
**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 12, 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)).
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Item 7.01 Regulation FD Disclosure

Beginning on January 12, 2015, Agile Therapeutics, Inc. (the "Company"), will participate in the 33rd Annual J.P. Morgan Healthcare Conference in San Francisco, California. Al Altomari, Chief Executive Officer and President of the Company, will present a corporate overview on Thursday, January 15, 2015 at 9:30 a.m. Pacific Time (12:30 p.m. Eastern Time). The Company is furnishing a copy of the presentation it intends to use at this conference, which is attached as Exhibit 99.1.

The live webcast of Mr. Altomari's presentation can be accessed via the Investor Relations section of the Company's website at <http://ir.agiletherapeutics.com/events.cfm>.

In accordance with General Instructions B.2 and B.6 of Form 8-K, the information included in this Current Report on Form 8-K (including Exhibit 99.1 hereto), 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 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

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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 12, 2015

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

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Agile Therapeutics Progress and Results

January, 2015



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; 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 Investment Thesis

Significant Market Opportunity

- \$4.1 Billion US market for combined hormonal contraceptives (CHC)
- Twirla will be the only low dose CHC patch

Twirla® is a Late-Stage Asset That We Continue to De-risk

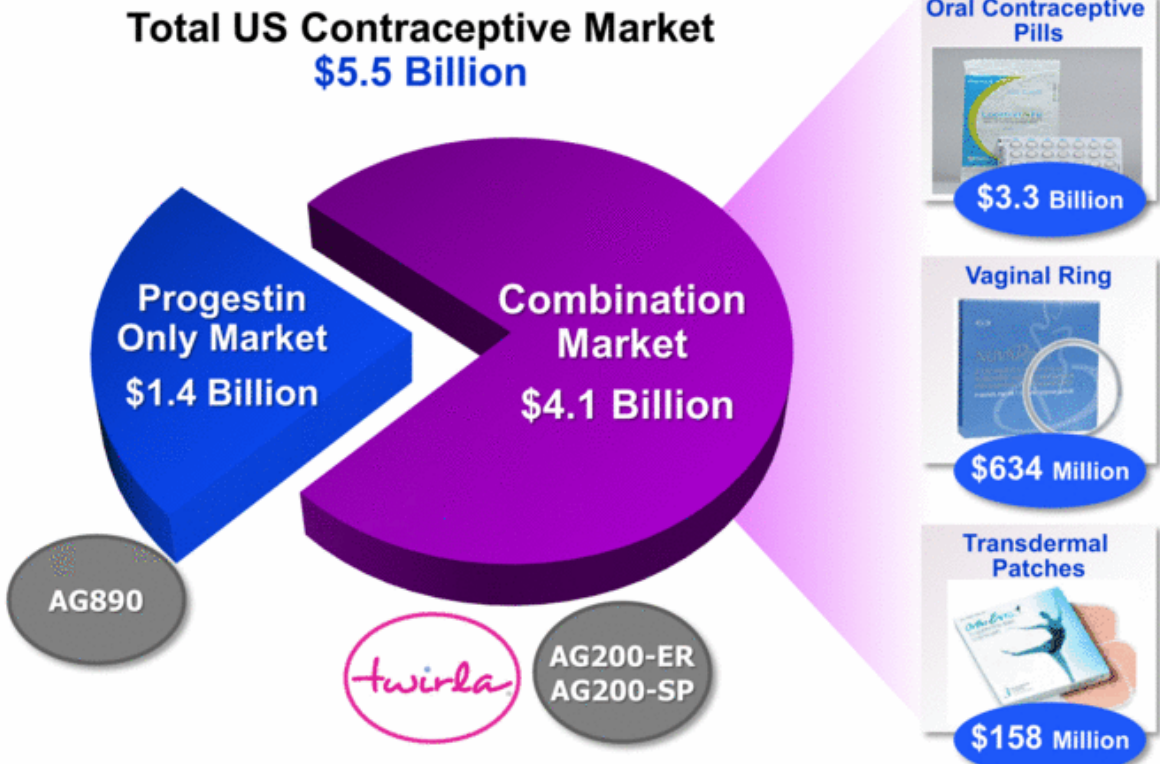
- One successful Pre-approval Inspection (PAI) completed
- Pharmacokinetic profile confirms low estrogen dose
- Significant clinical experience in over 1,500 women that showed favorable safety and tolerability

