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

October 10, 2017
Date of report (Date of earliest event reported)

Agile Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-36464**	**23-2936302**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

101 Poor Farm Road **Princeton, New Jersey**	**08540**
(Address of principal executive offices)	(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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425).

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12).

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)).

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter

Emerging growth company x

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. x

Item 7.01. Regulation FD Disclosure.

On October 10, 2017, Agile Therapeutics, Inc. ("Agile") will host its first analyst day presentation ("Analyst Day"). Members of Agile's executive team will review clinical data and discuss the commercialization plan for Twirla®, the company's lead investigational once weekly low-dose prescription contraceptive patch. Management will be joined by leading external experts who will provide clinical perspectives on Twirla, as well as regulatory and market access insights into today's contraceptive marketplace.

The Analyst Day will be webcast live. To access the live webcast, visit the Investor Relations section of Agile Therapeutics website at www.agiletherapeutics.com. A replay will be available on the company's website.

Copies of Agile's presentation that it intends to use in connection with Analyst Day is attached hereto 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 Number	Description
99.1	Agile Therapeutics, Inc. Presentation dated October 10, 2017.

SIGNATURES

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

Agile Therapeutics, Inc.

Dated: October 10, 2017

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

Agile® THERAPEUTICS

A Forward Thinking Women's Health Company
NASDAQ: AGRX

Analyst Day *October 10, 2017*

Welcome and Introduction

Al Altomari, Chairman and CEO

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 continue as a going concern; 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. For additional information about the risks and uncertainties that may affect our business please see the factors discussed in "Risk Factors" in the Company's Annual Report on for 10K for the year ended December 31, 2016 and in the quarterly reports filed with the SEC.

Agenda

Introduction - 11am ET

Overview of Agile Therapeutics - *Al Altomari, Chairman & CEO*
Contraceptive Market Landscape - *Renee Selman, Chief Commercial Officer*

Clinical Discussion - 11:15am

Perspective from Clinical Practice - *Robin Kroll, MD, FACOG*
SECURE Trial Results - *Elizabeth Garner, MD, MPH, Chief Medical Officer*
Perspective on Efficacy, Effectiveness, and the Pearl Index - *David J. Portman, MD, FACOG*
Regulatory Perspective - *Minnie Baylor Henry, JD, RPh*

Q&A, Break - 11:55am

Commercial Launch - 12:20pm

Market Access: Policy Perspective - *Adaeze Enekwechi, PhD, MPP*
Commercial Launch- *Renee Selman, Chief Commercial Officer*

Closing Remarks, Q&A - 1pm

A Look to the Future - *Al Altomari, Chairman & CEO*

Corporate Strategy: Become a Leader in Women's Health

Significant Near-Term Market Opportunity

Twirla™
(levonorgestrel/ethinyl estradiol)
120/30 mcg/day transdermal system

Low-dose, Weekly Contraceptive Patch

PDUFA Goal Date
December 26, 2017

$3.9B Addressable Market

Agile is Well-Positioned for Successful Twirla® Market Entry

- Experienced leadership team with the ability to execute
- Cash position expected to support launch
- Launch planning well underway

Agile is Building a Robust Women's Health Franchise

Establish Agile in Contraceptive Market with Lead Product Candidate → Become Contraceptive Market Leader with Product Pipeline → Broaden Women's Health Portfolio in Areas of Unmet Need

*Brand is defined as products approved under an NDA, Source: IMS NSP and NPA through Dec 2016

Executive Management Team

Deep Experience Including Women's Healthcare and Contraceptive Products

Al Altomari
Chairman and Chief Executive Officer

Johnson & Johnson · Barrier Therapeutics (Turning Science Into Practice) · Ortho Tri-Cyclen

Elizabeth Garner, MD, MPH
Sr. Vice President and Chief Medical Officer

MYRIAD · abbvie · MERCK

Renee Selman
Chief Commercial Officer

Johnson & Johnson · inVentiv Health · Ortho Evra · ETHICON Women's Health & Urology

Scott Coiante
Vice President and Chief Financial Officer

MEDAREX · EY

Geoff Gilmore
General Counsel

Bristol-Myers Squibb · Amicus Therapeutics

TriCyclen and Evra are registered trademarks of Johnson & Johnson, Inc.

Building Our Leadership Team: A Snapshot of New Hires

Joseph Chiodo III

Senior Medical Director

Lawrence Levey

Senior Director, Supply Chain

Emily Santaspirt (Riggins)

Senior Product Manager

Gregg Weinstein

Senior Director, Commercial Operations

Welcome and Thank You to Our Guest Speakers

Robin Kroll, MD, FACOG
Perspectives from Clinical Practice

Director, Seattle Women's: Health, Research, Gynecology
SECURE Trial Investigator

David J. Portman, MD, FACOG
Perspective on Efficacy, Effectiveness, and the Pearl Index

Director Emeritus, Columbus Center for Women's Health Research
CEO and Chief Medical Officer, Sermonix Pharmaceuticals

Minnie Baylor Henry, JD, RPh
Regulatory Perspective

Executive Partner, YourEncore
Former Director, Division of Drug Marketing, Advertising and Communications (DDMAC), Food and Drug Administration
Former Worldwide VP, Regulatory Affairs, Johnson & Johnson

Adaeze Enekwechi, PhD, MPP
Market Access - Policy Perspective

VP, McDermottPlus Consulting in Washington, D.C.
Former Associate Director for Health Programs, White House Office of Management and Budget under President Obama

Guest speakers will be compensated by Agile Therapeutics to speak at the event

Contraceptive Market Landscape

Renee Selman, Chief Commercial Officer

The Twirla® Opportunity

Twirla™

LOW DOSE

Expected to be the first and only low-dose contraceptive patch, delivering ~30µg/day EE

NON-DAILY

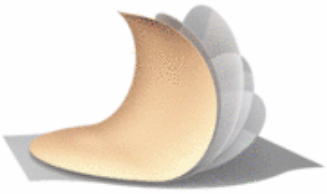
IN CONTROL

Less invasive than some methods (vaginal ring, IUDs, injections, implants)

"I want to eliminate the forgetfulness… but I don't want to lose that control either."
- Consumer, October 2016

Source: Qualitative consumer market research, Adelphi Research 2016

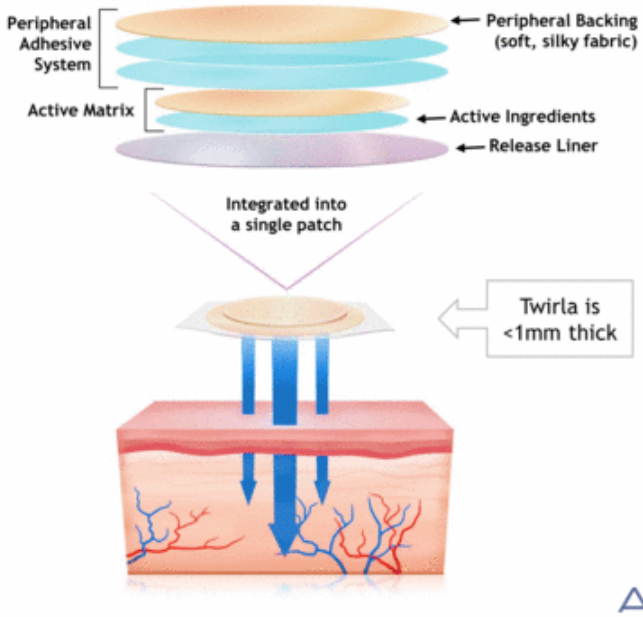
Proprietary Skinfusion® Technology for Improved Adhesion



Skinfusion® technology is designed to:

Improve 7-day adhesion
Minimize adhesive breakdown that causes "black ring"

Twirla® can be worn on the buttock, abdomen, or upper torso



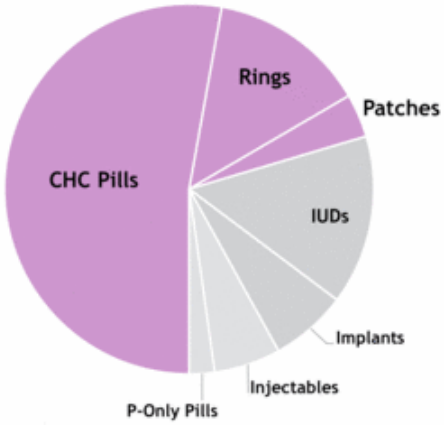
U.S. Hormonal Contraceptive Market is a Significant Opportunity

$5.5 Billion US Contraceptive Market in 2016		
Combined Hormonal Contraception (CHC)	**Progestin-Only (P-Only)**	**Long Acting Reversible Contraception (LARC)**
Pill, Patch, Ring	P-only Pill, Injection	IUD, Implant
$3.9 Billion	$443 Million	$1.2 Billion

