

# FibroGen Inc

## **COMPANY AND PIPELINE OVERVIEW REPORT**

A comprehensive coverage of the company and a summary of the drug pipeline portfolio.

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## ABOUT COMPANY AND PIPELINE OVERVIEW 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i.e. where the development status for the drug(s) is one of the following: No Development Reported, Discontinued, or Withdrawn.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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**PLEASE NOTE:** the financials section where present in the report includes: Share Information, Stock Performance chart (including the consensus recommendation), and Major Shareholders. Financial Performance presents graphical and tabular data on Worldwide Sales, Operating Income and Net Income over time, together with a Quarterly earnings update. Balance Sheet lists Assets, Liabilities and Stockholders Equity, and Forecasts includes: EPS Forecast and Other Forecasts. The data reported in all sections (except share information and major stock holders) are correct as of the publication date of the report (and not the download date). For share information and major stock holders the data is correct for the date shown with these sections



## **TABLE OF CONTENTS**

Company Overview	7
Company Profile	7
Company Financials	8
Product Portfolio Summary	12
Product Portfolio Financials	17
Product Portfolio Drugs	18



### FibroGen Inc

#### **COMPANY OVERVIEW**

Company Name	FibroGen Inc
Parent Company Name	FibroGen Inc
Website	http://www.fibrogen.com/
Country	US
Number of Drugs in Active Development	4
Number of Inactive Drugs	8
Number of Patents as Owner	73
Number of Patents as Third Party	2
Number of Deals	13
Key Indications	Anemia,Pancreas tumor,Glioma,Idiopathic pulmonary fibrosis,Diabetic nephropathy,Duchenne dystrophy,Focal segmental glomerulosclerosis,Glaucoma,Liver fibrosis,Ischemia
Key Target-based Actions	HIF prolyl hydroxylase inhibitor,TGF beta antagonist,Connective tissue growth factor ligand inhibitor,Bone morphogenetic protein-1 ligand inhibitor,HIF prolyl hydroxylase-1 modulator,Hydroxylase inhibitor,Angiotensin receptor antagonist,CD66e antagonist,CTGF gene inhibitor,Calcineurin inhibitor,Erythropoietin receptor agonist,HIF prolyl hydroxylase-1 inhibitor,Hydroxylase modulator,IL-6 agonist,LDL receptor antagonist,Prolyl hydroxylase inhibitor,TGF beta agonist
Key Technologies	Small molecule therapeutic,Biological therapeutic,Oral formulation,Protein recombinant,Capsule formulation,Monoclonal antibody human,Tablet formulation,Infusion,Intravenous formulation,Peptide

### **COMPANY PROFILE**

### **SUMMARY**

FibroGen Inc, a spin-out of Duke University, founded in 1994, is a privately held biotechnology company which has developed the only commercially viable method known to produce human collagen and human gelatin in recombinant systems. The company's therapeutic target areas include fibrotic disorders affecting the major organs, diabetes, surgical procedures, and fibroproliferative tumor progression and metastasis.

### **COMPANY LOCATION**

Fibrogen's headquarters are in San Francisco, CA. Fibrogen Europe, a subsidiary of Fibrogen based in Helsinki, Finland, is a biotechnology focused enterprise that specialises in the development of recombinant collagens and gelatins.

In March 2015, the Beijing Chinese FDA had completed the inspections and issued the Pharmaceutical Production Permit (PPP) to FibroGen China facility as per GMP standards.

#### LICENSING AGREEMENTS

In January 2001, FibroGen and Aventis Pasteur formed a collaboration agreement to develop, using FibroGen's proprietary technology, novel synthetic gelatins with the potential to confer optimum stabilization and activity attenuation specific for certain Aventis Pasteur vaccines.

As of October 1999, FibroGen had a research and development agreement with Medarex Inc to develop monoclonal antibodies to block the fibrogenic cascade. In July 1998, FibroGen signed an agreement with Medarex for the use of the HuMab mouse antibody technology to develop potential antifibrotic therapies using FibroGen's proprietary targets.

In September 1999, FibroGen announced a collaboration with Taisho Pharmaceutical Co Ltd to develop and commercialize human monoclonal antibodies for the treatment of fibrotic kidney diseases; however, no development has been reported by Taisho since May 2002 and in August 2005 this strategic alliance was not listed on FibroGen's



website.

