

Tokai Pharmaceuticals Inc

CORTELLIS COMPANY DETAILED PIPELINE REPORT

A comprehensive coverage of the the company's drug pipeline portfolio including detailed product records.

Publication Date: 01-Aug-2015

THOMSON REUTERS

3 Times Square
New York, New York 10036
United States

Tel: +1 646 223 4000

thomsonreuters.com

[Return to Table of Contents](#)



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 accurate and 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.

Cortellis Company Detailed Pipeline reports are the second in a series of that track pharmaceutical and biotechnology companies worldwide. All *Cortellis for Competitive Intelligence* content is subject to the most comprehensive editorial review process available, conducted by scientists, pharma professionals, regulatory experts, and generics specialists. Featuring timely drug pipeline information expertly uncovered and integrated from over 400 global meetings each year, you'll always be on top of the latest developments.

Chosen by leading life sciences companies, their executives and investors, *Cortellis for Competitive Intelligence* accelerates your deal-making and gives you timely insights on the development landscape.

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

DISCLAIMER

The information contained in this report is based on sources believed to be correct but Thomson Reuters does not guarantee the accuracy, timeliness, or completeness of this information. Opinions, if any, are those held by the author of any individual report or article at the time of initial publication and do not necessarily reflect the views of Thomson Reuters.

Information in this report on companies is intended for reference use only, and does not constitute a recommendation to buy or sell any particular security or other investment and does not constitute an offer to buy from or sell to any particular investor. Any company or securities mentioned in this report may not be suitable for any particular investor, depending on that investor's financial position and needs.

[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..... 10

 Phase 3 Clinical..... 11

[Return to Table of Contents](#)

Tokai Pharmaceuticals Inc

COMPANY OVERVIEW

Company Name	Tokai Pharmaceuticals Inc
Parent Company Name	Tokai Pharmaceuticals Inc
Website	http://www.tokaipharmaceuticals.com/
Country	US
Number of Drugs in Active Development	1
Number of Inactive Drugs	2
Number of Patents as Owner	11
Number of Patents as Third Party	0
Number of Deals	7
Key Indications	Hormone refractory prostate cancer,Pancreatic ductal adenocarcinoma,Prostate tumor,Breast tumor,Ovary tumor,Prostate hyperplasia,Alopecia,Anorexia nervosa,Cancer,Hirsutism
Key Target-based Actions	Cytochrome P450 17 inhibitor,Androgen receptor antagonist,Cytochrome P450 17A1 inhibitor,Androgen receptor modulator,Phosphoinositide 3-kinase inhibitor,Prostate specific antigen inhibitor,Topoisomerase II modulator,mTOR inhibitor
Key Technologies	Capsule formulation,Steroid,Drug combination,Oral formulation,Prodrug,Tablet formulation,Analytical method,Crystalline form,Drug screening,Formulation solid oral,Microparticle formulation

COMPANY PROFILE

SUMMARY

Tokai Pharmaceuticals, a privately-held biopharmaceutical company, focused on the development of treatments for prostate cancer.

FINANCIAL

In September 2014, Tokai priced its initial public offering of 6.48 million shares of common stock at a public offering price of \$15 each. The underwriters were granted a 30-day option to purchase up to an additional 972,000 shares of common stock, at the public offering price. Tokai's common stock began trading on The NASDAQ Global Market under the ticker symbol 'TKAI'; later that month, the offering which resulted in gross proceeds of \$97.2 million was closed. By September 2014, the company had raised an additional gross proceeds of \$8.1 million, following the partial exercise of their option by the underwriters to purchase additional shares of 540,000.

In May 2013, the company raised \$35.5 million in a series E financing.

In September 2011, Tokai raised \$23 million in a series D3 financing.