Addressable Market

Twirla™

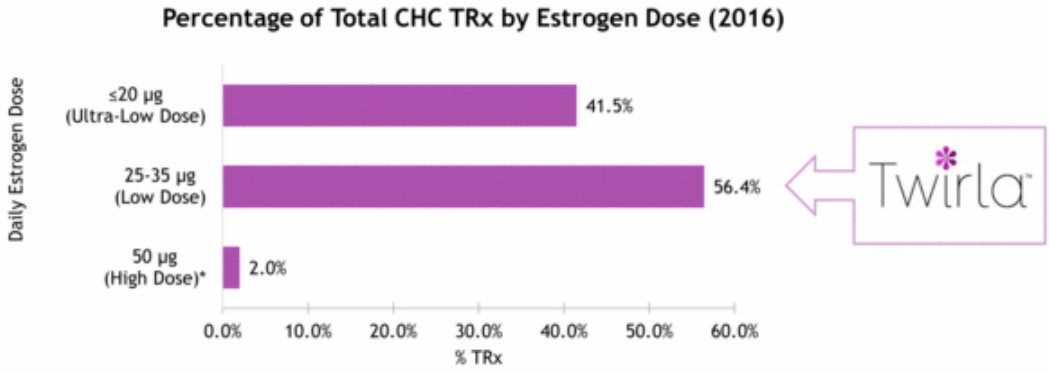
CHC Pills+Patch+Ring
=
$3.9 Billion



P-only Pills category includes emergency contraceptive prescriptions. Not Shown: "All Other" category with <1M TRx
Sources: IMS NSP through Dec 2016; ACOG FAQs

Majority of the CHC Market Demand Falls in Low-Dose Category

- Low-dose products, those delivering 25-35ug of estrogen, represented over half of the total CHC prescriptions in 2016
- Twirla® is designed to deliver ~30µg/day ethinyl estradiol (EE)



*Includes Ortho Evra and Xulane. While Evra and Xulane are labeled as 35µg, their second black box warning indicates the product delivers approximately 60% more estrogen that an oral contraceptive containing 35µg of estrogen.
Source:. IMS NPA through Dec 2016

Non-Daily CHC Forms Have Appeal For the Market

The current CHC market leader is a non-daily product

- Nuvaring annual sales for 2016 were $786 Million

Non-daily CHCs have reached significant peak TRx market shares

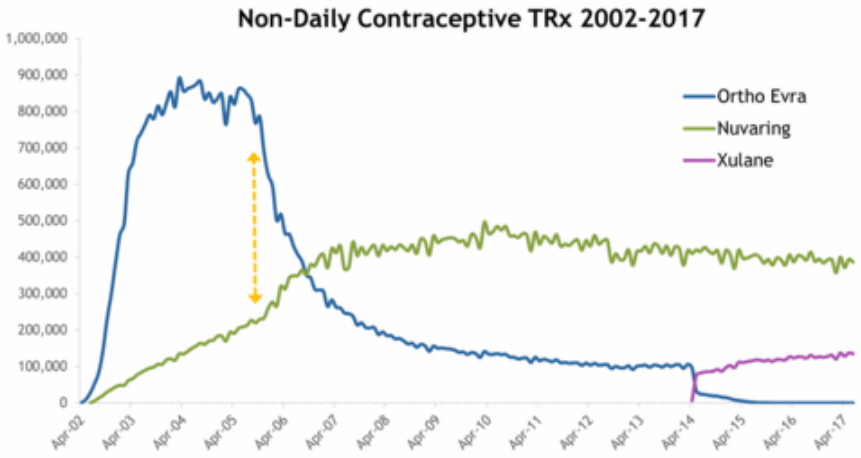
- Evra 11.1% (in 2005)
- Nuvaring 6.6% (in 2014)

The most successful contraceptive launch was a non-daily product

- Evra reached 10% TRx share 18 months after 2002 launch

*Includes branded and generic products (brands defined as products approved under an NDA, generics approved under an ANDA)
Evra is a registered trademark of Johnson & Johnson, Inc.; Xulane is a registered trademark of Mylan, Inc.;
Nuvaring is a registered trademark of Merck & Co., Inc.
Source: IMS NPA and NSP, through Dec 2016

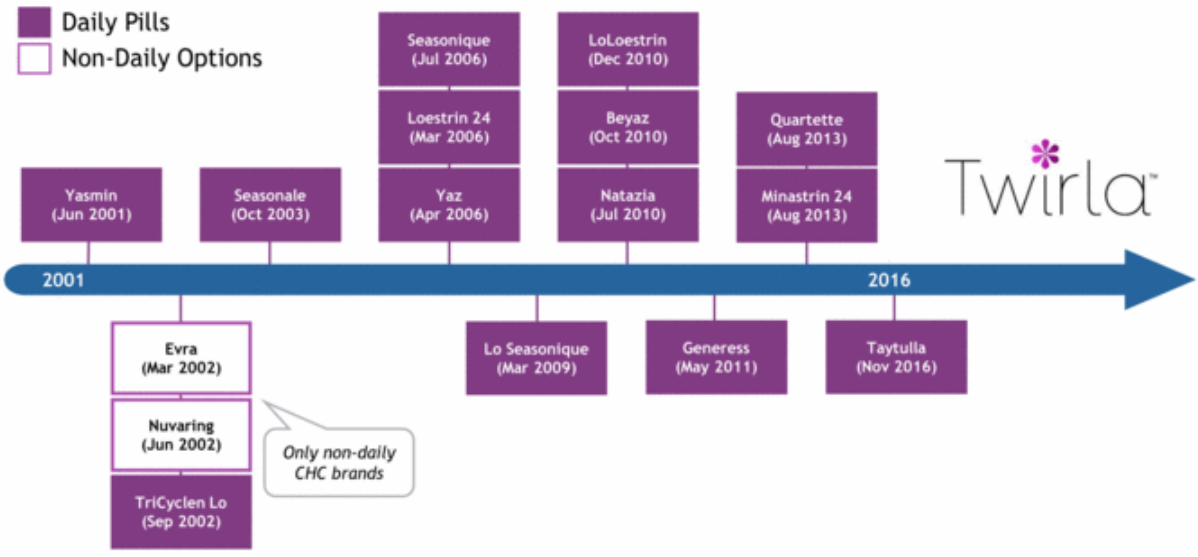
History of Ortho Evra® and Nuvaring® Market Shares Demonstrate Demand for Non-Daily Contraception



- 2002: Ortho Evra and Nuvaring launch as the first non-daily CHC methods
- 2005: The two products cumulatively account for 14% of the CHC market
- 2005: Ortho Evra relabeled with second black box warning. Evra share declined while Nuvaring growth escalated

Evra is a registered trademark of Johnson & Johnson, Inc.; Xulane is a registered trademark of Mylan, Inc.; Nuvaring is a registered trademark of Merck & Co., Inc.
Source: IMS NPA through Dec 2016

There is a Market Need for New Non-Daily CHC Options



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, Minastrin, and Taytulla are registered trademarks of Allergan, Inc.; Seasonale, Seasonique and Quartette are registered trademarks of Teva Pharmaceuticals USA, Inc.
Source: IMS NPA 2000-2016

Birth Control Video

Available at AgileTherapeutics.com

In Analyst Day Webcast Replay

Perspective from Clinical Practice

Robin Kroll, MD, FACOG

Robin Kroll, MD, FACOG

About

- Co-Founder and Director, Seattle Women's: Health, Research, Gynecology
- SECURE Trial Investigator
- Investigator in over 200 clinical trials in women's health
- Over 20 publications/presentations in women's health

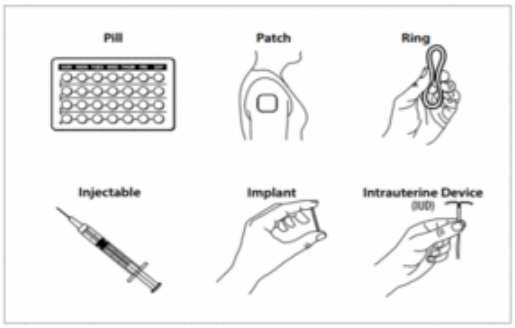
Key Topics

- Women need contraceptive options
  - Why options are important
  - Why non-daily and low-dose options are important
- Insights from clinical experience with Twirla

Contraceptive Patterns in U.S. Women

- Nearly all women use contraception at some point in their lifetimes[1,2]
  - Women use contraception for an average of 30 years across their lifetimes[1,2]
- ~50% of pregnancies in U.S. women are unintended[3]
  - 10-15% of sexually active women do not use contraception
- ~50% of women with unplanned pregnancies conceive while using a contraceptive method[4]
  - 90% of contraceptive failures are due to inconsistent and/or improper use[4]
- Hormonal methods are highly effective and among the most popular methods used[5]
  - Well-established safety and tolerability profile
  - Few absolute contraindications
  - Non-contraceptive benefits

