

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i.e. where the development status for the drug(s) is one of the following: No Development Reported, Discontinued, or Withdrawn.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

## **COMPANY OVERVIEW**

Company Name	Durata Therapeutics Inc
Parent Company Name	Durata Therapeutics Inc
Website	http://www.duratatherapeutics.com/
Country	US
Number of Drugs in Active Development	3
Number of Inactive Drugs	13
Number of Patents as Owner	24
Number of Patents as Third Party	2
Number of Deals	9
Key Indications	Bacterial infection,Bacterial skin infection,Gram positive bacterium infection,MRSA infection
Key Target-based Actions	Peptide deformylase inhibitor,N-acetylglucosamine deacetylase inhibitor,Unspecified enzyme inhibitor
Key Technologies	Small molecule therapeutic, Antibiotic, Oral formulation, Biological therapeutic, Dermatological formulation, Injectable formulation, Parenteral formulation unspecified, Peptide

## **COMPANY PROFILE**

#### **SUMMARY**

Durata Therapeutics Inc, a biopharmaceutical company, was formed in 2009 by a 5-member venture capital syndicate for the development of antibiotic programs to treat infectious diseases.

#### **ACQUISITIONS & SPIN-OFFS**

In December 2009, Durata acquired Vicuron Pharmaceuticals from Pfizer. The transaction was funded through a stock purchase by New Leaf Venture Partners, Domain Associates, Aisling Capital, Sofinnova Ventures and Canaan Partners. Durata obtained rights to dalbavancin and two undisclosed preclinical antibiotic programs.

#### **FINANCIAL**

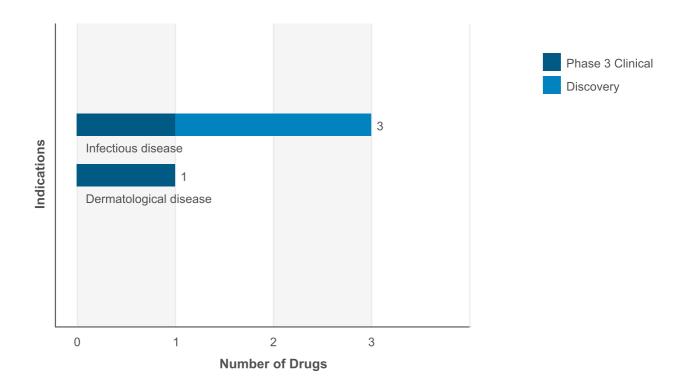
In March 2012, Durata planned to conduct an IPO; in July 2012, the company priced 7.5 million shares of common stock at \$9 each. The underwritters were granted 30-day option to purchase additional shares up to 1.125 million and the offering was expected to close on July 24, 2012. The company also reported that the shares would be traded on NASDAQ under the ticker symbol 'DRTX'; later that month, the IPO of 8.625 million common stock shares was closed before the underwriting discounts. By that time, a registration statement relating to these securities had been declared effective by the SEC; by September 2012, net proceeds of \$73.9 million had been raised from the offering.

# PRODUCT PORTFOLIO SUMMARY

## **DRUGS**

# Drugs by Indication

Active Drugs by Indication Chart

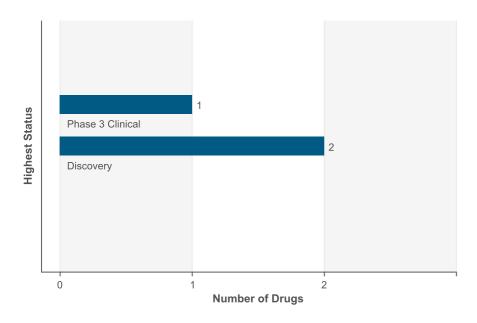


## Drugs by Indication Table

Indication	Active	Inactive	Total
Infectious disease	3	11	14
Dermatological disease	1	2	3

## **Drugs by Highest Status**

Active Drugs by Highest Status Chart



Drugs by Highest Status Table

Development Status	Number of Drugs
Phase 3 Clinical	1
Discovery	2
Discontinued	2
No Development Reported	7

# **DEALS**

Deal Type	Principal		Partner		Total
	Active	Inactive	Active	Inactive	
Technology - Other Proprietary	0	0	1	0	1
Drug - Asset Divestment	1	0	0	0	1
Drug - Early Research/Development	1	0	1	0	2
Drug - Development/Commercialization License	1	0	2	0	4
Drug - Manufacturing/Supply	0	0	1	0	1