[Return to Table of Contents](#)

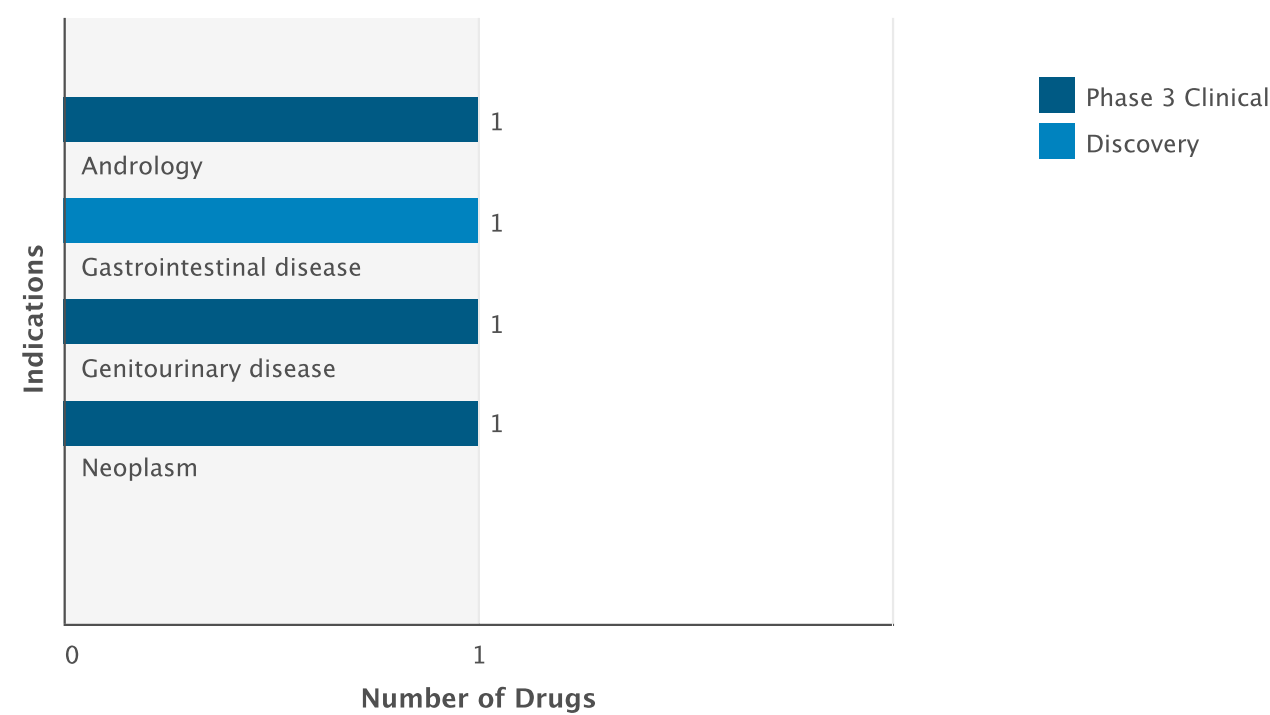


PRODUCT PORTFOLIO SUMMARY

DRUGS

Drugs by Indication

Active Drugs by Indication Chart



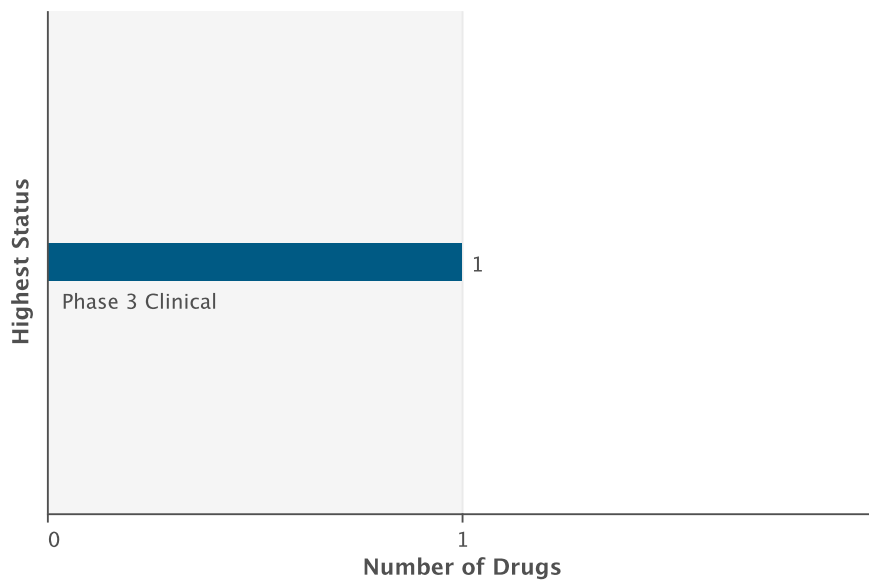
Drugs by Indication Table

Indication	Active	Inactive	Total
Neoplasm	1	1	2
Genitourinary disease	1	1	2
Gynecology and obstetrics	0	1	1
Surgical procedure	0	1	1
Andrology	1	0	1
Gastrointestinal disease	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 3 Clinical	1
No Development Reported	2

DEALS

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

[Return to Table of Contents](#)

CLINICAL TRIALS

Trials by Condition Studied

Condition Studied	Ongoing	All
Neoplasm	2	4
Andrology	2	4
Genitourinary disease	2	4

Trials by Phase

Phase	Ongoing	All
Phase 3	1	1
Phase 2	1	2
Phase 1	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
Immune disorder	1	0	1
Psychiatric disorder	2	0	2
Musculoskeletal disease	2	0	2
Neoplasm	11	0	11
Neurological disease	1	0	1
Respiratory disease	1	0	1
Toxicity and intoxication	1	0	1
Endocrine disease	8	0	8
Gastrointestinal disease	1	0	1
Genitourinary disease	10	0	10

[Return to Table of Contents](#)



Growth disorder	4	0	4
Hematological disease	2	0	2
Andrology	10	0	10
Dermatological disease	4	0	4
Gynecology and obstetrics	8	0	8

* 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

galeterone

galeterone SNAPSHOT

Drug Name	galeterone
Key Synonyms	galeterone
Originator Company	University of Maryland
Active Companies	Tokai Pharmaceuticals Inc;University of Maryland
Inactive Companies	
Highest Status	Phase 3 Clinical
Active Indications	Hormone refractory prostate cancer;Pancreatic ductal adenocarcinoma;Prostate tumor