Currently available hormonal contraceptive options



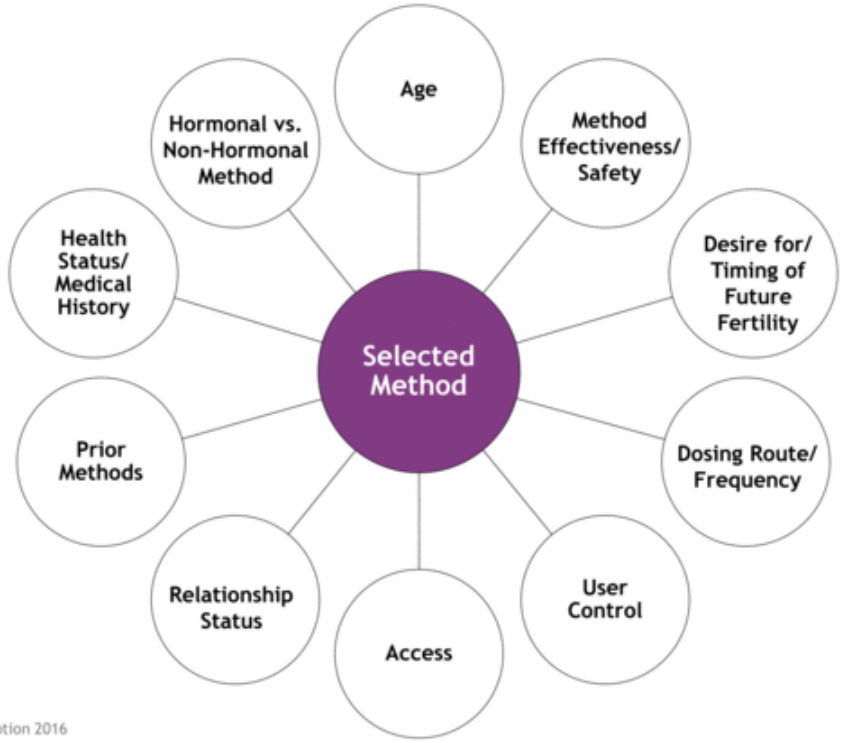
[1]Hamilton BE, Kirmeyer SE., National Center for Health Statistics. 2017; [2]Daniels K et al, National Center for Health Statistics. 2013
[3]Finer LB and Zolna MR, NEJM 2016; [4]Frost JJ and Darroch J., Perspectives on Sexual and Reproductive Health 2008
[5]Halpern V et al, Cochrane Review 2013

Why Contraceptive Options are Important

- Contraceptive method selection is influenced by several factors[1]
  - No single method is the method of choice for all women[2]
- Women typically use several different methods across their lifetimes as their needs and preferences change[2]
- Acceptability and tolerability of various methods are different for different women
  - 46% of women report have discontinued at least one method because they were dissatisfied with it[3]
- Women are more consistent with contraceptive use and stay with a method for longer when using a method of their choosing[4]

[1]Jackson AV et al, Contraception 2016
[2]Mansour D, Int J Women's Health 2014
[3]Moreau C et al, Contraception 2007
[4]Frost JJ and Darroch J, Perspectives on Sexual and Reproductive Health 2008

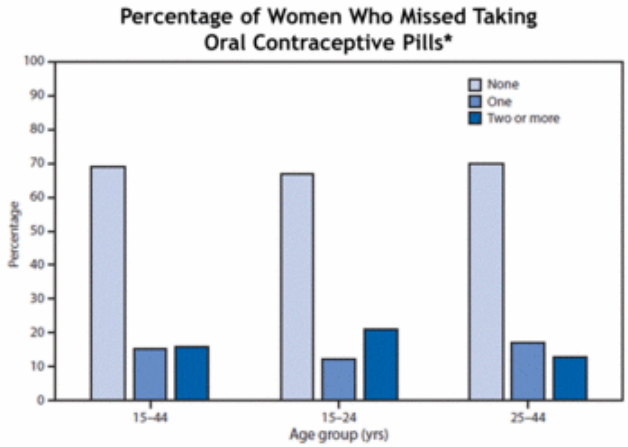
Factors that Influence Contraceptive Method Selection



Source: Jackson AV et al, Contraception 2016

Why Non-Daily Contraceptive Options are Important

- Oral contraceptives (OCs) are highly effective when used correctly, however women report inconsistent use[1,2]
  - ~ 30-50% of OC users miss one or more pills per month; > 20% miss two or more
- Human factors (including missed pills) lead to lower effectiveness (higher failure rate)[3]
  - Lowest expected use efficacy from highly selective clinical trials: 0.3% failure rate (i.e., lowest expected)
  - Actual use effectiveness: ~ 9% failure rate
- Methods that are not user dependent show little difference between perfect and actual use effectiveness
- Non-daily options decrease the chance of missed daily pill doses[4]



[1]Halpern V et al, Cochrane Review 2013
[2]CDC National Survey of Family Growth 2016
[3]Trussell J, Contraception 2011
[4]FDA Press Release-Ortho Evra Label Update 2005

Why a Low-Dose Non-Daily Option is Important

- All combined hormonal contraceptives (CHCs) increase the risk of blood clots (VTE)[1]
- The dose of estrogen in CHCs is believed to be the primary factor influencing the risk of VTEs[1]
- Since the first birth control pill was approved by the FDA in 1960, estrogen doses have decreased by up to 93%
  - Current low-dose products range from 10-35 mcg* of estrogen per day

Enovid
Approved 1960
150µg estrogen[2]

→

Low-Dose Products
Available today
10-35µg estrogen[3]

- There are no confirmed clinical differences in VTE risk between various low-dose products

*VTE=venous thromboembolism
*mcg=micrograms

Source: [1]Stegeman B. H., et al, BMJ 2013, [2]Planned Parenthood, *The Birth Control Pill: A History*, June 2015; [3]IMS NPA through July 2017

SECURE Trial Results

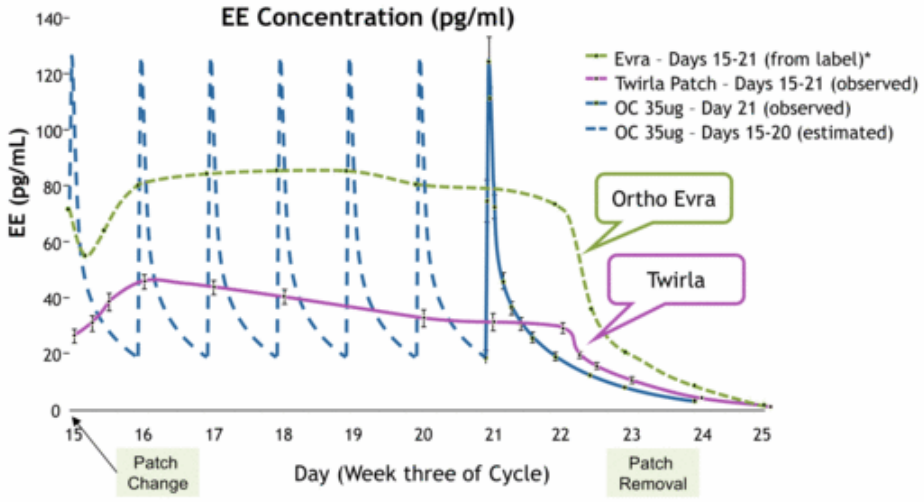
Dr. Elizabeth Garner, Chief Medical Officer

Regulatory Path to Potential Approval

- **Oct 2013 -** Type A Meeting: Agile agrees to execute Phase 3 Trial (SECURE)
- **Feb to Sept 2014 -** Agile and FDA discuss study design and analysis
  - Broad enrollment, including no BMI restriction
  - Pre-specified weight and BMI analyses
- **July 2015 -** FDA publishes meta-analysis on obesity and CHC effectiveness
- **March 2017 -** Pre-submission Meeting: Based on preliminary review of data, FDA indicated the SECURE trial results appear acceptable for resubmission
- **July 2017 -** FDA accepts resubmission as a complete response to the CRL
- ***December 26, 2017 -*** Established as the PDUFA goal date

Twirla® is a Low-Dose Contraceptive Patch

- Twirla is designed to deliver ~30 mcg of ethinyl estradiol (EE) per day
  - less than half the EE exposure of Ortho Evra



*Information on Ortho Evra is based on currently marketed product label and publicly available information; we have not performed a head-to-head comparison of Twirla to Ortho Evra
Sources: Archer D, et al, Contraception 2012; Archer D, et al, ACOG 2011

The SECURE Trial Was Rigorously Designed and Had Broad Entry Criteria

- Multicenter, single-arm, open-label 13-cycle trial at 102 experienced U.S. clinical sites
  - ~2000 healthy subjects aged ≥ 18 treated with laser-etched patches
- Representative sample of women seeking hormonal contraception
  - No exclusions for BMI/weight
- Stringent trial design
  - Frequent pregnancy testing
  - Exclusion of cycles for BOTH use of back-up contraception and lack of sexual activity
- Analysis
  - Efficacy measure was Pearl Index in an Intent To Treat (ITT) population of subjects 35 years of age and under
  - Pre-specified analysis related to BMI and body weight-requested by FDA

Positive Evidence of Efficacy in a Real-World Population

A tight confidence interval was achieved on the overall results:

Population (ITT)	Pearl Index	UB 95% CI
≤ 35 years of age	4.80	6.06

Prespecified analyses showed an effect of obesity:

BMI Category	BMI (kg/m^2)	% of Study Population	Pearl Index	UB 95% CI
Normal*	< 25	39%	3.03	4.62
Overweight	≥ 25 - < 30	25%	5.36	7.98
Obese	≥ 30	35%	6.42	8.88
Non-Obese*	< 30	65%	3.94	5.35
Obese	≥ 30	35%	6.42	8.88

