

## Agile 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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# 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i.e. where the development status for the drug(s) is one of the following: No Development Reported, Discontinued, or Withdrawn.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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# 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	1
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 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.

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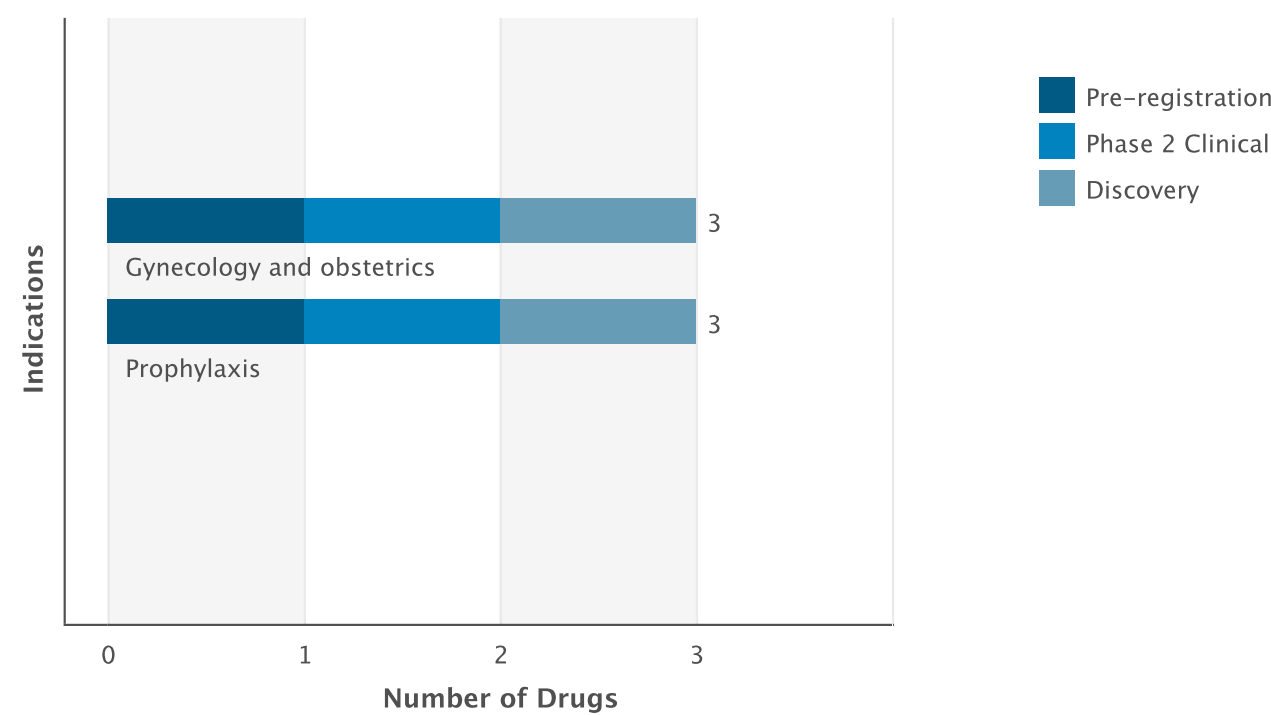


