



We are Agile

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 forward-looking statements.

In particular, the Company’s statements regarding projections 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, risks related to the FDA requiring us to reformulate Twirla, our ability to develop a reformulation that will address the FDA’s concerns, including showing bioequivalence, if necessary, our ability to successfully complete the suggested wear study and the potential that the results do not support a conclusion by the FDA that Twirla has demonstrated adequate adhesion, the potential that we may be required to conduct additional clinical trials, the likelihood that we will require additional correspondence with the FDA prior to the resubmission of the Twirla NDA, in addition to the planned correspondence regarding the design of the suggested wear study, our ability to resubmit and the timing of our resubmission of the NDA for Twirla, FDA acceptance and approval of the resubmitted NDA, or whether other issues will arise that will negatively impact acceptance, review, and approval of Twirla by the FDA, including a determination by the Advisory Committee that Twirla should not be approved, our ability to address the deficiencies identified by the FDA in the CRL issued in December 2017 and in the Type A meeting minutes issued in May 2018, the fact that our existing cash and cash equivalents may not be sufficient to fund the completion of the development and regulatory review process for Twirla, our ability to raise capital when needed to complete the development and regulatory review process for Twirla, and unforeseen market factors or events in our clinical and manufacturing development plans; 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, 2017 and in the quarterly reports filed with the SEC.



- A champion for healthcare choices women deserve, headquartered in Princeton, NJ
- Dedicated to building a robust Women's Health Franchise
- Twirla® is our initial opportunity

 <p>Twirla™ (levonorgestrel/ethinyl estradiol) 120/30 mcg/day transdermal system</p>	<p>Low-dose, Weekly Contraceptive Patch</p> <p>\$3.8B Addressable Market</p>	
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Agile's Corporate Strategy: Become a Leader in Women's Health

- **Short-Term Goal** - Establish Agile in the prescription contraceptive market with Twirla[®], our lead product candidate
- **Long-Term Mission** - Broaden our women's health portfolio in areas of unmet medical need

Establish Agile in
Contraceptive Market
with Lead Product
Candidate

Become
Contraceptive Market
Leader

Broaden Women's
Health Portfolio in
Areas of Unmet Need

Agile's Executive Management Team

Deep Experience Including Women's Healthcare and Contraceptive Products



Al Altomari

*Chairman
and Chief Executive Officer*



Elizabeth Garner, MD, MPH

*Sr. Vice President
and Chief Medical Officer*



Scott Coiante

*Vice President
and Chief Financial Officer*



Geoff Gilmore

General Counsel



Agile's Women's Health Mission Starts with Contraception

WHY CONTRACEPTION?

Women use contraception for an average of 30 years, and nearly all women use contraception at some point^{1,2}

~50% of pregnancies in U.S. women are unintended³

WHY DO WOMEN NEED MORE BIRTH CONTROL OPTIONS?

Nearly half of unintended pregnancies are due to inconsistent and/or improper use of contraception⁴

Women's individual preferences for contraceptive methods vary and change across their lifetimes as their needs change⁵

Women are more consistent with contraceptive use and stay with a method for longer when using a method of their choosing⁴

¹Hamilton BE, Kirmeyer SE., National Center for Health Statistics. 2017; ²Daniels K et al, National Center for Health Statistics. 2013

³Finer LB and Zolna MR, NEJM 2016; ⁴Frost JJ and Darroch J., Perspectives on Sexual and Reproductive Health 2008

⁵Mansour D, Int J Women's Health 2014

What is Missing From Available Hormonal Birth Control Options?

“Some women are just not good at remembering to take a pill at the same time every day...Others don't want something in their vagina while others don't want an injection.”

-Ob/Gyn

LOWER
ESTROGEN
DOSE

The dose of estrogen in CHCs is believed to be the primary factor influencing the risk of blood clots (VTEs)¹
The only non-daily transdermal patch currently available delivers a high dose of estrogen²

NON-
DAILY
OPTIONS

Decrease the chance of missed daily pills³
Oral contraceptives (OCs) are highly effective when used correctly, however women report inconsistent use^{4,5}

LESS
INVASIVE
METHODS

Preferred by some women⁶
Some women prefer to avoid injections, implants, and intrauterine devices

¹Stegeman B. H., et al, BMJ 2013; ²Xulane Package Insert; ³FDA Press Release-Ortho Evra Label Update 2005; ⁴Halpern V et al, Cochrane Review 2013; ⁵CDC National Survey of Family Growth 2016; ⁶Qualitative and quantitative HCP research, Kantar Health 2010; Third party research, 2017