Agile has Generated Significant Momentum

- Confirmatory Phase 3 trial initiated
- Continued market development and commercial launch planning
- Additional products in development
- 7 patents, expected protection to 2028
- Continuing to expand intellectual property portfolio
- Current capital on hand to fund operations through 1Q2016

Large Market Opportunity

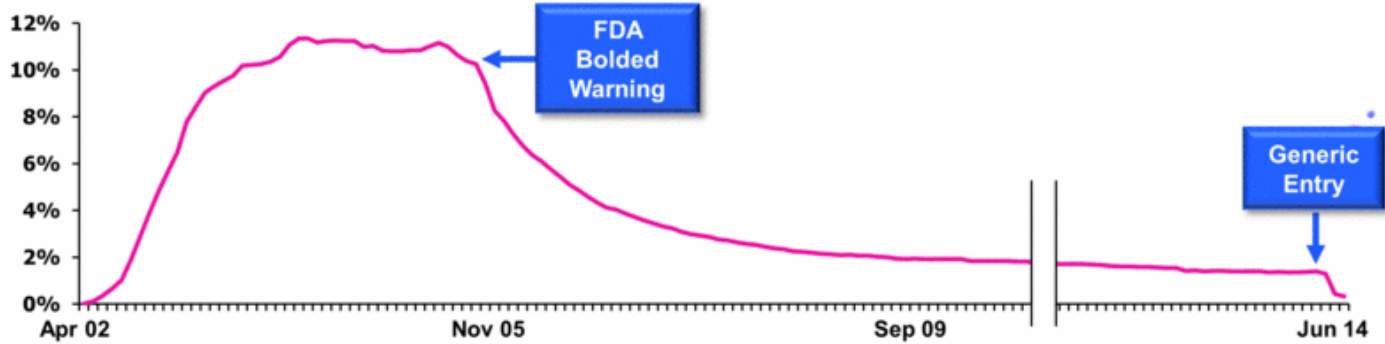
Contraceptive Market is a Significant Opportunity



*EC = Emergency Contraception
Source: IMS NSP, retail + non-retail through Sep 2014
Loestrin is a registered trademark of Actavis, Nuvaring is a registered trademark of Merck, Evra is a registered trademark of Johnson & Johnson

Ortho Evra Patch was the Most Successful Contraceptive Launch

Identification of higher than expected EE levels led to significant market share decline



Meteoric Rise

- Most successful contraceptive launch in history
- Reached TRx share of 11% and nearly \$400 million in annual sales
- Labeled as 20ug/day EE

Precipitous fall

- Thromboembolic events (VTEs) reported to FDA
- Studies showed EE levels higher than 20µg/day (~56µg/day)
- Bolded warning added to Evra label in Nov 2005
- Johnson & Johnson stopped active promotion