# **CLINICAL TRIALS**

## Trials by Condition Studied

Condition Studied	Ongoing	All
Infectious disease	1	22
Dermatological disease	1	8

## Trials by Phase

Phase	Ongoing	All
Phase 3	1	7
Phase 2	0	7
Phase 1	0	5
Phase not specified	0	7

#### **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	0	1	1
Genetic disorder	1	0	1
Metabolic disorder	1	0	1
Neurological disease	1	0	1
Degeneration	1	0	1
Dermatological disease	6	0	6
Gastrointestinal disease	2	1	3
Musculoskeletal disease	1	0	1
Respiratory disease	5	1	6
Infectious disease	22	2	24



Inflammatory disease 1 0 1
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<sup>\*</sup> This table represents a summary of the core patent coverage for this company covering Therapeutic EP, US and WO patents since 1990 only.

## PRODUCT PORTFOLIO DRUG PIPELINE DETAIL

PLEASE NOTE: Highest status refers to highest development of that drug for one of the active companies

#### dalbavancin

#### dalbavancin SNAPSHOT

Drug Name	dalbayancin
Drug Nume	dabavanom
Key Synonyms	Zeven;Exulett;dalbavancin
Originator Company	Biosearch Italia SpA
Active Companies	Durata Therapeutics Inc
Inactive Companies	RaQualia Pharma Inc;Pfizer Inc;Vicuron Pharmaceuticals Inc;Biosearch Italia SpA
Highest Status	Phase 3 Clinical
Active Indications	Gram positive bacterium infection;Bacterial skin infection;MRSA infection
Target-based Actions	
Other Actions	Systemic dermatological antibacterial product; Antibacterial; Bacterial cell wall synthesis inhibitor
Technologies	Intravenous formulation;Antibiotic;Glycoprotein;Infusion;Small molecule therapeutic
Last Change Date	04-Oct-2012

#### dalbavancin DEVELOPMENT PROFILE

#### **SUMMARY**

Durata Therapeutics, following its acquisition of Vicuron Pharmaceuticals (previously Versicor) from Pfizer, is developing dalbavancin (Zeven; Exulett; BI-397), a semisynthetic derivative of the natural glycopeptide A-40926 for the potential once-weekly iv treatment of complicated skin and soft tissue infections (cSSTI) caused by Gram-positive bacteria, including methicillin-resistant Staphylococcus aureus (MRSA),.

In December 2004, Vicuron filed an NDA for cSSTI. An MAA was filed in July 2007. However, in September 2008, Pfizer reported that it would withdraw its MAA and NDA and conduct an additional phase III trial, following feedback from regulatory authorities. Pfizer divested the drug to Durata in 2009. In April 2011, Durata began a phase III trial for acute bacterial skin and skin structure infections (abSSSI). In September 2012, the company planned to file the NDA in 1H13.

The drug was previously being investigated for the treatment of catheter-related bloodstream infections. By January 2004, phase II trials had been completed; however, in April 2006, Pfizer stated that it had no intention to conduct a phase III trial for this indication.

#### dalbavancin DEVELOPMENT STATUS

#### **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	<b>Development Status</b>	Date
			Peturn to T	able of Contents

Company	Indication	Country	<b>Development Status</b>	Date
Durata Therapeutics Inc	Bacterial skin infection	Canada	Phase 3 Clinical	06-Sep-2012
Durata Therapeutics Inc	Bacterial skin infection	Europe	Phase 3 Clinical	06-Sep-2012
Durata Therapeutics Inc	Bacterial skin infection	US	Phase 3 Clinical	21-Dec-2009
Durata Therapeutics Inc	Gram positive bacterium infection	Canada	Phase 3 Clinical	06-Sep-2012
Durata Therapeutics Inc	Gram positive bacterium infection	Europe	Phase 3 Clinical	06-Sep-2012
Durata Therapeutics Inc	Gram positive bacterium infection	US	Phase 3 Clinical	21-Dec-2009
Durata Therapeutics Inc	MRSA infection	US	Phase 3 Clinical	21-Dec-2009
Durata Therapeutics Inc	MRSA infection	Japan	Discovery	21-Dec-2010
Biosearch Italia SpA	Gram positive bacterium infection	Italy	Discontinued	03-Mar-2003
Pfizer Inc	Bacterial skin infection	US	Discontinued	21-Dec-2009
Pfizer Inc	Gram positive bacterium infection	US	Discontinued	21-Dec-2009
Pfizer Inc	MRSA infection	US	Discontinued	21-Dec-2009
Pfizer Inc	Sepsis	US	Discontinued	24-Apr-2006
RaQualia Pharma Inc	MRSA infection	Japan	Discontinued	21-Dec-2010
Vicuron Pharmaceuticals Inc	Bacterial skin infection	US	Discontinued	14-Sep-2005
Vicuron Pharmaceuticals Inc	Gram positive bacterium infection	US	Discontinued	14-Sep-2005
Vicuron Pharmaceuticals Inc	MRSA infection	US	Discontinued	14-Sep-2005
Vicuron Pharmaceuticals Inc	Sepsis	US	Discontinued	14-Sep-2005

