UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(D)
of the Securities Exchange Act of 1934

January 9, 2016
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:

☐ 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 2.02 Results of Operations and Financial Condition.

As discussed below, in connection with its participation in the 35th Annual J.P. Morgan Healthcare Conference in San Francisco, California beginning on January 9th, 2017, Agile Therapeutics, Inc. (the "Company") updated its corporate presentation to, among other things discussed below, include disclosure that the Company had $48.8 million of cash and cash equivalents as of December 31, 2016.

Because the Company's financial statements for the year ended December 31, 2016 have not yet been finalized or audited, the preliminary statement of the Company's cash and cash equivalents as of December 31, 2016 in this Item 2.02 is subject to change, and the Company's actual cash and cash equivalents as of the end of this period may differ materially from this preliminary estimate. Accordingly, you should not place undue reliance on this preliminary estimate.

Item 7.01 Regulation FD Disclosure

Beginning on January 9, 2017, the Company will participate in the 35th Annual J.P. Morgan Healthcare Conference in San Francisco, California. The Company has updated its corporate presentation that it intends to use in connection with presentations at conferences and meetings with investors. The updates primarily include disclosure regarding the Company's cash and cash equivalents as of December 31, 2016 as stated above and a summary of the top-line results of the Company's SECURE Phase 3 clinical trial ("SECURE") that were previously announced on January 3, 2017, including additional context regarding discontinuation rates and serious adverse events (SAEs) observed in previous Phase 3 clinical trials for other approved hormonal contraceptive products.

The information included in this Current Report on Form 8-K (including Exhibit 99.1) 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 the 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

SIGNATURES

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

Agile Therapeutics, Inc.

Dated: January 9, 2017

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

A Forward Thinking Women's Health Company

NASDAQ: AGRX

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, 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.

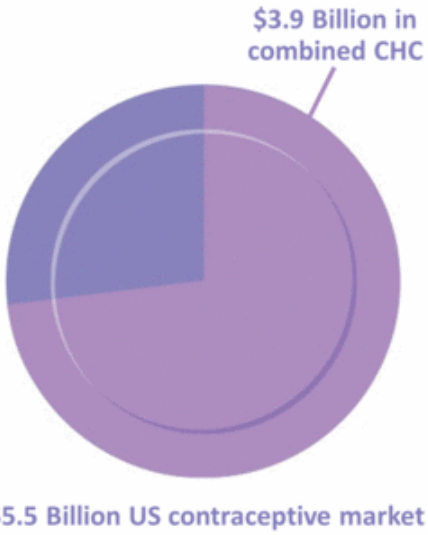
Agenda

- Corporate Overview and Vision
- Twirla® Update
  - Clinical Data Overview
  - Filing Strategy
  - Plans for Commercialization
  - Timeline
- Pipeline
- Corporate Summary

Corporate Overview

Significant Near-Term Market Opportunity

- ~$5.5 Billion US contraceptive market through June 2016 (MAT), with $3.9 Billion in combined hormonal contraceptives (CHC)
- Lead product candidate is Twirla®
- NDA resubmission planned 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

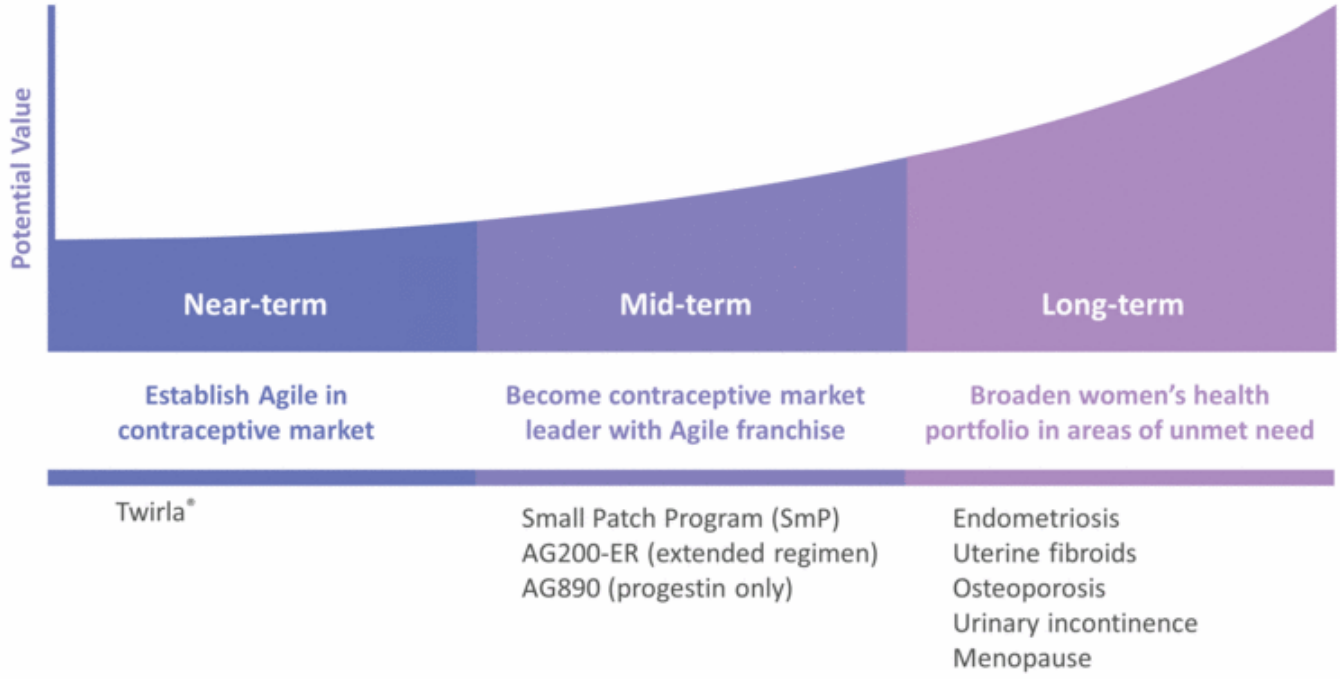


Agile is Building a Robust Women's Health Franchise

Agile is Well-Positioned for Successful Twirla Market Entry

*Brand is defined as products approved under an NDA, Source: IMS NSP and NPA as of June 2016 (moving annual total, MAT)

Corporate Strategy:
Become a Leader in Women's Health



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

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NASDAQ: AGRX

Twirla® is our Lead Product Candidate

Twirla is a once-weekly contraceptive patch

- Designed to deliver a low daily dose of estrogen, comparable to a low dose oral contraceptive
- Only one other contraceptive patch is available in the US, and delivers a higher dose of estrogen

Women want alternatives to a daily birth control pill

- Chief complaint is fitting daily pills into their busy lifestyles
- Women frequently forget to take their pill (1-4x per month)

Positive Phase 3 Clinical Trial Data Announced January 2017

twirla®

Sources: Qualitative consumer and HCP market research, RG&A 2012; ACE Survey 2013 Data on File, Agile Therapeutics

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The CRL Expressed a Clear Rationale for a New Study

CRL Focused on 2 Key Elements:

- Improved study conduct
  - Reduced loss to follow-up rate compared to previous Phase 3 trials
  - Support subject compliance and overall retention
- Demonstration of acceptable efficacy in a representative population
  - "An acceptable Pearl Index and upper bound of the 95% confidence interval"
  - "A representative sample of women in the U.S. who are seeking hormonal contraception"
  - "A sufficiently large and diverse population so that efficacy can be assessed in subgroups"

Quotes sourced from FDA correspondence

CRL = Complete Response Letter; FDA = Food & Drug Administration

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

An effect of obesity was observed:

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**

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

Favorable Safety and Tolerability Profile for Twirla in the SECURE Trial

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	2032	1043	3322	3597
Headache	4.3%	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**	1.8%	2.1%	6.4%	9.7%

**1.4% of subjects in the SECURE trial discontinued due to a bleeding-related adverse event

- Overall serious adverse events (SAEs) were observed in 1.7% 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%); 0.6% 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.
We have not performed a head-to-head comparison of Twirla to Ortho Evra or Quartette.

