

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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THOMSON REUTERS

3 Times Square
New York, New York 10036
United States

Tel: +1 646 223 4000

thomsonreuters.com

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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i.e. where the development status for the drug(s) is one of the following: No Development Reported, Discontinued, or Withdrawn.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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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, Prostate tumor, Breast tumor, Ovary tumor, Prostate hyperplasia, Alopecia, Anorexia nervosa, Cancer, Hirsutism, Bladder cancer, Bone tumor, Endometrioid carcinoma, Genitourinary tract tumor, Gonadal disease, Leukemia, Lung tumor, Lymphoma, Pancreas tumor, Skin cancer, Uterine cervix tumor |
| 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.

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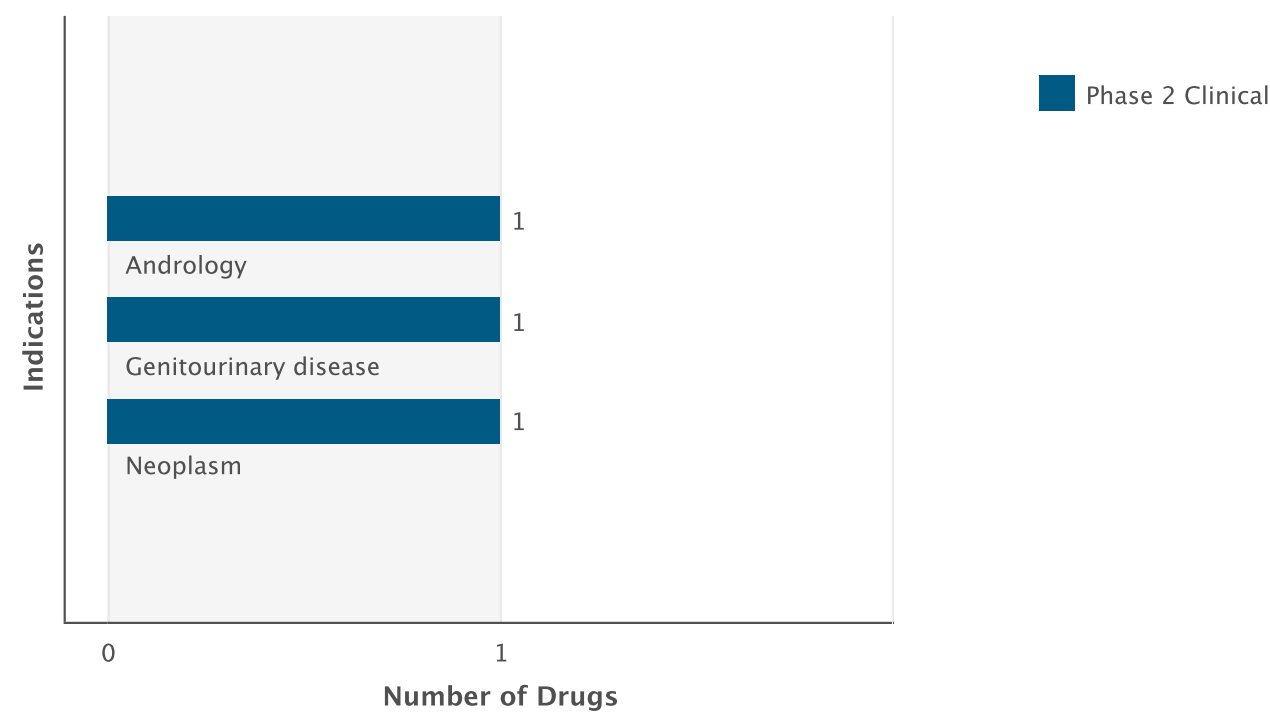


