

**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**

September 8, 2015
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)).

Item 8.01. Other Events.

On September 8, 2015, Agile Therapeutics, Inc. ("Agile") updated its corporate presentation that it intends to use in connection with presentations at conferences and meetings with investors. The updates include the recently announced completion of recruitment for its Phase 3 clinical trial for Twirla[®], its investigational contraceptive patch, and information relating to its plans for commercializing Twirla.

A copy of Agile's presentation is attached hereto as Exhibit 99.1 and is hereby incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Agile Therapeutics, Inc. Presentation.

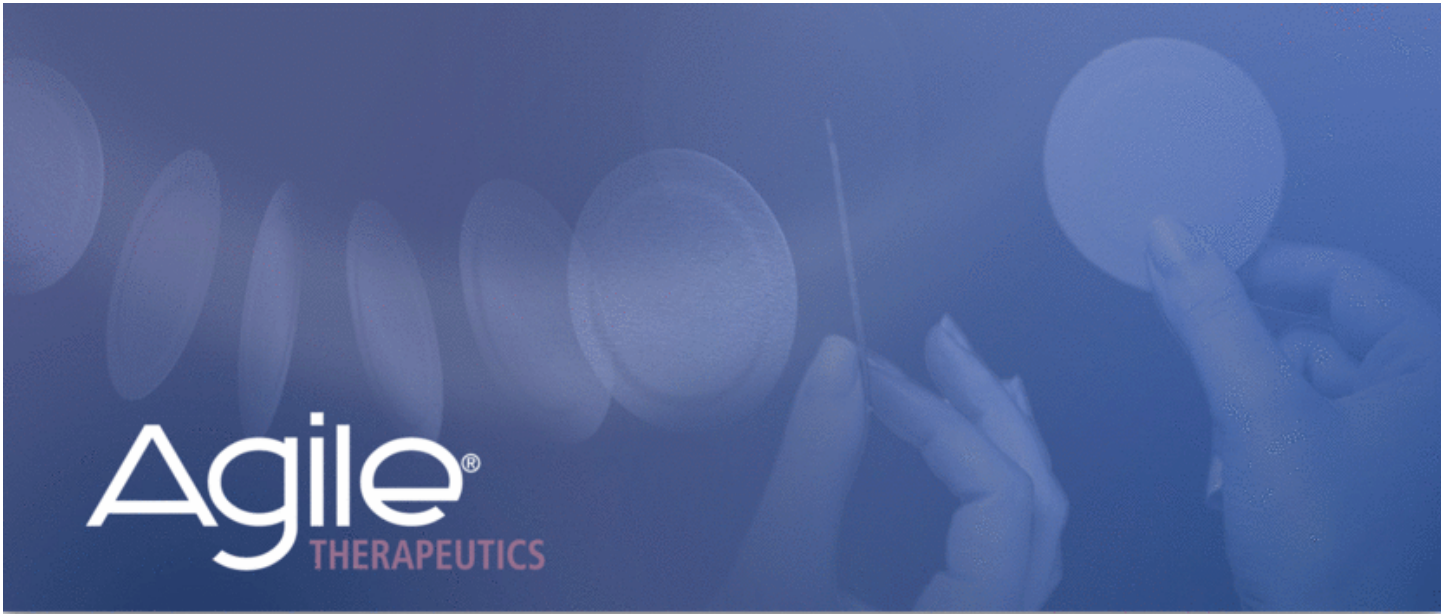
SIGNATURES

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: September 8, 2015

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

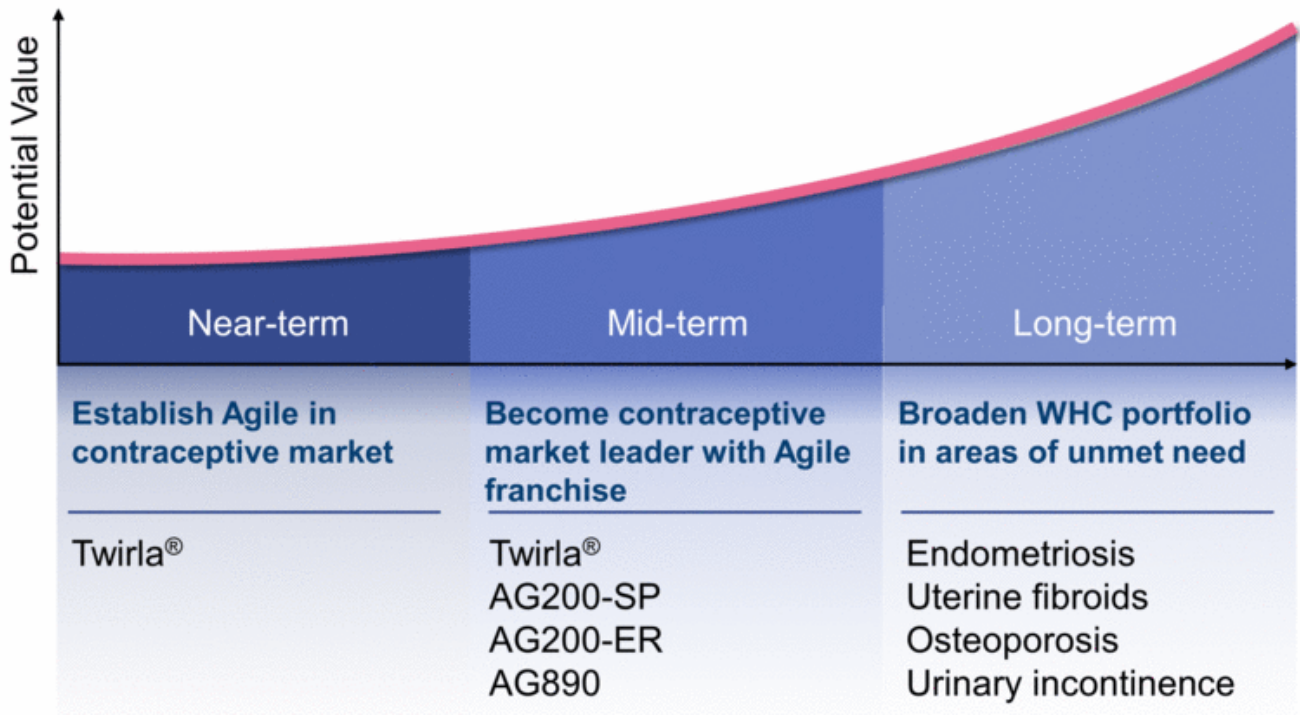


Women's Health Specialty Pharmaceutical Company
NASDAQ: AGRX

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 Strategy: Become a Leader in Women's Health



Agile Investment Thesis

Significant Near-Term Market Opportunity

- \$5.3 Billion US contraceptive market, \$4.0 Billion in combined hormonal contraceptives (CHC)
 - Lead product candidate, Twirla®, expected to complete Phase III in 2016, approval 2017
 - Twirla Manufacturing: One PAI completed, commercial scale-up ongoing
-

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
-

Agile is Well-Positioned for Successful Twirla Market Entry

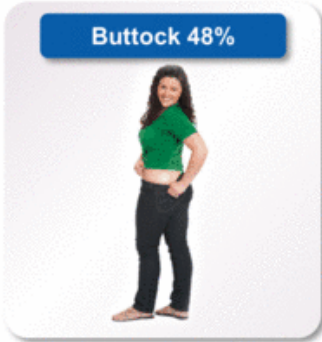
- Twirla is expected to be the only low-dose CHC patch
- Physicians and consumers show high interest in a low-dose patch
- Managed care environment for contraceptives is generally favorable
- Specialty focus and target consumer should allow for efficient marketing execution

The Twirla® Regimen is an Established 21/7 Schedule

How women will use Twirla

- Patch applied once weekly for three weeks followed by a 4th week with no patch
- Can be applied to abdomen, buttock, or upper torso
 - Buttock and abdomen are the most common patch placement choices

SUN	MON	TUE	WED	THU	FRI	SAT
1	2	3	4	5	6	7
			Patch 1			
8	9	10	11	12	13	14
			Patch 2			
15	16	17	18	19	20	21
			Patch 3			
22	23	24	25	26	27	28
		7 days no patch				
29	30	31				
			Patch 1			