## dalbavancin DEVELOPMENT STATUS

## HISTORICAL DEVELOPMENT STATUS

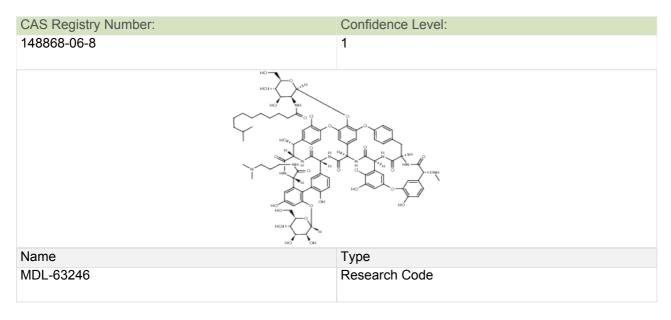
Company	Indication	Country	<b>Development Status</b>	Date
Pfizer Inc	Gram positive bacterium infection	Europe	Pre-registration	26-Jul-2007
Pfizer Inc	Gram positive bacterium infection	US	Pre-registration	21-Dec-2004
Vicuron Pharmaceuticals Inc	Gram positive bacterium infection	US	Pre-registration	21-Dec-2004
Pfizer Inc	Gram positive bacterium infection	US	Phase 3 Clinical	18-Dec-2002
Vicuron Pharmaceuticals Inc	Gram positive bacterium infection	US	Phase 3 Clinical	18-Dec-2002
Vicuron Pharmaceuticals Inc	Gram positive bacterium infection	US	Phase 2 Clinical	23-May-2001



Company	Indication	Country	<b>Development Status</b>	Date
Vicuron Pharmaceuticals Inc	Gram positive bacterium infection	US	Phase 1 Clinical	19-Sep-2000
Biosearch Italia SpA	Gram positive bacterium infection	Italy	Discovery	16-Sep-1998
RaQualia Pharma Inc	MRSA infection	Japan	Discovery	03-Jul-2008
Vicuron Pharmaceuticals Inc	Gram positive bacterium infection	US	Discovery	16-Feb-1999

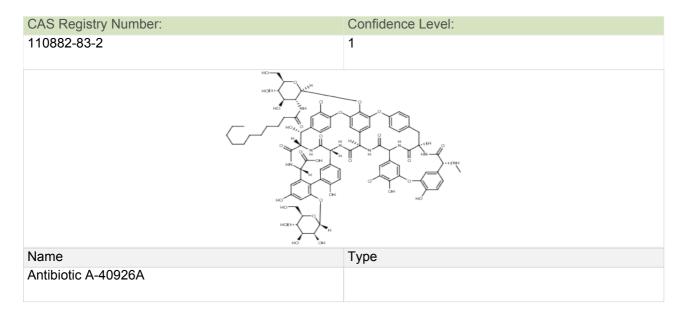
## dalbavancin CHEMICAL STRUCTURES

CAS Registry Number:	Confidence Level:
171500-79-1	1
Name	Туре
dalbavancin	INN
Zeven	Trade Name
BI-397	Research Code
MDL-63397	Research Code





CAS Registry Number:	Confidence Level:
114894-40-5	1
HO//// HO OH OH OH OH OH	OH HO
Name	Туре
Antibiotic A-40926 aglycone	





#### dalbavancin DRUG NAMES

Names	Туре
Zeven	Trade Name
BI-397	Research Code
A-40926	Research Code
Exulett	Trade Name
MDL-62476	Research Code, Analogue
MDL-63042	Research Code, Analogue
MDL-63246	Research Code
MDL-63397	Research Code
dalbavancin	INN
VGE, Vicuron	
V-glycopeptide	
VGE, Biosearch	
Antibiotic A-40926A	
A-40926 analog, Versicor	
Antibiotic A-40926 aglycone	

# dalbavancin SALES AND FORECASTS COMMENTARY

#### **CONSENSUS SALES INFORMATION**

No Consensus forecast data for Durata Therapeutics are currently available.

