

# **Ocular Therapeutix 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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#### **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i.e. where the development status for the drug(s) is one of the following: No Development Reported, Discontinued, or Withdrawn.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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Clinical	17
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# **Ocular Therapeutix Inc**

#### **COMPANY OVERVIEW**

Company Name	Ocular Therapeutix Inc
Parent Company Name	Ocular Therapeutix Inc
Website	http://www.ocutx.com/
Country	US
Number of Drugs in Active Development	4
Number of Inactive Drugs	2
Number of Patents as Owner	0
Number of Patents as Third Party	1
Number of Deals	0
Key Indications	Glaucoma, Allergic conjunctivitis, Conjunctivitis, Ocular inflammation, Ocular pain, Retinopathy, Angle closure glaucoma, Ocular hypertension, Open angle glaucoma
Key Target-based Actions	DNA gyrase inhibitor, Glucocorticoid agonist, Prostanoid receptor agonist, Topoisomerase IV inhibitor, VEGF receptor antagonist
Key Technologies	Sustained release formulation, Small molecule therapeutic, Ophthalmic gel formulation, Drug implant, Microparticle formulation, Ophthalmic formulation, PEGylated formulation, Antibiotic, Lipid, Ophthalmic drug

## **COMPANY PROFILE**

#### **SUMMARY**

Ocular Therapeutix Inc (formerly I-Therapeutix), founded in November 2006, aims to develop and commercialize ophthalmic therapeutic products and ocular drug delivery vehicles using its hydrogel technology. In September 2009, I-Therapeutix changed its name to Ocular Therapeutix.

#### **FINANCIAL**

In July 2014, Ocular priced an IPO of 5 million shares at \$13 per share. Underwriters were granted an overallotment option to purchase up to 0.75 million additional shares. Shares were expected to be traded on the NASDAQ Global Market under the ticker symbol 'OCUL' on July 25, 2014. In August 2014, the company raised gross and net proceeds of approximately \$74.8 and \$66.5 million, respectively through the IPO of 5.75 million shares including the full exercise of the over-allotment option.

In June 2013, Ocula secured additional financing.

In January 2013, Ocular raised \$23.8 million from a series D extension round of financing.

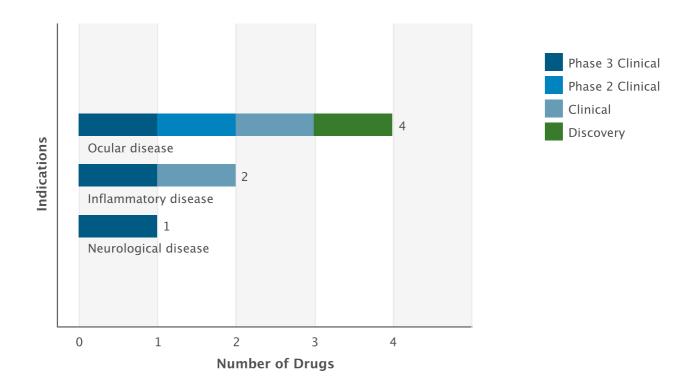
In February 2011, Ocular raised \$14 million from a series D financing round.

# PRODUCT PORTFOLIO SUMMARY

## **DRUGS**

## Drugs by Indication

Active Drugs by Indication Chart

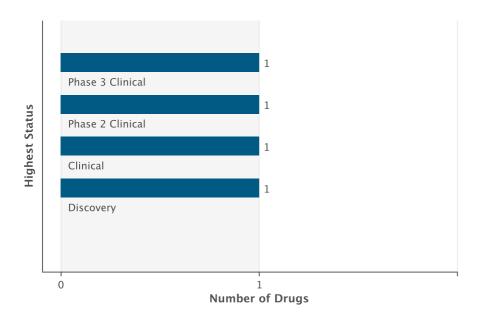


## Drugs by Indication Table

Indication	Active	Inactive	Total
Ocular disease	4	1	5
Inflammatory disease	2	0	2
Immune disorder	0	1	1
Neurological 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 3 Clinical	1
Phase 2 Clinical	1
Clinical	1
Discovery	1
No Development Reported	2