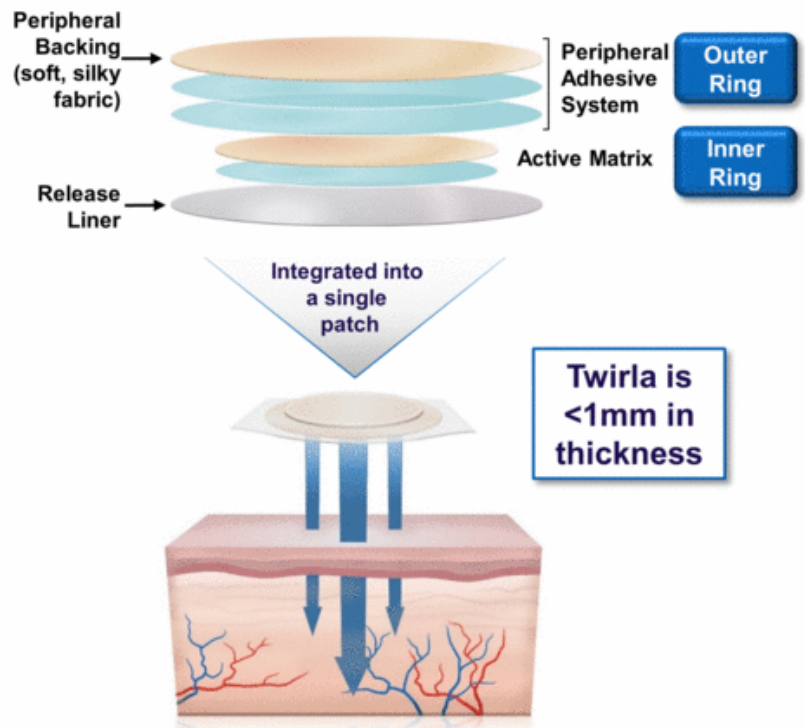


Source: Data on File, Agile Therapeutics
09.02.2015

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What Makes Twirla® Different?

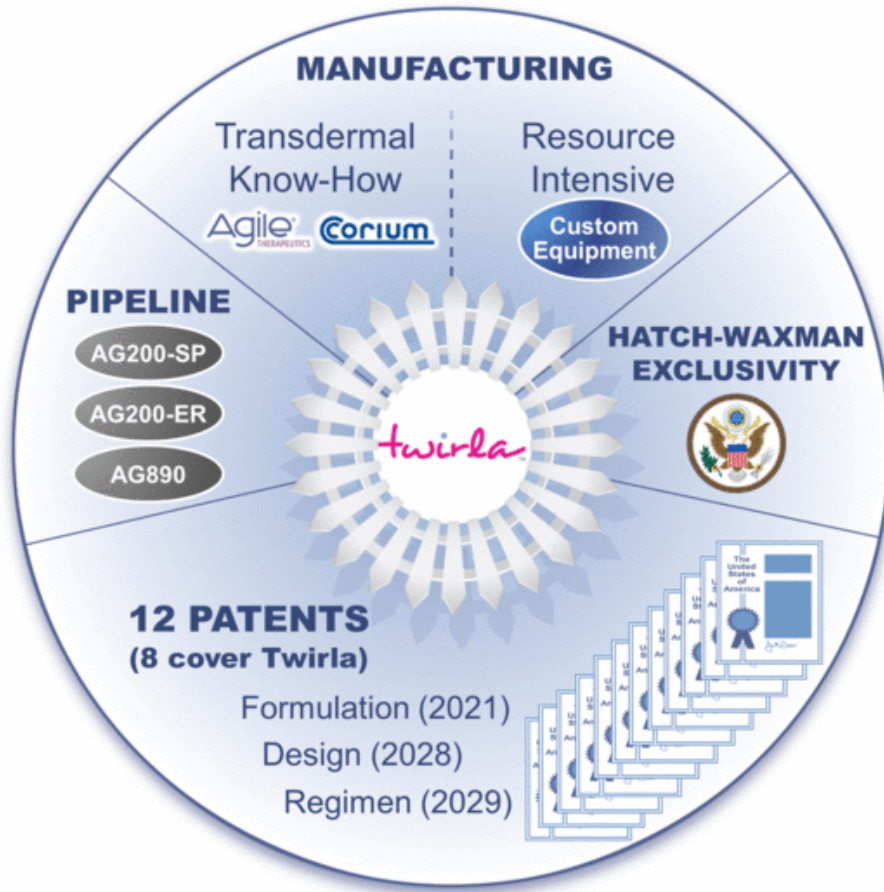
- Twirla will be the only low-dose contraceptive patch
 - Delivers 30µg/day EE
 - Evra®/Xulane® delivers 60% more EE than a 35µg pill
- Twirla contains levonorgestrel (LNG) and ethinyl estradiol (EE)
 - Only product to deliver LNG through the skin at a contraceptive dose
 - LNG and EE have over 25 years of established use in contraceptives
- Agile's proprietary Skinfusion® technology is cosmetically appealing



Evra is a registered trademark of Johnson&Johnson, Inc. Xulane is a registered trademark of Mylan, Inc.
09.02.2015

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Agile Intellectual Property Strategies For the Franchise