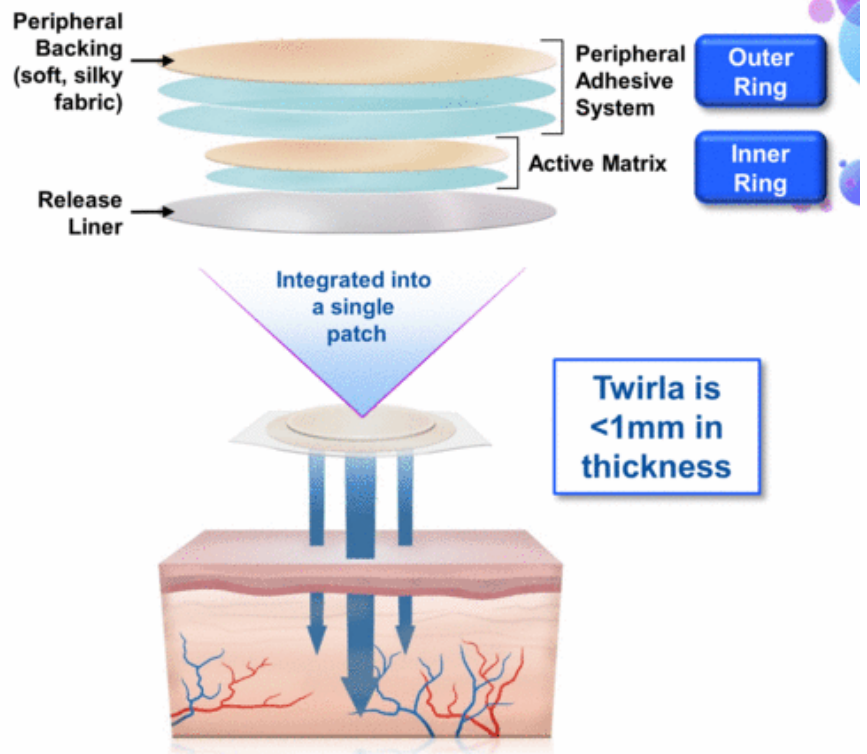
Generic Entry

- Mylan launched Xulane (generic equivalent to Evra) April 2014
- Total patch share of the market remains at 1.5% of TRx

Sources: IMS NPA and NSP, Sept 2014
Ortho Evra Package Insert and van den Heuvel, Contraception 2005;72:168-174

Twirla® will be the Only Low-Dose Contraceptive Patch

- Contains the active ingredients levonorgestrel (LNG) and ethinyl estradiol (EE), which have over 25 years of history of use in contraceptives
 - LNG is used as a standard for comparison of VTE risk among progestins
 - EE is the synthetic estrogen in most currently marketed contraceptives
- Agile's proprietary Skinfusion® technology provides hormone delivery in an appealing form



Agile®
THERAPEUTICS

How Would Women use Twirla?

- **Well-established 21/7 regimen**

- Women apply a patch once-a-week for three weeks followed by a 4th week without a patch

- **Can be applied to abdomen, buttock, or upper torso**

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			

Buttock 48%



Abdomen 40%



Upper Torso 12%



Source: Data on File, Agile Therapeutics

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THERAPEUTICS

Twirla Product Development Summary

- ✓ Completed Phase 2 and 3 studies have enrolled over 2,100 women
 - Over 1,500 women have received Twirla
 - 485 women have received Twirla for 12 months

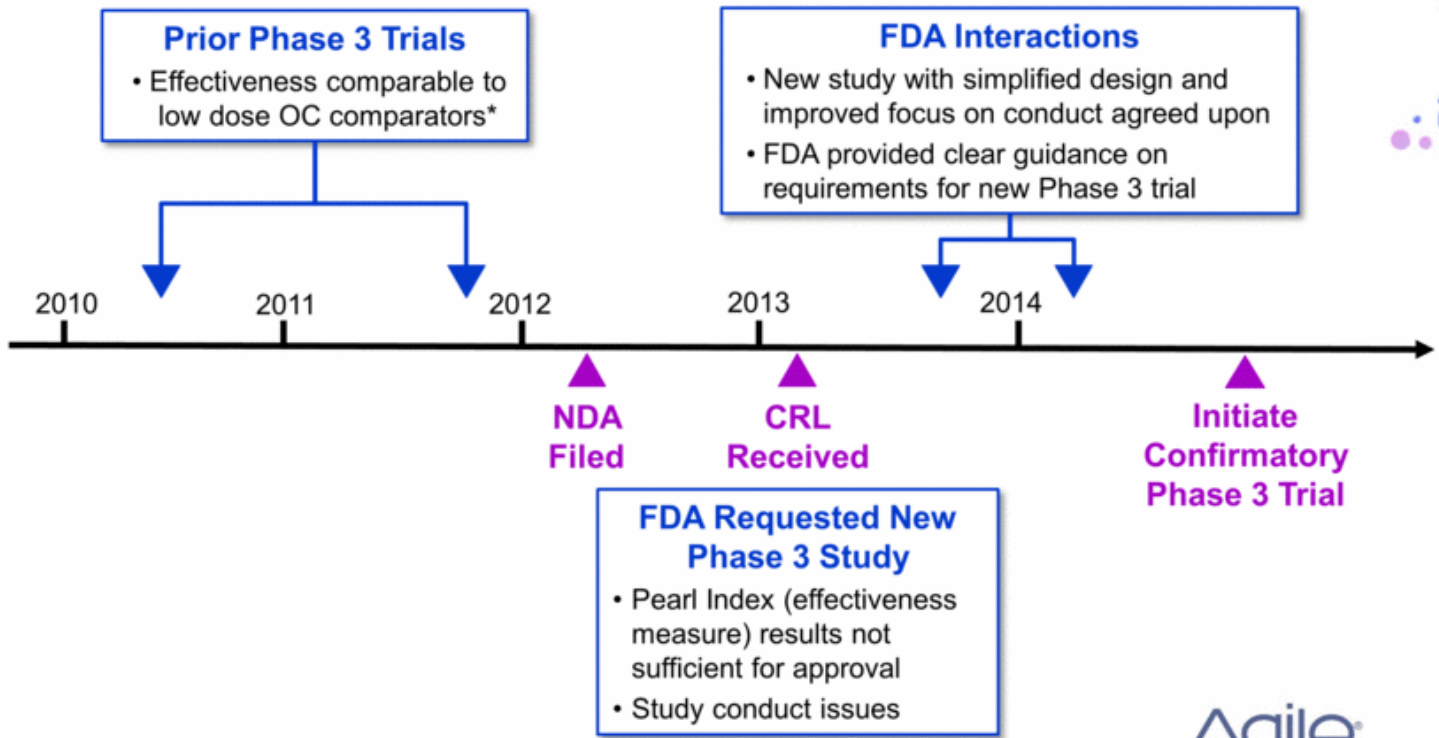
Results from prior studies have shown:

