

## **Tokai Pharmaceuticals 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i.e. where the development status for the drug(s) is one of the following: No Development Reported, Discontinued, or Withdrawn.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..... 10

    Phase 2 Clinical..... 11

[Return to Table of Contents](#)

# Tokai Pharmaceuticals Inc

## COMPANY OVERVIEW

Company Name	Tokai Pharmaceuticals Inc
Parent Company Name	Tokai Pharmaceuticals Inc
Website	<a href="http://www.tokaipharmaceuticals.com/">http://www.tokaipharmaceuticals.com/</a>
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](#)

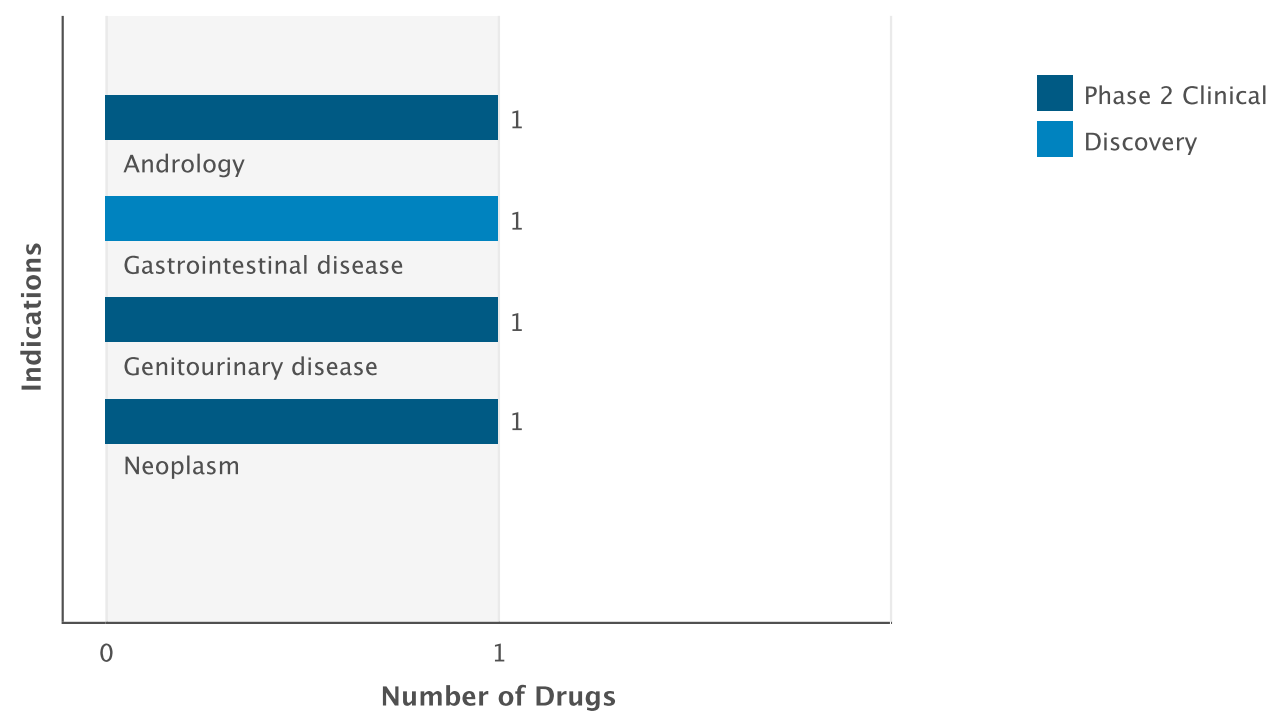


# PRODUCT PORTFOLIO SUMMARY

## DRUGS

### Drugs by Indication

Active Drugs by Indication Chart



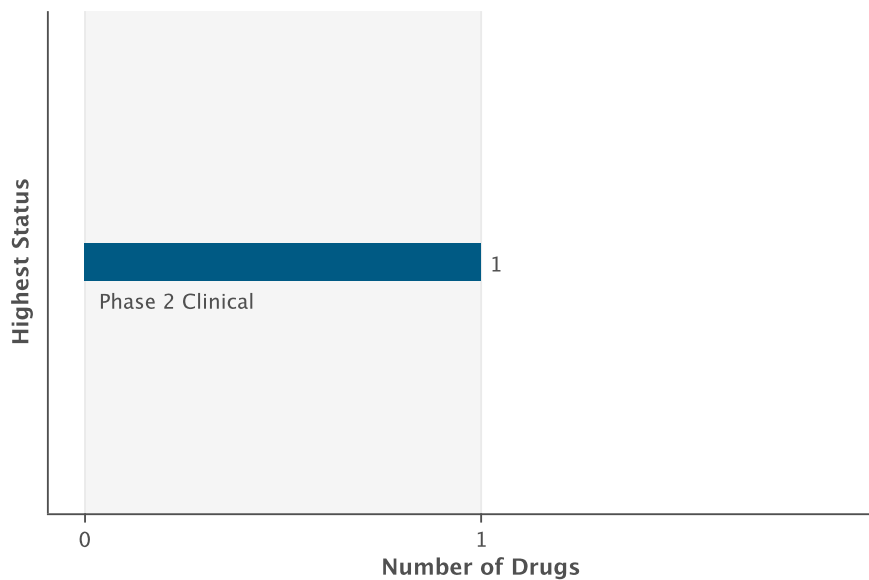
Drugs by Indication Table

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

## DEALS

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

[Return to Table of Contents](#)

## CLINICAL TRIALS

### Trials by Condition Studied

Condition Studied	Ongoing	All
Neoplasm	1	4
Andrology	1	4
Genitourinary disease	1	4

### Trials by Phase

Phase	Ongoing	All
Phase 3	0	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
Endocrine disease	8	0	8
Gastrointestinal disease	1	0	1
Genitourinary disease	10	0	10
Growth disorder	4	0	4
Hematological disease	2	0	2
Andrology	10	0	10
Immune disorder	1	0	1
Psychiatric disorder	2	0	2
Musculoskeletal disease	2	0	2
Neoplasm	11	0	11

[Return to Table of Contents](#)





Neurological disease	1	0	1
Respiratory disease	1	0	1
