

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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[Return to Table of Contents](#)



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[Return to Table of Contents](#)



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i.e. where the development status for the drug(s) is one of the following: No Development Reported, Discontinued, or Withdrawn.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

[Return to Table of Contents](#)



TABLE OF CONTENTS

Company Overview..... 5

Company Profile..... 6

Product Portfolio Summary..... 6

Product Portfolio Drug Pipeline Detail..... 9

[Return to Table of Contents](#)

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 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 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.

[Return to Table of Contents](#)

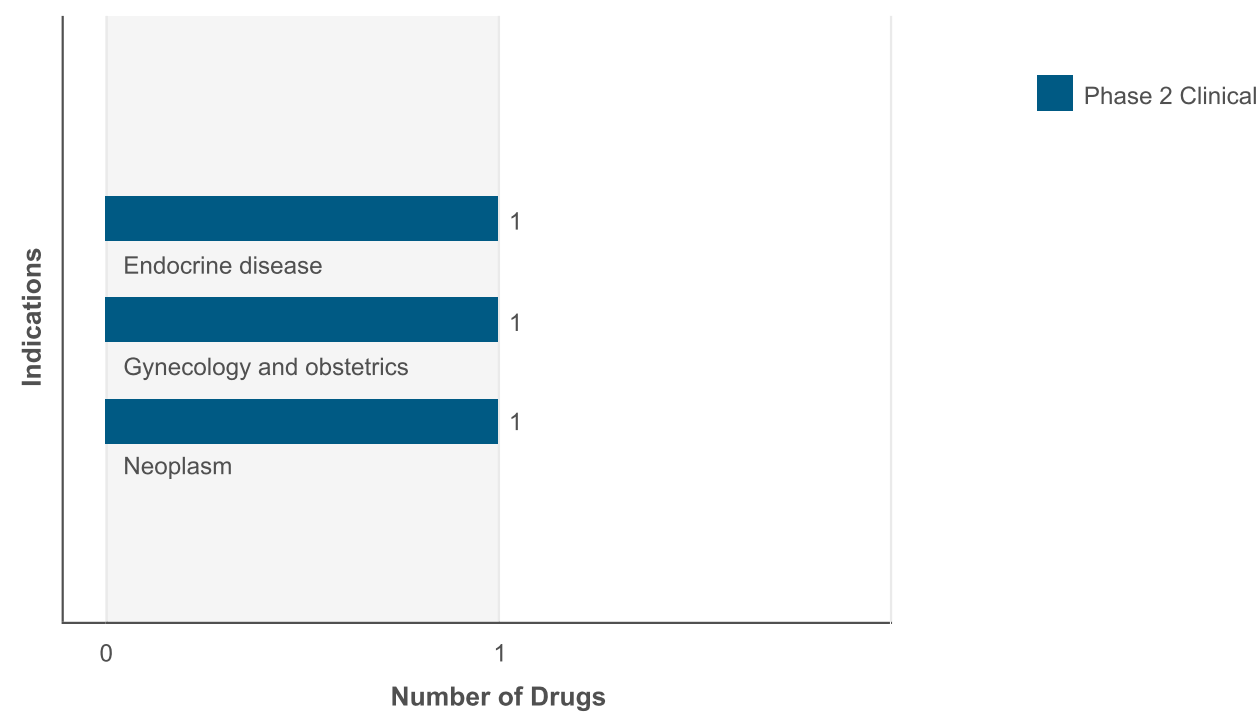


PRODUCT PORTFOLIO SUMMARY

DRUGS

Drugs by Indication

Active Drugs by Indication Chart



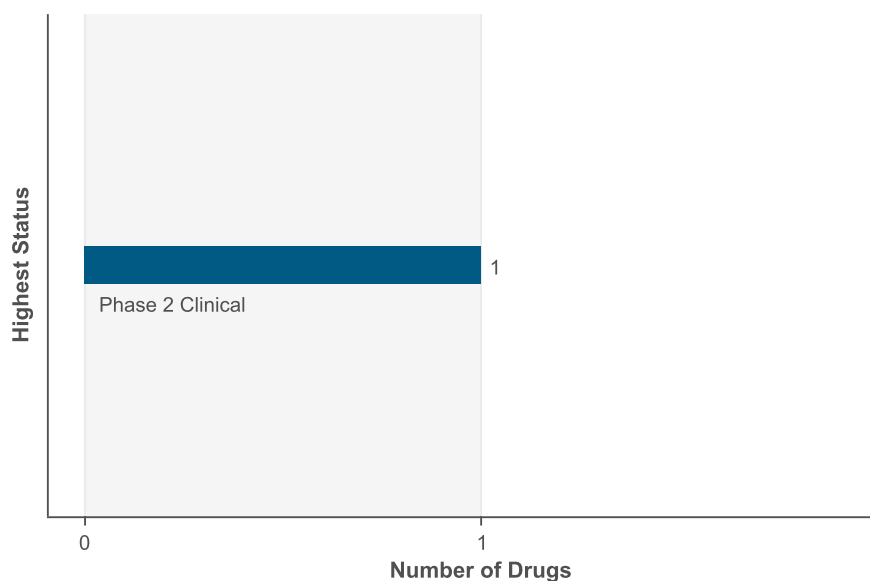
Drugs by Indication Table

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

[Return to Table of Contents](#)

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	5	14
Gynecology and obstetrics	4	9
Endocrine disease	4	9
Respiratory disease	0	2

[Return to Table of Contents](#)

Trials by Phase

Phase	Ongoing	All
Phase 3	1	1
Phase 2	2	3
Phase 1	2	20

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.

[Return to Table of Contents](#)

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
Other Actions	Anticancer protein kinase inhibitor
Technologies	Oral formulation;Tablet formulation;Small molecule therapeutic
Last Change Date	15-Aug-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. Puma planned to initiate clinical trials in second-line, HER2-positive, locally advanced or metastatic breast cancer in the first half of 2012 ; in August 2012, phase II studies for breast cancer and NCSLC were expected to begin later that year.

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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[Return to Table of Contents](#)



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 DEVELOPMENT STATUS

HISTORICAL DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
Pfizer Inc	Breast tumor	Australia and New Zealand	Phase 3 Clinical	16-Oct-2009
Pfizer Inc	Breast tumor	Canada	Phase 3 Clinical	16-Oct-2009
Pfizer Inc	Breast tumor	China	Phase 3 Clinical	16-Oct-2009
Pfizer Inc	Breast tumor	Europe	Phase 3 Clinical	16-Oct-2009
Pfizer Inc	Breast tumor	Japan	Phase 3 Clinical	16-Oct-2009

[Return to Table of Contents](#)

