Zacks Small-Cap Research

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Agile Therapeutics Inc. (AGRX-NASDAQ)

AGRX: Puts Forth Strong Case for Twirla® Ahead of PDUFA on Dec. 26, 2017…

Based on our probability adjusted DCF model that takes into account potential future revenues from Twirla®, AGRX is valued at $7.50/share. This model is highly dependent upon Twirla® attaining regulatory approval and its commercial success and will be adjusted accordingly based upon regulatory and commercial outcomes.

Current Price (10/13/17)	$5.31
Valuation	**$7.50**

OUTLOOK

On October 10, 2017, Agile Therapeutics Inc. (AGRX) held an analyst day and presented a clear and compelling rationale for why Twirla® is likely to be approved by the FDA and its strategy for commercial success. The results of the SECURE trial show that Twirla® is highly effective with a side effect profile that is very similar, if not slightly better, than other combined hormonal contraceptive products. We believe there is a high probability that Twirla® is approved on or before the PDUFA date of Dec. 26, 2017.

If approved, the company plans on rolling out Twirla in a controlled manner, with a step-wise approach to deploying sales representatives and a direct to consumer advertising campaign such that prescription numbers should begin accelerating in the second half of 2018.

SUMMARY DATA

52-Week High	**$7.80**
52-Week Low	**$2.04**
One-Year Return (%)	**-27.46**
Beta	**2.03**
Average Daily Volume (sh)	**328,377**
Shares Outstanding (mil)	**34**
Market Capitalization ($mil)	**$182**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**68**
Insider Ownership (%)	**4**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2016 Estimate	**N/A**
P/E using 2017 Estimate	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Value**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	0 A	0 A	0 A	0 A	0 A
2017	0 A	0 A	0 E	0 E	0 E
2018					18.5 E
2019					38.9 E

Earnings per Share
(EPS is operating earnings before non recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-$0.27 A	-$0.29 A	-$0.27 A	-$0.19 A	-$1.02 A
2017	-$0.26 A	-$0.26 A	-$0.25 E	-$0.24 E	-$1.01 E
2018					-$0.72 E
2019					-$0.30 E

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WHAT'S NEW

Agile Therapeutics, Inc. (AGRX) is a women's healthcare company focused on developing healthcare products to fulfill the unmet contraceptive needs of women. The company's lead candidate product, Twirla® (AG200-15), is a once-weekly low-dose hormonal contraceptive patch that contains the active ingredients ethinyl estradiol (EE, a synthetic estrogen) and levonorgestrel (LNG, a type of progestin). The patch utilizes the company's Skinfusion technology, which allows Twirla® to be the first contraceptive patch capable of delivering LNG across the skin in a reliable manner. The company has conducted a comprehensive development program for Twirla® that includes three Phase 3 clinical trials. Results from the latest Phase 3 trial were released in January 2017 and showed Twirla® to be effective, with a favorable safety profile in a highly diverse patient population.

Business Update

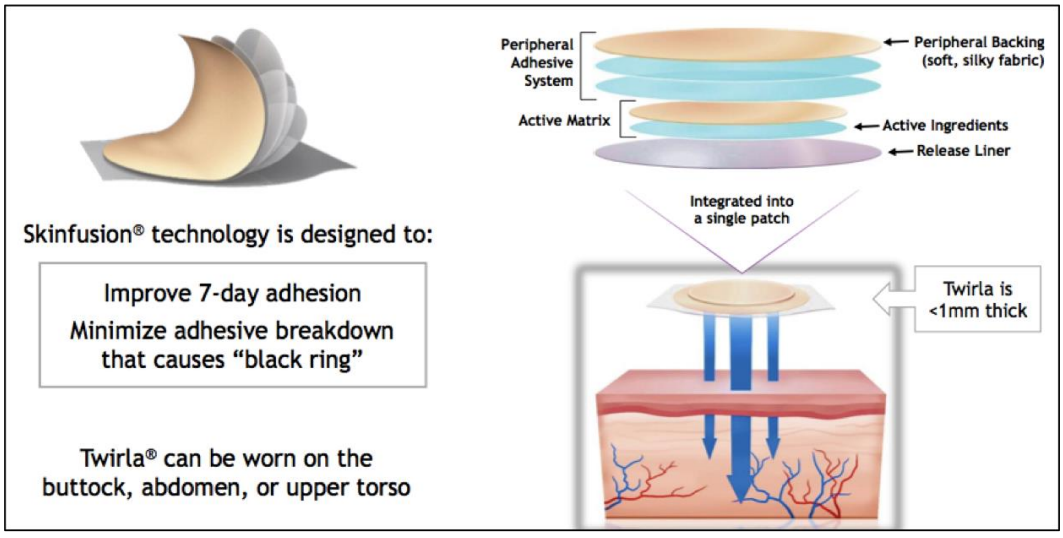
The Case for Twirla®

On October 10, 2017, Agile hosted an analyst day and provided a comprehensive overview of Twirla®, including a full discussion of the data from the Phase 3 SECURE trial in the context of other clinical and real world data seen with other combination hormonal contraceptive products. In addition, the company provided details on its commercialization strategy, which included a rough timeline for when various parts of that plan will be implemented. In the following report, we give a comprehensive overview of what was discussed such that investors can better understand Twirla® and the company's plan for commercialization success ahead of the scheduled PDUFA date of Dec. 26, 2017.

