

**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**

June 26, 2014

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 7.01 Regulation FD Disclosure

On June 26, 2014, Al Altomari, Chief Executive Officer and President of Agile Therapeutics, Inc. (the "Company"), and Scott Coiante, the Company's Vice President and Chief Financial Officer, participated at the Janney Capital Markets Boston Healthcare 1X1 Corporate Access Day in Boston, MA. The Company is furnishing a copy of the presentation used at this conference, which is attached as Exhibit 99.1.

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

Description

The advertisement features a central white circle with the Agile Therapeutics logo. Surrounding this are three circular images: a woman applying a patch to her shoulder, hands holding a patch, and a woman looking at a smartphone. Below the central logo are two boxes of Twirla transdermal systems. The Twirla logo and its active ingredients, (levonorgestrel/ethinyl estradiol), are also displayed.

twirla
(levonorgestrel/ethinyl estradiol)
transdermal system

Agile
THERAPEUTICS

Not for promotional purposes

Agile Therapeutics

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 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 success of the Company's license agreements; 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

Large Market Opportunity

- \$4.2 Billion combined hormonal contraceptive (CHC) market
- Significant Unmet Need: No low-dose CHC patch on the market today

Significant Clinical Experience

- Over 1,500 women have received Twirla in clinical trials that showed favorable safety and tolerability
- Two completed randomized phase 3 trials showed pregnancy rate comparable to comparator pills

Clear Regulatory Path

- CRL and FDA communications provide clear guidance on path forward with one single-arm trial
- Potential for near-term approval in late 2016

High Barriers to Generic Entry

- 6 issued patents, protection to 2028
- Technological and manufacturing know-how

Multiple Strategic Options

- Wholly owned assets means company is free to partner or sell
- Company can market directly through focused sales force