# PRODUCT PORTFOLIO SUMMARY

## DRUGS

### Drugs by Indication

Active Drugs by Indication Chart



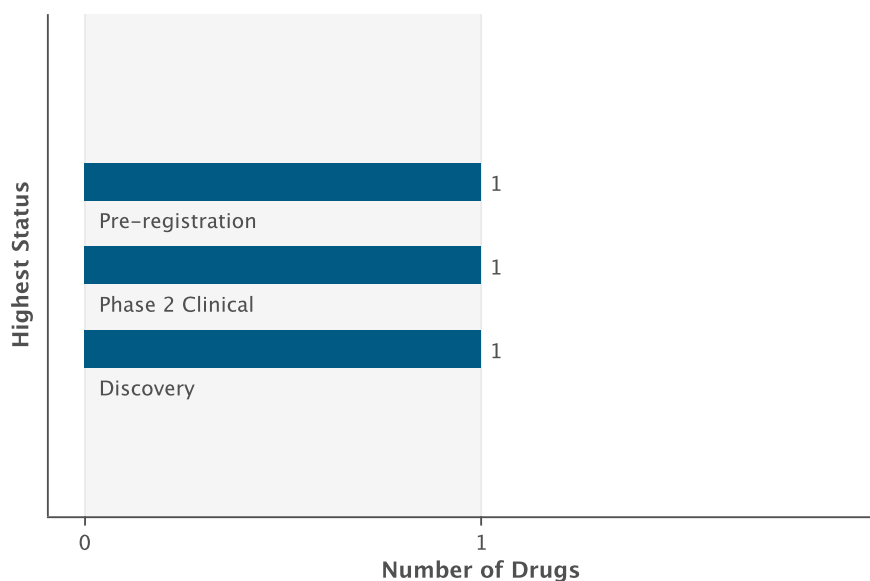
Drugs by Indication Table

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

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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
Phase 2 Clinical	1
Discovery	1

## DEALS

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

## CLINICAL TRIALS

Trials by Condition Studied

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

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## 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.

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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

### 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	Drug combination;Transdermal formulation;Patch formulation;Absorption enhancer transdermal;Small molecule therapeutic
Last Change Date	02-Dec-2014

#### 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,. By May 2012, an NDA had been submitted to the FDA ; in July 2012, the NDA was accepted by the FDA.

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

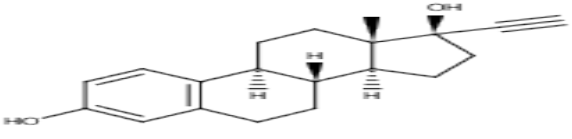
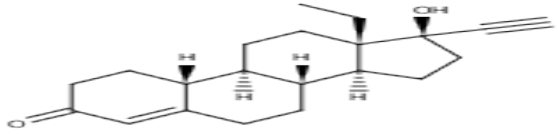
##### CURRENT DEVELOPMENT STATUS

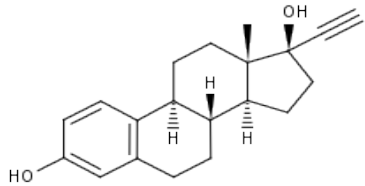
Company	Indication	Country	Development Status	Date
Agile Therapeutics Inc	Female contraception	US	Pre-registration	07-May-2012

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

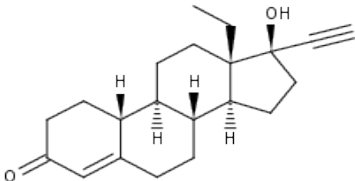
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CAS Registry Number:	Confidence Level:
	1
 	
Name	Type
Miranova	Trade Name
Levlite	Trade Name
DR-103	Research Code
AG-200-15	Research Code
ethinylestradiol + levonorgestrel	

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

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

#### 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

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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	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