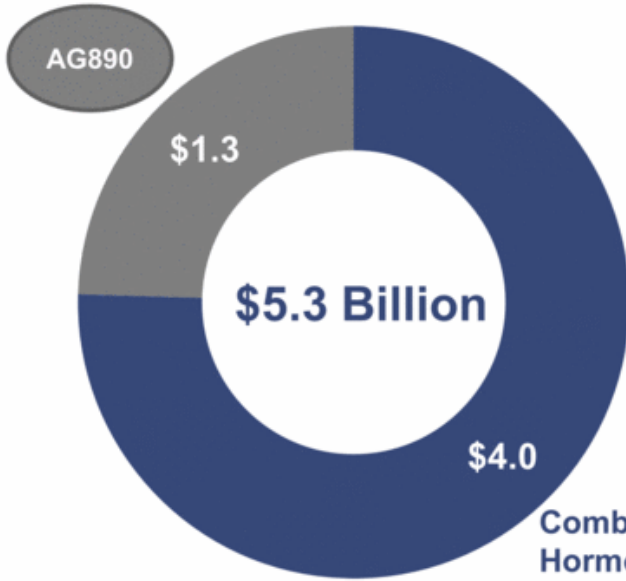


Agile Pipeline Strategy: Establish a Market-Leading Contraceptive Franchise

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)			<p>Unique New Products US Patents allowed in Aug 2015: Novel dosing regimens that employ a 'small patch' to deliver both EE and LNG during the withdrawal interval.</p>		<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

