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i.e. where the development status for the drug(s) is one of the following: No Development Reported, Discontinued, or Withdrawn.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

COMPANY OVERVIEW

Company Name	Otonomy Inc
Parent Company Name	Otonomy Inc
Website	http://www.otonomy.com/
Country	US
Number of Drugs in Active Development	3
Number of Inactive Drugs	0
Number of Patents as Owner	12
Number of Patents as Third Party	0
Number of Deals	2
Key Indications	Ear disease,Meniere disease,Tinnitus,Otitis media,Hearing disorder,Chronic sinusitis,Fungal infection,Hearing loss,Nasal polyps,Epistaxis,Inner ear disease,Nasopharyngeal carcinoma,Nose disease,Presbycusis,Sensorineural hearing loss,Vertigo
Key Target-based Actions	Glucocorticoid agonist,DNA gyrase inhibitor,Topoisomerase IV inhibitor,Metabotropic glutamate receptor 1 modulator,Metabotropic glutamate receptor 5 modulator,Metabotropic glutamate receptor modulator,NMDA receptor antagonist
Key Technologies	Otic gel formulation,Small molecule therapeutic,Sustained release formulation,Otic formulation,Injectable controlled release formulation,Steroid,Antibiotic,Injectable formulation,Parenteral formulation unspecified,Liquid-based formulation technology

COMPANY PROFILE

SUMMARY

Otonomy, founded in 2008, is a spin-off from the UC San Diego. It is an emerging biopharmaceutical company dedicated to developing and marketing therapeutics designed specifically for the middle and inner ear.

FINANCIAL

In January 2015, the company priced its follow-on public offering of 2,550,000 shares of its common stock at $29.25 each, for total gross proceeds of approximately $75 million. The offering was expected to close on January 28, 2015. The underwriters were granted a 30-day option to purchase up to an additional 382,500 shares of common stock. A registration statement relating to securities had been filed with the SEC and became effective on January 22, 2015; Later that month, the offering was closed, with total gross proceeds of approximately $86 million.

In January 2015, the company filed a registration statement on Form S-1 for the proposed follow-on public offering of $75 million of its common stock. At that time, the company planned to grant the underwriters a 30-day option to purchase up to an additional $11.25 million of its common stock. Later that month, the follow-on public offering was launched.

In October 2014, Otonomy was added to the Russell 2000 Index.

In July 2014, the company filed a registration statement on Form S-1 for the proposed initial public offering. In August 2014, the company priced its initial public offering of 6,250,000 shares of common stock, at $16 each. The underwriters were granted a 30-day option to purchase up to an additional 937,500 shares of common stock. At that time, the shares began trading on NASDAQ global select market under the symbol "OTIC". In September 2014, the underwriters purchased the additional 937,500 shares at $16 each. The company raised $104 million through the offering.

In April 2014, the company raised $49 million from an oversubscribed series D financing round.

In September 2013, Otonomy raised $45.9 million in a series C financing round.

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In August 2010, the company raised $38.5 million from a series B financing round.

