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Ambit Biosciences Corp

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i.e. where the development status for the drug(s) is one of the following: No Development Reported, Discontinued, or Withdrawn.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

COMPANY OVERVIEW

Company Name	Ambit Biosciences Corp
Parent Company Name	Ambit Biosciences Corp
Website	http://www.ambitbio.com/
Country	US
Number of Drugs in Active Development	3
Number of Inactive Drugs	11
Number of Patents as Owner	42
Number of Patents as Third Party	1
Number of Deals	10
Key Indications	Cancer,Inflammatory disease,Autoimmune disease,Acute myelogenous leukemia,Breast tumor,Leukemia,Myeloproliferative disorder,Acute lymphoblastic leukemia,Insulin dependent diabetes,Multiple sclerosis,Psoriasis,Solid tumor
Key Target-based Actions	CSF-1 antagonist,Flt3 tyrosine kinase inhibitor,Jak2 tyrosine kinase inhibitor,Kit tyrosine kinase inhibitor,PDGF receptor antagonist,Aurora protein kinase 2 inhibitor,Erbb4 tyrosine kinase receptor inhibitor,ABL family tyrosine kinase inhibitor,Protein kinase inhibitor,Raf B protein kinase inhibitor,VEGF-2 receptor antagonist
Key Technologies	Small molecule therapeutic,Oral formulation,Oral liquid formulation,Crystalline form,Salt synthesis,Antibody,Drug combination,Drug screening,Fluorescence,Formulation preservation,Intravenous formulation

COMPANY PROFILE

SUMMARY

Ambit Biosciences, based in San Diego, CA is a privately held biopharmaceutical company focused on the discovery and development of small molecule kinase inhibitors for cancer and other diseases. The company identifies and manufactures these molecules using its kinase profiling platform technology, KinomeScan.

COMPANY LOCATION

The company is based in San Diego, CA. It also has a research facility based in Toronto, Canada.

LICENSING AGREEMENTS

In November 2006, Ambit agreed to screen, discover and develop kinase inhibitors with Cephalon using its KinomeScan technology and Cephalon's kinase libraries. Cephalon would pay Ambit $18 million upfront and make milestone payments up to $232.5 million plus royalties. The companies also planned to advance two programs targeting undisclosed kinases.

In December 2005, Ambit and Bristol-Myers Squibb (BMS) expanded their collaboration to discover kinase inhibitors. The new, 5-year agreement provided BMS with access to Ambit's kinase profiling technology, KinomeScan, to accelerate its internal drug discovery and development efforts. Ambit received a license to a BMS preclinical kinase inhibitor program for the treatment of solid tumors. Ambit would also get an upfront payment, equity investment and profiling revenue from BMS. In January 2004, Ambit entered into separate kinase screening collaborations with Bristol-Myers Squibb Co and GlaxoSmithKline plc, whereby Ambit would employ its kinase platform to characterize the specificity of certain compounds from the companies' compound libraries. Ambit also entered into a compound profiling agreement with Pfizer Inc's La Jolla Laboratories. Ambit would employ its Reverse Screening technology to identify and characterize the protein targets of certain Pfizer drug discovery compounds and therefore elucidate their molecular mechanisms of actions.

In August 2004, Roche Holding AG and Ambit entered into a multiyear collaboration. Roche would use Ambit's kinase screening platform to profile and select small-molecule kinase inhibitors. Ambit would receive milestone payments and

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royalties on drugs developed through the collaboration.

In March 2003, Ambit signed a technology evaluation agreement with GlaxoSmithKline (GSK) to characterize small molecule kinase inhibitors using Ambit's ProteomeScan platform.

In April 2002, Ambit entered into a research collaboration agreement with AstraZeneca Pharmaceuticals LP (AZ), whereby AZ was to utilize Ambit's ProteomeScan platform to identify and isolate the protein targets of its portfolio of small molecules.

In November 2001, Medarex Inc and Ambit entered into a multiyear strategic collaboration to jointly develop and commercialize therapeutic monoclonal antibodies, utilizing Medarex's UltiMAb human antibody development system and Ambit's ProteomeScan screening technology. Both companies expected to share equally the costs and revenues associated with the preclinical and clinical development and subsequent commercialization of any resulting products. Additionally, Medarex made a $1 million equity investment in Ambit.

The company was founded to commercialize technology initially developed in Dr Austin's laboratory in the Chemistry Department at Yale University. This technology, called ProteomeScan, has been exclusively licensed by Ambit Biosciences from Yale University and is the subject of pending US and international patent applications.

FINANCIAL

In June 2013, Ambit was added to the Russell MicroCap Index effective at close of business on June 28, 2013.

In May 2013, Ambit priced its initial public offering of 8,125,000 shares of its common stock at $8 per share. Underwriters were granted a 30-day option to purchase an additional 1,218,750 shares. The common stock began trading on the NASDAQ Global Market under the symbol "AMBI"; by August 2013, the offering had been completed with net proceeds of $83 million .

In February 2013, Ambit filed a registration (form S-1) for an initial public common stock offering on the NASDAQ market.