US Hormonal Contraceptive Market is a Significant Opportunity

Progestin-Only



AG890

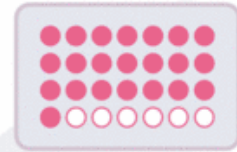
\$1.3

\$5.3 Billion

**Combination
Hormonal
Contraceptives**



AG200-ER
AG200-SP



**Pills
\$3.2 Billion**



**Vaginal Ring
\$654 Million**

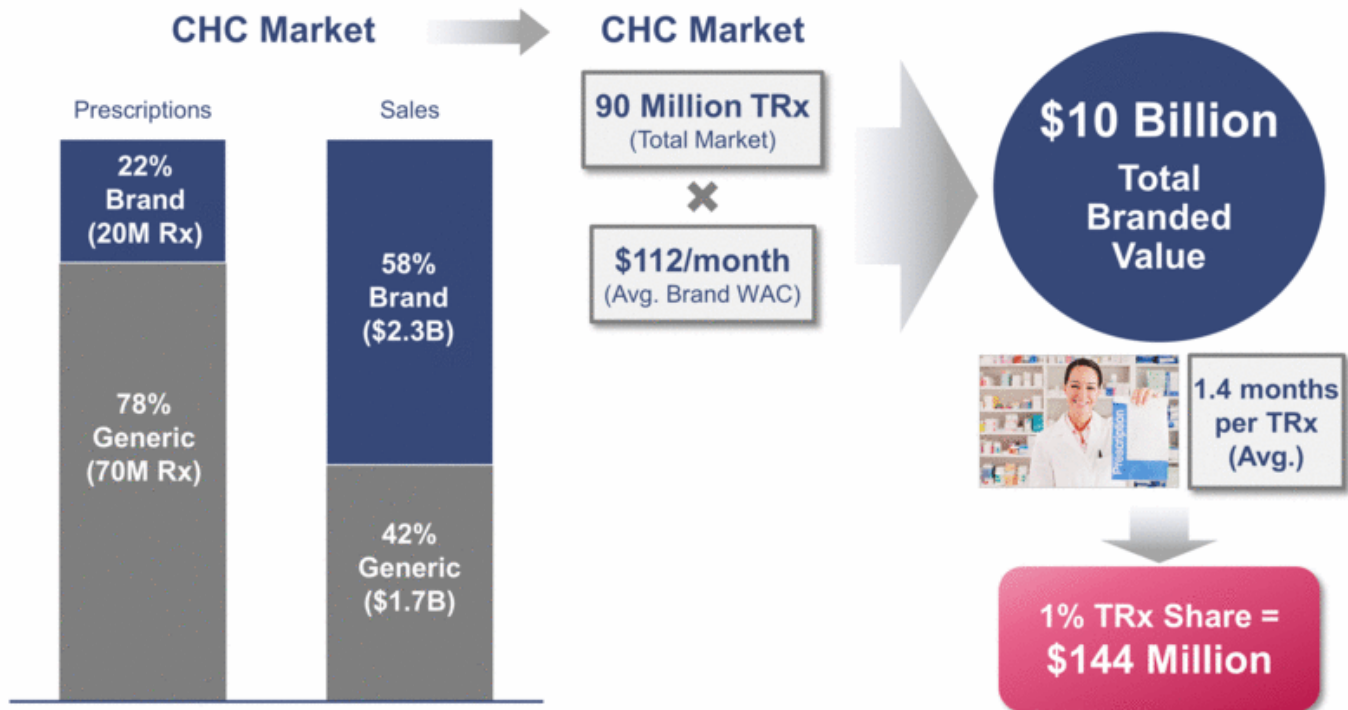


**Patches
\$153 Million**

Source: IMS NSP, retail + non-retail through Dec 2014
09.02.2015

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



Sources: IMS NPA Dec 2014 and MediSpan Price Rx Select, Aug 2015
09.02.2015

Twirla[®] Marketing Plan is Targeted and Efficient

**ObGyn/NP
Specialty
Market**



**Targeted
Consumer
Segment**



**Favorable
Managed Care
Environment**



Key Elements for Commercialization

- Physician Promotion