*Reflective of Historical CHC Trial Populations

$$\text{Pearl Index} = \frac{\text{\# On-treatment pregnancies}}{\text{\# Cycles}} \times 1300$$

Pearl Index with no contraception[1]: ~190

ITT = Intent to Treat; all results shown are based on ITT subjects ≤ 35 years of age; UB 95% CI = upper bound of the 95% confidence interval
Source: [1]Personal correspondence with Dr. James Trussell

Life Table Efficacy is a More Relevant Clinical Measure

- Failure rate (Life table analysis) is an important pre-specified, supplemental efficacy endpoint in contraceptive trials
  - More clinically relevant than Pearl Index
- Failure rate was 4.2% at Cycle 13, inclusive of all subjects regardless of BMI

95.8% of SECURE trial subjects did not have a pregnancy during the trial

Cycle	% of Subjects With a Pregnancy	UB of 95% CI
1	0.2	0.51
2	0.6	1.15
3	1.0	1.64
4	1.6	2.40
5	2.0	2.84
6	2.6	3.58
7	2.8	3.77
8	3.2	4.28
9	3.4	4.50
10	3.5	4.61
11	3.7	4.85
12	3.9	5.10
13	4.2	5.48

UB 95% CI = upper bound of the 95% confidence interval

Twirla® Had a Favorable Safety and Tolerability Profile in the Phase 3 Trials

Low rates of hormone-related adverse events, consistent with publicly available information for other low-dose combined hormonal products:

Adverse Event*	SECURE Trial	Prior Agile Phase 3 Trials	Ortho Evra Trials*	Quartette Trial*
Total in Safety Population	2031	1043	3322	3597
Headache	4.5%	3.7%	21.0%	12.2%
Nausea	4.1%	4.3%	16.6%	6.7%
Breast tenderness/pain/discomfort	2.0%	1.8%	22.4%	2.2%
Mood swings/changes/depression	2.7%	2.8%	6.3%	2.9%
Heavy/irregular vaginal bleeding	2.6%	2.1%	6.4%	9.7%

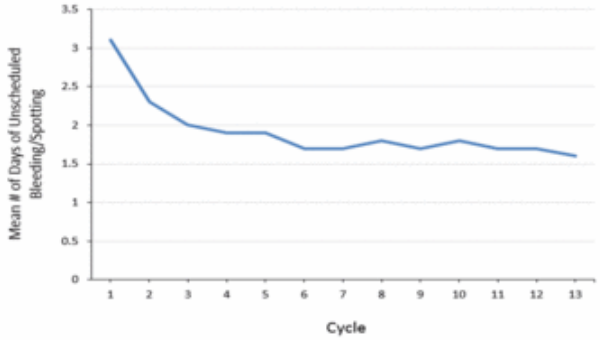
- Overall serious adverse events (SAEs) were observed in 1.97% of the SECURE trial study population; generally in line with those observed in other low-dose combined hormonal products* (rate in Quartette trial = 1.6%); 0.7% of subjects had SAEs that were considered potentially study drug related, including deep vein thrombosis (DVT), pulmonary embolism (PE), gallbladder disease, ectopic pregnancy, and depression
- In the combined safety database for Agile Phase 3 trials (n >3,000), there were 5 subjects with potentially study drug related DVTs or PEs, 4 of whom were obese (BMI >30kg/m^2)

*Information is based on currently marketed product labels and publicly available information; adverse event (AE) terms utilized in table (except nausea) represent composites of relevant specific AE preferred terms. Different terminology may be used in product labels and reports. We have not performed a head-to-head comparison of Twirla to Ortho Evra or Quartette.

Favorable Bleeding Profile Similar to Oral Low-Dose CHCs

- Bleeding-related side effects are among the top reasons women discontinue hormonal contraception[1]
- Monthly withdrawal bleeding duration (mean 3-3.7 days) in SECURE trial subjects was generally consistent with approved low-dose CHCs
- Breakthrough bleeding also generally consistent with approved low-dose CHCs[2] and decreased during the 13 cycles of the study
- 2.2% of SECURE trial subjects discontinued due to a bleeding-related adverse event (Quartette: 5%; Natazia: 2.3%; Ortho Evra 1.1%)

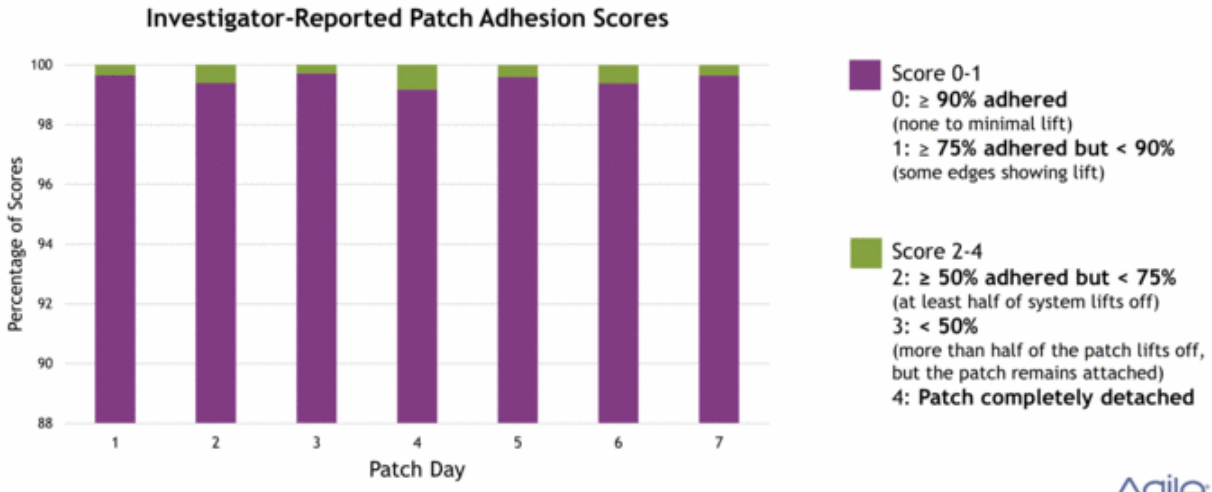
Mean Number of Unscheduled Bleeding/Spotting Days by Cycle



Analysis of subjects in the Safety Population of SECURE trial
Sources: [1]Moreau C, et al. *Contraception* 2007 ; [2]publicly available product labels

Twirla Had a Favorable Adhesion Profile in the SECURE Trial

- **99.2 - 99.7%** of patch adhesion scores ranged from no lifting of the patch (score = 0) to slight lifting at the edges (score = 1)
  - As rated by SECURE trial Investigators during routine subject visits, using a 5-point scale provided by the FDA



Perspective on Efficacy, Effectiveness and the Pearl Index

David J. Portman, MD, FACOG

David J. Portman, MD, FACOG

About

- Director Emeritus, Columbus Center for Women's Health Research
- CEO & CMO, Sermonix Pharmaceuticals
- Investigator in over 140 clinical trials in women's health
- Over 100 publications/presentations in women's health
- Co-author of *The Creeping Pearl* with Dr. James Trussell

Key Topics

- Evolution of the Pearl Index
- Context for SECURE Trial data
- How clinicians think about contraceptive efficacy

Pearl Index (PI): A Regulatory Measure With Limited Clinical Relevance

- PIs have increased over time, in particular over the past ~2 decades
- Although clinical relevance is limited, PI continues to be utilized by regulators and researchers due mainly to simplicity of calculation
- Numerous factors may be contributing to Pearl Creep
  - Differences in study design
    - pregnancy testing, cycle exclusion criteria
  - Increasingly diverse study populations
  - Lower adherence/compliance in clinical trial populations
  - Hormone doses
  - Increasing weight/BMI of the U.S. population


Contraception

Contraception

ELSEVIER

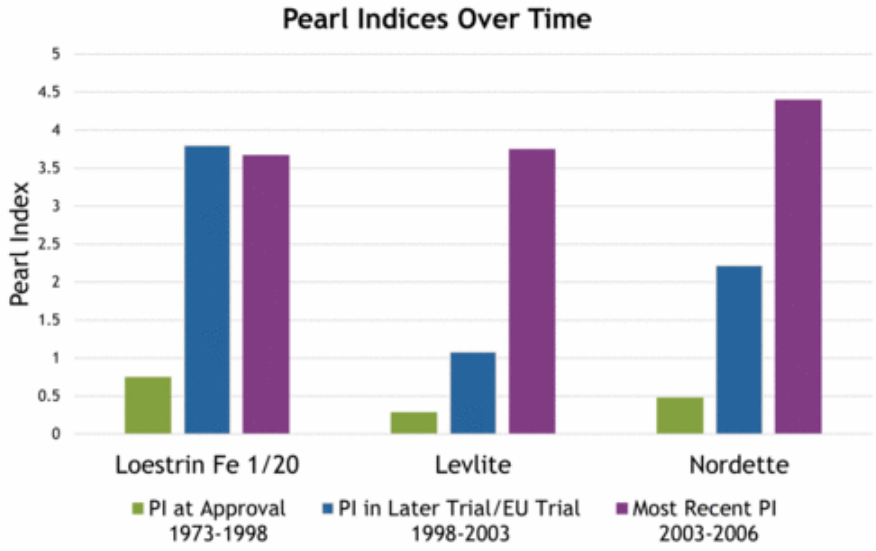
Review Article

The creeping pearl: why has the rate of contraceptive failure increased in clinical trials of combined hormonal contraceptive pills?☆,☆☆,☆☆,★,★★

