

## **Relypsa Inc**

### **CORTELLIS COMPANY DETAILED PIPELINE REPORT**

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

Publication Date: 19-Nov-2014

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# ABOUT CORTELLIS COMPANY DETAILED PIPELINE REPORT

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i.e. where the development status for the drug(s) is one of the following: No Development Reported, Discontinued, or Withdrawn.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

<b>Company Name</b>	Relypsa Inc
<b>Parent Company Name</b>	Relypsa Inc
<b>Website</b>	http://www.relypsa.com/
<b>Country</b>	US
<b>Number of Drugs in Active Development</b>	2
<b>Number of Inactive Drugs</b>	4
<b>Number of Patents as Owner</b>	10
<b>Number of Patents as Third Party</b>	0
<b>Number of Deals</b>	4
<b>Key Indications</b>	Hyperkalemia, Metabolic disorder, Congestive heart failure, Coronary artery disease, Hyperlipidemia, Non-alcoholic steatohepatitis, Non-insulin dependent diabetes, Pruritus, Alzheimers disease, End stage renal disease, Renal disease
<b>Key Target-based Actions</b>	Potassium channel modulator
<b>Key Technologies</b>	Small molecule therapeutic, Oral formulation, Oral suspension formulation, Formulation preservation, Capsule formulation, Formulation powder, Hydrolytic synthesis, Nucleophilic substitutional synthesis

## COMPANY PROFILE

### SUMMARY

Relypsa Inc, a spin out of Ilypsa, a subsidiary of Amgen, is a pharmaceutical company, is a clinical-stage biopharmaceutical company leading the discovery and development of novel non-absorbed polymeric drugs for important applications in cardiovascular and renal diseases.

### FINANCIAL

In June 2014, the company secured a loan facility of up to \$35 million and drew \$15 million immediately upon closing on May 30, 2014. At that time, the interest only payment period for the loan facility would be extended to December 2015 upon acceptance of the NDA for patiomer by the FDA and the company would draw an additional \$20 million in the second half of 2015.

In April 2014, Relypsa commenced an underwritten public offering of its common stock shares to raise aggregate proceeds of \$80 million. At that time, the company intended to grant a 30-day option to the underwriters to purchase up to an additional 15% of the number of shares sold; later that month, the company priced the offering of 3,591,836 shares of its common stock at \$24.50 per share to raise gross proceeds of approximately \$88 million. At that time, the underwriters were granted a 30-day option to buy up to an additional 538,775 shares and the offering was expected to close on April 16, 2014. Later that month, the offering was closed for gross proceeds of approximately \$101 million. At that time, the net proceeds from the offering were expected to be approximately \$94 million. Later that month, the company raised net proceeds of \$94.4 million from the follow-on offering.

In November 2013, the company was to raise net proceeds of \$67.4 million from an initial public offering of 6.85 million shares of its common stock at \$11.00 per share. The underwriters were granted a 30-day option to buy up to an additional 1,027,500 shares to cover any over-allotments. The shares began trading on the NASDAQ Global Select market under the ticker symbol 'RLYP'. Later in the month, the offering was closed and the underwriters fully exercised their overallotment option, with estimated net proceeds of \$77.9 million.

In August 2012, the company raised \$80 million in a series C preferred stock financing round.

In September 2010, the company raised \$70 million in a series B financing round.

In October 2007, the company raised \$33 million in a series A financing round.