- ✓ Pharmacokinetic profile is consistent with a low-dose contraceptive*
- ✓ Twirla was well-tolerated with low rate of estrogen-associated adverse events**
- ✓ The Skinfusion technology performed well with daily activities and conditions, including showering, exercise, swimming, and heat/humidity
- ✓ Effectiveness in prior Phase 3 studies generally comparable to approved low-dose oral contraceptive (OC) comparators**

*Archer DF, et al, Contraception 2012 Jun;85(6):595-601

**Kaunitz A, et al, Obstetrics and Gynecology 2014 Feb;123(2):1-10

Twirla Regulatory Interactions and Clear Path Forward



*Pooled data from 2 clinical trials, CL-12 and CL-13. Data on File, Agile Therapeutics, CRL response to FDA, Aug 2013

Impact of New Users and Minorities on Twirla Pearl Index

- The Pearl Index (PI) is the primary measure of effectiveness for contraceptives
 - The highest approved PI in the US is 3.2, and the highest approved upper bound of the 95% confidence interval is ~5.0
- We believe clinical results were affected by study conduct issues at several sites, including rapid enrollment, high discontinuation and loss to follow-up rates
 - 36% of on-drug pregnancies reported at 4 of 96 sites*
- Study population comprised high proportion of new users of hormonal contraception and minorities who are known to be at higher risk of non-compliance and pregnancy**

Twirla PI Stratified by New Users and Minority Subjects	
Current users ^a	0.0
Experienced users ^b	3.0
New users ^c	8.7
Black subjects who were new users	16.0

(a) Current users = subjects who used a hormonal contraceptive within seven days of enrollment

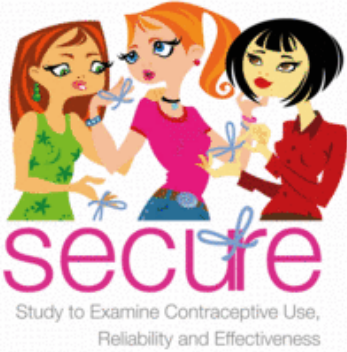
(b) Experienced users = recent (used a hormonal contraceptive within 6 months of enrollment) and current users

(c) New users = never used hormonal contraception (HC) or had not used HC in the 6 months prior to enrollment

*These 4 sites represented 15% of the randomized subject population

**Hatcher, et al. Contraceptive Technology 20th Ed, 2011, page 50 and Pooled data from 2 clinical trials, CL-12 and CL-13.
Data on File, Agile Therapeutics, CRL response to FDA, Aug 2013

