Zacks Small-Cap Research

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Agile Therapeutics Inc. (AGRX-NASDAQ)

AGRX: NDA for Twirla® Refiled with FDA; Six Month Review Time Expected…

Based on our probability adjusted DCF model that takes into account potential future revenues from Twirla®, AGRX is valued at $7/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 (06/28/17)	$3.86
Valuation	**$7.00**

OUTLOOK

On June 27, 2017, Agile Therapeutics, Inc. (AGRX) announced it resubmitted the new drug application (NDA) to the U.S. Food and Drug Administration (FDA) for its lead product, Twirla® (AG200-15), a once-weekly low–dose combination hormonal contraceptive patch. We anticipate the FDA announcing a PDUFA date within approximately 30 days, which is likely to indicate a six-month review.

We recently initiated coverage on Agile, a summary of which is included in this report. Twirla® is set to enter a hormonal contraceptive market in the U.S. that had total market sales of approximately $3.7 billion in 2016. With only one other contraceptive patch on the market, which has limitations due to a higher level of hormones and negative physical characteristics, we believe Twirla® could attain significant market share. With a current valuation of only $110 million, Agile may offer investors the chance for outsized returns.

SUMMARY DATA

52-Week High	**$7.82**
52-Week Low	**$2.04**
One-Year Return (%)	**-47.91**
Beta	**1.81**
Average Daily Volume (sh)	**219,281**
Shares Outstanding (mil)	**29**
Market Capitalization ($mil)	**$111**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**80**
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 E	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	-$0.25 E	-$0.25 E	-$0.26 E	-$1.03 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®, 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

NDA for Twirla® Resubmitted

On June 27, 2017, Agile announced that it resubmitted the new drug application (NDA) to the U.S. Food and Drug Administration (FDA) for its lead product, Twirla® (AG200-15), a once-weekly low–dose combination hormonal contraceptive patch. We anticipate the FDA announcing a PDUFA date within approximately 30 days, which is likely to indicate a six-month review.

We recently initiated coverage of Agile, a summary of which is included in this report. We are enthusiastic about Twirla's® opportunity in a market that was estimated to be worth $3.7 billion in 2016. We believe that the company has adequately addressed all the concerns raised by the FDA in the complete response letter (CRL) received regarding Twirla's® initial application, and we anticipate Twirla® being approved in late 2017.

Twirla®

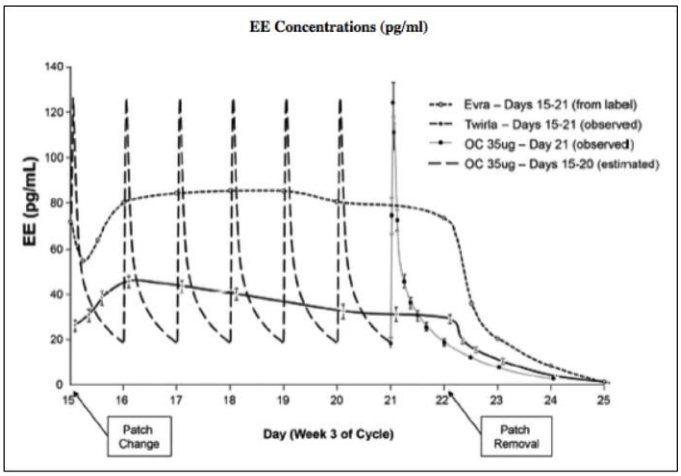
Twirla® is a combination hormonal contraceptive (CHC) product that contains both ethinyl estradiol (EE) and levonorgestrel (LNG). It is a patch that is applied once-weekly for three weeks, with no patch applied during the fourth week of a 28-day cycle. As a patch, Twirla® is designed to eliminate the 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.



Twirla® Development Program

Agile has conducted a comprehensive development program that consisted of three Phase 1, one Phase 2, and three Phase 3 clinical trials.

Pharmacokinetic Data: While the company has not performed a head-to-head comparison of Twirla® to Xulane®, the generic version of the first ever approved contraceptive patch Ortho Evra® (which was discontinued in the U.S. in 2015), a pharmacokinetic (PK) study conducted with Twirla® was similar in design to one conducted with Ortho Evra®. The following graph shows the PK data for Twirla® compared to oral contraceptives (OC) containing 35 µg of EE and the Ortho Evra® patch. The Ortho Evra® data was estimated based on the graph provided in that products label. The OC data prior to day 21 was estimated steady-state data based on Day 21 EE concentrations observed during the PK study. The data shows that the level of EE administered from Twirla® leads to a lower EE plasma concentration, which likely contributes to the decreased side effect profile of Twirla® compared to Ortho Evra® or daily contraceptive pills.



Source: Agile Therapeutics, Inc.

First Two Phase 3 Trials: The two Phase 3 trials completed prior to the more recent Phase 3 SECURE trial enrolled over 1,900 subjects. Each of those trials included an active comparator arm with an approved low-dose oral contraceptive. The results showed that Twirla® was generally well tolerated and adverse events were comparable to those seen with low-dose oral contraceptives. In addition, subjects using the patch self-reported a higher level of compliance than those using oral contraceptives. The primary measure of efficacy was the Pearl Index (PI), which is a measurement of the rate of pregnancies over a specific period of time in a clinical trial and corresponds to the number of unintended pregnancies that would be expected in 100 woman-years of exposure. The pooled PI value for the first two Phase 3 clinical trials was 5.76 for those using Twirla® and 6.72 for those using oral contraceptives. These values were much higher than the range for PI values seen in other pivotal studies for products approved by the FDA in the last 10 years (1.34 to 3.19). One possible explanation for the unusually high PI numbers could be due to the relatively high percentage of new users and minority subjects compared to studies for other approved products, as shown in the following table. While the underlying reasons are not well understood, multiple reports in the literature state that contraceptive failure rates are highest in black and Hispanic subjects (Sundaram *et al*., 2017; Dehlendorf *et al*., 2014).