World Class Team

- Deep experience in women's health and contraceptive products

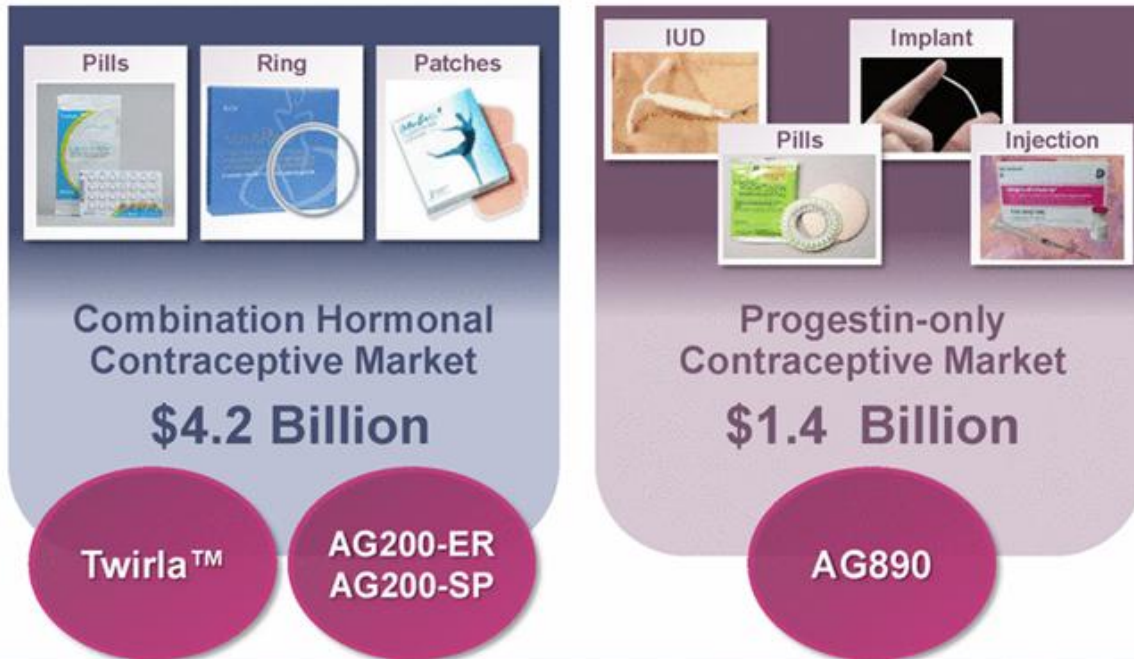
Agile Executive Management Team

Deep Experience in Women's Healthcare and Contraceptive Products

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

Contraceptive Market is a Large Opportunity

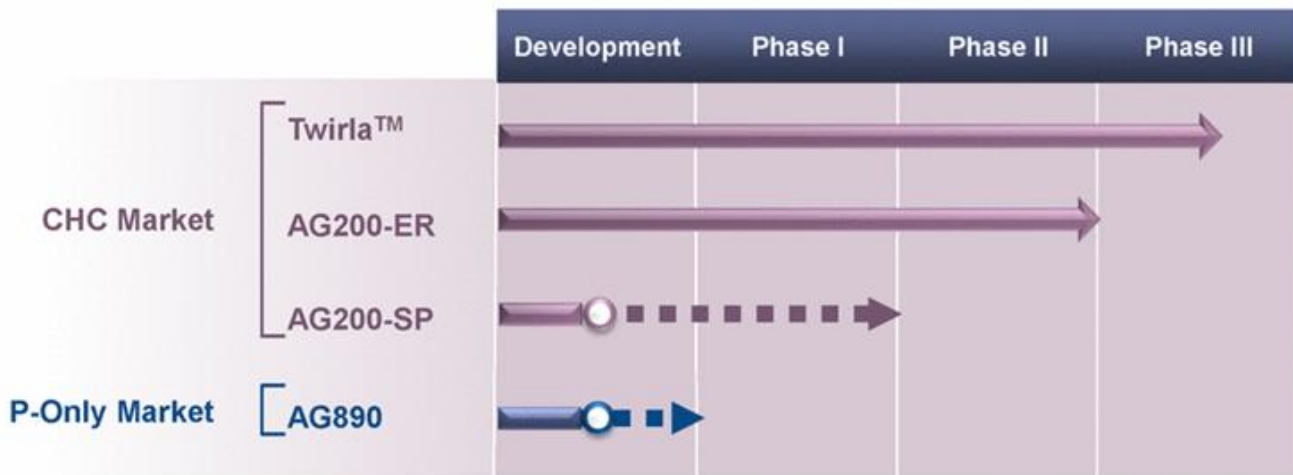
Agile products are designed to provide convenience and facilitate compliance



Source: IMS NSP, retail + non-retail, Dec 2013
 Loestrin is a registered trademark of Actavis. Evra and Micronor are registered trademarks of Johnson & Johnson
 Depo-Provera is a registered trademark of Pfizer

Property of Agile Therapeutics – 06.26.2014

Agile Has Four Products in Development



CHC = Combined Hormonal Contraception, P-Only = Progestin-Only Contraception

○ = Additional patch development to determine optimal formulation and dose

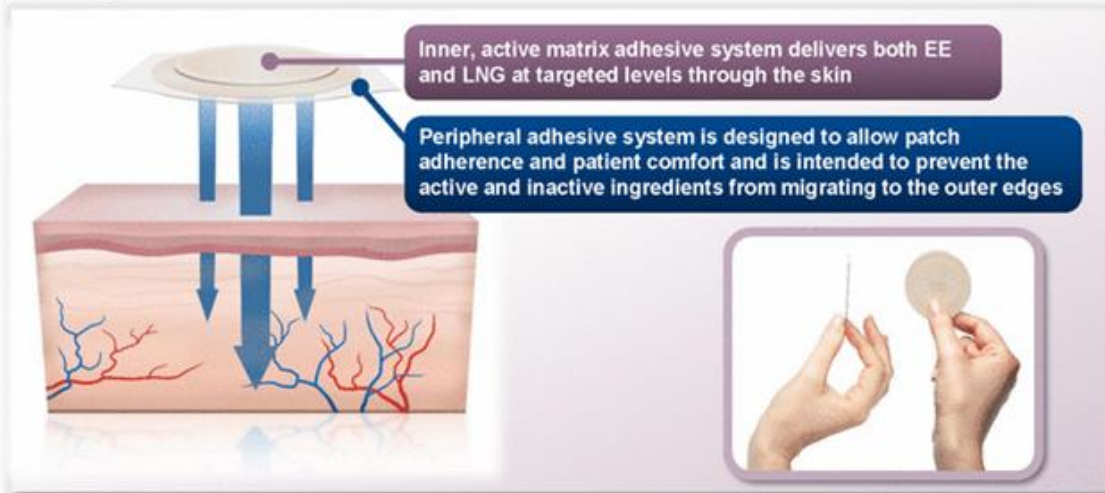
■ ■ ► = Indicates phase to enter following patch development