- Consumer Promotion
- Sales Force



Approx. \$40-\$60M annual cost*

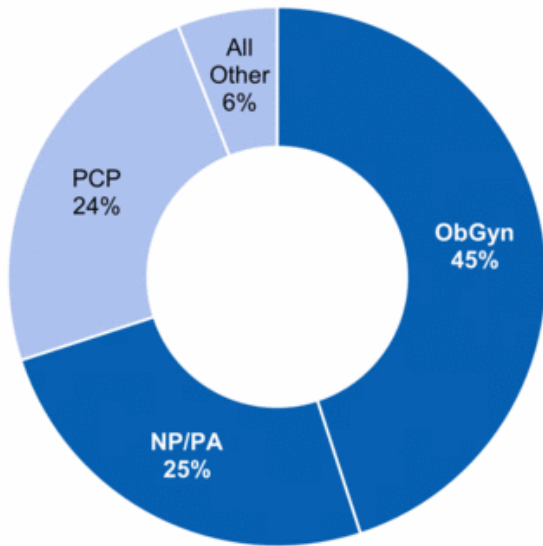
*Annual cost based on current assumptions and is subject to change. Does not include all costs specific to Twirla pre-launch and launch activities
09.02.2015

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ObGyns and Nurse Practitioners are the Key Contraceptive Prescribers

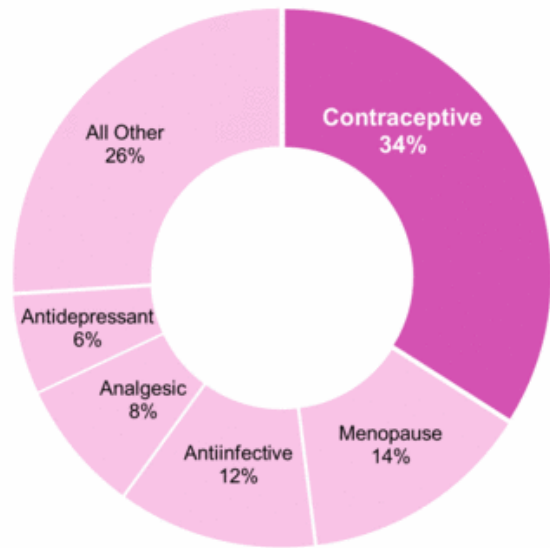
70% of US Contraceptive TRx are Written by ObGyns/NPs/PAs

CHC Prescriptions by Prescriber Type



ObGyns Prescribe Contraceptives More than any Other Therapy

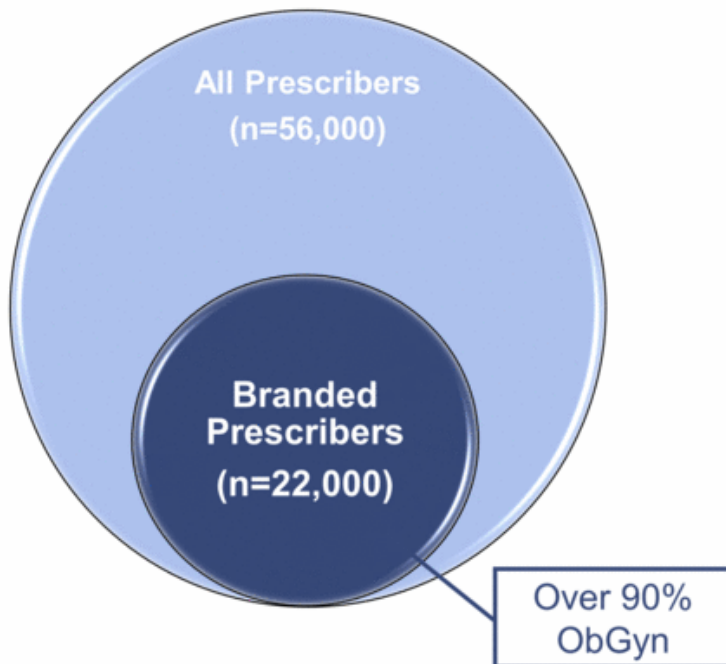
ObGyn TRx by Category



Source: IMS NPA, TRx Volume by Prescriber Type, 2014
Source: IMS NPA, TRX Volume by Category, 2010
09.02.2015