Target-based Actions	Androgen receptor antagonist;Cytochrome P450 17A1 inhibitor
Other Actions	Anticancer
Technologies	Capsule formulation;Oral formulation;Small molecule therapeutic;Steroid;Tablet formulation
Last Change Date	25-Jun-2015

galeterone DEVELOPMENT PROFILE

SUMMARY

Tokai Pharmaceuticals is developing a spray dried dispersed tablet formulation of galeterone (TOK-001, VN/124-1), a semi-synthetic steroid analog which is a specific androgen receptor antagonist and a Cyp17A1 lyase inhibitor, presumed to have been licensed from the University of Maryland, which has investigated a series of CYP17 inhibitors including galeterone, for the potential oral treatment of castration-resistant prostate cancer and pancreatic ductal adenocarcinoma (PDAC),,. In June 2015, a phase III trial was initiated and at that time, the top-line data were expected by the end of 2016. In October 2011, the company was seeking to outlicense the drug.

Qiagen is developing a companion diagnostic to be used with its circulating tumor cell (CTC) enrichment technology and used in the phase III ARMOR3-SV trial ,.

Tokai Pharmaceuticals was previously developing the drug as an oral capsule formulation, for the potential treatment of castration-resistant prostate cancer,,. However, in January 2014, the company focused on the development of spray dried dispersed tablet formulation as the capsule formulation showed inconsistent gastrointestinal absorption due to a significant food effect.

galeterone DEVELOPMENT STATUS

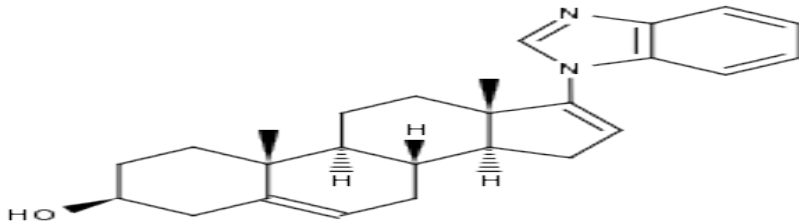
CURRENT DEVELOPMENT STATUS

[Return to Table of Contents](#)