New Phase 3 Confirmatory Trial Initiated

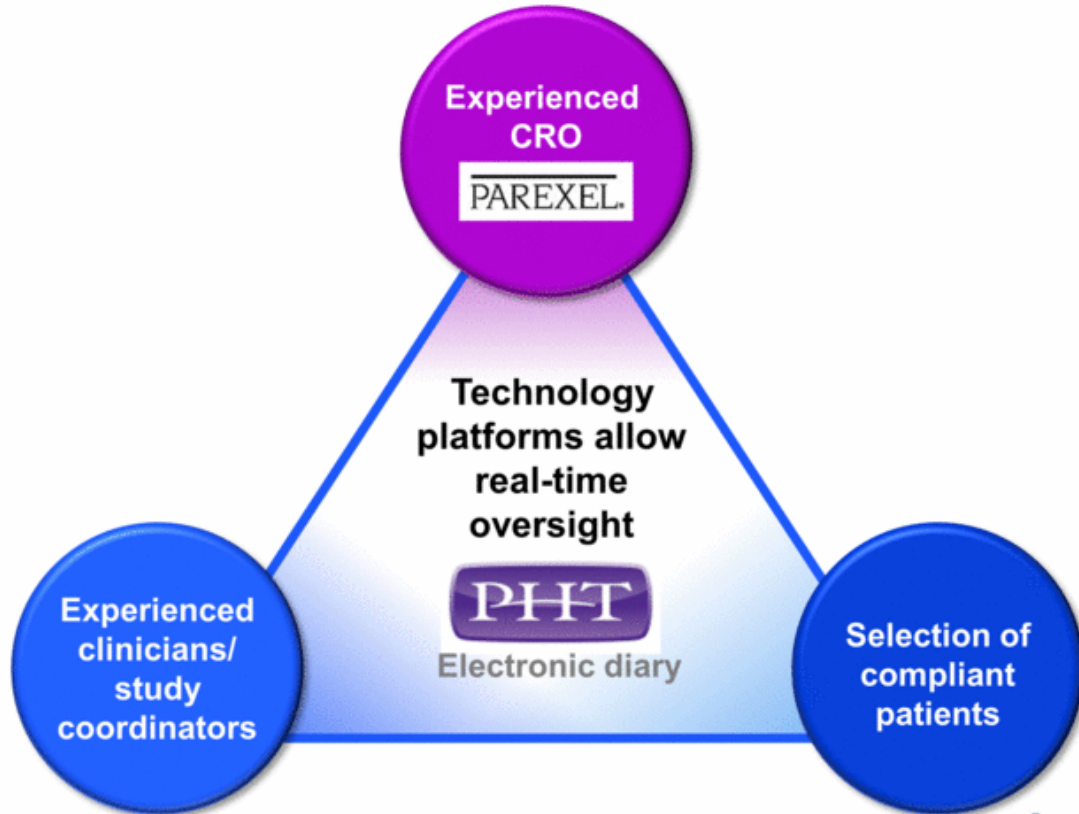


Simplified Study Design:

- Single-arm, open-label study
- ~2,100 subjects treated for up to 1 year

- ✓ Two Investigator meetings conducted
- ✓ 74 experienced sites selected and trained
- ✓ Subject screening, eDiary run-in commenced Sep 2014
- ✓ Active treatment phase ongoing

Why We Think the SECURE Study Will Be Successful



secure Materials to Aid Compliance

eDiary

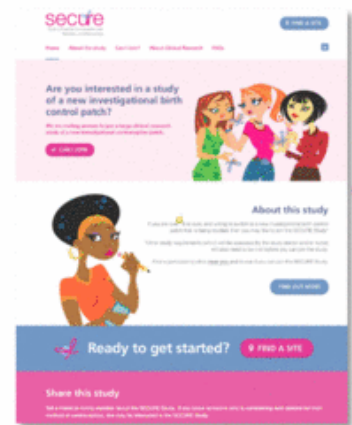


Text Messages

Flip Chart



Website



Study Guide

Clinic visits and study phone calls

There will be 12 scheduled clinic visits and telephone calls during the study. Clinic visits include Cycle 1 and Cycle 12 (starting Day 1) and the final clinic visit on Day 112 (starting between Day 8 and 12). The last telephone call will take place around 12 days after you remove your last patch. Additional unscheduled visits may be required.

There is space near the back of this booklet for you to record your clinic appointments.

It is important to attend all clinic visits and study phone call appointments. Please contact us if you need to reschedule any appointments.

