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 7, 2019
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** (Address of principal executive offices)	**08540** (Zip Code)

Registrant's telephone number, including area code **(609) 683-1880**

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

o 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))

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 2.02 Results of Operations and Financial Condition.

As discussed below, in connection with its participation in the 37th Annual J.P. Morgan Healthcare Conference in San Francisco, California beginning on January 7, 2019, Agile Therapeutics, Inc. (the "Company") updated its corporate presentation to include disclosure that the Company had $7.8 million of cash and cash equivalents (unaudited) as of December 31, 2018.

Because the Company's financial statements for the year ended December 31, 2018 have not yet been finalized or audited, the preliminary statement of the Company's cash and cash equivalents as of December 31, 2018 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 8.01. Other Events

Beginning on January 7, 2019, the Company will participate in the 37th 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 its presentation at the Biotech Showcase 2019 on Tuesday January 8, 2019 at 10:00 a.m. Pacific Time and in meetings with investors. The updates primarily include disclosure regarding the Company's cash and cash equivalents as of December 31, 2018 and an update regarding the Company's regulatory path forward for Twirla®, including planned timelines for completion of a comparative wear study with Xulane®, resubmission of the Twirla NDA, a likely U.S. Food and Drug Administration advisory committee on Twirla's efficacy and benefit/risk profile, and for Twirla's potential approval.

A copy of the Company's corporate presentation is attached hereto as Exhibit 99.1 and is hereby incorporated by reference herein.

Xulane® is a registered trademark of Mylan N.V.

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, 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: January 7, 2019

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

Exhibit 99.1

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.

Agile® THERAPEUTICS

- 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

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

Low-dose, Weekly Contraceptive Patch

$3.8B Addressable Market

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

Agile's 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

Elizabeth Garner, MD, MPH

Sr. Vice President
and Chief Medical Officer

MYRIAD · abbvie · MERCK

Scott Coiante

Vice President
and Chief Financial Officer

MEDAREX · EY

Geoff Gilmore

General Counsel

Bristol-Myers Squibb · Amicus Therapeutics

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 unintended[3]
WHY DO WOMEN NEED MORE BIRTH CONTROL OPTIONS?	Nearly half of unintended pregnancies are due to inconsistent and/or improper use of contraception[4]
	Women's individual preferences for contraceptive methods vary and change across their lifetimes as their needs change[5]
	Women are more consistent with contraceptive use and stay with a method for longer when using a method of their choosing[4]

[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]Mansour 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 estrogen[2]

NON-DAILY OPTIONS

Decrease the chance of missed daily pills[3]

Oral contraceptives (OCs) are highly effective when used correctly, however women report inconsistent use[4,5]

LESS INVASIVE METHODS

Preferred by some women[6]

Some women prefer to avoid injections, implants, and intrauterine devices

[1]Stegeman B. H., et al, BMJ 2013; [2]Xulane Package Insert; [3]FDA Press Release-Ortho Evra Label Update 2005; [4]Halpern V et al, Cochrane Review 2013; [5]CDC National Survey of Family Growth 2016; [6]Qualitative 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

Pill Regimen: Once-a-day

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

U.S. Hormonal Contraceptive Market is a Significant Opportunity

$5.6 Billion US Contraceptive Market in 2017

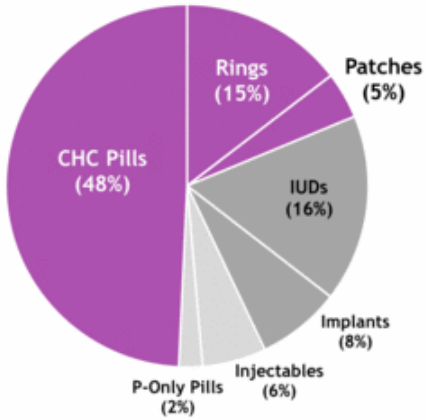
Combined Hormonal Contraception (CHC)	Progestin-Only (P-Only)	Long Acting Reversible Contraception (LARC)
CHC Pill, Ring, Patch	P-only Pill, Injection	IUD, Implant
$3.8 Billion	$439 Million	$1.4 Billion