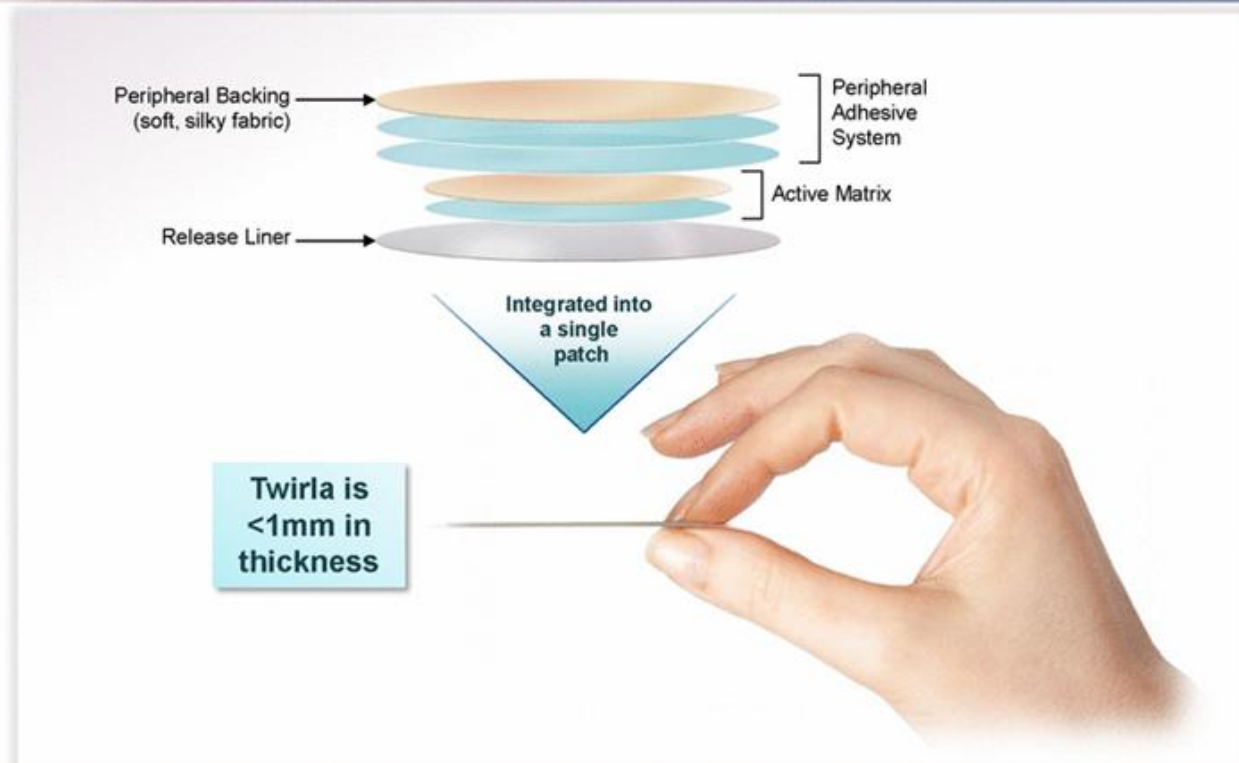
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Twirla is a Low-Dose Contraceptive Patch





- 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



Skinfusion Technology in Twirla



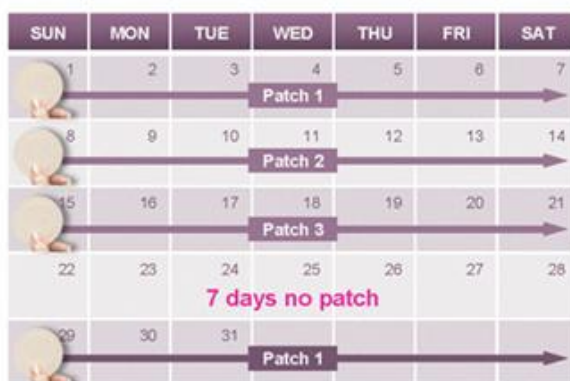
Agile Exclusivity/Competition Strategies for Twirla

	Expected Hatch-Waxman exclusivity (3 years)
	6 issued patents to list in Orange Book <ul style="list-style-type: none"> • Issued patents expire in 2021 (4) & 2028 (2) • Additional patents under prosecution
	Limited patch manufacturers <ul style="list-style-type: none"> • Specialized equipment
	Transdermal know-how
	Agile pipeline / line extensions



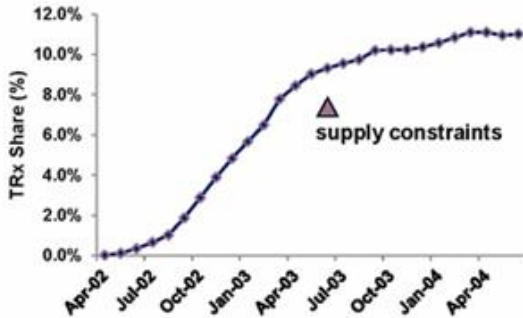
How Would Women use Twirla?

- **21/7- day regimen like many birth control pills**
 - Women apply a patch once-a-week for three weeks followed by 4th week without a patch
- **Can be applied to abdomen, buttock, or upper torso**



Evra Contraceptive Patch History

Ortho Evra quickly gained share: the most successful contraceptive launch

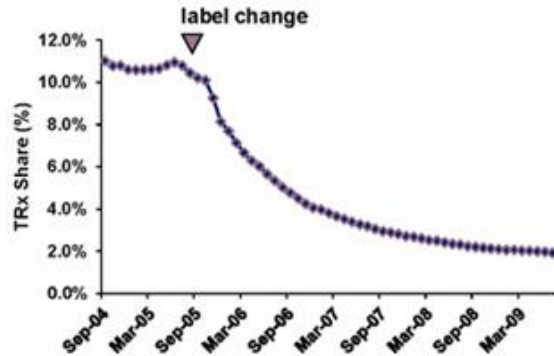


Ortho Evra – A Meteoric Rise...

