

Relypsa Inc

CORTELLIS COMPANY DETAILED PIPELINE REPORT

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

Publication Date: 05-Aug-2014

THOMSON REUTERS

3 Times Square New York, New York 10036 United States

Tel: +1 646 223 4000

thomsonreuters.com



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.

This report was created by Thomson Reuters, using information from *Thomson Reuters Cortellis*™ for *Competitive Intelligence*; a comprehensive, proven intelligence solution that leverages the most accurate, complete, and widely respected drug pipeline information. From drug discovery and development activities to patent reports, the latest deals, and partnering opportunities, *Cortellis* can provide the confidence to make the most informed business decisions, faster. *Cortellis for Competitive Intelligence* provides accurate and validated information on pharmaceutical and biotechnology companies globally, their drug pipelines, deals, patents, and clinical trials, plus breaking industry news and conference coverage. All contained in one simple, highly intuitive research platform.

Cortellis Company Detailed Pipeline reports are the second in a series of that track pharmaceutical and biotechnology companies worldwide. All Cortellis for Competitive Intelligence content is subject to the most comprehensive editorial review process available, conducted by scientists, pharma professionals, regulatory experts, and generics specialists. Featuring timely drug pipeline information expertly uncovered and integrated from over 400 global meetings each year, you'll always be on top of the latest developments.

Chosen by leading life sciences companies, their executives and investors, *Cortellis for Competitive Intelligence* accelerates your deal-making and gives you timely insights on the development landscape.

Discover undiscovered opportunities in drug development and licensing faster with *Thomson Reuters Cortellis™ for Competitive Intelligence*

DISCLAIMER

The information contained in this report is based on sources believed to be correct but Thomson Reuters does not guarantee the accuracy, timeliness, or completeness of this information. Opinions, if any, are those held by the author of any individual report or article at the time of initial publication and do not necessarily reflect the views of Thomson Reuters.

Information in this report on companies is intended for reference use only, and does not constitute a recommendation to buy or sell any particular security or other investment and does not constitute an offer to buy from or sell to any particular investor. Any company or securities mentioned in this report may not be suitable for any particular investor, depending on that investor's financial position and needs.



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.

THOMSON REUTERS

TABLE OF CONTENTS

Company Overview	5
Company Profile	6
Product Portfolio Summary	7
Product Portfolio Drug Pipeline Detail	9
Phase 3 Clinical	10
Discovery	17



Relypsa Inc

COMPANY OVERVIEW

Company Name	Relypsa Inc
Parent Company Name	Relypsa Inc
Website	http://www.relypsa.com/
Country	US
Number of Drugs in Active Development	2
Number of Inactive Drugs	4
Number of Patents as Owner	10
Number of Patents as Third Party	0
Number of Deals	4
Key Indications	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
Key Target-based Actions	Potassium channel modulator
Key Technologies	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 patiromer 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.

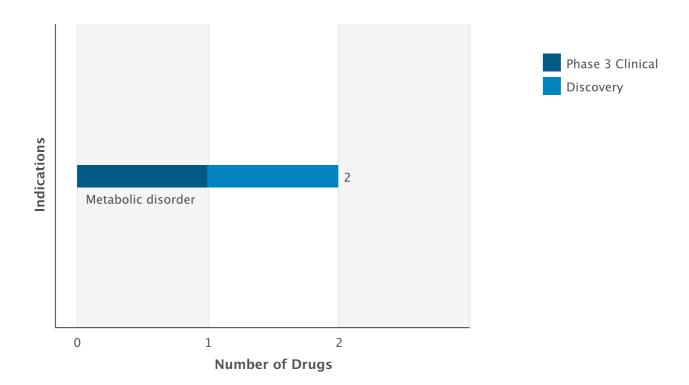


PRODUCT PORTFOLIO SUMMARY

DRUGS

Drugs by Indication

Active Drugs by Indication Chart



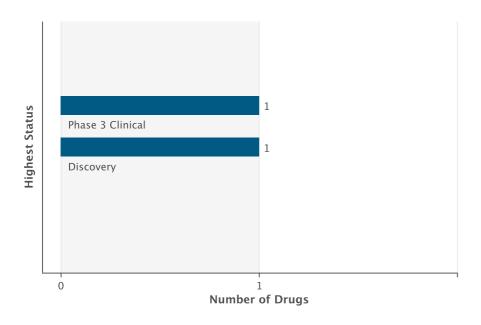
Drugs by Indication Table

Indication	Active	Inactive	Total
Metabolic disorder	2	2	4
Cardiovascular disease	0	2	2
Genitourinary disease	0	1	1