CHC Pills + Ring + Patch =

$3.8 Billion

Potential Addressable Market for

Twirla™

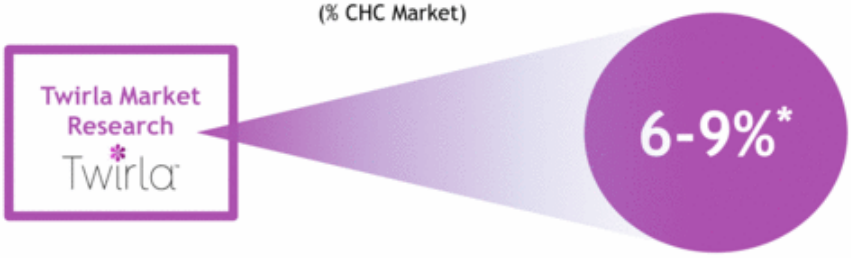


P-only Pills category includes emergency contraceptive prescriptions. Not Shown: "All Other" category with <1M TRx
Sources: IMS NSP through Dec 2017; ACOG FAQs

Twirla® has the Potential for Significant Market Share

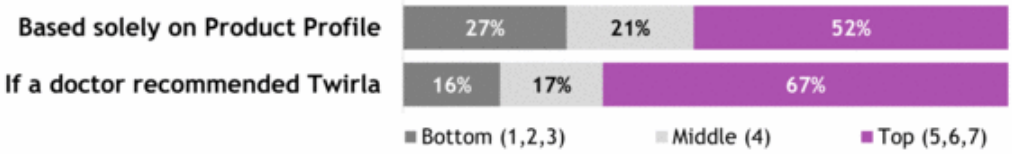
Twirla Potential Peak TRx - HCP Market Research

(% 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	• Frequent Pregnancy Testing • Stringent cycle exclusion
	Representative of Women Seeking Hormonal Contraception	• No exclusions for weight or BMI • SECURE trial population one of the heaviest for a CHC trial
Important Scientific Data	Efficacy	• Tight confidence interval achieved on overall results • Pearl Index higher than previously approved products • Effect of obesity observed
	Safety and Tolerability	• 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	• 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

Path To Potential Twirla® Approval

ISSUE RAISED BY FDA CRL	CLARIFICATION FROM FDA FOR NEXT STEPS
Adhesion Test Methods	☑ New method appears reasonable and will be a review issue
Manufacturing Inspection Observations	☑ Responses to initial PAI submitted. Likely subject to another PAI
In Vivo Adhesion	☑ FDR completed; FDA recommended Comparative Wear Study with Xulane
High Pearl Index	☑ FDA anticipates reviewing efficacy and benefit/risk at Advisory Committee

NEXT STEPS	
	☐ Comparative Wear Study with Xulane ☐ Resubmit NDA ☐ Likely PAI at Corium ☐ Anticipated Advisory Committee on Efficacy and Benefit/Risk

Agile Knows How to Scale Up for Commercialization of Twirla

MANUFACTURING	MARKET ACCESS	LAUNCH NETWORK	SALES FORCE
▪ Corium is an experienced contract patch manufacturer ▪ Qualification of commercial scale equipment in final stages ▪ Plan for completion of validation after approval	▪ Agile knows its market ▪ Top 8 payers expected to cover majority of commercial lives[1] ▪ Strategic contracting to place Twirla in competitive reimbursement position	▪ Relationships with experienced vendors to facilitate commercial launch ▪ Vendors have expertise in marketing, PR, market access, and supply chain	▪ 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

Sources: [1]Symphony Health Phast, July 2017

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

WHAT IS OUR INITIAL FOCUS?	▪ A low-dose, non-daily, less invasive contraceptive option – **Twirla®**
WHY ARE WE WELL-POSITIONED TO EXECUTE OUR PLAN?	▪ 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

WHAT ARE OUR 2019 MILESTONES?