- Most successful contraceptive launch in history
- Reached TRx share of 11% and nearly \$400 million in annual sales in 2004
- Labeled as 20µg/day EE
- Sales hampered by supply constraints

...and a precipitous fall

- Thromboembolic events (VTEs) reported to FDA
- Study published in 2005 showing higher EE levels than ring and low-dose pill
- Bolded warning added to Evra label in Nov 2005
- Johnson & Johnson stopped active promotion
- Mylan launched Evra generic in April 2014



Twirla Product Profile Compared to Ortho Evra

Comparison of Twirla and Evra Product Characteristics*

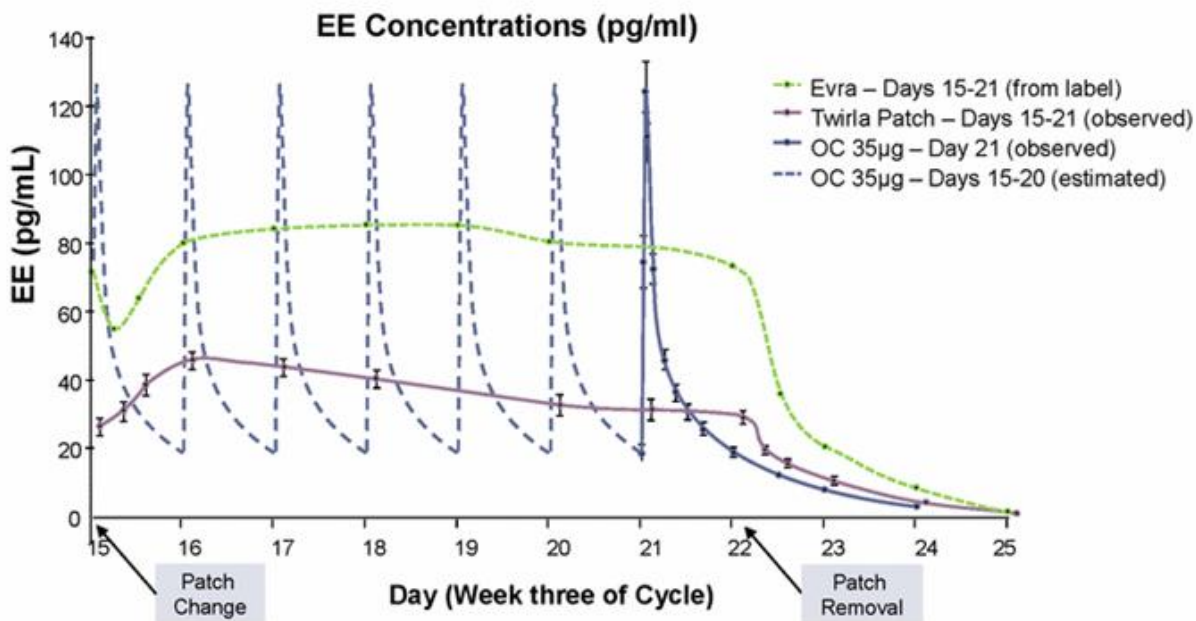
Characteristic	Twirla (levonorgestrel/ethinyl estradiol) transdermal system	Ortho Evra (norelgestromin/ethinyl estradiol) transdermal system
Form of product	Transdermal patch Round, approximately 28 square centimeters Soft, silky, stretchy fabric	Transdermal patch Square, approximately 20 square centimeters Smooth, plastic film
Active ingredients	EE, LNG	EE, norelgestromin
Pharmacokinetic profile EE delivered per day	~30 micrograms	60% higher than that of an oral contraceptive containing 35 micrograms (~56 micrograms)**
Regimen	One patch weekly 21 days active/7 days patch-free	Same as Twirla
Package configurations	1 box of 3 patches = 1 cycle 1 box with 1 patch = replacement	Same as Twirla
Top four adverse events/reactions in clinical trials	Nausea 3.0% Application site irritation 2.4% Breast tenderness 2.1% Headache 2.0%	Breast symptoms 22.4% Headache 21.0% Application site disorders 17.1% Nausea 16.6%

*Information is based upon the characteristics of Twirla and other Twirla attributes observed in our Phase 3 clinical trials and the currently marketed Evra product label and publicly-available information. We have not performed a head-to-head comparison of Twirla to Evra.

**The Evra package insert indicates a strength of 35µg EE per day

Twirla PK Profile Compared to 35µg Oral Contraceptive and Ortho Evra

Lower dose of EE from Twirla compared to Evra



Data are not a head-to-head comparison of Twirla to Evra. The Evra curve was estimated based on the graph provided in the Evra label.



