005 DRUG NAMES**

Names	Туре
FX-005	Research Code
intra-articular osteoathritis treatment, Flexion/Merck Serono	

## **FX-005 CLINICAL TRIALS**

## Trials by Phase and Condition Studied

Phase 4 Clinical		Phase 3 Clinical		Phase 2 Phase 1 Clinical Clinical			ase ecified	To	tal		
On- going	All	On- going	All	On- going	All	On- going	All	On- going	All	On- going	All
Pain											
0	0	0	0	0	1	0	0	0	0	0	1

## Total Trials by Phase and Status

	se 4 lical		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	1	0	0	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)

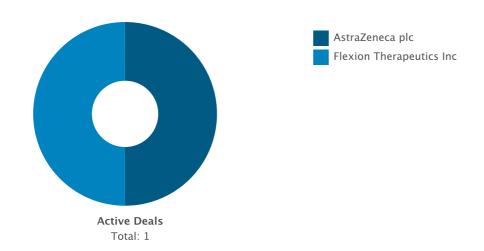
## Phase 1 Clinical

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

# **FX-005 DEALS AND PATENTS**

DEALS

Deals by Parent Company Chart



# **Deals by Parent Company Table**

Company Name	<b>Principal</b> Active Inactive		Partner Active Inactive		Total
Flexion Therapeutics Inc	0	0	1	0	1
AstraZeneca plc	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

# triamcinolone acetonide (pain), Flexion

# triamcinolone acetonide (pain), Flexion SNAPSHOT

Drug Name	triamcinolone acetonide (pain), Flexion
Key Synonyms	triamcinolone acetonide
Originator Company	Flexion Therapeutics Inc
Active Companies	Flexion Therapeutics Inc
Inactive Companies	
Highest Status	Phase 2 Clinical
Active Indications	Pain
Target-based Actions	Glucocorticoid agonist
Other Actions	Steroidal anti-inflammatory;Analgesic
Technologies	Sustained release formulation;Intra-articular formulation;Small molecule therapeutic;Steroid
Last Change Date	14-Nov-2014

## triamcinolone acetonide (pain), Flexion DEVELOPMENT PROFILE

#### **SUMMARY**

Flexion is developing FX-006, a sustained-release triamcinolone acetonide formulation, for the potential intra-articular treatment of pain in patients with osteoarthritis (OA) of knee . In June 2012, a phase IIa trial was initiated in patients with OA of the knee in Canada and Australia ; in December 2012, data were reported ; by April 2013, enrollment had been completed in the US, Canada, and Australia ; in June 2013, phase IIb top-line data were reported. In September 2014, a phase III trial was planned to be initiated in late 2014 .

#### triamcinolone acetonide (pain), Flexion DEVELOPMENT STATUS

## **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	<b>Development Status</b>	Date
Flexion Therapeutics Inc	Pain	Australia	Phase 2 Clinical	30-Jun-2012
Flexion Therapeutics Inc	Pain	Canada	Phase 2 Clinical	30-Jun-2012
Flexion Therapeutics Inc	Pain	US	Phase 2 Clinical	18-Apr-2013

triamcinolone acetonide (pain), Flexion CHEMICAL STRUCTURES

CAS Registry Number:	Confidence Level:
76-25-5	1
HO	OH OH OH H
Name	Туре
triamcinolone acetonide	USAN
Azmacort	Trade Name
Visagen	Trade Name
Tri-Nasal	Trade Name
AllerNaze	Trade Name
MaQaid	Trade Name
CLS-1001	Research Code
CLS-1003	Research Code

# triamcinolone acetonide (pain), Flexion DRUG NAMES

Names	Туре
triamcinolone acetonide	USAN
FX-006	Research Code
triamcinolone acetonide (pain), Flexion	

# triamcinolone acetonide (pain), Flexion CLINICAL TRIALS

# Trials by Phase and Condition Studied

Phase 4 Phase 3 Clinical Clinical			Phase 2 Clinical		Phase 1 Clinical		Phase Unspecified		Total		
On- going	All	On- going	All	On- going	All	On- going	All	On- going	All	On- going	All
Pain											
0	0	1	1	0	3	0	0	0	0	1	4



Osteoarthritis											
0	0	0	0	0	2	0	0	0	0	0	2
Carpal tu	Carpal tunnel syndrome										
0	0	0	0	0	0	0	0	1	1	1	1

## Total Trials by Phase and Status

	se 4 nical		ise 3 nical		se 2 nical	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	3	0	0	1	1	2	5

