

Agile Therapeutics Inc

CORTELLIS COMPANY DETAILED PIPELINE REPORT

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

Publication Date: 02-May-2015

THOMSON REUTERS

3 Times Square
New York, New York 10036
United States

Tel: +1 646 223 4000

thomsonreuters.com

[Return to Table of Contents](#)

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.

[Return to Table of Contents](#)



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.

[Return to Table of Contents](#)



TABLE OF CONTENTS

Company Overview..... 5

Company Profile..... 6

Product Portfolio Summary..... 6

Product Portfolio Drug Pipeline Detail..... 9

 Pre-registration..... 10

 Phase 2 Clinical..... 16

 Discovery..... 23

[Return to Table of Contents](#)

Agile Therapeutics Inc

COMPANY OVERVIEW

Company Name	Agile Therapeutics Inc
Parent Company Name	Agile Therapeutics Inc
Website	http://www.agiletherapeutics.com/
Country	US
Number of Drugs in Active Development	3
Number of Inactive Drugs	0
Number of Patents as Owner	8
Number of Patents as Third Party	2
Number of Deals	2
Key Indications	Female contraception,Depression,Parkinsons disease,Alzheimers disease,Central nervous system disease,Migraine,Nausea,Pain
Key Target-based Actions	Progesterone receptor agonist,Estrogen receptor agonist,5-HT 3 receptor antagonist,MAO B inhibitor
Key Technologies	Patch formulation,Transdermal formulation,Small molecule therapeutic,Absorption enhancer transdermal,Drug combination,Formulation preservation,Absorption enhancer,Controlled release formulation,Matrix

COMPANY PROFILE

SUMMARY

Agile Therapeutics, founded in 1997, is a late-stage, privately-held pharmaceutical company focusing on women's health products.

FINANCIAL

In February 2015, a first tranche of \$16.5 million was funded upon execution of the loan agreement and \$15.5 million would be used to repay Agile's existing term loan facility. Under the terms of the loan agreement, Agile was not obligated to draw an additional tranche of up to \$8.5 million prior to July 1, 2016, subject to the achievement of certain clinical milestones, which may be extended to December 31, 2016. At that time, Agile issued Hercules a warrant to purchase 180,274 shares of Agile common stock at an exercise price of \$5.89 each.

In January 2015, the company entered into a definitive stock purchase agreement with a group of institutional accredited investors for the private placement of 3.4 million of common stock shares at \$5.85 per share and the gross proceeds were expected to be \$20 million. At that time, the private placement was expected to close on or about January 23, 2015. Later that month, the company raised net proceeds of approximately \$19.3 million.

In June 2014, the company's stock was added to the Russell Microcap Index.

In March 2014, Agile filed form S-1 with the US SEC for a proposed IPO of common stock. In May 2014, the company priced the offering of 9,166,667 shares at \$6 per share. The underwriters were granted a 30-day option to buy up to an aggregate of 1,375,000 additional shares of common stock, to cover any over-allotments. The offering was expected to close on May 29, 2014. At that time, the shares were expected to initiate trading on the NASDAQ Global Market, on May 23, 2014, under the symbol "AGRX".

In January 2013, the company closed a term loan facility for up to \$15 million with Oxford Finance.

In July 2012, the company raised \$40 million from a series C financing.

In June 2010, Agile raised \$45 million from a series B preferred stock financing.

In December 2007, Agile raised \$5.6 million from a series E financing round.

[Return to Table of Contents](#)