2019 MILESTONE	PROJECTED TIMING
Complete comparative wear study & announce results	Q1
Resubmission/Acceptance of Twirla NDA	1st Half
Likely Advisory Committee on Twirla	2nd Half
Potential Twirla approval	Year End

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:

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

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 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

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

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:

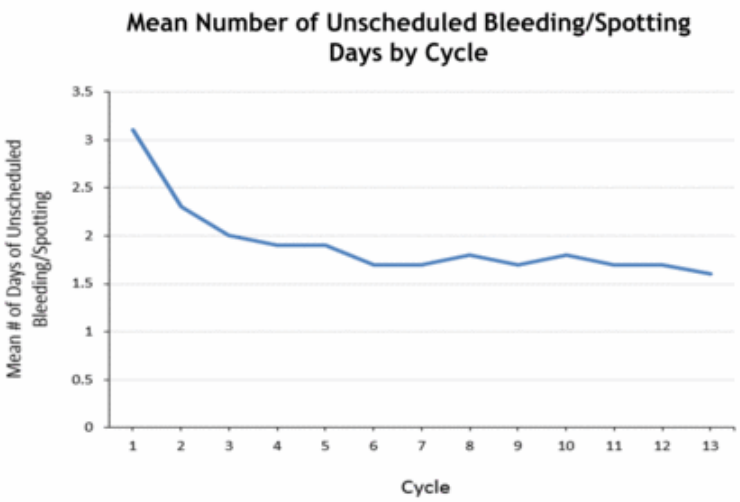
Adverse Event*	SECURE Trial	Prior Agile Phase 3 Trials	Ortho Evra Trials*	Quartette Trial*
Total in Safety Population	2031	1043	3322	3597
Headache	4.5%	3.7%	21.0%	12.2%
Nausea	4.1%	4.3%	16.6%	6.7%
Breast tenderness/pain/discomfort	2.0%	1.8%	22.4%	2.2%
Mood swings/changes/depression	2.7%	2.8%	6.3%	2.9%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

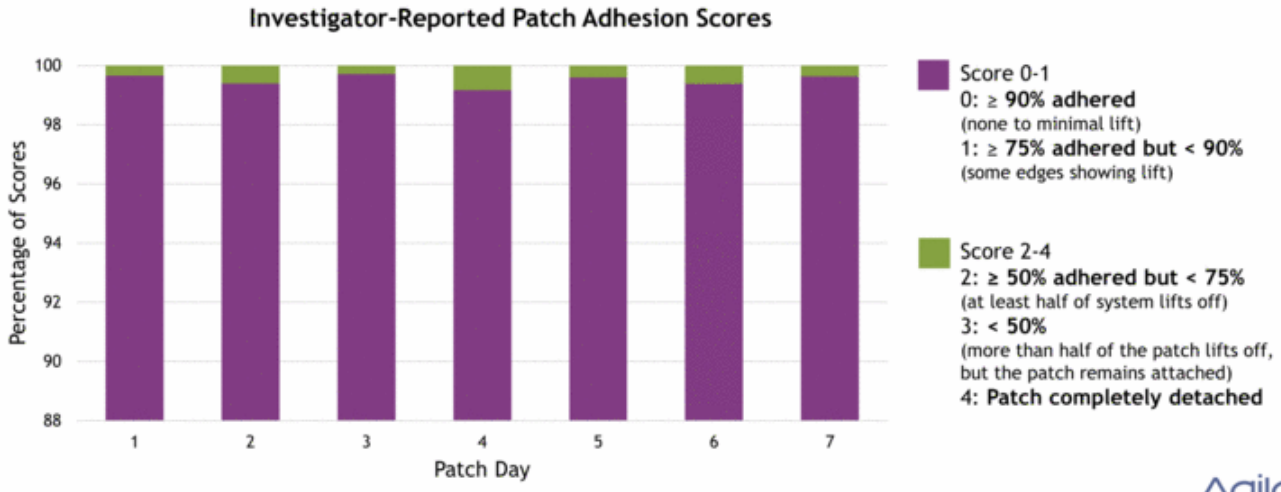
- Bleeding-related side effects are among the top reasons women discontinue hormonal contraception[1]
- Monthly withdrawal bleeding duration (mean 3-3.7 days) in SECURE trial subjects was generally consistent with approved low-dose CHCs
- Breakthrough bleeding also generally consistent with approved 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%)



