
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

**Pursuant to Section 13 or 15(D)
of the Securities Exchange Act of 1934**

January 11, 2016

Date of report (Date of earliest event reported)

Agile Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36464
(Commission
File Number)

23-2936302
(IRS Employer
Identification No.)

101 Poor Farm Road
Princeton, New Jersey
(Address of principal executive offices)

08540
(Zip Code)

Registrant's telephone number, including area code **(609) 683-1880**

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425).
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12).
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)).
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c)).
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Item 2.02 Results of Operations and Financial Condition.

As discussed below, in connection with its participation in the 34th Annual J.P. Morgan Healthcare Conference in San Francisco, California beginning on January 11, 2016, Agile Therapeutics, Inc. (the "Company") updated its corporate presentation to include disclosure that the Company had \$34.4 million of cash and cash equivalents as of December 31, 2015.

Because the Company's financial statements for the year ended December 31, 2015 have not yet been finalized or audited, the preliminary statement of the Company's cash and cash equivalents as of December 31, 2015 in this Item 2.02 is subject to change, and the Company's actual cash and cash equivalents as of the end of this period may differ materially from this preliminary estimate. Accordingly, you should not place undue reliance on this preliminary estimate.

Item 7.01 Regulation FD Disclosure

Beginning on January 11, 2016, the Company will participate in the 34th Annual J.P. Morgan Healthcare Conference in San Francisco, California. The Company has updated its corporate presentation that it intends to use in connection with presentations at conferences and meetings with investors. The

updates primarily include disclosure regarding the Company's cash and cash equivalents as of December 31, 2015 as stated above.

The information included in this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing made by the Company under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Agile Therapeutics, Inc. Presentation

2

SIGNATURES

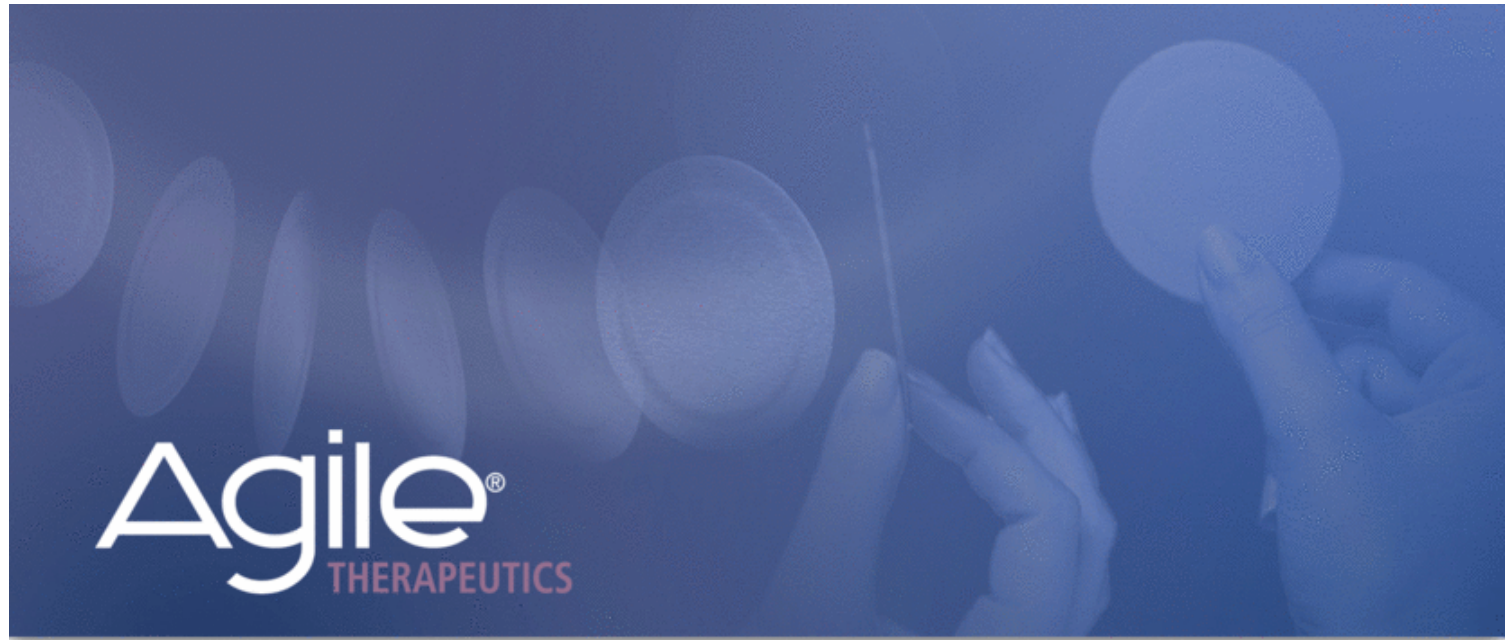
Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Agile Therapeutics, Inc.

Dated: January 11, 2016

By: /s/ Alfred Altomari
Name: Alfred Altomari
Title: President and Chief Executive Officer

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Agile[®]
THERAPEUTICS

Women's Health Specialty Pharmaceutical Company
NASDAQ: AGRX

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NASDAQ: AGRX

Forward-Looking Statement

Certain information contained in this presentation and other matters discussed today or answers that may be given in response to questions may include "forward-looking statements". We may, in some cases, use terms such as "predicts," "believes," "potential," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. In particular, the Company's statements regarding trends and potential future results are examples of such forward-looking statements. The forward-looking statements are subject to important factors, risks and uncertainties, including, but not limited to, the success, timing and cost of our ongoing clinical trials and anticipated clinical trials for our current product candidates, including statements regarding the timing of initiation, enrollment and completion of the trials; the timing of and our ability to obtain and maintain U.S. Food and Drug Administration or other regulatory authority approval of, or other action with respect to, our product candidates; the Company's ability to obtain the capital necessary to fund its operations; the Company's ability to generate revenues; the successful implementation of the Company's research and development programs and collaborations; the acceptance by the market of the Company's products; the Company's ability to successfully defend its intellectual property or obtain the necessary licenses at a cost acceptable to the Company, if at all; the cost of our efforts to commercialize and promote our product candidates once they are approved; and other factors, including general economic conditions and regulatory developments, not within the Company's control. These factors could cause actual results and developments to be materially different from those expressed in or implied by such statements. The forward-looking statements are made only as of the date of this presentation and the Company undertakes no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstance.