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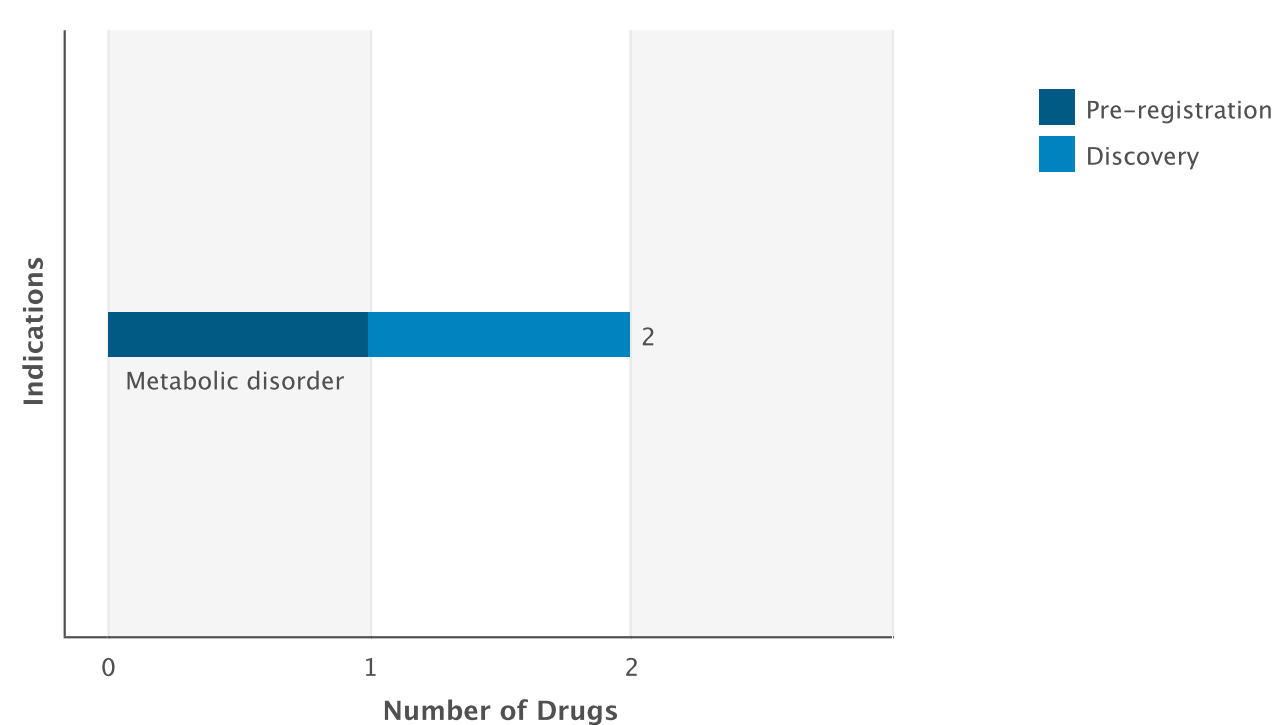


# PRODUCT PORTFOLIO SUMMARY

## DRUGS

### Drugs by Indication

Active Drugs by Indication Chart



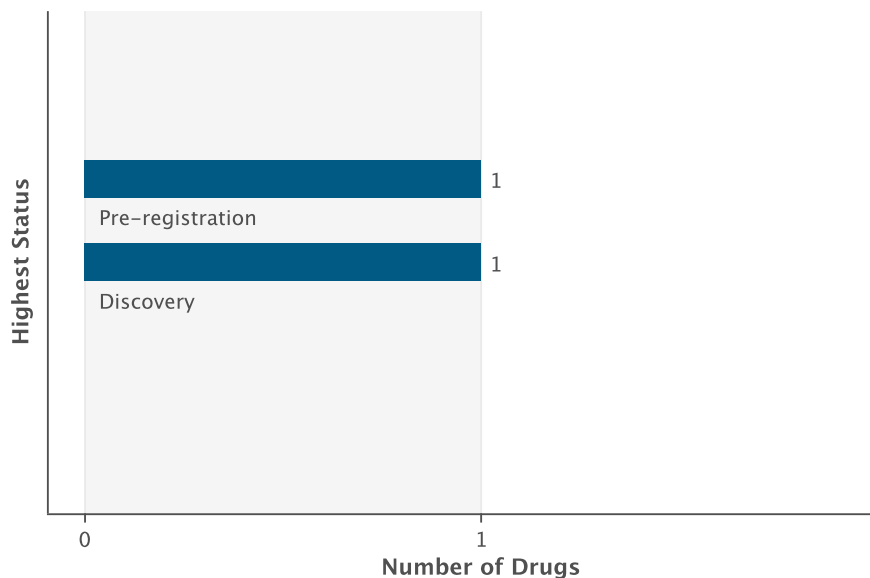
Drugs by Indication Table

Indication	Active	Inactive	Total
Metabolic disorder	2	2	4
Cardiovascular disease	0	2	2
Genitourinary disease	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
Pre-registration	1
Discovery	1
No Development Reported	4

## DEALS

Deal Type	Principal		Partner		Total
	Active	Inactive	Active	Inactive	
Drug - Funding	1	0	0	0	1
Drug - Manufacturing/Supply	0	0	3	0	3

## CLINICAL TRIALS

Trials by Condition Studied

Condition Studied	Ongoing	All
Metabolic disorder	0	8
Genitourinary disease	0	1

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## Trials by Phase

Phase	Ongoing	All
Phase 3	0	1
Phase 2	0	5
Phase 1	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

