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Akebia 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

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.

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i.e. where the development status for the drug(s) is one of the following: No Development Reported, Discontinued, or Withdrawn.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

COMPANY OVERVIEW

Company Name	Akebia Therapeutics Inc
Parent Company Name	Akebia Therapeutics Inc
Website	http://akebia.com/
Country	US
Number of Drugs in Active Development	2
Number of Inactive Drugs	3
Number of Patents as Owner	9
Number of Patents as Third Party	0
Number of Deals	2
Key Indications	Cancer,Anemia,Ocular disease,Bacterial infection,Diabetes mellitus,Sepsis,Fungal infection,Hypertension,Peripheral vascular disease,Staphylococcus aureus infection,Viral infection,Wound healing
Key Target-based Actions	HIF prolyl hydroxylase inhibitor,HIF prolyl hydroxylase-2 inhibitor,Hypoxia inducible factor-1 stimulator,VEGF receptor agonist,HIF prolyl hydroxylase-1 inhibitor,Hypoxia inducible factor-2 alpha modulator,Hypoxia inducible factor-1 alpha modulator,Protein tyrosine phosphatase beta inhibitor,Hypoxia inducible factor-1 alpha inhibitor,Hypoxia inducible factor-1 beta modulator,VEGF receptor antagonist
Key Technologies	Small molecule therapeutic,Condensational synthesis,Drug combination,Nucleophilic substitutional synthesis,Ophthalmic formulation

COMPANY PROFILE

SUMMARY

Akebia Therapeutics Inc is a venture-backed start-up pharmaceutical company specializing in the development of products for ischemia and vascular disease.

FINANCIAL

In November 2014, a personal stock purchasing plan was established in compliance with Section 10b5-1 of the Securities Exchange Act of 1934, to acquire shares of the company's common stock and the transactions under 10b5-1 purchasing plan would commence not earlier than December 15, 2014.

In June 2014, Akebia was added to the Russell 3000, Russell 2000 and Russell Global Indexes.

In February 2014, planned to conduct an IPO of its common stock and applied for listing of its common stock on the NASDAQ Stock Market under the ticker symbol 'AKBA'; in March 2014, the company initiated the pricing of its initial public offering of 5,882,353 shares of common stock at an offering price of $17 per share. The company had also granted the underwriters a 30-day over-allotment option to buy up to an additional 879,647 shares at the initial public offering price. The trading of company's shares on the NASDAQ global market began under the ticker symbol "AKBA." The offering was expected to close on March 25, 2014; later that month, the company closed the public offering of 6,762,000 shares of common stock and raised net proceeds of approximately $106.9 million.

In June 2013, Akebia completed a $41 million series C financing.

In April 2011, the company closed a $22 million series B preferred stock financing. At that time, the company raised $14 million from the first closing, with the access to another $8 million through the end of 2011. In January 2012, the company raised $4.1 million from the closing of a tranche in series B financing.

In July 2009, Akebia raised $12 million from the first closing of series A preferred stock financing round, and was to raise $4 million from the second closing. By that time, the company had raised $9 million from a prior round of the series A financing. In June 2010, the company raised $5 million from the closing of its second tranche of series A financing (tranche was increased from $4 million to $5 million). A total of $28 million was raised from all the rounds of series A financing.

