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i.e. where the development status for the drug(s) is one of the following: No Development Reported, Discontinued, or Withdrawn.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

COMPANY OVERVIEW

Company Name	Puma Biotechnology Inc
Parent Company Name	Puma Biotechnology Inc
Website	http://www.pumabiotechnology.com/
Country	US
Number of Drugs in Active Development	1
Number of Inactive Drugs	0
Number of Patents as Owner	1
Number of Patents as Third Party	0
Number of Deals	1
Key Indications	Breast tumor
Key Target-based Actions	
Key Technologies	

COMPANY PROFILE

SUMMARY

Puma Biotechnology Inc is a biopharmaceutical company that acquires and develops cancer therapeutics.

ACQUISITIONS & SPIN-OFFS

In October 2011, in conjunction with a $55 million private placement, Puma completed a reverse merger with Innovative Acquisitions with Puma surviving as a wholly owned operating subsidiary of Innovative. Following this, Puma was merged into Innovative and Puma stockholders received shares of Innovative. Innovative was then renamed as Puma Biotechnology.

FINANCIAL

In October 2012, Puma increased and priced the previously announced public offering of 6.5 million shares to 7.5 million shares of common stock at $16 each, to raise $120 million. At that time, the company also granted the underwriters a 30-day option to purchase up to 1.125 million additional common stock shares; later that month, the underwriters elected to exercise in full their option to buy additional common stock shares at the public offering price, less the underwriting discount. The additional purchase, which increased the total offering size to $138 million, was expected to close concurrently with the closing for the initial purchase on October 24, 2012; later that month, the company raised net proceeds of approximately $129.1 million from the closing of the underwritten public offering of 8.62 million shares.

In April 2012, Puma was approved for quoting its common stock on the OTC Bulletin Board and the OTC Market Group's OTC Link under the symbol 'PBYI'. The common stock would begin trading on April 18, 2012. In October 2012, the company began trading its shares on the New York Stock Exchange.

In October 2011, Puma raised gross proceeds of $55 million from a private placement of 14.7 million shares priced at $3.75 per share; in November 2011, Puma completed the second tranche of its $60 million private financing. The company raised gross proceeds of $5 million from the private placement of 1.3 million shares of its common stock priced at $3.75 per share.

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PRODUCT PORTFOLIO SUMMARY

DRUGS

Drugs by Indication

Active Drugs by Indication Chart

Drugs by Indication Table

Indication	Active	Inactive	Total
Endocrine disease	1	0	1
Neoplasm	1	0	1
Gynecology and obstetrics	1	0	1

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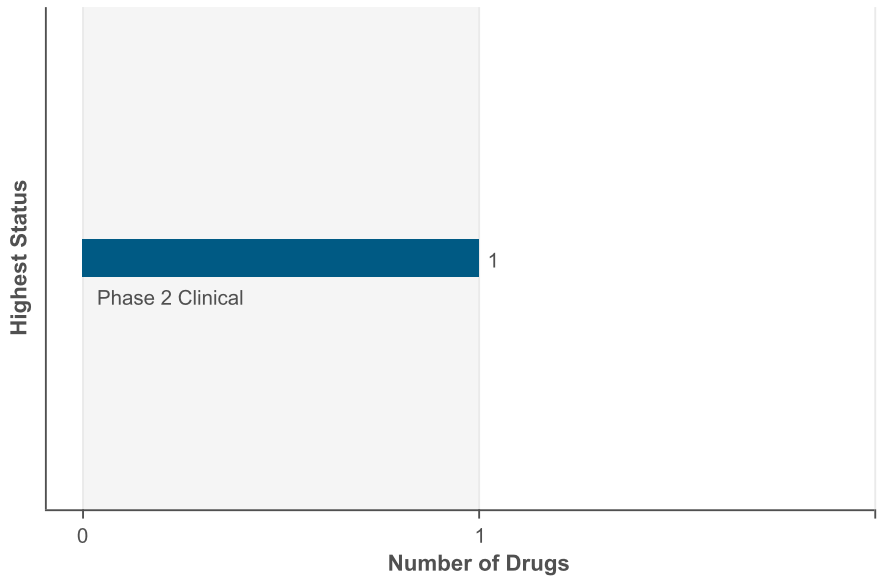
Drugs by Highest Status

Active Drugs by Highest Status Chart



Drugs by Highest Status Table

Development Status	Number of Drugs
Phase 2 Clinical	1

DEALS

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

CLINICAL TRIALS

Trials by Condition Studied

Condition Studied	Ongoing	All
Neoplasm	6	15
Gynecology and obstetrics	5	10
Endocrine disease	5	10
Respiratory disease	0	2