Twirla® Designed to Fill A Hormonal Birth Control Market Need

Twirla™



LOW DOSE

NON-DAILY

LESS INVASIVE

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

Patch Regimen: Once-a-week

S	M	T	W	T	F	S
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						

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

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

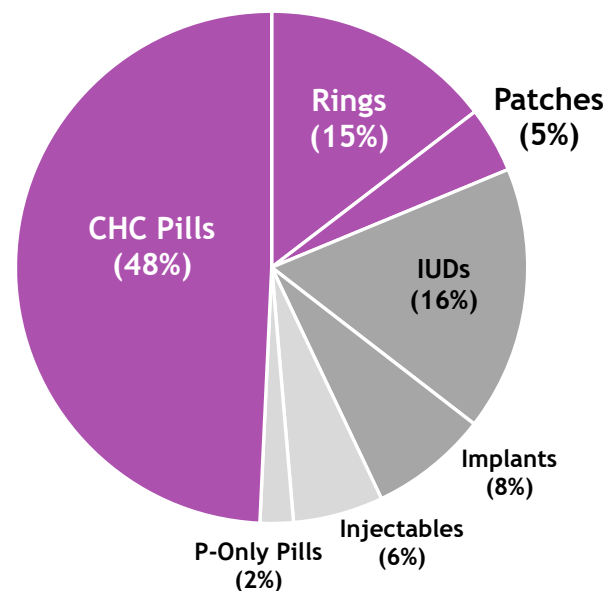
Agile
THERAPEUTICS
NASDAQ: AGRX

U.S. Hormonal Contraceptive Market is a Significant Opportunity

\$5.6 Billion US Contraceptive Market in 2017

Combined Hormonal Contraception (CHC)	Progestin-Only (P-Only)	Long Acting Reversible Contraception (LARC)
CHC Pill, Ring, Patch	P-only Pill, Injection	IUD, Implant
<i>\$3.8 Billion</i>	\$439 Million	\$1.4 Billion

CHC Pills + Ring + Patch =
\$3.8 Billion
 Potential Addressable Market for

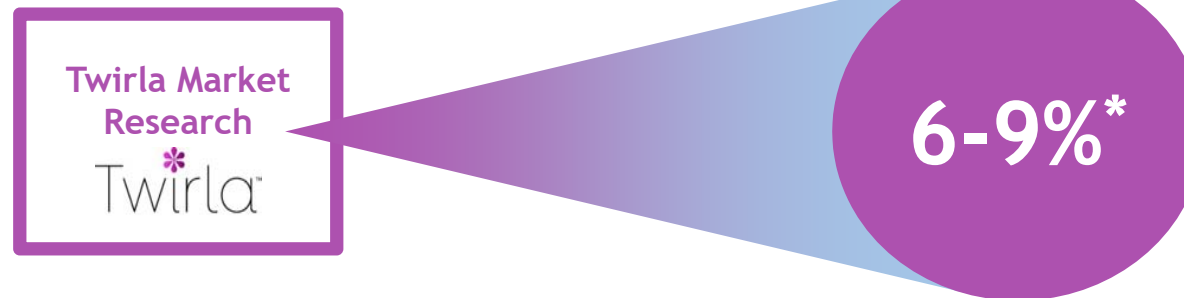



P-only Pills category includes emergency contraceptive prescriptions. Not Shown: "All Other" category with <1M TRx
 Sources: IMS NSP through Dec 2017; ACOG FAQs

Twirla[®] has the Potential for Significant Market Share

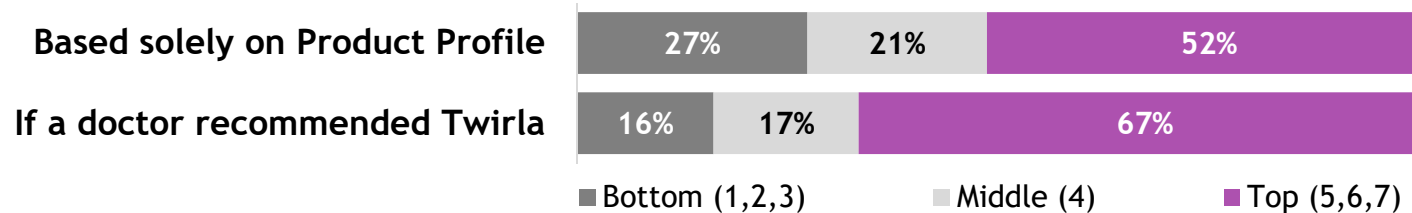
Twirla Potential Peak TRx - HCP Market Research