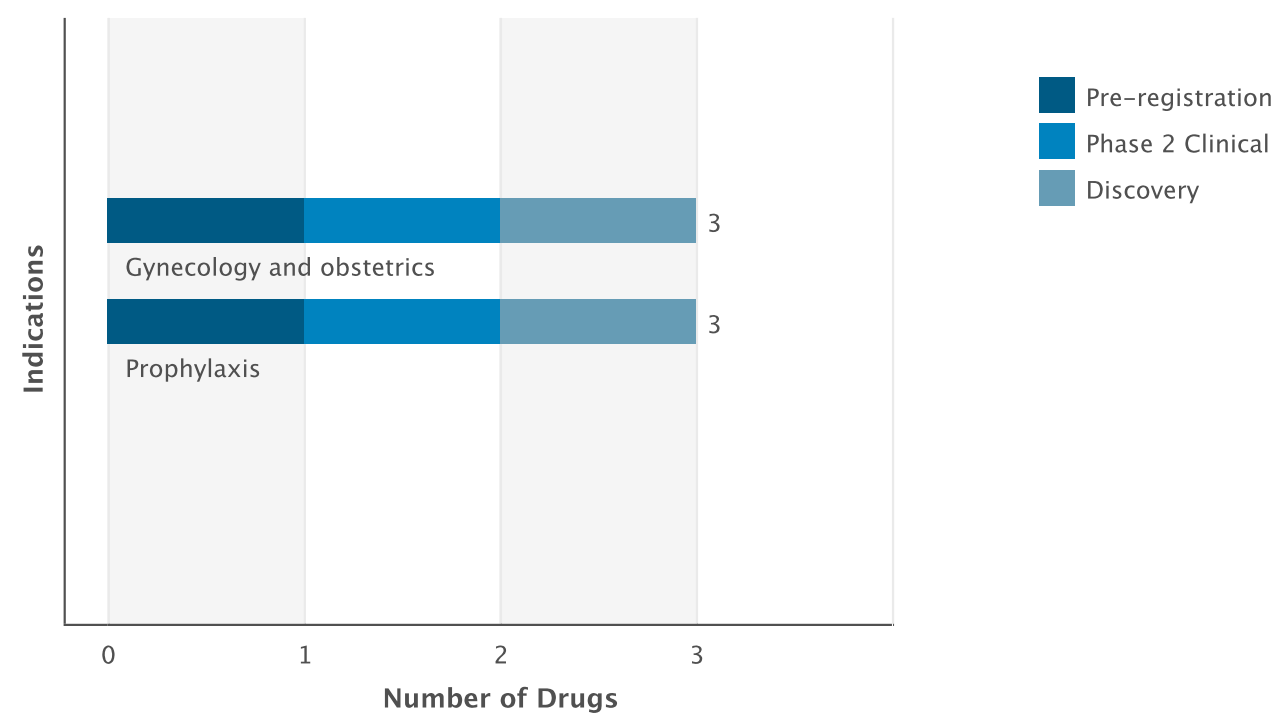


PRODUCT PORTFOLIO SUMMARY

DRUGS

Drugs by Indication

Active Drugs by Indication Chart



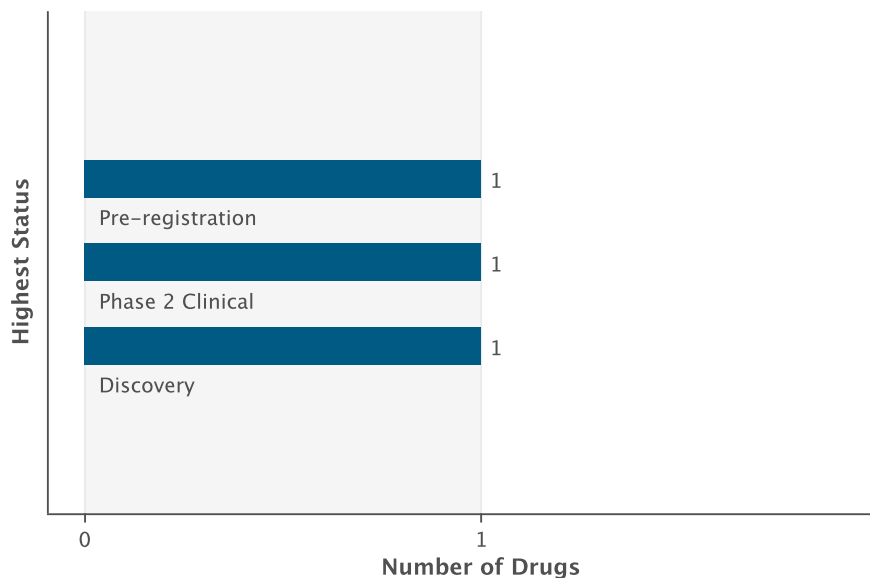
Drugs by Indication Table

Indication	Active	Inactive	Total
Prophylaxis	3	0	3
Gynecology and obstetrics	3	0	3

[Return to Table of Contents](#)

Drugs by Highest Status

Active Drugs by Highest Status Chart



Drugs by Highest Status Table

Development Status	Number of Drugs
Pre-registration	1
Phase 2 Clinical	1
Discovery	1

DEALS

Deal Type	Principal		Partner		Total
	Active	Inactive	Active	Inactive	
Drug - Manufacturing/Supply	0	0	1	0	1
Drug - Development Services	0	0	1	0	1

CLINICAL TRIALS

Trials by Condition Studied

Condition Studied	Ongoing	All
Gynecology and obstetrics	0	4
Prophylaxis	0	4

[Return to Table of Contents](#)



Trials by Phase

Phase	Ongoing	All
Phase 3	1	4
Phase 2	0	3
Phase 1	0	4

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
Gastrointestinal disease	0	1	1
Degeneration	0	1	1
Psychiatric disorder	0	2	2
Neurological disease	0	2	2
Prophylaxis	11	0	11
Gynecology and obstetrics	11	0	11

* This table represents a summary of the core patent coverage for this company covering Therapeutic EP, US and WO patents since 1990 only.