The NDA Resubmission is Expected to Address the Clinical CRL Questions

We expect to submit a robust data package that more clearly defines the risk/benefit profile for Twirla:

- Substantially improved study conduct
  - Lower discontinuation rate compared to previous Phase 3 trial; rate and reasons for discontinuation in line with other Phase 3 clinical trials for approved hormonal contraceptives*
  - Lower loss to follow up rate (11.3%) compared to previous Phase 3 trial (20.3%)
  - Greater confidence in the reliability of the results based on improved loss to follow-up rate and focus on data quality
- Study population reflects the broad entry criteria for the trial
  - Allowed for efficacy to be assessed across different groups
  - No restrictions on BMI (unlike historical contraceptive trials)
- Evidence of efficacy and safety
  - Positive evidence of efficacy observed in a real-world study population
  - Favorable safety profile; rates of adverse events consistent with publicly available information for other low-dose combined hormonal products

*Information is based on publicly available information.

Why Women Would Use Twirla®

- Expected to be the only low-dose contraceptive patch, delivering ~30µg/day EE
- Don't have to remember it every day
- 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	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

Patch Regimen: Once a week

SUN	MON	TUE	WED	THU	FRI	SAT
1	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						

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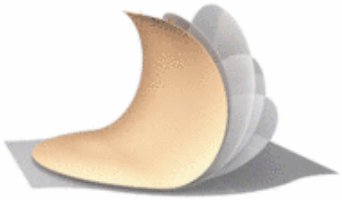
NASDAQ: AGRX

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

Designed for Aesthetic Appeal and the Flexibility to Choose

Proprietary Skinfusion® technology is designed to:

- minimize adhesive breakdown that causes "black ring"
- improve 7-day adhesion



Women can choose where to apply the patch:

Buttock 48%

Abdomen 40%

Upper Torso 12%

1.6 Source:. Kaunitz et al Obstetrics and Gynecology Feb 2014

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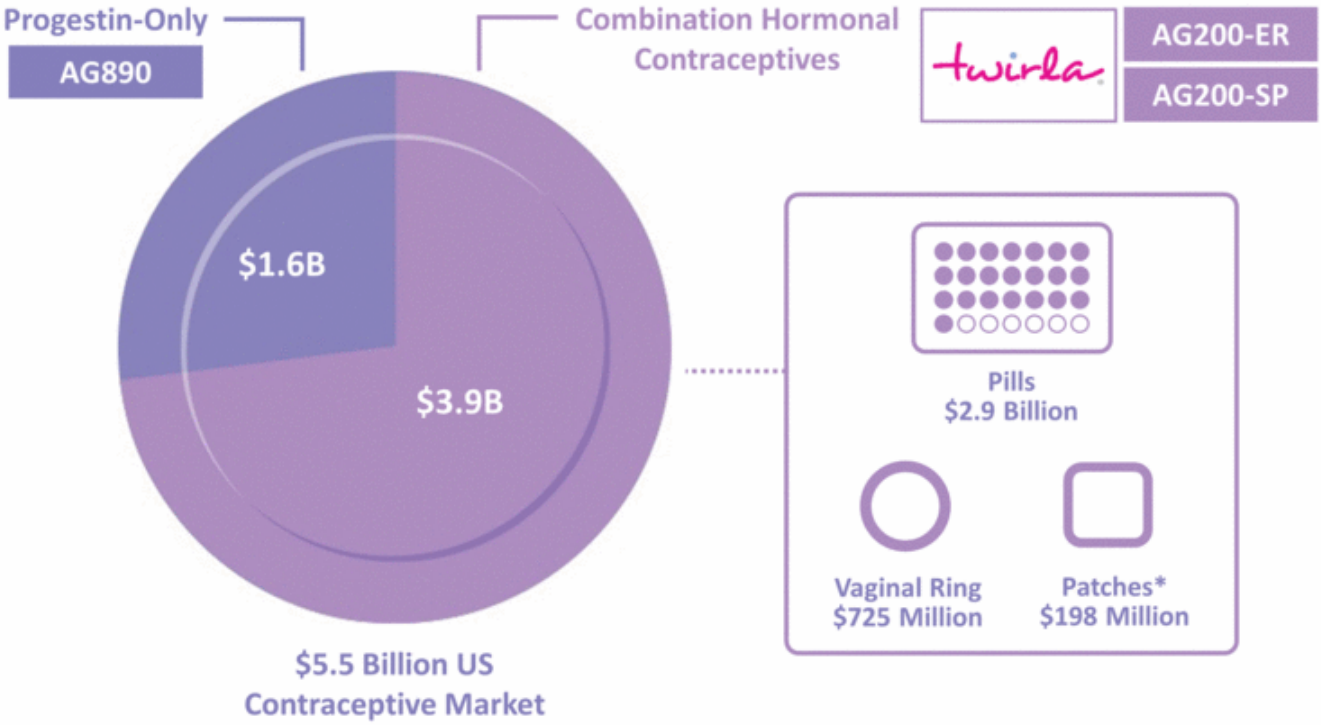
US Hormonal Contraceptive Market is a Significant Opportunity



*Patches includes sales of both Evra and Xulane

1.6 Source: IMS NSP, retail + non-retail as of June 2016 (MAT)

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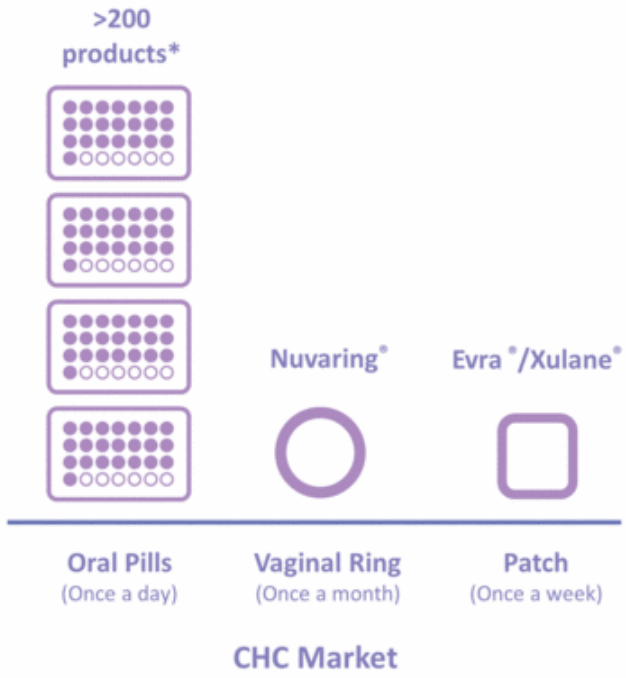
Non-Oral CHC Forms Have Appeal For the Market