## PATENTS \*

Indication	As Owner	As Third Party	Total
Cardiovascular disease	12	0	12
Endocrine disease	4	0	4
Gastrointestinal disease	4	0	4
Genitourinary disease	6	0	6
Degeneration	2	0	2
Metabolic disorder	13	0	13
Neurological disease	2	0	2
Inflammatory disease	3	0	3
Dermatological disease	3	0	3

\* 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

### patiomer calcium

#### patiomer calcium SNAPSHOT

Drug Name	patiomer calcium
Key Synonyms	patiomer;patiomer calcium
Originator Company	Relypsa Inc
Active Companies	Relypsa Inc
Inactive Companies	
Highest Status	Pre-registration
Active Indications	Hyperkalemia
Target-based Actions	
Other Actions	Potassium metabolism modulator
Technologies	Oral formulation;Oral suspension formulation;Small molecule therapeutic
Last Change Date	30-Oct-2014

#### patiomer calcium DEVELOPMENT PROFILE

##### SUMMARY

Relypsa is developing patiomer calcium (RLY-5016), a potassium binder, as an oral suspension formulation, for the potential prevention and treatment of hyperkalemia in chronic heart failure and chronic kidney disease patients,. In March 2012, the company was seeking to outlicense its program.

In October 2014, Relypsa filed an NDA with the FDA for the treatment of hyperkalemia. In August 2014, US approval was anticipated in late 2015. In February 2013, a pivotal, two-part phase III trial, which was conducted in the US and Europe began in hyperkalemia patients ; in September 2013 and October 2013, positive topline data from part A and B, respectively, were reported.

The company was developing a second potassium binder, RLY-105, for the same indication. However, no development has been reported for some time and the company is presumed to have discontinued development of the drug.

#### patiomer calcium DEVELOPMENT STATUS

##### CURRENT DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
Relypsa Inc	Hyperkalemia	US	Pre-registration	22-Oct-2014

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Company	Indication	Country	Development Status	Date
Relypsa Inc	Hyperkalemia	Europe	Phase 3 Clinical	20-Feb-2013

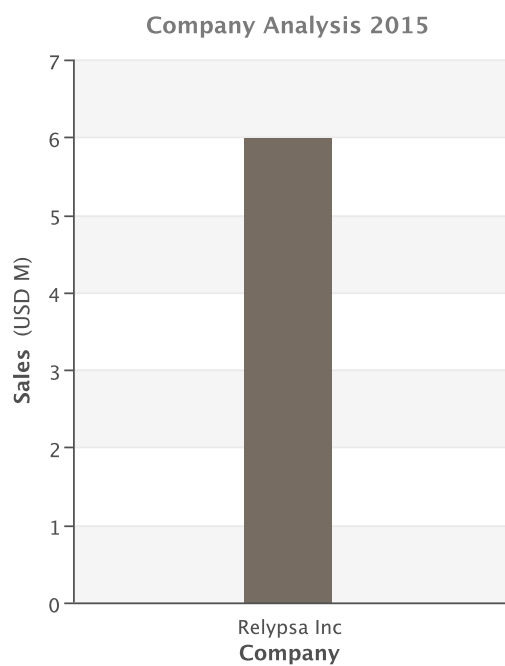
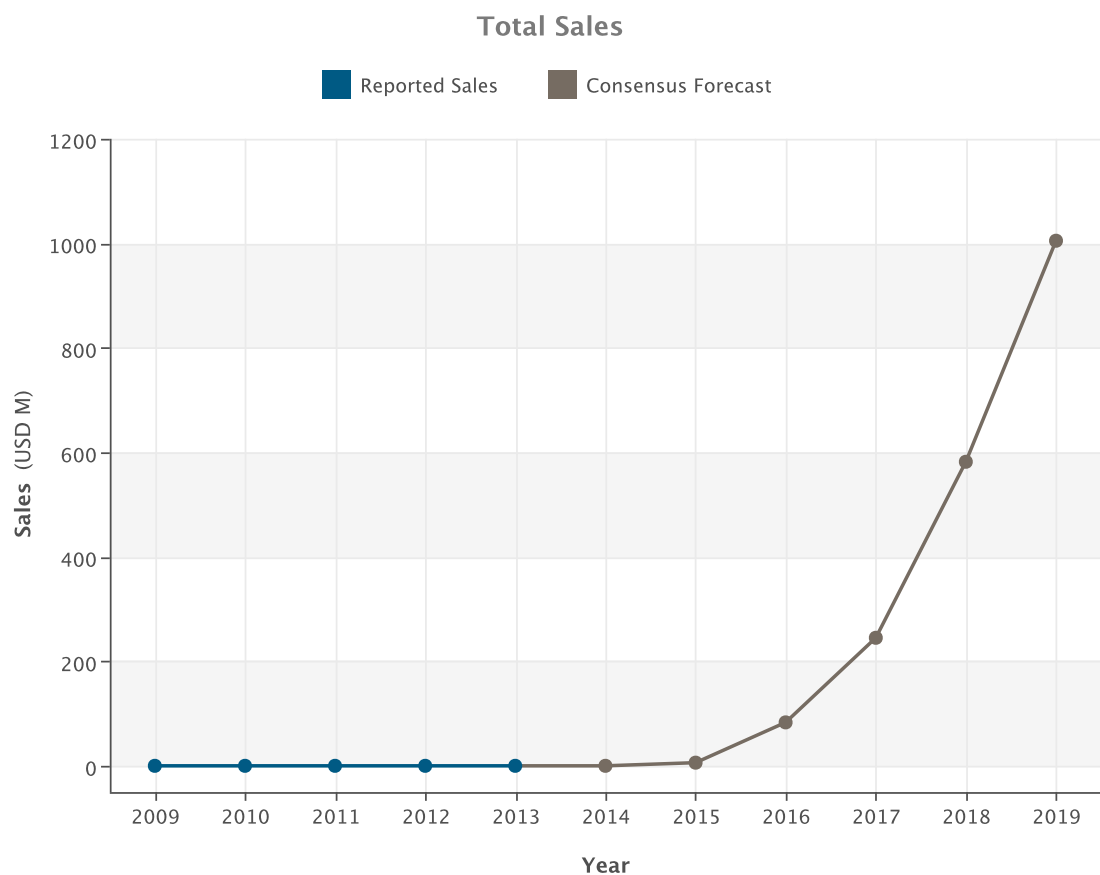
### patiomer calcium DRUG NAMES