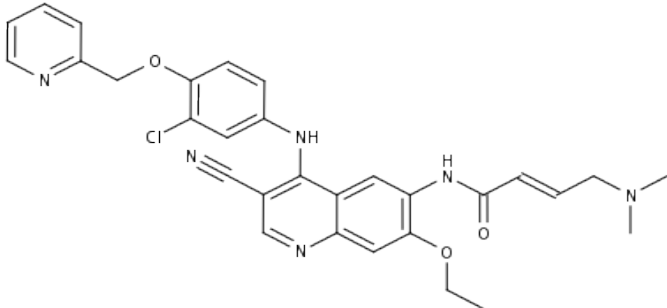


Company	Indication	Country	Development Status	Date
Pfizer Inc	Breast tumor	Middle East	Phase 3 Clinical	16-Oct-2009
Pfizer Inc	Breast tumor	South America	Phase 3 Clinical	16-Oct-2009
Pfizer Inc	Breast tumor	South East Asia	Phase 3 Clinical	16-Oct-2009
Pfizer Inc	Breast tumor	South Korea	Phase 3 Clinical	16-Oct-2009
Pfizer Inc	Breast tumor	UK	Phase 3 Clinical	16-Oct-2009
Pfizer Inc	Breast tumor	US	Phase 3 Clinical	16-Oct-2009
Wyeth	Breast tumor	Australia and New Zealand	Phase 3 Clinical	31-Jul-2009
Wyeth	Breast tumor	Canada	Phase 3 Clinical	31-Jul-2009
Wyeth	Breast tumor	China	Phase 3 Clinical	31-Jul-2009
Wyeth	Breast tumor	Europe	Phase 3 Clinical	31-Jul-2009
Wyeth	Breast tumor	Japan	Phase 3 Clinical	31-Jul-2009
Wyeth	Breast tumor	Middle East	Phase 3 Clinical	31-Jul-2009
Wyeth	Breast tumor	South America	Phase 3 Clinical	31-Jul-2009
Wyeth	Breast tumor	South East Asia	Phase 3 Clinical	31-Jul-2009
Wyeth	Breast tumor	South Korea	Phase 3 Clinical	31-Jul-2009
Wyeth	Breast tumor	UK	Phase 3 Clinical	31-Jul-2009
Wyeth	Breast tumor	US	Phase 3 Clinical	31-Jul-2009
Pfizer Inc	Breast tumor	Africa	Phase 2 Clinical	16-Oct-2009
Pfizer Inc	Breast tumor	Central America	Phase 2 Clinical	16-Oct-2009
Pfizer Inc	Breast tumor	Russian Federation	Phase 2 Clinical	16-Oct-2009
Pfizer Inc	Solid tumor	US	Phase 2 Clinical	29-May-2009
Wyeth	Breast tumor	Africa	Phase 2 Clinical	28-Feb-2009
Wyeth	Breast tumor	Australia	Phase 2 Clinical	28-Feb-2009
Wyeth	Breast tumor	Canada	Phase 2 Clinical	28-Feb-2009
Wyeth	Breast tumor	Central America	Phase 2 Clinical	28-Feb-2009
Wyeth	Breast tumor	Europe	Phase 2 Clinical	28-Feb-2009

[Return to Table of Contents](#)

Company	Indication	Country	Development Status	Date
Wyeth	Breast tumor	Japan	Phase 2 Clinical	28-Feb-2009
Wyeth	Breast tumor	Middle East	Phase 2 Clinical	28-Feb-2009
Wyeth	Breast tumor	Russian Federation	Phase 2 Clinical	28-Feb-2009
Wyeth	Breast tumor	South East Asia	Phase 2 Clinical	28-Feb-2009
Wyeth	Breast tumor	South Korea	Phase 2 Clinical	28-Feb-2009
Wyeth	Breast tumor	UK	Phase 2 Clinical	28-Feb-2009
Wyeth Research	Breast tumor	US	Phase 2 Clinical	31-Mar-2006
Wyeth Research	Non-small-cell lung cancer	Europe	Phase 2 Clinical	30-Nov-2005
Wyeth Research	Non-small-cell lung cancer	US	Phase 2 Clinical	30-Nov-2005
Wyeth Research	Cancer	US	Phase 1 Clinical	02-Jun-2004
Puma Biotechnology Inc	Breast tumor	US	Discovery	05-Oct-2011
Wyeth Research	Cancer	US	Discovery	04-Sep-2000

neratinib CHEMICAL STRUCTURES

CAS Registry Number: 698387-09-6	Confidence Level: 1
	
Name neratinib	Type INN; USAN
PF-5208767	Research Code
HKI-272	Research Code

[Return to Table of Contents](#)

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
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

[Return to Table of Contents](#)

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)