In November 2012, Ambit raised $25 million in the first tranche of a new $50 million stock financing round.

In June 2011, Ambit raised $30 million from a series D-2 equity financing round.

In November 2010, Ambit filed a registration statement for an IPO with the SEC. Later that month, the IPO was reported to be expected to raise $86.3 million.

In November 2007, Ambit raised $49.3 million from a series D equity financing round. Ambit would use the proceeds to advance its pipeline products.

In May 2005, Ambit closed a series C financing, led by Roche, raising a total of $31 million. The first $21 million tranche was secured in August 2004.

The company raised $10 million in November 2001.

In November 2000, Ambit raised $18.8 million from a series B financing round.

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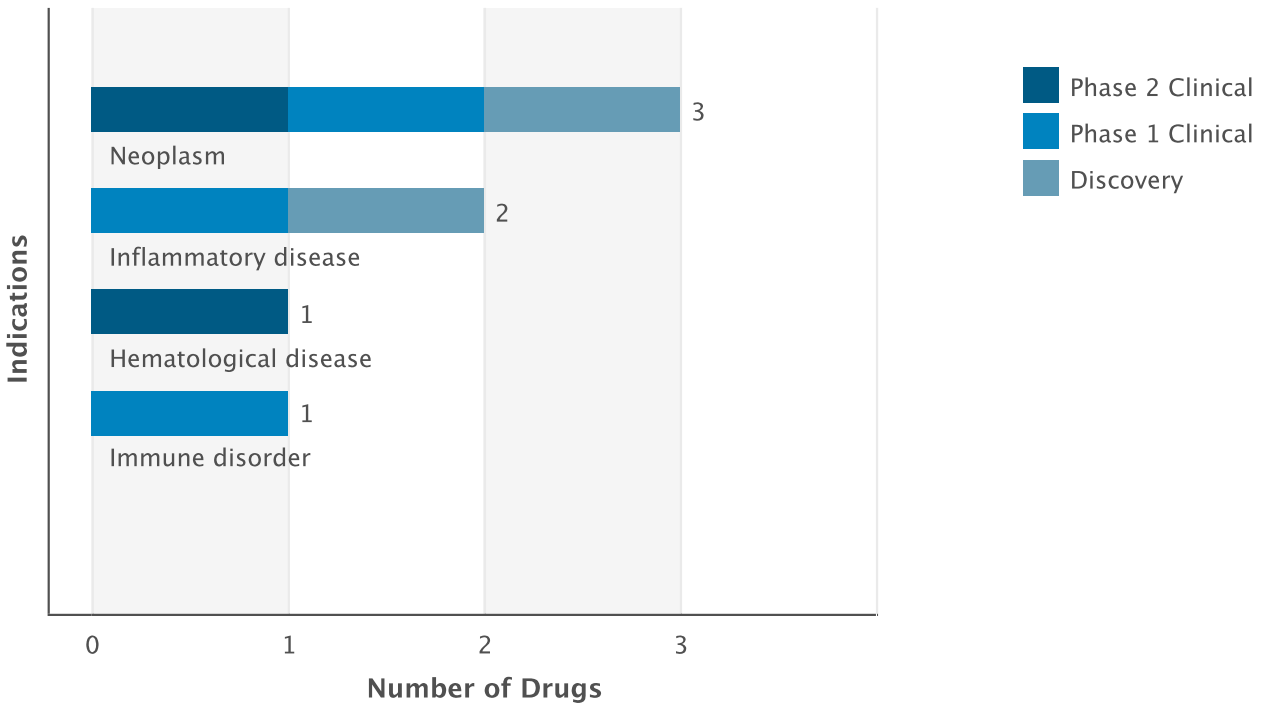
PRODUCT PORTFOLIO SUMMARY

DRUGS

Drugs by Indication

Active Drugs by Indication Chart



Drugs by Indication Table

Indication	Active	Inactive	Total
Neoplasm	3	10	13
Inflammatory disease	2	2	4
Immune disorder	1	1	2
Neurological disease	0	2	2
Hematological disease	1	1	2
Musculoskeletal disease	0	1	1
Cardiovascular disease	0	1	1

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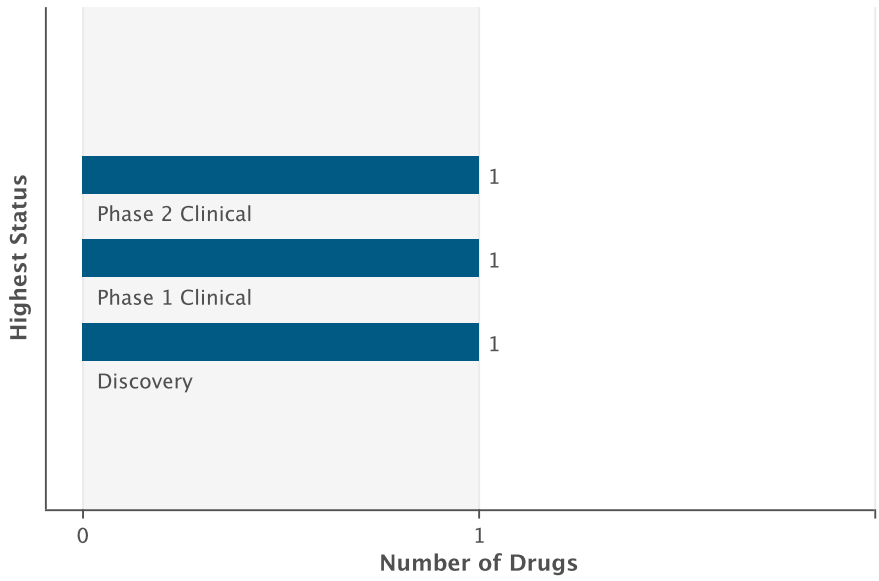
Drugs by Highest Status