Names	Type
potassium binder (hyperkalemia), Relypsa	
patiomer	USAN
RLY-5016	Research Code
patiomer calcium	USAN, INN
potassium binder (oral suspension formulation, hyperkalemia), Relypsa	

### patiomer calcium SALES AND FORECASTS

### CHARTS

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## COMMENTARY

### CONSENSUS SALES INFORMATION

Consensus forecast data for Relypsa are presented.

### REGIONAL DEVELOPMENT AND MARKETING RIGHTS

Relypsa holds worldwide development and marketing rights.

### patiomer calcium 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
Hyperkalemia											
0	0	0	1	0	4	0	3	0	0	0	8
Kidney dialysis											
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	0	5	0	3	0	0	0	9

#### 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)

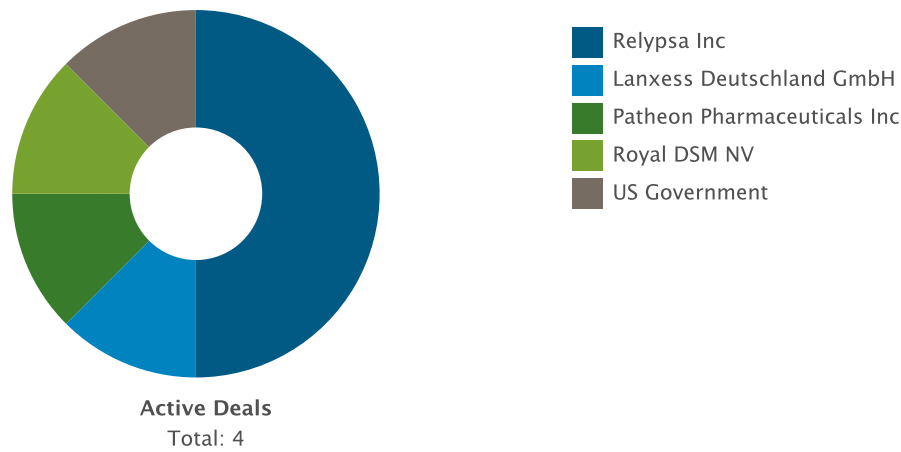
##### Phase 1 Clinical

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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DEALS