Sources: Archer, et al. Contraception 2012;85:595-601
Archer, et al. Oral presentation at American Society of Reproductive Medicine (ASRM), 2010

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The Path Forward – New Twirla Trial

What we believe were the issues

- CRO lacked experience with large contraceptive trials
- Poor study conduct at several clinical sites
- Study population at higher risk for non-compliance
- No utilization of technology

Why a new trial can be successful

- New Team / Chief Medical Officer - Dr. Elizabeth Garner
- New top-tier CRO - Parexel
- Data-driven site selection
- Rigorous screening of subjects
- Use of technology for improved study oversight – PHT e-diary



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Twirla Product Development Summary

- ✓ Comprehensive clinical program enrolled over 2,100 women
 - Over 1,500 women have received Twirla
 - 485 women have received Twirla for 12 months
- ✓ Pharmacokinetic profile is consistent with a low-dose contraceptive*
- ✓ Effectiveness in Phase 3 studies generally comparable to approved low-dose oral contraceptive (OC) comparators**
- ✓ 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

*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 Phase 3 Clinical Results Primary Effectiveness Measure

- Pearl Index (PI) = Pregnancies per 100 women-years of product use

$$\frac{\text{Number of On-drug pregnancies}}{\text{Number of 28-day On-drug cycles}} \quad (13) \quad (100)$$

Observed PIs in Phase 3 Trials		
Twirla Phase 3 Trials*	Pill	6.72
	Twirla	5.76
Highest PI approved to date**		3.19

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

**Quartette package insert. Quartette is a registered trademark of Teva, Inc.

Impact of New Users and Minorities on Twirla PI

- We believe clinical results were affected by study conduct issues at several sites
 - 36% of on-drug pregnancies reported at 4 of 96 sites*
- Study population comprised high proportion of new users and minorities who are known to be at higher risk of non-compliance and pregnancy**
 - New users had ~3 times higher non-compliance than experienced users
 - These factors impacted the observed PIs

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

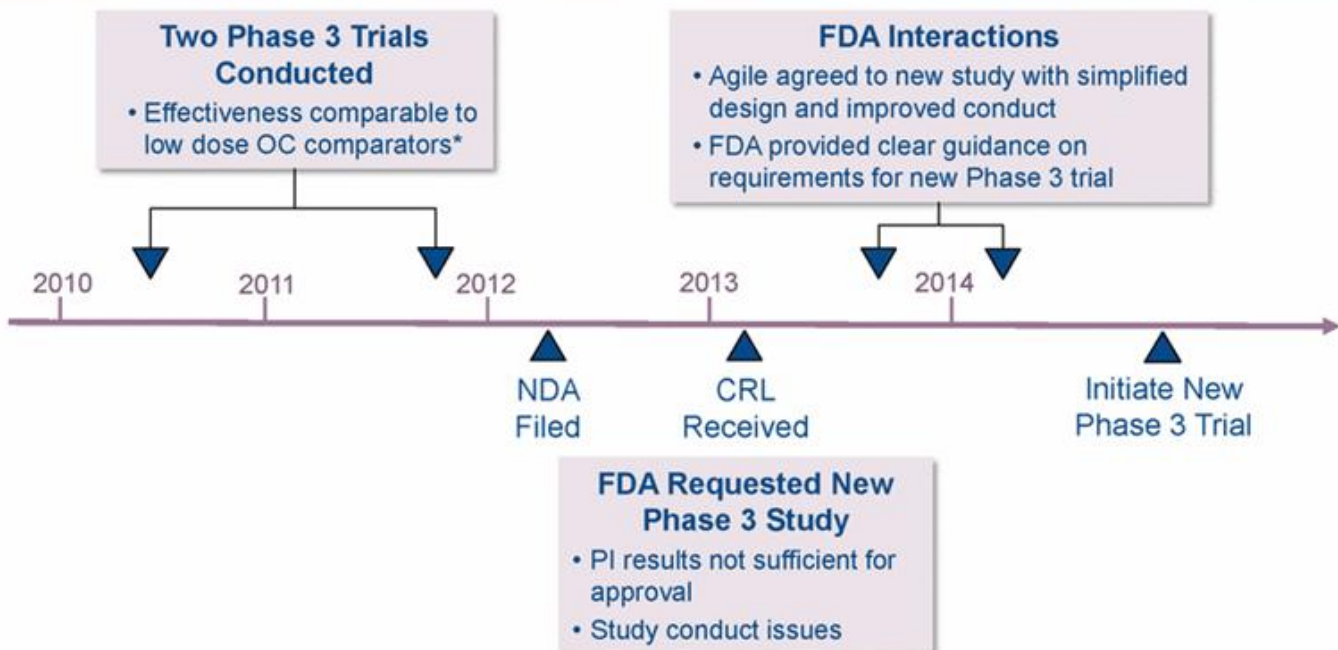
**Hatcher, et al. Contraceptive Technology 20th Ed, 2011, page 50 and Pooled data from 2 clinical trials, CL-12 and CL-13. Data on File, Agile Therapeutics. CRL response to FDA, Aug 2013



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Twirla Regulatory Interactions and Path Forward