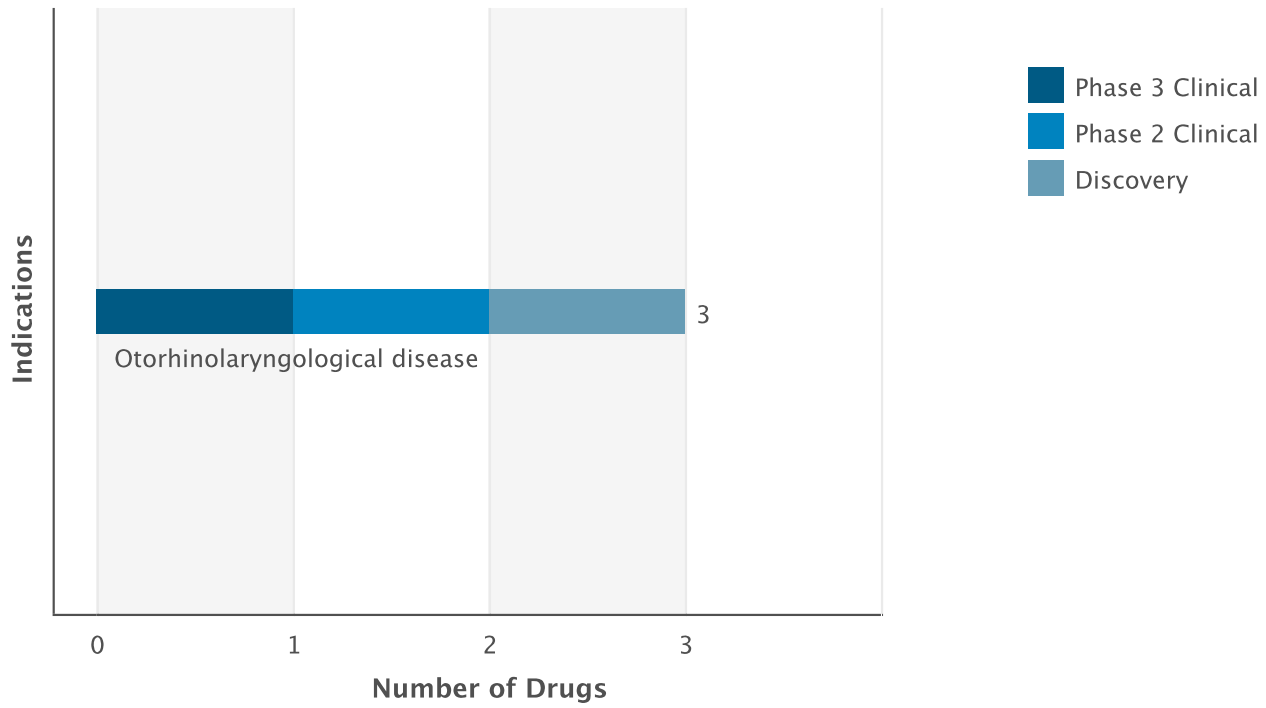
In June 2010, the company raised $10 million from a series A financing round.

PRODUCT PORTFOLIO SUMMARY

DRUGS

Drugs by Indication

Active Drugs by Indication Chart



Drugs by Indication Table

Indication	Active	Inactive	Total
Otorhinolaryngological disease	3	0	3

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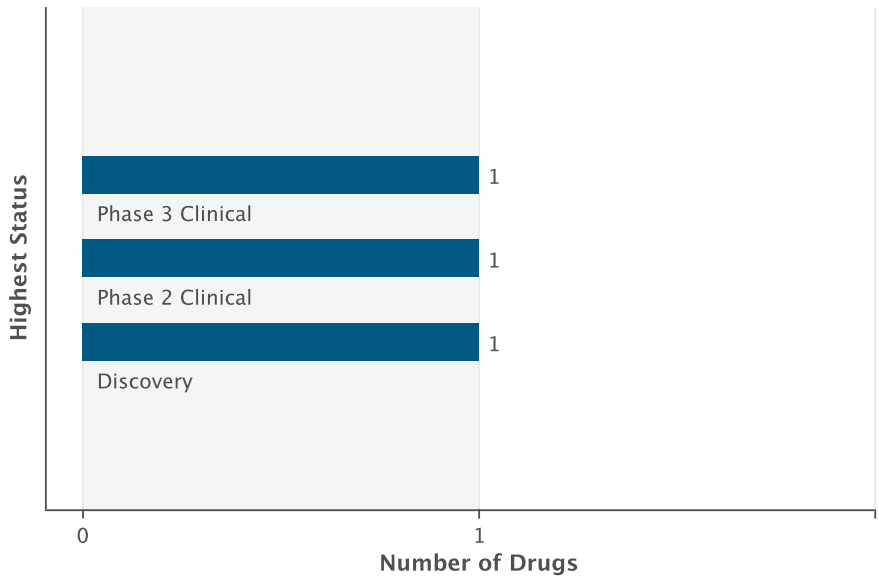
Drugs by Highest Status