Active Drugs by Highest Status Chart



Drugs by Highest Status Table

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

DEALS

Deal Type	Principal		Partner		Total
	Active	Inactive	Active	Inactive	
Technology - Other Proprietary	1	0	0	0	1
Drug - Screening/Evaluation	5	0	0	0	5
Drug - Early Research/Development	1	0	1	0	2
Drug - Development/Commercialization License	1	0	1	0	2

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CLINICAL TRIALS

Trials by Condition Studied

Condition Studied	Ongoing	All
Neoplasm	6	12
Hematological disease	5	8
Immune disorder	0	2
Inflammatory disease	0	1
Musculoskeletal disease	0	1

Trials by Phase

Phase	Ongoing	All
Phase 3	1	1
Phase 2	1	2
Phase 1	4	10

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	8	1	9
Endocrine disease	16	1	17
Gastrointestinal disease	14	1	15
Genitourinary disease	12	0	12
Growth disorder	2	0	2
Hematological disease	25	1	26
Degeneration	3	0	3
Andrology	2	0	2
Immune disorder	25	1	26

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Psychiatric disorder	1	0	1
Musculoskeletal disease	7	0	7
Neoplasm	37	1	38
Ocular disease	6	0	6
Genetic disorder	2	0	2
Metabolic disorder	11	1	12
Neurological disease	14	1	15
Nutritional disorder	1	0	1
Respiratory disease	12	0	12
Infectious disease	5	0	5
Unidentified indication	2	0	2
Inflammatory disease	28	0	28
Otorhinolaryngological disease	2	0	2
Gynecology and obstetrics	10	0	10
Dermatological disease	9	0	9
Surgical procedure	0	1	1

* 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

quizartinib dihydrochloride

quizartinib dihydrochloride SNAPSHOT

Drug Name	quizartinib dihydrochloride
Key Synonyms	quizartinib;quizartinib dihydrochloride
Originator Company	Ambit Biosciences Corp
Active Companies	Ambit Biosciences Corp
Inactive Companies	Astellas Pharma Inc
Highest Status	Phase 2 Clinical
Active Indications	Acute myelogenous leukemia
Target-based Actions	Flt3 tyrosine kinase inhibitor;PDGF receptor antagonist;Kit tyrosine kinase inhibitor
Other Actions	Apoptosis stimulator;Anticancer protein kinase inhibitor
Technologies	Oral formulation;Oral liquid formulation;Small molecule therapeutic
Last Change Date	30-Dec-2013

quizartinib dihydrochloride DEVELOPMENT PROFILE

SUMMARY

Ambit Biosciences is developing quizartinib dihydrochloride (AC-220; ASP-2689; structure shown), the lead candidate from a series of Flt3 and Kit tyrosine kinase inhibitors, for the potential oral treatment of cancer and non-cancer indications ,. In May 2011, the drug was listed as being in Phase III development for AML patients with flt3/ITD mutation ; however, in July 2012, the drug was listed as being in phase II development for second line/third line AML. In January 2010, a phase I trial for solid tumor was initiated; in April 2012, the study was ongoing . In June 2011, a phase III trial was being planned ; in June 2013, the study was expected to start early in 2014,.

Astellas Pharma was codeveloping quizartenib with Ambit. In February 2010, Astellas listed the compound as being in phase II trials in Europe and the US for AML ; in May 2011, this was still the case. In February 2013, phase I trials were underway in Japan for AML. However in March 2013, Astllas stated that it would terminating the license agreement with Ambit for strategic reasons in September that year and in May 2013 deleted the drug from its development pipeline.

In December 2009, Astellas and Ambit also planned to investigate other Flt-3 inhibitors from the series for the same indications.

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Ambit Biosciences and Astellas Pharma were codeveloping quizartinib dihydrochloride (AC-220; ASP-2689; structure shown), the lead candidate from a series of Flt3 and Kit tyrosine kinase inhibitors, for the potential oral treatment of solid tumors ,. In January 2010, a phase I trial for solid tumor was initiated; in April 2012, the study was ongoing . By March 2013, the drug was no longer developed for solid tumors.