James Trussell[a,b,*], David Portman[c,d]

*PI = # pregnancies/# cycles x 1300
Trussell J and Portman D, Contraception 2013

Pearl Indices In Initial FDA Registration Studies Increased In Later Trials



PI = Pearl Indices
Sourced from publicly available NDA Reviews

Efficacy Results from Modern Contraceptive Trials are Looking More Like Real-World Effectiveness

Efficacy

How well CHCs work in "ideal" conditions of clinical trials

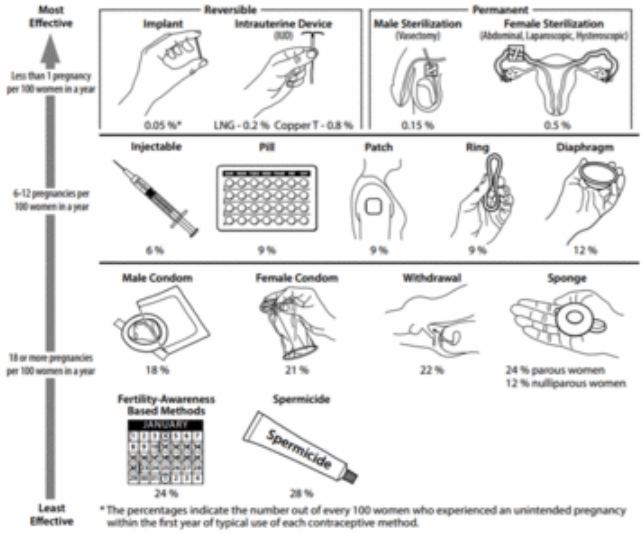
Effectiveness

How well CHCs work in actual use "real world" settings

- With increasingly diverse study populations, there is a narrowing of the gap between efficacy and effectiveness
- From a clinical standpoint, this is a favorable trend that helps inform decision making

Healthcare Providers Think About Typical Use Effectiveness

CDC *Effectiveness of Family Planning Methods*



- Twirla®, if approved, will have similar effectiveness as other Tier 2 products
- 85% of women using no contraception experience a pregnancy within 1 year
- Estimated Pearl Indices:
  - IUDs < 1
  - Condoms ~ 20
  - No method ~ 190

Sources: CDC *Effectiveness of Family Planning Methods* Chart; Trussell, et al., *The Creeping Pearl* (2013); Personal correspondence with Dr. James Trussell

Regulatory Perspective

Minnie Baylor-Henry, JD, RPh

Minnie Baylor-Henry, JD, RPh

About

- Executive Partner, YourEncore
- Former Worldwide Vice President, Regulatory Affairs, Johnson & Johnson
- Former Director, Division of Drug Marketing, Advertising and Communication (DDMAC), FDA

Key Topics

- Trend toward inclusive clinical trial design
- How the FDA considers contraceptive products
- Importance of the FDA meta analysis
- Historical perspective on Ortho Evra

Trend Toward Real World Settings for Clinical Trials

- Limitations of trials conducted in highly controlled settings with selective populations are increasingly being recognized[1,2]
- Real-world studies in broad study populations provide greater generalizability to individuals who will likely use the products being tested[1,2]
- FDA Office of Women's Health, in partnership with NIH Office of Research on Women's Health is sponsoring the:

Diverse Women in Clinical Trials Initiative[3]

- Raise awareness about the importance of diverse women in clinical trials
- Share best practices about clinical study design, recruitment, and data analyses
- *"Increasing the diversity of women in clinical trials can help improve healthcare for all women"*

Sources: [1]Califf RM and Sugarman, Clin Trials 2015; [2]Ford I et al, NEJM 2016; [3]FDA.gov Diverse Women in Clinical Trials Campaign Partner Toolkit

How the FDA Considers Contraceptive Products

- Approval is based on a risk/benefit assessment
- Efficacy is assessed versus no contraception
  - Comparator trials are not required
- There is no firm Pearl Index endpoint requirement
  - No pre-specified statistical definitions of success
  - No formal statistical testing (no p-values)
- Contraceptive options are important; FDA accepts a range of effectiveness levels (contraceptive categories) to allow for more choices for women

Source: FDA ACRHD Meeting Summary Minutes January 2007

FDA Meta-Analysis: The Effect of Obesity on HC Effectiveness

- Since the 1980's, HCPs have suspected obesity may increase CHC failure[1]
- The contribution of obesity has been difficult to measure; most prospective CHC trials have excluded obese women
- FDA meta-analysis demonstrates importance of obesity in CHC effectiveness[2]
  - Publication suggests 44% increased risk of pregnancy during CHC use in obese compared to non-obese women
  - FDA authors called for more data on obese women from Phase 3 clinical trials


an international reproductive health journal
Contraception

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Original research article

Effect of obesity on the effectiveness of hormonal contraceptives: an individual participant data meta-analysis

Michiyo Yamazaki[a], Kate Dwyer[b], Mahboob Sobhan[b], Daniel Davis[c], Myong-Jin Kim[a], Lisa Soule[c], Gerald Willett[c], Chongwoo Yu[a,*]

[a]Division of Clinical Pharmacology 3, Office of Clinical Pharmacology, Office of Translational Sciences (OTS), Center of Drug Evaluation and Research (CDER), US Food and Drug Administration (FDA), Silver Spring, MD, USA
[b]Division of Biostatistics 3, Office of Biostatistics, OTS, CDER, FDA, Silver Spring, MD, USA
[c]Division of Bone, Reproductive, and Urologic Products, Office of New Drugs, CDER, FDA, Silver Spring, MD, USA

Received 20 August 2014; revised 27 July 2015; accepted 31 July 2015

Sources: [1]Boden DC, Med J Aust 1980 ; [2]Yamazaki M et al, Contraception 2015; 92: 445-52

Historical Perspective on Ortho Evra®

- Ortho Evra label negotiations resulted in weight language regarding efficacy, which did not affect approvability of the product

Original Ortho Evra Label, Nov 2001

INDICATIONS AND USAGE

ORTHO EVRA™ is indicated for the prevention of pregnancy.

Like oral contraceptives, ORTHO EVRA™ is highly effective if used as recommended in this label.

In 3 large clinical trials in North America, Europe and South Africa, 3,330 women (ages 18-45) completed 22,155 cycles of ORTHO EVRA™ use, pregnancy rates were approximately 1 per 100 women-years of ORTHO EVRA™ use. The racial distribution was 91% Caucasian, 4.9% Black, 1.6% Asian, and 2.4% Other.

With respect to weight, 5 of the 15 pregnancies reported with ORTHO EVRA™ use were among women with a baseline body weight ≥198 lbs. (90kg), which constituted <3% of the study population. The greater proportion of pregnancies among women at or above 198 lbs. was statistically significant and suggests that ORTHO EVRA™ may be less effective in these women.

Health Care Professionals who consider ORTHO EVRA for women at or above 198 lbs should discuss the patient's individual needs in choosing the most appropriate contraceptive option.

Source: FDA.gov Ortho Evra Label, 11/20/2001. Ortho Evra is a registered trademark of Johnson and Johnson, Inc.

Clinical Summary - Key Takeaways

- Contraceptive options are important for women
- Historical examples have demonstrated clear demand for non-daily, low-dose methods; none have been approved since 2001
- Twirla® has a favorable efficacy and safety profile and has the potential, if approved, to fill this gap
- Clinicians think in contraceptive categories and would consider Twirla as a Tier 2 method with similar effectiveness to OCs, pills, and rings
- We expect that if approved, the Twirla label would be similar to the original Ortho Evra label

Source: FDA.gov Ortho Evra Label, 11/20/2001. Ortho Evra is a registered trademark of Johnson and Johnson, Inc.