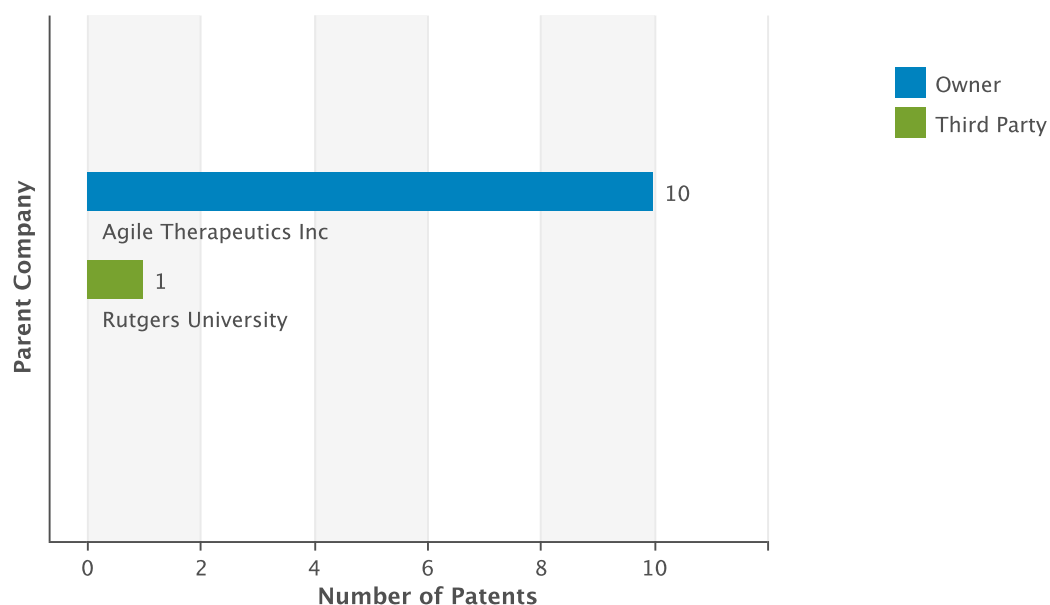
Includes Phase 1, Phase 1a, Phase 1, Phase 1/2 (where enrolment count is under 100 or not specified), Phase 0

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

### PATENTS

#### Patents by Parent Company Chart

Chart displayed by Owner/Third Party

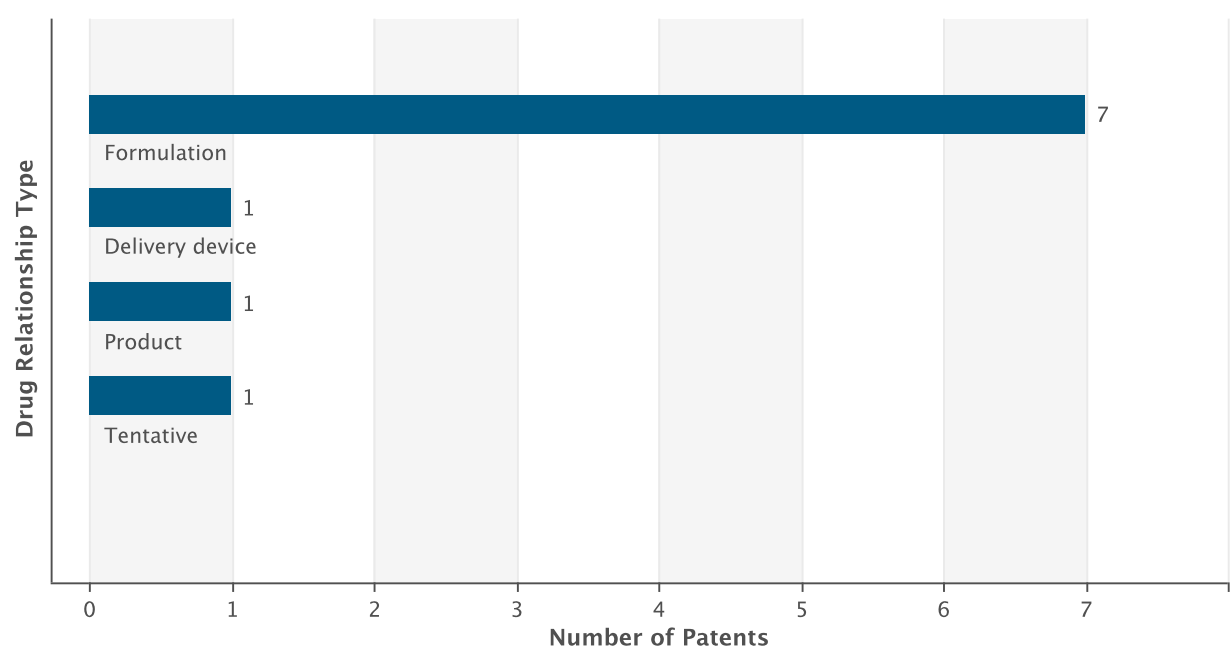


#### Patents by Parent Company Table

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

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Patents by Drug Relationship Type Chart