Active Drugs by Highest Status Chart



Drugs by Highest Status Table

Development Status	Number of Drugs
Phase 3 Clinical	1
Phase 2 Clinical	1
Discovery	1

DEALS

Deal Type	Principal		Partner		Total
	Active	Inactive	Active	Inactive	
Drug - Asset Divestment	0	0	1	0	1
Drug - Early Research/Development	0	0	1	0	1

CLINICAL TRIALS

Trials by Condition Studied

Condition Studied	Ongoing	All
Otorhinolaryngological disease	2	6

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Trials by Phase

Phase	Ongoing	All
Phase 3	0	2
Phase 2	2	2
Phase 1	0	2

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
Cardiovascular disease	1	0	1
Immune disorder	1	0	1
Neoplasm	1	0	1
Mouth disease	1	0	1
Neurological disease	4	0	4
Respiratory disease	1	0	1
Infectious disease	1	0	1
Injury	1	0	1
Inflammatory disease	1	0	1
Otorhinolaryngological disease	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.

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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

ciprofloxacin (intratympanic sustained release gel, otitis media), Otonomy

ciprofloxacin (intratympanic sustained release gel, otitis media), Otonomy SNAPSHOT

Drug Name	ciprofloxacin (intratympanic sustained release gel, otitis media), Otonomy
Key Synonyms	ciprofloxacin;AuriPro
Originator Company	Otonomy Inc
Active Companies	Otonomy Inc
Inactive Companies	
Highest Status	Phase 3 Clinical
Active Indications	Otitis media
Target-based Actions	DNA gyrase inhibitor;Topoisomerase IV inhibitor
Other Actions	Bacterial nucleic acid synthesis inhibitor;Antibacterial
Technologies	Injectable formulation;Small molecule therapeutic;Parenteral formulation unspecified;Otic gel formulation;Antibiotic;Sustained release formulation
Last Change Date	09-Jan-2015

ciprofloxacin (intratympanic sustained release gel, otitis media), Otonomy DEVELOPMENT PROFILE

SUMMARY

Otonomy is developing AuriPro (previously OTO-201; OTO-203), a sustained release gel formulation of ciprofloxacin, delivered using intratympanic injection, for the potential treatment of otitis media,,. In November 2013, two phase III trial were initiated in the US and Canada, ; in July 2014, positive data were reported. In January 2015, NDA was planned to be filed in the first quarter of 2015. At that time, the drug was expected to be launched in the US in the first half of 2016. In November 2013, the company was seeking to outlicense the drug.

ciprofloxacin (intratympanic sustained release gel, otitis media), Otonomy DEVELOPMENT STATUS

CURRENT DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
Otonomy Inc	Otitis media	Canada	Phase 3 Clinical	11-Dec-2013
Otonomy Inc	Otitis media	US	Phase 3 Clinical	11-Nov-2013

ciprofloxacin (intratympanic sustained release gel, otitis media), Otonomy CHEMICAL STRUCTURES

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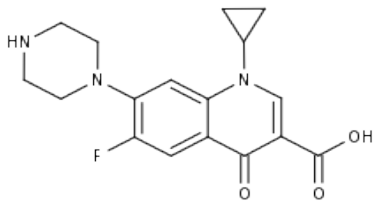
CAS Registry Number:	Confidence Level:
85721-33-1	1



Name	Type
ciprofloxacin	BANN; INN; USAN
Pulmaquin	Trade Name
OTO-201	Research Code
OBM-A-03	Research Code
Cipro NDS	

ciprofloxacin (intratympanic sustained release gel, otitis media), Otonomy DRUG NAMES