Q&A Session

Followed by a 15-Minute Break

Commercial Launch

Renee Selman, Chief Commercial Officer

Market Access - Policy Perspective

Adaeze Enekwechi, PhD, MPP

Adaeze Enekwechi, PhD, MPP

About

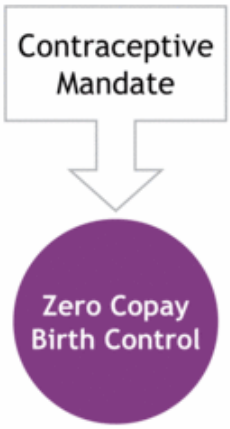
- Vice President, McDermott+Consulting
- Former Associate Director for Health Programs at the White House Office of Management and Budget (OMB)
  - Over $1 trillion in budget and policy oversight covering all domestic health programs
  - One of the most influential federal agencies covering all spending and implementation policies for the Administration
- Former Senior Policy Analyst at the Medicare Payment Advisory Commission (MedPAC)
- Former Analyst at the Congressional Budget Office (CBO)

Key Topics

- ACA Contraceptive Mandate perspective
- Why birth control is good policy

Affordable Care Act (ACA) Contraceptive Mandate

- Mandatory coverage of contraceptives with no copay remains the law as ACA has not been repealed
- Zero copay coverage mandated for at least 1 product in 18 unique methods delineated by the FDA
- Covered contraceptive methods include:
  - Barrier methods, like diaphragms and sponges
  - Hormonal methods, like birth control pills and vaginal rings
  - Implanted devices, like intrauterine devices (IUDs)
  - Emergency contraception, like Plan B® and ella®
  - Sterilization procedures
  - Patient education and counseling



Source: Healthcare.gov

State Initiatives Show Broad Support for Contraceptive Coverage

- Policymakers in many states have proposed and/or passed measures to preserve the contraceptive benefit regardless of federal law[1]
  - **28 states** require health insurance plans in their states to cover contraceptive services
  - **3 states** have added additional requirements barring delays in coverage, copays, or limits in methods of contraceptives covered
  - **8 states** do not permit any employer or insurer to refuse to comply with the mandate[2]
- October 6, 2017 - A regulation narrowing the mandate was issued allowing a broader set of employers and insurers to claim exemptions from the requirement to cover contraceptives for moral and religious reasons[3]
  - No single health insurer has ever sought such an exemption
  - Religious and closely-affiliated institutions can already claim exemptions
  - It is unlikely that many large employers will suddenly claim exemptions on moral grounds
    - Fewer than 100 employers covering ~22,000 employees sought the original exemption on religious or moral grounds[4]

Sources: [1]Guttmacher Institute, *Laws Affecting Reproductive Health and Rights: State Policy Trends at Midyear*, 2017
[2]Guttmacher Institute, *Insurance Coverage for Contraceptives*, October 1, 2017
[3]U.S. Department of Health and Human Services, *Trump Administration Issues Rules Protecting the Conscience Rights of All Americans*, October 6, 2017
[4]Mother Jones, *It's Not Just Hobby Lobby*, 2014

Contraceptive Coverage is Good Math and Good Policy

15-17% — Savings on healthcare costs for employers covering contraception vs. unintended pregnancy[1]

$1.4 Billion — Dollars women saved on birth control pills alone in 2013, due to the ACA[2]

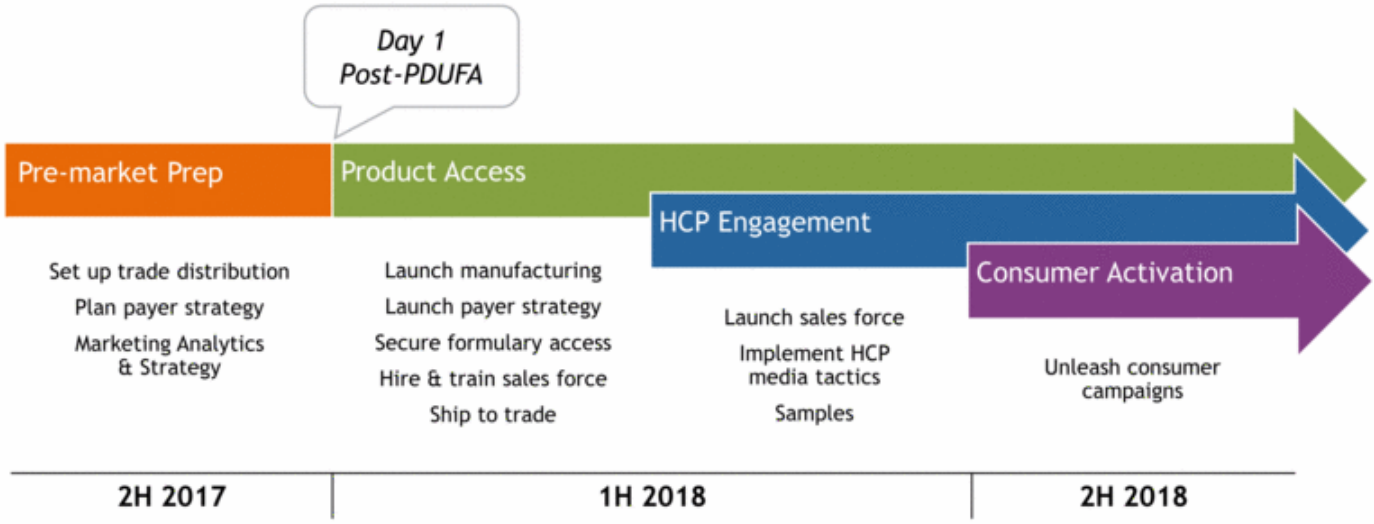
$21.0 Billion — Total public expenditures on unintended pregnancies nationwide in 2010
$14.6B federal, $6.4B state[3]

Source: [1]Guttmacher Institute, *Testimony of Guttmacher Institute, Submitted to the Committee on Preventative Services for Women*
[2]Kaiser Family Foundation; [3]Guttmacher Institute, *Unintended Pregnancy in the United States*

Commercial Launch

Renee Selman, Chief Commercial Officer

Commercial Launch Strategy



Building the Commercial Team

Manufacturing and Supply Readiness Ramping Up

Corium

- Significant expertise in transdermal patch development and manufacturing
- Longstanding exclusive contract manufacturing relationship
  - No royalties
- Collaborating closely on commercial scale-up

Market Access Strategy

Ashfield Market Access

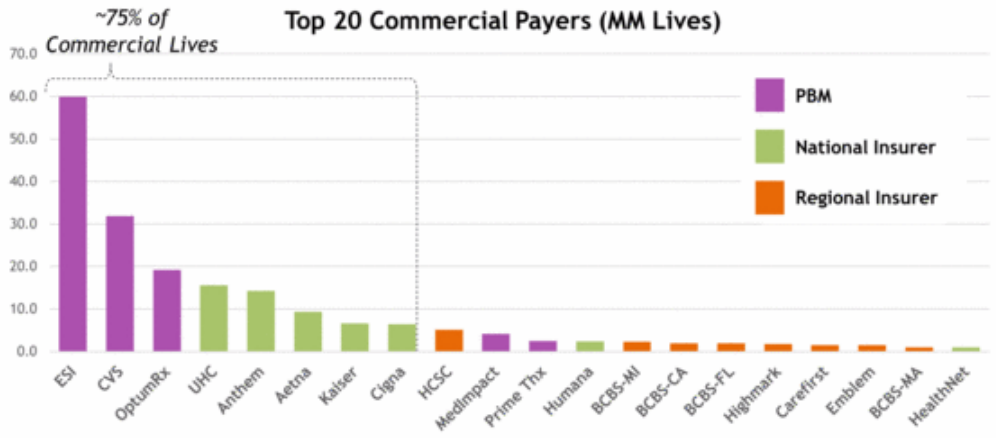
- Developing a market access strategy that:
  - Focuses on the clinical and economic differentiation of Twirla®
  - Leverages current provisions provided in the ACA
  - Contains contingency strategy in the event of an ACA repeal/replace
  - Via contracting, places Twirla in a competitive reimbursement position

Day 1 Post-PDUFA

Key Activity	Pre-PDUFA	Post-PDUFA
Payer Strategy Development		
Acct. Manager Training		
Account Management		
Initiate Payer Appointments		
Introductory Presentations		
Contracting Process		

Targeting Top 8 Payers Expected to Cover Majority of Commercial Lives

79% of the total CHC market and 86% of the Branded CHC market are Commercial Rx

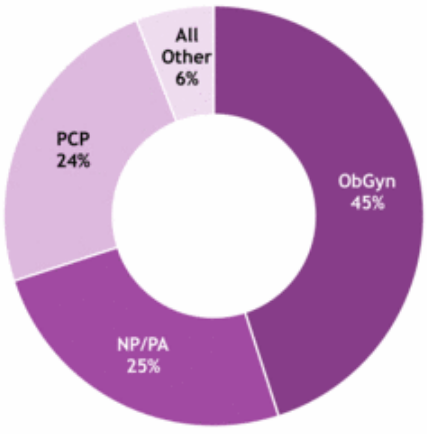


Source: Symphony Health Phast 07/2017

ObGyns and Nurse Practitioners Drive Contraceptive Prescribing

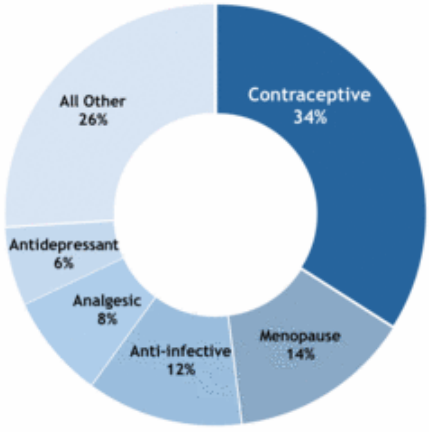
70% of US Contraceptive TRx are Written by ObGyns/NPs/PAs