Twirla®

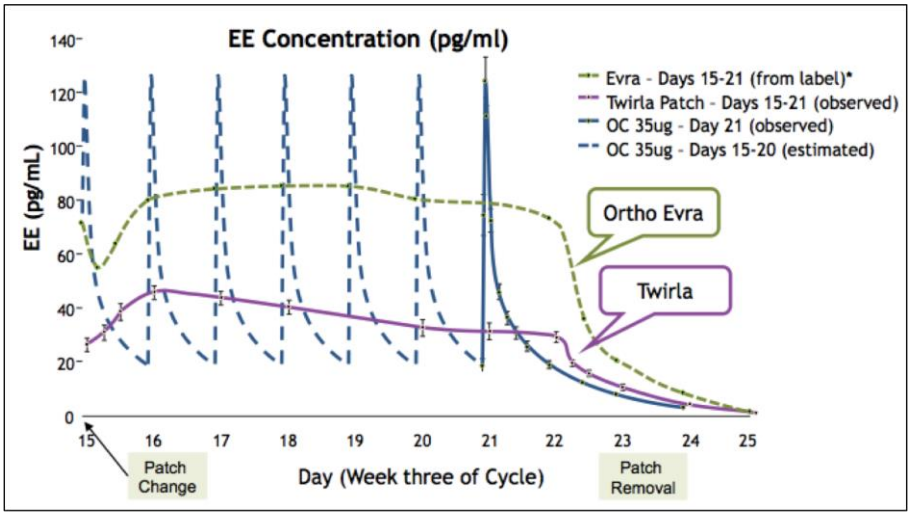
Twirla® is a combination hormonal contraceptive (CHC) product that contains both ethinyl estradiol (EE) and levonorgestrel (LNG). It is a patch that is applied once-weekly for three weeks, with no patch applied during the fourth week of a 28-day cycle. As a patch, Twirla® is designed to eliminate the need to take a daily pill, which is necessary with oral contraceptive products. It may be applied to the upper torso (excluding the breasts), abdomen, or buttock.

The patch is made of a soft, flexible fabric that utilizes the company's proprietary Skinfusion® technology. It is a matrix composed of multiple layers that contain the active ingredients EE and LNG along with inactive ingredients intended to aid in transport of the active ingredients across the skin. The adhesive is separated from the active ingredients by a barrier layer, which prevents their dispersal to the periphery of the patch and interfering with adhesion. Lastly, the patch is designed to prevent adhesive material from collecting along the edge of the patch, where it could collect dirt and leave behind a "black ring", a common complain from users of other contraceptive patches.



Source: Agile Therapeutics Inc.

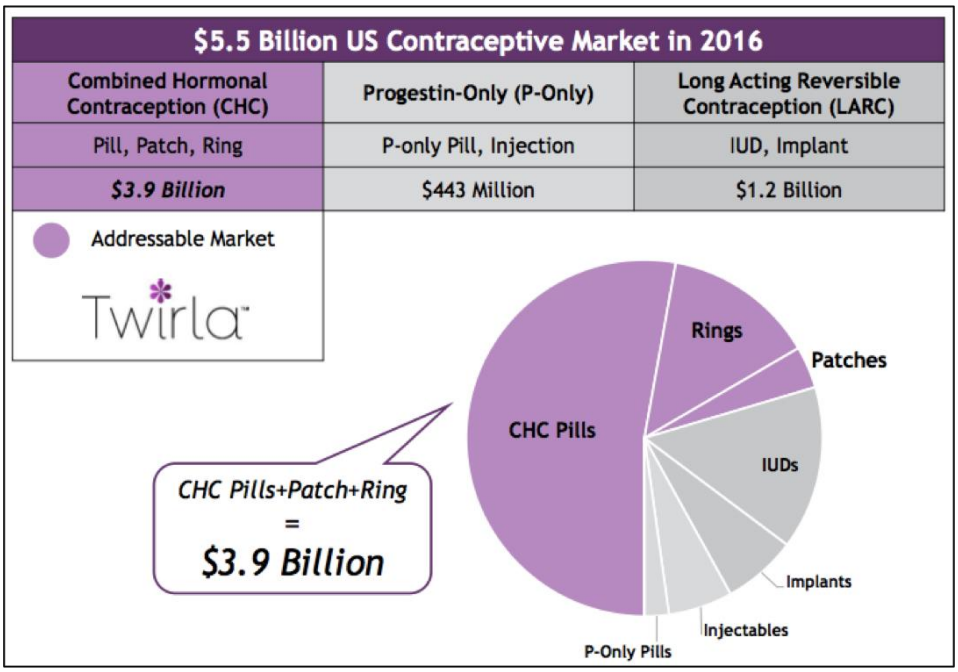
Twirla® is a low-dose contraceptive patch designed to deliver approximately 30 µg/day EE. This is in stark contrast to the only other once-weekly CHC patch on the market (Xulane®, the generic form of Ortho Evra®). The following graph shows the pharmacokinetic (PK) profile observed for Twirla®, along with the estimated PK profile for Ortho Evra® (taken from the label) and a CHC pill containing 35 µg EE. The data show that the amount of EE delivered by Twirla® is less than half that of Ortho Evra®, which leads to a reduction in adverse events while maintaining similar efficacy.



Source: Agile Therapeutics Inc.