(% CHC Market)



Consumer Market Research

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



*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

Twirla® Pivotal Phase 3 SECURE Trial

Single-arm 13-cycle trial of ~2000 healthy subjects aged ≥ 18 at 102 U.S. clinical sites

SECURE Study Design	Rigorous Design <ul style="list-style-type: none">• Frequent Pregnancy Testing• Stringent cycle exclusion
	Representative of Women Seeking Hormonal Contraception <ul style="list-style-type: none">• No exclusions for weight or BMI• SECURE trial population one of the heaviest for a CHC trial
Important Scientific Data	Efficacy <ul style="list-style-type: none">• Tight confidence interval achieved on overall results• Pearl Index higher than previously approved products• Effect of obesity observed
	Safety and Tolerability <ul style="list-style-type: none">• Low rate of hormone-related adverse events• Serious adverse events observed in 1.97% of subjects• Bleeding profile similar to low-dose oral CHCs
	Wearability <ul style="list-style-type: none">• Low levels of detachments, patch site irritation, and itching• Adhesion performance improved over time with increased use• Observed learning curve may be addressable through training

Recent Regulatory History

June 2017
Resubmission of Twirla
NDA to FDA

Dec. 2017
Complete
Response
Letter (CRL)
from FDA

April 2018
Type A End of Review
Meeting to Discuss CRL

June 2018
Formal Dispute Resolution (FDR)
on Adhesion Initiated

Oct. 2018
Resolution of FDR &
Potential Path Forward
for Resubmission

2017

2018

Path To Potential Twirla® Approval

ISSUE RAISED BY FDA CRL	CLARIFICATION FROM FDA FOR NEXT STEPS
Adhesion Test Methods	<input checked="" type="checkbox"/> New method appears reasonable and will be a review issue
Manufacturing Inspection Observations	<input checked="" type="checkbox"/> Responses to initial PAI submitted. Likely subject to another PAI
In Vivo Adhesion	<input checked="" type="checkbox"/> FDR completed; FDA recommended Comparative Wear Study with Xulane
High Pearl Index	<input checked="" type="checkbox"/> FDA anticipates reviewing efficacy and benefit/risk at Advisory Committee
NEXT STEPS	<input type="checkbox"/> Comparative Wear Study with Xulane <input type="checkbox"/> Resubmit NDA <input type="checkbox"/> Likely PAI at Corium <input type="checkbox"/> Anticipated Advisory Committee on Efficacy and Benefit/Risk

Agile Knows How to Scale Up for Commercialization of Twirla

MANUFACTURING

- Corium is an experienced contract patch manufacturer
- Qualification of commercial scale equipment in final stages
- Plan for completion of validation after approval

MARKET ACCESS

- Agile knows its market
- Top 8 payers expected to cover majority of commercial lives¹
- Strategic contracting to place Twirla in competitive reimbursement position

LAUNCH NETWORK

- Relationships with experienced vendors to facilitate commercial launch
- Vendors have expertise in marketing, PR, market access, and supply chain

SALES FORCE

- Small, targeted sales force (70-100 reps) to launch
- Phased hiring linked to formulary acceptance
- Focus on high-prescribing Ob/Gyns and women's health NP/PAs



AGRX Financial Overview

Balance Sheet

\$16.9 Million cash on hand at September 30, 2018

\$7.8 Million cash on hand (unaudited) at December 31, 2018

- Debt fully paid off on December 1, 2018
-

Shares Outstanding

34.4 Million common shares outstanding at September 30, 2018

- 34.4 Million weighted average shares outstanding 3 months ended Sept 30, 2018
 - 34.3 Million weighted average shares outstanding 9 months ended Sept 30, 2018
-