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

US Contraceptive Prescribers



Source: Wolters Kluwer 2012 (# of prescribers) and IMS Prescriber Profiler 2009: %TRx written by ObGyns in Dec 3-10 of contraceptive writers 09.02.2015

Detailing



Samples



Medical Education

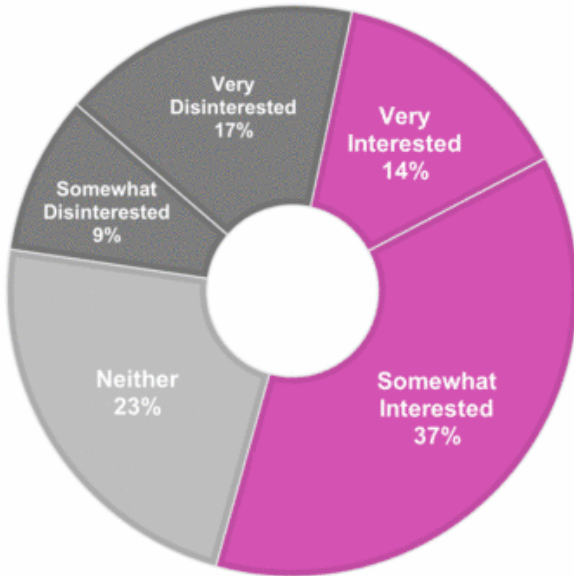


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We Know the Twirla® Target Consumer

Among women considering starting birth control:

How interested would you be in using Twirla as your birth control?



The Twirla Consumer is Busy

Twirla interest is highest among:

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



Source: Survey of 1000 women age 15-44, conducted by RG&A 2012. Data for 'seekers' (n=565) considering starting birth control 09.02.2015

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Reaching Contraceptive Consumers Means Going Digital

Where She Goes

Online

- Social Networks
- Discussion Forums
- Blogs & Online Magazines

Mobile

- Mobile apps
- Text messaging

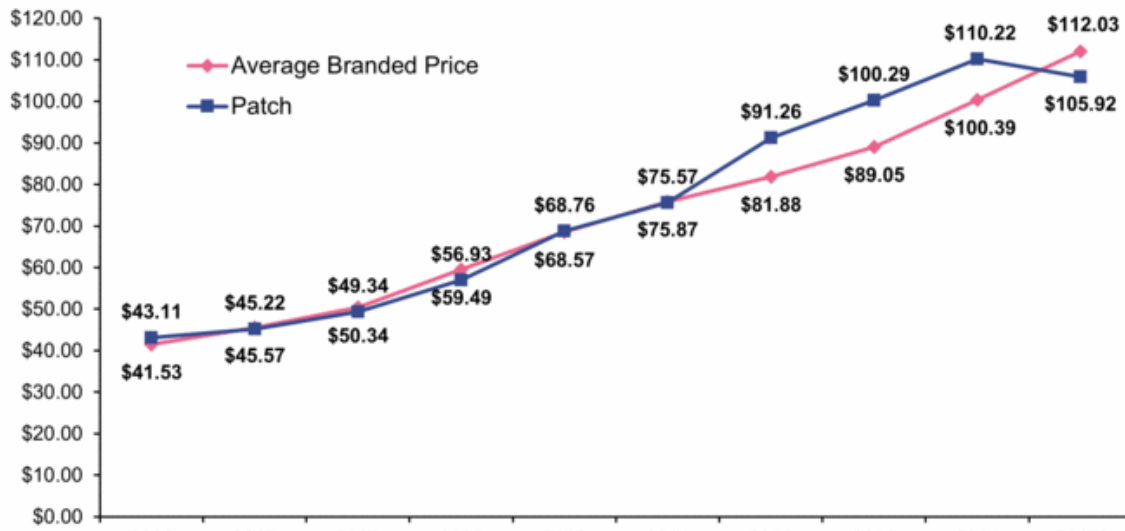
Magazines



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)



	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015*
Avg. Annual Price Increase	12.2%	9.7%	10.3%	17.3%	13.5%	11.6%	7.7%	8.5%	11.3%	11.7%