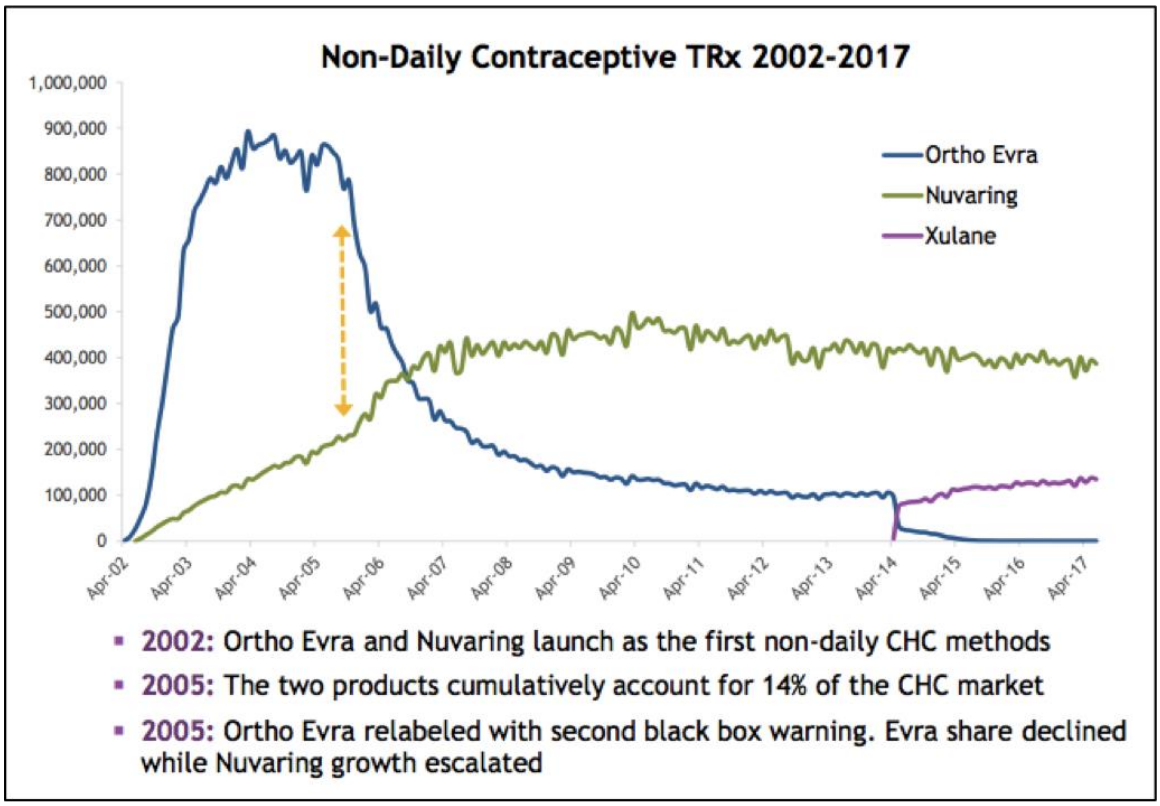
Contraceptive Market

Competition in the contraceptive market is intense as there are a large number of pharmaceutical, specialty pharmaceutical, generic, and medical device companies that produce a wide range of products. If approved, Twirla® will face competition from both non-hormonal products (e.g., diaphragm, cervical cap, condom) as well as hormonal products (e.g., oral contraceptives, injections, implants, intrauterine devices, vaginal rings). According to the 2016 FDA Birth Control Chart, there are 18 unique forms of birth control, each of which could be considered a competitor to Twirla®, however the main competition will be in the CHC market. The following figure shows that Twirla will potentially be entering a market valued at approximately $3.9 billion, which includes sales of oral contraceptives, CHC patch, and vaginal rings.



Source: Agile Therapeutics Inc.

The CHC market has very few "non-daily" options, with most products being a once-daily pill. There are currently only two non-daily choices: the vaginal ring (Nuvaring®) and a once-a-week patch (Xulane®). Ortho Evra® was the first contraceptive patch approved by the FDA in 2002. It was an immediate commercial success and achieved a 10% share of the combined hormonal contraceptive market within two years of launch. However, in November 2005 Johnson and Johnson revised the label of Ortho Evra® to indicate that the amount of EE a patient was exposed to was approximately 60% higher than that from an oral contraceptive containing 35 µg of EE. The labeling change included a black box warning on an increased risk of venous thromboembolism and the PK profile of EE. Following the label change, the market share for Ortho Evra® declined rapidly, from a peak of 11% in 2005 to 1.4% in 2013. A generic version of Ortho Evra® (Xulane®) was introduced by Mylan in April 2014, and in early 2015 Johnson and Johnson discontinued production of Ortho Evra® in the U.S. This is shown in the following figure. Thus far, no other generic equivalents of Ortho Evra® have been introduced in the U.S. Total revenues for Xulane® in 2016 were $211 million.



Source: Agile Therapeutics Inc.

We believe the aforementioned market opportunity and lack of choices for consumers who want a non-daily CHC option support the idea of Twirla® being a commercial success. Its clear that consumers are receptive to a once-weekly patch, as shown by the amazing growth in prescriptions for Ortho Evra® following its launch. Had there not bee issues with its PK profile, Ortho Evra® would likely have continued to generate significant revenue for Johnson and Johnson. As mentioned previously, the PK issues with Ortho Evra® will not be an issue with Twirla®, as it is designed to deliver approximately 30 µg/day EE, significantly lower than the amount of EE being delivered by Ortho Evra®.

Perspective from Clinical Practice

Dr. Robin Kroll, the Co-founder and Director of Seattle Women's: Health, Research, Gynecology and a SECURE trial investigator, gave a presentation on the need for women to have more contraceptive options, particularly options that are low-dose and non-daily. She began by discussing the contraceptive patterns in the U.S. and the fact that almost all women will use contraception at some point in their lives. However, approximately 50% of all pregnancies in the U.S. are still unintended (Finer *et al*., 2016).

