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

April 29, 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** (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:

☐ 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 8.01. Other Events.

On April 29, 2017, Anita Nelson, MD, Professor and Chair, Obstetrics and Gynecology, College of Osteopathic Medicine of the Pacific, and Co-Principal Investigator of the Agile Therapeutics, Inc., SECURE Phase 3 clinical trial made a presentation entitled "*An Update on Hormonal Contraception and The Changing U.S. Population*" at the 2017 Academy of the Women's Health Congress on April 29, 2017 at 8:00am ET at the Crystal Gateway Marriott in Arlington, VA. The presentation focused on real-world contraceptive study design and outcomes.

The presentation also included data from the Phase 3 clinical trial evaluating Twirla, also known as the SECURE clinical trial. SECURE was a one-year, multicenter, single-arm, open-label trial that evaluated the safety, efficacy and tolerability of Twirla in 2032 healthy women, aged 18 and over, at 102 experienced investigative sites across the United States. Agile announced top-line results of the SECURE clinical trial in January 2017.

The Company plans to resubmit its new drug application ("NDA") for Twirla by the end of the second quarter of 2017.

Copies of the presentation are attached hereto as Exhibit 99.1 and is hereby incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Agile Therapeutics, Inc. Presentation dated April 29, 2017.

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: May 2, 2017

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

Exhibit 99.1


25th Anniversary!
Congress on Women's Health
April 27-30, 2017
ACADEMY OF WOMEN'S HEALTH
best practices for better outcomes

An Update on Hormonal Contraception and The Changing U.S. Population

Anita Nelson, MD
Professor and Chair
Department of Obstetrics and Gynecology
Western University of Health Sciences

Women's Health Congress, 2017

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

- Individual participant data meta-analysis of 6 pivotal combination oral contraceptive (COC) trials and 1 contraceptive patch trial
- Analysis suggests 44% increased risk of pregnancy during COC use in obese compared to non-obese women
- 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
- A candidate patch AG200-15 has just completed Phase 3 studies and a potential effect of increased BMI was observed, consistent with the FDA findings
- We undertook a review of contraceptive trials outcomes over time, with a focus on the role of obesity

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

Yamazaki M et al, Contraception 2015; 92: 445-52

Measures of Contraceptive Efficacy in Clinical Trials

- The primary measure of efficacy used by FDA is the Pearl Index (PI):

$$\frac{\text{Number of On-drug } \mathbf{pregnancies}}{\text{Number of On-drug } \mathbf{cycles}} \quad (13)\ (100)$$

- On-drug pregnancies have an estimated date of conception between start date of study drug and 7-14 days after date of last study drug use
- Cycles in which study subjects use an alternate method of contraception are not counted in the PI denominator
- For some trials, cycles in which subjects report no sexual activity are also excluded from the PI calculation

Yamazaki M et al, Contraception 2015; 92: 445-52

Impact of Study Populations in Contraceptive Trial Outcomes

- Enrollment of All-Comers
  - BMI/weight
  - Racial/ethnic minorities
  - Range of experience with contraception
- Stringent Trial Design
  - Cycle exclusion rules
- In addition to study design changes, variety of other factors shown to impact study outcomes
  - Socioeconomics
  - Race/ethnicity
  - Prior pregnancy
  - Prior hormonal contraceptive use
- Some factors may be surrogates for non-compliance:
  - Difference between probability of contraceptive failure during typical (incorrect/inconsistent) and perfect use (correct/consistent) shows impact of imperfect use

Trussell et al, 2011
Westhoff et al, Contraception 2012
Gerlinger et al, Contraception 2014

Creeping Pearl: Changing Study Design and Populations Over Time

- Pearl Indices from early contraceptive trials were typically <1
- Trussell describes steadily increasing Pearl Index results from pivotal hormonal contraceptive trials over past 30+ years
- Reasons not entirely clear:
  - Better detection of pregnancies
    - More frequent testing/home testing
    - More sensitive tests
  - Less adherent study populations
    - "Because study populations appear to be increasingly representative of the likely actual use once the product is marketed, *we can expect to see even higher failure rates in ongoing and future studies*."