[Return to Table of Contents](#)



PRODUCT PORTFOLIO DRUG PIPELINE DETAIL

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

ethinylestradiol + levonorgestrel (female contraception, patch, Skinfusion), Agile

ethinylestradiol + levonorgestrel (female contraception, patch, Skinfusion), Agile SNAPSHOT

Drug Name	ethinylestradiol + levonorgestrel (female contraception, patch, Skinfusion), Agile
Key Synonyms	Twirla
Originator Company	Agile Therapeutics Inc
Active Companies	Agile Therapeutics Inc
Inactive Companies	
Highest Status	Pre-registration
Active Indications	Female contraception
Target-based Actions	Estrogen receptor agonist;Progesterone receptor agonist
Other Actions	Female contraceptive
Technologies	Patch formulation;Absorption enhancer transdermal;Small molecule therapeutic;Drug combination;Transdermal formulation
Last Change Date	25-Feb-2015

ethinylestradiol + levonorgestrel (female contraception, patch, Skinfusion), Agile DEVELOPMENT PROFILE

SUMMARY

Agile Therapeutics is developing AG-200-15 (Twirla), a low-dose weekly patch containing ethinylestradiol (EE) and levonorgestrel (LNG), based on company's Skinfusion technology, for the potential use as a female contraceptive. In April 2012, an NDA was submitted to the FDA; in July 2012, the NDA was accepted by the FDA. In September 2014, approval was expected later in 2016.


ethinylestradiol + levonorgestrel (female contraception, patch, Skinfusion), Agile DEVELOPMENT STATUS

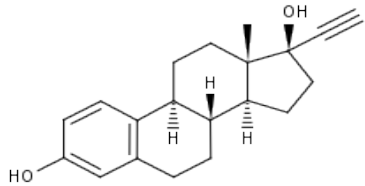
CURRENT DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
Agile Therapeutics Inc	Female contraception	US	Pre-registration	30-Apr-2012

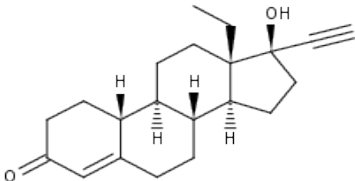
ethinylestradiol + levonorgestrel (female contraception, patch, Skinfusion), Agile CHEMICAL STRUCTURES

[Return to Table of Contents](#)

CAS Registry Number:	Confidence Level:
	1
	
Name	Type
Miranova	Trade Name
Levlite	Trade Name
DR-103	Research Code
AG-200-15	Research Code
ethinylestradiol + levonorgestrel	

CAS Registry Number:	Confidence Level:
57-63-6	1
	
Name	Type
ethinylestradiol	BANN; INN
ethynylestradiol	USAN
ethinyl estradiol	USAN

[Return to Table of Contents](#)

CAS Registry Number:	Confidence Level:
797-63-7	1
	
Name	Type
levonorgestrel	BANN; INN
NorLevo	Trade Name
Skyla	Trade Name

ethinylestradiol + levonorgestrel (female contraception, patch, Skinfusion), Agile DRUG NAMES

Names	Type
AG-200-15	Research Code
Twirla	Trade Name
ethinylestradiol + levonorgestrel (female contraception, patch, Skinfusion), Agile	
ethinylestradiol + levonorgestrel	

ethinylestradiol + levonorgestrel (female contraception, patch, Skinfusion), Agile 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
Female contraception											
0	0	0	1	0	1	0	1	0	0	0	3

[Return to Table of Contents](#)

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	1	4	0	3	0	3	0	0	1	10

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)