THOMSON REUTERS

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	1
No Development Reported	4

DEALS

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

CLINICAL TRIALS

Trials by Condition Studied

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



Trials by Phase

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

THOMSON REUTERS

PRODUCT PORTFOLIO DRUG PIPELINE DETAIL

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

patiromer calcium

patiromer calcium SNAPSHOT

Drug Name	patiromer calcium
Key Synonyms	patiromer;patiromer calcium
Originator Company	Relypsa Inc
Active Companies	Relypsa Inc
Inactive Companies	
Highest Status	Phase 3 Clinical
Active Indications	Hyperkalemia
Target-based Actions	
Other Actions	Potassium metabolism modulator
Technologies	Oral formulation;Oral suspension formulation;Small molecule therapeutic
Last Change Date	17-Jul-2014

patiromer calcium DEVELOPMENT PROFILE

SUMMARY

Relypsa is developing patiromer 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 February 2013, a pivotal, two-part phase III trial began in hyperkalemia patients; in September 2013, positive topline data from part A of the trial were reported; in October 2013, positive topline data from part B of the trial were reported. In January 2014, an NDA was expected to be filed in 3Q14.

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.

patiromer calcium DEVELOPMENT STATUS

CURRENT DEVELOPMENT STATUS

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



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

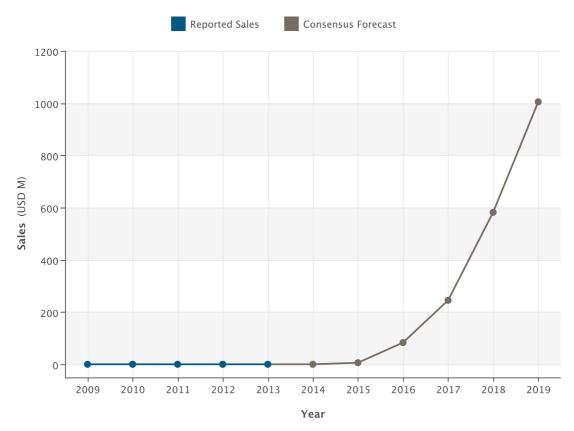
patiromer calcium DRUG NAMES

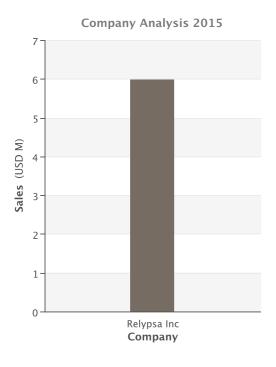
Names	Туре
potassium binder (hyperkalemia), Relypsa	
patiromer	USAN
RLY-5016	Research Code
patiromer calcium	USAN, INN
potassium binder (oral suspension formulation, hyperkalemia), Relypsa	

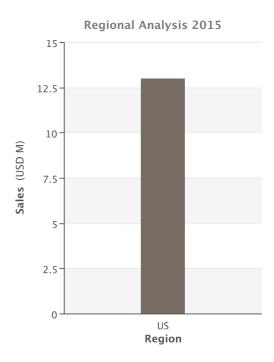
patiromer calcium SALES AND FORECASTS

CHARTS

Total Sales









COMMENTARY

CONSENSUS SALES INFORMATION

Consensus forecast data for Relypsa are presented.