In 1997, FibroGen licensed ArQule's Mapping Array program to discover and develop drug candidates for fibrosis and excessive scarring; however, since 2002, no development had been reported on this deal.

### **EARLY R&D/TECHNOLOGY UPDATES/IP NEWS**

In December 1998, FibroGen received US-05837258, covering the use of connective tissue growth factor to induce the repair of connective tissue, including bone, cartilage and skin.

As of June 1998, programs were underway at FibroGen for the development of small-molecules which modulate collagen scar formation and human antibodies to neutralize cytokine and enzyme targets.

#### **FINANCIAL**

In October 2014, FibroGen filed a registration statement on Form S1 with the US SEC relating to a proposed initial public offering of shares of its common stock. In November 2014, the company announced the pricing of 8,100,000 shares of its common stock at a public offering price of \$18.00 per share before underwriting discounts and commissions on the NASDAQ Global Market under the ticker symbol 'FGEN'. At that time, the underwriters were granted a 30-day option to purchase upto 1,215,000 additionally at the initial offering price and the offering was expected to be closed on November 19, 2014; later that month, the company announced that the underwriters of its initial public offering were exercised in full option to purchase an additional 1,215,000 shares of common stock from FibroGen less than the underwriting discount. The initial public offering was a total of 9,315,000 shares of common stock of FibroGen, with gross proceeds of approximately \$167.7 million, prior to deducting the underwriting discount and estimated offering expenses. The Company's common stock started trading on the NASDAQ Global Select Market. At that time, the company raised a net proceeds of \$171.8 million from the IPO.

In February 2005, FibroGen raised net proceeds of \$100 million from a completed a private placement of convertible preferred stock, 15% of which was sold to existing investors. The funds would be used to expand the company's clinical trial activities including anemia, idiopathic pulmonary fibrosis and diabetic nephropathy. New clinical programs in acute renal failure and in rare diseases in anemia and in fibrosis would also be launched, and the metastatic cancers program extended. The funds would also be used for efficacy studies and commercial-scale manufacturing of injectable recombinant human collagen.

In September 2000, FibroGen completed a \$56.7 million private placement of convertible preferred stock.

#### **R&D GRANTS**

In April 1999, the Finnish government reported that it would fund 50% of the company's recombinant collagen and gelatin costs.

#### **COMPANY FINANCIALS**

#### **SHARE INFORMATION**

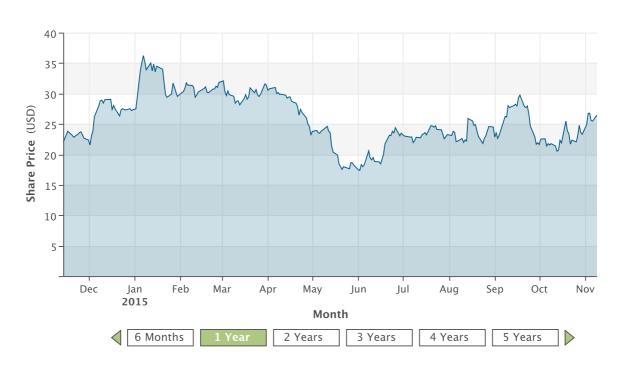
Close Price (USD)	26.45
Change (USD)	1.00 (3.93%)
Previous Close Price (USD)	25.45
Volume	545,379
52-Week High (USD)	40.59
52-Week Low (USD)	16.95
Date	09-Nov-2015
Exchange	NASDAQ(COMPOSITE)
Current Number of Shares Outstanding	59,267,869