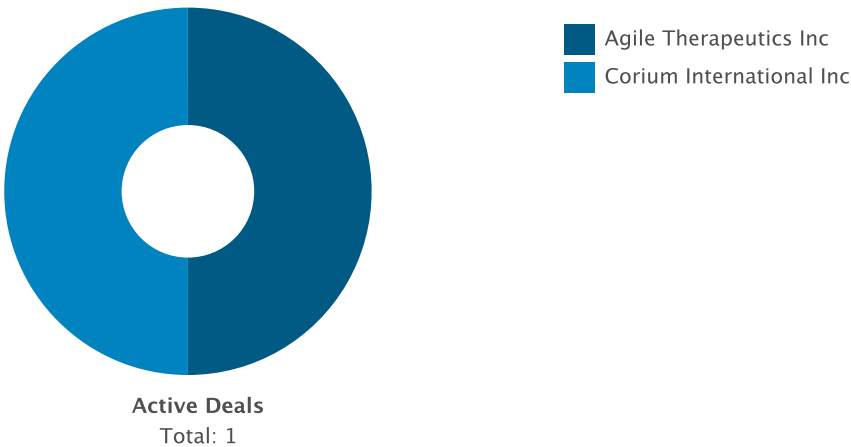
Phase 1 Clinical

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

ethinylestradiol + levonorgestrel (female contraception, patch, Skinfusion), Agile DEALS AND PATENTS

DEALS

Deals by Parent Company Chart

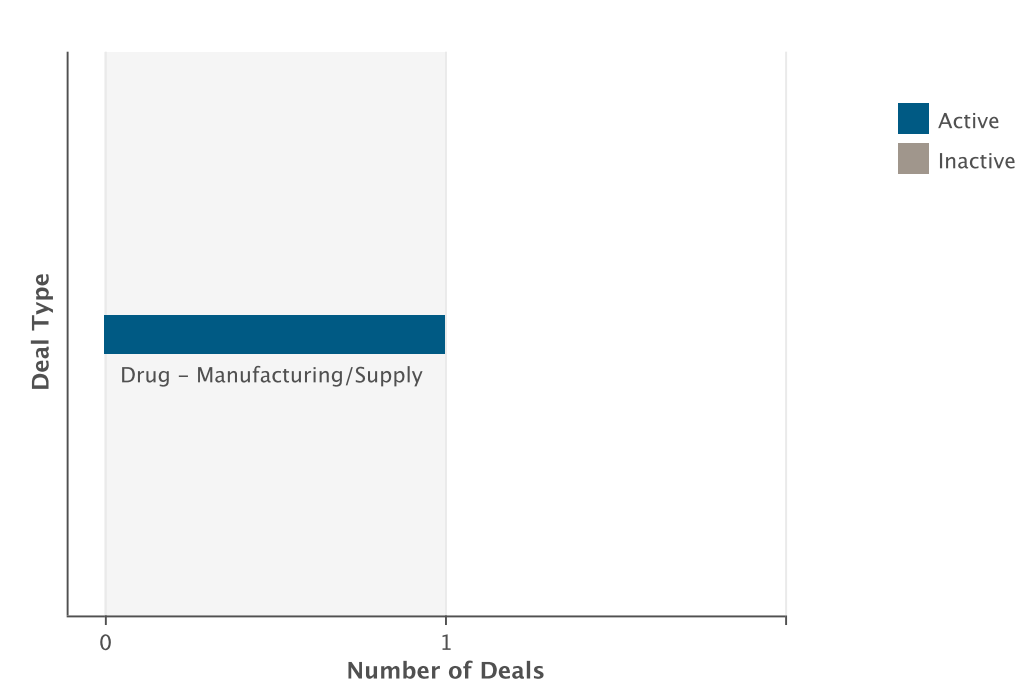


[Return to Table of Contents](#)

Deals by Parent Company Table

Company Name	Principal		Partner		Total
	Active	Inactive	Active	Inactive	
Agile Therapeutics Inc	0	0	1	0	1
Corium International Inc	1	0	0	0	1

