UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

	FORM 8-K	
	CURRENT REPORT	
of	Pursuant to Section 13 or 15(d) the Securities Exchange Act of 1934	
Da	July 12, 2016 ate of report (Date of earliest event reported)	
	Agile Therapeutics, Inc. ct name of registrant as specified in its charter) 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	3-1880
(Former n	name or former address, if changed since last rep	ort)
ppropriate box below if the Form 8-K is intend	led to simultaneously satisfy the filing obligation	n of the registrant under any of the follo

Check the ap owing 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 July 12, 2016, Agile Therapeutics, Inc. ("Agile") issued a press release announcing that preparations are underway for an initial Phase 2 clinical trial of a novel contraceptive regimen, which will begin the development of its pipeline beyond its current lead product candidate, Twirla®, a once weekly contraceptive patch currently in Phase 3 development. The planned Phase 2 clinical trial will examine the use of Twirla in an innovative regimen designed to allow women to experience shorter, lighter periods, using a smaller lower dose combination ethinyl estradiol/levonorgestrel patch ("SmP"). Agile has started preparations for the trial and expects to initiate dosing in the first quarter of 2017. Agile also announced that it has plans to develop an extended cycle regimen for Twirla (AG200-ER) that may also utilize the SmP with the goal of allowing women to have fewer periods each year.

On July 12, 2016, Agile also updated its corporate presentation that it intends to use in connection with presentations at conferences and meetings with investors. The updates include the information on its pipeline announced in the press release referenced above and the appointment of a new chief commercial officer, which was previously announced.

Copies of Agile's press release and presentation are attached hereto as Exhibits 99.1 and 99.2, respectively, and are hereby incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Agile Therapeutics, Inc. Press Release dated July 12, 2016.
99.2	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: July 13, 2016 By: /s/ Alfred Altomari

Name: Alfred Altomari

Title: President and Chief Executive Officer

3

Agile Therapeutics Announces Plans to Advance Contraceptive Pipeline

Preparations Underway for Phase 2 Clinical Trial of Novel Twirla® Line Extension

PRINCETON, **New Jersey**, **July 12**, **2016** - Agile Therapeutics, Inc. (Nasdaq: AGRX), a women's health specialty pharmaceutical company focused on the development and commercialization of new prescription contraceptive products, today announced that preparations are underway for an initial Phase 2 clinical trial of a novel contraceptive regimen, which will begin the development of its pipeline beyond its current lead product candidate, Twirla®, a once weekly contraceptive patch currently in phase 3 development. The planned Phase 2 clinical trial will examine the use of Twirla in an innovative regimen designed to allow women to experience shorter, lighter periods.

"Today marks an important step for Agile as we begin to execute our strategic plan to develop our pipeline of new product candidates based on Twirla," said Elizabeth Garner, M.D., M.P.H., Chief Medical Officer of Agile. "Agile's pipeline is designed to build on our current patch regimen and offer women additional, convenient non-daily contraceptive options that provide flexibility to meet their needs."

Agile plans to conduct an initial phase 2 study of a novel 28-day contraceptive patch regimen (AG200-SP) designed to optimize the bleeding profile by delivering hormones beyond the typical 21 day regimen using a smaller lower dose combination ethinyl estradiol/levonorgestrel patch (SmP) in the fourth week of the cycle. The SmP regimen is intended to allow women to experience shorter, lighter periods, an attribute that research suggests is highly desirable to women seeking hormonal contraception. The planned study is aimed at identifying the optimal dose of the SmP, and will evaluate bleeding profiles, pharmacokinetic parameters, ovulation inhibition and safety over 3 cycles of treatment. Up to 150 subjects are expected to be enrolled at highly experienced sites that are also participating in the ongoing Phase 3 SECURE clinical trial. The Company has started preparations for the study and expects to initiate dosing in the first quarter of 2017. Agile also plans to develop an extended cycle regimen for Twirla (AG200-ER) that may also utilize the SmP with the goal of allowing women to have fewer periods each year.

"Expanding our pipeline is a key element of our strategic plan," said Al Altomari, Chief Executive Officer and President of Agile. "Based on patent protection expected to extend into 2029, we believe we are in a strong position to build a women's health franchise that will enable us to be commercially competitive and expand our market potential."

About Agile Therapeutics, Inc.