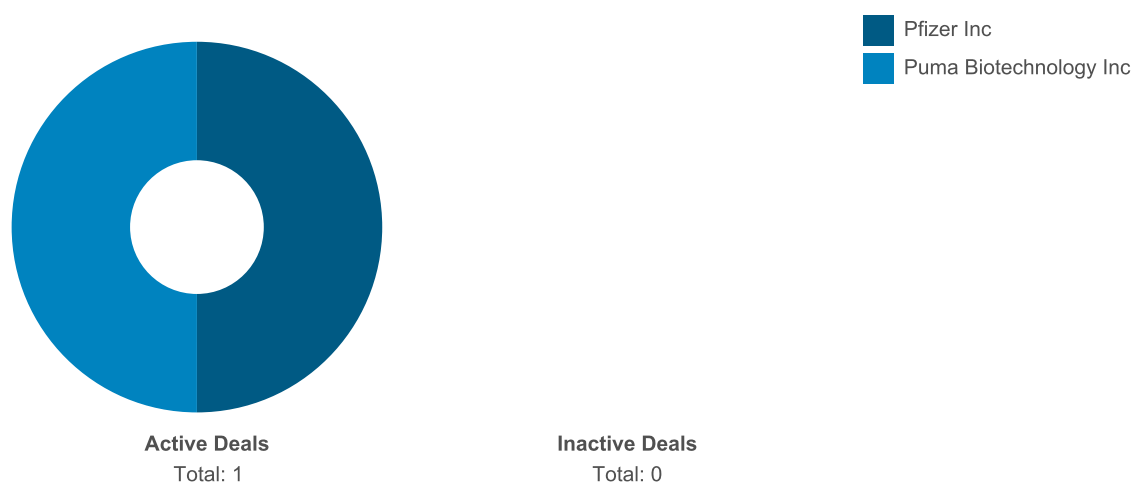
Phase 1 Clinical

Includes Phase 1, Phase 1a, Phase 1, Phase 1/2 (where enrolment count is under 100 or not specified), Phase 0

neratinib DEALS AND PATENTS

DEALS

Deals by Parent Company Chart

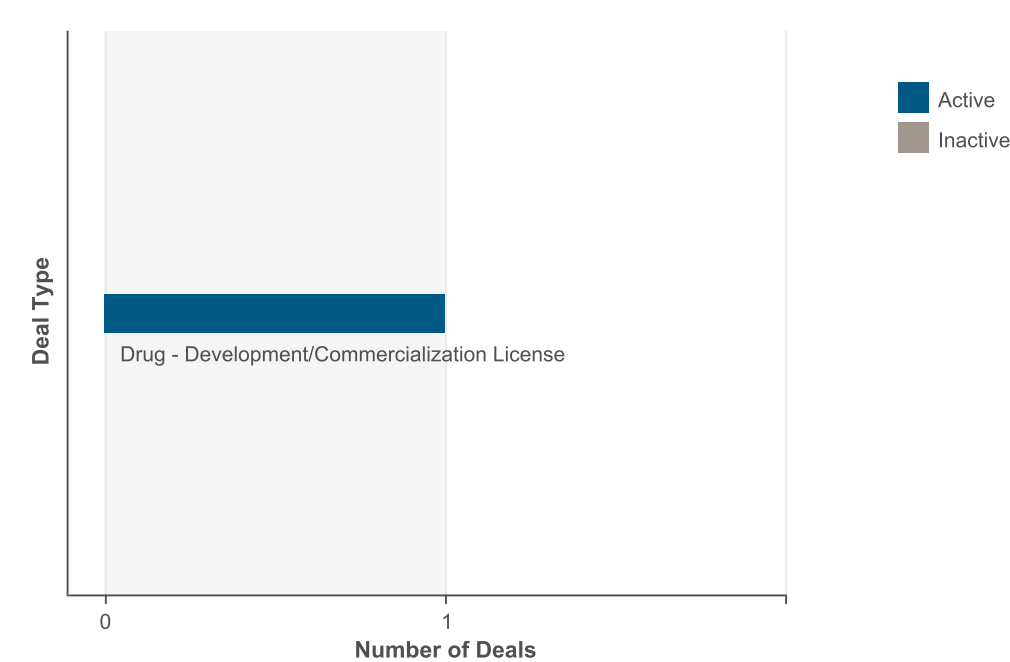


[Return to Table of Contents](#)