CHC Prescriptions by Prescriber Type



ObGyns Prescribe Contraceptives More than any Other Therapy

ObGyn TRx by Category

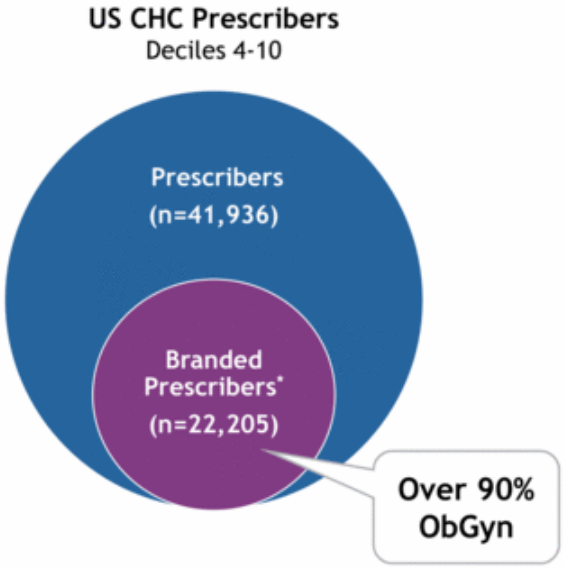


Source: IMS NPA, TRx Volume by Prescriber Type, 2014
Source: IMS NPA, TRx Volume by Category, 2010

Fine-Tuned Sales Targeting

Identify HCPs who:

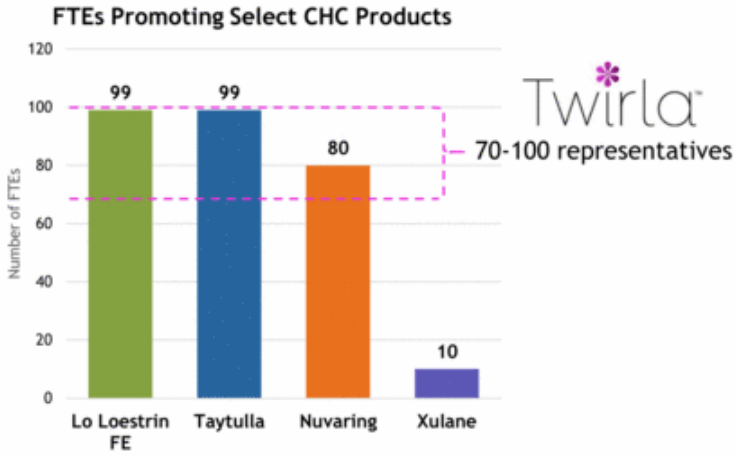
- Are high volume prescribers of CHC
- Initiate contraceptive Rx
- Are likely to adopt new products/technology early
- Have patient base with favorable access
- See a high volume of Twirla® consumer target personas



*Branded prescribers = non-Medicaid only
Source: xPonent plantrak data, July 2017

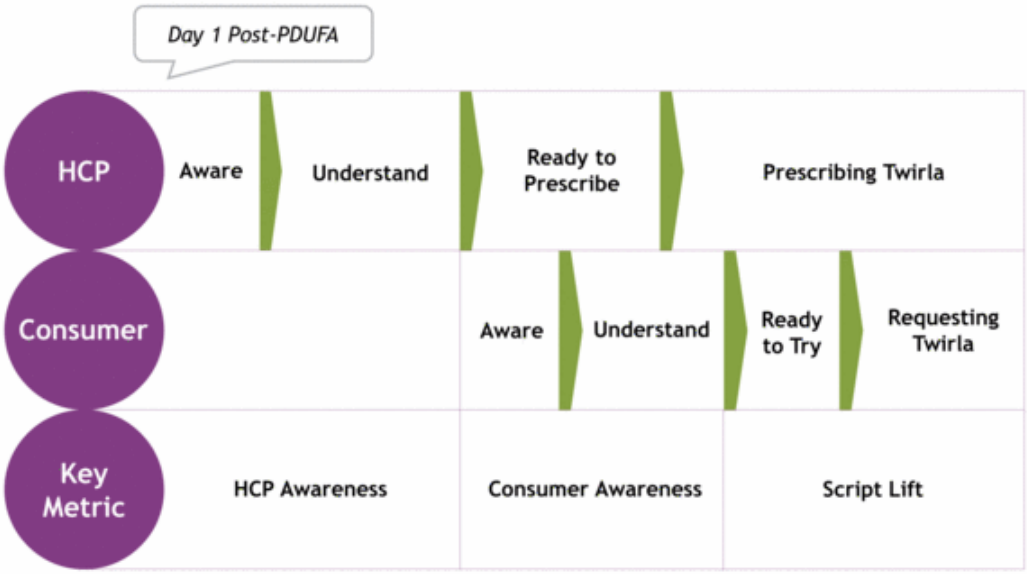
Phased Sales Force Implementation, Size Range in Line with Other Marketed CHC Products

- Planned 70-100 Reps expected to cover 50-60% of CHC Scripts
- Phased sales force hiring linked to formulary acceptance
- Provide a technologically advanced approach to 1-1 selling

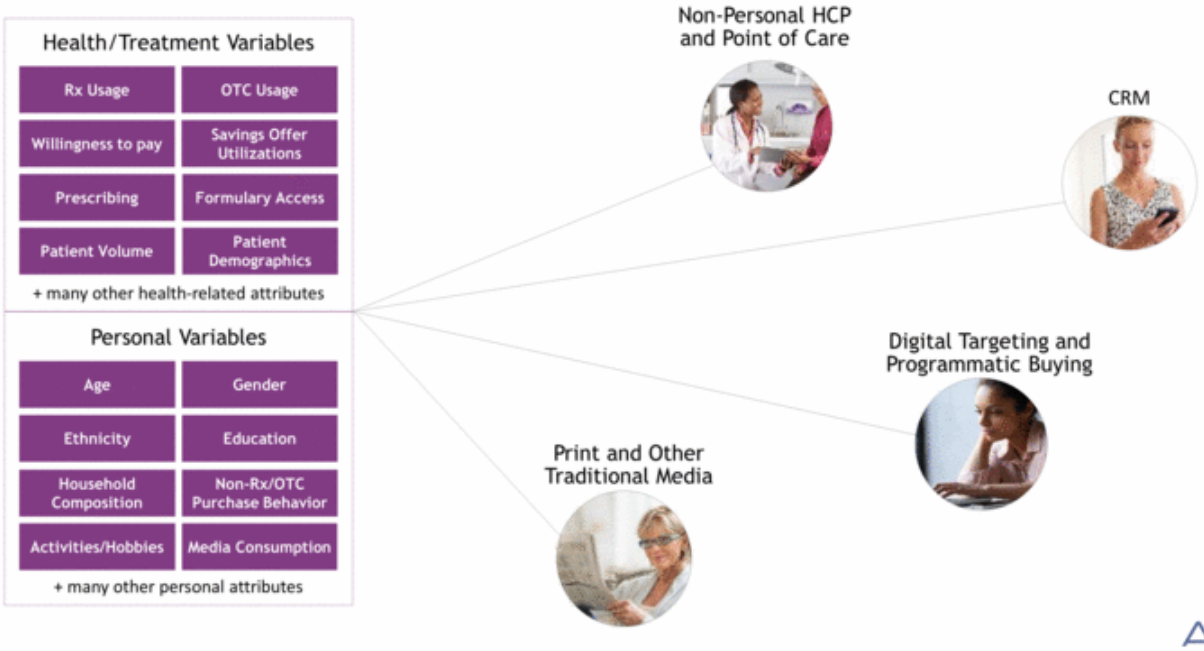


Source: Third party market research, 2017

Phased Approach to Media Plan



Robust Data Enables Focused Targeting of HCPs and Consumers



Create an Integrated Twirla® Brand Experience for the Target Consumer

Mobile RM Program • Cause Marketing • Social Media & Advocacy Platforms • Influencer Marketing

Experiential Event Marketing • Hyper-Targeted Digital Media • Point-of-Care Convergence

HCPs Underscored Twirla's Dosing Convenience, Recognized Differences in Sub-Populations

Benefits	Concerns
	
"... The patient doesn't have to remember taking pills daily. The patch is easy and effective..." - HCP survey respondent	***Product profile made specific reference to reduced efficacy in patients > 202 lbs**
"... I like the convenience, patient satisfaction, and efficacy..." - HCP survey respondent	*"... I'm worried that I would be unable to use [Twirla] in obese population because it's not as efficacious. And I still have hesitation regarding concern for VTE ..."* - HCP survey respondent
"... No black box warning and comparable to low dose oral contraceptives...." - HCP survey respondent	*"... I don't see [Twirla] as good in obese patients ..."* - HCP survey respondent

Source: Third party market research, 2017

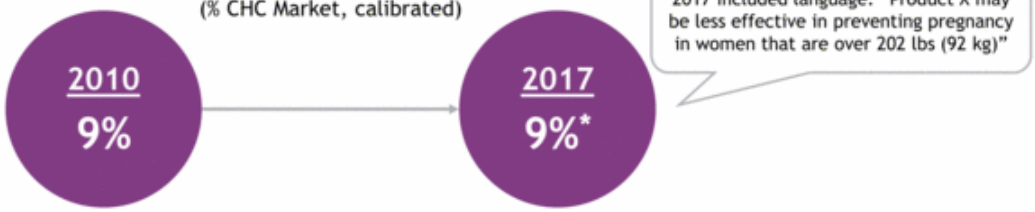
Consumers Highlighted Ease of Use as Key Benefit, Noted Few Dislikes