Agile Corporate Overview

Significant Near-Term Market Opportunity

- \$5.3 Billion US contraceptive market, \$4.0 Billion in combined hormonal contraceptives (CHC)
- Lead product, Twirla®, Phase III expected to complete in 2H 2016, submission 1H 2017
- Twirla® expected to be the first non-oral CHC brand introduced in over 15 years and is an improvement on the currently available contraceptive patch

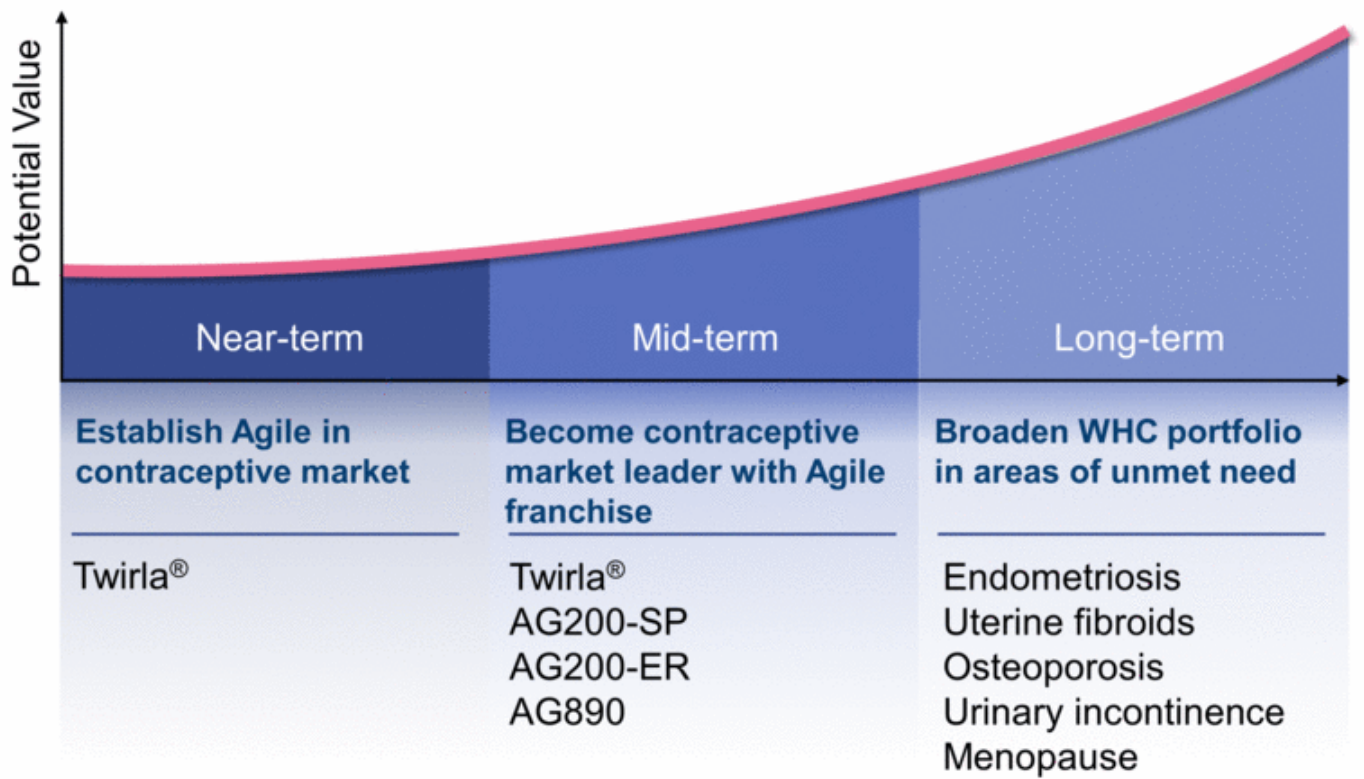
Agile is Building a Robust Contraceptive Franchise

- Three additional unique product candidates in the pipeline that address high market needs
- Intellectual Property supports Twirla (latest expiry 2028) and development of pipeline product candidates (latest expiry 2029)
- Expertise in complex patch technology and manufacturing; one PAI completed, commercial scale-up ongoing

Agile is Well-Positioned for Successful Twirla Market Entry

- Twirla is expected to be the only low-dose CHC patch
- Physicians and consumers show high interest in a low-dose patch
- Managed care environment for contraceptives is generally favorable
- Specialty focus and target consumer should allow for efficient marketing execution
- Agile team members have prior experience commercializing many successful women's health brands

Agile Corporate Strategy: Become a Leader in Women's Health



Agile Executive Management Team

Deep Experience in Women's Healthcare and Contraceptive Products

<p>Al Altomari President and Chief Executive Officer</p>	 
<p>Scott Coiante Vice President and Chief Financial Officer</p>	 
<p>Elizabeth Garner, M.D., M.P.H. Sr. Vice President and Chief Medical Officer</p>	  
<p>Katie MacFarlane, Pharm. D. Chief Commercial Officer</p>	   

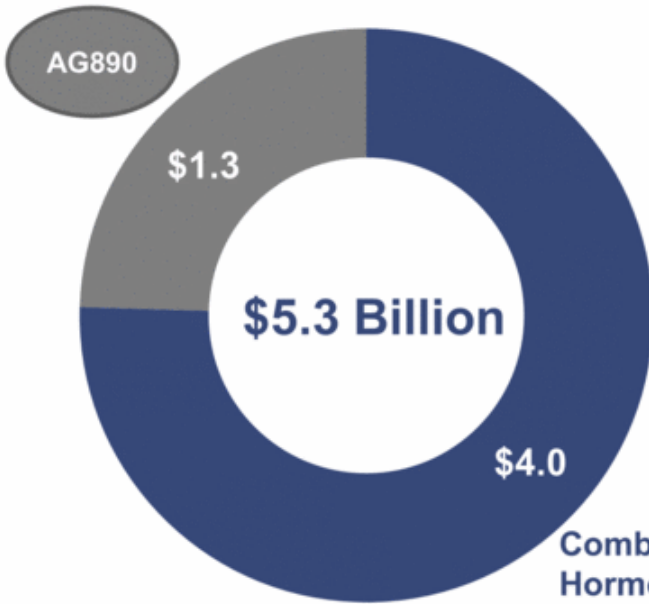
Agile team members have commercialized many successful contraceptive brands

 <p>Highest peak market share of any contraceptive</p>	 <p>Most successful contraceptive launch</p>	 <p>First 24-day regimen; became market leader</p>
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US Hormonal Contraceptive Market is a Significant Opportunity