Scheduled clinic visits and study phone calls

Visit number	1	2	3	4	5	6	7	8	9	10	11	12	13	Follow-up call
Clinic visit	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Phone call	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓

Notes and procedures to be carried out at clinic visits and study phone calls

Instruction	Clinic visits	Phone calls
Remember to bring your study diary and contraception kit	✓	✓
Bring your patch and genital hygiene kit	✓	✓
Bring your diary	✓	✓
Remember to bring your temperature, headache, side, mood, common, fatigue, and weight	✓	✓
Read and show your instructions, including drug warning	✓	✓
Remember to bring your diary with you to clinic visits	✓	✓
Remember to bring your diary with you to study phone calls	✓	✓
Remember to bring your diary with you to study phone calls	✓	✓
Remember to bring your diary with you to study phone calls	✓	✓

Patch change days are:

Cycle Day 8 and **Cycle Day 15**

Don't forget to remove your patch on Cycle Day 22 for the patch-free week!

What's the difference between spotting and bleeding?

Spotting: minimal blood – you only need pantyliners or no protection
Bleeding (can be light, normal or heavy): you need at least one tampon or sanitary pad

If you are going away... remember to take your patches and your eDiary with you!

If you need help with your diary... Customer Service is there to help you 24/7 at: 800-PHY-KNOW (800-748-5648)

eDiary Insert

Appointment Reminder

Your next SECURE Study appointments are scheduled for:

CLINIC VISIT

Date: _____
 Time: _____
 Cycle Number: _____
 You do not need to fast for 10-12 hours before this clinic visit.

TELEPHONE VISIT

Date: _____
 Time: _____
 Cycle Number: _____
 Please bring your Study Guide, all used patch pouches, and your eDiary with you to clinic visits.
 *If this is your last clinic visit, please return any unused patches.
 *Study home kit return is necessary.

Instructional Video

- new birth control product
- how to apply your patch
- important product information