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Trials by Phase

Phase	Ongoing	All
Phase 3	1	1
Phase 2	2	3
Phase 1	3	21

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
Neoplasm	1	0	1
Endocrine disease	1	0	1
Gynecology and obstetrics	1	0	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

neratinib

neratinib SNAPSHOT

Drug Name	neratinib
Key Synonyms	neratinib
Originator Company	Wyeth
Active Companies	Puma Biotechnology Inc
Inactive Companies	Wyeth;Pfizer Inc;Wyeth Research
Highest Status	Phase 2 Clinical
Active Indications	Breast tumor
Target-based Actions	Epidermal growth factor antagonist;Erbb2 tyrosine kinase receptor inhibitor;Erbb4 tyrosine kinase receptor inhibitor;mTOR inhibitor
Other Actions	Anticancer protein kinase inhibitor
Technologies	Oral formulation;Tablet formulation;Small molecule therapeutic
Last Change Date	10-Dec-2012

neratinib DEVELOPMENT PROFILE

SUMMARY

Puma Biotechnology, under license from Pfizer (previously Wyeth), is developing neratinib (PB-272; HKI-272), an irreversible Erbb1, ErbB2 and ErbB4 tyrosine kinase inhibitor, for the potential oral treatment of HER2-positive, locally advanced or metastatic breast cancer in patients who have received prior trastuzumab-based therapy , ,. In July 2009, worldwide phase III breast cancer trials were initiated by Wyeth ; in December 2011, Puma presented data from the phase I/II trials. In October 2011, following its acquisition of development and commercialization rights, Puma intended to stop enrollment of patients and terminate the ongoing Pfizer-sponsored trials. In August 2012, phase II studies for breast cancer and NSCLC were expected to begin later that year ; in November 2012, Puma planned to initiate a phase II trial in patients with NSCLC and a phase III trial in HER2 positive breast cancer later in 2012 or early 2013. Also, the company expected to initiate a phase III trial in breast cancer in 2013.

Previously, neratinib was also being developed for the potential treatment of non-small cell lung cancer (NSCLC). In November 2005, phase II trials were initiated in the US and Europe for the indication ; however, in March 2008, the drug was listed on Wyeth's pipeline as being in phase II trials for breast cancer only.

neratinib DEVELOPMENT STATUS

CURRENT DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date

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Company	Indication	Country	Development Status	Date
Puma Biotechnology Inc	Breast tumor	Asia	Phase 2 Clinical	09-Dec-2011
Puma Biotechnology Inc	Breast tumor	Europe	Phase 2 Clinical	09-Dec-2011
Puma Biotechnology Inc	Breast tumor	US	Phase 2 Clinical	09-Dec-2011
Pfizer Inc	Breast tumor	Africa	Discontinued	05-Oct-2011
Pfizer Inc	Breast tumor	Australia and New Zealand	Discontinued	05-Oct-2011
Pfizer Inc	Breast tumor	Canada	Discontinued	05-Oct-2011
Pfizer Inc	Breast tumor	Central America	Discontinued	05-Oct-2011
Pfizer Inc	Breast tumor	China	Discontinued	05-Oct-2011
Pfizer Inc	Breast tumor	Europe	Discontinued	05-Oct-2011
Pfizer Inc	Breast tumor	Japan	Discontinued	05-Oct-2011
Pfizer Inc	Breast tumor	Middle East	Discontinued	05-Oct-2011
Pfizer Inc	Breast tumor	Russian Federation	Discontinued	05-Oct-2011
Pfizer Inc	Breast tumor	South America	Discontinued	05-Oct-2011
Pfizer Inc	Breast tumor	South East Asia	Discontinued	05-Oct-2011
Pfizer Inc	Breast tumor	South Korea	Discontinued	05-Oct-2011
Pfizer Inc	Breast tumor	UK	Discontinued	05-Oct-2011
Pfizer Inc	Breast tumor	US	Discontinued	05-Oct-2011
Wyeth	Non-small-cell lung cancer	Europe	No Development Reported	04-Mar-2008
Wyeth	Non-small-cell lung cancer	US	No Development Reported	04-Mar-2008

neratinib CHEMICAL STRUCTURES

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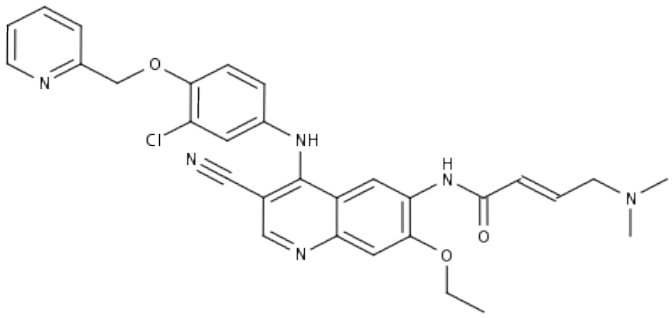
CAS Registry Number:	Confidence Level:
698387-09-6	1