Creeping Pearl-Trussell

Pearl indices and study characteristics for OCs

Year approved	Regimen (product name)	Study length	Sample size	Mean age	Mean BMI (kg/m^2)/weight (lb)	Pearl Index
1982	EE 30 mcg/LNG 150 mcg (Nordette)	–	–	–	–	0.51
1989	EE 35 mcg/NGM 250 mcg (Ortho-Cyclen)	–	1695	–	–	0.96
1992	EE 30 mcg/DSG 150 mcg (Ortho-Cept)	–	1195	–	–	1.12
1992	EE 35 mcg/NGM 180/215/250 mcg (Ortho Tri-Cyclen)	–	4756	–	–	1.21
1997	EE 20 mcg/LNG 100 mcg (Alesse)	13 cycles	1477	27	Wt: 146.3	0.84
1998	EE 20 mcg/LNG 100 mcg (Levlite)	6 cycles	820	25.6	Wt: 138.2	0.29
2001	EE 30 mcg/DRSP 3 mg (Yasmin)	2 years	2629	25.5	–	<1.00
2003	EE 30 mcg/LNG 150 mcg (Seasonale)	1 year	1376	26.3	Wt: 157	1.98
2006	EE 20 mcg/Norethindrone 1 mg (Loestrin 24 Fe)	6 cycles	743	27.6	–	1.82
2006	EE 30 mcg/LNG 150 mcg (Seasonique)	1 year	1006	28	Wt: 156	1.34
2007	EE 20 mcg/DRSP 3 mg (Yaz)	1 year	1027	25	BMI: 24	1.41
2007	EE 20 mcg//LNG 90 mcg (Lybrel)	Up to 1 year	2134	28.8	BMI: 26	2.38
2008	EE 20 mcg/LNG 100 mcg (LoSeasonique)	1 year	2185	–	Wt: 159	2.74
2010	EV/Dienogest 3 mg (Natazia)	Up to 2.2 years	421	38.2	BMI: 26	1.64 (US) 1.04 (EU)
2013	EE 20,25,30 mcg/LNG 150 mcg/EE 10 mcg (Quartette)	1 year	2943	27.1	BMI: 27.4	3.19

EE=ethinyl estradiol; LNG=levonorgestrel; DSG=desogestrel; NGM=norgestimate; DRSP=drospirenone; EV=estradiol valerate.

Trussell and Portman
Contraception 2013

Examples of Oral Contraceptives With 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

2002 Publication Draws Attention to a Potential Relationship Between Obesity and Hormonal Contraceptive Effectiveness

- "Body Weight and Risk of Oral Contraceptive Failure"
  - Retrospective case-control analysis comprising 755 group health cooperative enrollees
  - Relative risk of 1.6 of OC failure for women in highest body weight quartile (≥ 70.5 kg) compared to women of lower weight
- Follow-up study titled "Body Mass Index, Weight, and Oral Contraceptive Failure Risk"
  - Risk of pregnancy 60% higher in women with BMI > 27.3 kg/m^2 and over 70% higher in women with BMI > 32.2 kg/m^2
  - Risk of pregnancy was more than doubled in women with BMI > 27.3 kg/m^2, over 70% higher in women weighing > 74.8 kg, and nearly doubled in women weighing > 86.2 kg among consistent users of oral contraceptives