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

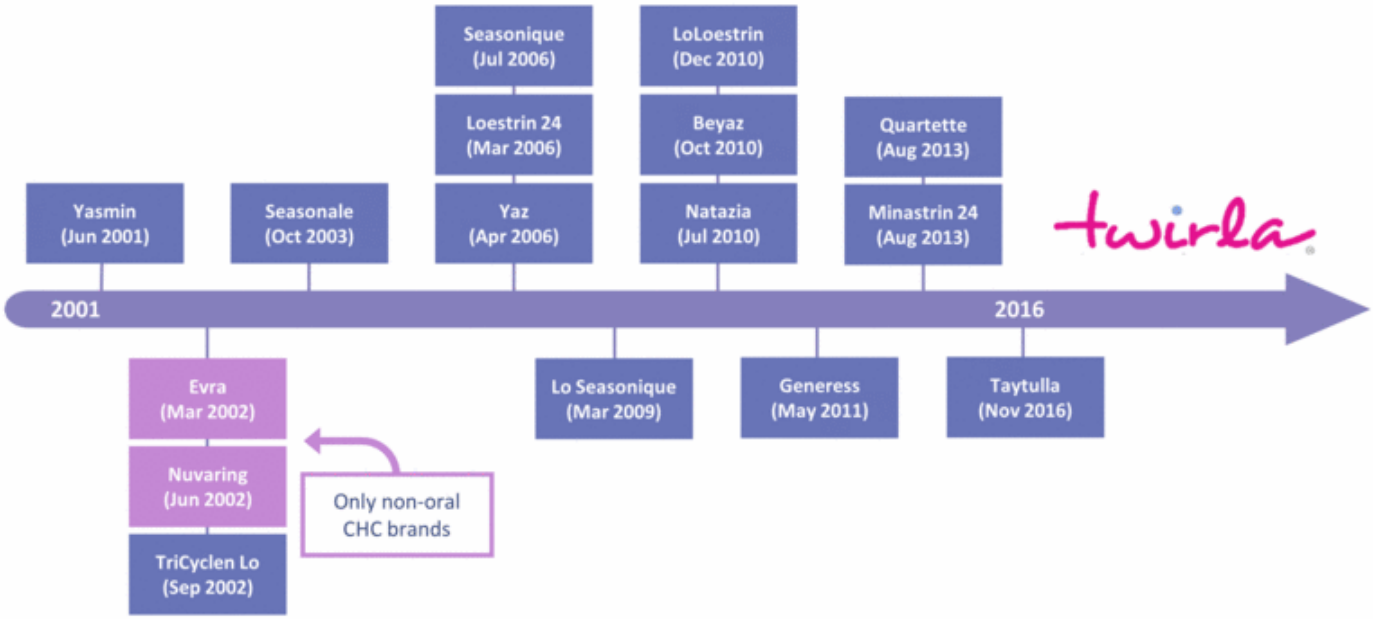
- Nuvaring annual sales for MAT June 2016 $725 Million

The most successful contraceptive launch was a non-oral product

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

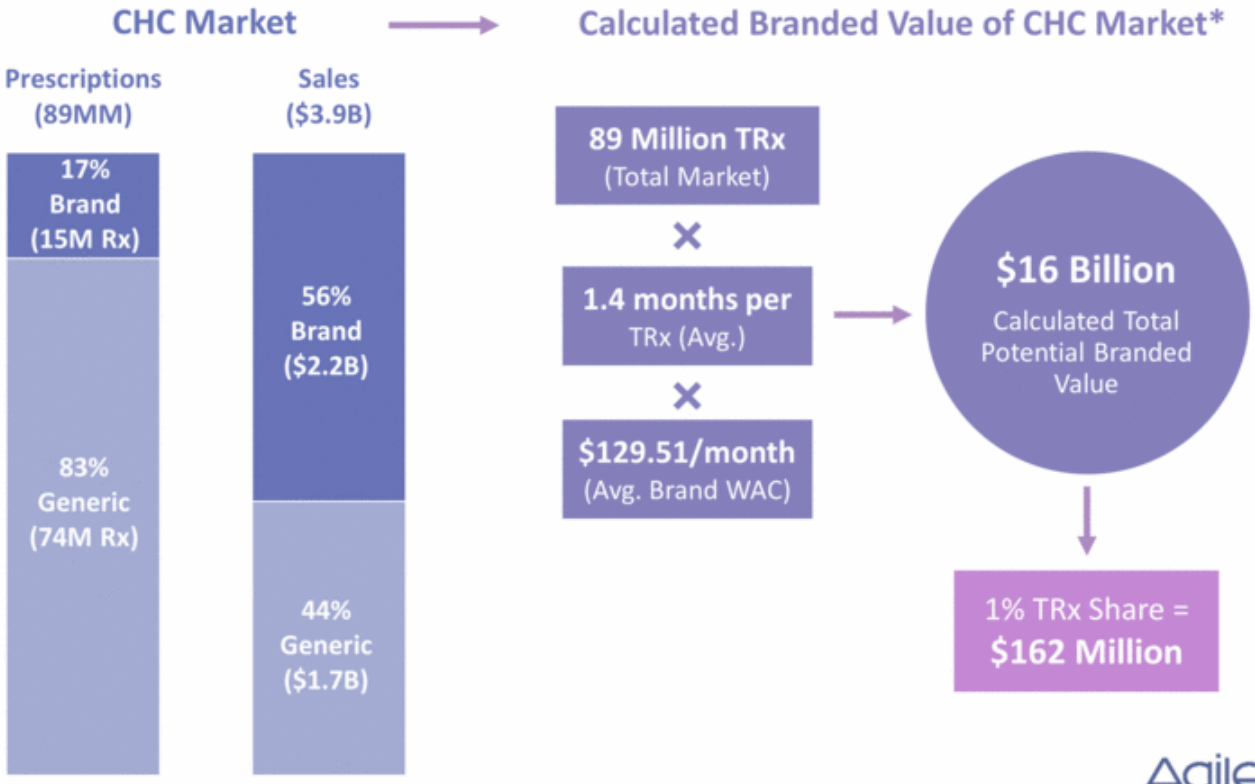
*includes brands and generic products (brands defined as products approved under an NDA, generics approved under an ANDA)
Source: IMS NPA and NSP, as of June 2016 (MAT)
Evra is a registered trademark of Johnson & Johnson, Inc.; Xulane is a registered trademark of Mylan, Inc.;
Nuvaring is a registered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

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



1.6 Source: IMS NPA 2000-2016

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



*Market value if all prescriptions were branded, to demonstrate value of 1% TRx share of a brand

1.6 Sources: IMS NPA June 2016 (MAT) and MediSpan Price Rx Select, October 2016

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Twirla® Marketing Plan is a 3-Pronged Approach

Managed Care

- Potentially favorable Managed Care environment for Twirla®, with or without the Affordable Care Act (ACA) Contraceptive Mandate

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 introductions 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

"…the ACA has affected my ability to prescribe a broader range of contraceptives…affordability has changed everything. The patient truly has choice now."

– Nurse Practitioner
October 2016

"I am happy to see [Twirla]! It's time another patch came to the market."

– OB/GYN
October 2016

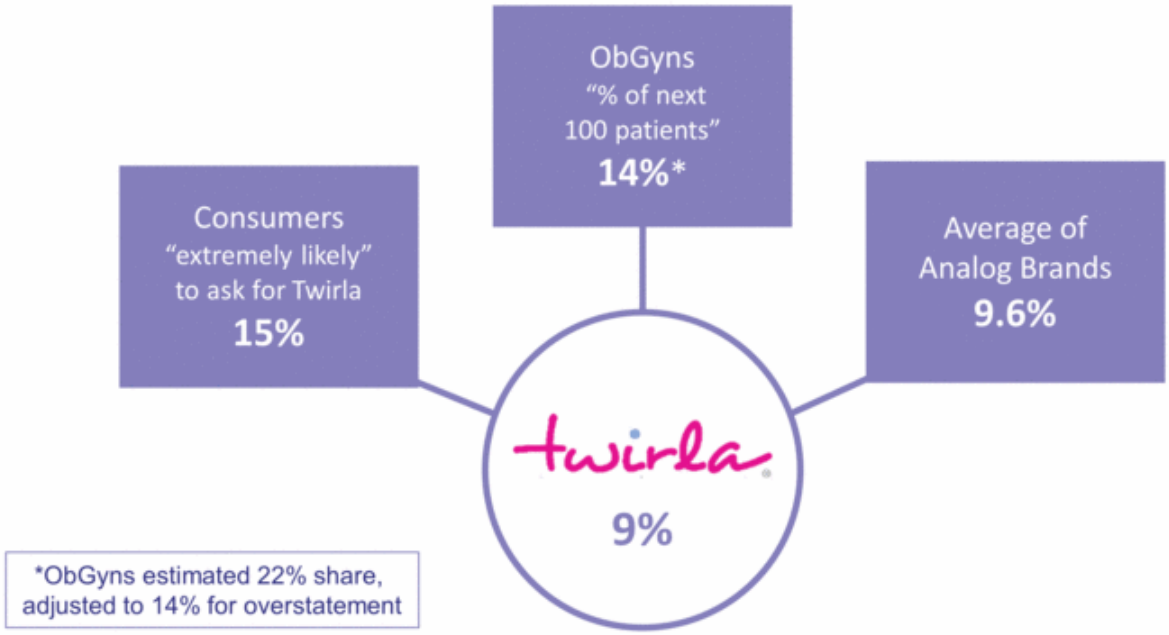
"I want to eliminate the forgetfulness… but I don't want to lose that control either."