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Brands Dominate

The CHC Market is Dominated by Branded Products

Pills



Ring



Patches



Combination Hormonal Contraceptive Market

\$4.1 Billion

twirla

AG200-ER
AG200-SP

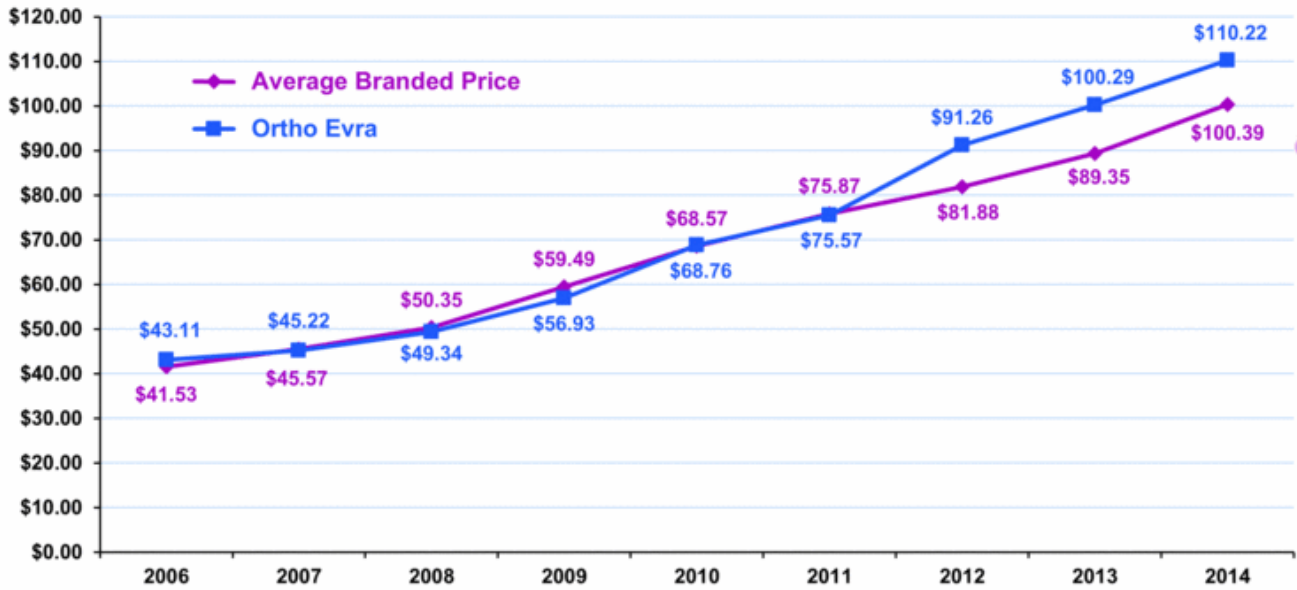
8 Brands account for ~ 50% of sales

Leading Brands	Form	2014 Sales* (\$Millions)
Nuvaring (Merck)	Ring	\$634
Tri-Cyclen-Lo (Johnson & Johnson)	Pill	\$481
LoLoestrin (Actavis/Warner Chilcott)	Pill	\$330
Loestrin 24/Minastrin 24 (Actavis/Warner Chilcott)	Pill	\$285
Beyaz (Bayer)	Pill	\$110
Ortho Evra (Johnson & Johnson)	Patch	\$109
Generess (Actavis)	Pill	\$103
Yaz (Bayer)	Pill	\$51
Total Sales		\$2.1 Billion

*Source: IMS sales retail + non-retail, MAT through Sept 2014
Loestrin and Minastrin a registered trademarks of Actavis (formerly Warner-Chilcott), Ortho Evra and Tri-Cyclen are registered trademarks of J&J, Yaz is a registered trademark of Bayer, Nuvaring is a registered trademark of Merck

Branded Contraceptives Continue to Take Aggressive Price Increases

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



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

Source: Price Rx Select, as of Dec 2014. *Includes price increases which occurred through Dec 15, 2014
 Avg. Price/cycle calculation includes 13 leading branded contraceptive products. Xulane launch price \$95.12 Apr 2014.

Twirla has Significant Peak Revenue Potential

Revenue Potential for each Market Share Point is Significant

$$\begin{matrix} \boxed{89.5 \text{ Million TRx} \\ \text{(Total Market, 2014)}} & \times & \boxed{\$100 \text{ per cycle} \\ \text{(Avg. WAC, 2014)}} & \times & \boxed{1.4 \text{ cycles/TRx} \\ \text{(Avg. Rx size, 2014)}} & \times & \boxed{1\%} = \boxed{\$126 \text{ Million} \\ & & & & & & \text{per 1\% TRx} \\ & & & & & & \text{share}} \end{matrix}$$

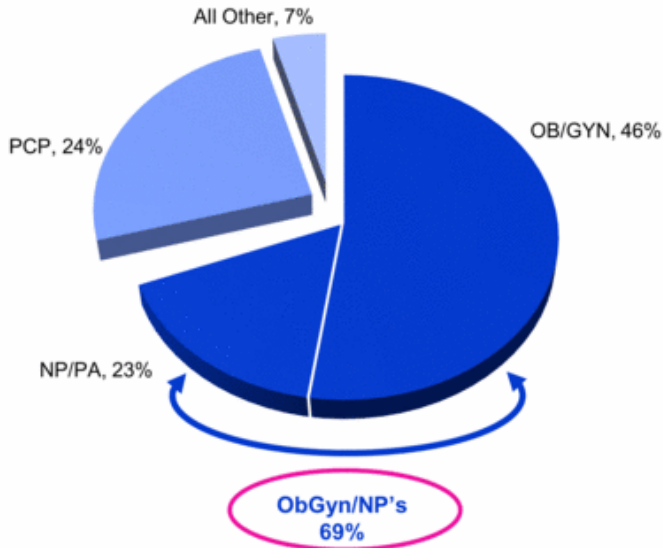
Twirla Annual Peak Sales Projection Based on Market Share Potential	
9% TRx Share (based on market research)	\$1,134 Million

Sources: IMS NPA Sept 2014 and Wolters Kluwer Price Rx Select, Dec 2014

ObGyn Focus on Contraceptives Allows for Small Sales Force of ~70 to 100 Reps

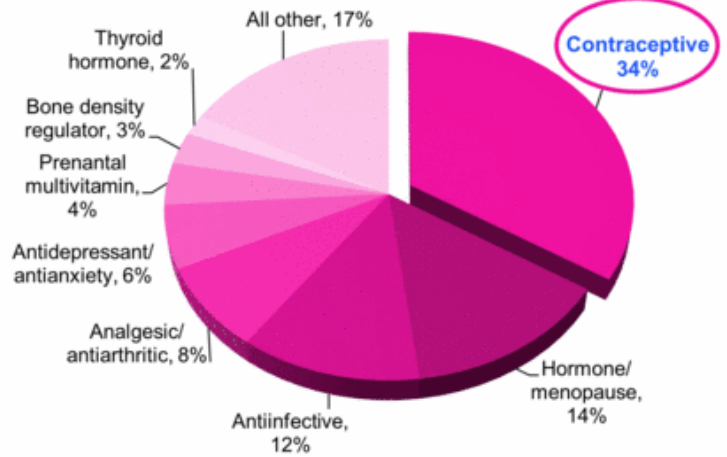
ObGyns and NP/PAs Account for ~70% of U.S. Contraceptive Prescriptions