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

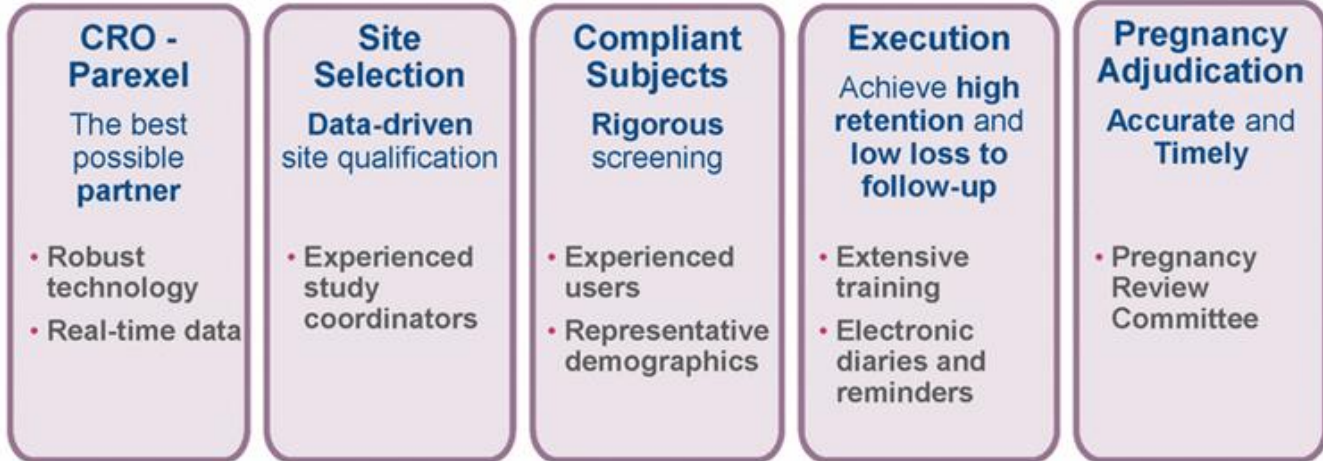


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Planned Twirla Phase 3 Trial

- Single-arm, open-label study
- ~2,000 sexually active subjects will receive Twirla for up to one year
- 50 to 70 sites U.S. sites



Twirla Value Proposition




Right product and right dose for physicians and patients

- Patch designed to offer convenience and compliance
 - Physicians want products that offer their patients convenience → give them confidence in compliance
- Selection of hormones at right dose
 - Levonorgestrel is one of the progestins with the lowest risk of VTE
 - Over 25 years of market experience
 - Delivers low daily dose (~ 30µg) of ethinyl estradiol
- Has unique selling proposition for patients
 - Offers convenience and compliance
 - Fits with the busy lifestyle of today's women



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 III Responding to CRL
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 I/II trial conducted Additional product development required

Combination Hormonal Contraceptive Market is a Large Opportunity



Leading Brands	Form	2013 Sales (\$Millions)
Nuvaring (Merck)	Ring	\$569
Tri-Cyclen-Lo (Johnson & Johnson)	Pill	\$469
Loestrin/Minastrin 24 (Actavis/Warner Chilcott)	Pill	\$413
LoLoestrin (Actavis/Warner Chilcott)	Pill	\$272
Evra (Johnson & Johnson)	Patch	\$152
Beyaz (Bayer)	Pill	\$111
Generess (Actavis)	Pill	\$82
Yaz (Bayer)	Pill	\$53

CHC Products Recently Approved and In Development

Contraceptive Patch Products

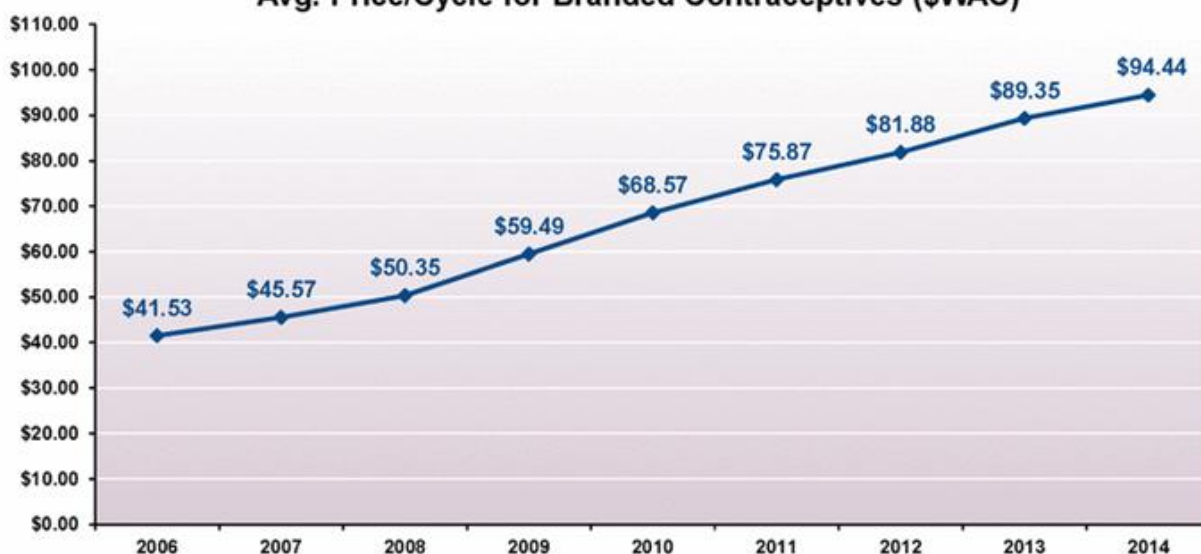
Product	Description	Status
Xulane™ (Mylan)	Generic equivalent to Ortho Evra Same label as Evra	Launch announced Apr 2014 WAC price = \$95.12/cycle
Bay86-5016 (Bayer)	Transdermal Patch containing: Gestodene + EE 20ug/d Transparent patch	US Phase III completed Sep 2010 US NDA not submitted Approved in Europe, Feb 2014