## **CLINICAL TRIALS**

## Trials by Condition Studied

Condition Studied	Ongoing	All
Ocular disease	1	12
Inflammatory disease	1	5
Neurological disease	1	3
Surgical procedure	0	1



#### Trials by Phase

Phase	Ongoing	All
Phase 3	1	2
Phase 2	0	4
Phase 1	0	1
Phase not specified	0	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

#### **PATENTS** \*

Indication	As Owner	As Third Party	Total
Ocular disease	0	1	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

# dexamethasone (punctum plug, ocular inflammation/pain), Ocular Therapeutix

dexamethasone (punctum plug, ocular inflammation/pain), Ocular Therapeutix SNAPSHOT

Drug Name	dexamethasone (punctum plug, ocular inflammation/pain), Ocular Therapeutix
Key Synonyms	dexamethasone
Originator Company	Ocular Therapeutix Inc
Active Companies	Ocular Therapeutix Inc
Inactive Companies	
Highest Status	Phase 3 Clinical
Active Indications	Allergic conjunctivitis;Ocular inflammation;Ocular pain
Target-based Actions	Glucocorticoid agonist
Other Actions	Analgesic;Anti-inflammatory;Ophthalmological corticosteroid;Steroidal anti-inflammatory
Technologies	Sustained release formulation;Ophthalmic formulation;Ophthalmic drug implant;Small molecule therapeutic
Last Change Date	13-Nov-2014

# dexamethasone (punctum plug, ocular inflammation/pain), Ocular Therapeutix DEVELOPMENT PROFILE

#### **SUMMARY**

Ocular Therapeutix is developing OTX-DP, a one-time, sustained-release, dexamethasone-loaded hydrogel punctum plug, for the potential intracanalicular treatment of post-operative ocular inflammation, pain and allergic conjunctivitis,.

In March 2014, a phase III trial was initiated for post-operative inflammation and pain. At that time, a second phase III trial was expected to start later in 2014. In October 2014, the company planned to submit results to the FDA in 2015. In March 2014, a phase II/III trial for allergic conjunctivitis was initiated; in November 2014, results were reported. At that time, phase III results were expected in 1Q15 and an NDA was planned to be filed with the FDA in 2Q15.

# dexamethasone (punctum plug, ocular inflammation/pain), Ocular Therapeutix DEVELOPMENT STATUS

## **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	<b>Development Status</b>	Date
Ocular Therapeutix Inc	Allergic conjunctivitis	US	Phase 3 Clinical	31-Mar-2014
Ocular Therapeutix Inc	Ocular inflammation	US	Phase 3 Clinical	17-Mar-2014



Company	Indication	Country	<b>Development Status</b>	Date
Ocular Therapeutix Inc	Ocular pain	US	Phase 3 Clinical	17-Mar-2014

# dexamethasone (punctum plug, ocular inflammation/pain), Ocular Therapeutix CHEMICAL STRUCTURES

CAS Registry Number:	Confidence Level:
50-02-2	1
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	H >
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0	
Name	Туре
dexamethasone	BANN; INN
Ozurdex	Trade Name
S24.43%	Trade Name
Surodex	Trade Name
OTO-104	Research Code
TLC-x99	Research Code
IBI-10090	Research Code
EGP-437	Research Code
OTX-DP	Research Code
CD-102	Research Code
ISV-305	Research Code
Oncocort	

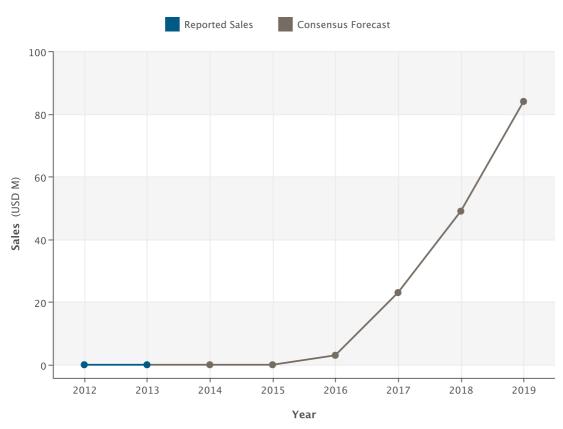
# dexamethasone (punctum plug, ocular inflammation/pain), Ocular Therapeutix DRUG NAMES