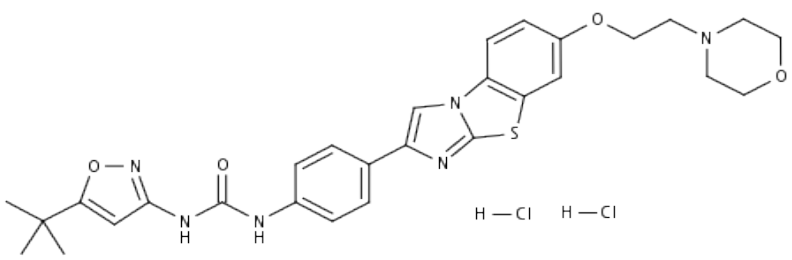
quizartinib dihydrochloride DEVELOPMENT STATUS

CURRENT DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
Ambit Biosciences Corp	Acute myelogenous leukemia	Europe	Phase 2 Clinical	12-Nov-2009
Ambit Biosciences Corp	Acute myelogenous leukemia	US	Phase 2 Clinical	04-Aug-2009
Astellas Pharma Inc	Acute myelogenous leukemia	Europe	Discontinued	13-May-2013
Astellas Pharma Inc	Acute myelogenous leukemia	Japan	Discontinued	13-May-2013
Astellas Pharma Inc	Acute myelogenous leukemia	US	Discontinued	13-May-2013
Ambit Biosciences Corp	Solid tumor	US	No Development Reported	13-Jan-2010
Astellas Pharma Inc	Solid tumor	US	No Development Reported	13-Jan-2010

quizartinib dihydrochloride CHEMICAL STRUCTURES

CAS Registry Number:	Confidence Level:
	3



Name	Type
quizartinib dihydrochloride	USAN
AC-220	Research Code

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CAS Registry Number:	Confidence Level:
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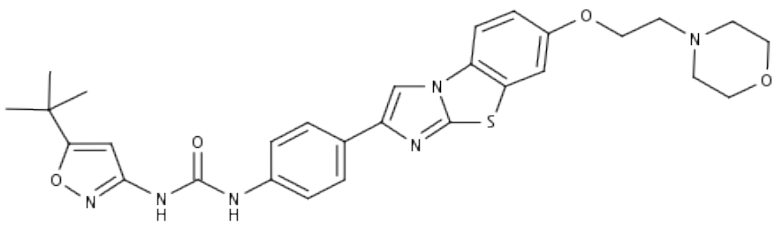
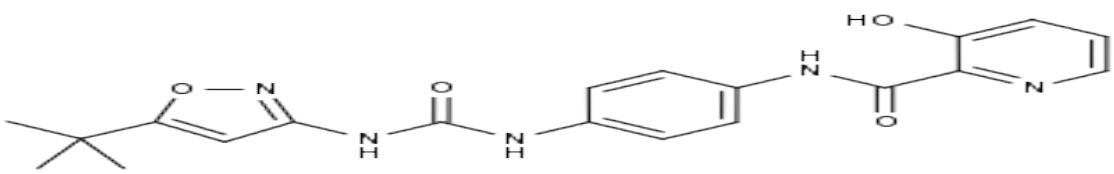


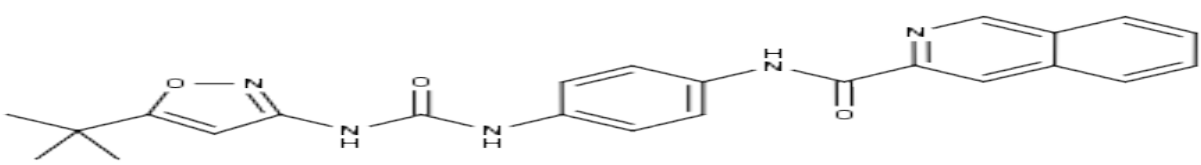
Name	Type
quizartinib	INN; USAN

CAS Registry Number:	Confidence Level:
	4



Name	Type
AB-200434	Research Code

CAS Registry Number:	Confidence Level:
	3



Name	Type
AB-460	Research Code

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CAS Registry Number:	Confidence Level:
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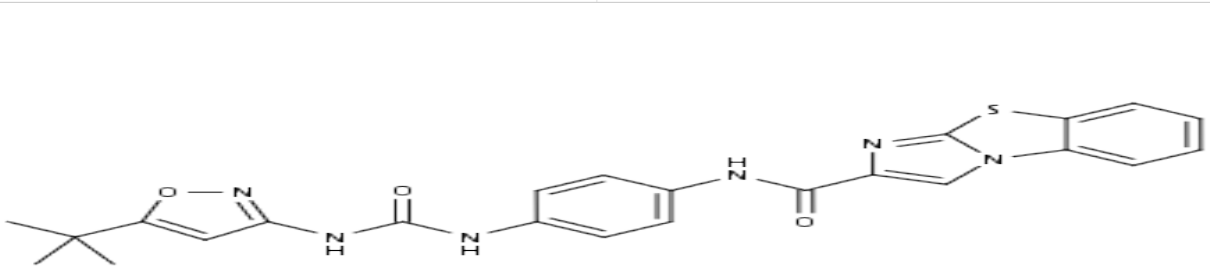