Other CHC Products in Development

Product	Description	Status
DR-102 (Teva)	Oral contraceptive	Phase III
Nomac/E2 (Merck)	Oral contraceptive	Phase III
Yaz Flex (Bayer)	Oral contraceptive	Phase III
Vaginal Ring (Actavis & Pop Council)	Vaginal Ring	Phase II
Nestragel™ (Antares & Pop Council)	Topical gel contraceptive	Phase II
Estelle (Actavis)	Oral contraceptive	Phase II

Branded Contraceptives Continue to Take Aggressive Price Increases

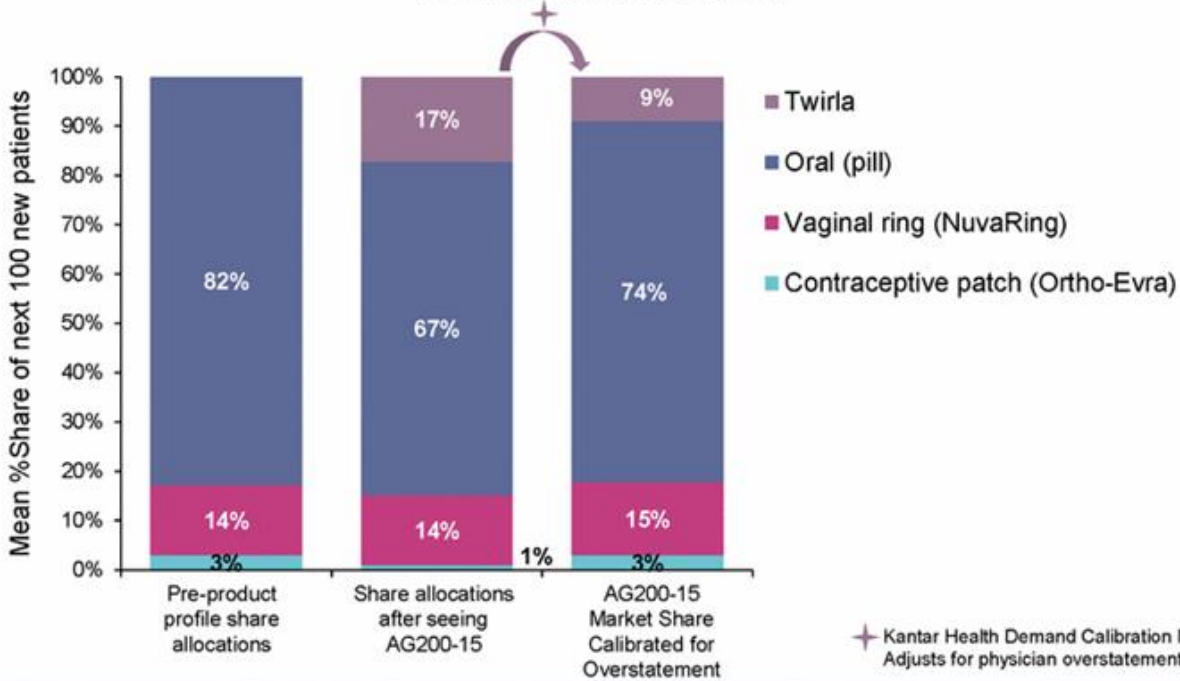
Avg. Price/Cycle for Branded Contraceptives (\$WAC)



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%	5.6%

ObGyns Estimate Use of Twirla in 9% of New Contraceptive Patients

Product Share Allocations: Pre- and Post- Twirla Product Profile
% of next 100 new patients



Source: Contraceptive Patch Assessment Study (n=152 ObGyns), Kantar Health, Dec 2010

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Twirla has Significant Peak Revenue Potential

Revenue Potential for each Market Share Point is Significant

$$\begin{array}{ccccccc}
 \boxed{88 \text{ Million TRx}} & \times & \boxed{\$88 \text{ per cycle}} & \times & \boxed{1.4 \text{ cycles/TRx}} & \times & \boxed{1\%} = \boxed{\$108 \text{ Million}} \\
 \text{(Total Market, 2013)} & & \text{(Avg. WAC, 2013)} & & \text{(Avg. Rx size, 2013)} & & \text{per 1\% TRx share}
 \end{array}$$

AG200-15 Annual Peak Sales Projection Based on Market Share Potential	
9% TRx Share (based on market research)	\$972 Million