– Consumer
October 2016

1.6 Source: SK&A Physician Access Study 2010, Qualitative HCP and Consumer market research, Adelphi Research 2016 and RG&A 2012

Twirla® Peak Share Estimate Rationale

Based on Consumer & Physician Market Research and Market Analogs



*ObGyns estimated 22% share, adjusted to 14% for overstatement

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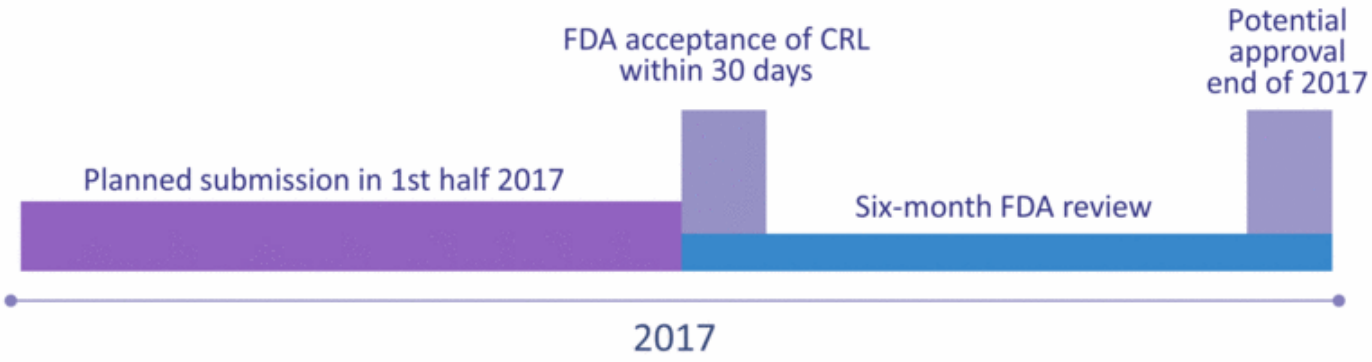
 Sources: IMS NPA, 2002-2014. Qualitative and Quantitative HCP and Consumer market research, Adelphi Research 2016

Potential for Approval By End of 2017

We are proud of the SECURE Trial and looking forward to sharing the data with the FDA



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Pipeline: Offering More Options For Women

twirla®

Patch Regimen: Once a week

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

Recent research suggests AG200-SP could expand Agile potential share of CHC market when introduced after Twirla

AG200-ER

AG200-ER: 8-week extended cycle regimen

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

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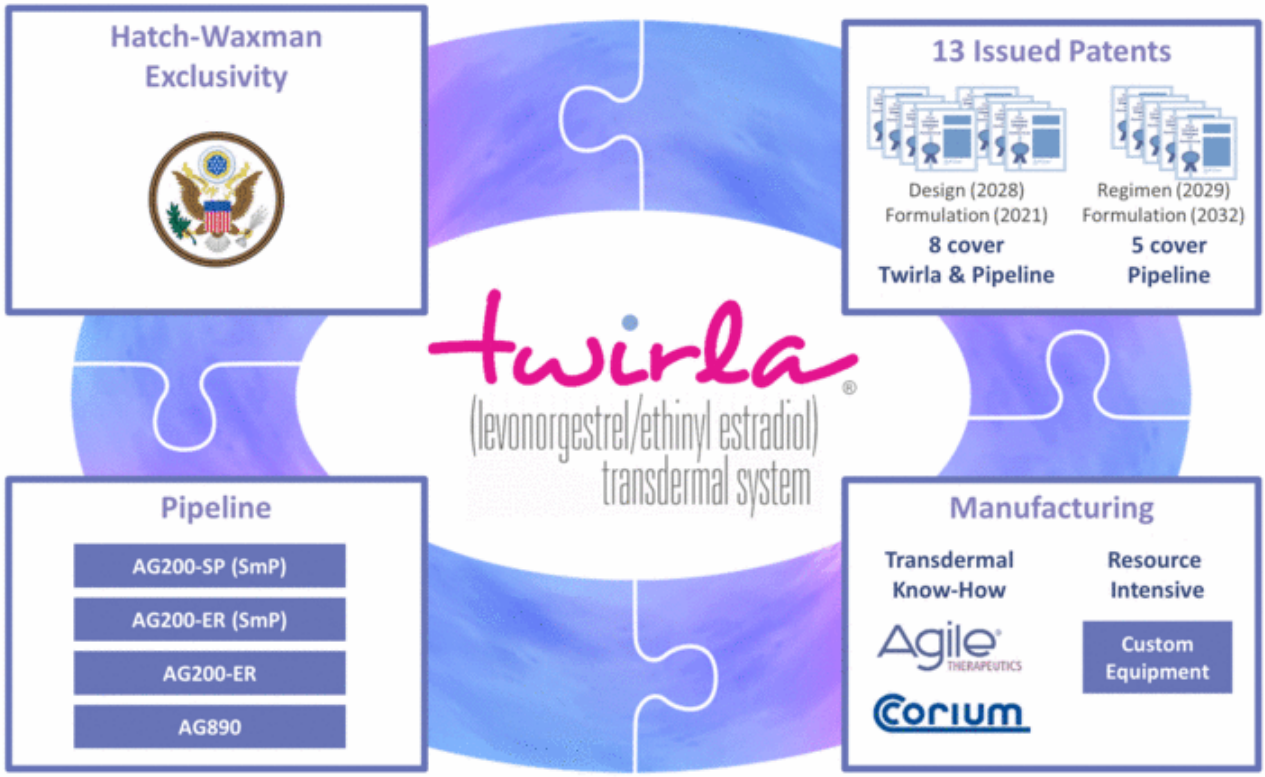
1.6 Source: Quantitative HCP market research, conducted by Adelphi 2016

Intellectual Property Strategies For the U.S. Franchise



Financial Profile

Balance Sheet Data

- $51.7 Million cash on hand at September 30, 2016
- $48.8 Million cash on hand (unaudited) at December 31, 2016
- 28.8 Million common shares outstanding at November 4, 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)

Corporate Summary

- ✓ Positive top-line data announced in January 2017
- ✓ NDA resubmission expected to address the clinical CRL questions
- ✓ Near-term catalyst: NDA resubmission expected 1H 2017
- ✓ 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
- ✓ Planning for commercialization
- ✓ Exciting pipeline opportunities for the future

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Agile®
THERAPEUTICS

Agile Position

Championing the healthcare choices women deserve.

Agile is a forward-thinking women's healthcare company dedicated to fulfilling the unmet health needs of today's women.