Names	Type
AuriPro	Trade Name
OTO-201	Research Code
OTO-203	Research Code
ciprofloxacin (intratympanic sustained release gel, otitis media), Otonomy	
ciprofloxacin	BANN, INN, USAN

ciprofloxacin (intratympanic sustained release gel, otitis media), Otonomy 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
Otitis media											
0	0	0	2	0	0	0	1	0	0	0	3

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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	2	0	0	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

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dexamethasone (sustained release/intratympanic injection, ear disorders), Otonomy

dexamethasone (sustained release/intratympanic injection, ear disorders), Otonomy SNAPSHOT

Drug Name	dexamethasone (sustained release/intratympanic injection, ear disorders), Otonomy
Key Synonyms	dexamethasone
Originator Company	Otonomy Inc
Active Companies	Otonomy Inc
Inactive Companies	
Highest Status	Phase 2 Clinical
Active Indications	Meniere disease;Ear disease
Target-based Actions	Glucocorticoid agonist
Other Actions	Steroidal anti-inflammatory
Technologies	Otic formulation;Injectable controlled release formulation;Small molecule therapeutic;Otic gel formulation;Steroid
Last Change Date	09-Jan-2015

dexamethasone (sustained release/intratympanic injection, ear disorders), Otonomy DEVELOPMENT PROFILE

SUMMARY

Otonomy is developing OTO-104, a local-acting, sustained-release thermosensitive gel formulation of dexamethasone, delivered via intratympanic injection, for the potential injectable treatment of ear diseases, including Meniere disease. In November 2013, a phase II/III trial for Meniere disease was ongoing. In February 2011, the company planned to initiate clinical trials for noise- and chemotherapy-induced hearing loss . In August 2013, the company was advancing the formulation into late-stage clinical trials. In January 2015, results from the phase IIb trial were expected in the the second quarter of 2015. In October 2014, a multiple dose safety study of OTO-104 was initiated in UK and at that time, the company planned to start clinical development activities outside of North America. In September 2009, the company was seeking to outlicense the drug outside the US ; in November 2013, this was still the case.

dexamethasone (sustained release/intratympanic injection, ear disorders), Otonomy DEVELOPMENT STATUS

CURRENT DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
Otonomy Inc	Meniere disease	Canada	Phase 2 Clinical	11-Dec-2013
Otonomy Inc	Meniere disease	US	Phase 2 Clinical	11-Sep-2011
Otonomy Inc	Meniere disease	UK	Clinical	09-Oct-2014
Otonomy Inc	Ear disease	US	Discovery	21-Sep-2009

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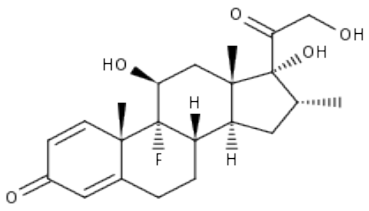
dexamethasone (sustained release/intratympanic injection, ear disorders), Otonomy CHEMICAL STRUCTURES

CAS Registry Number:	Confidence Level:
50-02-2	1



Name	Type
dexamethasone	BANN; INN
Ozurdex	Trade Name
Surodex	Trade Name
CD-102	Research Code
EGP-437	Research Code
OTO-104	Research Code
IBI-10090	Research Code
OTX-DP	Research Code
ISV-305	Research Code
TLC-x99	Research Code
Oncocort	

dexamethasone (sustained release/intratympanic injection, ear disorders), Otonomy DRUG NAMES

Names	Type
dexamethasone (sustained release/intratympanic injection, ear disorders), Otonomy	
OTO-104	Research Code
dexamethasone	BANN, INN

dexamethasone (sustained release/intratympanic injection, ear disorders), Otonomy CLINICAL TRIALS

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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
Meniere disease											
0	0	0	0	2	2	0	1	0	0	2	3

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	2	2	0	1	0	0	2	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