Agile Therapeutics is a women's health specialty pharmaceutical company focused on the development and commercialization of new prescription contraceptive products. Our product candidates are designed to provide women with contraceptive options that offer greater convenience and facilitate compliance. Our lead product candidate, Twirla®, (ethinyl estradiol and levonorgestrel transdermal system), also known as AG200-15, is a once-weekly prescription contraceptive patch currently in Phase 3 clinical development. Twirla is based on our proprietary transdermal patch technology, called Skinfusion®, which is designed to provide advantages over

currently available patches and is intended to optimize patch adherence and patient acceptability. For more information, please visit the Company website at www.agiletherapeutics.com. The Company may occasionally disseminate material, nonpublic information on the Company website.

Forward-Looking Statement

Certain information contained in this press release includes "forward-looking statements" related to the Company's, product candidate pipeline, timing and conduct of clinical trials and potential market opportunity for its product candidates. We may, in some cases use terms such as "predicts," "believes," "potential," "continue," "anticipates," "estimates," "expects," "plans," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of the future events or outcomes to identify these forward-looking statements. Our forward-looking statements are based on current expectations that involve risks, potential changes in circumstances, assumptions and uncertainties. Any or all of the forward-looking statements may turn out to be wrong, or be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. For example, our statements about the timing and conduct of our clinical trials and our ability to potentially commercialize our product candidates, could be affected by the potential that we experience slower than expected enrollment, we identify serious side effects or other safety issues, we do not have clinical supply of our product candidate that is adequate in amount and quality and supplied in a timely fashion, and the inherent risks of clinical development; our statements about the potential commercial opportunity could be affected by the potential that our product does not receive regulatory approval, does not receive reimbursement by third party payors, or a commercial market for the product does not develop because of any of the risks inherent in the commercialization of contraceptive products. For all these reasons, actual results and developments could be materially different from those expressed in or implied by our forward-looking statements. All forward looking statements are subject to risks detailed in our filings with the U.S. Securities and Exchange Commission, including the Company's Annual Report on Form 10-K and our Quarterly Reports on Form 10-Q. You are cautioned not to place undue reliance on these forward-looking statements, which are made only as of the date of this press release. We undertake no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstances.

Source: Agile Therapeutics

Contact: Mary Coleman — 609-356-1921



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 forwardlooking 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.



Corporate Overview

Significant Near-Term Market Opportunity

- ~\$5.6 Billion US contraceptive market in 2015, with \$4.0 Billion in combined hormonal contraceptives (CHC)
- Lead product candidate, Twirla[®], Phase 3 trial expected to complete in 4Q 2016, submission in 1H 2017
- Twirla expected to be the first non-oral CHC brand* introduced in over 15 years and is designed to be an improvement on the currently available contraceptive patch

Agile is Building a Robust Contraceptive Franchise

- Additional unique product candidates in the pipeline designed to 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 pre-approval inspection completed, commercial scale-up ongoing

Agile is Well-Positioned for Successful Twirla Market Entry

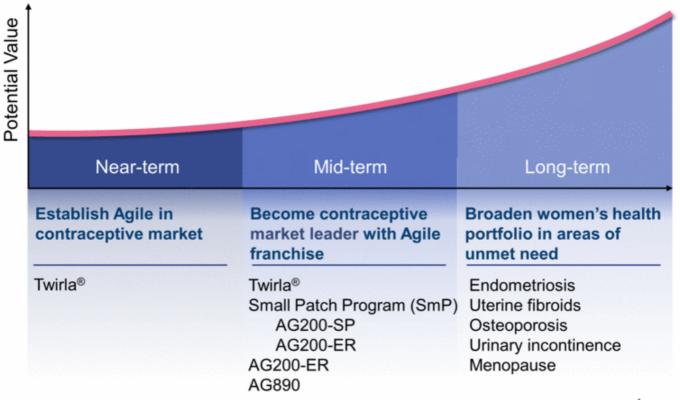
- Twirla is expected to be the only low-dose CHC patch, if approved
- Physicians and consumers show high interest in a low-dose patch
- Managed care environment for contraceptives is generally favorable
- Specialty focus and target consumer should allow for efficient marketing execution
- Agile team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