Benefits	Concerns
	
"… Easily hidden. Not too many side effects. Convenient and easy to use …" - Patient survey respondent *"… It is very similar to low dose birth control pills …"* - Patient survey respondent *"… I would say it is as effective as birth control pills, with low amounts of hormones …"* - Patient survey respondent	*"… I still don't like that it would be a visible sign of birth control method …"* - Patient survey respondent *"… There is nothing I dislike about the product. I don't know the cost of the patch but if it is expensive then it is something I would dislike…."* - Patient survey respondent *"… There's nothing that I dislike about this product so far …"* - Patient survey respondent

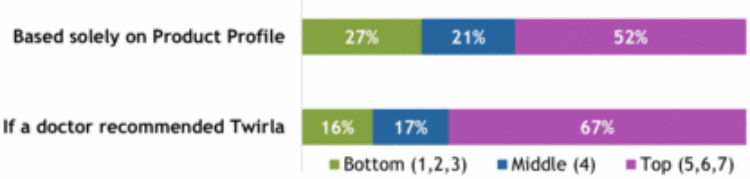
Source: Third party market research, 2017

Twirla® Market Research Sentiment Has Remained Consistent Since 2010

Twirla Peak TRx
(% CHC Market, calibrated)



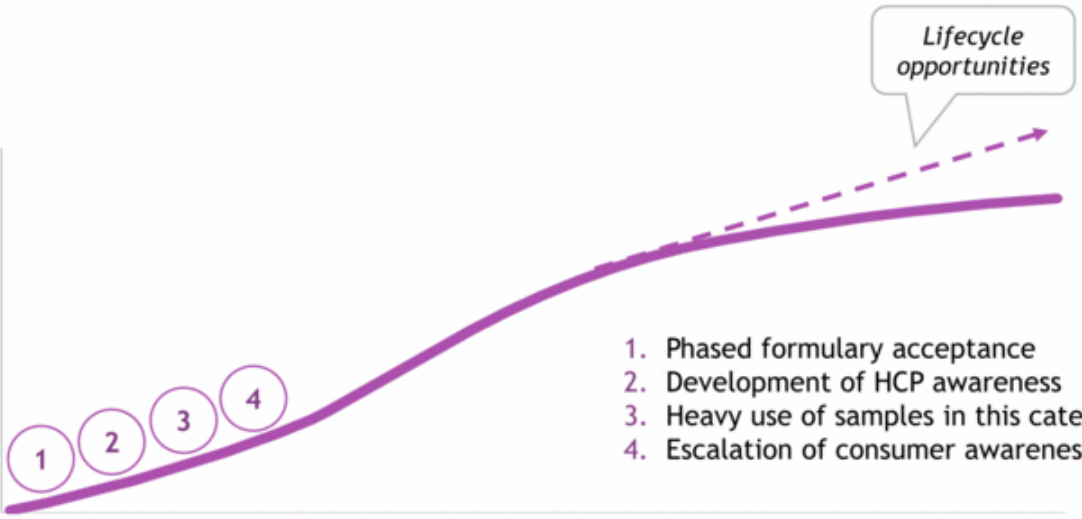
Consumer: Likelihood to Ask for a Prescription for Twirla
Rate 1-7, Not at all likely (1) to Extremely likely (7)



Consumers "extremely likely" to ask for Twirla
15%

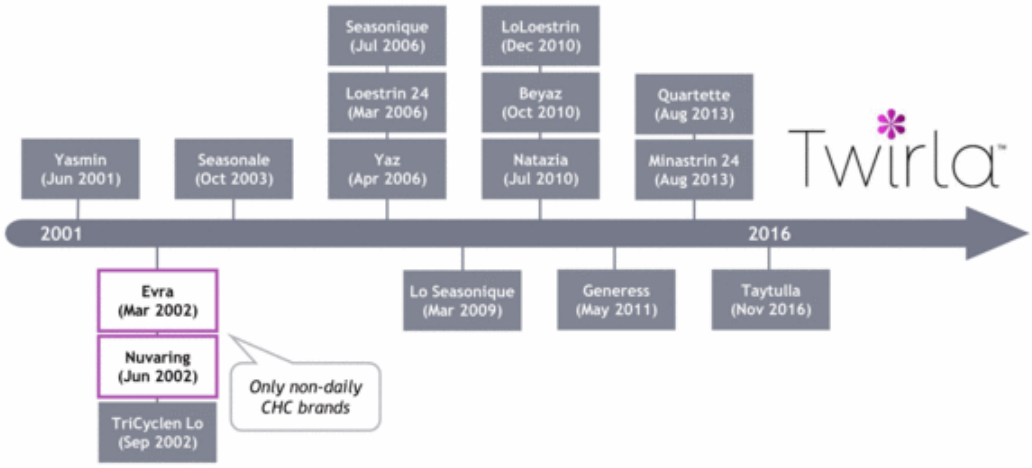
*Assumes consumer activation with unaided awareness of 70%
Sources: Qualitative and quantitative HCP research, Kantar Health 2010; Third party research, 2017; Qualitative and quantitative consumer market research, Adelphi Research 2016

Dynamics of Contraceptive Launches



Graph for illustrative purposes only

"I am happy to see [Twirla®]!
It's time another patch came to the market." *- OB/GYN*
Market Research, October 2016



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, Minastrin, and Taytulla are registered trademarks of Allergan, Inc.; Seasonale, Seasonique and Quartette are registered trademarks of Teva Pharmaceuticals USA, Inc.
Source: IMS NPA 2000-2016; Qualitative HCP market research, Adelphi Research 2016

A Look Toward the Future

Al Altomari, Chairman and CEO

Summary of Key Assumptions

Regulatory

- PDUFA Goal Date: December 26, 2017
- No plans to provide interim updates on FDA's review

Commercial

- 70-100 contract sales representatives planned 1H 2018
- Trade shipments and sales force launch planned 1H 2018
- TRx growth expected to ramp up 2H 2018
- Peak Twirla® TRx market share expected to be approximately 9% based on current assumptions

AGRX Financial Snapshot

Cash

$43.8 Million cash on hand at September 30, 2017

- Expected to fund operations into Q2 2018

Shares Outstanding

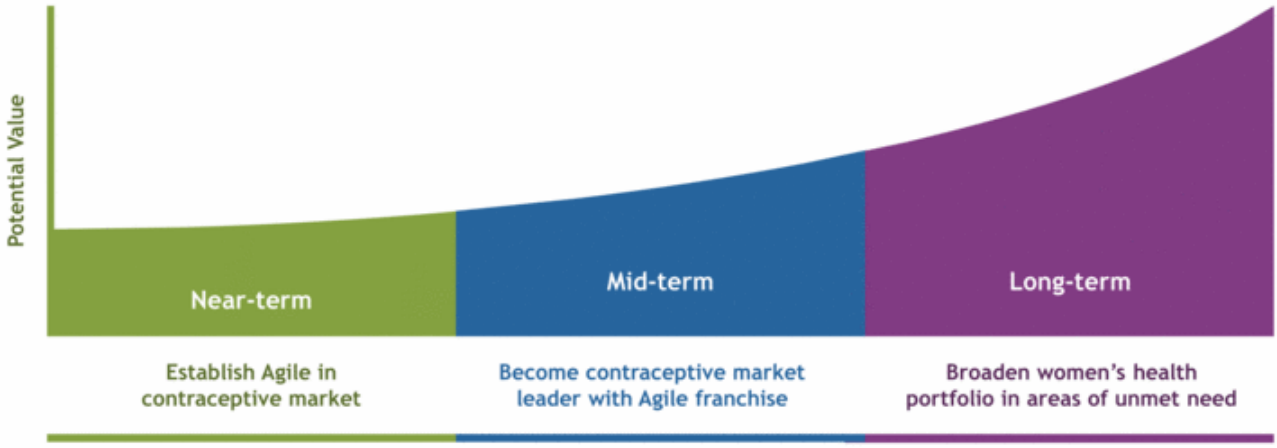
34.2 Million common shares outstanding at September 30, 2017

- 29.8 Million weighted average shares outstanding 3 months ended Sept 30, 2017
- 31.9 Million weighted average shares outstanding 9 months ended Sept 30, 2017

Potential Future Capital

$8.5 Million (debt) potentially available from Hercules

Laying the Foundation for Growth



Establish Agile in contraceptive market	Become contraceptive market leader with Agile franchise	Broaden women's health portfolio in areas of unmet need
Twirla™	Small Patch Program (SmP) AG200-ER (extended regimen) AG890 (progestin only)	Endometriosis Uterine fibroids Osteoporosis Urinary incontinence Menopause

Agile Corporate Summary

Significant Market Opportunity
▪ $3.9 Billion U.S. market for combined hormonal contraceptives (CHC)
Twirla® Potential Approval *December 26, 2017*
▪ Twirla is expected to be the first and only low-dose CHC patch
Ability to Execute Successful Twirla Launch
▪ Experienced leadership team ▪ Cash position expected to support launch ▪ Launch planning well underway

Thank You

Q&A Session