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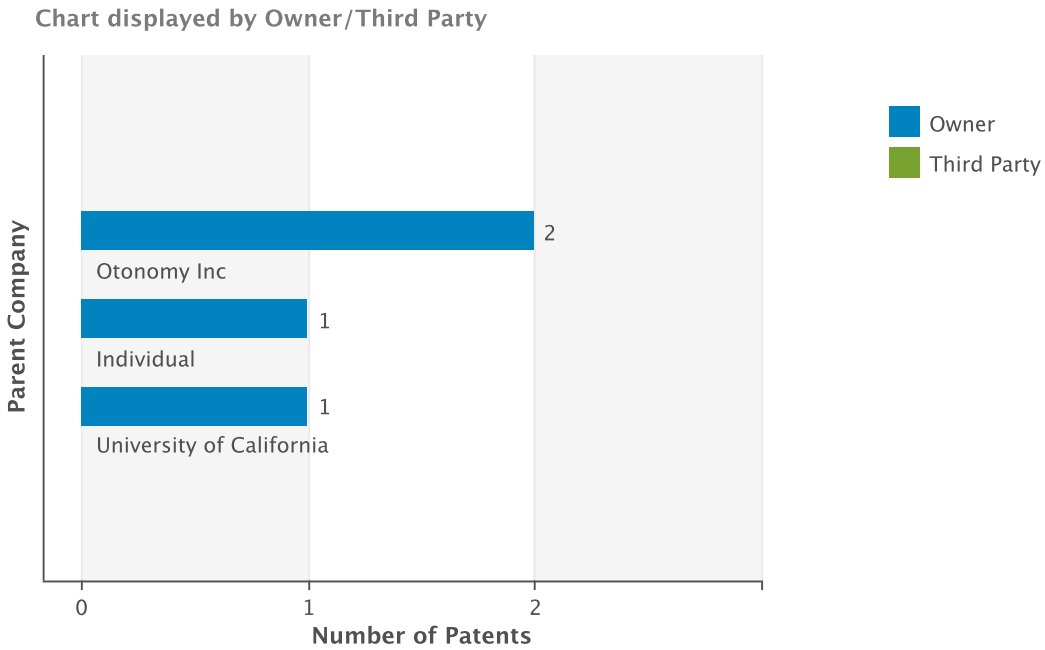
PATENTS

Patents by Parent Company Chart



Patents by Parent Company Table

Company Name	As Owner	As Third Party	Total
Otonomy Inc	2	0	2
Individual	1	0	1
University of California	1	0	1

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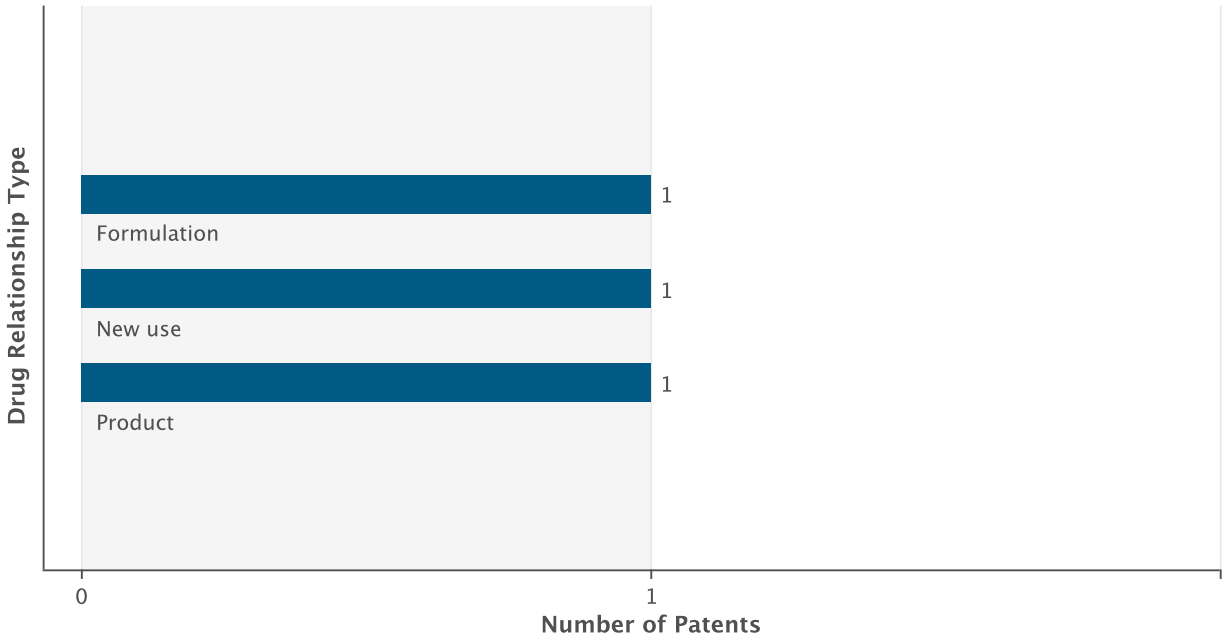
Patents by Drug Relationship Type Chart