Company	Indication	Country	Development Status	Date
Tokai Pharmaceuticals Inc	Hormone refractory prostate cancer	US	Phase 3 Clinical	24-Jun-2015
Tokai Pharmaceuticals Inc	Hormone refractory prostate cancer	Australia	Discovery	27-Feb-2015
Tokai Pharmaceuticals Inc	Hormone refractory prostate cancer	Canada	Discovery	27-Feb-2015
Tokai Pharmaceuticals Inc	Hormone refractory prostate cancer	Europe	Discovery	27-Feb-2015
Tokai Pharmaceuticals Inc	Pancreatic ductal adenocarcinoma	US	Discovery	20-Apr-2015
University of Maryland	Prostate tumor	US	Discovery	31-Dec-2006

galeterone CHEMICAL STRUCTURES

CAS Registry Number: 851983-85-2	Confidence Level: 2
	
Name galeterone	Type INN; USAN
VN/124-1	Research Code
TOK-001	Research Code

galeterone DRUG NAMES

Names	Type
SARM/LI inhibitor (prostate cancer), Tokai Pharmaceuticals	
TOK-001	Research Code
VN/124-1	Research Code
galeterone	INN, USAN

galeterone CLINICAL TRIALS

Trials by Phase and Condition Studied

[Return to Table of Contents](#)

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
Hormone refractory prostate cancer											
0	0	1	1	1	2	0	1	0	0	2	4
Metastasis											
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	1	2	0	1	0	0	2	4

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)

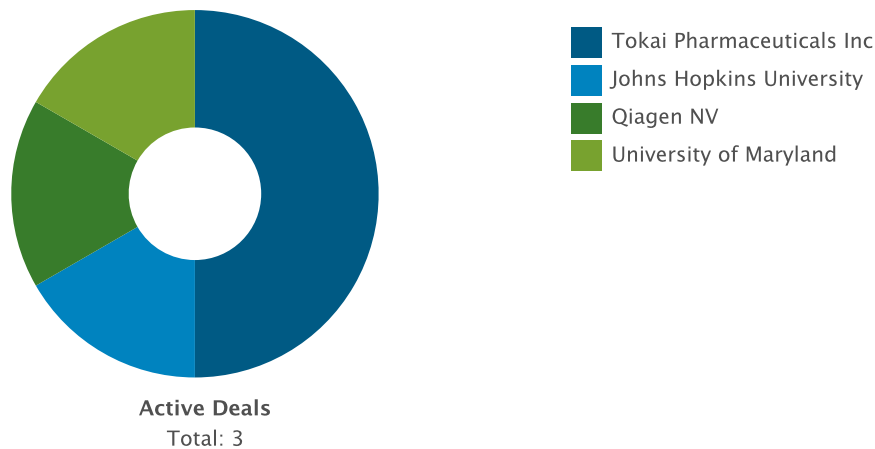
Phase 1 Clinical

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

[Return to Table of Contents](#)