Name	Type
AB-530	Research Code

quizartinib dihydrochloride DRUG NAMES

Names	Type
AB-200432	Research Code
AC-220	Research Code
AB-530	Research Code
quizartinib	INN, USAN
AB-200243	Research Code
AC-886	Research Code
Flt3 tyrosine kinase inhibitors, Ambit	
Flt3 tyrosine kinase inhibitors, Ambit/Astellas	
AB-200382	Research Code
AB-460	Research Code
AB-515	Research Code
quizartinib dihydrochloride	USAN
ASP-2689	Research Code
AB-200434	Research Code

quizartinib dihydrochloride CLINICAL TRIALS

Trials by Phase and Condition Studied

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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
Acute myelogenous leukemia											
0	0	2	2	1	2	4	6	1	1	8	11
Myelodysplastic syndrome											
0	0	1	1	0	0	2	3	1	1	4	5
Solid tumor											
0	0	0	0	0	0	1	1	0	0	1	1
Leukemia											
0	0	0	0	0	0	0	1	0	0	0	1
Acute lymphoblastic leukemia											
0	0	0	0	0	0	0	1	0	0	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	2	2	1	2	5	7	1	1	9	12

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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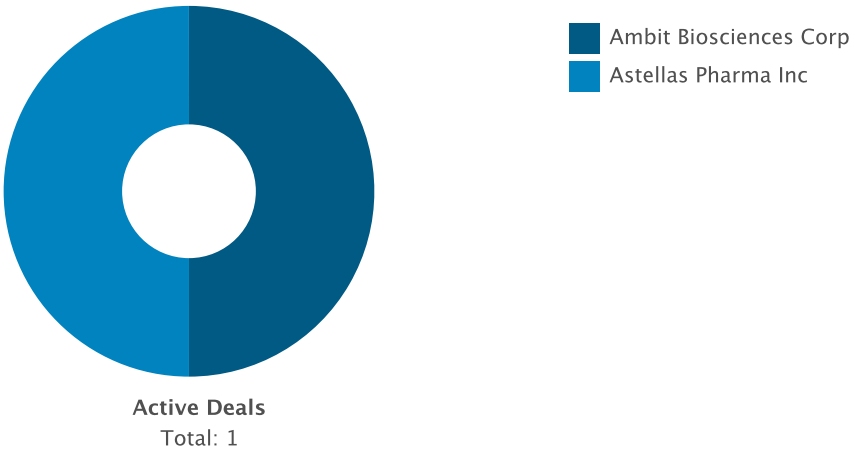
DEALS

Deals by Parent Company Chart



Deals by Parent Company Table

Company Name	Principal		Partner		Total
	Active	Inactive	Active	Inactive	
Ambit Biosciences Corp	1	0	0	0	1
Astellas Pharma Inc	0	0	1	0	1

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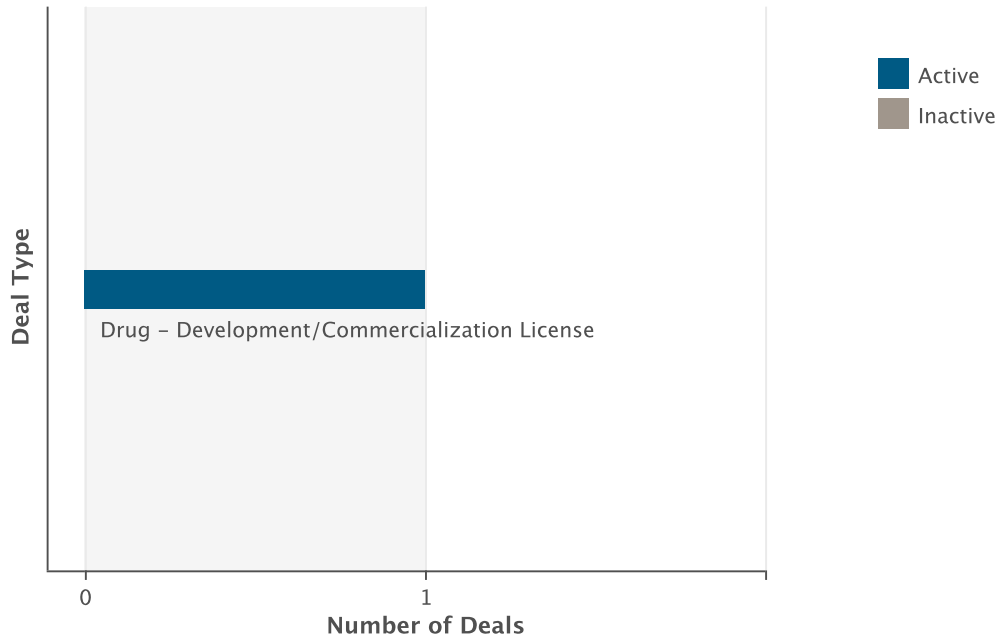
Deals by Type Chart



