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FibroGen 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

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 accurateand 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.

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Discover undiscovered opportunities in drug development and licensing faster with *Thomson Reuters Cortellis™ for Competitive Intelligence*

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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i.e. where the development status for the drug(s) is one of the following: No Development Reported, Discontinued, or Withdrawn.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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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	72
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

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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.

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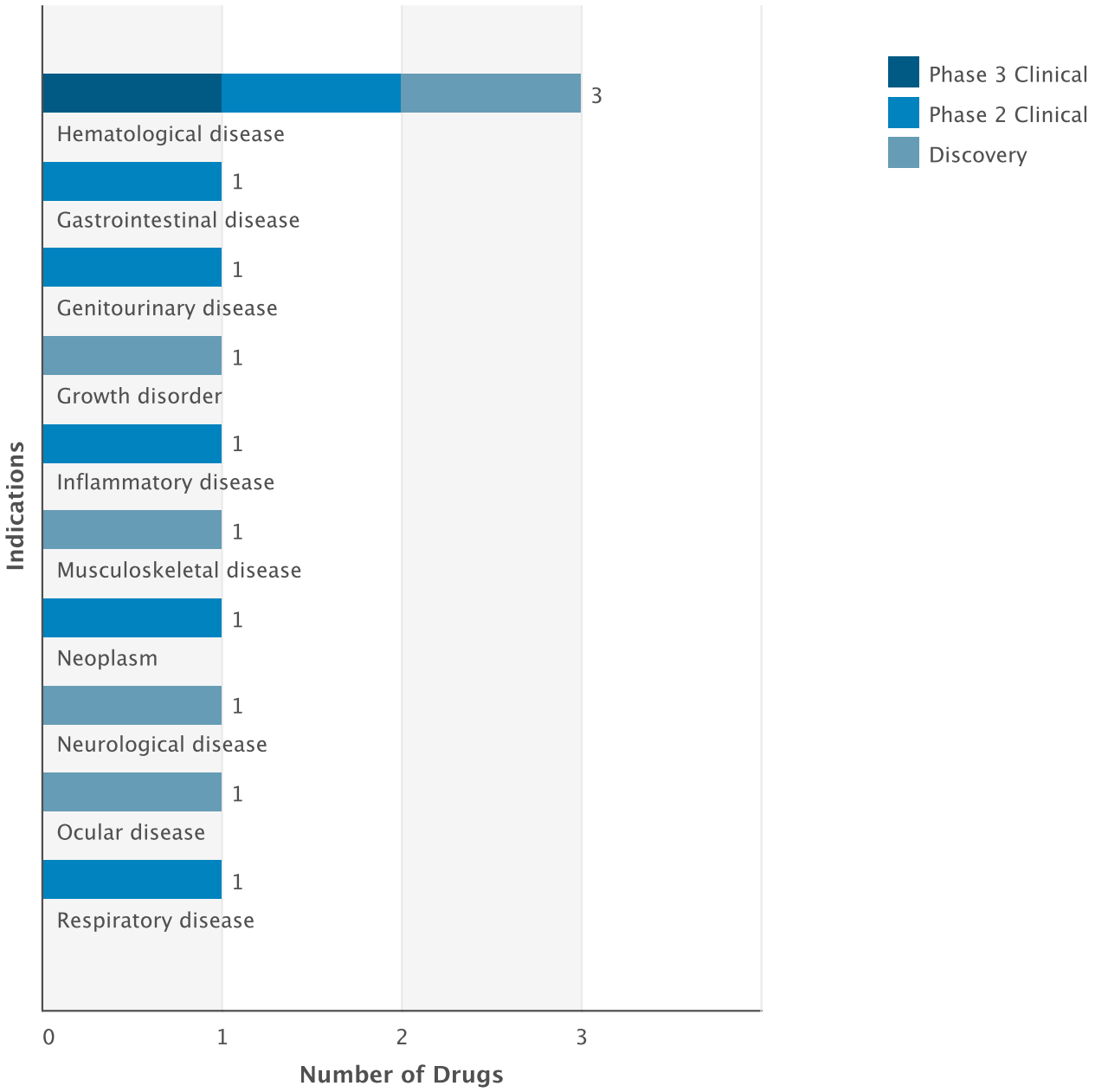
PRODUCT PORTFOLIO SUMMARY

DRUGS

Drugs by Indication

Active Drugs by Indication Chart



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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
Genitourinary disease	1	1	2
Gastrointestinal disease	1	1	2
Neoplasm	1	1	2
Cardiovascular disease	0	2	2
Injury	0	2	2
Dermatological disease	0	1	1
Genetic disorder	0	1	1
Immune disorder	0	1	1
Respiratory disease	1	0	1
Ocular disease	1	0	1
Growth disorder	1	0	1