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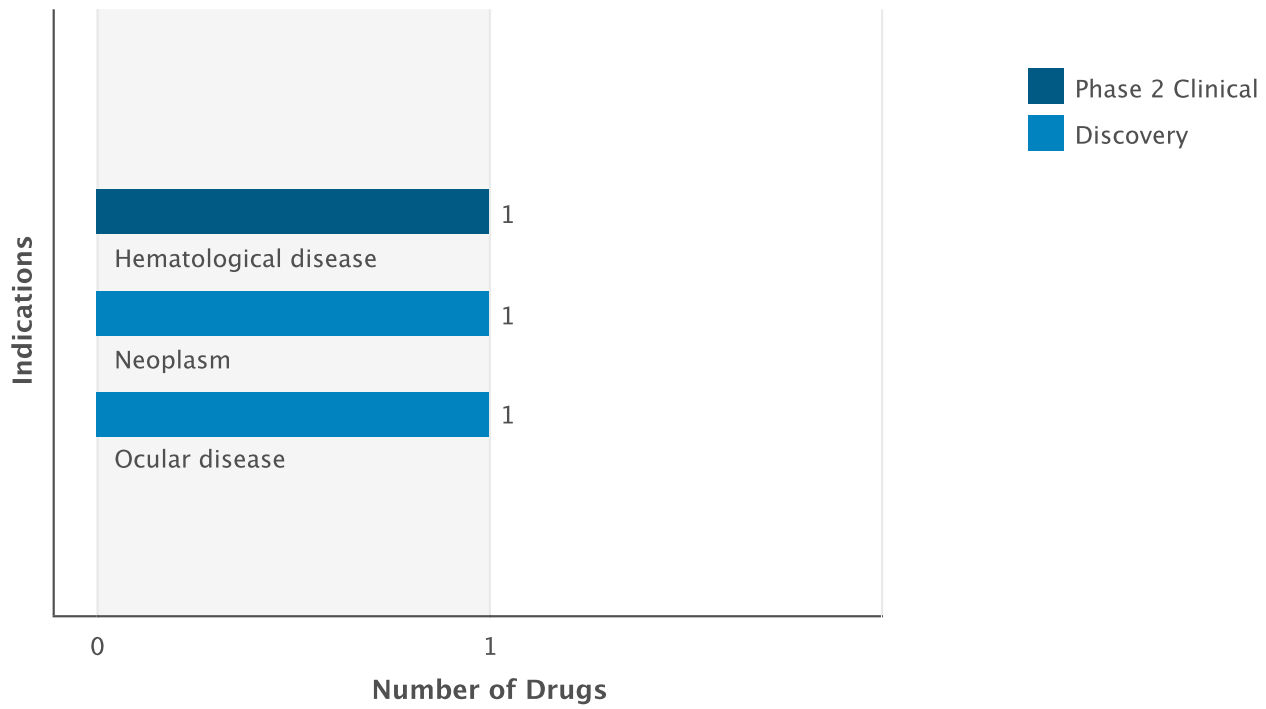
PRODUCT PORTFOLIO SUMMARY

DRUGS

Drugs by Indication

Active Drugs by Indication Chart



Drugs by Indication Table

Indication	Active	Inactive	Total
Ocular disease	1	2	3
Neoplasm	1	0	1
Cardiovascular disease	0	1	1
Infectious disease	0	1	1
Hematological disease	1	0	1

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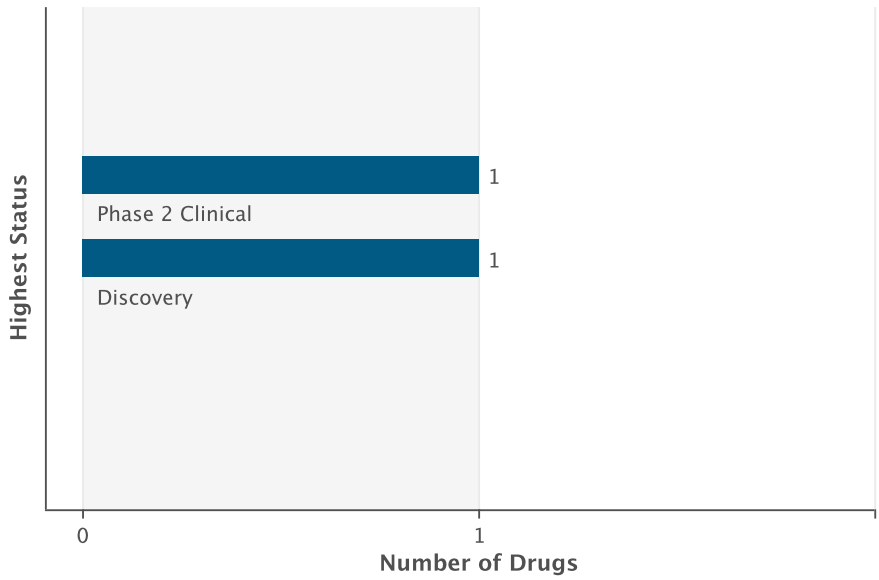
Drugs by Highest Status

Active Drugs by Highest Status Chart



Drugs by Highest Status Table

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

DEALS

Deal Type	Principal		Partner		Total
	Active	Inactive	Active	Inactive	
Drug - Development/Commercialization License	0	0	2	0	2