*Data reflect average as of Aug 2015. Source: MediSpan Price Rx Select, Aug 2015
 Avg. Price/cycle calculation includes 13 leading branded contraceptive products.
 Patch Pricing reflects Ortho Evra price 2006-2014, Xulane in 2015

09.02.2015

Managed Care Environment Likely to Allow Access to Twirla®

Current Landscape: Consumers Have Good Access to Contraceptives

- All contraceptives are generally available and reimbursed
 - Most branded contraceptives are on Tier 3 or 4 (with a copay)
 - Manufacturers utilize copay coupons to offset the copay cost
 - Branded copay average = \$35-50, with copay coupon: \$20-30
-

Potential Upside: ACA Contraceptive Mandate

- HHS FAQ May 2015: 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
- Twirla has potential to be preferred patch, available with no copay



Sources: Managed Care research, Campbell Alliance and Fingertip Formulary, Feb 2015
HHS FAQs About ACA Implementation (Part XXVI), May 11 2015, https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/aca_implementation_faqs26.pdf

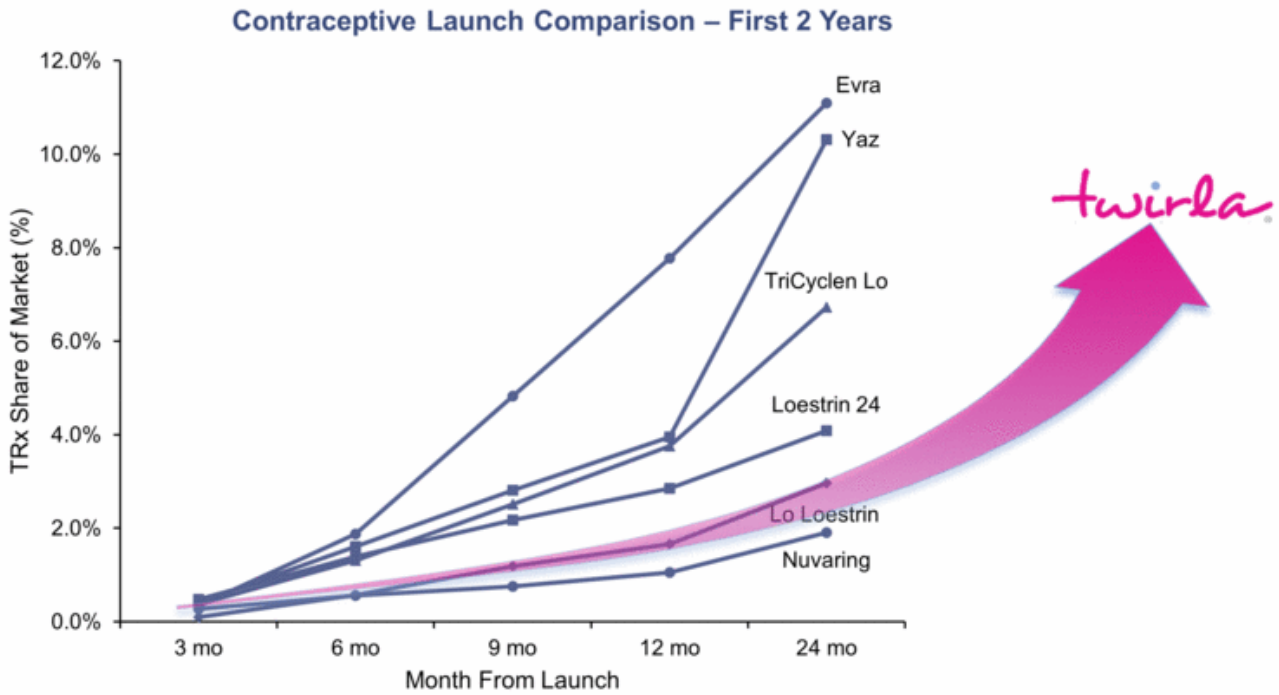
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Twirla® Peak Share Estimate = 9.0%

Early uptake estimate comparable to promoted brand launches



Sources: IMS NPA, 2002-2014

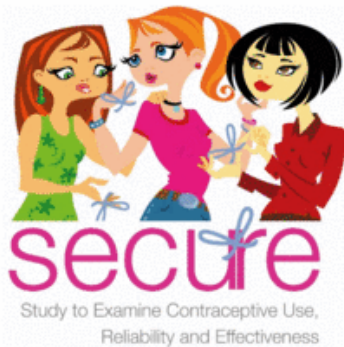
Twirla estimated peak TRx share based on market research conducted by Kantar Health. ObGyns estimated 17% share, adjusted to 9%

09.02.2015

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Twirla® Phase 3 Trial Expected to Complete in 2016



Simplified Study Design:

- Single-arm, open-label study
- ~2,100 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.