Progestin-Only



AG890

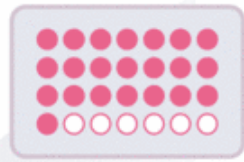
\$1.3

\$5.3 Billion

**Combination
Hormonal
Contraceptives**

twirla

AG200-ER
AG200-SP



**Pills
\$3.2 Billion**



**Vaginal Ring
\$654 Million**



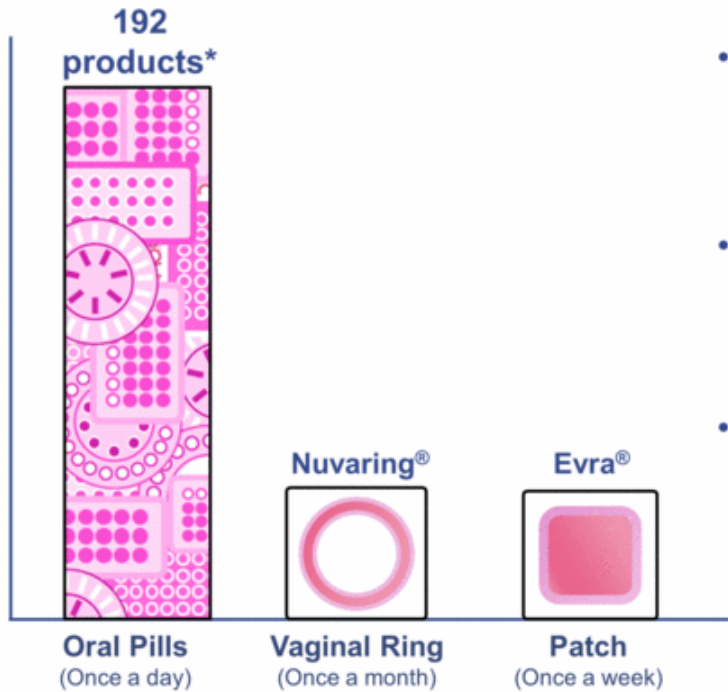
**Patches
\$153 Million**

Source: IMS NSP, retail + non-retail through Dec 2014

1.8.2016

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Only 2 Non-Oral CHC Forms Are Available and Both Became Market-Leading Brands



- Non-oral CHCs have reached significant peak market shares
 - Evra 11.1%
 - Nuvaring 6.6%
- The current market leader is a non-oral product
 - Nuvaring 2014 annual sales \$654 Million
- The most successful contraceptive launch was a non-oral product
 - Evra reached 10% TRx share in 18 months

*includes brands and branded generic products

Source: IMS NPA and NSP

Evra is a registered trademark of Johnson & Johnson, Inc. Nuvaring is a registered trademark of Merck & Co., Inc.

1.8.2016

Twirla® is our Lead Product

- **Twirla is a once-weekly contraceptive patch**
 - Only one other contraceptive patch is available on the market
 - Twirla delivers a lower daily dose of estrogen than the currently available patch
- **Women want alternatives to an oral contraceptive**
 - Pill users' chief complaint is having to take something daily and fitting this into their busy lifestyles
 - Women frequently forget to take their pill (1-4x per month)
- **Twirla is currently conducting Phase III, with data expected 2H 2016**
- **Agile has a comprehensive commercial launch plan in place for Twirla**



"One less thing to do every day"

"You can forget about it and you're not stressed about taking a pill at the same time every day"



Why Women Would Use Twirla®

- Don't have to remember it every day
- Visual reassurance that they are protected
- Less invasive than some methods (vaginal ring, IUDs, Injectables, Implants)

Pill Regimen: Once a day

SUN	MON	TUE	WED	THU	FRI	SAT
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28

Patch Regimen: Once a week

SUN	MON	TUE	WED	THU	FRI	SAT
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28