Current Market Capitalization	1,541,376,705
EPS (Date Reported)	-3.16932

### STOCK PERFORMANCE

### **Stock Performance**



## **MAJOR SHAREHOLDERS**

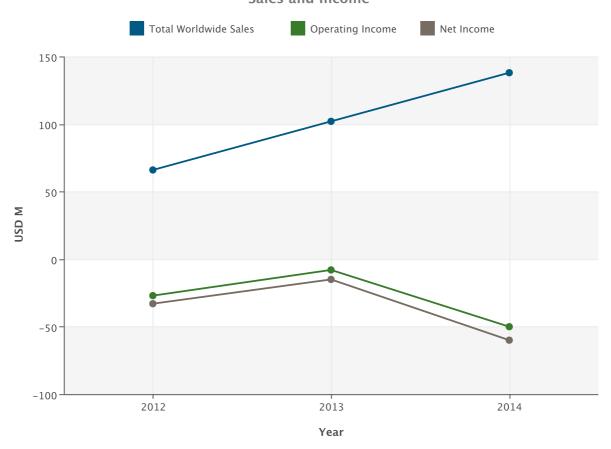
Shareholder	Туре	Country	Shares held	% of shares held	Change in holding	% changes in shares held	Date
Neff (Thomas B)	Individua I Investor	United States	3,929,705	6.49	-81,000	-0.02	30-Oct-2015
iShares Russell 2000 ETF	Mutual Fund	United States	715,080	1.18	-16,817	-0.02	31-Oct-2015
iShares Russell 2000 Growth ETF	Mutual Fund	United States	369,293	0.61	1,239	0	31-Oct-2015
Kearns (Thomas F Jr)	Individua I Investor	United States	267,736	0.44	-7,800	-0.03	21-Oct-2015
Yu (K Peony)	Individua I Investor	United States	164,930	0.27	-10,000	-0.06	19-Oct-2015
Valone (Frank H)	Individua I Investor	United States	61,544	0.1	0	0	02-Nov-2015
iShares Russell 3000 ETF	Mutual Fund	United States	12,917	0.02	104	0.01	31-Oct-2015



iShares Morningstar Small-Cap Growth ETF	Mutual Fund	United States	11,880	0.02	-56	-0	31-Oct-2015
SEI Institutional Managed - Small Cap Fund	Mutual Fund	United States	10,963	0.02	0	0	31-Oct-2015
Fidelity MSCI Health Care Index ETF	Mutual Fund	United States	10,272	0.02	-639	-0.06	31-Oct-2015
ProFund Advisors LLC	Investme nt Advisor	United States	8,277	0.01	-3	-0	31-Oct-2015
iShares Russell 3000 Growth ETF	Mutual Fund	United States	3,511	0.01	17	0	31-Oct-2015
Guggenheim Investments	Investme nt Advisor/ Hedge Fund	United States	1,876	0	0	0	31-Oct-2015
ProShares Hedge Replication ETF	Mutual Fund	United States	49	0	-3	-0.06	31-Oct-2015

### FINANCIAL PERFORMANCE

### Sales and Income





	2012	2013	2014	
Sales (USD M)	65.933	102.17	137.601	
Operating Income (USD M)	-27.223	-7.949	-50.102	
Net Income (USD M)	-32.571	-14.943	-59.504	

## **Quarterly earnings update**

Period	Sales (USD M)	Operating Income (USD M)	Net Income (USD M)
2015 Q2	120.55	59.315	57.055
2015 Q1	16.298	-44.723	-46.367
2014 Q4	16.105	-47.974	-50.56
2014 Q3	13.662	-37.095	-18.797
2014 Q2	89.958	49.173	26.093
2014 Q1	17.876	-14.206	-16.24
2013 Q4	12.39	-24.955	-15.528
2013 Q3	71.248	41.176	28.058
2013 Q2	15.695	-7.484	-9.297
2013 Q1	2.837	-16.686	-18.176

## **BALANCE SHEET**

## Assets (USD M)

	2012	2013	2014	
Cash & Short Term Investments	39.889	122.809	179.819	
Inventories - Total	0	0	0	
Current Assets - Total	52.803	143.643	198.238	
Property, Plant And Equipment - Net	123.664	129.898	132.171	
Other Assets - Total	0.254	0.801	1.596	
Total Assets	265.588	296.952	483.528	

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## Liabilities (USD M)

	2012	2013	2014	
Accounts Payable	3.107	1.066	4.551	
Short Term Debt & Current Portion Of Long Term Debt	1.698	1.113	0.587	
Current Liabilities - Total	23.678	37.479	62.754	
Long Term Debt	110.546	114.847	113.283	
Deferred Taxes	0	0		
Other Liabilities	5.809	6.115	5.827	
Total Liabilities	143.404	189.349	242.852	

### Stockholders Equity (USD M)

	2012	2013	2014	
Minority Interest	27.7	27.875	19.271	
Preferred Stock	304.749	304.749	0	
Common Stock	0.132	0.132	0.59	
Treasury Stock	0	0		
Total Liabilities & Shareholders' Equity	265.588	296.952	483.528	