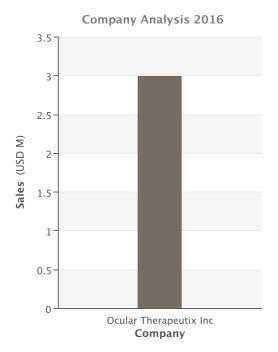
Names	Туре
OTX-DP	Research Code
dexamethasone (punctum plug, ocular inflammation/pain), Ocular Therapeutix	
dexamethasone	BANN, INN



# dexamethasone (punctum plug, ocular inflammation/pain), Ocular Therapeutix SALES AND CHARTS











#### **COMMENTARY**

#### **CONSENSUS SALES INFORMATION**

Consensus forecast data for Ocular Therapeutix are presented.

#### **REGIONAL DEVELOPMENT AND MARKETING RIGHTS**

Ocular Therapeutix holds worldwide development and marketing rights.

# dexamethasone (punctum plug, ocular inflammation/pain), Ocular Therapeutix CLINICAL TRIALS

#### Trials by Phase and Condition Studied

	se 4 lical		se 3 nical	Pha Clin	se 2 iical		se 1 nical	Pha Unspe		То	tal
On- going	All	On- going	All	On- going	All	On- going	All	On- going	All	On- going	All
Ocular in	flammatio	n									
0	0	1	2	0	1	0	0	0	0	1	3
Ocular pa	ain										
0	0	1	2	0	1	0	0	0	0	1	3
Allergic conjunctivitis											
0	0	0	0	0	1	0	0	0	0	0	1

## Total Trials by Phase and Status

	se 4 lical		se 3 nical		se 2 nical		se 1 nical		ase ecified	То	tal
On- going	All	On- going	All	On- going	All	On- going	All	On- going	All	On- going	All
Total by Phase and Status											
0	0	1	2	0	2	0	0	0	0	1	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 1a, Phase 1, Phase 1/2 (where enrolment count is under 100 or not specified), Phase 0

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# travoprost (sustained release/punctal plug delivery system, glaucoma), Ocular Therapeutix

# travoprost (sustained release/punctal plug delivery system, glaucoma), Ocular Therapeutix SNAPSHOT

Drug Name	travoprost (sustained release/punctal plug delivery system, glaucoma), Ocular Therapeutix
Key Synonyms	travoprost
Originator Company	Ocular Therapeutix Inc
Active Companies	Ocular Therapeutix Inc
Inactive Companies	
Highest Status	Phase 2 Clinical
Active Indications	Glaucoma
Target-based Actions	Prostanoid receptor agonist
Other Actions	Antiglaucoma agent;PGF2 alpha agonist
Technologies	Lipid;Drug implant;Sustained release formulation;Microparticle formulation;Small molecule therapeutic;Ophthalmic gel formulation
Last Change Date	14-Nov-2014

travoprost (sustained release/punctal plug delivery system, glaucoma), Ocular Therapeutix DEVELOPMENT PROFILE

#### **SUMMARY**

Ocular Therapeutix is developing sustained-release formulations of travoprost, including OTX-TP, OTX-TP1 and OTX-TP2, delivered using the company's punctum plug delivery system, for the potential treatment of glaucoma,.

In May 2012, a feasibility study of OTX-TP1, a 30-day sustained-release formulation, was initiated in glaucoma patients; in July 2012, data were reported. In August 2012, a pilot phase II trial was initiated using OTX-TP2, a 2-month sustained-release formulation; in October 2012, data were reported. In November 2014, patient enrollment was initiated in a phase IIb trial.

The company is also investigating the treatment as OTX-TP2, a 60-day sustained-release formulation of travoprost; at that time, phase II trials were expected later in 2012.