Large choices of contraceptives are important, since the ultimate choice of contraceptive method is influenced by several factors. There is no single "best" option for all women, and most women will use several different contraceptive methods over their lifetime as their needs and preferences change. In addition, multiple choices of

non-daily contraceptives are important due to the fact that while oral contraceptives are highly effective, approximately 30-50% of users miss one or more pills per month. This leads to a decrease in 'real-world' efficacy for oral contraceptives of approximately 91%, compared to the 99.7% effective rate seen in clinical trials. Contraceptive methods that are not as heavily user dependent (such as a once-weekly patch) show little difference between perfect and actual use effectiveness.

The use of a low-dose non-daily option is also important, as the dose of estrogen is likely the primary factor influencing the risk of developing a venous thromboembolism. Since the first birth control pill was approved in 1960, estrogen doses in CHC products have decreased 93%. Twirla is a low-dose CHC as it delivers approximately 30 µg/day EE (vs. a high dose treatment of 50 µg/day EE).

SECURE Trial Results

Dr. Elizabeth Garner, Agile's Chief Medical Officer, gave an overview of the SECURE Phase 3 clinical trial results. We've covered those previously (see our initiation report for an analysis of the results), however Dr. Garner did present additional details that we believe are important. The first is a report of the overall efficacy of Twirla® from a Life Table analysis, which is more clinically relevant than the Pearl Index. The overall failure rate of Twirla® was 4.2% at Cycle 13, meaning that 95.8% of trial subjects did not have a pregnancy during the trial.

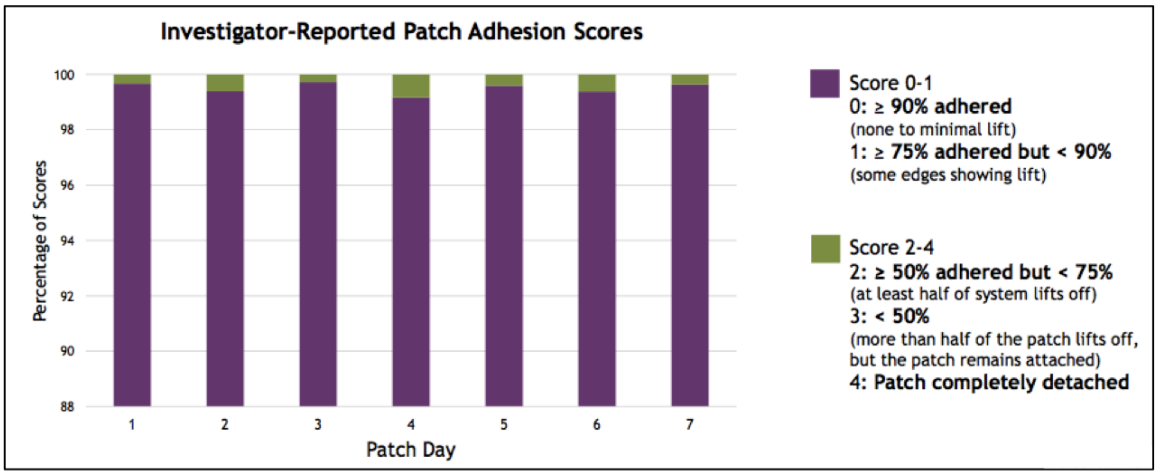
- Failure rate (Life table analysis) is an important pre-specified, supplemental efficacy endpoint in contraceptive trials
  - More clinically relevant than Pearl Index
- Failure rate was 4.2% at Cycle 13, inclusive of all subjects regardless of BMI

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

Source: Agile Therapeutics Inc.

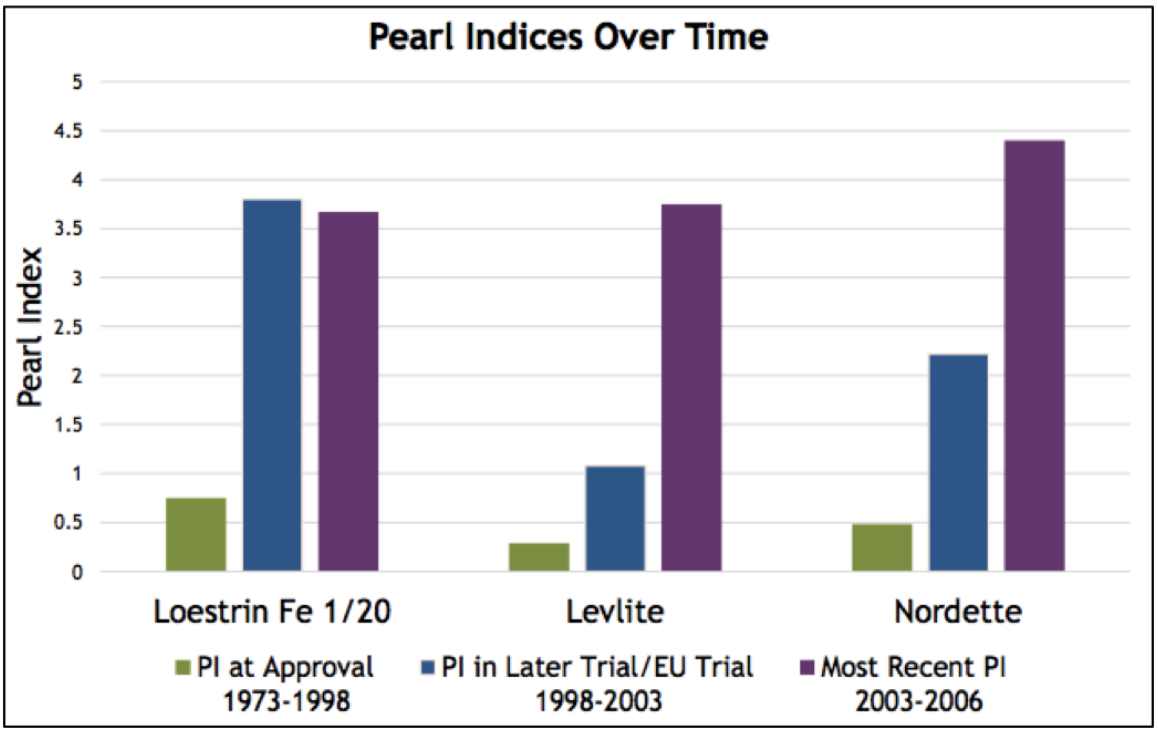
In addition, Twirla® had a favorable adhesion profile, with 99.2-99.7% of patch adhesion scores ranging from no lifting of patch (score=0) to slight lifting at edges (score=1). SECURE trial investigators rated the patches during subject visits using a 5-point scale supplied by the FDA. Many complaints of Ortho Evra® centered on the patch itself, which sometimes led to a "black ring" of dirt that would form around the patch (due to lifting of the edges). That does not appear to be an issue with Twirla®.