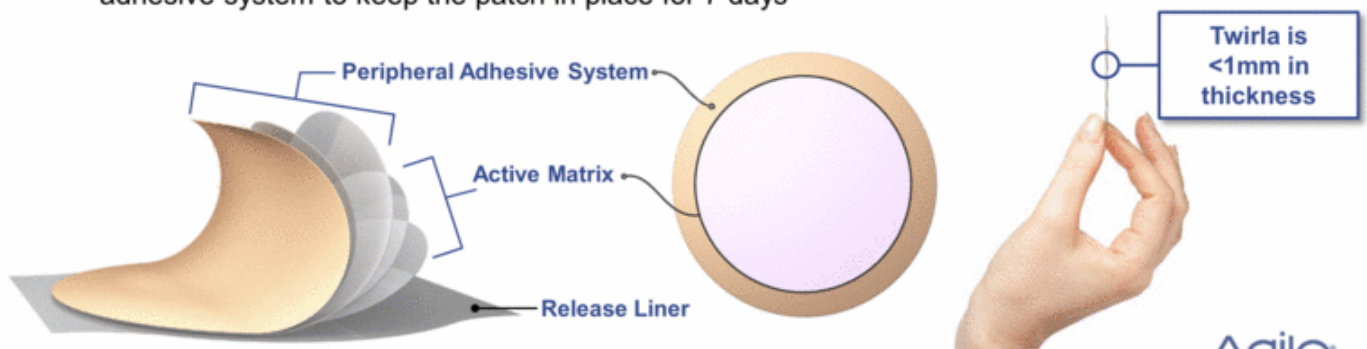
7 days no patch

Women can choose where to apply the patch: buttock, abdomen, or upper torso

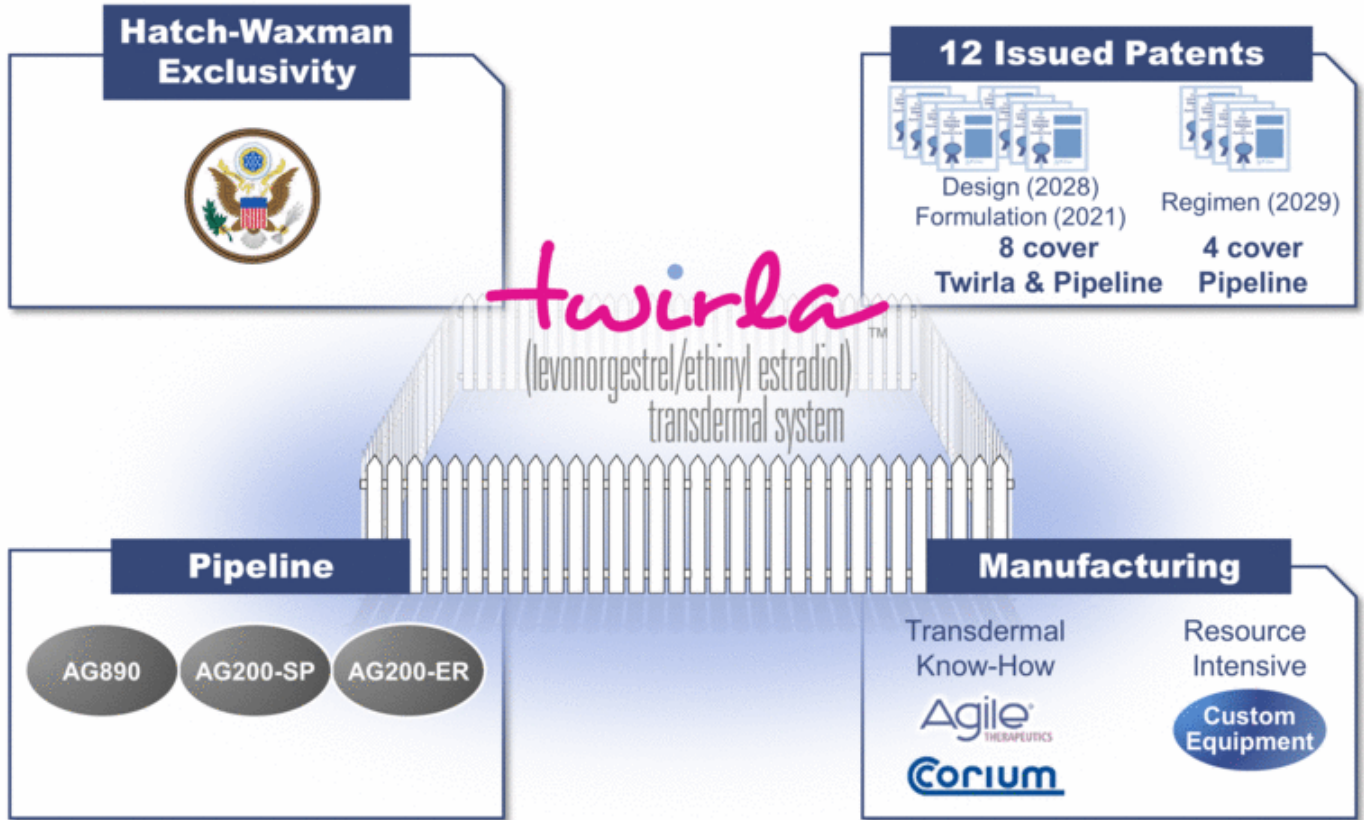


What Makes Twirla[®] Different?

- **There is only one other patch on the market, and Twirla will be the only low-dose contraceptive patch**
 - Delivers ~30µg/day EE
 - Evra[®]/Xulane[®] delivers ~60% more EE than a 35µg pill
- **Twirla is the first and only product candidate to deliver LNG through the skin at a contraceptive dose**
 - Twirla contains levonorgestrel (LNG) and ethinyl estradiol (EE)
 - LNG and EE have over 25 years of established use in contraceptives
- **Agile's proprietary Skinfusion[®] technology is cosmetically appealing**
 - Active ingredients are contained the central active matrix, designed to allow the peripheral adhesive system to keep the patch in place for 7 days



Agile Intellectual Property Strategies For the Franchise

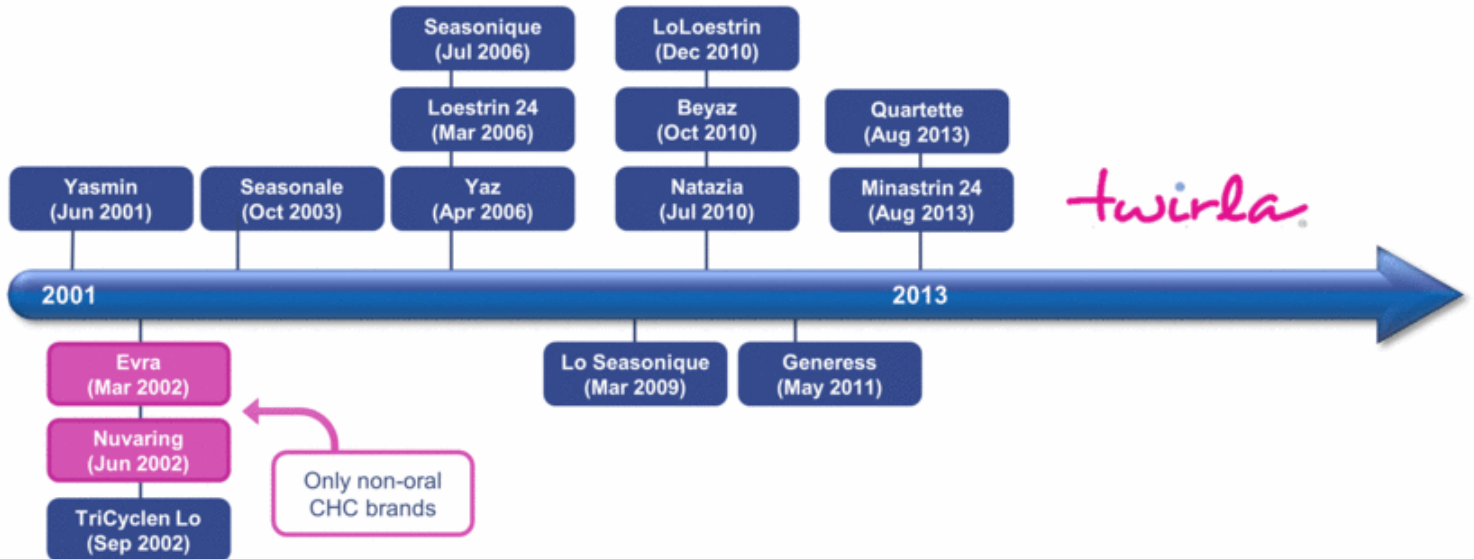


Agile Pipeline Strategy: Establish a Market-Leading Contraceptive Franchise

Agile Contraceptive Pipeline						
Product	Indication	Preclinical	Phase I	Phase II	Phase III	Status
Twirla®	Contraception (21/7 cycle)					<ul style="list-style-type: none"> Phase III results expected 2H 2016
AG200-SP	Contraception (shorter, lighter periods)					<ul style="list-style-type: none"> Phase II PK/PD trial design and planning underway
AG200-ER	Contraception (extended cycle)					<ul style="list-style-type: none"> Phase II PK/PD trial design and planning underway
AG890	Contraception (Progestin-only)					<ul style="list-style-type: none"> Phase II PK/PD trial complete Additional product development required