Toxicity and intoxication	1	0	1
Gynecology and obstetrics	8	0	8
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.

[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	University of Maryland;Tokai Pharmaceuticals Inc
Inactive Companies	
Highest Status	Phase 2 Clinical
Active Indications	Hormone refractory prostate cancer;Prostate tumor;Pancreatic ductal adenocarcinoma
Target-based Actions	Androgen receptor antagonist;Cytochrome P450 17A1 inhibitor
Other Actions	Anticancer
Technologies	Oral formulation;Capsule formulation;Tablet formulation;Small molecule therapeutic;Steroid
Last Change Date	21-Apr-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 December 2012, a phase II trial was initiated; in February 2015, clinical data were presented . In November 2014, the company planned to initiate a pivotal phase III trial in the first half of 2015. 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

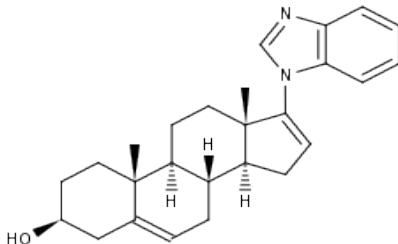
##### CURRENT DEVELOPMENT STATUS

[Return to Table of Contents](#)



Company	Indication	Country	Development Status	Date
Tokai Pharmaceuticals Inc	Hormone refractory prostate cancer	US	Phase 2 Clinical	11-Oct-2011
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	Type
galeterone	INN; USAN
VN/124-1	Research Code
TOK-001	Research Code

## galeterone DRUG NAMES

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

## 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	0	1	1	2	0	1	0	0	1	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	0	1	1	2	0	1	0	0	1	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)