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

Deals by Type Chart

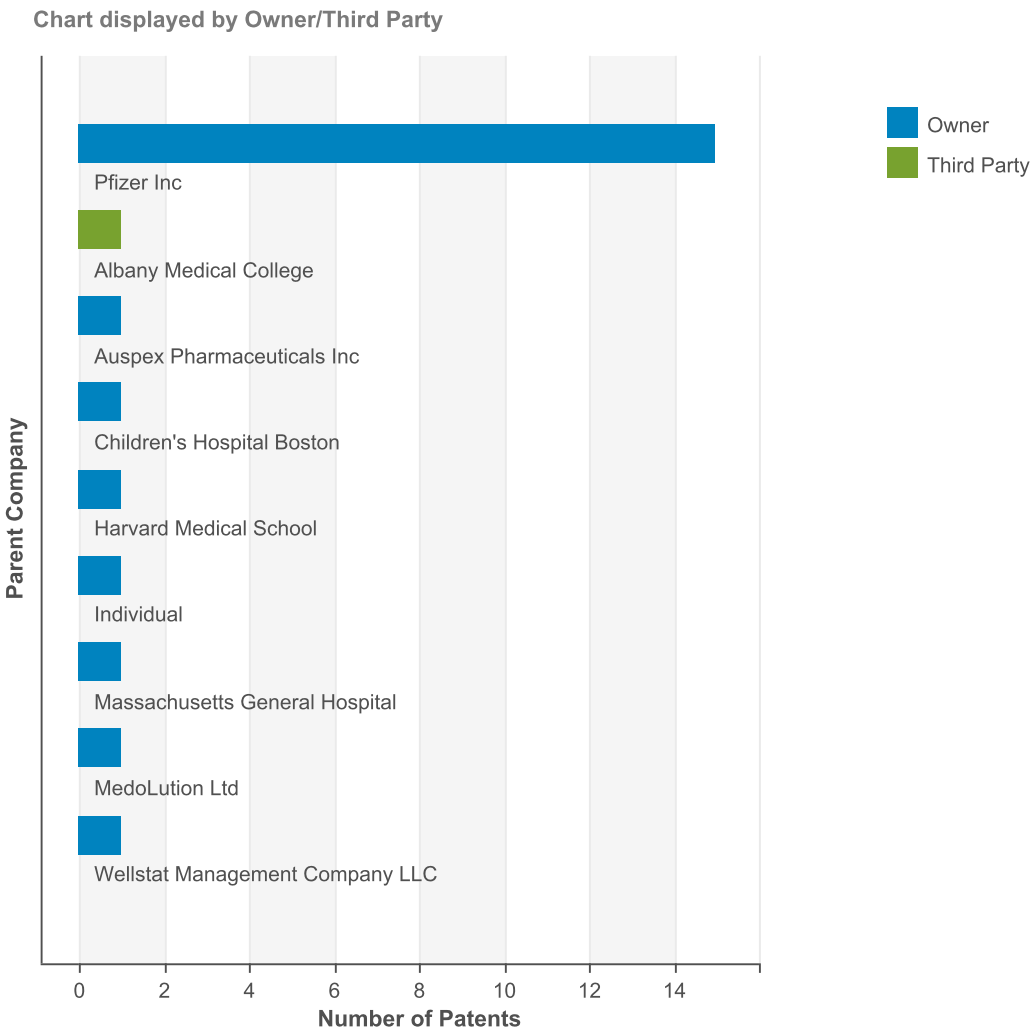


Deals by Type Table

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

PATENTS

Patents by Parent Company Chart

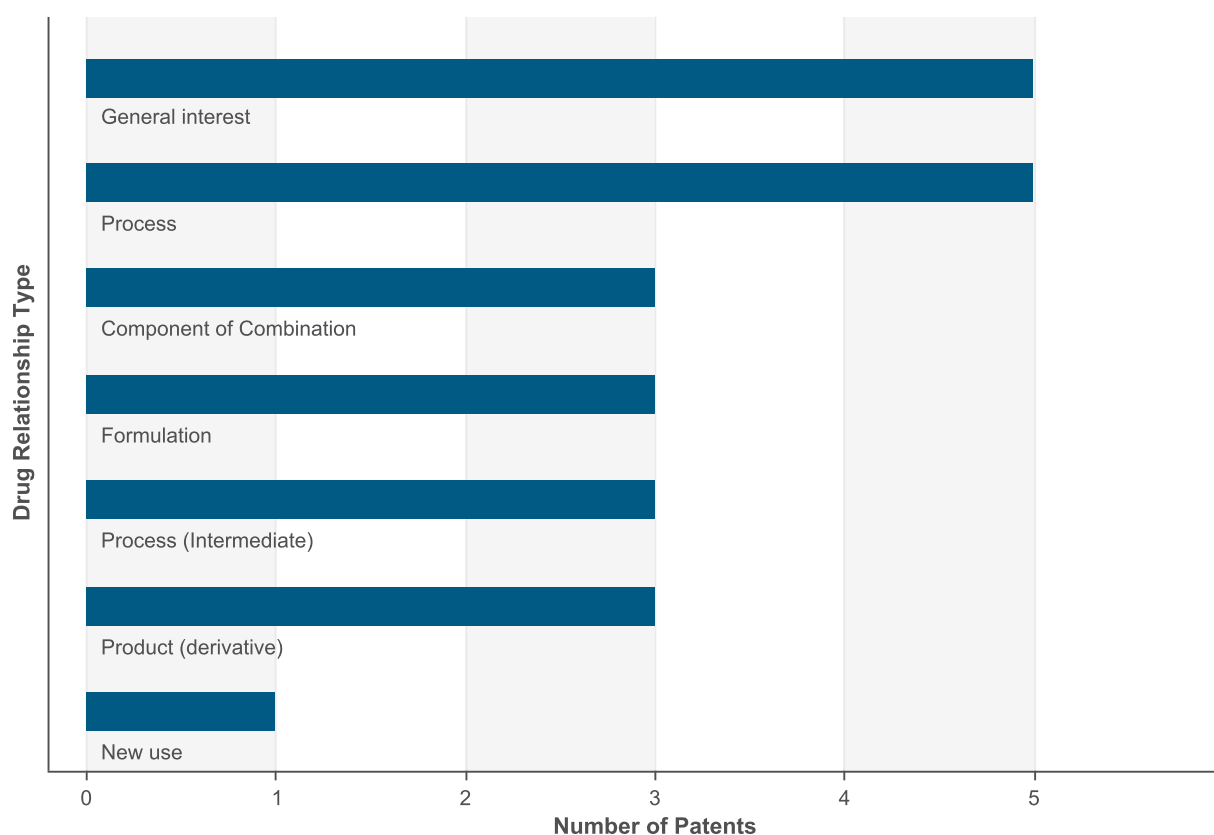


[Return to Table of Contents](#)

Patents by Parent Company Table

Company Name	As Owner	As Third Party	Total
Pfizer Inc	15	0	15
Massachusetts General Hospital	1	0	1
Albany Medical College	0	1	1
MedoLution Ltd	1	0	1
Harvard Medical School	1	0	1
Auspex Pharmaceuticals Inc	1	0	1
Wellstat Management Company LLC	1	0	1
Individual	1	0	1
Children's Hospital Boston	1	0	1

Patents by Drug Relationship Type Chart



[Return to Table of Contents](#)

Patents by Drug Relationship Type Table

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

[Return to Table of Contents](#)

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[Return to Table of Contents](#)