REGIONAL DEVELOPMENT AND MARKETING RIGHTS

Relypsa holds worldwide development and marketing rights.

patiromer calcium CLINICAL TRIALS

Trials by Phase and Condition Studied

	se 4 nical		se 3 nical	Pha Clin	se 2 lical		se 1 nical		ase ecified	То	tal
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	2	0	1	0	8
Kidney dialysis											
0	0	0	0	0	1	0	0	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	On- going	All	On- going	All	On- going	All	On- going	All
Total by Phase and Status											
0	0	0	1	0	5	0	2	0	1	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

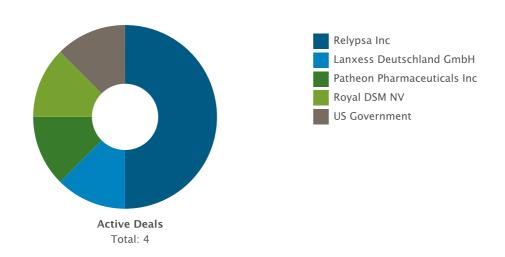
Includes Phase 1, Phase 1a, Phase 1, Phase 1/2 (where enrolment count is under 100 or not specified), Phase 0

THOMSON REUTERS

patiromer calcium DEALS AND PATENTS

DEALS

Deals by Parent Company Chart

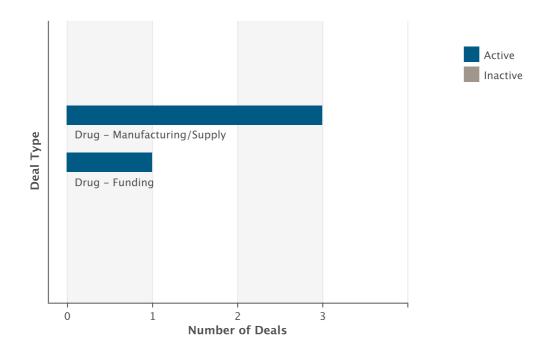


Deals by Parent Company Table

Company Name	Prin Active	icipal Inactive		tner Inactive	Total
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



Deals by Type Chart



Deals by Type Table

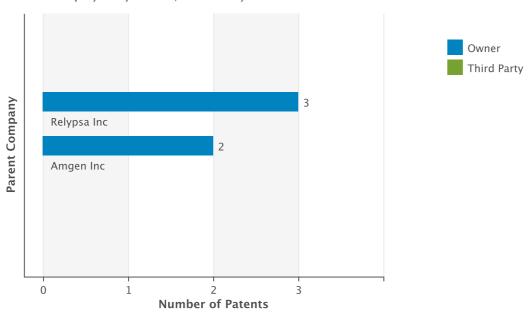
Deal Type	Active	Inactive	Total
Drug - Manufacturing/Supply	3	0	3
Drug - Funding	1	0	1



PATENTS

Patents by Parent Company Chart

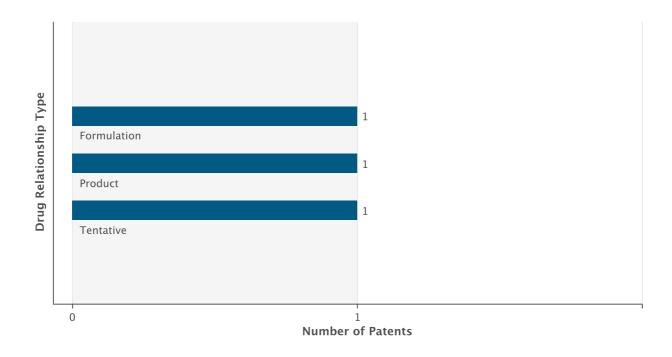
Chart displayed by Owner/Third Party



Patents by Parent Company Table

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

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	Туре
RLY-6002	Research Code



This report was created by Thomson Reuters, using information from *Thomson Reuters Cortellis*™ *for Competitive Intelligence*; a comprehensive, proven intelligence solution that leverages the most accurate, complete, and widely respected drug pipeline information.

For more information about *Cortellis for Competitive Intelligence*, visit: http://cortellis.thomsonreuters.com/cortellis_for_you/?cid=thomsonone.

For subscription information, e-mail scientific.lifesciences@thomsonreuters.com.

© 2012 Thomson Reuters. All rights reserved. Republication or redistribution of Thomson Reuters content, including by framing or similar means, is prohibited without the prior written consent of Thomson Reuters. 'Thomson Reuters' and the Thomson Reuters logo are registered trademarks and trademarks of Thomson Reuters and its affiliated companies.

THOMSON REUTERS