There is a Market Need for New Contraceptive Products

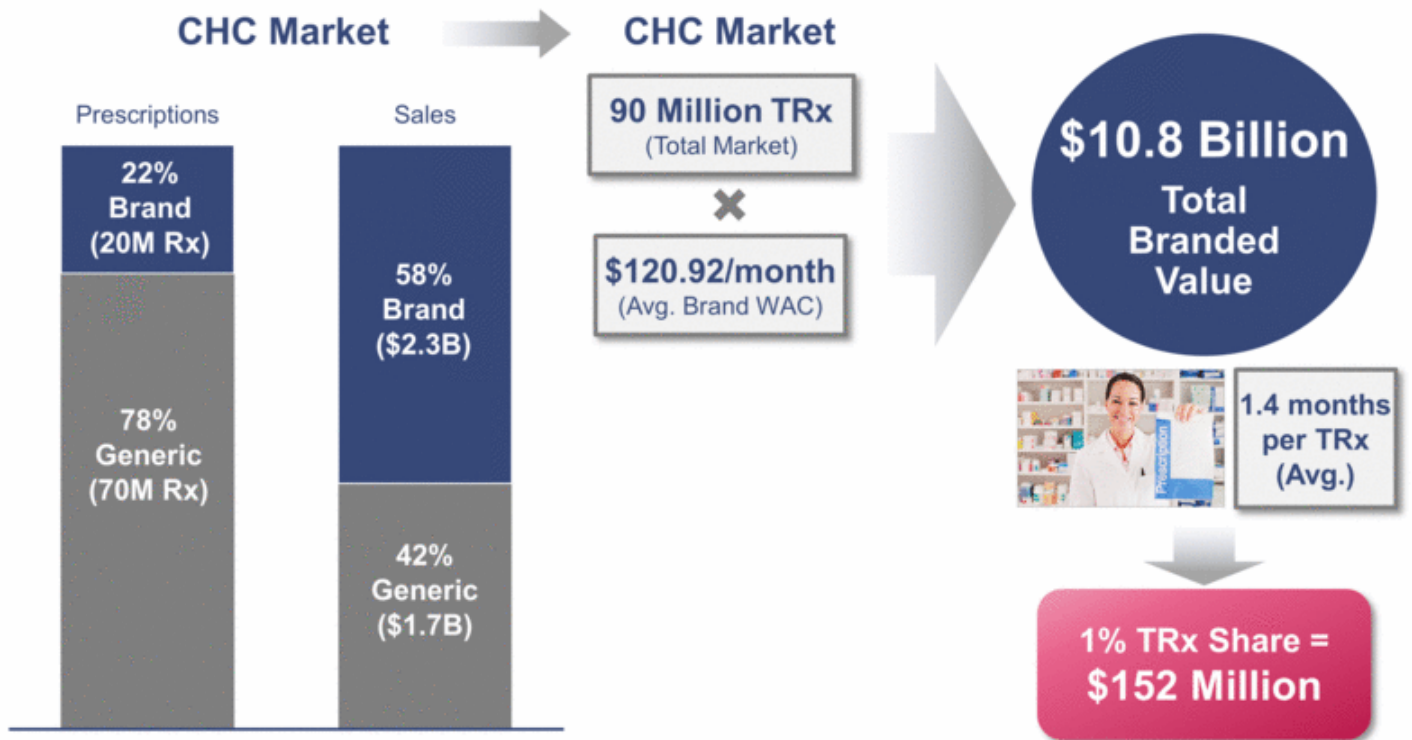
- Twirla will be the first new CHC brand introduced since 2013
- Twirla will be the first non-oral CHC brand introduced since 2002






twirla

TriCyclen and Evra are registered trademarks of Johnson & Johnson, Inc. Nuvaring is a registered trademark of Merck & Co., Inc. Yasmin, Yaz, Beyaz, and Natazia are registered trademarks of Bayer. Xulane is a registered trademark of Mylan, Inc. Loestrin, Generess, and Minastrin are registered trademarks of Allergan, Inc. Seasonique and Quartette are registered trademarks of Teva Pharmaceuticals USA, Inc.

US Branded Combined Hormonal Contraceptives (CHC) Have High Potential Market Value



Twirla® Marketing Plan is a 3-Pronged Approach

<p>ObGyn/NP Specialty Market</p> <ul style="list-style-type: none"> • Specialty market allows for sales force of only 70-100 reps • Access to ObGyns is high – among the lowest “no-see” rate of all specialties • Lack of introduction of new CHC products means opportunity for Twirla® to have high share of voice 	 <p>“This is good. There was a void after we stopped using Ortho Evra...patients like the patch.”*</p> <p>“I’m excited. Patients ask for the patch all the time.”*</p>
<p>Targeted Consumer Segment</p> <ul style="list-style-type: none"> • Consumers have active role in product choice • Twirla target demographic responds to digital marketing • Women want contraception that is easy to use, non-daily, and less invasive 	 <p>“...I want the freedom to not have to take something every day, so I’m willing to try it.”*</p> <p>“Birth control without the stress”*</p>
<p>Managed Care</p> <ul style="list-style-type: none"> • ACA Contraceptive Mandate provides a favorable Managed Care environment for Twirla® 	

Sources: SK&A Physician Access Study 2010,

*RG&A Interviews with ObGyns and NPs (n=74), 2012, RG&A Consumer Research Study (n=30), 2012

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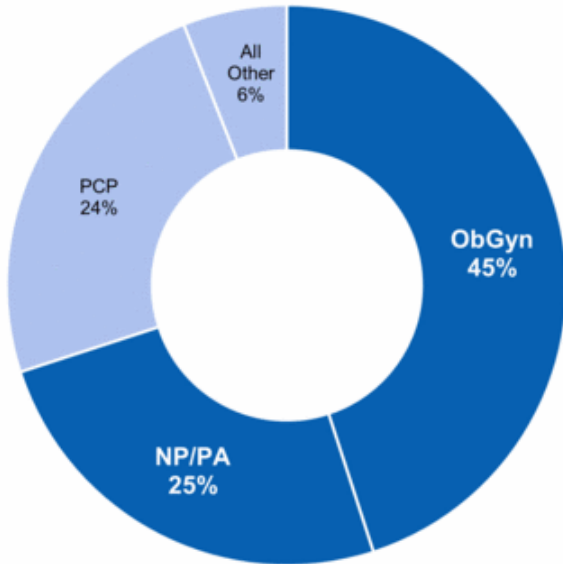
NASDAQ: AGRX

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ObGyns and Nurse Practitioners are the Key Contraceptive Prescribers

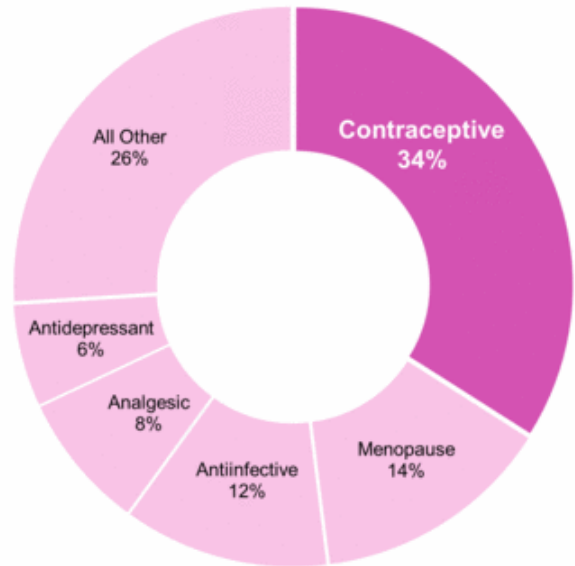
70% of US Contraceptive TRx are Written by ObGyns/NPs/PAs