Contraceptive TRx Volume by Prescriber Type




ObGyns and NP/PAs Prescribe Contraceptives More than any Other Therapy

ObGyn TRx Volume by Category








Source: IMS NPA, TRx Volume by Prescriber Type, 2013
 Source: IMS NPA, TRX Volume by Category, 2010

Agile Has Additional Products in Development

Product	Rationale	Development
	<ul style="list-style-type: none"> • Standard contraceptive regimen • Validated market opportunity 	<ul style="list-style-type: none"> • Currently in Phase 3 • CRL response planned
AG200-ER Extended Cycle Regimen	<ul style="list-style-type: none"> • Fewer periods per year • Potential advantage over OC regimens 	<ul style="list-style-type: none"> • No new product development required • Potential to progress into Phase 3 in 2015
AG200-SP Shortened Hormone-Free Interval (SHFI)	<ul style="list-style-type: none"> • Shorter, lighter periods • Potential to improve contraceptive effectiveness 	<ul style="list-style-type: none"> • Requires product development • Potential to initiate Phase I in 2015
AG890 Progestin-Only Regimen	<ul style="list-style-type: none"> • Designed for women who are unable or unwilling to take estrogen 	<ul style="list-style-type: none"> • Initial Phase 1/2 trial conducted • Additional product development required

Agile Exclusivity Strategies for Twirla

	Expected Hatch-Waxman exclusivity (3 years)
	7 issued patents to list in Orange Book <ul style="list-style-type: none">• Issued patents expire in 2021 (5) & 2028 (2)• Additional patents under prosecution
	Limited patch manufacturers <ul style="list-style-type: none">• Transdermal know-how
	Specialized equipment
	Agile pipeline / line extensions

Agile Corporate Accomplishments

- ✓ Feb 2014 Dan Shames, MD joined Scientific Advisory Board (SAB)
Former FDA Director, Division of Reproductive and Urologic Products/CDER
- ✓ Mar 2014 William McKee appointed to Board of Directors
Former CFO, Barr Pharmaceuticals, LLC
- ✓ May 2014 Completed initial public offering (IPO) for \$55 Million
- ✓ Jun 2014 Sixth U.S. patent granted on Skinfusion® transdermal technology – to list in Orange Book
- ✓ Jun 2014 Agile joins Russell Microcap® Index
- ✓ Jul 2014 Seventh U.S. patent - additional claims allowed for Skinfusion
- ✓ Aug 2014 **secure** clinical trial initiated
- ✓ Oct 2014 James Tursi, MD appointed to Board of Directors
Chief Medical Officer, Auxilium Pharmaceuticals
- ✓ Nov 2014 John Hubbard, Ph.D. appointed to Board of Directors
Former Head of Development Operations, Pfizer, Inc.

Financial Profile

Background

- Founded in 1997
- Initial Public Offering (IPO) completed in May 2014
- **\$45.7 Million** cash on hand at September 30, 2014
- 18.6 million common shares outstanding at September 30, 2014

Use of proceeds

- **\$55.0 Million** gross proceeds (~**\$49.7 Million** net proceeds)
 - **\$31 Million** for additional Phase 3 clinical trial for Twirla
 - Continuation of the qualification and validation of equipment related to the expansion of manufacturing capabilities
 - Development of product candidate pipeline including line extensions
 - Principal (beginning Feb 2015) and interest payments on term loan continuing through Jul 2017

Development Milestones

Agile Milestones	2014		2015				2016			
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Twirla Phase 3 Trial			1					2	3	
Qualification of Commercial Manufacturing										4
AG200-ER/AG200-SP Program Design			5							

- 1 1H 2015: Expected completion of patient enrollment
- 2 1H 2016: Expected last patient, last visit
- 3 1H 2016: Potential submission of CRL response
- 4 2H 2016: Qualification of commercial manufacturing line – expect completion of validation Q4 2016
- 5 1H 2015: Select product regimen; potential to initiate development of pipeline product

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