Patents by Drug Relationship Type Table

Drug Relationship	Total
Formulation	1
New use	1
Product	1

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OTO-311

OTO-311 SNAPSHOT

Drug Name	OTO-311
Key Synonyms	gacyclidine
Originator Company	DURECT Corp
Active Companies	Otonomy Inc
Inactive Companies	NeuroSystec Corp;DURECT Corp
Highest Status	Discovery
Active Indications	Tinnitus
Target-based Actions	NMDA receptor antagonist
Other Actions	Analgesic
Technologies	Nanoparticle formulation injectable;Otic formulation;Injectable controlled release formulation;Small molecule therapeutic;Local formulation unspecified;Drug implant;Sustained release formulation
Last Change Date	09-Jan-2015

OTO-311 DEVELOPMENT PROFILE

SUMMARY

Otonomy under license from NeuroSystec, (under exclusive license from DURECT), is developing OTO-311 (NST-001), a squalene-based nanoparticle formulation of gacyclidine, an NMDA receptor antagonist delivered directly into the cochlear using Otonomy's proprietary drug delivery technology (previously delivered using Neuroject implantable continuous delivery system), for the potential injectable treatment of tinnitus,. In November 2014, Otonomy was planning clinical trials for the following year. In January 2015, the company planned to file an IND and initiate a phase I trial in 2015. In November 2013, the drug was listed as being in preclinical development and at that time, the company was seeking to outlicense the drug.

OTO-311 DEVELOPMENT STATUS

CURRENT DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
Otonomy Inc	Tinnitus	US	Discovery	06-Nov-2013
DURECT Corp	Tinnitus	France	Discontinued	21-Jun-2004
NeuroSystec Corp	Tinnitus	France	Discontinued	31-Oct-2013

OTO-311 CHEMICAL STRUCTURES

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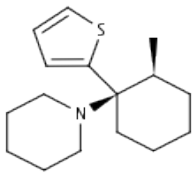
CAS Registry Number:	Confidence Level:
68134-81-6	1



Name	Type
gacyclidine	INN
NST-001	Research Code
GK-11	Research Code

OTO-311 DRUG NAMES

Names	Type
OTO-311	Research Code
gacyclidine	INN
NMDA receptor antagonist (nanoparticle implant, tinnitus), Otonomy	
NMDA antagonist (nanoparticle implant, tinnitus), NeuroSystec Corp	
NST-001	Research Code
gacyclidine (nanoparticle implant, tinnitus), NeuroSystec Corp	
NMDA receptor antagonist (nanoparticle implant, tinnitus), NeuroSystec Corp	

OTO-311 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
Tinnitus											
0	0	0	0	0	0	0	1	0	0	0	1

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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	0	0	1	0	0	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