7.11.2016

*Brand is defined as products approved under an NDA

Corporate Strategy: Become a Leader in Women's Health



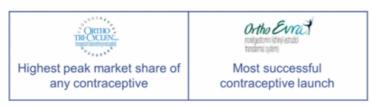


Executive Management Team

Deep Experience in Women's Healthcare and Contraceptive Products

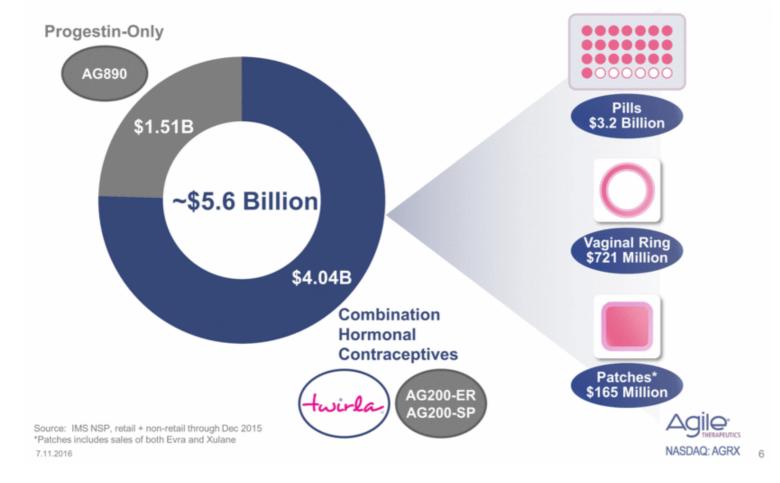
Al Altomari President and Chief Executive Officer	Johnson Johnson Barrier Therapeutics Turning Science into Practice
Scott Coiante Vice President and Chief Financial Officer	MEDAREX EY
Elizabeth Garner, M.D., M.P.H. Sr. Vice President and Chief Medical Officer	MYRIAD abbyie • MERCK
Renee Selman Chief Commercial Officer	Johnson Johnson CATALINA ETHICON Women's Health & Urology inVentiv Health

Agile team members have commercialized successful contraceptive brands

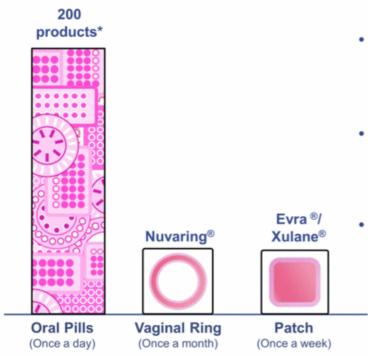




US Hormonal Contraceptive Market is a Significant Opportunity



Only 2 Non-Oral CHC Forms Have Been Approved



- Non-oral CHCs have reached significant peak market shares
 - Evra 11.1% (in 2005)
 - Nuvaring 6.6% (in 2014)
- The current market leader is a non-oral product
 - Nuvaring 2015 annual sales \$721 Million
- The most successful contraceptive launch was a non-oral product
 - Evra reached 10% TRx share in 18 months after 2002 launch

Evra is a registered trademark of Johnson & Johnson, Inc.; Xulane is a registered trademark of Mylan, Inc.; Nuvaring is a registered 7.11.2016 trademark of Merck & Co., Inc.



Forms of CHC Approved

^{*}includes brands and generic products (brands defined as products approved under an NDA, generics approved under an ANDA)
Source: IMS NPA and NSP, through Dec 2015

Twirla® is our Lead Product Candidate

- Twirla is a once-weekly contraceptive patch
 - Only one other contraceptive patch is available in the United States
 - Twirla is designed to deliver 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 in Phase 3, with completion of trial expected in 4Q 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	6	5	6	7
8	9	1 0	11	12	13	1 4
15	16	1 7	18	19	20	2 1
22	23	O ²⁴	25	26 0	27 0	28

Patch Regimen: Once a week

SUN	MON	TUE	WED	THU	FRI	SAT	
	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







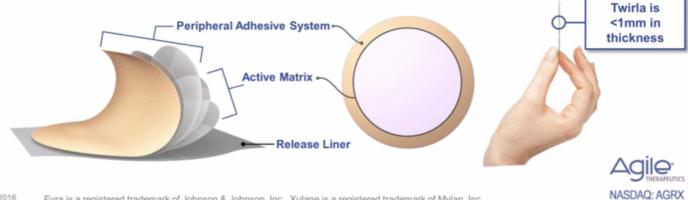


7.11.2016 Source:

Source: Qualitative and quantitative consumer research, RG&A 2012. Data on File, Agile Therapeutics

What Makes Twirla® Different?