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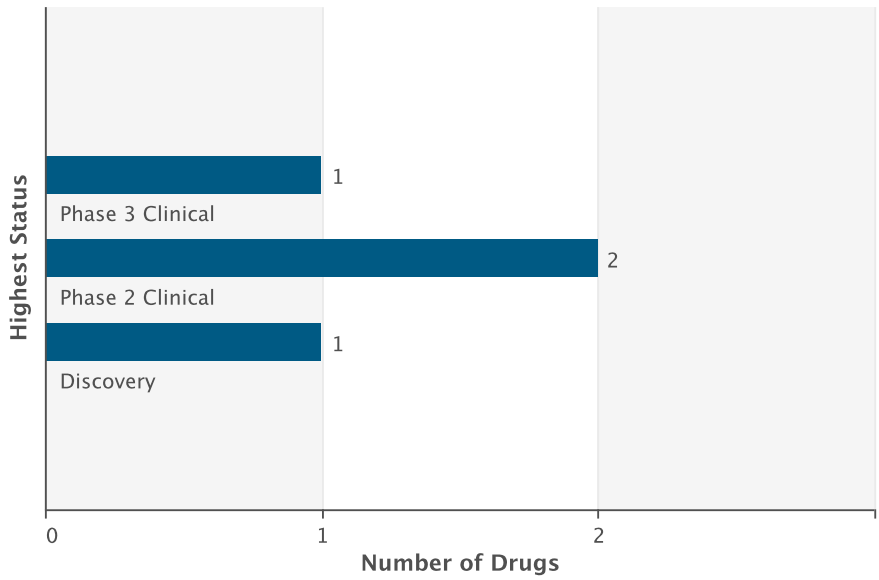
Drugs by Highest Status

Active Drugs by Highest Status Chart



Drugs by Highest Status Table

Development Status	Number of Drugs
Phase 3 Clinical	1
Phase 2 Clinical	2
Discovery	1
No Development Reported	8

DEALS

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

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CLINICAL TRIALS

Trials by Condition Studied

Condition Studied	Ongoing	All
Hematological disease	9	23
Genitourinary disease	0	8
Gastrointestinal disease	2	5
Inflammatory disease	2	5
Respiratory disease	2	3
Endocrine disease	0	3
Metabolic disorder	0	3
Neoplasm	1	2
Neurological disease	0	1
Cardiovascular disease	0	1
Dermatological disease	0	1
Genetic disorder	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
Cardiovascular disease	34	1	35

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Endocrine disease	13	0	13
Gastrointestinal disease	24	0	24
Genitourinary disease	25	1	26
Growth disorder	3	0	3
Hematological disease	24	0	24
Degeneration	1	0	1
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	23	0	23
Infectious disease	7	0	7
Injury	6	0	6
Gynecology and obstetrics	3	0	3
Dermatological disease	5	0	5
Ulcer	2	0	2
Surgical procedure	0	1	1
Inflammatory disease	30	3	33

* This table represents a summary of the core patent coverage for this company covering Therapeutic EP, US and WO patents since 1990 only.

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PRODUCT PORTFOLIO DRUG PIPELINE DETAIL

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

roxadustat

roxadustat SNAPSHOT

Drug Name	roxadustat
Key Synonyms	ciclopirox;roxadustat
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	Capsule formulation;Oral formulation;Small molecule therapeutic;Tablet formulation
Last Change Date	02-Sep-2015

roxadustat DEVELOPMENT PROFILE

SUMMARY

FibroGen, Astellas Pharma and AstraZeneca are developing roxadustat (FG-4592, AZD-9941, ASP-1517), a hypoxia-inducible factor-prolyl hydroxylase (HIF-PH) inhibitor, for the potential oral treatment of anemia in patients with end-stage renal disease (ESRD) and chronic kidney disease (CKD) ,,.

In November 2012, a phase III trial sponsored by FibroGen with collaboration from Astellas and AstraZeneca was initiated in the US in CKD patients not on dialysis ; in May 2013, a phase III trial sponsored by Astellas with collaboration from FibroGen began in Europe in CKD patients not on dialysis. In December 2013, a phase III trial sponsored by FibroGen with collaboration from Astellas and AstraZeneca was initiated in Europe for anemia in patients newly initiated on dialysis with ESRD. In June 2014, a pivotal US phase III study sponsored by AstraZeneca was initiated for anemia in CKD patients on dialysis,. In March 2015, the phase III program was expected to enroll approximately 7,300 dialysis and pre-dialysis patients. In March 2015, filings for anemia in CKD/ESRD were expected in 2018 in the US ; at that time, an MAA submission was expected to precede the planned NDA filing in 2018 . In February 2013, phase II trials were underway in Japan in CKD patients on dialysis ; in February 2015, this was still the case. By July 2014, a phase II trial in Japan in non-dialysis patients had been initiated .

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