# travoprost (sustained release/punctal plug delivery system, glaucoma), Ocular Therapeutix DEVELOPMENT STATUS

#### **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	<b>Development Status</b>	Date
Ocular Therapeutix Inc	Glaucoma	South Africa	Phase 2 Clinical	20-Aug-2012
Ocular Therapeutix Inc	Glaucoma	Singapore	Clinical	04-May-2012



### travoprost (sustained release/punctal plug delivery system, glaucoma), Ocular Therapeutix **CHEMICAL STRUCTURES**

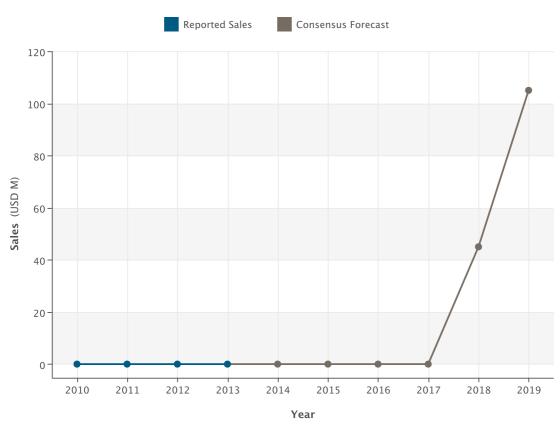
CAS Registry Number:	Confidence Level:
157283-68-6	1
HO HO OH	
Name	Туре
travoprost	BANN; INN; USAN
Travatan	Trade Name
Izba	Trade Name
AL-6221	Research Code
GLT-137	Research Code

#### travoprost (sustained release/punctal plug delivery system, glaucoma), Ocular Therapeutix DRUG **NAMES**

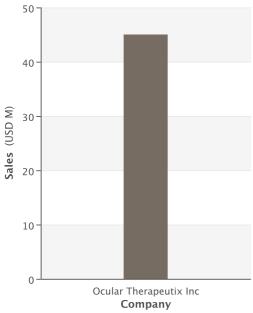
Names	Туре
OTX-TP2	Research Code
travoprost	USAN, BANN, INN
travoprost (sustained release/punctal plug delivery system, glaucoma), Ocular Therapeutix	
OTX-TP	Research Code
prostaglandin (ophthalmic sustained release/punctal plug delivery system), Ocular Therapeutix	
OTX-TP1	Research Code

# travoprost (sustained release/punctal plug delivery system, glaucoma), Ocular Therapeutix CHARTS

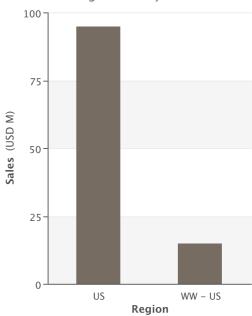








## Regional Analysis 2018





#### **COMMENTARY**

#### **CONSENSUS SALES INFORMATION**

Consensus forecast data for Ocular Therapeutix are presented.

#### REGIONAL DEVELOPMENT AND MARKETING RIGHTS

Ocular Therapeutix holds worldwide development and marketing rights.

# travoprost (sustained release/punctal plug delivery system, glaucoma), Ocular Therapeutix 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
Open angle glaucoma											
0	0	0	0	0	2	0	1	0	1	0	4
Ocular hypertension											
0	0	0	0	0	2	0	0	0	0	0	2

#### Total Trials by Phase and Status

	se 4 lical		se 3 nical		se 2 iical		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	2	0	1	0	1	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

# moxifloxacin (ophthalmic sustained release/punctal plug delivery system, bacterial conjunctivitis), Ocular Therapeutix

moxifloxacin (ophthalmic sustained release/punctal plug delivery system, bacterial conjunctivitis), Ocular Therapeutix SNAPSHOT

Drug Name	moxifloxacin (ophthalmic sustained release/punctal plug delivery system, bacterial conjunctivitis), Ocular Therapeutix
Key Synonyms	moxifloxacin
Originator Company	Ocular Therapeutix Inc
Active Companies	Ocular Therapeutix Inc
Inactive Companies	
Highest Status	Clinical
Active Indications	Conjunctivitis
Target-based Actions	DNA gyrase inhibitor;Topoisomerase IV inhibitor
Other Actions	Bacterial nucleic acid synthesis inhibitor;Ophthalmological antibacterial
Technologies	PEGylated formulation;Drug implant;Sustained release formulation;Antibiotic;Microparticle formulation;Small molecule therapeutic;Ophthalmic gel formulation
Last Change Date	05-Jun-2013

moxifloxacin (ophthalmic sustained release/punctal plug delivery system, bacterial conjunctivitis), Ocular Therapeutix DEVELOPMENT PROFILE