## **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)

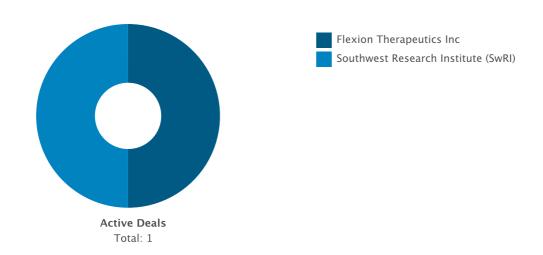
#### Phase 1 Clinical

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

# triamcinolone acetonide (pain), Flexion DEALS AND PATENTS

DEALS

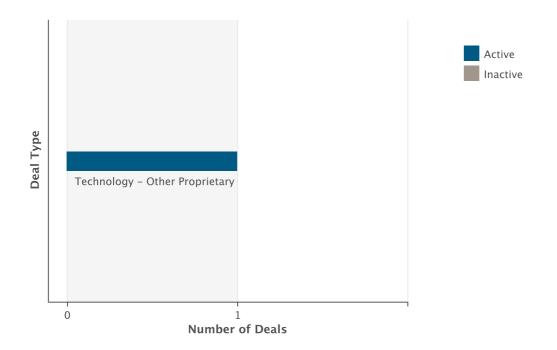
Deals by Parent Company Chart



# **Deals by Parent Company Table**

Company Name	<b>Principal</b> Active Inactive		Partner Active Inactive		Total
Flexion Therapeutics Inc	0	0	1	0	1
Southwest Research Institute (SwRI)	1	0	0	0	1

# **Deals by Type Chart**



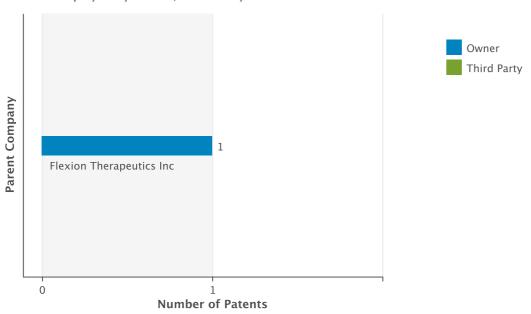
# **Deals by Type Table**

Deal Type	Active	Inactive	Total
Technology - Other Proprietary	1	0	1

## **PATENTS**

## **Patents by Parent Company Chart**

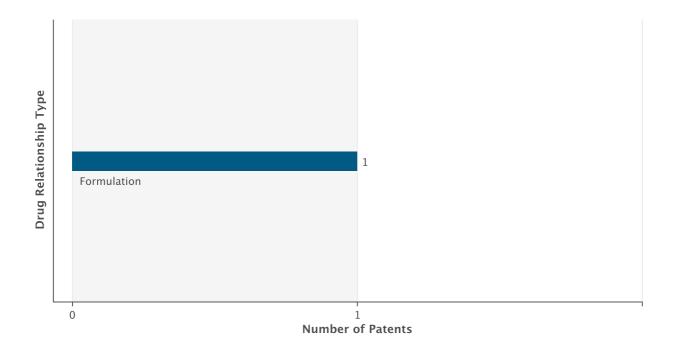
Chart displayed by Owner/Third Party



# **Patents by Parent Company Table**

Company Name	As Owner	As Third Party	Total
Flexion Therapeutics Inc	1	0	1

# **Patents by Drug Relationship Type Chart**





# **Patents by Drug Relationship Type Table**

Drug Relationship	Total
Formulation	1



## **FX-007**

#### **FX-007 SNAPSHOT**

Drug Name	FX-007
Key Synonyms	
Originator Company	Flexion Therapeutics Inc
Active Companies	Flexion Therapeutics Inc
Inactive Companies	
Highest Status	Discovery
Active Indications	Pain
Target-based Actions	TrkA receptor antagonist
Other Actions	Anti-inflammatory;Analgesic
Technologies	Sustained release formulation;Intra-articular formulation;Small molecule therapeutic
Last Change Date	04-Mar-2014

#### **FX-007 DEVELOPMENT PROFILE**

#### **SUMMARY**

Flexion is investigating FX-007, a sustained-release formulation of a small-molecule TrkA receptor antagonist for the potential intra-articular treatment of refractory pain in end-stage disease/joint replacement. In June 2013, development was ongoing. In March 2013, a pre-IND meeting was to be requested and proof-of-concept bunionectomy clinical trial to be initiated in 2H 2014; data were expected in 1H 2015.

#### **FX-007 DEVELOPMENT STATUS**

## **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	<b>Development Status</b>	Date	
Flexion Therapeutics Inc	Pain	US	Discovery	25-Oct-2011	

#### **FX-007 DRUG NAMES**

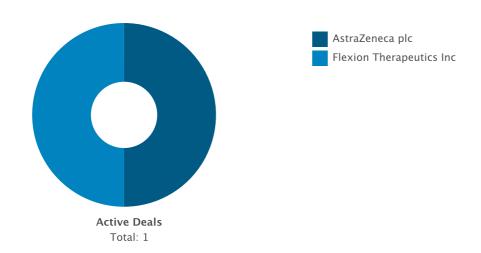
Names	Туре
FX-007	Research Code



# **FX-007 DEALS AND PATENTS**

DEALS

Deals by Parent Company Chart



# **Deals by Parent Company Table**

Company Name		<b>cipal</b> Inactive		tner Inactive	Total
AstraZeneca plc	1	0	0	0	1
Flexion Therapeutics Inc	0	0	1	0	1

# **Deals by Type Chart**



# **Deals by Type Table**

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

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