Potential Future Capital

\$100.0 Million Universal Shelf Registration Statement on Form S-3

Summary of Agile Therapeutics Opportunity

<p>WHAT IS OUR INITIAL FOCUS?</p>	<ul style="list-style-type: none"> ▪ A low-dose, non-daily, less invasive contraceptive option - Twirla® 										
<p>WHY ARE WE WELL-POSITIONED TO EXECUTE OUR PLAN?</p>	<ul style="list-style-type: none"> ▪ Experienced management team with the ability to plan and execute ▪ Productive interactions with FDA and realizable next steps ▪ Foundation for Twirla® launch planning is established 										
<p>WHAT ARE OUR 2019 MILESTONES?</p>	<table border="1"> <thead> <tr> <th data-bbox="562 984 1501 1055">2019 MILESTONE</th> <th data-bbox="1501 984 1858 1055">PROJECTED TIMING</th> </tr> </thead> <tbody> <tr> <td data-bbox="562 1055 1501 1112">Complete comparative wear study & announce results</td> <td data-bbox="1501 1055 1858 1112">Q1</td> </tr> <tr> <td data-bbox="562 1112 1501 1169">Resubmission/Acceptance of Twirla NDA</td> <td data-bbox="1501 1112 1858 1169">1st Half</td> </tr> <tr> <td data-bbox="562 1169 1501 1226">Likely Advisory Committee on Twirla</td> <td data-bbox="1501 1169 1858 1226">2nd Half</td> </tr> <tr> <td data-bbox="562 1226 1501 1286">Potential Twirla approval</td> <td data-bbox="1501 1226 1858 1286">Year End</td> </tr> </tbody> </table>	2019 MILESTONE	PROJECTED TIMING	Complete comparative wear study & announce results	Q1	Resubmission/Acceptance of Twirla NDA	1 st Half	Likely Advisory Committee on Twirla	2 nd Half	Potential Twirla approval	Year End
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BACK-UP SLIDES

Evidence of Efficacy in a Representative 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:

*Reflective of Historical CHC Trial Populations

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

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

Pearl Index with no contraception¹: ~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: ¹Personal correspondence with Dr. James Trussell

Life Table Efficacy is Another 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

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%

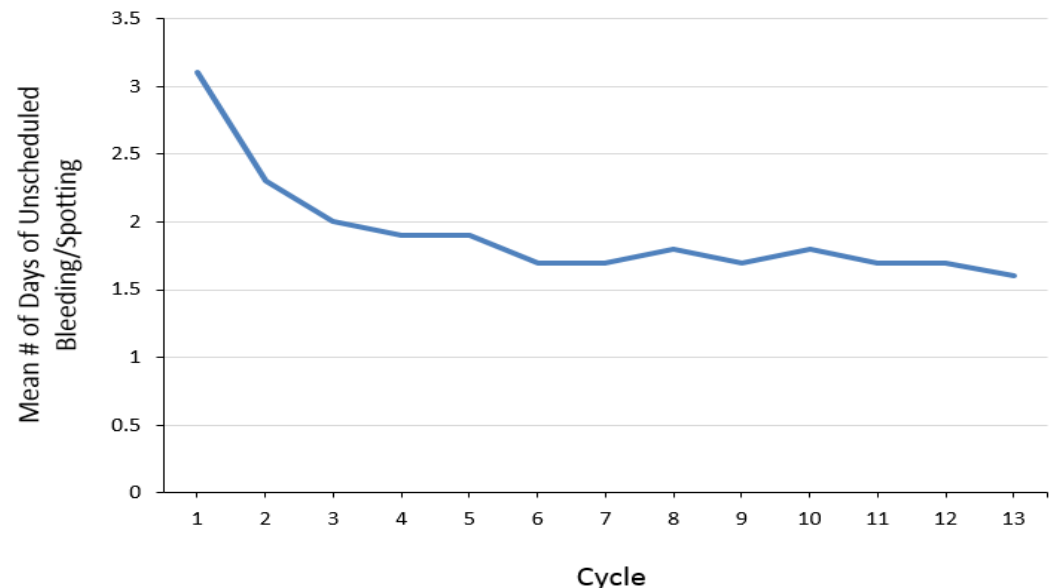
- Overall serious adverse events (SAEs) were observed in 1.97% of the SECURE trial study population; generally in line with those observed in other low-dose combined hormonal products* (rate in Quartette trial = 1.6%); 0.7% of subjects had SAEs that were considered potentially study drug related, including 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/m²)

*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.