DEALS

Deals by Parent Company Chart

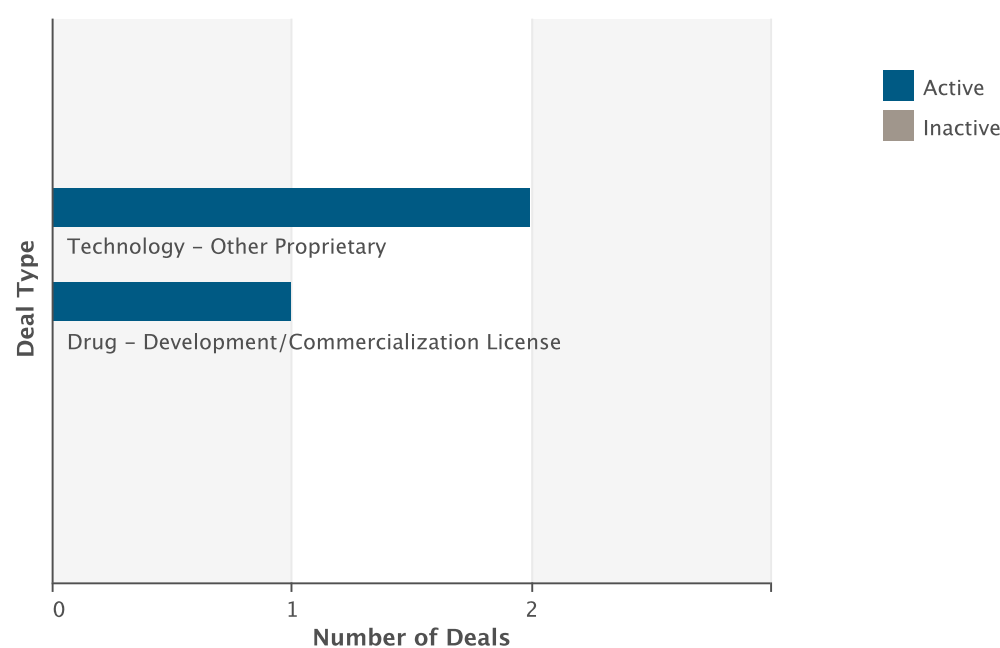


Deals by Parent Company Table

Company Name	Principal		Partner		Total
	Active	Inactive	Active	Inactive	
Tokai Pharmaceuticals Inc	0	0	3	0	3
Qiagen NV	1	0	0	0	1
University of Maryland	1	0	0	0	1
Johns Hopkins University	1	0	0	0	1

[Return to Table of Contents](#)

Deals by Type Chart



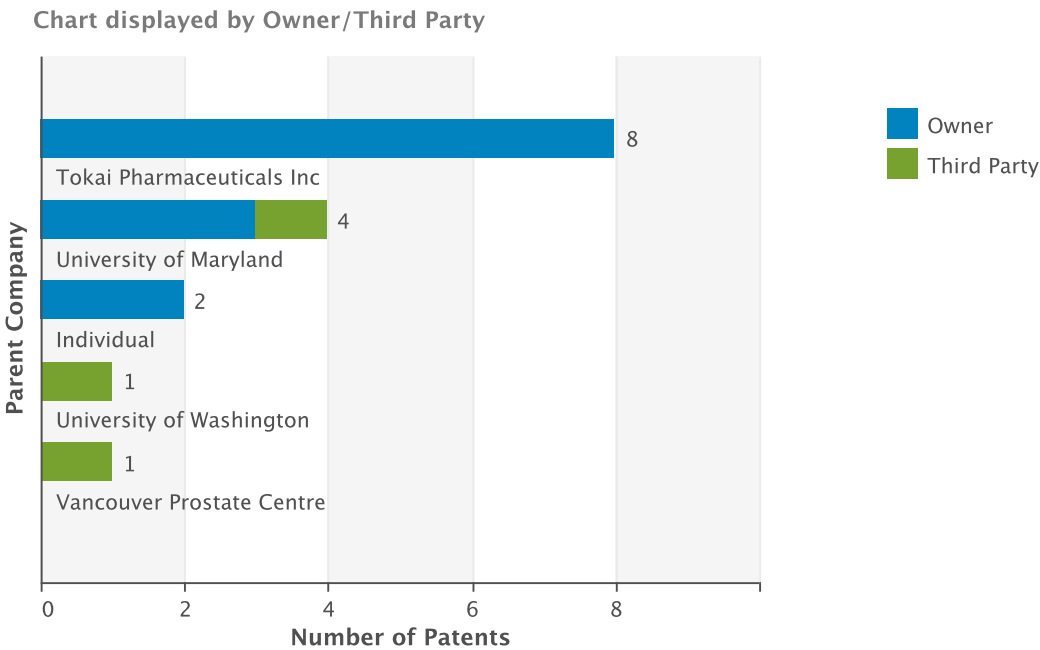
Deals by Type Table

Deal Type	Active	Inactive	Total
Technology - Other Proprietary	2	0	2
Drug - Development/Commercialization License	1	0	1