Source: Agile Therapeutics Inc.

Perspective on Efficacy, Effectiveness, and the Pearl Index

Dr. David Portman, the Director Emeritus of the Columbus Center for Women's Health Research and currently the CEO and CMO of Sermonix Pharmaceuticals, gave a presentation on putting the SECURE trial data into context based on how the Pearl Index seems to be changing over time. Dr. Portman is the author of a paper on the "creeping Pearl Index", which is a phenomenon investigators have noted over the past 20 years or so and is likely the result of a number of different factors: differences in study design for different contraceptives, increasingly diverse study populations, lower adherence in clinical trials, different hormone doses, and increasing BMI of the U.S. population. The following chart shows that Pearl Indices are increasing over time even for products that were approved many years ago, thus it is not just a function of the new products being developed but also involves the makeup of the study populations themselves. The most recent data for each of those products (all oral CHCs) puts their Pearl Indices in line with the results of the SECURE trial, where Twirla® had an overall Pearl Index of 4.80.



Source: Agile Therapeutics Inc.

Regulatory Perspective

Ms. Minnie Baylor-Henry, an Executive Partner at YourEncore and a former Director, Division of Drug Marketing, Advertising and Communications at the FDA, spoke about how the FDA considers contraceptive products and the importance of the FDA meta analysis that was conducted on the Pearl Index and rising BMI. The most important takeaway from Ms. Baylor-Henry's talk was that the FDA bases approval of a contraceptive product on a risk/benefit assessment and there is no firm Pearl Index endpoint requirement. Thus, it is improper to compare the Pearl Index from the SECURE trial to previous trials of other CHC products as a means of determining whether Twirla® will be approved or not. Instead, the FDA will examine the totality of the data, with the understanding that multiple contraceptive options (with multiple ranges of efficacy) are important.

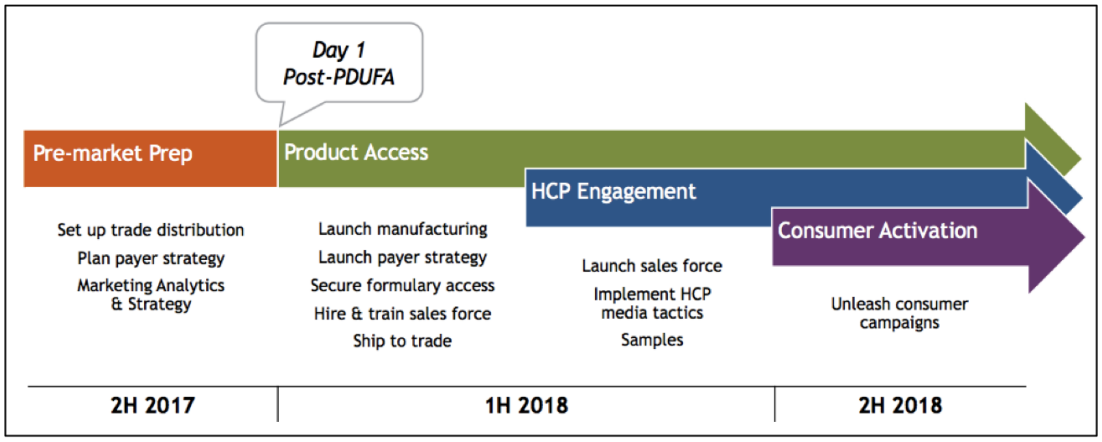
In 2015, the FDA published a meta-analysis on the effect of obesity on hormonal contraceptives and determined that there is a 44% increased risk of pregnancy in obese vs. non-obese women using CHCs. The authors of the study called for more data from Phase 3 studies of hormonal contraceptives in order to better understand this phenomenon. The SECURE trial was specifically designed to capture data on obesity as it relates to the Pearl Index, and the data did in fact show a correlation between BMI and the Pearl Index, with a higher Pearl Index seen in obese vs. non-obese subjects. However, the fact remains that Twirla® has a favorable efficacy and safety profile, and if approved will be thought of by physicians as having similar efficacy to oral contraceptives and rings.

Market Access

Dr. Adaeze Enekwchi , the Vice President of McDermott+Consulting and a Former Associate Director for Health Programs at the White House Office of Management and Budget, gave an overview of the Affordable Care Act (ACA, "ObamaCare") contraceptive mandate and why birth control is good policy. The ACA requires mandatory coverage of contraceptives with zero copay for at least one product from each of the 18 unique methods delineated by the FDA. While there has been talk of repealing all or a portion of the ACA, it remains the law and the zero copay mandate is still in effect. To circumvent anything that happens on the Federal level, 28 states have passed laws requiring health insurance plans to cover contraceptive services. Very recently, a new regulation was issued that allows a broader set of employers and insurers to exclude contraceptives based on moral or religious reasons, however we do not believe any insurance company or large employer will claim an exemption.