CHC Prescriptions by Prescriber Type



ObGyns Prescribe Contraceptives More than any Other Therapy

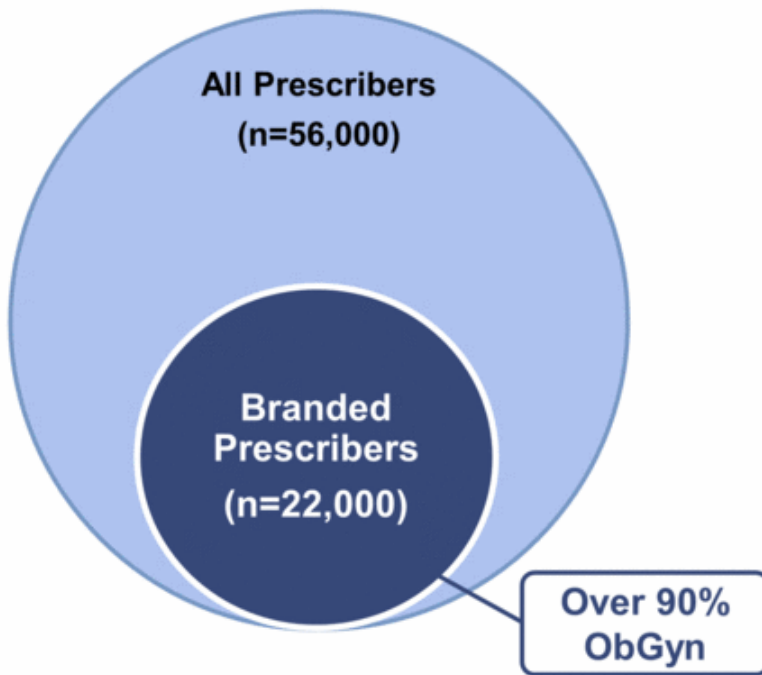
ObGyn TRx by Category



Source: IMS NPA, TRx Volume by Prescriber Type, 2014
Source: IMS NPA, TRX Volume by Category, 2010
1.8.2016

A Sales Force of 70-100 Reps is Estimated for Twirla®

US Contraceptive Prescribers



Detailing



Samples



Medical Education



Source: Wolters Kluwer 2012 (# of prescribers) and IMS Prescriber Profiler 2009: %TRx written by ObGyns in Dec 3-10 of contraceptive writers 1.8.2016

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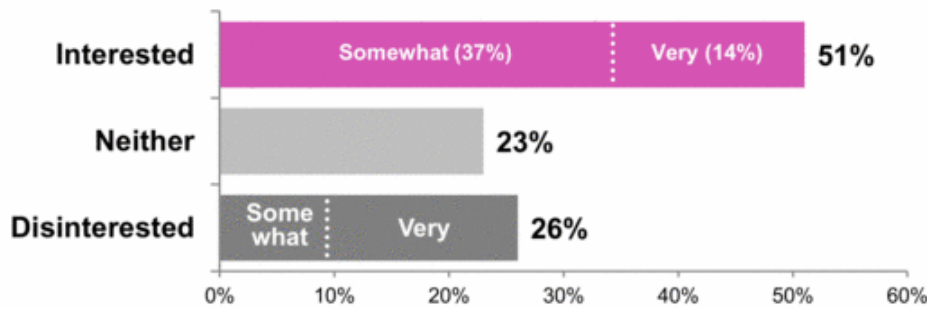
We Know the Twirla® Target Consumer

Women would choose Twirla® because they are busy

A once-weekly patch is a convenient alternative to a once-a-day pill



Q: How Interested Would You Be In Using Twirla As Your Birth Control?



Reaching Contraceptive Consumers Means Going Digital

Who She Is

Twirla interest is highest among:

- 20-29 years old
- College or graduate student
- Employed
- Women in a committed relationship

Where She Goes

Online

- Social Networks
- Discussion Forums
- Blogs & Online Magazines

Mobile

- Mobile apps
- Text messaging

Magazines

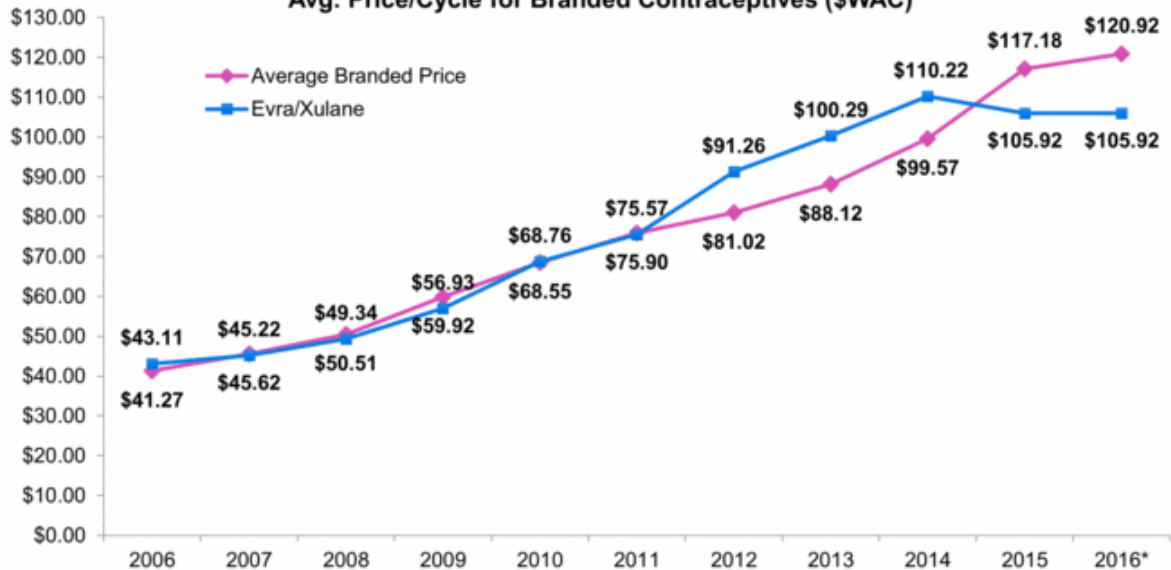


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Branded Contraceptives Continue to Take Aggressive Price Increases

Twirla expected to be well-positioned to compete and gain managed care access

Avg. Price/Cycle for Branded Contraceptives (\$WAC)



Avg. Annual Price Increase	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016*
	12.2%	9.7%	10.3%	17.3%	13.5%	11.6%	7.7%	8.5%	11.3%	16.8%	3.3%

Source: MediSpan Price Rx Select, Jan 2016. *Values for 2016 are YTD through Jan 6 2016
 Avg. Price/cycle calculation includes 13 leading branded contraceptive products.
 Patch Pricing reflects Ortho Evra price 2006-2014, Xulane in 2015

1.8.2016

Managed Care Environment is Favorable For a New Contraceptive Patch

ACA 'Contraceptive Mandate' now in effect

Requires coverage with no cost sharing of at least one product in each form of contraception per FDA Birth Control Guide

- "Patch" is a unique form
- Twirla and Xulane (Evra generic) will be the only 2 products available in Patch form
- Xulane current price = \$105.92/cycle

Possible Formulary Scenarios

If Twirla is the preferred patch:

Patients will be able to fill a prescription with

- no copay
- no deductible
- no coinsurance



If Twirla is not the preferred patch:

Most branded contraceptives are on Tier 3 or 4

- Manufacturers utilize copay coupons to offset the copay cost
- Branded copay average = \$35-50, with copay coupon: \$20-30