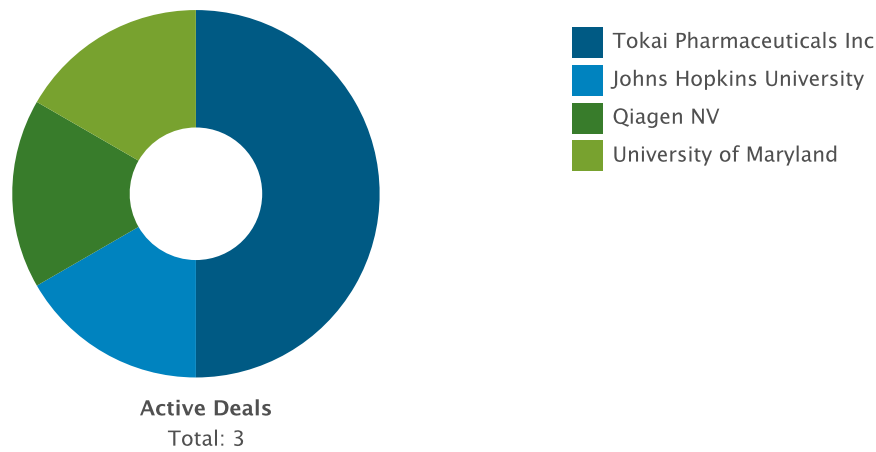
#### Phase 1 Clinical

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

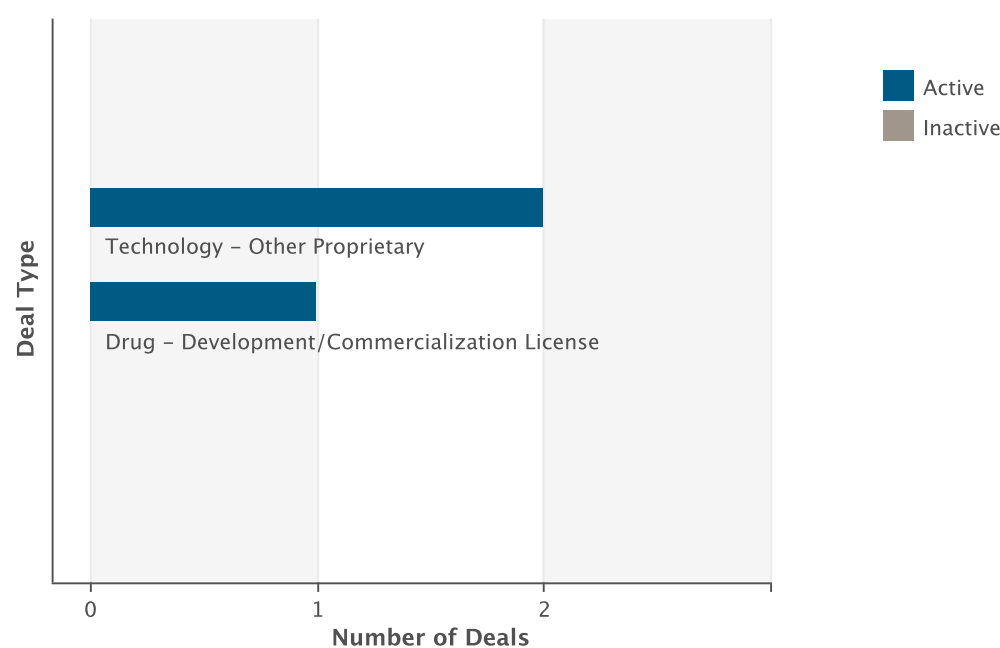
Deals by Parent Company Chart



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

Deals by Type Chart



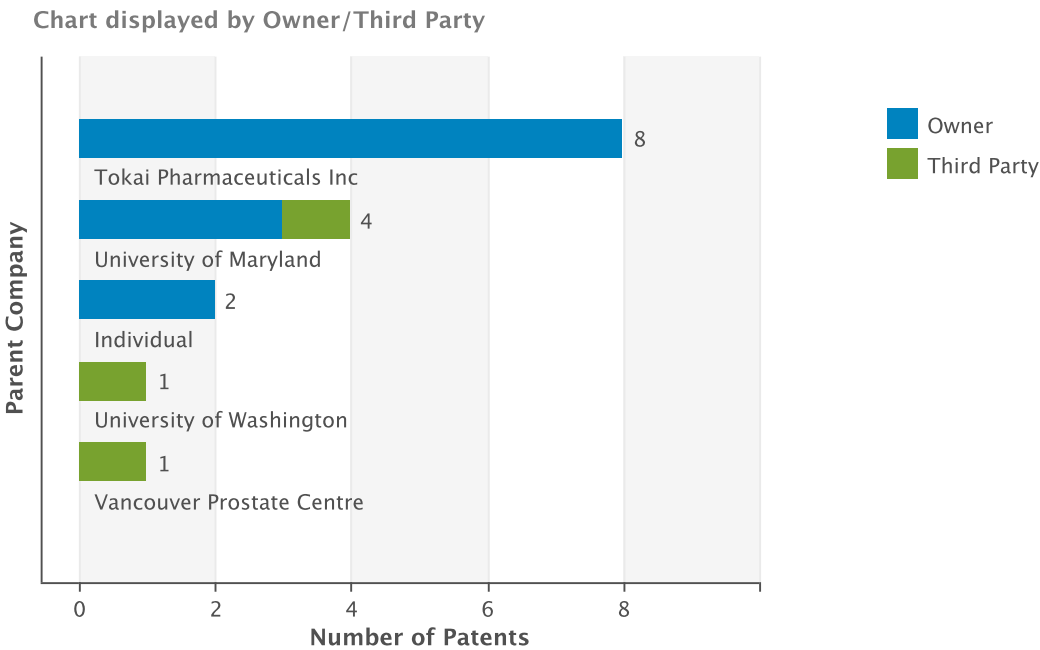