Deals by Type Table

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

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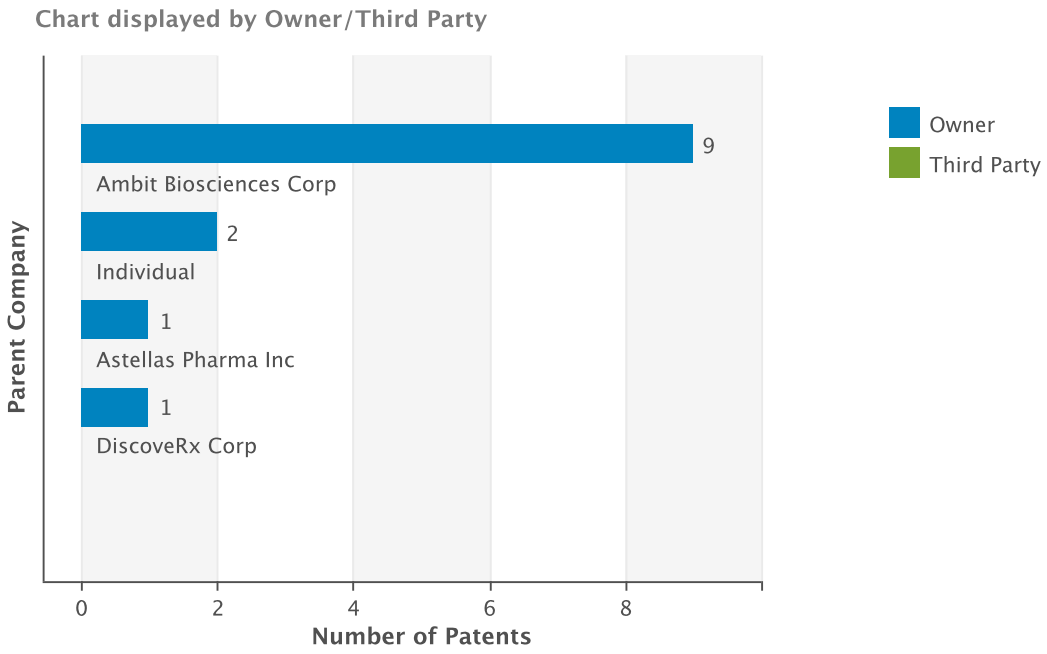
PATENTS

Patents by Parent Company Chart



Patents by Parent Company Table

Company Name	As Owner	As Third Party	Total
Ambit Biosciences Corp	9	0	9
Individual	2	0	2
Astellas Pharma Inc	1	0	1
DiscoveRx Corp	1	0	1

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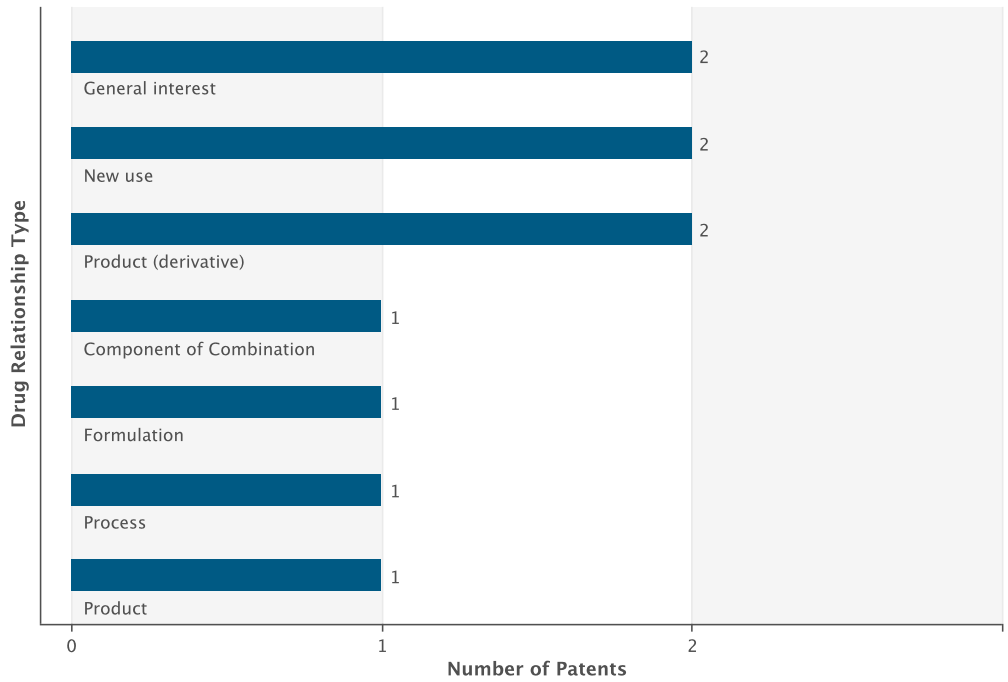
Patents by Drug Relationship Type Chart



Patents by Drug Relationship Type Table

Drug Relationship	Total
New use	2
Product (derivative)	2
General interest	2
Process	1
Product	1
Component of Combination	1
Formulation	1

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AC-410

AC-410 SNAPSHOT

Drug Name	AC-410
Key Synonyms	
Originator Company	Ambit Biosciences Corp
Active Companies	Ambit Biosciences Corp
Inactive Companies	
Highest Status	Phase 1 Clinical
Active Indications	Cancer;Inflammatory disease;Autoimmune disease
Target-based Actions	Jak2 tyrosine kinase inhibitor
Other Actions	Anti-inflammatory;Anticancer protein kinase inhibitor
Technologies	Oral formulation;Small molecule therapeutic
Last Change Date	21-Aug-2013