Sources: HHS FAQs About ACA Implementation (Part XXVI), May 11 2015
Managed Care research, Campbell Alliance and Fingertip Formulary, Feb 2015

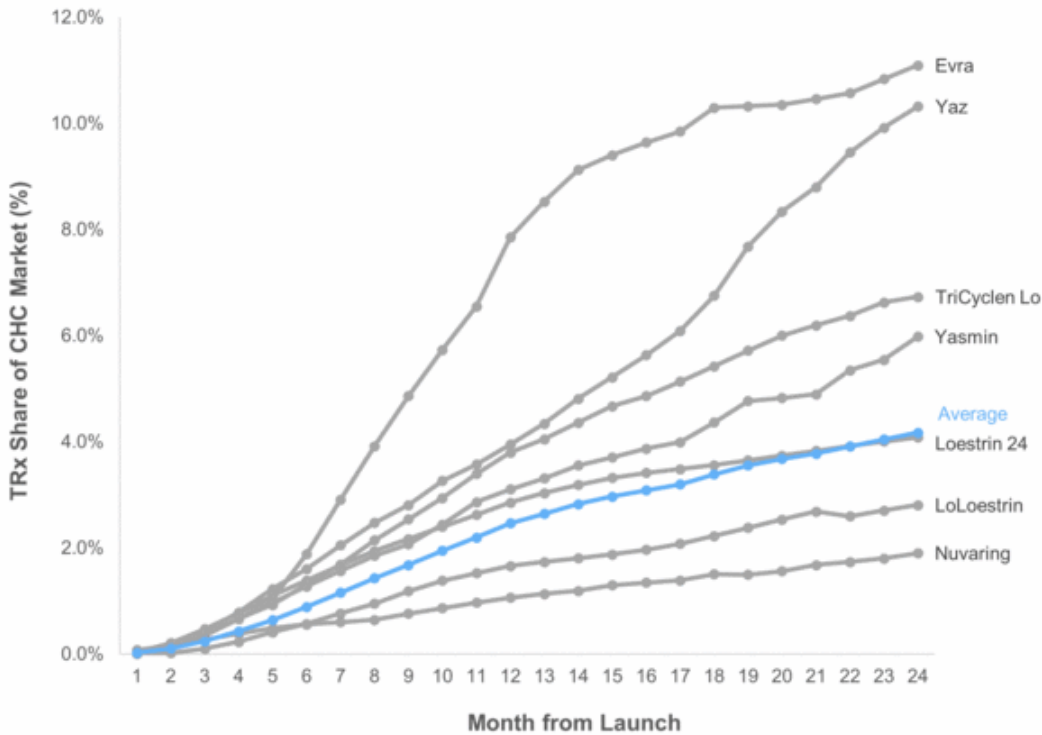
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Unique Contraceptive Brands Have Achieved High Market Share in the CHC Market

Contraceptive Market Analogs - First 2 years TRx Share (%)



Product	Peak TRx Share*
Evra	11.1%
Yaz	13.1%
TriCyclen Lo	9.1%
Yasmin	12.9%
Loestrin 24	10.2%
LoLoestrin	4.0%
Nuvaring	6.6%
Average	9.6%

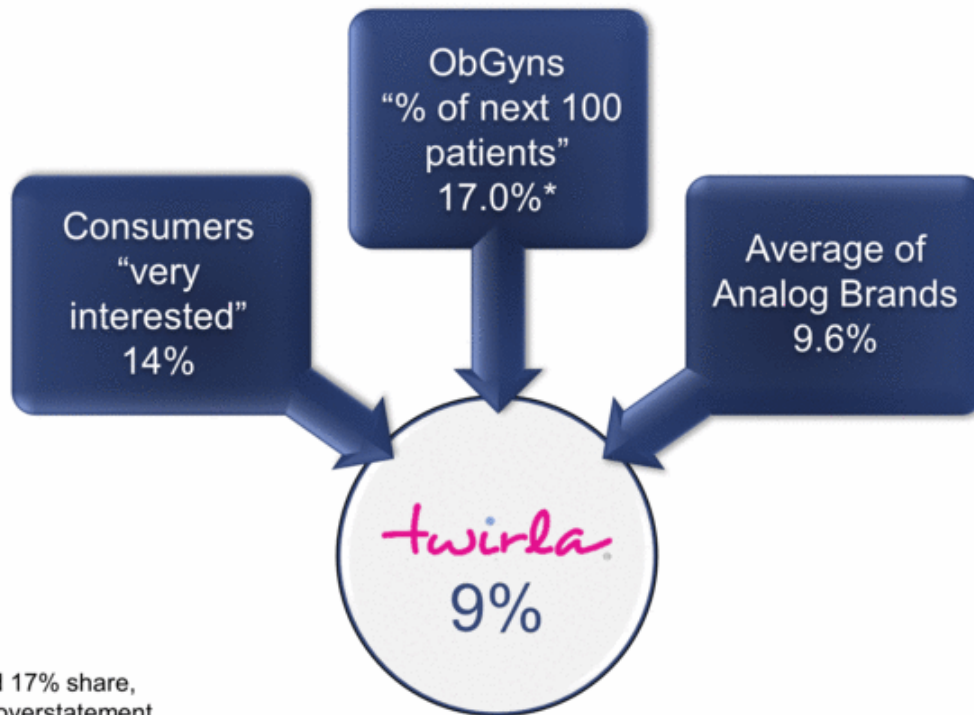
*Time to peak TRx share varies by product, and in most instances occurred after the first two years post launch

Source: IMS NPA, 2002-2015

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Twirla® Peak Share Estimate Rationale

Based on Consumer & Physician Market Research and Market Analogs



*ObGyns estimated 17% share, adjusted to 9% for overstatement

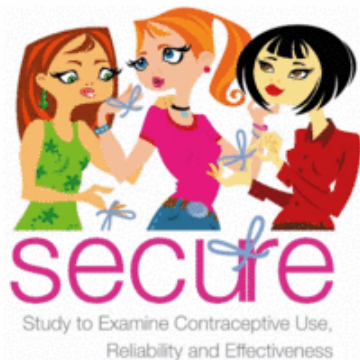
Sources: IMS NPA, 2002-2014

ObGyn market research conducted by Kantar Health, 2010.

Consumer market research conducted by RG&A, 2012. 14% of consumers considering starting birth control "very interested in using Twirla"

1.8.2016

Twirla® Phase 3 Trial Expected to Complete in 2H 2016



Simplified Study Design:

- Single-arm, open-label study
- Over 2,000 subjects treated for up to 1 year
- Focus on subject compliance, retention and reduced loss to follow up
- Primary efficacy measure = Pearl Index (PI)

$$PI = \frac{\text{Number of on-drug pregnancies}}{\text{Number of 28-day on-drug cycles}} (1300)$$

- Highest approved by FDA to date:
 - Pearl Index = 3.19
 - Upper bound of the 95% confidence interval around the PI = 5.03

Source: Quartette package inserts and Seasonale SBOA. Quartette and Seasonale are registered trademarks of Teva, Inc.