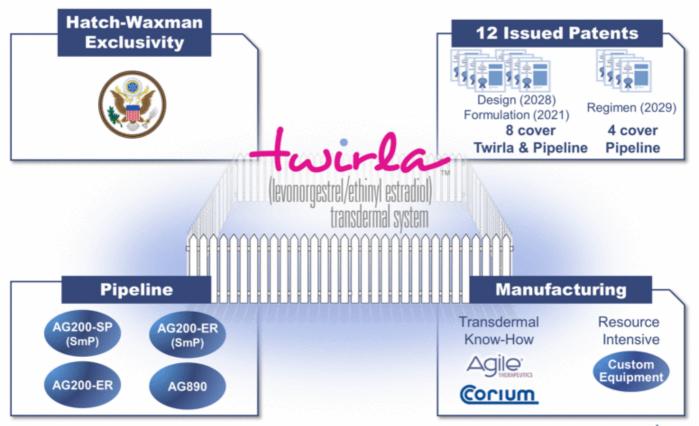
- There is only one other patch on the market, and Twirla is expected to be the only low-dose contraceptive patch
 - Delivers ~30µg/day EE
 - Evra®/Xulane® delivers ~60% more EE than a 35µg pill
- Twirla is the first and only product candidate designed to deliver LNG through the skin at a contraceptive 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 in the central active matrix, designed to allow the peripheral adhesive system to keep the patch in place for 7 days



7.11.2016

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

Intellectual Property Strategies For the Franchise

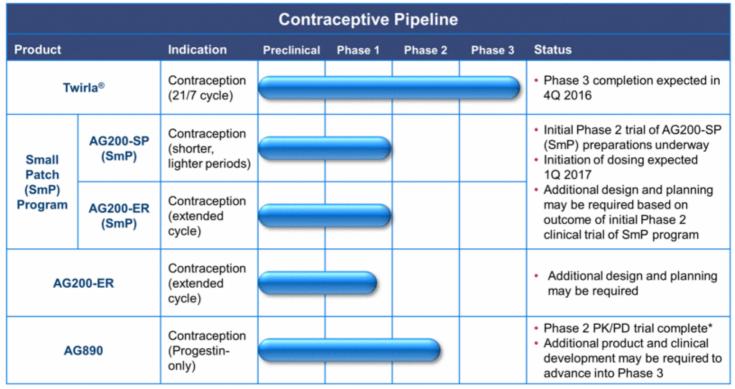


NASDAQ: AGRX

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Pipeline Strategy: Establish a Market-Leading Contraceptive Franchise



^{*}Data analysis from Phase 2 trial is under evaluation

Agile°
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12

Pipeline Products: Offering More Options For Women

twirla **Current lead** product candidate in Phase 3

SUN	MON	TUE	WED	THU	FRI	SAT		
	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								

Small Patch (SmP) product candidates in development

AG200-SP



AG200-SP: 4-week regimen

- · Designed for shorter, lighter periods
- · Small patch (SmP) is a smaller, lower dose LNG/EE patch worn in the 4th week of a cycle

AG200-ER: 8-week extended cycle regimen

- Designed for fewer periods a
- · Small patch (SmP) worn in 8th week



Small patch -



Planned Initial Phase 2 Trial with Small Patch (SmP)

Study Plan

- Up to 150 subjects to be enrolled at highly experienced sites that are also participating in the ongoing Phase 3 SECURE trial
- Initiation of dosing expected in 1Q 2017

Clinical **Objectives**

- Identify optimal dose for SmP
- Characterize:
 - Withdrawal bleeding profile
 - Ovulation inhibition
 - Side effects

Business Objectives

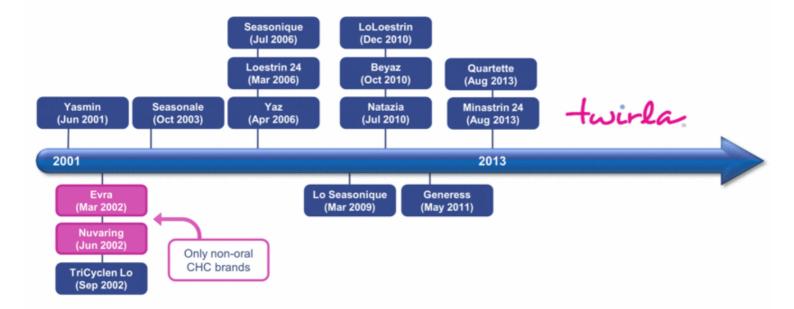
- Expand business franchise to increase Agile potential share of the contraceptive market
 - Current 3-month fixed regimen products = <4% TRx share*
 - A larger opportunity may exist; up to 17% of women use 21-day regimens consecutively to extend the time between their periods
- Capitalize on patents into 2029