PRODUCT PORTFOLIO SUMMARY

DRUGS

Drugs by Indication

Active Drugs by Indication Chart



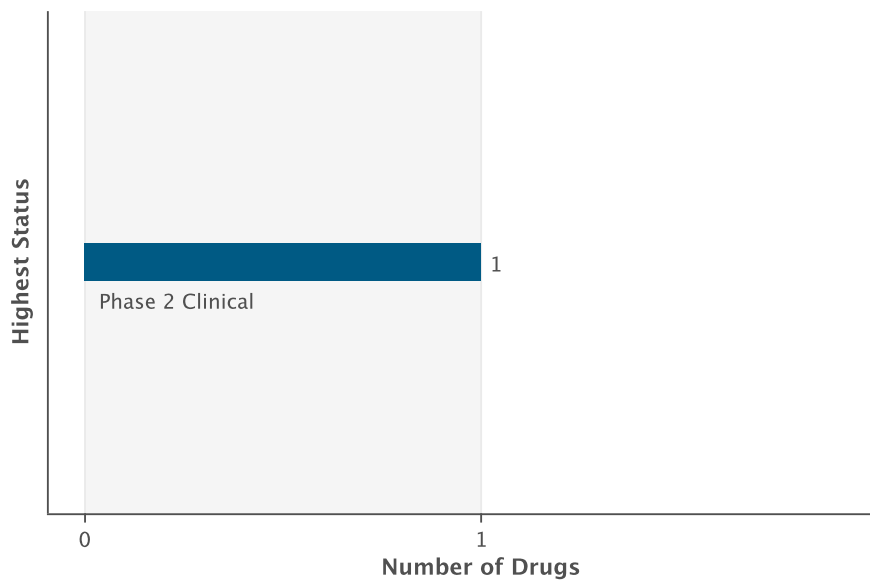
Drugs by Indication Table

| Indication | Active | Inactive | Total |
|---------------------------|--------|----------|-------|
| Genitourinary disease | 1 | 1 | 2 |
| Neoplasm | 1 | 1 | 2 |
| Andrology | 1 | 0 | 1 |
| Gynecology and obstetrics | 0 | 1 | 1 |
| Surgical procedure | 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 |
| 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 |

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CLINICAL TRIALS

Trials by Condition Studied

| Condition Studied | Ongoing | All |
|-----------------------|---------|-----|
| Neoplasm | 0 | 3 |
| Andrology | 0 | 3 |
| Genitourinary disease | 0 | 3 |

Trials by Phase

| Phase | Ongoing | All |
|---------|---------|-----|
| Phase 2 | 0 | 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 |
| Neurological disease | 1 | 0 | 1 |

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| | | | |
|---------------------------|---|---|---|
| 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.

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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

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 |
| 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 | 20-Nov-2014 |

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,. In December 2012, a phase II trial was initiated; in January 2014, positive interim 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.

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

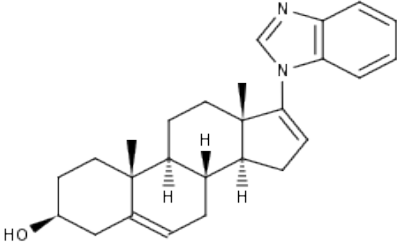
| Company | Indication | Country | Development Status | Date |
|---------------------------|------------------------------------|---------|--------------------|-------------|
| Tokai Pharmaceuticals Inc | Hormone refractory prostate cancer | US | Phase 2 Clinical | 11-Oct-2011 |

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| Company | Indication | Country | Development Status | Date |
|------------------------|----------------|---------|--------------------|-------------|
| University of Maryland | Prostate tumor | US | Discovery | 31-Dec-2006 |

galeterone CHEMICAL STRUCTURES

| CAS Registry Number: | Confidence Level: |
|---|-------------------|
| 851983-85-2 | 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

| 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 | 0 | 0 | 2 | 0 | 1 | 0 | 0 | 0 | 3 |

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| 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 | 0 | 0 | 2 | 0 | 1 | 0 | 0 | 0 | 3 |

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)