#### REGIONAL DEVELOPMENT AND MARKETING RIGHTS

In January 1999, Versicor Inc gained North American marketing rights from Biosearch Italia [311500]. In March 2003, Biosearch merged with Versicor to form Vicuron Pharmaceuticals [483671], and in June 2005, Pfizer acquired Vicuron, gaining dalbavancin development and marketing rights [480469], [607651]. In December 2009, Durata Therapeutics acquired Vicuron from Pfizer [1065287].

RaQualia Pharma (a spin-out of Pfizer) obtained the rights to dalbavancin in Japan from Pfizer in 2008. In December 2010, RaQualia Pharma signed a licensing agreement with Durata, granting Durata Japanese development and commercialization rights, meaning Durata owns full marketing rights worldwide [1170686], [1178040].



#### dalbavancin CLINICAL TRIALS

## Trials by Phase and Condition Studied

	ise 4 nical		se 3 nical	Pha Clin	se 2 nical		ise 1 nical		ase ecified	То	tal
On- going	All	On- going	All	On- going	All	On- going	All	On- going	All	On- going	All
Gram po	sitive bact	erium infe	ction								
0	0	0	0	0	1	0	2	0	4	0	7
Skin infe	ction										
0	0	0	3	0	1	0	0	0	1	0	5
Bacterial	skin infec	tion									
0	0	1	3	0	0	0	0	0	0	1	3
Bacterial	infection										
0	0	0	0	0	1	0	2	0	0	0	3
Staphylo	coccus au	reus infect	tion								
0	0	0	0	0	1	0	0	0	1	0	2
MRSA in	fection										
0	0	0	2	0	0	0	0	0	0	0	2
Staphylo	coccus inf	ection									
0	0	0	0	0	0	0	1	0	0	0	1

## Total Trials by Phase and Status

	se 4 nical		se 3 nical		se 2 nical		se 1 nical		ase ecified	То	tal
On- going	All	On- going	All								
Total by	Phase an	d Status									
0	0	1	5	0	3	0	4	0	7	1	19

## **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

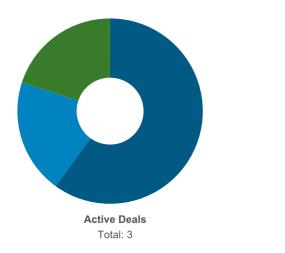
Includes Phase 1, Phase 1a, Phase 1, Phase 1/2 (where enrolment count is under 100 or not specified), Phase 0



## dalbavancin DEALS AND PATENTS

DEALS

Deals by Parent Company Chart



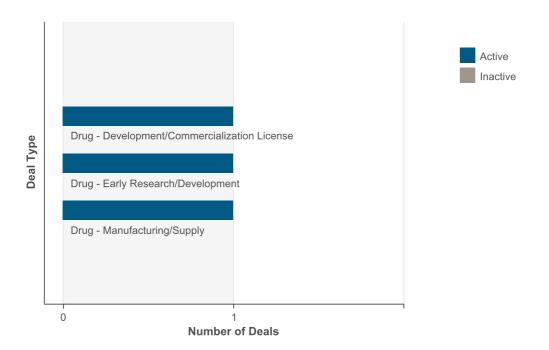


Inactive Deals
Total: 0

## **Deals by Parent Company Table**

Company Name	Principal Active Inactive		Partner Active Inactive		Total
Durata Therapeutics Inc	0	0	3	0	3
Pfizer Inc	1	0	0	0	1
RaQualia Pharma Inc	1	0	0	0	1

## **Deals by Type Chart**



## **Deals by Type Table**

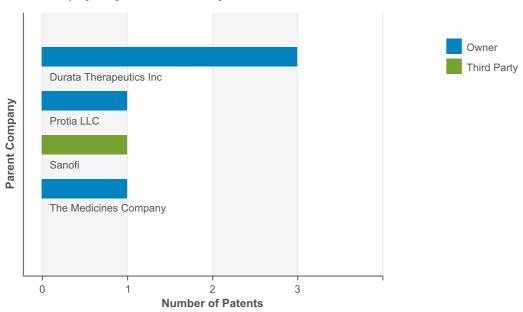
Deal Type	Active	Inactive	Total
Drug - Early Research/Development	1	0	1
Drug - Manufacturing/Supply	1	0	1
Drug - Development/Commercialization License	1	0	1