Agile Values

- Authentic listening and building trust to better understand and anticipate women's health and wellness needs
- Passionate determination to design and deliver inspiring and relevant women's healthcare solutions like no one else
- Innovative business practices that enable more efficient and effective customer experiences and partnerships

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
Elizabeth Garner, M.D., M.P.H. Sr. Vice President and Chief Medical Officer	MYRIAD abbvie MERCK
Renee Selman Chief Commercial Officer	Johnson & Johnson CATALINA ETHICON Women's Health & Urology inVentiv Health
Scott Coiante Vice President and Chief Financial Officer	MEDAREX EY

ORTHO TRI-CYCLEN (norgestimate/ethinyl estradiol)

Ortho Evra (norelgestromin/ethinyl estradiol transdermal system)

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

Corporate Strategy (Short term & Midterm): Establish a Market-Leading Contraceptive Franchise

Contraceptive Pipeline							
Product		Indication	Preclinical	Phase 1	Phase 2	Phase 3	Status
twirla		Contraception (21/7 cycle)					▪ Phase 3 clinical trial top-line data announced Jan 2017
Small Patch (SmP) Program	AG200-SP (SmP)	Contraception (shorter, lighter periods)					▪ Initial Phase 2 trial of AG200-SP (SmP) preparations underway ▪ Initiation of dosing expected 1Q 2017 ▪ Additional design and planning may be required based on outcome of initial Phase 2 clinical trial of SmP program
	AG200-ER (SmP)	Contraception (extended cycle)					
AG200-ER		Contraception (extended cycle)					▪ Additional design and planning may be required
AG890		Contraception (Progestin-only)					▪ Phase 2 PK/PD trial complete* ▪ Additional product and clinical development may be required to advance into Phase 3

*Data analysis from Phase 2 trial is under evaluation

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The SECURE Trial Was Designed to Assess the Efficacy and Safety of Twirla® in a Real-World Population

Rigorous trial design was focused on key elements of the CRL

- Multicenter, single-arm, open-label 13-cycle trial at 102 experienced U.S. clinical sites
  - ~ 2,000 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 ITT population of subjects 35 years of age and under
  - Prespecified analysis related to BMI and body weight

CRL = Complete Response Letter; ITT = Intent to Treat

Demographics Reflect the Broad Entry Criteria of the SECURE Trial

Study	SECURE	Ortho Evra Trials	Quartette Trial
Age			
Mean age	28 years	28 years	27 years
≤ 35 years	90%	83%	90%
> 35	10%	17%	10%
Body Mass Index			
Mean BMI*	28.3 kg/m^2	23.6 kg/m^2	27.4 kg/m^2
< 25 (normal)	39%	Not available	47%
25 - < 30 (overweight)	25%		25%
≥ 30 (obese)	35%		28%
Race			
White	67%	91%	64%
Black	24%	5%	19%
Asian	3%	2%	2%
Other	6%	2%	14%
Ethnicity			
Hispanic	20%	Not available	11%
Non-Hispanic	80%		89%
Hormonal Contraception Use			
Current user	35%	Not available	44%
Recent user	13%		
Former user	43%		39%
New user	9%		17%

*Based on CDC BMI categories

Information is based on currently marketed Ortho Evra and Quartette product labels and publicly available information. We have not performed a head-to-head comparison of Twirla to Ortho Evra or Quartette.

Percentages in table are rounded to nearest integer; may not add up to 100%

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SECURE Achieved a Lower Loss to Follow-Up Rate

Loss to follow-up rate substantially reduced compared to prior Agile Phase 3 trial, and in line with other contraceptive trials

	SECURE		Agile Prior Phase 3*		Quartette†	
Metric	n	%	n	%	n	%
Enrolled	2032	100.0	1129	100.0	3597	100.0
Discontinued**	1043	51.4	644	57.0	1453	40.3
Lost to Follow-up	229	11.3	229	20.3	480	13.3
Completed	988	48.6	485	43.0	2144	59.6

**Main reasons for subject discontinuation from SECURE trial: subject decision, adverse event, loss to follow-up

- Discontinuation rate and reasons for discontinuation were in line with other Phase 3 clinical trials for approved hormonal contraceptives, for example: Seasonique (51.5%), Lybrel (56.8%), Natazia (48%)†

*Includes only subjects originally randomized to patch arm

†Information is based on currently marketed product labels and publicly available information for Quartette, Seasonique, Lybrel, and Natazia. We have not performed a head-to-head comparison of Twirla to these products.

Twirla® Had a Favorable Wearability Profile in the SECURE Trial

Rates of patch-site irritation, itching, and patch detachment were low

- Of reported patches worn, 83% had no patch site irritation and 65% had no itching
  - If reported, most irritation and itching was mild
  - Overall, severe itching or irritation were observed in approximately 2.3% and 1.5% of patches worn
- Of reported patches worn, the rate of detachments was low across the trial
  - Ranged from 10% (Cycle 1) to 2% (Cycle 13)
  - Ortho Evra: Subjects with 1 patch completely detached ranged from 6% (Cycle 1) to 2% (Cycle 13)

*Information is based on currently marketed Ortho Evra product label and publicly available information. We have not performed a head-to-head comparison of Twirla to Ortho Evra.

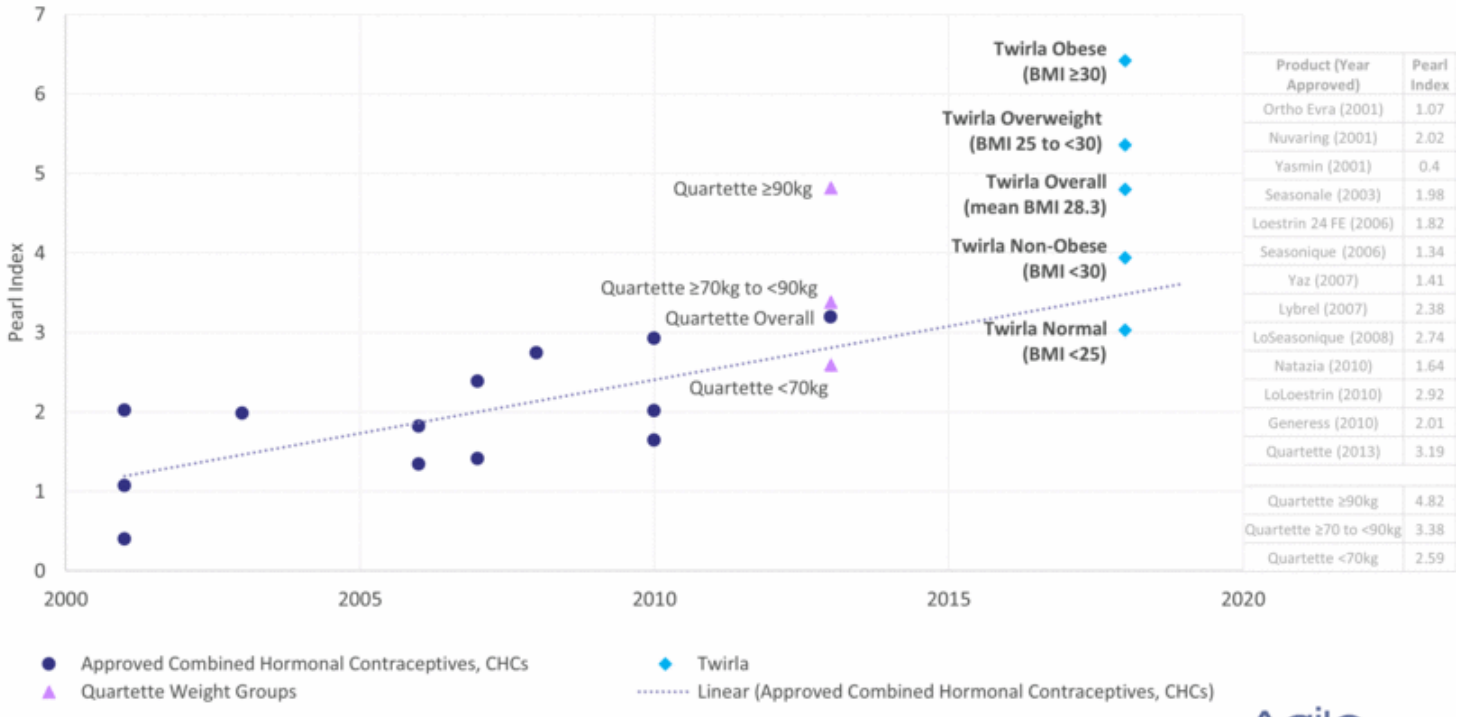
Summary of Recommendations from the 2007 FDA Advisory Committee Meeting on Contraceptive Trial Design