### **FORECASTS**

## **EPS Forecast**

Year ending	Current Forecast	1 month ago	3 months ago
31-Dec-2015	-0.81	-0.96	-1.31
31-Dec-2016	-1.25	-1.29	-1.46
31-Dec-2017	-1.89	-2.06	-1.67

### **Other Forecasts**

Year ending	DPS	CPS	Pretax	Sales
31-Dec-2015	0		-47.32	211.03
31-Dec-2016	0		-82.16	174.58
31-Dec-2017	0		-126.47	174.08

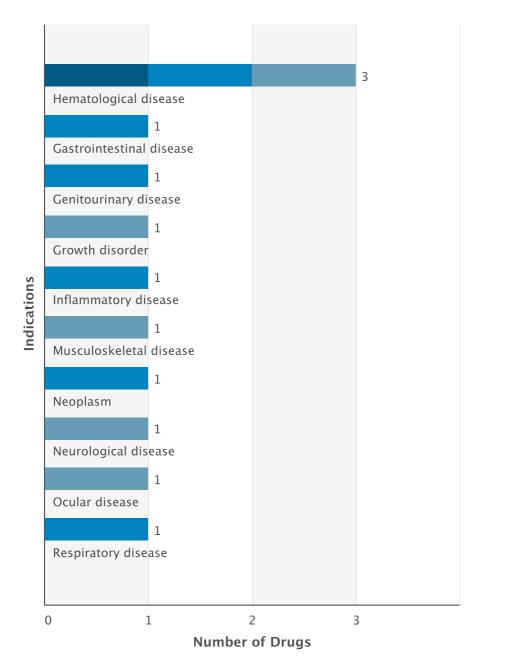


# PRODUCT PORTFOLIO SUMMARY

### **DRUGS**

## Drugs by Indication

Active Drugs by Indication Chart



Phase 3 Clinical
Phase 2 Clinical
Discovery



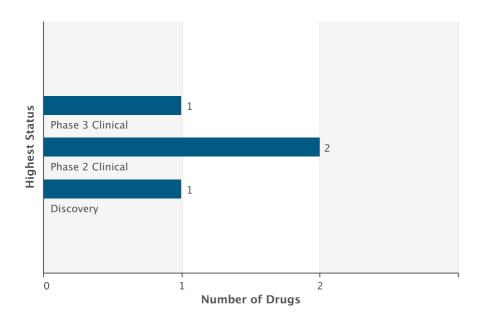
# Drugs by Indication Table

Indication	Active	Inactive	Total
Inflammatory disease	1	4	5
Hematological disease	3	1	4
Musculoskeletal disease	1	2	3
Neurological disease	1	2	3
Gastrointestinal disease	1	1	2
Cardiovascular disease	0	2	2
Neoplasm	1	1	2
Injury	0	2	2
Genitourinary disease	1	1	2
Ocular disease	1	0	1
Dermatological disease	0	1	1
Growth disorder	1	0	1
Genetic disorder	0	1	1
Immune disorder	0	1	1
Respiratory 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
No Development Reported	8
Discovery	1
Phase 2 Clinical	2

### **DEALS**

Deal Type	Prin	cipal	Par	tner	Total
	Active	Inactive	Active	Inactive	
Drug - Development/Commercialization License	4	0	1	0	5
Patent - Exclusive Rights	0	0	1	0	1
Drug - Funding	3	0	0	0	3
Technology - Other Proprietary	1	0	2	0	3
Technology - Target Validation	0	0	1	0	1



### **CLINICAL TRIALS**

### Trials by Condition Studied

Condition Studied	Ongoing	All
Hematological disease	9	23
Genitourinary disease	0	8
Inflammatory disease	2	5
Gastrointestinal disease	2	5
Respiratory disease	2	3
Metabolic disorder	0	3
Endocrine disease	0	3
Neoplasm	1	2
Dermatological disease	0	1
Cardiovascular disease	0	1
Genetic disorder	0	1
Neurological disease	0	1

### Trials by Phase

Phase	Ongoing	All
Phase 3	8	9
Phase 2	4	16
Phase 1	1	13
Phase not specified	0	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  $\,$ 