Deals by Parent Company Chart

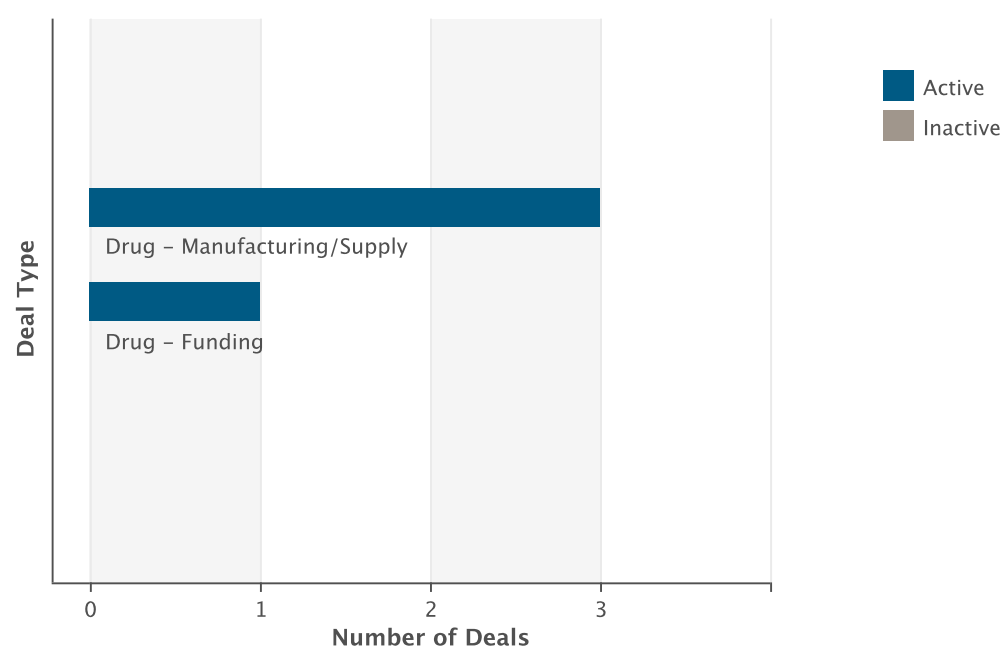


Deals by Parent Company Table

Company Name	Principal		Partner		Total
	Active	Inactive	Active	Inactive	
Relypsa Inc	1	0	3	0	4
Patheon Pharmaceuticals Inc	1	0	0	0	1
US Government	0	0	1	0	1
Lanxess Deutschland GmbH	1	0	0	0	1
Royal DSM NV	1	0	0	0	1

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Deals by Type Chart



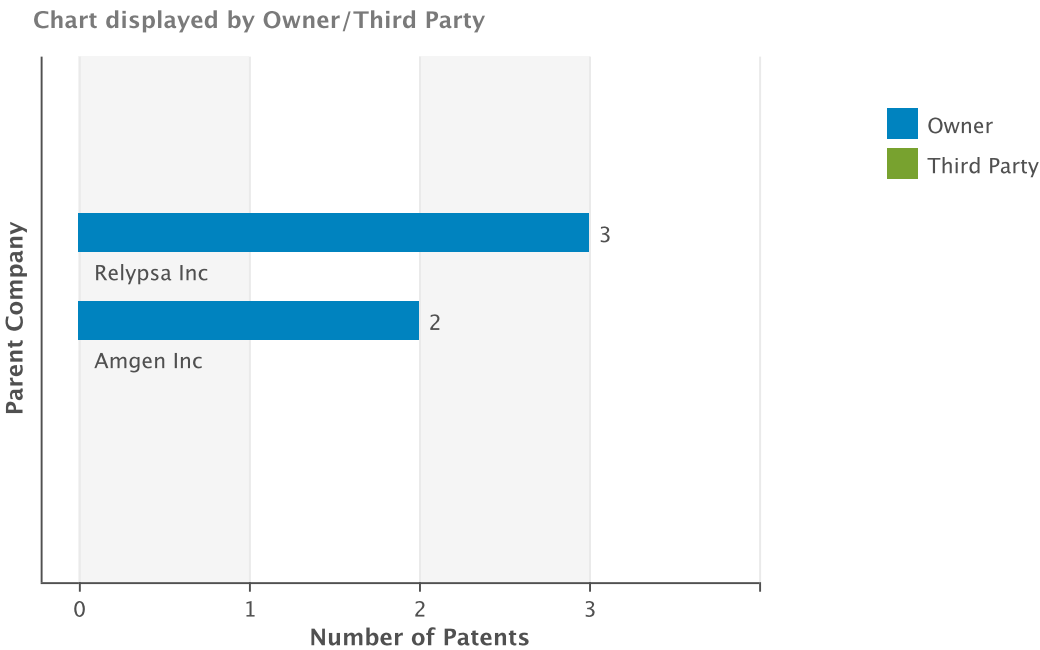
Deals by Type Table

Deal Type	Active	Inactive	Total
Drug - Manufacturing/Supply	3	0	3
Drug - Funding	1	0	1