#### **SUMMARY**

Ocular Therapeutix is developing a sustained-release formulation of moxifloxacin, a PEG hyrogel rod comprising of free and poly (lactic-co-glycolic acid) encapsulated moxifloxacin particles, delivered using the company's punctum plug delivery system, for the potential treatment of bacterial conjunctivitis. In October 2010, positive clinical results were reported; in May 2013, further clinical data were reported.

moxifloxacin (ophthalmic sustained release/punctal plug delivery system, bacterial conjunctivitis), Ocular Therapeutix DEVELOPMENT STATUS

#### **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	<b>Development Status</b>	Date
Ocular Therapeutix Inc	Conjunctivitis	US	Clinical	12-Oct-2010

moxifloxacin (ophthalmic sustained release/punctal plug delivery system, bacterial conjunctivitis), Ocular Therapeutix CHEMICAL STRUCTURES

CAS Registry Number:	Confidence Level:
151096-09-2	1
H H H H H H H H H H H H H H H H H H H	O N O O H
Name	Туре
moxifloxacin	BANN; INN
Avalox	Trade Name
Avelox	Trade Name

moxifloxacin (ophthalmic sustained release/punctal plug delivery system, bacterial conjunctivitis), Ocular Therapeutix DRUG NAMES

Names	Туре
moxifloxacin	BANN, INN
moxifloxacin (ophthalmic sustained release/punctal plug delivery system, bacterial conjunctivitis), Ocular Therapeutix	

moxifloxacin (ophthalmic sustained release/punctal plug delivery system, bacterial conjunctivitis), Ocular Therapeutix CLINICAL TRIALS

Trials by Phase and Condition Studied

Phase 4 Clinical		Phase 3 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
Conjuncti	ivitis										
0	0	0	0	0	0	0	0	0	1	0	1

## Total Trials by Phase and Status

Phase 4 Clinical		Phase 3 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
Total by Phase and Status											
0	0	0	0	0	0	0	0	0	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 1, Phase 1, Phase 1/2 (where enrolment count is under 100 or not specified), Phase 0



# anti-VEGF protein therapeutic (sustained release depot, retinal disease), Ocular Therapeutix

# anti-VEGF protein therapeutic (sustained release depot, retinal disease), Ocular Therapeutix SNAPSHOT

Drug Name	anti-VEGF protein therapeutic (sustained release depot, retinal disease), Ocular Therapeutix				
Key Synonyms					
Originator Company	Ocular Therapeutix Inc				
Active Companies	Ocular Therapeutix Inc				
Inactive Companies					
Highest Status	Discovery				
Active Indications	Retinopathy				
Target-based Actions	VEGF receptor antagonist				
Other Actions					
Technologies	PEGylated formulation;Sustained release formulation;Ophthalmic formulation;Small molecule therapeutic;Peptide				
Last Change Date	13-Nov-2014				

# anti-VEGF protein therapeutic (sustained release depot, retinal disease), Ocular Therapeutix DEVELOPMENT PROFILE

#### **SUMMARY**

Ocular Therapeutix is investigating a posterior segment sustained release depot formulation of an anti-VEGF protein therapeutic, delivered using PEG hydrogel technology, for the potential intravitreal treatment of back of the eye disease,. In January 2014, development was ongoing. In October 2014, the program was listed as being in preclinical development.

# anti-VEGF protein therapeutic (sustained release depot, retinal disease), Ocular Therapeutix DEVELOPMENT STATUS

#### **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	<b>Development Status</b>	Date
Ocular Therapeutix Inc	Retinopathy	US	Discovery	10-Jan-2014

# anti-VEGF protein therapeutic (sustained release depot, retinal disease), Ocular Therapeutix DRUG NAMES

Names	Туре
anti-VEGF protein therapeutic (sustained release depot, retinal disease), Ocular Therapeutix	



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