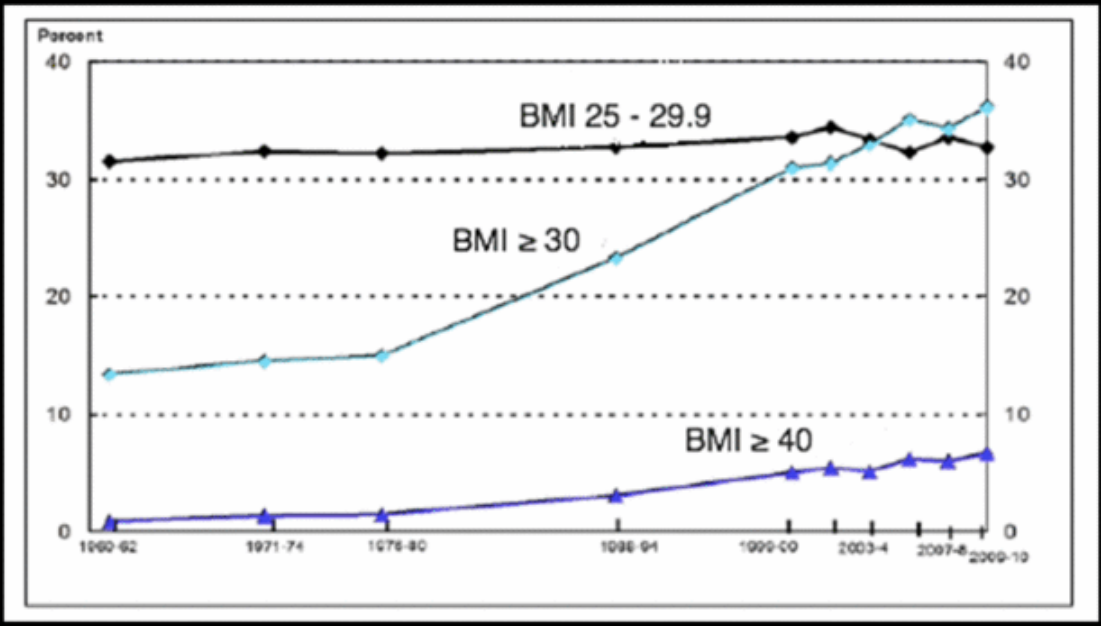
Holt et al, 2002
Holt et al, 2005

Reproductive Health Considerations Related to BMI

- BMI is a significant risk factor for multiple outcomes related to reproductive health
  - Higher morbidity and mortality with pregnancy and childbirth
  - Higher risk of VTE with hormonal contraception
  - Growing evidence of greater risk of hormonal contraceptive failure
- Although risk of morbidity and mortality on hormonal contraception higher in women of high BMI, pregnancy-related risk of bad outcomes due to VTE and other events still higher
- Women of high BMI need contraceptive options--not all will want IUD or other LARC
- Understanding the role of weight in contraceptive effectiveness is important for women and prescribers

ACOG Practice Bulletin No. 156, Dec 2015.
Ovesen P et al. Effect of Prepregnancy Maternal Overweight and Obesity on Pregnancy Outcome. Obstet Gynecol 2011; 118: 305-312.

United States Weight Trends



BMI Trends Among Adults Aged 20 to 74 years: United States, 1960-1962 Through 2009-2010

Source: CDC/NCHS. National Health and Nutrition Examination Survey

Contraceptive Trials Historically Enrolled Only Women of Normal Weight/BMI

Mean baseline weight and Pearl Index results from pivotal phase 3 trials of contraceptives conducted from 1980-2000:

Product	Year	Mean Weight/BMI‡	U.S. Pearl Index
Nordette	1982	Not available	0.48
Ortho-Cyclen	1989	61 kg	0.96
Ortho Tri-Cyclen	1992	60 kg	1.21
Ortho-Cept	1992	Not available	1.12
Alesse	1997	66 kg	0.84
Levlite	1998	63 kg	1.08
Mircette	1998	23.5 kg/m^2	1.11
Yasmin	2001	63 kg	0.40

- Yasmin's clinical trials contained an inclusion criterion requiring subjects to be "within 25% of ideal body weight"

Sourced from publicly available NDA Reviews and product labels

Impact of Body Weight on Hormonal Contraceptive Effectiveness-Ortho Evra

- FDA concluded during review that Ortho Evra effectiveness was reduced for women weighing ≥ 90 kg.
  - ≤ 3% of the Ortho Evra study population had a baseline weight≥ 198 pounds (90 kg), but accounted for 33% of the pregnancies
  - 17% of subjects had baseline weight 74 to 94 kg, but accounted for 27% of the pregnancies
- Data published by M Zieman et al, 2002
- Ortho Evra (*Xulane) label advises the patch "may be less effective in preventing pregnancy in women who weigh 198 lbs. (90 kg) or more."

*Xulane is the generic equivalent of the Ortho Evra patch

Zieman M et al, Fertil Steril 2002
Sourced from publicly available NDA Reviews and product labels

Quartette Trial Results

- The Phase 3 study for Quartette enrolled a racially and ethnically diverse population of subjects
  - 18 to 40 years of age
    - 28.3% were obese (BMI ≥ 30 kg/m^2)
    - 44% weighed < 70kg, 28% weighed ≥ 70 to < 90kg, and 18% weighed ≥ 90kg

Quartette Sub-Analysis by Weight:

Weight	Pearl Index	UB 95% CI
28-Day Cycle-Equivalents		
All	3.19	4.03
< 70 kg	2.59	3.67
≥ 70 kg to < 90 kg	3.38	5.17
≥ 90 kg	4.82	7.60
91-Day Cycles		
All	3.52	4.44
< 90 kg	3.14	4.12
≥ 90 kg	5.37	8.45