Deals by Type Chart



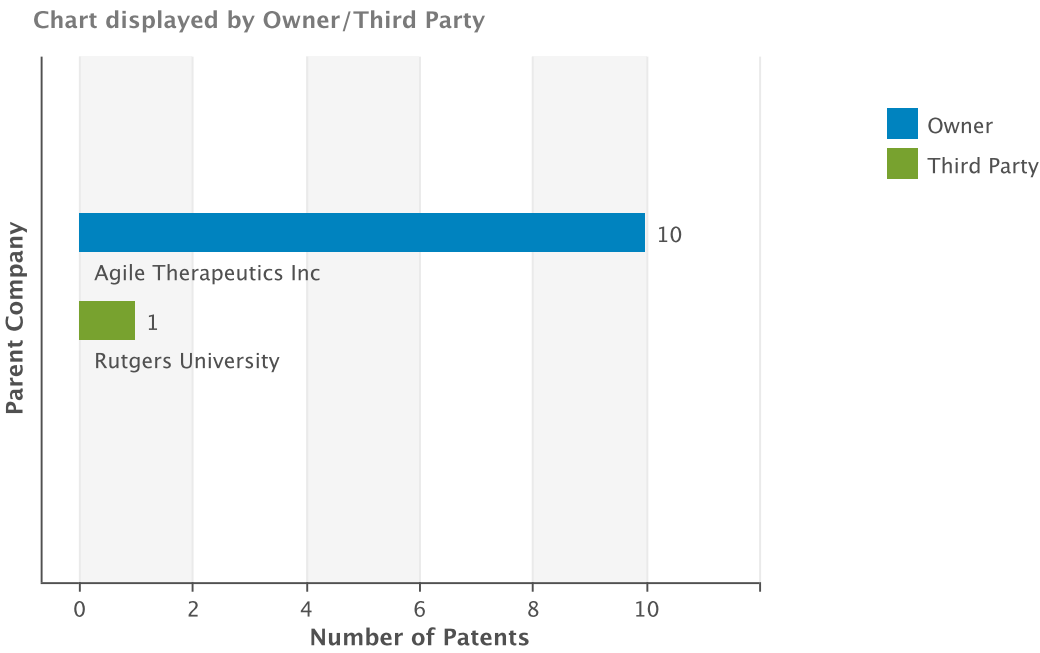
Deals by Type Table

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

[Return to Table of Contents](#)

PATENTS

Patents by Parent Company Chart

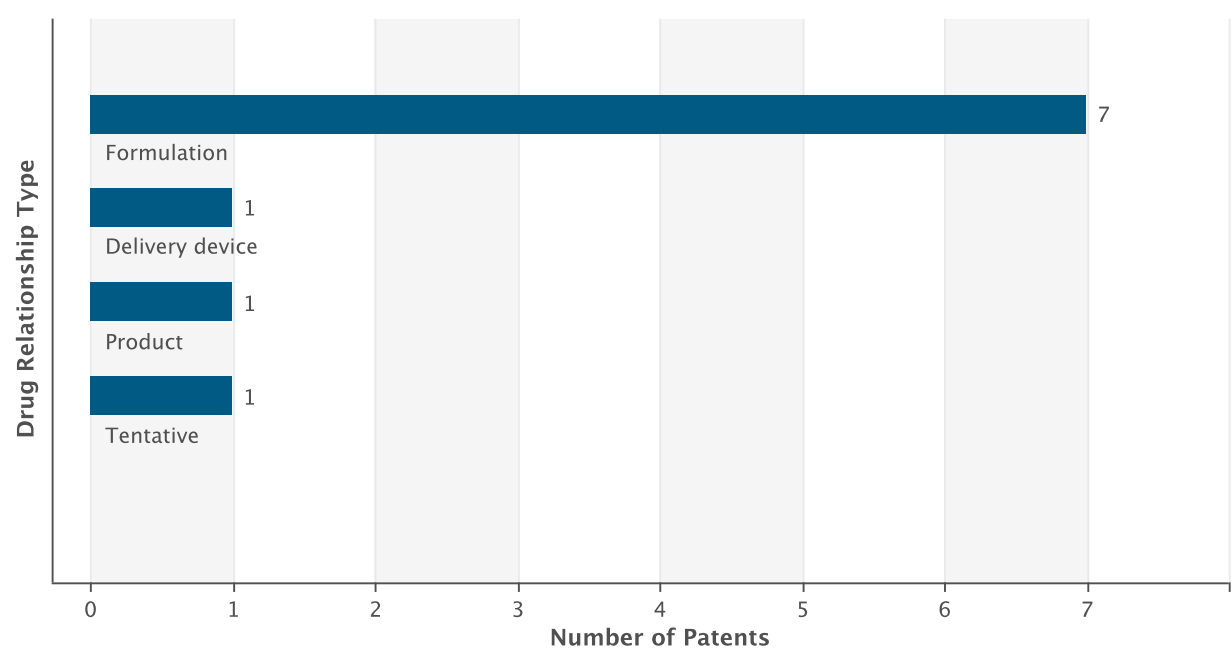


Patents by Parent Company Table

Company Name	As Owner	As Third Party	Total
Agile Therapeutics Inc	10	0	10
Rutgers University	0	1	1

[Return to Table of Contents](#)