AC-410 DEVELOPMENT PROFILE

SUMMARY

Ambit is developing the lead AC-410, the single enantiomer of AC-430 (the racemic mixture of AC-410 and AC-409), from a program of Jak2 kinase inhibitors, for the potential oral treatment of cancer, including myelodysplastic syndrome, myeloproliferative disease and lymphoma, autoimmune disorders, including rheumatoid arthritis, and inflammation,,. In December 2010, a phase I trial of AC-430 was initiated ; in June 2011, the study was completed. By February 2013, AC-410 had been selected over AC-430 and AC-409 for further clinical development due to superior pharmacokinetics exhibited in the phase I trial . In February 2012, the company was seeking to outlicense the drug.

AC-410 DEVELOPMENT STATUS

CURRENT DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
Ambit Biosciences Corp	Autoimmune disease	US	Phase 1 Clinical	20-Dec-2010
Ambit Biosciences Corp	Cancer	US	Phase 1 Clinical	20-Dec-2010
Ambit Biosciences Corp	Inflammatory disease	US	Phase 1 Clinical	20-Dec-2010

AC-410 CHEMICAL STRUCTURES

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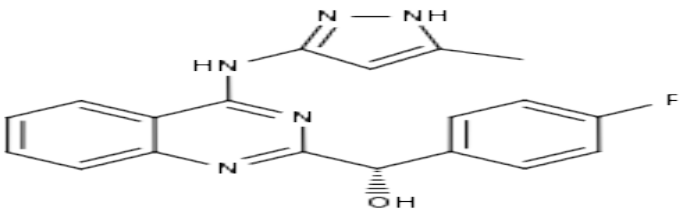
CAS Registry Number:	Confidence Level:
	5



CAS Registry Number:	Confidence Level:
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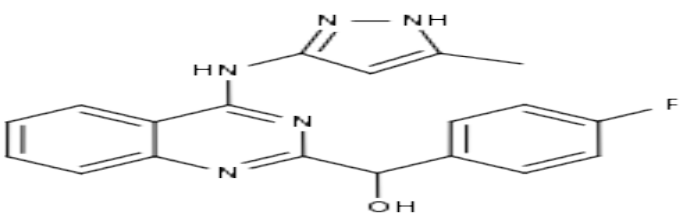

Name	Type
AC-430	Research Code

AC-410 DRUG NAMES

Names	Type
AC-430	Research Code
Jak2 kinase inhibitors (myelodysplastic syndrome), Ambit	
AC-410	Research Code
AC-409	Research Code

AC-410 CLINICAL TRIALS

Trials by Phase and Condition Studied

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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
Cancer											
0	0	0	0	0	0	0	1	0	0	0	1
Rheumatoid arthritis											
0	0	0	0	0	0	0	1	0	0	0	1
Autoimmune disease											
0	0	0	0	0	0	0	1	0	0	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	2	0	0	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

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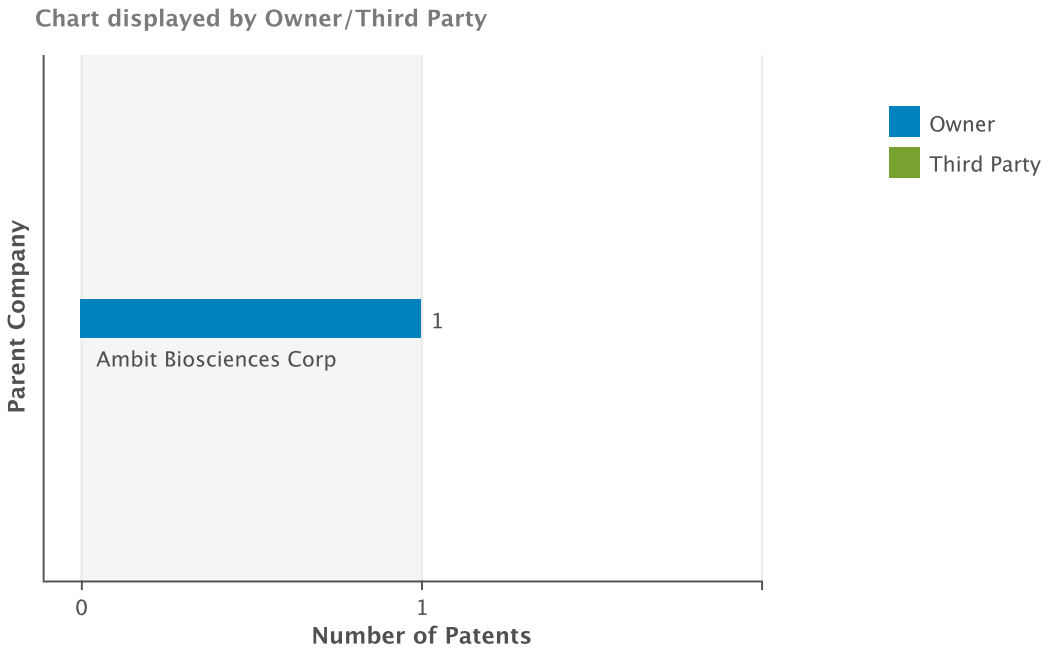
AC-410 DEALS AND PATENTS