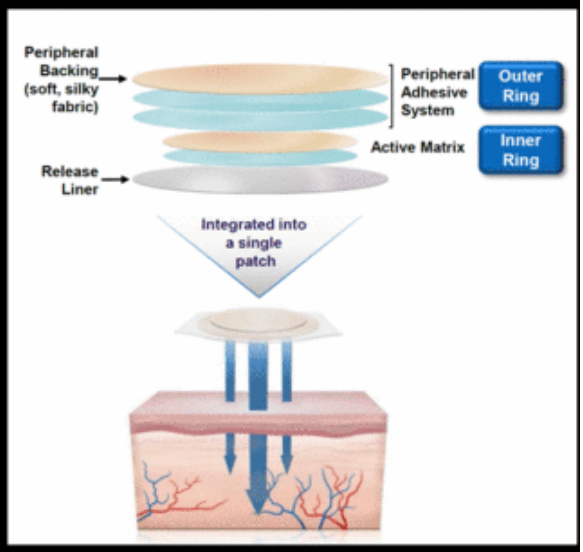
- The Quartette label does not contain information regarding BMI or weight impact on the product's effectiveness

Sourced from publicly available Quartette package insert and NDA review

AG200-15 Candidate Hormonal Contraceptive Patch

AG200-15 is a once-weekly contraceptive patch

- Comprises Levonorgestrel (LNG) and ethinyl estradiol (EE)
- Intended to improve convenience and compliance[1]
- Designed to deliver approximately 30 mcg of EE per day and approximately 120 mcg of LNG per day[2]
  - Currently available patch delivers approximately 56mcg of EE per day[3]



Alternatives to daily birth control pills are important

- Women report fitting daily pills into their busy lifestyles can be challenging[4]
- Women frequently forget to take their pills (approximately 1-4x per month)[4]; up to 15% of birth control users have difficulty taking pills consistently and correctly[5]
- Inconsistent use of oral contraceptives is a major contributor to unplanned pregnancy[6]

[1]Archer et al, Contraception 2004; [2]Kaunitz et al, Contraception 2014; [3]Devineni et al, J Clin Pharmacol 2007; [4]Qualitative consumer and HCP market research, RG&A 2012; ACE Survey 2013; [5]Rosenberg et al, Contraception 1995; [6]Finer et al, Perspect Sex Reprod Health 2006

The AG200-15 Regimen is Based on an Established 21/7 Schedule

- Patch applied once weekly for three weeks followed by a 4th week with no patch
- Can be applied to abdomen, buttock, or upper torso
  - Buttock and abdomen were the most common patch placement choices in clinical trials

SUN	MON	TUE	WED	THU	FRI	SAT
1	2	3	4 Patch 1	5	6	7
8	9	10	11 Patch 2	12	13	14
15	16	17	18 Patch 3	19	20	21
22	23	24 7 days no patch	25	26	27	28
29	30	31	Patch 1			

Buttock 48%

Abdomen 40%

Upper Torso 12%

Source: Data on File, Agile Therapeutics

The AG200-15 Development Program

- Comprehensive clinical program conducted
- Over 4,100 women enrolled; over 3,500 have received the AG200-15 patch
- Phase 1 and Phase 2 trials support hormone delivery consistent with current 30mcg OCs
- In Phase 3 studies, over 1,000 women have received AG200-15 for 12 months
- Approval was originally sought for AG200-15 in 2012 based on two original Phase 3 trials (CL12 and CL13); FDA denied approval and requested a third Phase 3 trial (CL23-The SECURE Trial)
- Based on data from the SECURE trial, resubmission for the AG200-15 patch is expected by the end of June, 2017, with potential for FDA approval by the end of 2017

Source: Data on File, Agile Therapeutics

The SECURE Trial Was Designed to Assess the Efficacy and Safety of AG200-15 in a Real-World Population

- 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
  - Subject daily entries in electronic diaries
  - Frequent pregnancy testing, including provision of home pregnancy tests
  - 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 analyses related to BMI and body weight

CRL = Complete Response Letter; ITT = Intent to Treat

Impact of Study Population and Study Design
SECURE Trial Design vs Historical Trials

Factor	Study Design	
	Historical	SECURE Trial
Study Design		
Enrollment Criteria		
BMI	• Restricted	• All comers-representative of US population seeking HC
Race/ethnicity	• Majority Caucasian	• Representative of US population seeking HC
New users	• Experienced populations	• Enroll substantial number of new users
Ex-US subjects	• Substantial proportion of European subjects supported US approvals	• Approvability based on US-only data
Study Conduct		
Pregnancy testing	• If pregnancy suspected	• Every visit • Provide home pregnancy tests/encourage testing • Serum hCG at final visit
Primary Analysis		
BMI	• Exclude subjects with BMI above 35/30	• Include all BMI categories
Cycle exclusion	• Use of back-up contraception	• Use of back-up contraception • Lack of sexual intercourse

SECURE Study Population Demographics

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%

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 AG200-15 to Ortho Evra or Quartette.