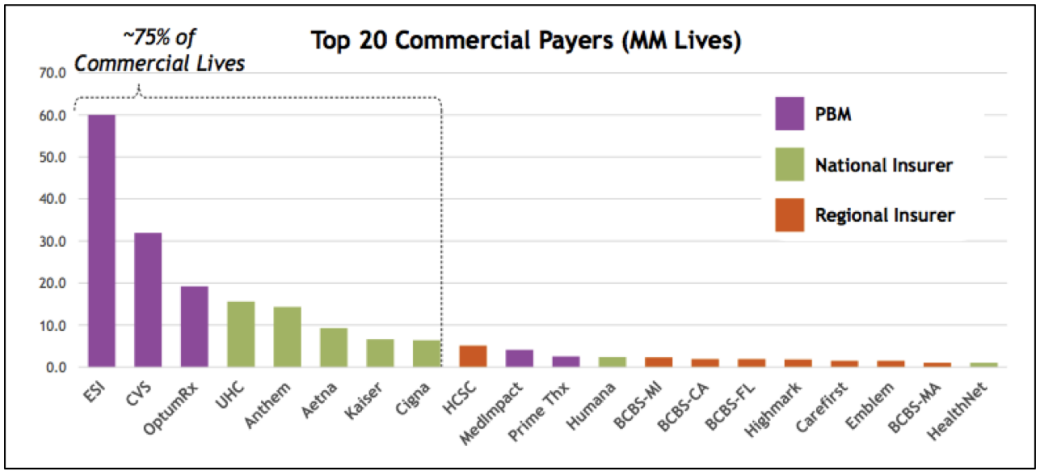
Commercial Launch

Ms. Renee Selman, Agile's Chief Commercial Officer, gave an overview of the company's strategy for launch, assuming Twirla® is approved. The following figure shows the company's plan, which is purposely arranged in a step-wise fashion that begins with ramping up manufacturing and getting formulary access, then launching the sales force and sampling, and finally initiating the advertising campaigns in the second half of 2018. The reason that the consumer outreach is delayed is because the company wants to make sure everything is in place to avoid potential negative situations, such as the consumer asking their doctor for Twirla® before the doctor has been reached by a sales representative, or a consumer getting a prescription written that their pharmacy is unable to fill.



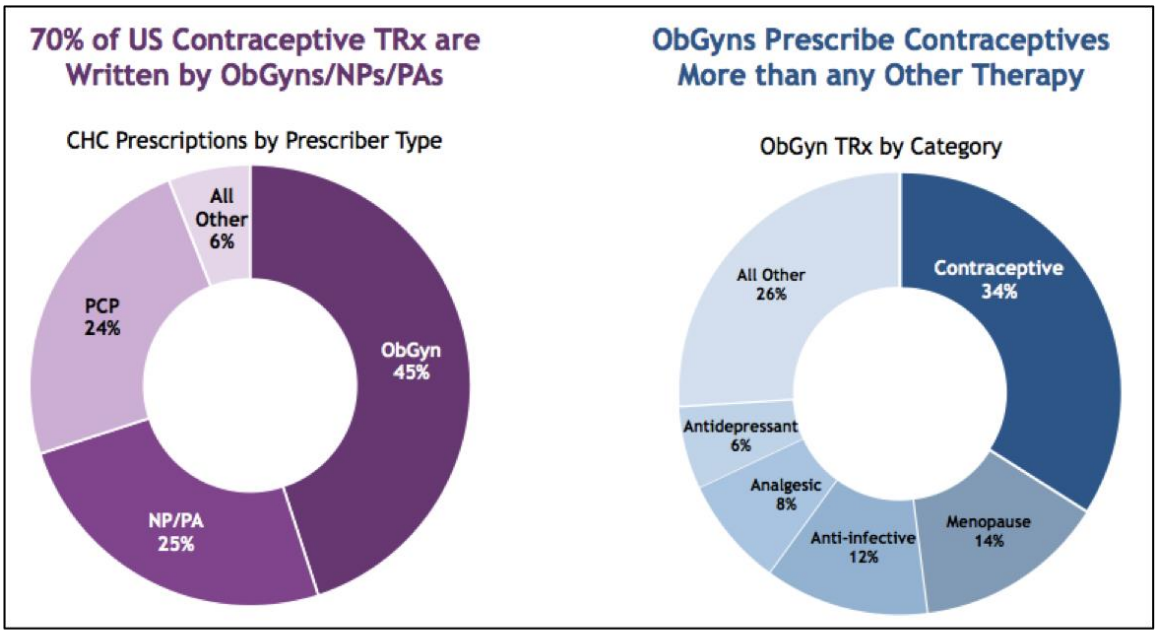
Source: Agile Therapeutics Inc.

Agile is fully focused on working through any formulary issues that may arise following commercialization. While the contraceptive mandate is still the law (meaning that contraceptives must be covered by insurance plans), the company is putting a contingency plan into place in case something changes through the use of contracting to ensure reimbursement is in place for the as many individuals as possible. To do this, Agile is targeting the top eight payers, as they cover 75% of commercial lives.



Source: Agile Therapeutics Inc.