Bleeding Profile Similar to Oral Low-Dose CHCs

- Bleeding-related side effects are among the top reasons women discontinue hormonal contraception¹
- 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 CHCs² 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

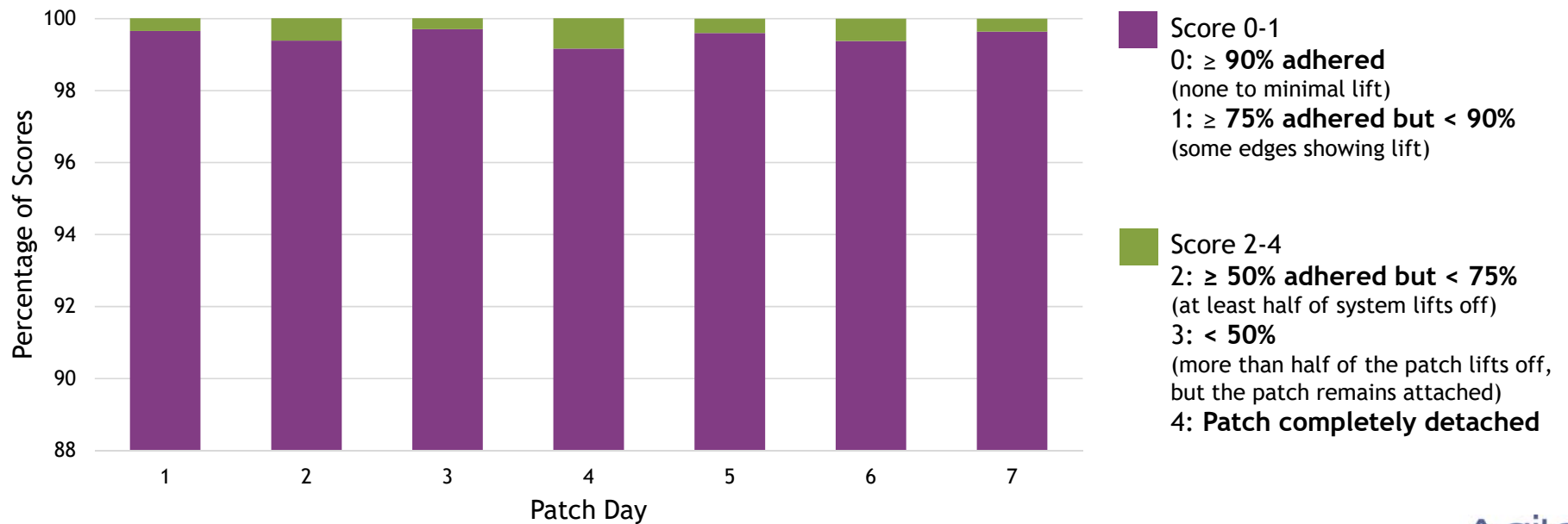


Adhesion Profile in the SECURE Trial

- 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)

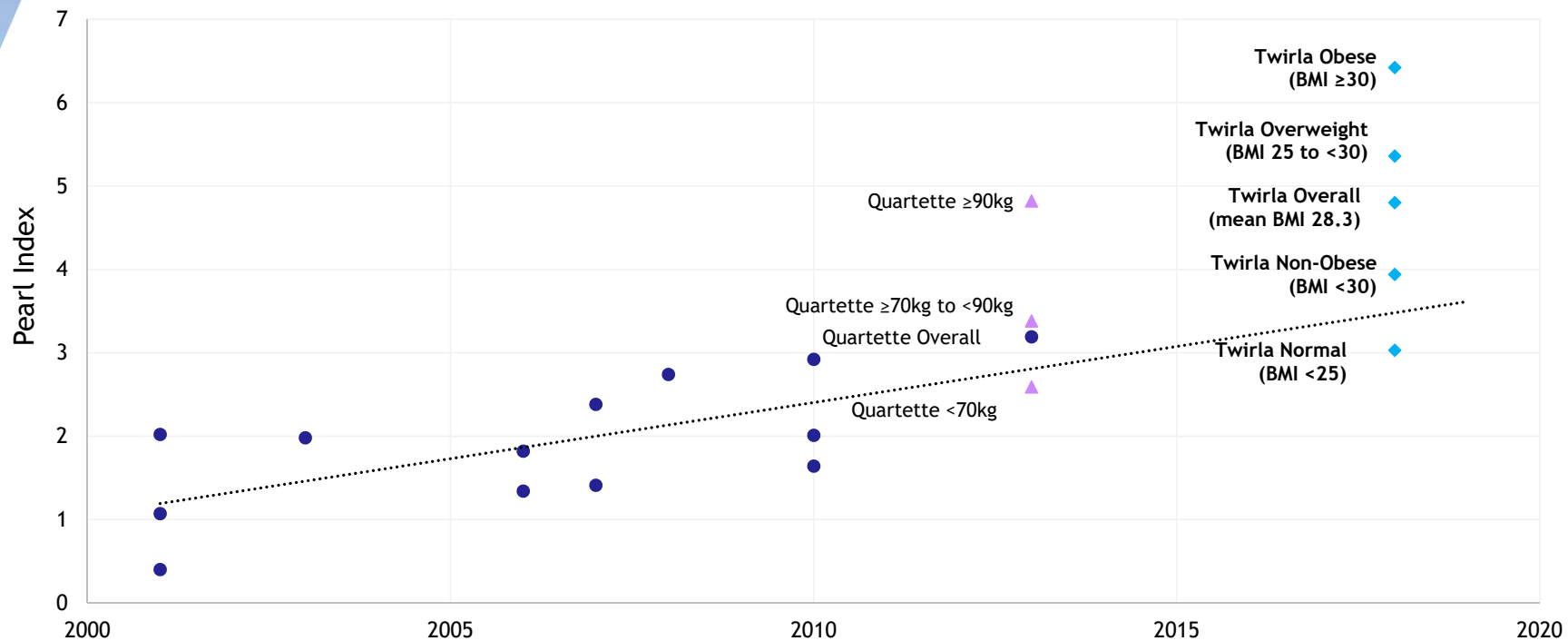
— As rated by SECURE trial Investigators during routine subject visits, using a 5-point scale provided by the FDA