Sources: IMS NPA Dec 2013 and Wolters Kluwer Price Rx Select, Sep 2013



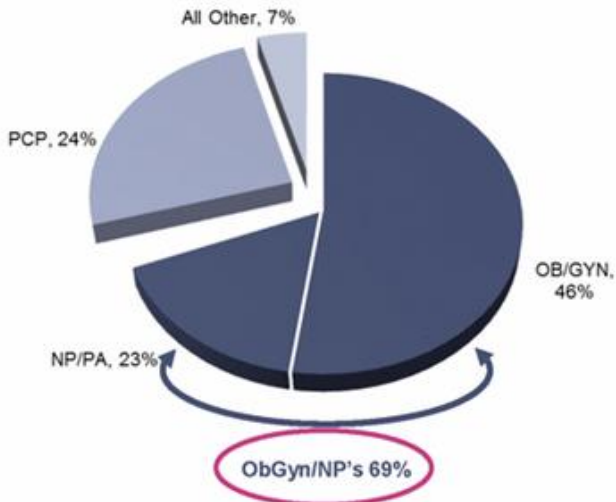
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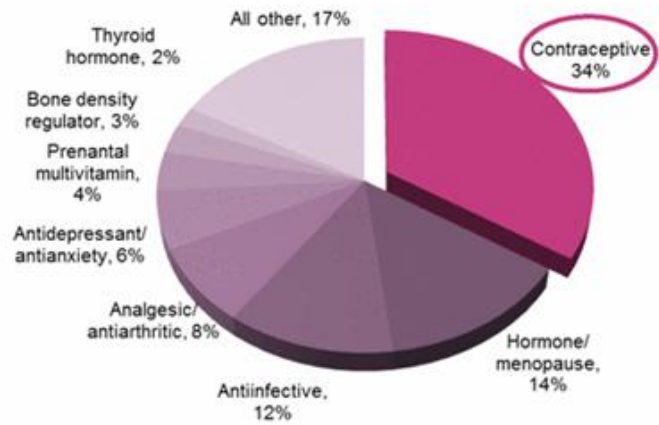
ObGyn Focus on Contraceptives Allows for Small Sales Force of ~70 to 100 Representatives

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

Contraceptive TRx Volume by Prescriber Type



ObGyn TRx Volume by Category



Agile is Prepared for Commercial-Scale Manufacturing



Agile has an exclusive agreement with Corium International, Inc.

- Corium responsible for all aspects of manufacturing
- Substantial build-out of manufacturing facilities completed
- Robust process developed for commercial-scale manufacturing
- >\$10 Million investment by Agile in commercial-scale equipment
- Same process for clinical trials and commercial materials

Financial Profile

Background

- Founded in 1997
- Approximately **\$121.2 Million** of funding from inception to December 31, 2013
- Non-dilutive sources of capital
 - **\$15 Million** venture debt (Dec 2012)
 - **\$3.6 Million** from sale of state NOLs (Feb 2014)
- **\$3.0 Million** cash on hand at 3/31/14
 - **\$3.0 Million** bridge financing (Apr 2014)

Use of proceeds

- **\$55.0 Million** gross proceeds (~**\$49.1 Million** net proceeds)
 - **\$31 Million** for additional Phase 3 clinical trial for Twirla
 - Completion of equipment validation and 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



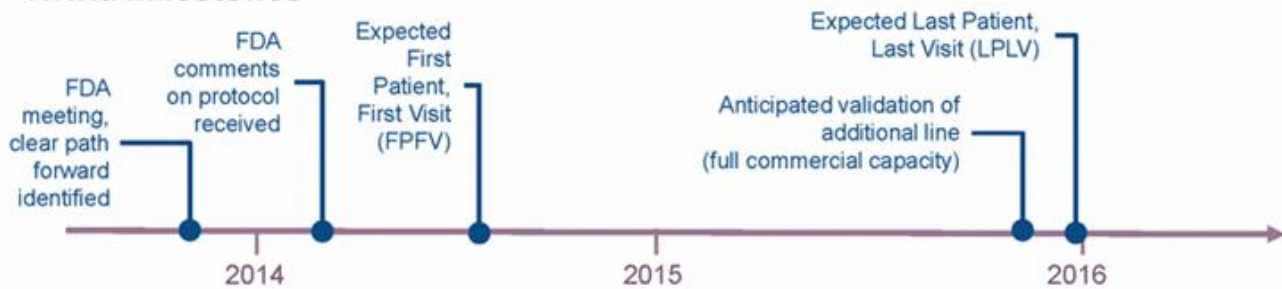
Agile Corporate Accomplishments

- ✓ Jan 2014 Elizabeth Garner, MD joined as Chief Medical Officer (CMO)
- ✓ Feb 2014 Received \$3.6 Million through New Jersey Technology Business Tax Certificate Transfer (NOL) program
- ✓ 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
- ✓ Mar 2014 Filed registration statement (S-1) for proposed initial public offering (IPO)
- ✓ Mar 2014 Katie MacFarlane, PharmD joined as Chief Commercial Officer (CCO)
- ✓ 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



Development Milestones

Twirla Milestones



Line Extensions and New Products



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