Name	Type
neratinib	INN; USAN
PF-5208767	Research Code
HKI-272	Research Code

neratinib DRUG NAMES

Names	Type
HKI-272	Research Code
neratinib	INN, USAN
PF-5208767	Research Code
PB-272	Research Code

neratinib 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
Metastatic breast cancer											
0	0	0	0	6	8	2	3	0	0	8	11
Breast tumor											
0	0	1	1	1	1	1	4	0	0	3	6
Solid tumor											
0	0	0	0	1	1	2	5	0	0	3	6

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Advanced solid tumor											
0	0	0	0	1	1	0	4	0	0	1	5
Non-small-cell lung cancer											
0	0	0	0	0	1	0	3	0	0	0	4
Cancer											
0	0	0	0	0	0	0	2	0	0	0	2
Central nervous system disease											
0	0	0	0	0	1	0	0	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	1	1	7	10	4	23	0	0	12	34

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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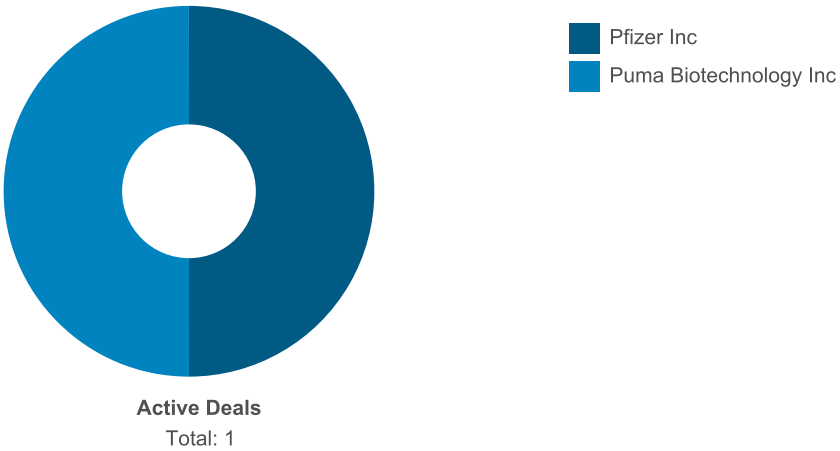
neratinib DEALS AND PATENTS

DEALS

Deals by Parent Company Chart



Deals by Parent Company Table

Company Name	Principal		Partner		Total
	Active	Inactive	Active	Inactive	
Puma Biotechnology Inc	0	0	1	0	1
Pfizer Inc	1	0	0	0	1

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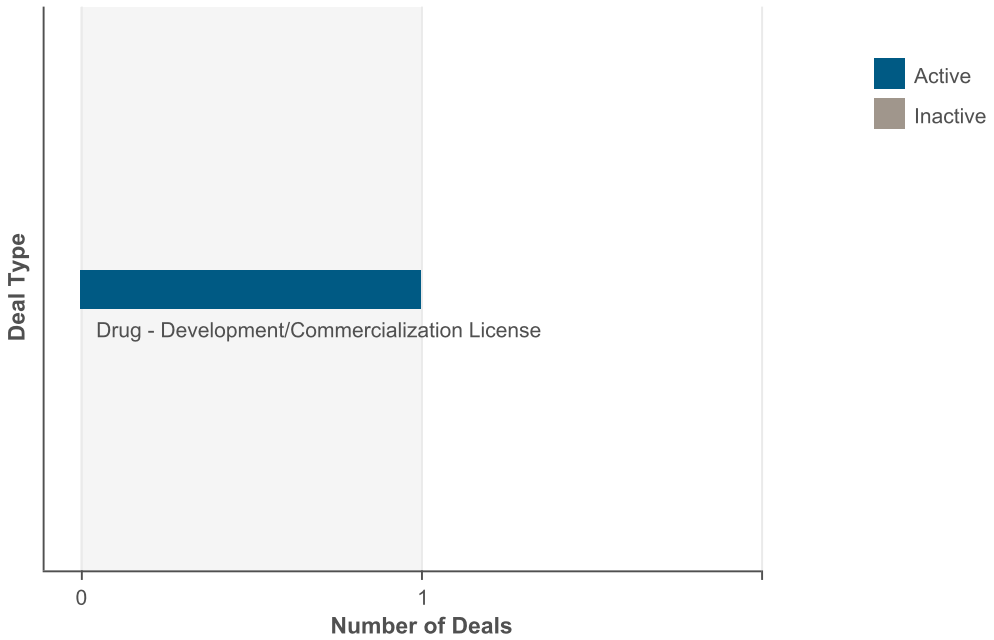
Deals by Type Chart