Patents by Drug Relationship Type Chart



Patents by Drug Relationship Type Table

Drug Relationship	Total
Formulation	7
Tentative	1
Product	1
Delivery device	1

levonorgestrel (Skinfusion patch, female contraception), Agile

levonorgestrel (Skinfusion patch, female contraception), Agile SNAPSHOT

Drug Name	levonorgestrel (Skinfusion patch, female contraception), Agile
Key Synonyms	levonorgestrel
Originator Company	Agile Therapeutics Inc
Active Companies	Agile Therapeutics Inc
Inactive Companies	
Highest Status	Phase 2 Clinical
Active Indications	Female contraception
Target-based Actions	Progesterone receptor agonist
Other Actions	Female contraceptive
Technologies	Patch formulation;Small molecule therapeutic;Transdermal formulation
Last Change Date	09-Apr-2014

levonorgestrel (Skinfusion patch, female contraception), Agile DEVELOPMENT PROFILE

SUMMARY

Agile Therapeutics is developing AG-890 (AG-900, AG-1000), a low-dose weekly patch containing levonorgestrel, based on company's Skinfusion technology, for the potential use as a contraceptive in breast-feeding mothers and women with contraindications to estrogen,. By January 2011, a phase I/II trial had been initiated of two different doses (AG-1000-6.5 and AG-1000-12.5). In July 2012, the drug was listed as being in phase II development ; in March 2014, this was still the case and at that time, an NDA filing was expected in 2015 .

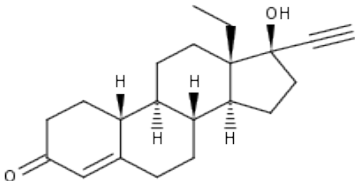
levonorgestrel (Skinfusion patch, female contraception), Agile DEVELOPMENT STATUS

CURRENT DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
Agile Therapeutics Inc	Female contraception	US	Phase 2 Clinical	09-Jan-2011

levonorgestrel (Skinfusion patch, female contraception), Agile CHEMICAL STRUCTURES

[Return to Table of Contents](#)

CAS Registry Number:	Confidence Level:
797-63-7	1
	
Name	Type
levonorgestrel	BANN; INN
NorLevo	Trade Name
Skyla	Trade Name

levonorgestrel (Skinfusion patch, female contraception), Agile DRUG NAMES

Names	Type
progestin-only patch (transdermal contraceptive delivery system), Agile	
AG-890-6.5	Research Code
AG-890	Research Code
AG-1000-12.5	Research Code
AG-1000	Research Code
AG-890-12.5	Research Code
levonorgestrel (Skinfusion patch, female contraception), Agile	
levonorgestrel	BANN, INN
AG-1000-6.5	Research Code
AG-900	Research Code

levonorgestrel (Skinfusion patch, female contraception), Agile CLINICAL TRIALS

Trials by Phase and Condition Studied

[Return to Table of Contents](#)

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
Female contraception											
0	0	0	0	0	0	0	1	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	1	0	1	0	0	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)

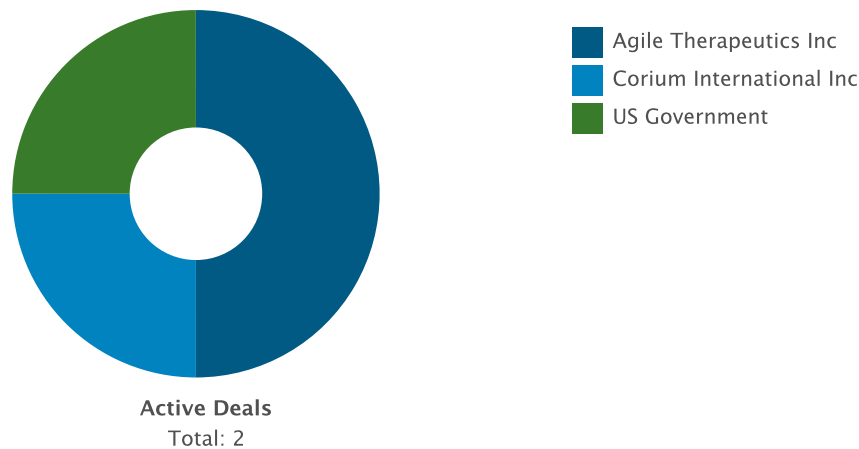
Phase 1 Clinical

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

[Return to Table of Contents](#)