CLINICAL TRIALS

Trials by Condition Studied

Condition Studied	Ongoing	All
Hematological disease	1	8
Genitourinary disease	0	2

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Trials by Phase

Phase	Ongoing	All
Phase 2	1	5
Phase 1	0	3
Phase not specified	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	5	0	5
Endocrine disease	2	0	2
Gastrointestinal disease	5	0	5
Genitourinary disease	3	0	3
Hematological disease	6	0	6
Immune disorder	6	0	6
Musculoskeletal disease	5	0	5
Neoplasm	6	0	6
Ocular disease	4	0	4
Genetic disorder	1	0	1
Metabolic disorder	4	0	4
Neurological disease	4	0	4
Respiratory disease	2	0	2
Infectious disease	4	0	4
Injury	1	0	1
Inflammatory disease	4	0	4

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Gynecology and obstetrics	1	0	1
Dermatological disease	4	0	4

* 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

AKB-6548

AKB-6548 SNAPSHOT

Drug Name	AKB-6548
Key Synonyms	
Originator Company	Procter & Gamble Pharmaceuticals Inc
Active Companies	Akebia Therapeutics Inc
Inactive Companies	Procter & Gamble Pharmaceuticals Inc
Highest Status	Phase 2 Clinical
Active Indications	Anemia
Target-based Actions	Hypoxia inducible factor-2 alpha modulator;HIF prolyl hydroxylase inhibitor
Other Actions	Blood system agent;Hematopoietic stimulant;Erythropoietin release stimulator
Technologies	Oral formulation;Small molecule therapeutic
Last Change Date	17-Nov-2014

AKB-6548 DEVELOPMENT PROFILE

SUMMARY

Akebia Therapeutics, under license from Procter & Gamble Pharmaceuticals, is developing AKB-6548, the lead from a series of orally active small-molecule hypoxia-inducible factor prolyl hydroxylase (HIF-PH) inhibitors that stabilize HIF2 alpha, for the potential treatment of anemia and related disorders,. In July 2010, a phase II study began ; in October 2010, positive data were reported from the trial. In June 2011, a phase IIa study began ; in April 2012, the trial was completed and results were reported . In July 2013, a phase IIb trial for anemia with chronic kidney disease (CKD) was initiated and the study was expected to complete in November 2014; in October 2014, positive top-line results were reported. In September 2014, a phase II trial in patients with anemia related to CKD undergoing dialysis was initiated. At that time, data were expected in the third quarter of 2015. In October 2014, the company planned to initiate global phase III registration studies in 2015. In January 2012, the company was seeking to outlicense the drug for the initiation of phase III pivotal studies.

AKB-6548 DEVELOPMENT STATUS

CURRENT DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
Akebia Therapeutics Inc	Anemia	US	Phase 2 Clinical	22-Jul-2010
Procter & Gamble Pharmaceuticals Inc	Anemia	US	Discontinued	17-Sep-2007

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AKB-6548 DRUG NAMES

Names	Type
HIF-PH inhibitors (anemia), Akebia	
hypoxia-inducible factor prolyl hydroxylase inhibitors (anemia), Akebia/Procter & Gamble	
AKB-6548	Research Code

AKB-6548 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
Anemia											
0	0	0	0	1	5	0	2	0	1	1	8
End stage renal disease											
0	0	0	0	0	2	0	0	0	0	0	2

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	1	5	0	3	0	1	1	9

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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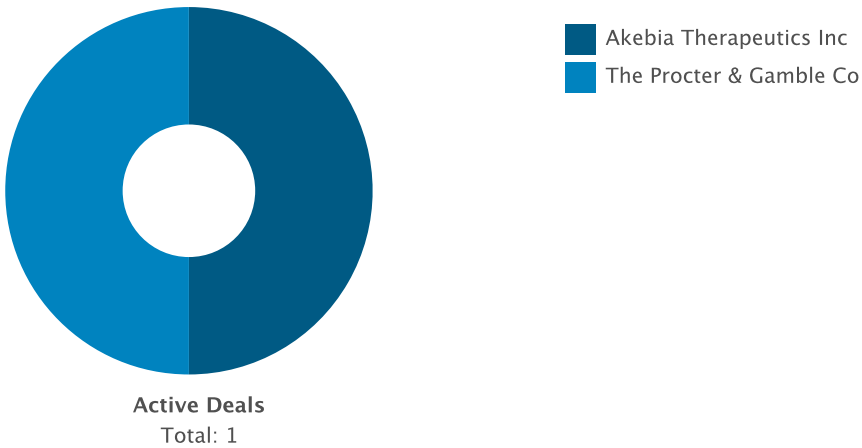
AKB-6548 DEALS AND PATENTS