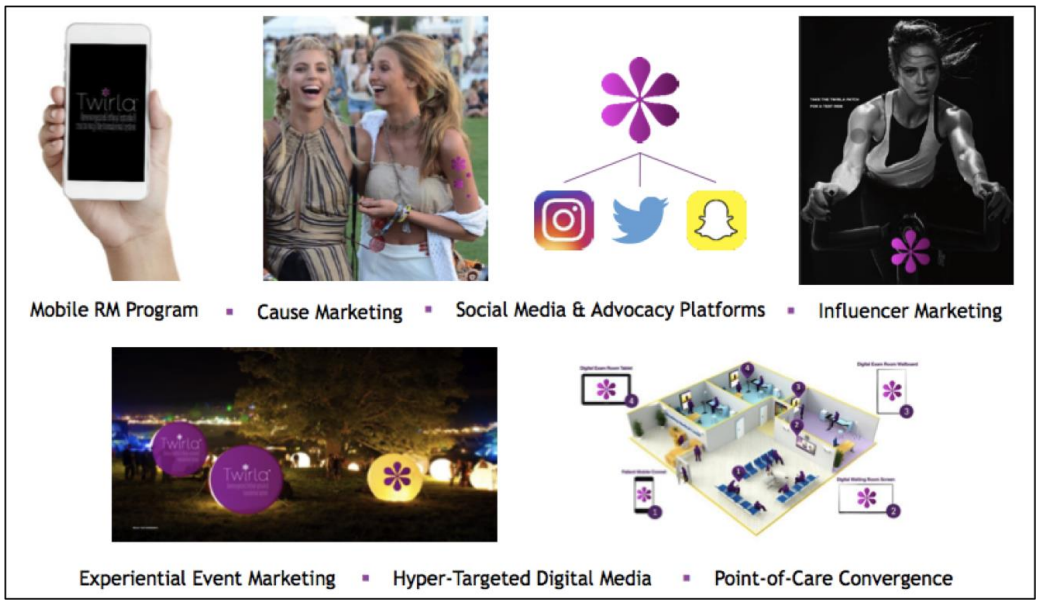
For the sales force, ObGyns and Nurse Practitioners/Physician Assistants write approximately 70% of US CHC prescriptions. In addition, ObGyns prescribe more contraceptives more than any other therapy. Thus, Agile has a firm grasp on where to direct efforts with the sales force. Of the approximately 22,000 prescribers of branded CHC products, >90% of those are ObGyns.



Source: Agile Therapeutics Inc.

Agile's current thinking is to utilize a contract sales organization that will use approximately 70-100 sales representatives (likely at the lower end of that). This is similar to other organizations sales representative for CHC products, which range from 80-99 for Lo Loestrin FE, Taytulla, and Nuvaring. The sales representatives will likely be deployed in tranches, in other words a small group will initially begin calls while additional sales representatives will be deployed as formulary coverage increases.

In order to increase awareness of Twirla® Agile will be using a phased approach that begins by increasing health care provider awareness of the product first, which may include clearing up any misconceptions that may exist or negative ideas about a patch based on poor past experiences with Xulane®, and getting the health care providers ready to prescribe Twirla®. Only after the company is satisfied that there is widespread awareness of Twirla® among health care providers will the company begin engaging the consumer. Agile will be using a wide range of medium's to interact with the consumer, which includes an app, social media, digital media, and point-of-care coverage.



Source: Agile Therapeutics Inc.

Ms. Selman discussed some of the market research that Agile has conducted over the past couple of years. Health care providers had a number of positive remarks about Twirla®, including the fact that patients would not need to remember a daily pill and there will (likely) be no black box warning. Some of the concerns had to do with the potential for decreased efficacy in heavier patients, something that the company is planning to be fully upfront about and which sales representatives will use to make sure the health care providers have the proper type of patients in mind when thinking about who Twirla® would be best for. Based on the market research performed back in 2010 and again in 2017, the company continues to believe that a 9% peak market share is attainable.

Valuation

We value Agile using a probability adjusted discounted cash flow model that takes into account potential future revenues for Twirla® based on a launch in the second quarter of 2018.

Even with a Pearl Index that is slightly higher than has previously been seen in other approved hormonal contraceptive products, we do not believe this is a reason for the FDA not to approve Twirla®. The company has done a good job of showing why the Pearl Index is higher than previously seen in other hormonal contraceptive trials based on a correlation with BMI. Trials for previous hormonal contraceptive products typically had an upper limit for BMI to be included in the trial, thus it is not surprising those trials would show a lower Pearl Index than the SECURE trial. Once approved, we don't believe the slightly higher Pearl Index will have an adverse impact on peak revenues. We base this on the information presented by the company showing that clinicians do not discuss Pearl Index values with their patients and instead focus on the characteristics of each product that may fit best with a particular patients lifestyle while assuming that if approved by the FDA the product is effective at preventing pregnancy. Lastly, we believe the SECURE trial adequately addressed all the concerns the FDA had when the CRL for Twirla® was issued, thus we anticipate the product being approved on or before the PDUFA date of December 26, 2017.

We forecast for Agile to attain 9% market share 7 years after launch in 2018. This leads to peak revenues of approximately $400 million. After accounting for operating expenses, an estimated 35% tax rate, a 12% discount rate, and an 85% probability of approval we value Twirla® at $301 million. When taking into account estimated capital requirements for the launch of Twirla® of $20 million, and dividing by the fully diluted share count of 38.4 million shares, this leads to a valuation of approximately $7.50 per share.