- Entry criteria should be more reflective of real-world prescribing regarding BMI, smoking, VTE family history
  - Subgroup analyses could be performed to assess efficacy
- Arbitrary limits for the UB of the 95% CI should be avoided in order to promote the widest range of new contraceptive products being developed and brought to market
- Substantial flexibility should be exercised in accepting given point estimates and UB of CI
- Provide all the information to the clinician and patient in an easily understandable format in labeling and let them make the final decision on which product is most appropriate
- Phase 4 trials may be used to obtain better estimates of true "actual use" effectiveness
- Product labeling should be modified to include pregnancy rates or safety data for subgroups when available

Source: 2007 FDA Advisory Committee for Reproductive Health Drugs, Summary of Recommendations
http://www.fda.gov/ohrms/dockets/ac/07/minutes/2007-4274m1.pdf

Observable Trend in Pearl Indices for Approved Combined Hormonal Contraceptives (CHCs)

Historical Pearl Indices for CHCs Approved Since 2000 and the Pearl Indices Observed in the SECURE Trial



Product (Year Approved)	Pearl Index
Ortho Evra (2001)	1.07
Nuvaring (2001)	2.02
Yasmin (2001)	0.4
Seasonale (2003)	1.98
Loestrin 24 FE (2006)	1.82
Seasonique (2006)	1.34
Yaz (2007)	1.41
Lybrel (2007)	2.38
LoSeasonique (2008)	2.74
Natazia (2010)	1.64
LoLoestrin (2010)	2.92
Generess (2010)	2.01
Quartette (2013)	3.19
Quartette ≥90kg	4.82
Quartette ≥70 to <90kg	3.38
Quartette <70kg	2.59

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1.6 Sources: Trussell, et al., *The Creeping Pearl* (2013), currently marketed product labels, and publicly available information

Approved Hormonal Contraceptive Products Had Higher Pearl Indices When Used As Comparators in Later Studies

Product	Trial	Year	Mean Weight/BMI	Pearl Index	UB 95% CI
Loestrin Fe 1/20	Original U.S. Registration	1973	Not available	0.75	Not available
	Ortho Tri-Cyclen Lo Phase 3	2002	23.6 kg/m^{2*}	3.80	
	Loestrin 24 Fe U.S. Phase 3	2006	68.2 kg	3.67	13.20
Levlite	Original German Registration	1998	62.7 kg	0.29	0.91†
	Original U.S. Registration	1998	63.0 kg	1.08	2.34†
	Seasonale Phase 3	2003	69.7 kg	3.75	8.60
Nordette	Original U.S. Registration	1982	Not available	0.48	1.04†
	Seasonale Phase 3	2003	71.0 kg	2.22	6.38
	Seasonique Phase 3	2006	71.8 kg	4.40	Not available

Sourced from publicly available NDA Reviews
**Mean weight not available*
†Calculated based on cycle and pregnancy data in NDA review

Contraceptive Trials Have Historically Excluded Obese Women

Product	BMI/Weight Effect Observed	Trial Exclusions for BMI/Weight
Twirla 2017*	YES	No exclusions for BMI/weight
Quartette 2013	YES	No exclusions for BMI/weight
Agile 2013 FDA CRL		
Minastrin 2013	No	BMI > 35 kg/m^2 excluded from trials
Generess 2011	YES	
LoLoestrin Fe 2010	No	
Natazia 2010	No	BMI > 30 kg/m^2 excluded from trials
LoSeasonique 2008	No	No exclusions for BMI/weight
Lybrel 2007	No	No exclusions for BMI/weight
2007 FDA Advisory Committee for Reproductive Health Drugs		
Loestrin 24 Fe 2006	No	BMI > 35 kg/m^2 excluded from trials
Seasonique 2006	No	No exclusions for BMI/weight
Yaz 2006	No	BMI > 35 kg/m^2 excluded from trials
Seasonale 2003	No	No exclusions for BMI/weight
Ortho TriCyclen Lo 2002	No	Subjects were to be "within 35% of acceptable BMI"
Ortho Evra 2001	YES	Subjects were to be of "acceptable BMI"
Nuvaring 2001	No	BMI > 30 kg/m^2 excluded from trials
Yasmin 2001	No	Subjects were to be "within 25% of ideal body weight"

**Candidate product*

BMI = Body Mass Index; CRL = Complete Response Letter
Information from publicly available information in NDA reviews and product labels

FDA Meta-Analysis on the Effect of Obesity on HC Effectiveness

The Division requested weight/BMI-based analyses for the Agile SECURE trial

- FDA authors called for more data in obese women from Phase 3 clinical trials after an FDA meta-analysis showed an effect of obesity on hormonal contraceptive effectiveness.
- Publication suggests 44% increased risk of pregnancy during CHC use in obese compared to non-obese women

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

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

CRL was February 2013; Source: Yamazaki M et al, Contraception 2015; 92: 445-52

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Healthcare Providers Focus on Typical Use Contraceptive Effectiveness

U.S. FOOD & DRUG ADMINISTRATION
www.fda.gov/birthcontrol

BIRTH CONTROL GUIDE

If you do not want to get pregnant, there are many birth control options to choose from. No one product is best for everyone. Some methods are more effective than others at preventing pregnancy. Check the pregnancy rates on this chart to get an idea of how effective the product is at preventing pregnancy. The pregnancy rates tell you the number of pregnancies expected per 100 women during the first year of typical use. Typical use shows how effective the different methods are during actual use (including sometimes using a method in a way that is not correct or not consistent). The only sure way to avoid pregnancy is not to have any sexual contact. Talk to your healthcare provider about the best method for you.

Most Effective ↑ ↓ Least Effective

FDA-Approved Methods	Number of pregnancies expected (per 100 Women)*	Use	Some Risks or Side Effects* This chart does not list all of the risks and side effects for each product.
Sterilization Surgery for Women	Less than 1	Onetime procedure. Permanent.	Pain Bleeding Infection or other complications after surgery
Sterilization Implant for Women	Less than 1	Onetime procedure. Permanent.	Pain/ cramping Pelvic or back discomfort Vaginal bleeding
Sterilization Surgery for Men	Less than 1	Onetime procedure. Permanent.	Pain Bleeding Infection
IUD Copper	Less than 1	Inserted by a healthcare provider. Lasts up to 10 years.	Cramps Heavier, longer periods Spotting between periods
IUD with Progestin	Less than 1	Inserted by a healthcare provider. Lasts up to 3-5 years, depending on the type.	Irregular bleeding No periods (amenorrhea) Abdominal/pelvic pain
Implantable Rod	Less than 1	Inserted by a healthcare provider. Lasts up to 3 years.	Menstrual Changes; Mood swings or depressed mood Weight gain; Headache Acne
Shot/ Injection	6	Need a shot every 3 months.	Loss of bone density Irregular bleeding/ Bleeding between periods Headaches; Weight gain Nervousness; Dizziness Abdominal discomfort
Oral Contraceptives "The Pill" (Combined Pill)	9	Must swallow a pill every day.	Spotting/ bleeding between periods Nausea Breast tenderness Headache
Oral Contraceptives "The Pill" (Extended/ Continuous Use Combined Pill)	9	Must swallow a pill every day.	Spotting/ bleeding between periods Nausea Breast tenderness Headache
Oral Contraceptives "The Mini Pill" (Progestin Only)	9	Must swallow a pill at the same time every day.	Spotting/ bleeding between periods Nausea Breast tenderness Headache
Patch	9	Put on a new patch each week for 3 weeks (21 total days). Don't put on a patch during the fourth week.	Spotting or bleeding between menstrual periods Nausea; Stomach pain Breast tenderness; Headache Skin irritation
Vaginal Contraceptive Ring	9	Put the ring into the vagina yourself. Keep the ring in your vagina for 3 weeks and then take it out for one week.	Vaginal discharge, discomfort in the vagina, and mild irritation. Headache; Mood changes Nausea; Breast tenderness
Diaphragm with Spermicide	12	Must use every time you have sex.	Irritation Allergic reactions Urinary tract infection
Sponge with Spermicide	12-24	Must use every time you have sex.	Irritation
Cervical Cap with Spermicide	17-23	Must use every time you have sex.	Irritation Allergic reactions Abnormal Pap test
Male Condom	18	Must use every time you have sex. Provides protection against some STDs.	Irritation Allergic reactions
Female Condom	21	Must use every time you have sex. Provides protection against some STDs.	Discomfort or pain during insertion or sex. Burning sensation, rash or itching
Spermicide Alone	28	Must use every time you have sex.	Irritation Allergic reactions Urinary tract infection