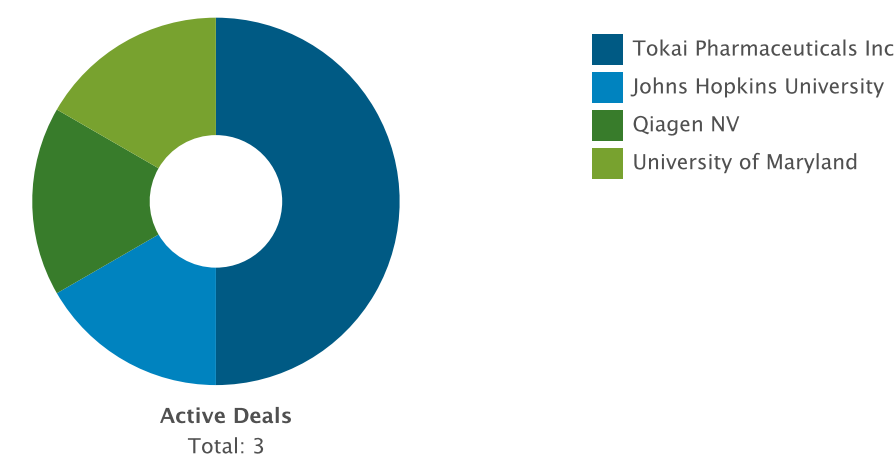
Phase 1 Clinical

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

galeterone DEALS AND PATENTS

DEALS

Deals by Parent Company Chart

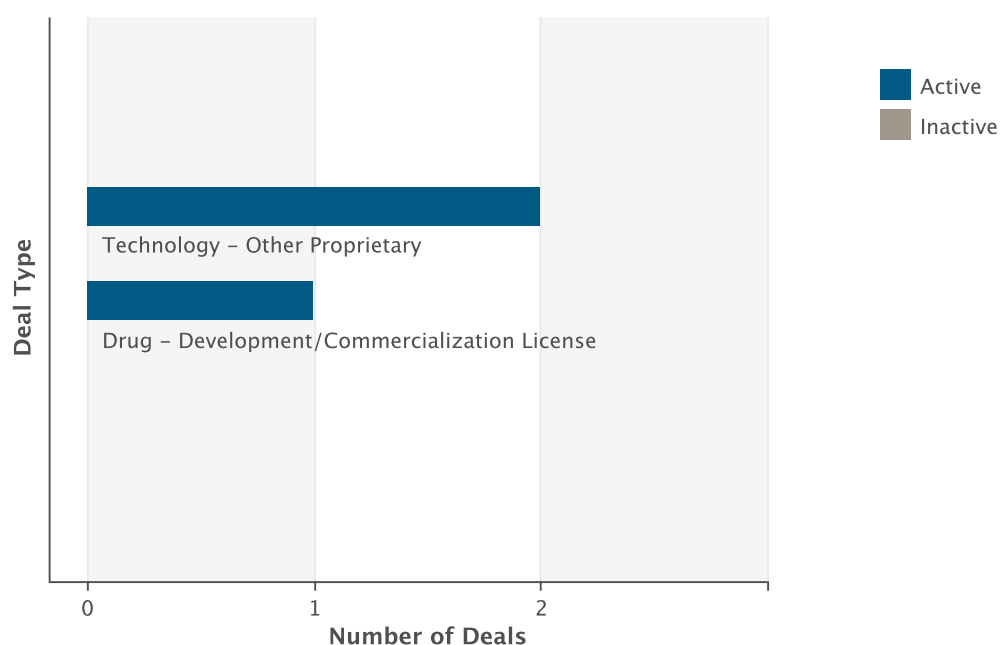


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Deals by Parent Company Table