*Percentage of TRx in CHC market 2015 for Seasonale, Seasonique, LoSeasonique and all generics, IMS NPA Source: Lakehomer H, et al. Characteristics of scheduled bleeding manipulation with combined hormonal contraception in university students. Contraception 2013; 88:426-430



There is a Market Need for New Contraceptive Brands

- Twirla® would be the first new CHC brand introduced since 2013
- Twirla would be the <u>first non-oral CHC brand</u> introduced since 2002



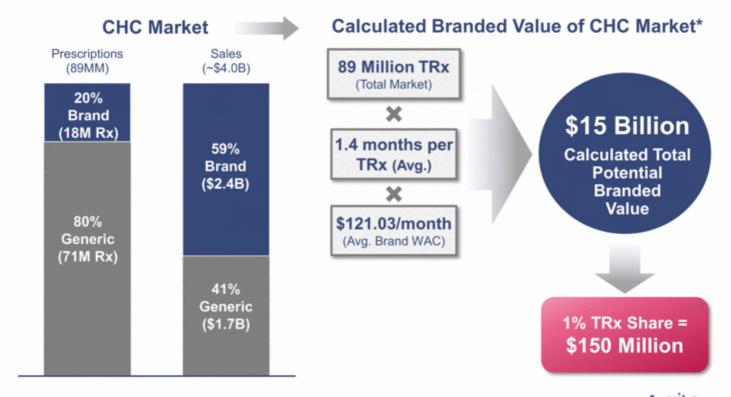
TriCyclen and Evra are registered trademarks of Johnson & Johnson, Inc.; Nuvaring is a registered trademark of Merck & Co., Inc.; Yasmin, Yaz, Beyaz and Natazia are registered trademarks of Bayer; Loestrin, Generess and Minastrin are registered trademarks of Allergan, Inc.; Seasonale, Seasonique and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

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15

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



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*Market value if all prescriptions were branded, to demonstrate value of 1% TRx share of a brand Sources: IMS NPA Dec 2015 and MediSpan Price Rx Select, March 2016

Twirla® Marketing Plan is a 3-Pronged Approach

ObGyn/NP Specialty Market

- Specialty market allows for an estimated 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 brands means opportunity for Twirla® to have high share of voice

Targeted Consumer Segment

- · 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

Managed Care

 Affordable Care Act (ACA) Contraceptive Mandate provides a potentially favorable Managed Care environment for Twirla®



"This is good. There was a void after we stopped using Ortho Evra...patients like the patch."*

> "I'm excited. Patients ask for the patch all the time."*



"Birth control without the stress"*



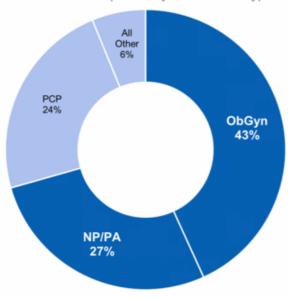


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ObGyns and Nurse Practitioners are the Key Contraceptive Prescribers

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

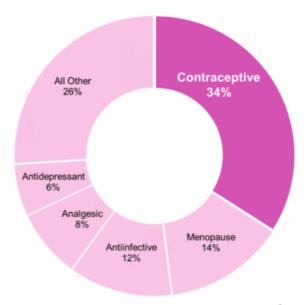
CHC Prescriptions by Prescriber Type



Source: IMS NPA, TRx Volume by Prescriber Type, 2015 Source: IMS NPA, TRX Volume by Category, 2010 7.11.2016

ObGyns Prescribe Contraceptives More than any Other Therapy

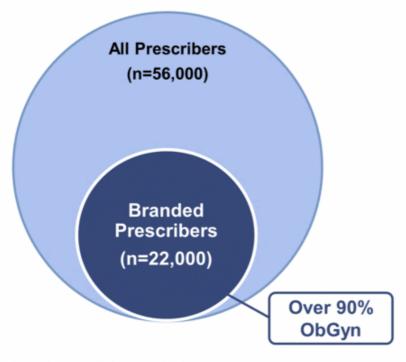
ObGyn TRx by Category





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

US Contraceptive Prescribers



Detailing



Samples



Medical Education



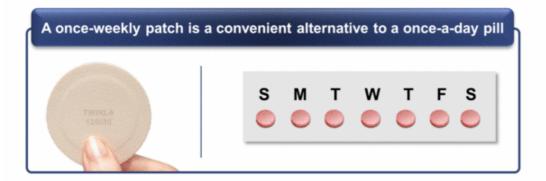
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NASDAQ: AGRX