If approved, we expect Twirla to be included with other Tier 2 methods

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Datamonitor Analyst Study on FDA CRLs

- CRLs were received by 42% of NDAs/BLAs
  - 29% of NDAs receiving CRLs were withdrawn
  - 71% were resubmitted or open at time of analysis; of resubmitted NDAs with a documented FDA decision, 80 of 81 were approved
- Most failures to gain approval were because the applicant chose not to resubmit

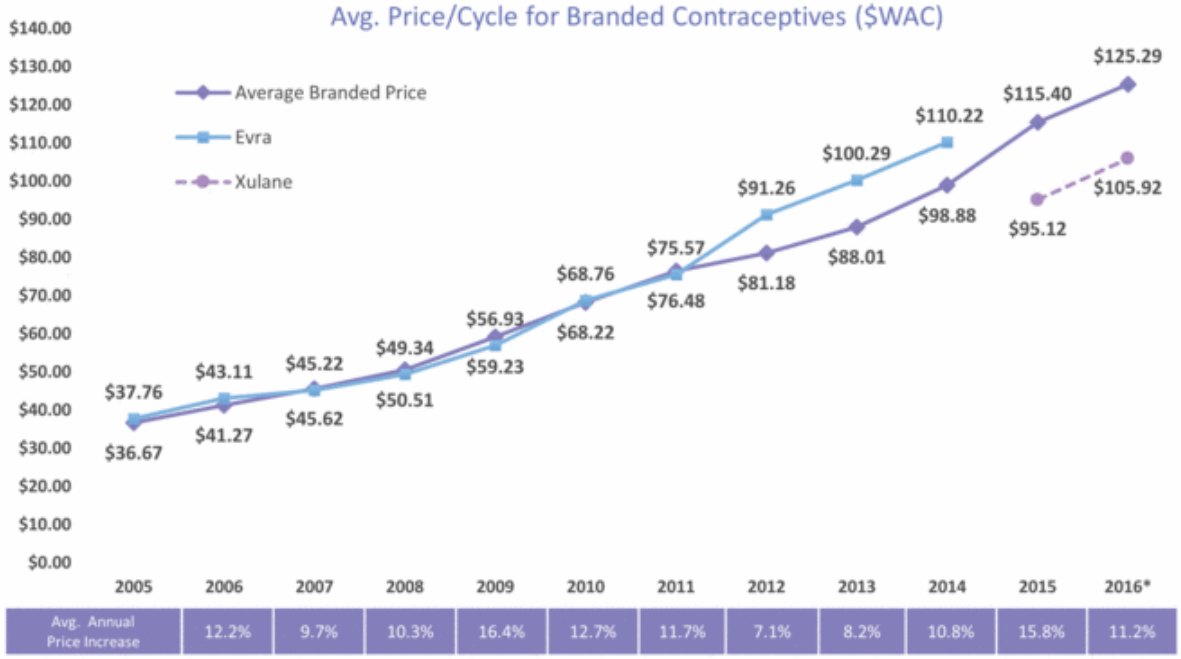
DATAMONITOR Healthcare

Complete Response Letter Trends and Influence on Approval Delays

CRL = Complete Response Letter
Source: Datamonitor Analysis-Analyst Opinion; study of 356 NDAs/BLAs from Oct 2008 to Sept 2012; Jan 2013.

Branded Contraceptives Continue to Take Consistent Price Increases

The current highest WAC for a branded combination contraceptive is $165.45



Avg. Annual Price Increase	12.2%	9.7%	10.3%	16.4%	12.7%	11.7%	7.1%	8.2%	10.8%	15.8%	11.2%

Source: MediSpan Price Rx Select, October 2016. *Values for 2016 are YTD through October 24, 2016

1.6 Avg. Price/cycle calculation includes 13 leading branded contraceptive products.

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We Believe 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

Possible Formulary Scenarios

If Twirla® is the preferred patch:

Patients will be able to fill a prescription with

- no copay
- no deductible
- no coinsurance

If Twirla is not the preferred patch:

Most branded contraceptives are on Tier 3 or 4

- Non-preferred brand copay median = $51-75
- Manufacturers utilize copay coupons to offset the copay cost

We believe Twirla will be competitive in the managed care environment, with or without the ACA

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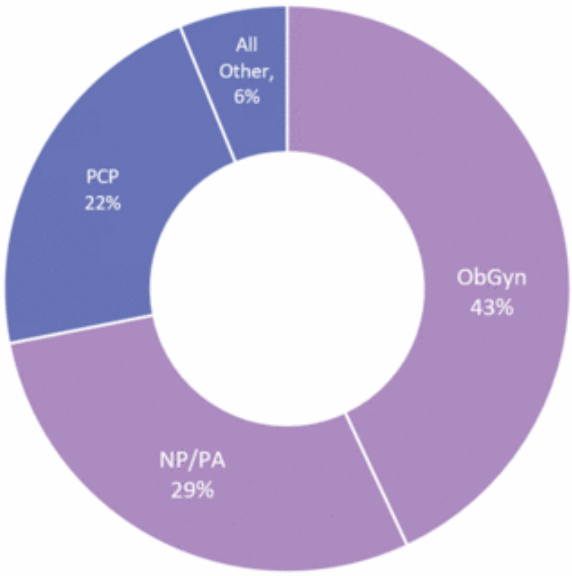
1.6 Sources: HHS FAQs About ACA Implementation (Part XXVI), May 11 2015; Managed Care research, Access Pointe 2016

ObGyns and Nurse Practitioners are the Key Contraceptive Prescribers

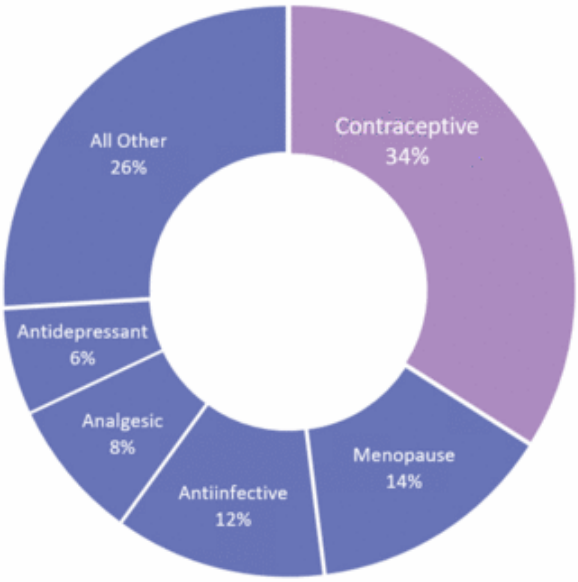
Over 70% of US Contraceptive TRx are Written by ObGyns/NPs/PAs