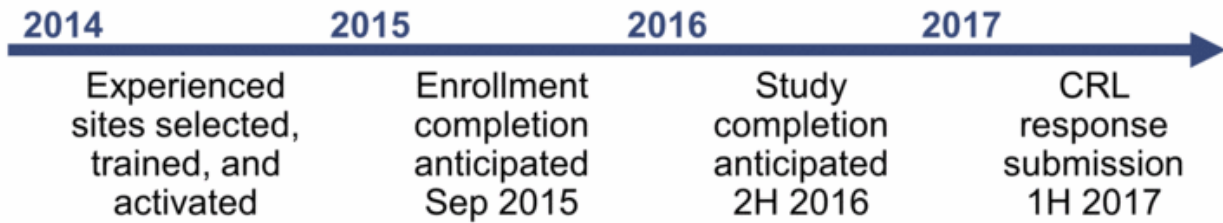
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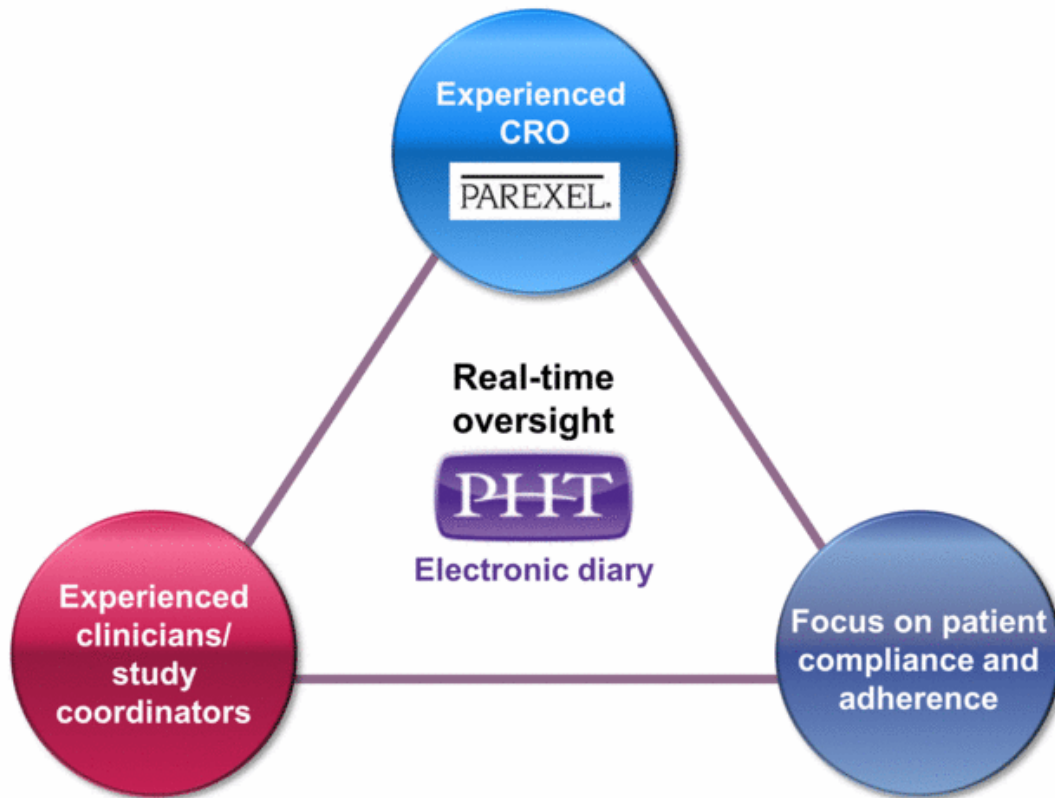
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secure Study Timeline

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					
Qualification of Commercial Manufacturing					
AG200-ER/AG200-SP Program Design					

- 1 2H 2015: Expected completion of patient enrollment by end of Q3 2015
- 2 2H 2016: Expected last patient, last visit
- 3 1H 2017: Potential submission of CRL response
- 4 2H 2016: Qualification of commercial manufacturing line
- 5 1H 2015: Select product regimen(s); develop clinical plan for pipeline product

Agile Financial Profile

Balance Sheet Data

- \$46.4 Million cash on hand at June 30, 2015
- 22.3 Million common shares outstanding at Aug 12, 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 Investment Thesis

Significant Near-Term Market Opportunity

Building a Robust Contraceptive Franchise

Well-Positioned for Successful Twirla Market Entry



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