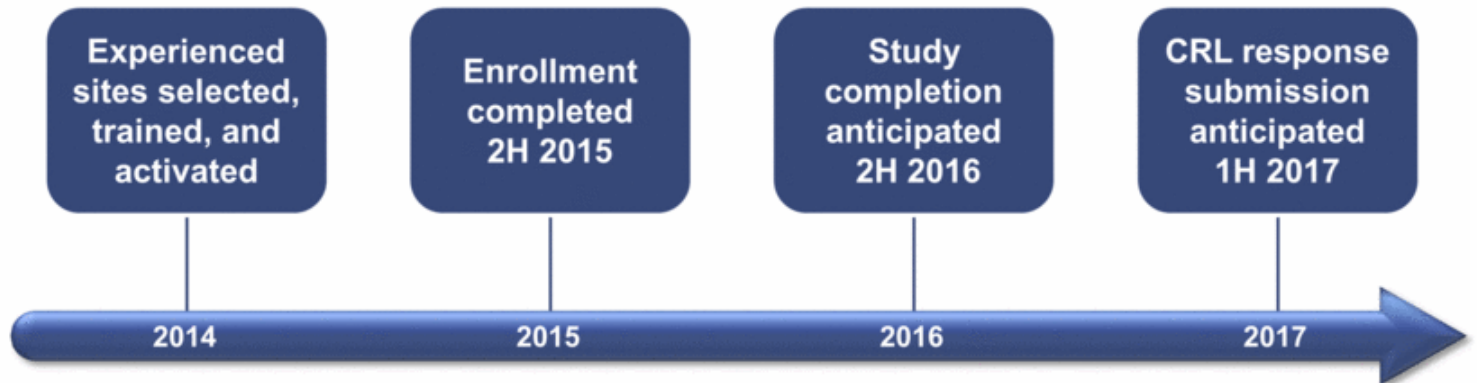
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THERAPEUTICS

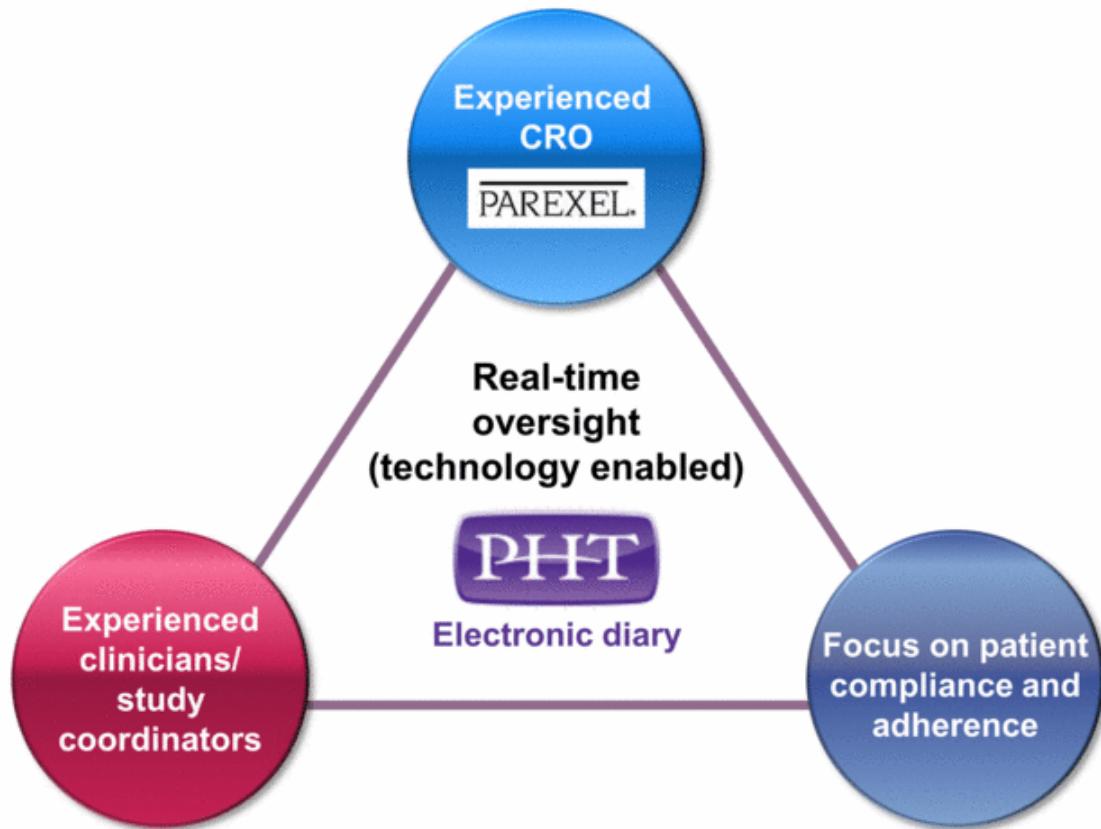
NASDAQ: AGRX 24

secure Study Timeline

Study to Examine Contraceptive Use,
Reliability and Effectiveness



Why We Believe The SECURE Study Will be Successful



Development Milestones

Agile Milestones	2015		2016		2017
	1H	2H	1H	2H	1H
Twirla Phase 3 Trial		1		2	3
Ongoing qualification of Commercial Manufacturing Equipment				4	→
AG200-ER/AG200-SP Program Design	5	6			

- 1 2H 2015: Patient enrollment completed
- 2 2H 2016: Expected last patient, last visit
- 3 1H 2017: Potential submission of CRL response
- 4 2H 2016: Ongoing qualification of commercial manufacturing line
- 5 1H 2015: Select product regimen(s)
- 6 2H 2015: Develop clinical plan for pipeline product

Agile Financial Profile

Balance Sheet Data

- \$39.4 Million cash on hand at September 30, 2015
- \$34.4 Million cash on hand at December 31, 2015
- 22.3 Million common shares outstanding at November 9, 2015

Background and Recent Financings

- Initial Public Offering
 - Completed in May 2014
 - \$55.0 Million gross proceeds (~\$49.7 Million net proceeds)
- Private Placement
 - Completed in January 2015
 - \$20.0 Million gross proceeds (~\$19.3 Million net proceeds)
- Debt Facility of up to \$25.0 Million (Hercules Technology Growth Capital)
 - Completed in February 2015
 - \$16.5 Million funded at loan closing (primarily to repay prior debt)

Agile Corporate Summary

- ✓ **Near-term catalyst – Phase III data 2H 2016**
- ✓ **Phase III asset in multi-billion dollar market**
- ✓ **Twirla expected to be the first low-dose alternative to an oral CHC in over 15 years**
- ✓ **Pipeline with patent protection to 2029**
- ✓ **Targeted specialty market commercialization**
- ✓ **Favorable managed care environment**
- ✓ **Management team with proven success launching contraceptive products**



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