DEALS

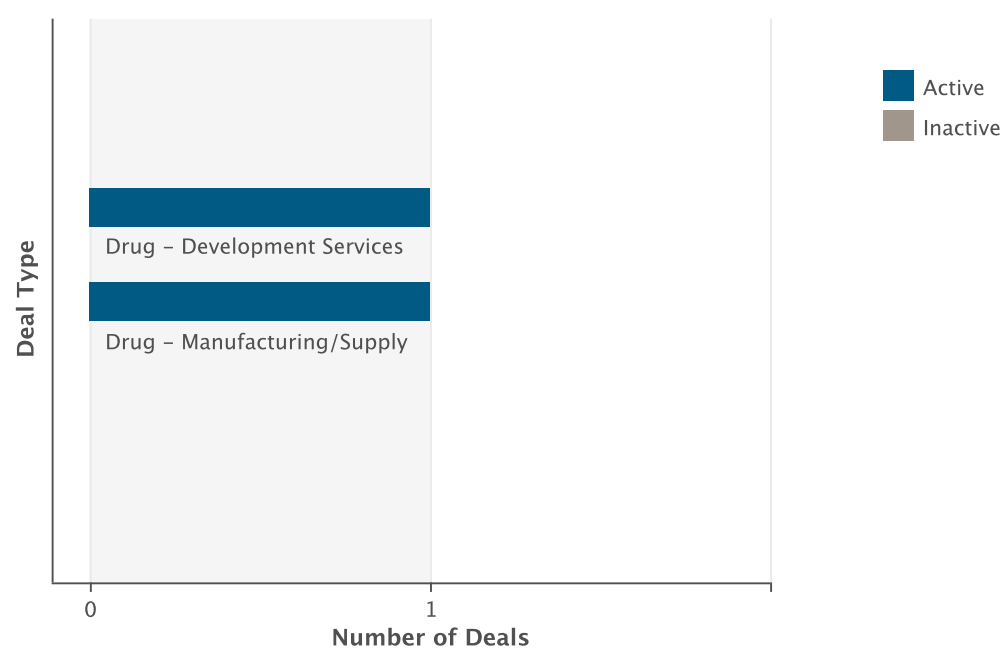
Deals by Parent Company Chart



Deals by Parent Company Table

Company Name	Principal		Partner		Total
	Active	Inactive	Active	Inactive	
Agile Therapeutics Inc	0	0	2	0	2
US Government	1	0	0	0	1
Corium International Inc	1	0	0	0	1

Deals by Type Chart

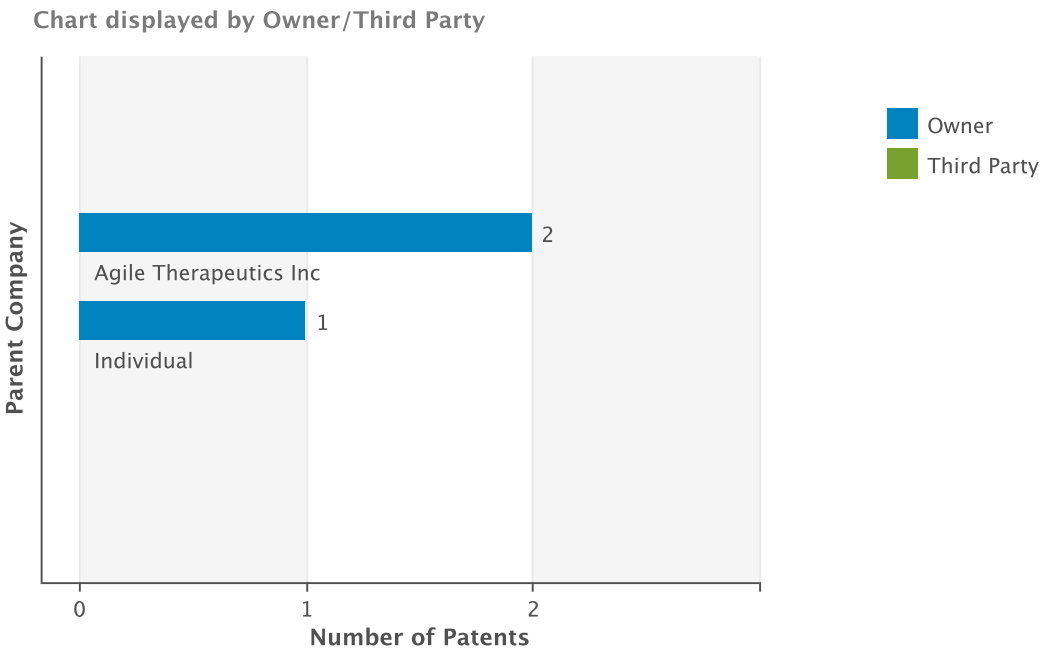


Deals by Type Table

Deal Type	Active	Inactive	Total
Drug - Manufacturing/Supply	1	0	1
Drug - Development Services	1	0	1