Deals by Type Table

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

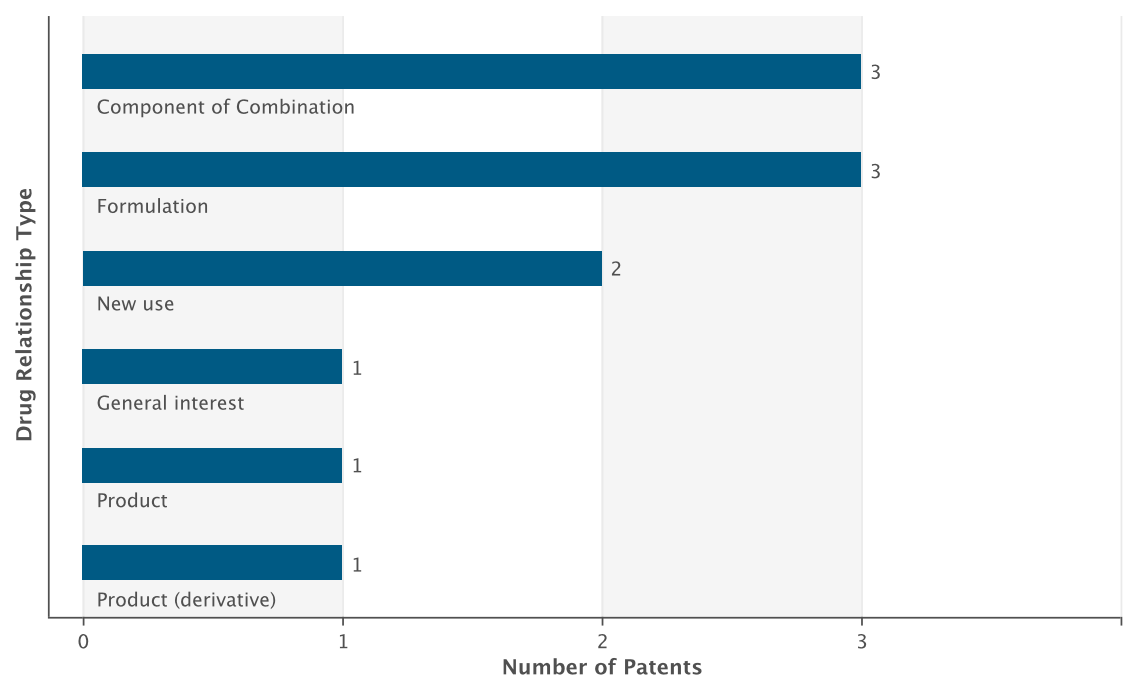


Patents by Parent Company Table

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

[Return to Table of Contents](#)



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[Return to Table of Contents](#)