Deals by Type Table

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

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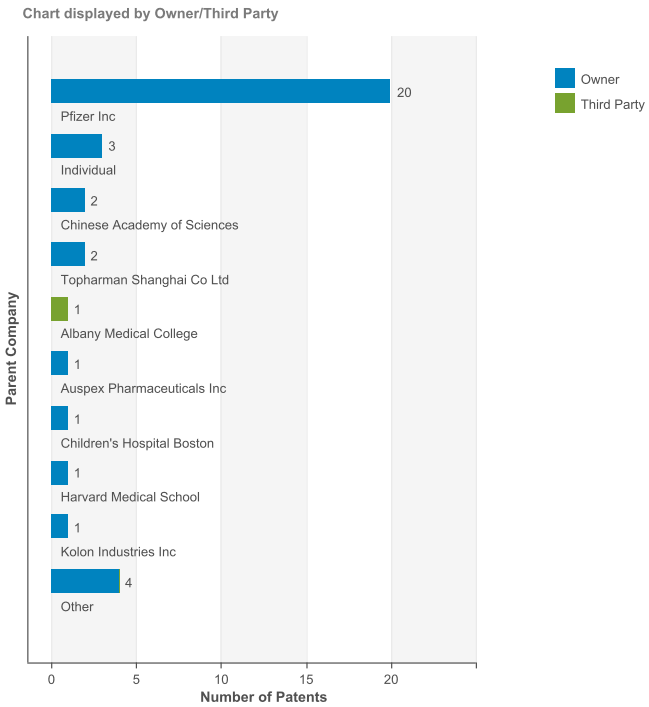
PATENTS

Patents by Parent Company Chart



Patents by Parent Company Table

Company Name	As Owner	As Third Party	Total
Pfizer Inc	20	0	20
Individual	3	0	3
Chinese Academy of Sciences	2	0	2
Topharman Shanghai Co Ltd	2	0	2
Kolon Industries Inc	1	0	1
Auspex Pharmaceuticals Inc	1	0	1
Wellstat Management Company LLC	1	0	1
MedoLution Ltd	1	0	1
Puma Biotechnology Inc	1	0	1
Children's Hospital Boston	1	0	1
Albany Medical College	0	1	1
Massachusetts General Hospital	1	0	1
Harvard Medical School	1	0	1

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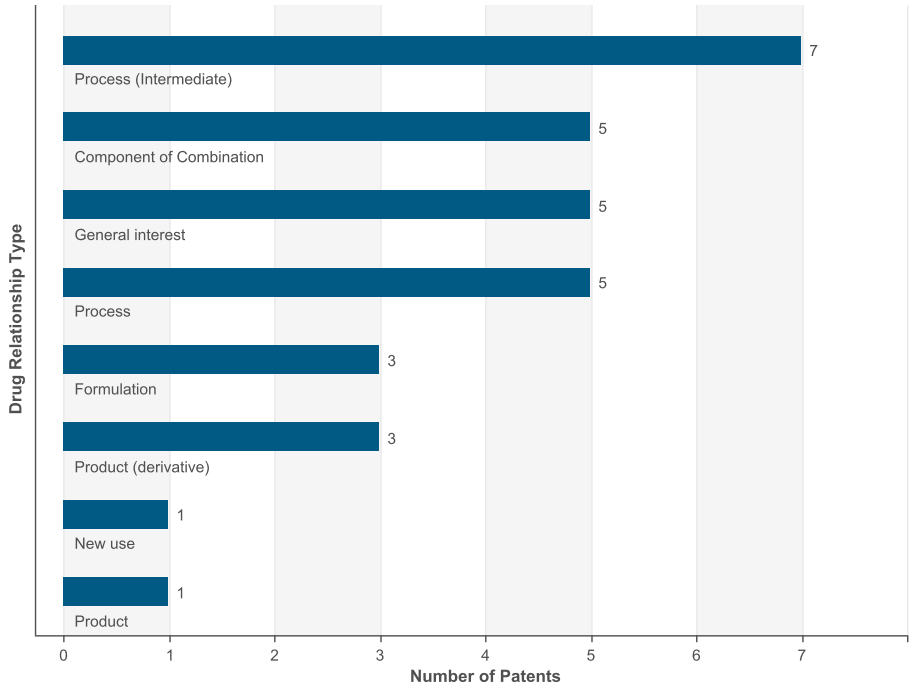
Patents by Drug Relationship Type Chart



Patents by Drug Relationship Type Table

Drug Relationship	Total
Process (Intermediate)	7
Component of Combination	5
General interest	5
Process	5
Formulation	3
Product (derivative)	3
Product	1
New use	1

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