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

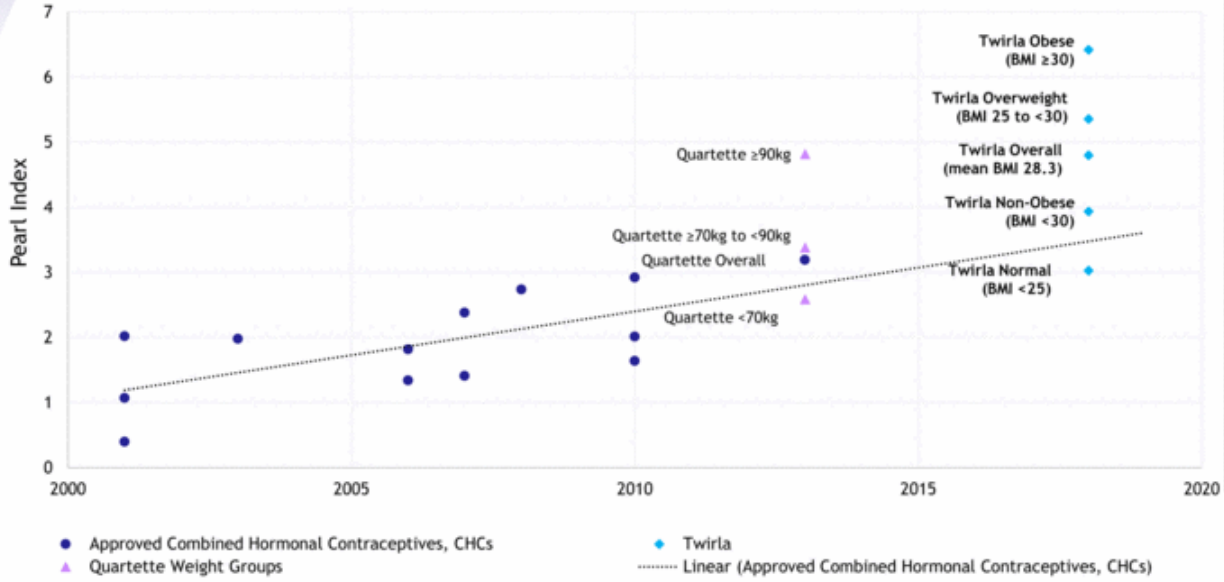
Adhesion Profile in the SECURE Trial

- **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



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



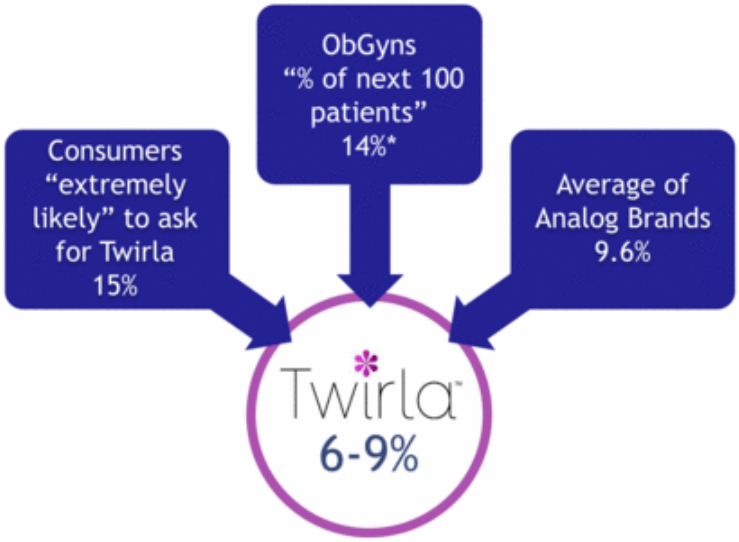
Product (Year Approved)	Pearl Index
Ortho Evra (2001)	1.07
Nuvaring (2001)	2.02
Yasmin (2001)	0.4
Seasonale (2003)	1.98
Loestrin 24 FE (2006)	1.82
Seasonique (2006)	1.34
Yaz (2007)	1.41
Lybrel (2007)	2.38
LoSeasonique (2008)	2.74
Natazia (2010)	1.64
LoLoestrin (2010)	2.92
Generess (2010)	2.01
Quartette (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