PROJECTED FINANCIALS

Agile Therapeutics, Inc.
Income Statement

Agile Therapeutics, Inc.	2016 A	Q1 A	Q2 A	Q3 E	Q4 E	2017 E	2018 E	2019 E
Twirla	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$18.9**	**$38.5**
YOY Growth	-	-	-	-	-	-	*#DIV/0!*	*103.7%*
Licensing / Development	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
Total Revenues	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$18.9	$38.5
YOY Growth	-	*#REF!*	*#REF!*	*#REF!*	*#REF!*	*#DIV/0!*	*#DIV/0!*	*103.7%*
Cost of Goods Sold	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$3.0	$6.0
Product Gross Margin	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*84.1%*	*84.4%*
SG&A	$8.8	$2.4	$3.2	$3.4	$3.5	$12.5	$25.0	$30.0
% SG&A	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*132.3%*	*77.9%*
R&D	$20.9	$4.7	$3.8	$3.5	$3.3	$15.3	$18.0	$17.0
% R&D	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*95.2%*	*44.2%*
Operating Income	($29.7)	($7.1)	($7.0)	($6.9)	($6.8)	($27.8)	($27.1)	($14.5)
Operating Margin	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*-143.4%*	*-37.7%*
Interest Income / Net	($2.1)	($0.4)	($0.5)	($0.5)	($0.5)	($1.8)	($1.6)	($0.5)
Pre-Tax Income	($31.8)	($7.5)	($7.4)	($7.4)	($7.3)	($29.7)	($28.7)	($15.0)
Taxes	($3)	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($28.7)	($7.5)	($7.4)	($7.4)	($7.3)	($29.7)	($28.7)	($15.0)
YOY Growth	*#REF!*	-	-	-	-	*3.2%*	*-3.2%*	*-47.7%*
Net Margin	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*-151.9%*	*-39.0%*
Reported EPS	($1.02)	($0.26)	($0.26)	($0.25)	($0.24)	($1.01)	($0.72)	($0.30)
Fully Diluted Shares	28.3	28.8	28.8	29.8	30.0	29.3	40.0	50.0

Source: David Bautz, PhD - Zacks Investment Research, Inc.

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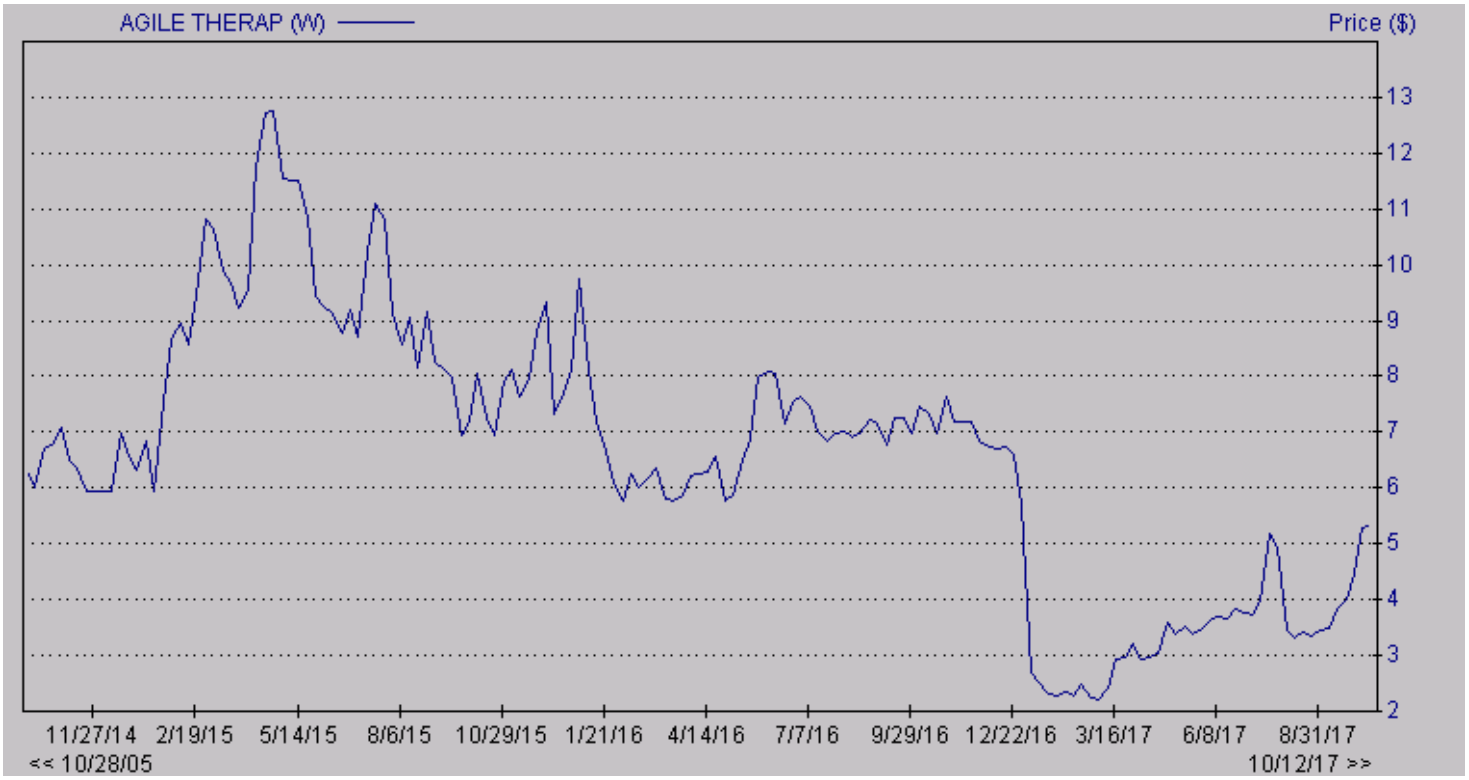
HISTORICAL STOCK PRICE



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