| 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



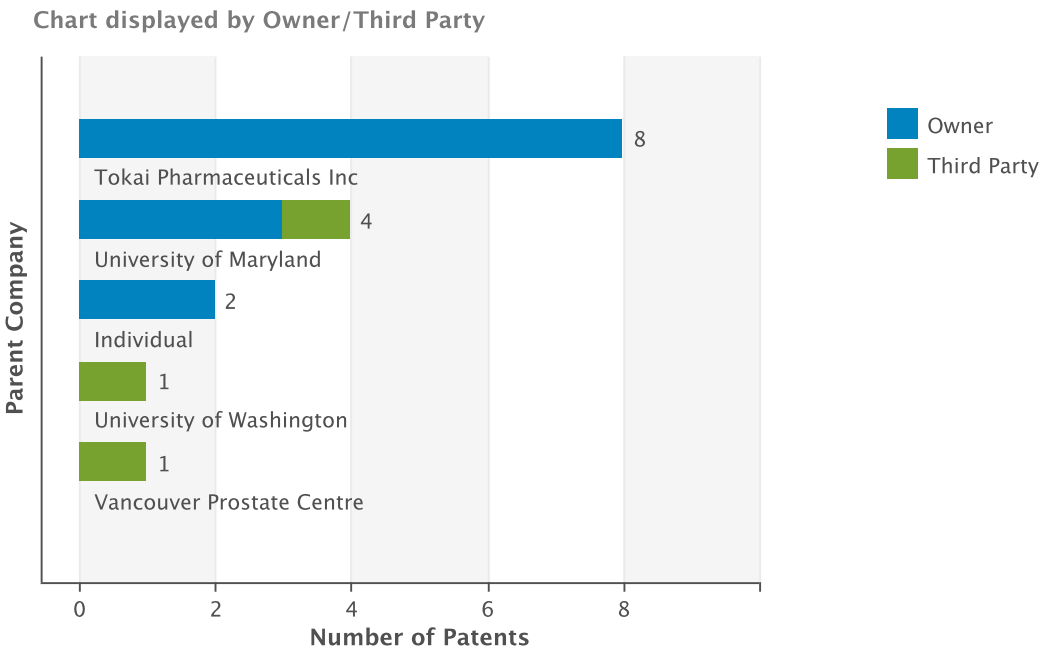
Deals by Type Table

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

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PATENTS

Patents by Parent Company Chart

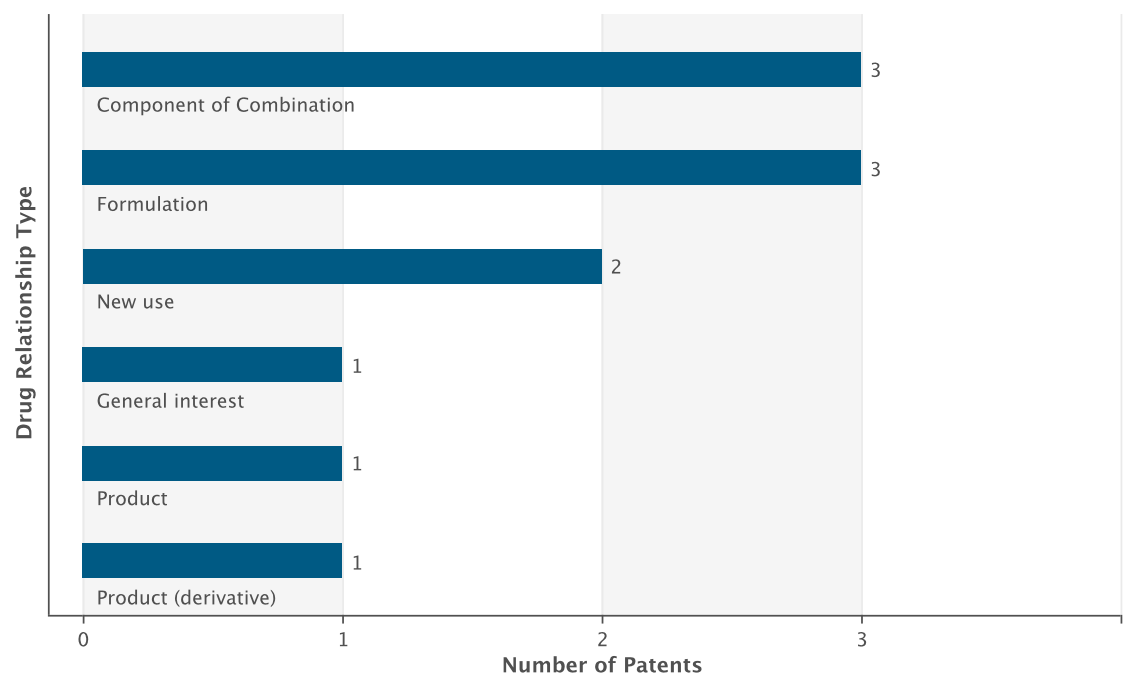


Patents by Parent Company Table

| 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 |

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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 |

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