PATENTS

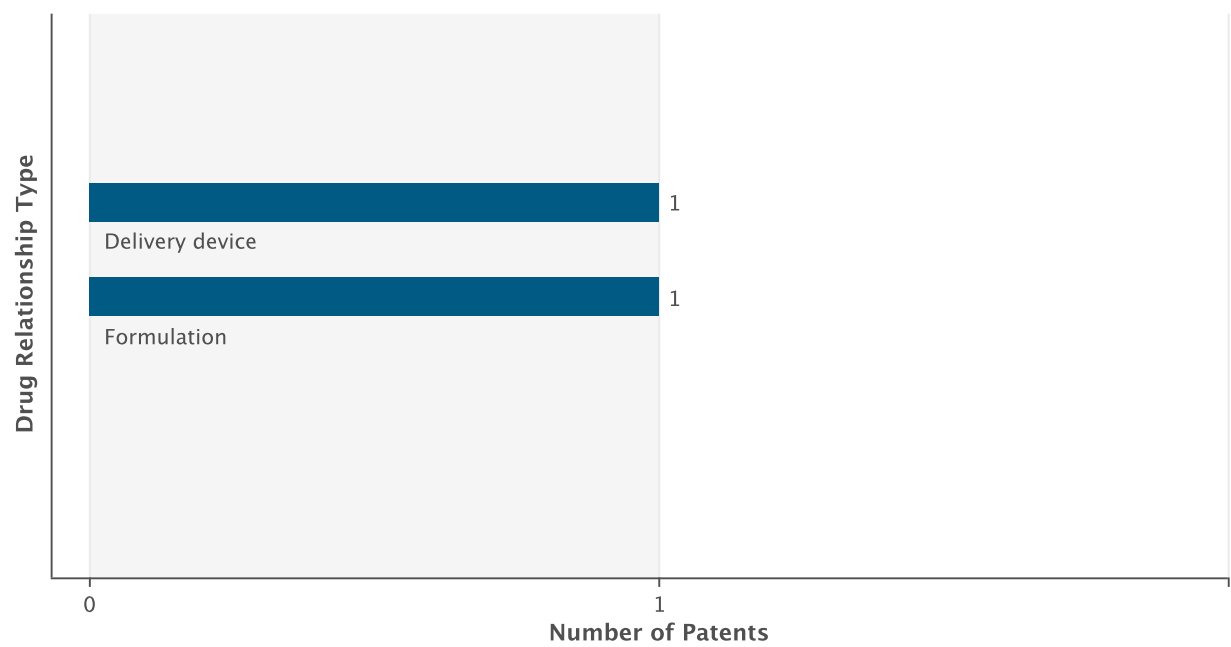
Patents by Parent Company Chart



Patents by Parent Company Table

Company Name	As Owner	As Third Party	Total
Agile Therapeutics Inc	2	0	2
Individual	1	0	1

Patents by Drug Relationship Type Chart



Patents by Drug Relationship Type Table

Drug Relationship	Total
Formulation	1
Delivery device	1

undisclosed patch programs (female contraception), Agile Therapeutics

undisclosed patch programs (female contraception), Agile Therapeutics SNAPSHOT

Drug Name	undisclosed patch programs (female contraception), Agile Therapeutics
Key Synonyms	
Originator Company	Agile Therapeutics Inc
Active Companies	Agile Therapeutics Inc
Inactive Companies	
Highest Status	Discovery
Active Indications	Female contraception
Target-based Actions	
Other Actions	Contraceptive;Unspecified drug target
Technologies	Patch formulation;Absorption enhancer transdermal;Small molecule therapeutic;Transdermal formulation
Last Change Date	17-Mar-2014

undisclosed patch programs (female contraception), Agile Therapeutics DEVELOPMENT PROFILE

SUMMARY

Agile is investigating a program of contraceptive patches, based on company's Skinfusion technology, for the potential use as a female contraceptive. In July 2012, the program was listed as being in preclinical development; at that time the leads from the program were ready to move into clinical development ; in March 2014, this was still the case.

undisclosed patch programs (female contraception), Agile Therapeutics DEVELOPMENT STATUS

CURRENT DEVELOPMENT STATUS

Company	Indication	Country	Development Status	Date
Agile Therapeutics Inc	Female contraception	US	Discovery	27-Jul-2012

undisclosed patch programs (female contraception), Agile Therapeutics DRUG NAMES

Names	Type
undisclosed patch programs (female contraception), Agile Therapeutics	

[Return to Table of Contents](#)



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.

[Return to Table of Contents](#)