Source: Wolters Kluwer 2012 (# of prescribers) and IMS Prescriber Profiler 2009: %TRx written by ObGyns in Dec 3-10 of contraceptive writers 7.11.2016

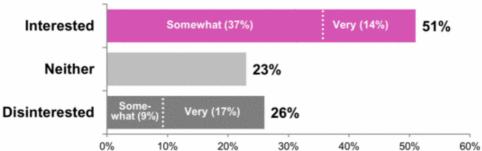
We Know the Twirla® Target Consumer

Women would choose Twirla® because they are busy











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

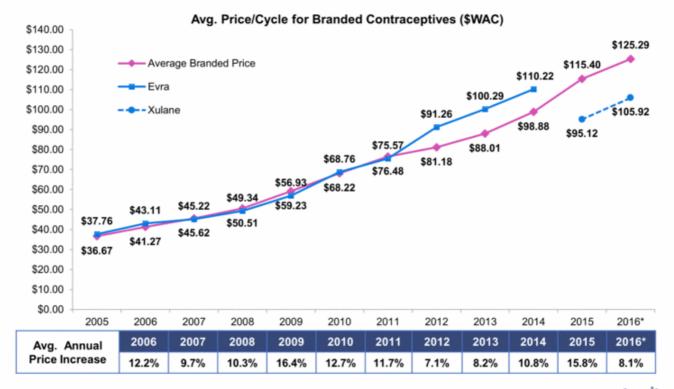


7.11.2016 Sources: Survey of 1000 women age 15-44, RG&A 2012. Data for 'seekers' (n=565) considering starting birth control and Pew Research

IASDAQ: AGRX

Branded Contraceptives Continue to Take Aggressive Price Increases

The current highest WAC for a branded combination contraceptive is \$150.55



Source: MediSpan Price Rx Select, July 2016. *Values for 2016 are YTD through July 7, 2016 Avg. Price/cycle calculation includes 13 leading branded contraceptive products.



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) are expected to be the only 2 products available in patch form
- Xulane current price = \$105.92/cycle

If Twirla® is the preferred patch:

Patients will be able to fill a prescription with

- no copay
- no deductible
- no coinsurance



Possible Formulary Scenarios

If Twirla is not the preferred patch:

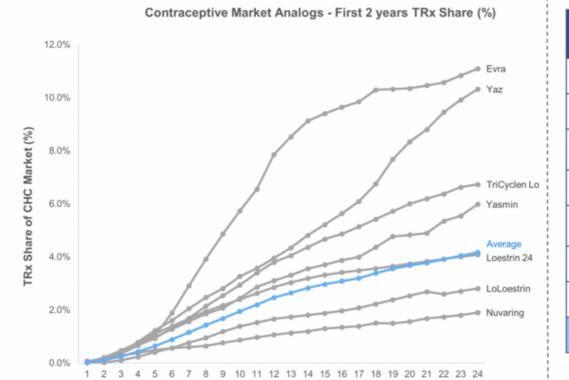
Most branded contraceptives are on Tier 3 or 4

- 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 *Event sponsored by Agile Therapeutics



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



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

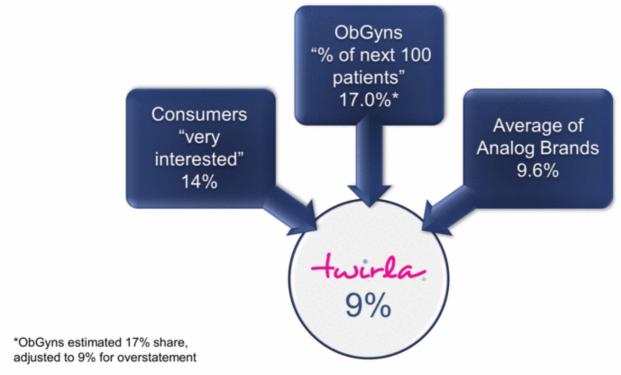
Month from Launch

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Twirla® Peak Share Estimate Rationale