OTO-311 DEALS AND PATENTS

DEALS

Deals by Parent Company Chart

Active Deals
Total: 3

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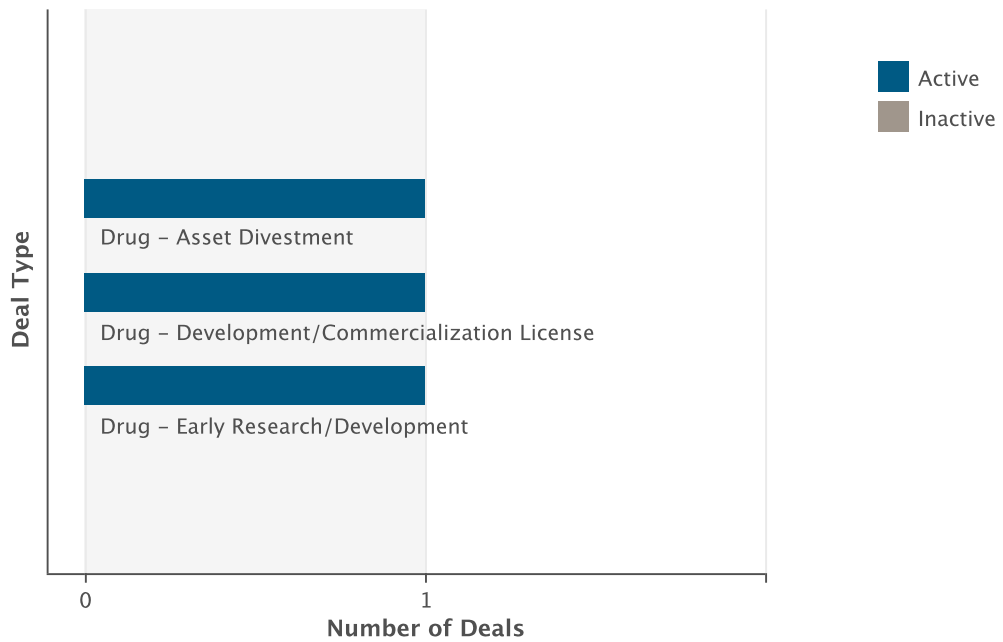
Deals by Parent Company Table

Company Name	Principal		Partner		Total
	Active	Inactive	Active	Inactive	
Otonomy Inc	0	0	2	0	2
NeuroSystec Corp	1	0	1	0	2
Ipsen	1	0	0	0	1
DURECT Corp	1	0	0	0	1

Deals by Type Chart



Deals by Type Table

Deal Type	Active	Inactive	Total
Drug - Early Research/Development	1	0	1
Drug - Asset Divestment	1	0	1
Drug - Development/Commercialization License	1	0	1

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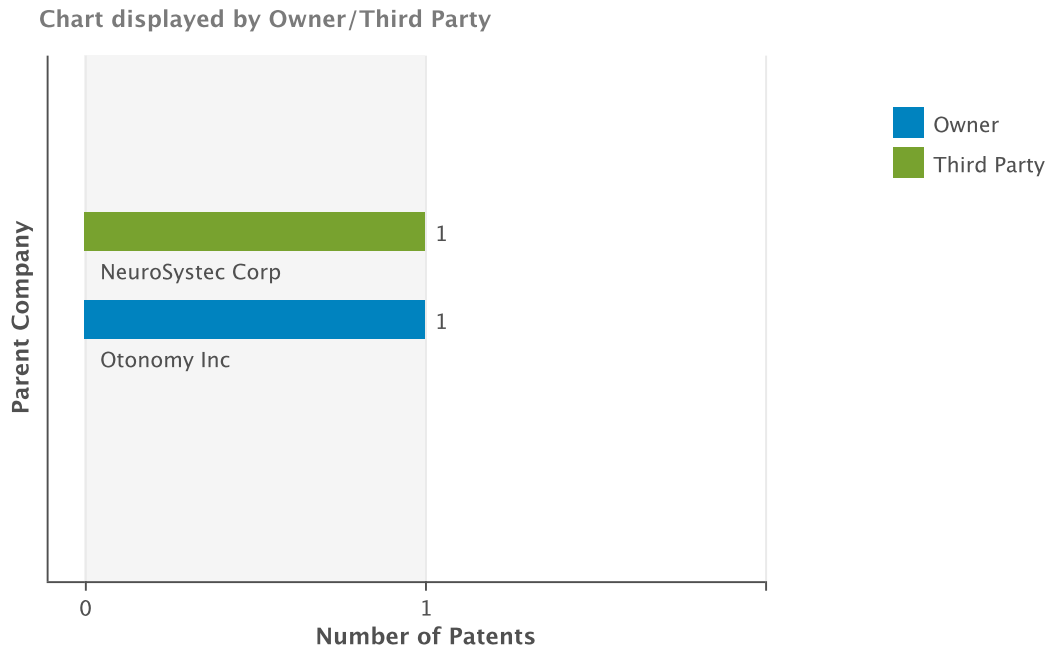
PATENTS