## **PATENTS**

## **Patents by Parent Company Chart**

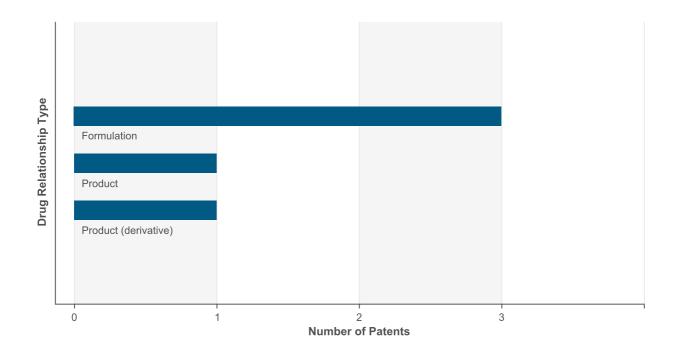
Chart displayed by Owner/Third Party



# **Patents by Parent Company Table**

Company Name	As Owner	As Third Party	Total
Durata Therapeutics Inc	3	0	3
Protia LLC	1	0	1
The Medicines Company	1	0	1
Sanofi	0	1	1

## **Patents by Drug Relationship Type Chart**



# **Patents by Drug Relationship Type Table**

Drug Relationship	Total
Formulation	3
Product (derivative)	1
Product	1



## lincosamide antibacterials, Durata

#### lincosamide antibacterials, Durata SNAPSHOT

Drug Name	lincosamide antibacterials, Durata
Key Synonyms	
Originator Company	Vicuron Pharmaceuticals Inc
Active Companies	Durata Therapeutics Inc
Inactive Companies	Vicuron Pharmaceuticals Inc
Highest Status	Discovery
Active Indications	Bacterial infection
Target-based Actions	
Other Actions	Bacterial protein synthesis inhibitor;Ribosome binding agent
Technologies	Antibiotic;Small molecule therapeutic
Last Change Date	23-Aug-2011

## lincosamide antibacterials, Durata DEVELOPMENT PROFILE

#### **SUMMARY**

Durata Therapeutics, following its acquisition of Vicuron Pharmaceuticals (previously Versicor) from Pfizer, is investigating a series of lincosamide antibiotics for the potential treatment of bacterial infections. In August 2011, development was ongoing.

Vicuron Pharmaceuticals was previously investigating VIC-105555 (VIC-5555), a lead from the series of lincosamide antibiotics for bacterial infections. In September 2004, Vicuron expected VIC-105555 to enter clinical trials in the first half of 2005; however, no further development was reported since the aquisition of Vicuron by Durata.

## lincosamide antibacterials, Durata DEVELOPMENT STATUS

#### **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	<b>Development Status</b>	Date
Durata Therapeutics Inc	Bacterial infection	US	Discovery	21-Dec-2009
Vicuron Pharmaceuticals Inc	Bacterial infection	US	Discontinued	30-Sep-2004



## lincosamide antibacterials, Durata DRUG NAMES

Names	Туре
VIC-5555	Research Code
VIC-105403	Research Code
VIC-105404	Research Code
VIC-105555	Research Code
lincosamide antibacterials, Durata	
lincosamide antibacterials, Pfizer	
lincosamide antibacterials, Vicuron	
bacterial protein synthesis inhibitors (ribosome binding), Pfizer	
bacterial protein synthesis inhibitors (ribosome-binding), Vicuron	



# pleuromutilins (bacterial infections), Durata

## pleuromutilins (bacterial infections), Durata SNAPSHOT

Drug Name	pleuromutilins (bacterial infections), Durata	
Key Synonyms		
Originator Company	Vicuron Pharmaceuticals Inc	
Active Companies	Durata Therapeutics Inc	
Inactive Companies		
Highest Status	Discovery	
Active Indications	Bacterial infection	
Target-based Actions		
Other Actions	Antibacterial;Protein synthesis inhibitor	
Technologies	Antibiotic;Small molecule therapeutic	
Last Change Date	23-Aug-2011	

## pleuromutilins (bacterial infections), Durata DEVELOPMENT PROFILE

## **SUMMARY**

Durata Therapeutics is investigating a series of pleuromutilins, that inhibit protein synthesis, for the potential treatment of bacterial infections. In December 2009, the program was in preclinical studies; in August 2011, development was ongoing.

# pleuromutilins (bacterial infections), Durata DEVELOPMENT STATUS

#### **CURRENT DEVELOPMENT STATUS**

Company	Indication	Country	<b>Development Status</b>	Date
Durata Therapeutics Inc	Bacterial infection	US	Discovery	21-Dec-2009

## pleuromutilins (bacterial infections), Durata DRUG NAMES

Names	Туре
antibiotics (bacterial infection), Durata	
pleuromutilins (bacterial infections), Durata	



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