DEALS

Deals by Parent Company Chart



Deals by Parent Company Table

Company Name	Principal		Partner		Total
	Active	Inactive	Active	Inactive	
The Procter & Gamble Co	1	0	0	0	1
Akebia Therapeutics Inc	0	0	1	0	1

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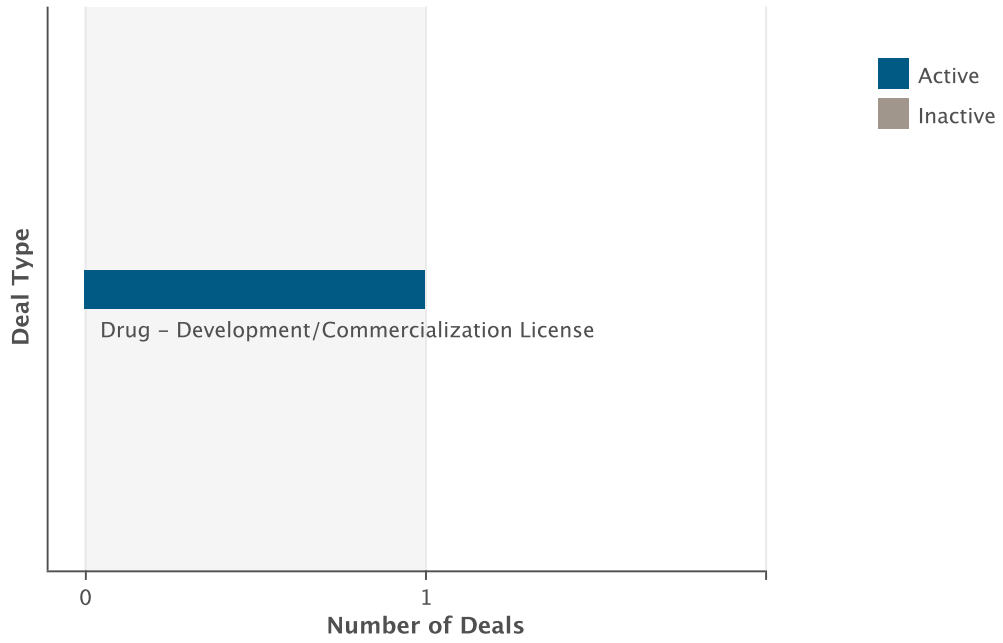
Deals by Type Chart



Deals by Type Table

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

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AKB-6899

AKB-6899 SNAPSHOT

Drug Name	AKB-6899
Key Synonyms	
Originator Company	Akebia Therapeutics Inc
Active Companies	Akebia Therapeutics Inc
Inactive Companies	
Highest Status	Discovery
Active Indications	Cancer;Ocular disease
Target-based Actions	HIF prolyl hydroxylase inhibitor;VEGF receptor agonist
Other Actions	Erythropoietin release stimulator;Anticancer
Technologies	Small molecule therapeutic
Last Change Date	06-May-2014

AKB-6899 DEVELOPMENT PROFILE

SUMMARY

Akebia Therapeutics is investigating AKB-6899, a hypoxia inducible factor-prolyl hydroxylase (HIF-PH) inhibitor, for the potential treatment of cancer and ocular diseases. In May 2014, the drug was listed as being in preclinical development and at that time, the company planned filing an IND to initiate a phase I trials.

AKB-6899 DEVELOPMENT STATUS

CURRENT DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
Akebia Therapeutics Inc	Cancer	US	Discovery	05-May-2014
Akebia Therapeutics Inc	Ocular disease	US	Discovery	05-May-2014

AKB-6899 DRUG NAMES

Names	Type
hypoxia inducible factor-prolyl hydroxylase inhibitor (cancer/ocular disease), Akebia	
AKB-6899	Research Code

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