[Return to Table of Contents](#)

PATENTS

Patents by Parent Company Chart

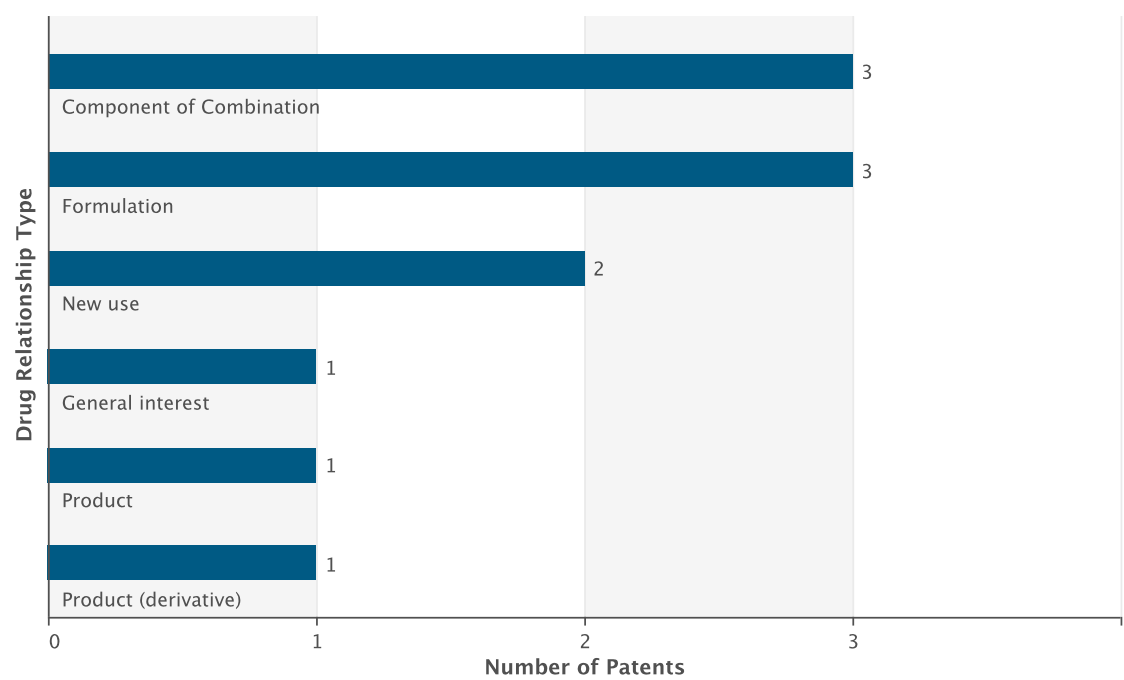


Patents by Parent Company Table

Company Name	As Owner	As Third Party	Total
Tokai Pharmaceuticals Inc	8	0	8
University of Maryland	3	1	4
Individual	2	0	2
University of Washington	0	1	1
Vancouver Prostate Centre	0	1	1

[Return to Table of Contents](#)

Patents by Drug Relationship Type Chart



Patents by Drug Relationship Type Table

Drug Relationship	Total
Component of Combination	3
Formulation	3
New use	2
Product (derivative)	1
Product	1
General interest	1

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.

For more information about *Cortellis for Competitive Intelligence*, visit:

http://cortellis.thomsonreuters.com/cortellis_for_you/?cid=thomsonone.

For subscription information, e-mail scientific.lifesciences@thomsonreuters.com.

© 2012 Thomson Reuters. All rights reserved.
Republication or redistribution of Thomson Reuters content, including by framing or similar means, is prohibited without the prior written consent of Thomson Reuters. 'Thomson Reuters' and the Thomson Reuters logo are registered trademarks and trademarks of Thomson Reuters and its affiliated companies.

[Return to Table of Contents](#)