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PATENTS

Patents by Parent Company Chart

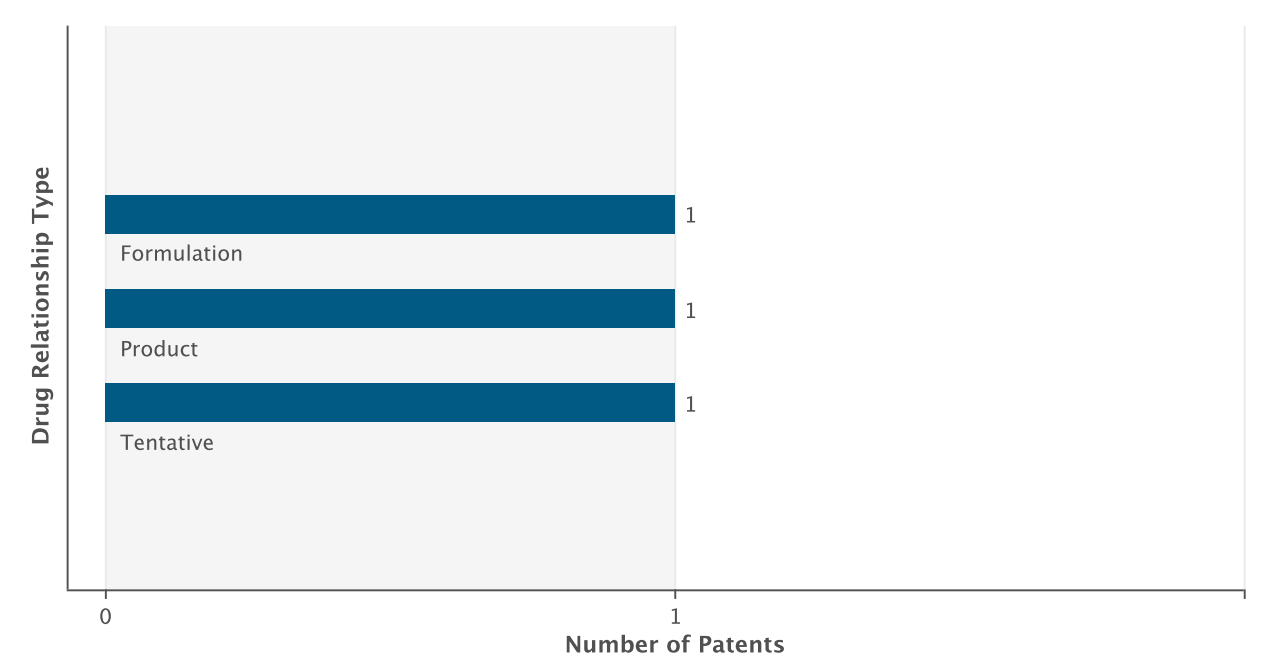


Patents by Parent Company Table

Company Name	As Owner	As Third Party	Total
Relypsa Inc	3	0	3
Amgen Inc	2	0	2

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Patents by Drug Relationship Type Chart



Patents by Drug Relationship Type Table

Drug Relationship	Total
Product	1
Formulation	1
Tentative	1



## RLY-6002

### RLY-6002 SNAPSHOT

Drug Name	RLY-6002
Key Synonyms	
Originator Company	Relypsa Inc
Active Companies	Relypsa Inc
Inactive Companies	
Highest Status	Discovery
Active Indications	Metabolic disorder
Target-based Actions	
Other Actions	Hypoglycemic agent
Technologies	Small molecule therapeutic
Last Change Date	09-Jan-2014

### RLY-6002 DEVELOPMENT PROFILE

#### SUMMARY

Relypsa is investigating RLY-6002, nonabsorbed polymeric drug developed using its proprietary polymer platform technology for the potential treatment of metabolic disease including type 2 diabetes mellitus. In January 2014, the drug was listed as being in preclinical development.

### RLY-6002 DEVELOPMENT STATUS

#### CURRENT DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
Relypsa Inc	Metabolic disorder	US	Discovery	09-Jan-2014

### RLY-6002 DRUG NAMES

Names	Type
RLY-6002	Research Code

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