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

Pearl Indices for AG200-15 Patch--SECURE Trial

Overall results:

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

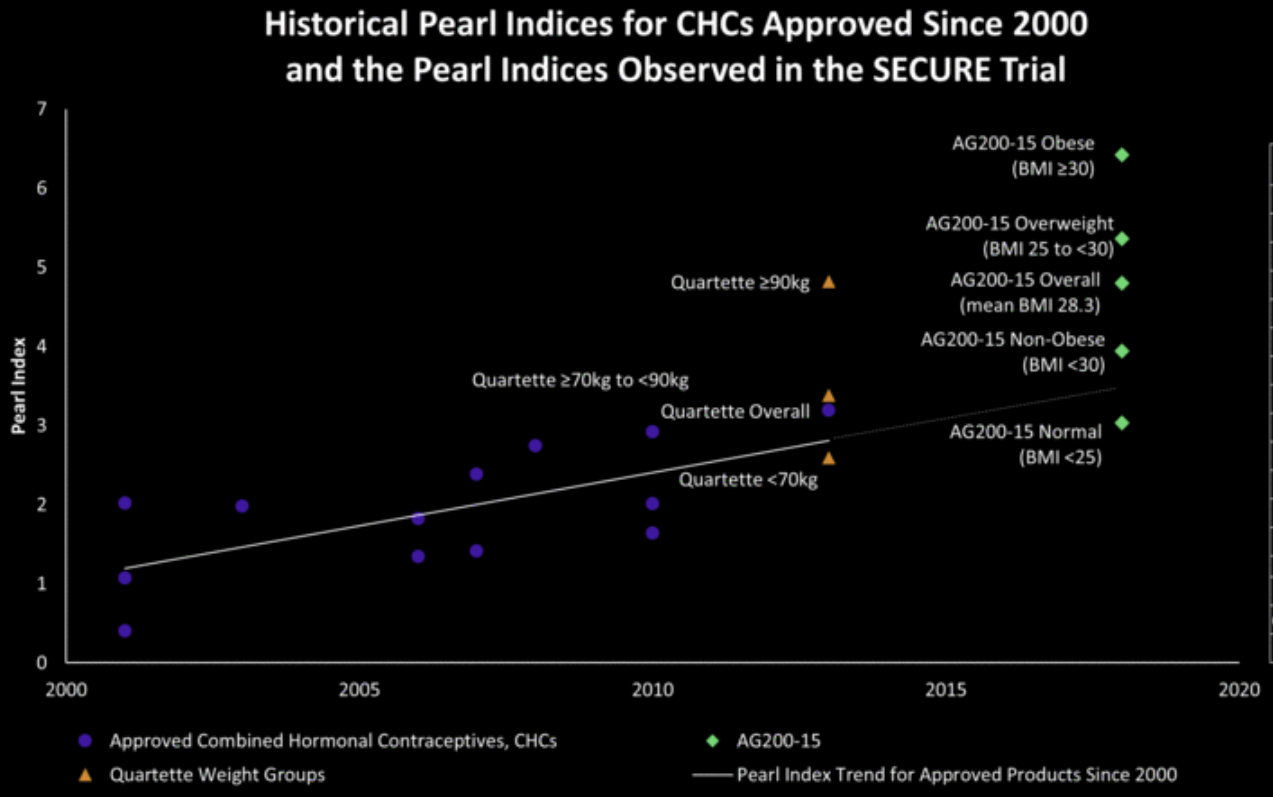
An effect of obesity was observed:

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

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



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

Conclusions

- Women of all weight categories need contraceptive choices
- There is increasing evidence that obesity may affect hormonal contraceptive effectiveness; the SECURE trial has contributed to this evidence
- The weight of women of reproductive age in the U.S. is increasing, making this effect more important to understand and quantify to inform contraceptive choices
- More research is needed to understand the role of other factors, including compliance, race/ethnicity, pharmacokinetics, etc.

DISCUSSION