PATENTS

Patents by Parent Company Chart



Patents by Parent Company Table

Company Name	As Owner	As Third Party	Total
Ambit Biosciences Corp	1	0	1

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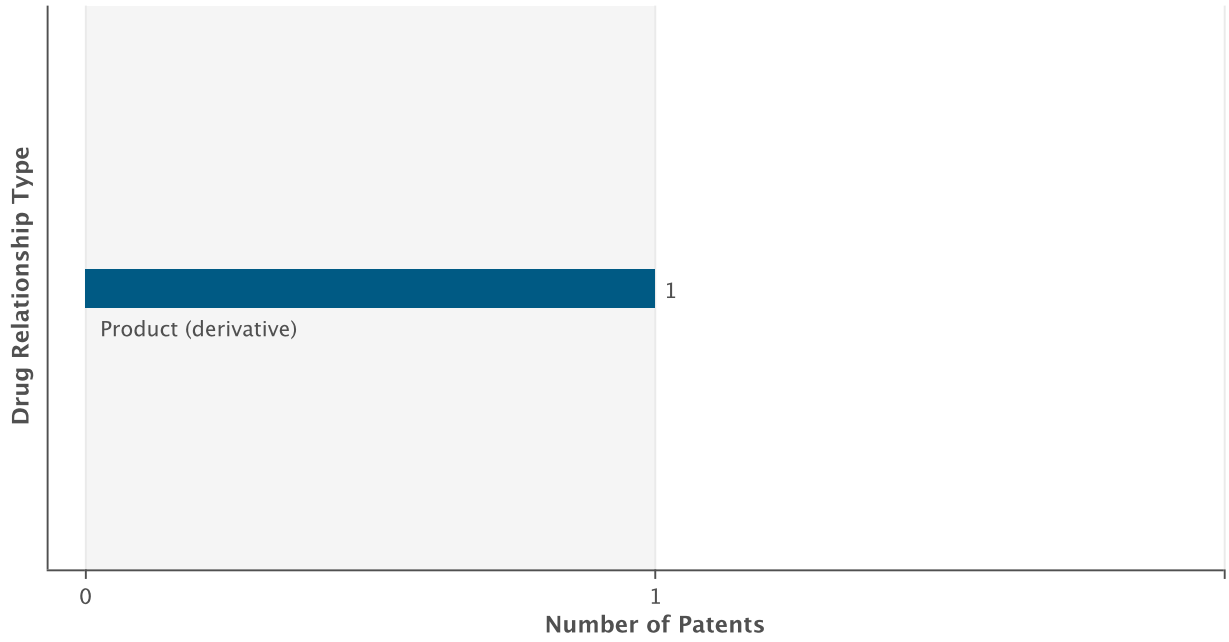
Patents by Drug Relationship Type Chart



Patents by Drug Relationship Type Table

Drug Relationship	Total
Product (derivative)	1

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AC-708

AC-708 SNAPSHOT

Drug Name	AC-708
Key Synonyms	
Originator Company	Ambit Biosciences Corp
Active Companies	Ambit Biosciences Corp
Inactive Companies	
Highest Status	Discovery
Active Indications	Cancer;Inflammatory disease
Target-based Actions	CSF-1 antagonist
Other Actions	Bone modulator;Anti-inflammatory;Anticancer protein kinase inhibitor
Technologies	Small molecule therapeutic
Last Change Date	20-Dec-2013

AC-708 DEVELOPMENT PROFILE

SUMMARY

Ambit Biosciences is investigating AC-708, the lead from colony stimulating factor 1 receptor (CSF1R) inhibitors for the potential treatment of cancer and inflammation,. In February 2013, the drug was listed as being in preclinical development. In August 2013, an IND was planned to be submitted in the second quarter of 2014. In February 2012, the company was seeking to outlicense the program.

The company is also investigating another CSF1R inhibitor, AC-855, for the potential treatment of same indications.

The company was previously investigating the program, for the treatment of bone disease. In March 2010, lead optimization was ongoing. However, in November 2010, the indication was no longer listed on the company's pipeline.

AC-708 DEVELOPMENT STATUS

CURRENT DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
Ambit Biosciences Corp	Cancer	US	Discovery	09-Dec-2008
Ambit Biosciences Corp	Inflammatory disease	US	Discovery	28-Feb-2012
Ambit Biosciences Corp	Bone disease	US	No Development Reported	08-Nov-2010

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AC-708 DRUG NAMES

Names	Type
CSF1R inhibitors (cancer/inflammation), Ambit Biosciences	
AC-708	Research Code
CSF1R inhibitor (cancer/bone disease), Ambit	
colony stimulating factor 1 receptor inhibitors (cancer/inflammation), Ambit Biosciences	

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