Patents by Drug Relationship Type Table

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

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## 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	Transdermal formulation;Patch formulation;Small molecule therapeutic
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

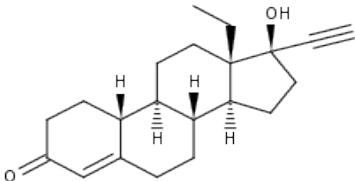
#### CURRENT DEVELOPMENT STATUS

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

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

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

#### Trials by Phase and Condition Studied

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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

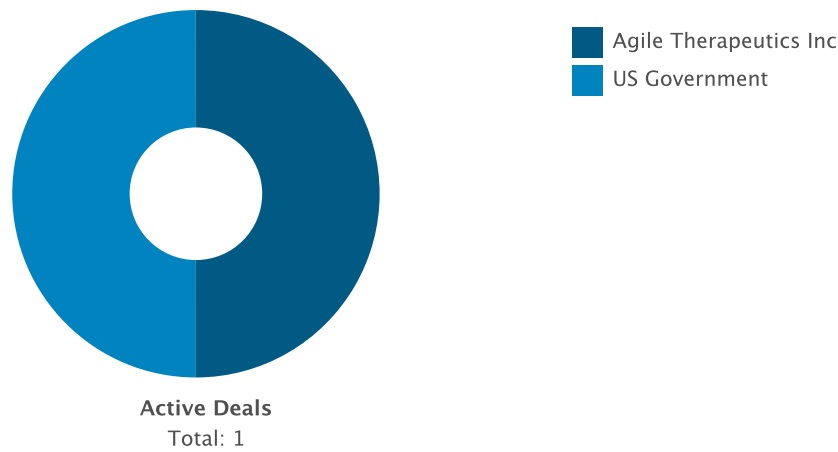
Includes Phase 1, Phase 1a, Phase 1, Phase 1/2 (where enrolment count is under 100 or not specified), Phase 0

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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	1	0	1
US Government	1	0	0	0	1