### **PATENTS** \*

Indication	As Owner	As Third Party	Total
Immune disorder	10	0	10



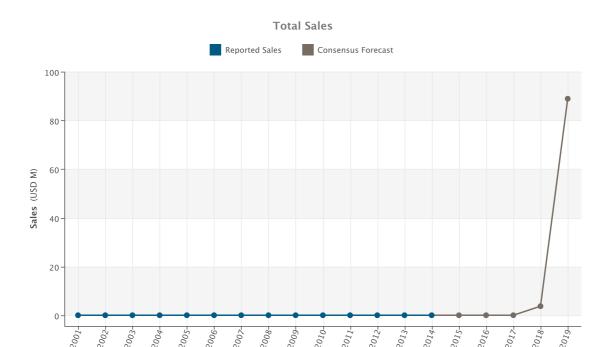
Psychiatric disorder	1	0	1
Musculoskeletal disease	17	2	19
Neoplasm	15	1	16
Ocular disease	6	0	6
Genetic disorder	1	0	1
Metabolic disorder	18	2	20
Neurological disease	15	1	16
Nutritional disorder	2	0	2
Prophylaxis	1	0	1
Respiratory disease	24	0	24
Infectious disease	7	0	7
Injury	6	0	6
Cardiovascular disease	35	1	36
Endocrine disease	13	0	13
Gastrointestinal disease	24	0	24
Genitourinary disease	25	1	26
Growth disorder	3	0	3
Hematological disease	25	0	25
Degeneration	1	0	1
Surgical procedure	0	1	1
Dermatological disease	5	0	5
Ulcer	2	0	2
Gynecology and obstetrics	3	0	3
Inflammatory disease	30	3	33

<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.



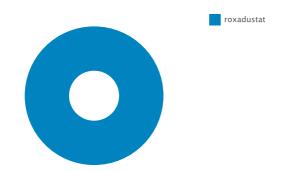
### PRODUCT PORTFOLIO FINANCIALS

### **DRUG SALES AND FORECASTS**



Drug Sales as a Share of the Total Sales 2018

Year





### **PRODUCT PORTFOLIO DRUGS**

PLEASE NOTE: Highest status refers to highest development of that drug for one of the active companies

### roxadustat

Drug Name	roxadustat
Key Synonyms	roxadustat, ciclopirox
Originator Company	FibroGen Inc
Active Companies	Astellas Pharma Inc, AstraZeneca plc, FibroGen Inc
Inactive Companies	Zeneca Group plc
Highest Status	Phase 3 Clinical
Active Indications	Anemia
Target-based Actions	HIF prolyl hydroxylase inhibitor
Other Actions	Erythropoietin modulator
Technologies	Tablet formulation, Oral formulation, Capsule formulation, Small molecule therapeutic
Last Change Date	28-Sep-2015

### FG-3019

Drug Name	FG-3019
Key Synonyms	pamrevlumab
Originator Company	FibroGen Inc
Active Companies	FibroGen Inc
Inactive Companies	Taisho Pharmaceutical Co Ltd
Highest Status	Phase 2 Clinical
Active Indications	Diabetic nephropathy, Duchenne dystrophy, Liver fibrosis, Pancreas tumor, Glaucoma, Glioma, Focal segmental glomerulosclerosis, Idiopathic pulmonary fibrosis
Target-based Actions	Connective tissue growth factor ligand inhibitor
Other Actions	Anticancer monoclonal antibody, Angiogenesis inhibitor, Fibrosuppressant
Technologies	Biological therapeutic, Intravenous formulation, Infusion, Protein recombinant, Monoclonal antibody human
Last Change Date	14-Aug-2015



## FG-2216

Drug Name	FG-2216
Key Synonyms	
Originator Company	FibroGen Inc
Active Companies	FibroGen Inc, Astellas Pharma Inc
Inactive Companies	Yamanouchi Pharmaceutical Co Ltd
Highest Status	Phase 2 Clinical
Active Indications	Anemia
Target-based Actions	HIF prolyl hydroxylase inhibitor
Other Actions	Erythropoietin release stimulator, Hematopoietic stimulant
Technologies	Oral formulation, Small molecule therapeutic
Last Change Date	03-Feb-2015

# next generation HIF-PH inhibitors (anemia), FibroGen

Drug Name	next generation HIF-PH inhibitors (anemia), FibroGen
Key Synonyms	
Originator Company	FibroGen Inc
Active Companies	FibroGen Inc
Inactive Companies	
Highest Status	Discovery
Active Indications	Anemia
Target-based Actions	HIF prolyl hydroxylase inhibitor
Other Actions	Blood system agent
Technologies	Small molecule therapeutic
Last Change Date	25-Sep-2014

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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.

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