Investigator-Reported Patch Adhesion Scores



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

- Approved Combined Hormonal Contraceptives, CHCs
- ▲ Quartette Weight Groups

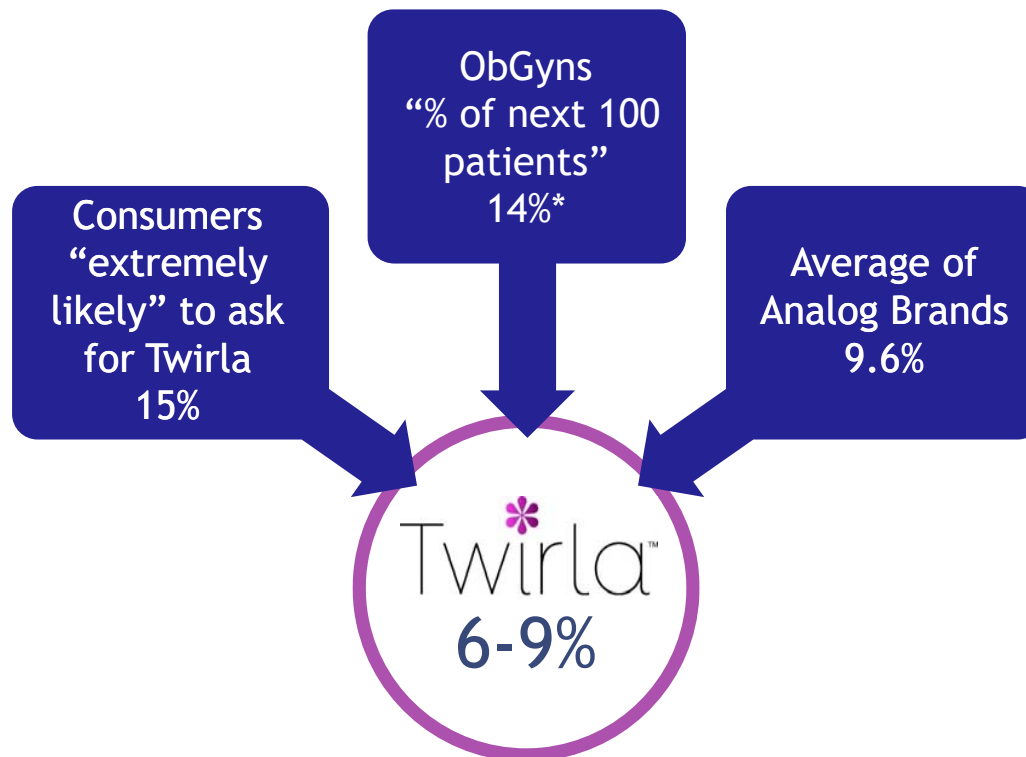
- ◆ Twirla
- Linear (Approved Combined Hormonal Contraceptives, CHCs)

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



Twirla® Peak Share Estimate Rationale

Based on Consumer & Physician Market Research and Market Analogs



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

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