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Deals by Type Chart



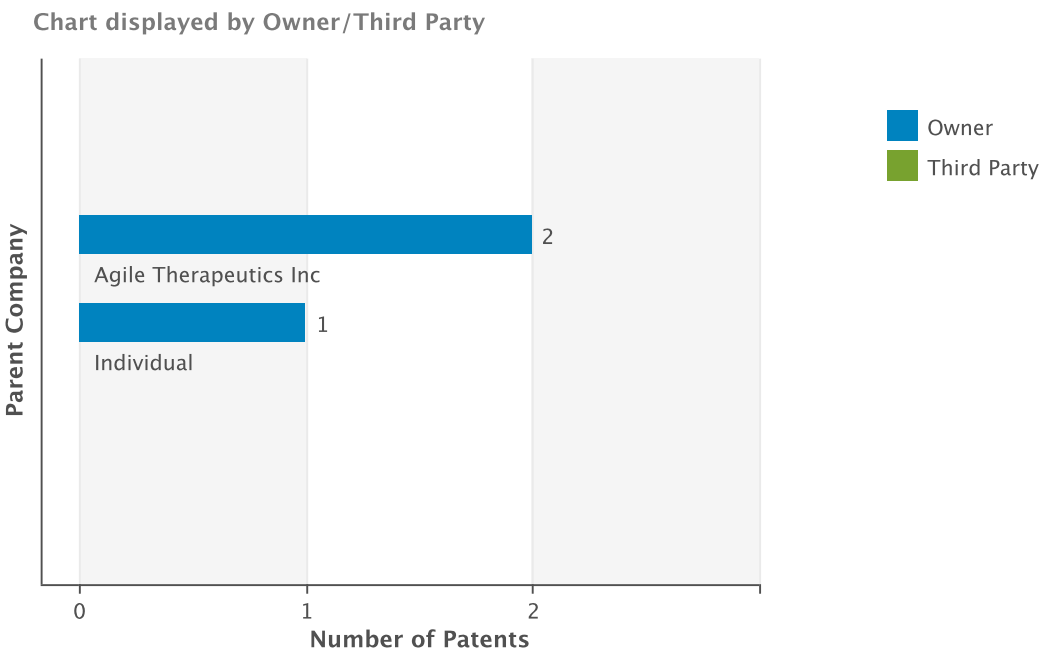
Deals by Type Table

Deal Type	Active	Inactive	Total
Drug - Development Services	1	0	1

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PATENTS

Patents by Parent Company Chart

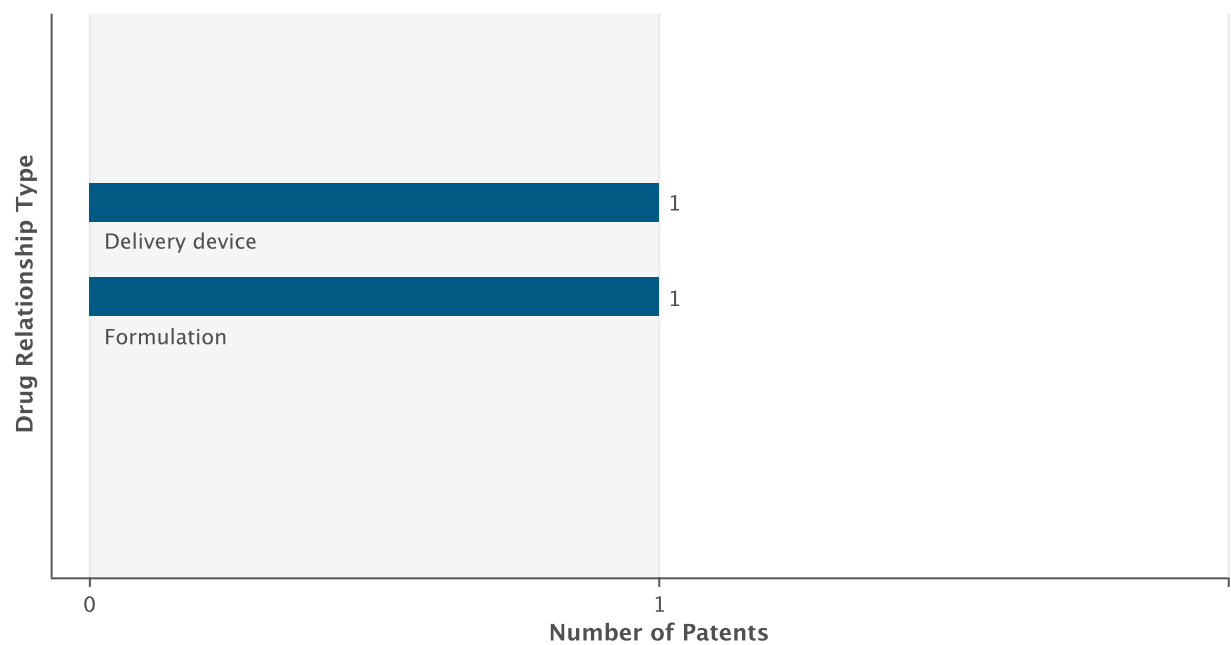


Patents by Parent Company Table

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

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Patents by Drug Relationship Type Chart



Patents by Drug Relationship Type Table

Drug Relationship	Total
Formulation	1
Delivery device	1

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## undisclosed patch programs (female contraception), Agile Therapeutics

### undisclosed patch programs (female contraception), Agile Therapeutics SNAPSHOT

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

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