Patents by Parent Company Chart



Patents by Parent Company Table

Company Name	As Owner	As Third Party	Total
Otonomy Inc	1	0	1
NeuroSystec Corp	0	1	1

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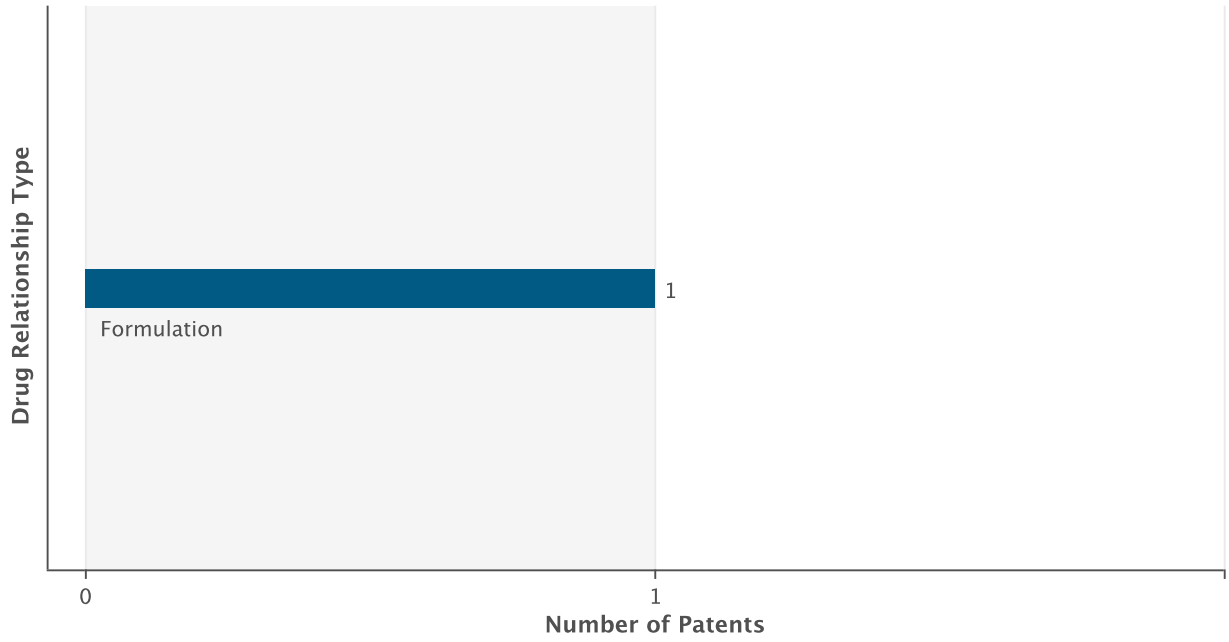
Patents by Drug Relationship Type Chart



Patents by Drug Relationship Type Table

Drug Relationship	Total
Formulation	1

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