CHC Prescriptions by Prescriber Type



ObGyns Prescribe Contraceptives More than Any Other Therapy

ObGyn TRx by Category



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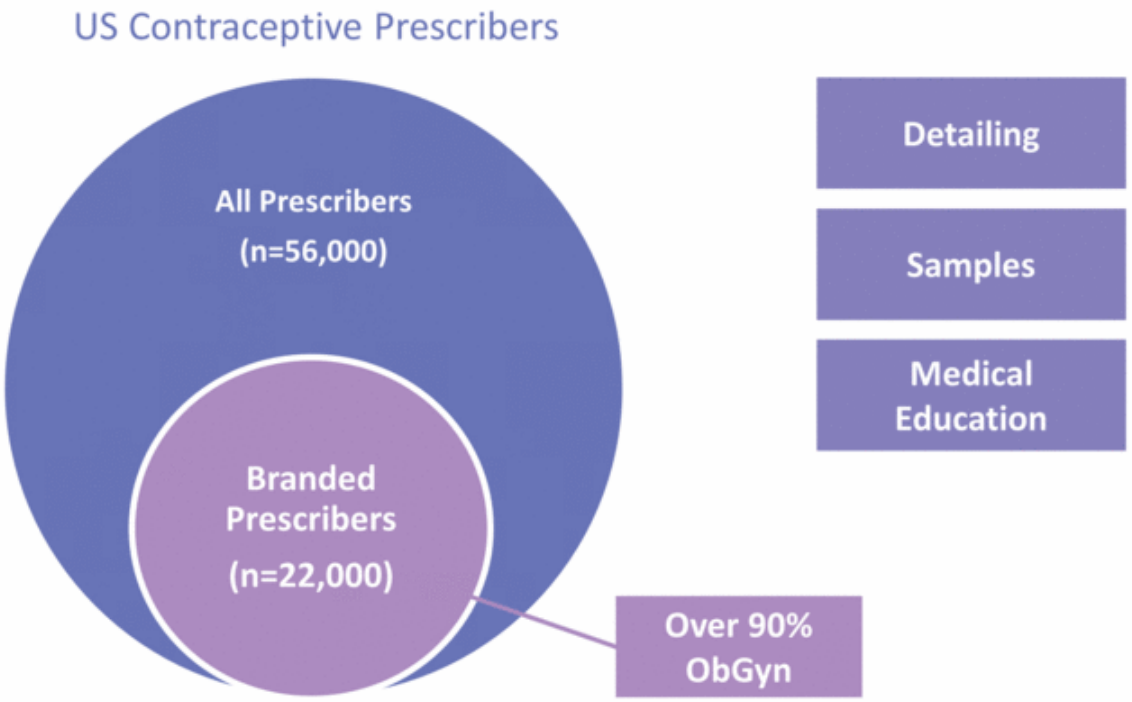
1.6 Source: IMS NPA, TRx Volume by Prescriber Type, MAT Sept 2016; IMS NPA, TRX Volume by Category, 2010

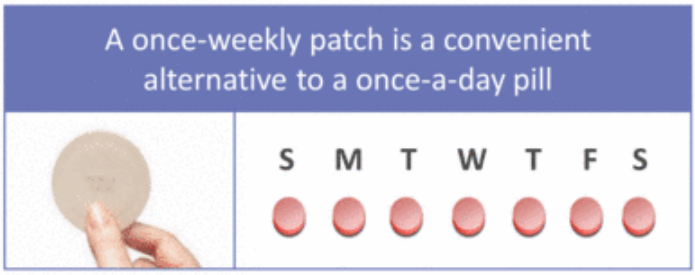
A Sales Force of 70-100 Reps is Estimated for Twirla®



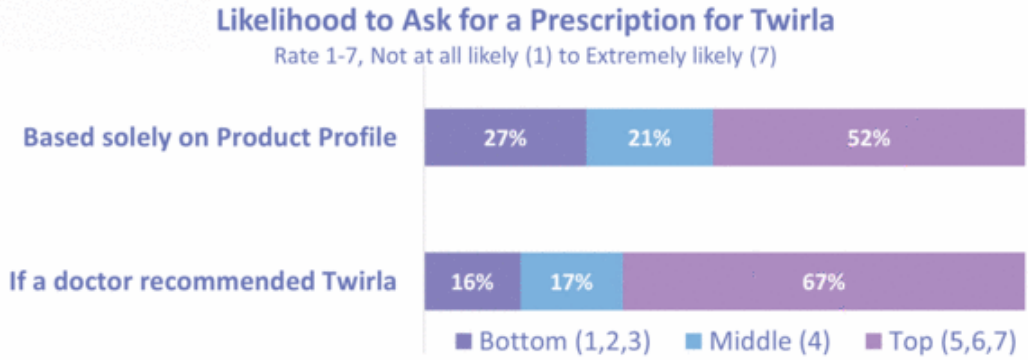
1.6 Source: Wolters Kluwer 2012 (# of prescribers) and IMS Prescriber Profiler 2009: %TRx written by ObGyns in Deciles 3-10 of contraceptive writers

We Know the Twirla® Target Consumer

Women would choose Twirla because it's **weekly** and **easy to remember**



"I like that it's weekly. That will be easier to remember. You see it too, so that's a reminder to change it."
– Consumer
October 2016



Source: Qualitative and Quantitative Consumer market research, Adelphi Research 2016

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

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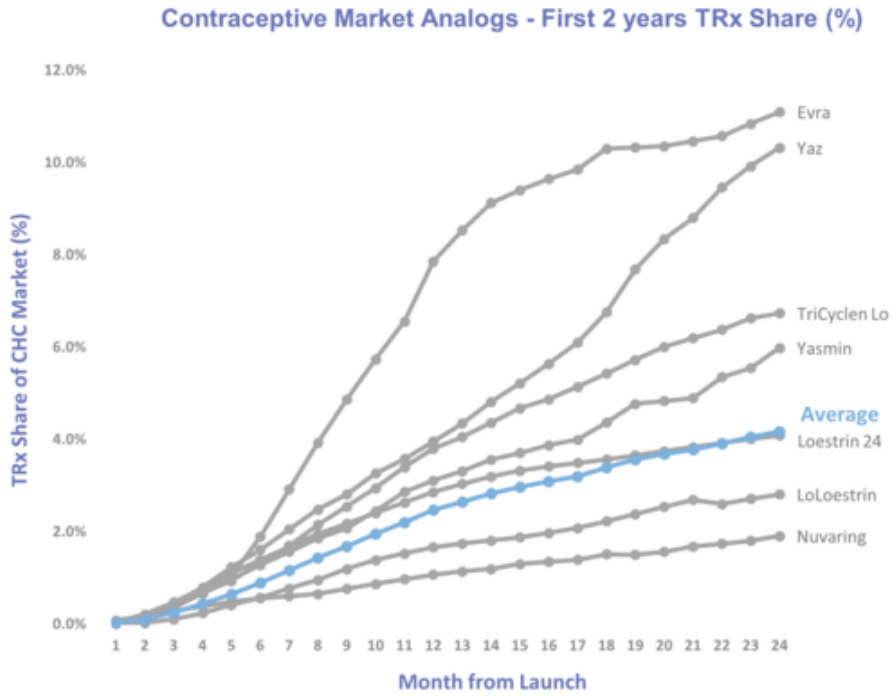
1.6 Sources: Survey of 1000 women age 15-44, RG&A 2012. Data for 'seekers' (n=565) considering starting birth control and Pew Research

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

1.6 Source: IMS NPA, 2002-2015

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