Based on Consumer & Physician Market Research and Market Analogs



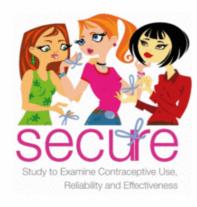
Sources: IMS NPA, 2002-2014

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"



Twirla® Phase 3 Trial Expected to Complete in 4Q 2016



Simplified Study Design:

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

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

Note: Highest approved by FDA to date:

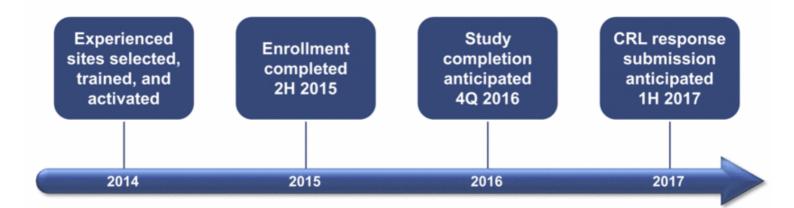
- Pearl Index = 3.19
- Upper bound of the 95% confidence interval around the PI = 5.03

*Usable cycles defined as: on-drug, completed diary, sexually active, no backup contraception.

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

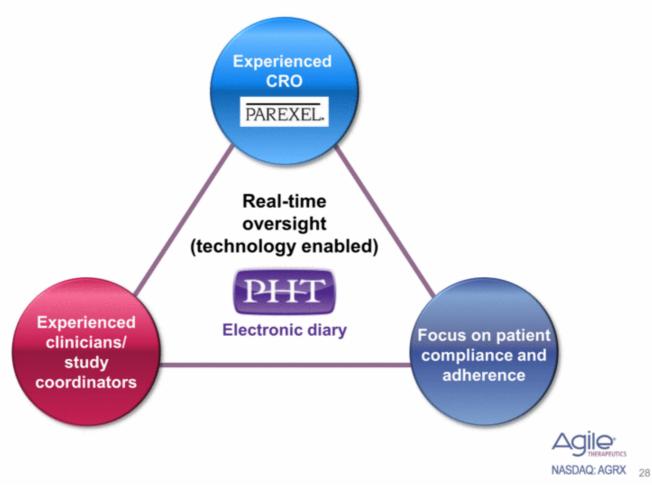


Reliability and Effectiveness



NASDAQ: AGRX 27

Why We Believe The SECURE Study Will be Successful



Development Milestones

	2016		20	17
Planned Milestones	1H	2H	1H	2H
Completion of Twirla® SECURE clinical trial: 4Q 2016				
Potential submission of Twirla CRL response: 1H 2017				
Potential approval of Twirla (assuming 6 month FDA review): 2H 2017				
Qualification of commercial manufacturing line (ongoing) for Twirla: 2H 2016		•		
Small Patch (SmP) program initial Phase 2 clinical trial preparations: 2H 2016				
SmP Program initial Phase 2 clinical trial initiation of dosing expected: 1Q 2017				



Financial Profile

Balance Sheet Data

- \$65.5 Million cash on hand at March 31, 2016
- 28.7 Million common shares outstanding at May 5, 2016

Background and Recent Financings

- Initial Public Offering (May 2014)
 - \$55.0 Million gross proceeds (~\$49.7 Million net proceeds)
- Private Placement (January 2015)
 - \$20.0 Million gross proceeds (~\$19.3 Million net proceeds)
- Debt Facility of up to \$25.0 Million (Hercules Capital) (February 2015)
 - \$16.5 Million funded at loan closing (primarily to repay prior debt)
- Follow-on Public Offering (February 2016)
 - \$40.25 Million gross proceeds (~\$37.5 Million net proceeds)

Agile°
NASDAQ: AGRX

Corporate Summary

- ✓ Near-term catalyst Phase 3 completion expected in 4Q 2016
- ✓ Phase 3 asset in multi-billion dollar market
- ✓ Twirla® expected to be the first low-dose alternative to an oral CHC introduced in over 15 years
- ✓ Pipeline with expected patent protection to 2029, initial Phase 2 trial preparations underway
- **✓** Targeted specialty market commercialization
- **✓** Favorable managed care environment
- ✓ Management team with proven success launching contraceptive products

Agile*
NASDAO: AGRX

7.11.2016

31