		Product (Year Approved) % of Subjects*					
Parameter		Twirla	Seasonique (2006)	Yaz (2006)	Lo-seasonique (2008)	Natazia (2010)	Quartette (2013)
Hormonal Contraception Use							
Current Users		18	-	60	-	59	-
Within 6 Months of Enrollment	Yes	44	68	-	61	-	44
	No	56	32	-	39	-	56
Race/Ethnicity	Hispanic	15	5	5	10	13	11
	Black	22	11	4	12	7	18

*Data derived from two Phase 3 clinical trials for Twirla prior to SECURE and from FDA medical review documents for each product

Source: Agile Therapeutics, Inc. / Zacks SCR

In February 2013, Agile received a complete response letter (CRL) from the FDA that indicated approval of Twirla® would not be possible at that time and that data from an additional Phase 3 clinical trial would be necessary. In addition, the FDA wished to see improved study conduct, including additional site monitoring and data collection procedures. The FDA requested that Twirla® be studied in a representative sample of U.S. women, with no enrollment restrictions based on demographic characteristics such as, race, ethnicity, or body mass index (BMI). Weight and/or BMI exclusion criteria have been employed in most contraceptive clinical trials in the past.

SECURE Trial: Agile's third Phase 3 clinical trial for Twirla® was a multicenter, single-arm, open-label, 13-cycle trial that enrolled 2,032 women aged 18 and over at 102 experienced investigative sites in the U.S. The trial was designed in consultation with the FDA and included a number of stringent trial design elements, such as exclusion of treatment cycles for both use of back-up contraception and lack of sexual activity. The broad enrollment criteria led to the inclusion of a large proportion of subjects with high BMI, a group that had typically been excluded from prior contraceptive studies. Demographic data from the SECURE trial, as well as from other contraceptive studies for Ortho Evra® and Quartette®, is shown in the table below.

Study	SECURE	Ortho Evra Trials	Quartette Trial
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%

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%

Source: Agile Therapeutics, Inc.

A number of measures were utilized in the SECURE trial to improve overall study conduct, and in particular to improve upon the 'lost to follow-up' rate. These measures included working with a highly experienced contract research organization, selecting experienced sites based on assessing performance in previous clinical trials, increasing and improving monitoring and training (including the use of text messaging to provide reminders to subjects for patch application), and the use of electronic diaries for subjects.

The following table shows that discontinuation rates due to 'lost to follow-up' were much lower for the SECURE trial than for the previous Phase 3 clinical trials of Twirla® and slightly better than for the Quartette® trial. The discontinuation rates for SECURE are also in line with several previously conducted contraceptive trials leading to FDA approvals.

	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

Source: Agile Therapeutics, Inc.

The primary outcome of the SECURE trial was the PI in an intent-to-treat (ITT) population of subjects 35 years of age and under. The FDA also requested a pre-specified efficacy analysis regarding BMI, body weight, and the PI. The overall PI for the ITT population was 4.80 with an upper bound of 6.06. An effect on the PI by both BMI and weight was observed, as shown in the following table and graphs.

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

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: Agile Therapeutics, Inc.

Figure 2: % Pregnancy vs. Weight categories

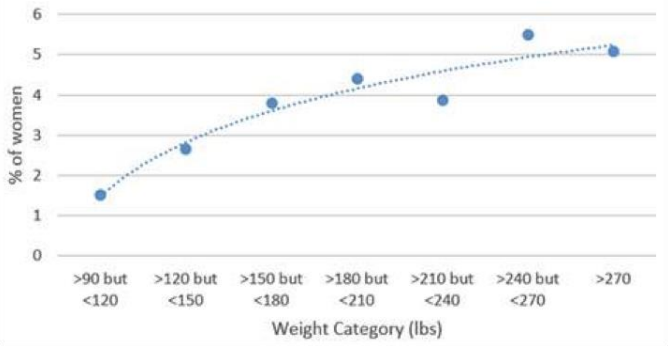
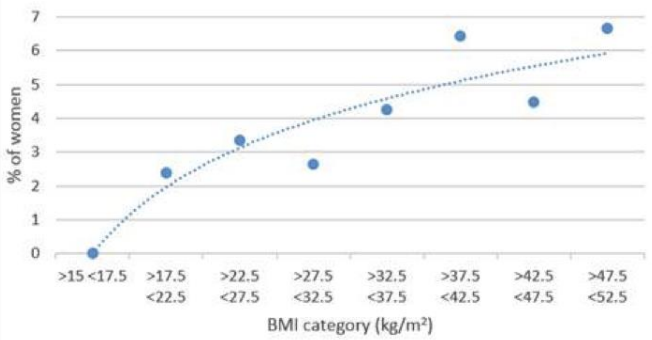


Figure 3: % Pregnancy vs. BMI categories



Source: Nelson et al., 2017

Twirla® was very well tolerated with rates of adverse events that were in line with previous clinical trials and much lower than for trials of other low-dose combination hormonal products, as shown in the following table. The company recently reported that unscheduled bleeding/spotting days per month decreased from a mean of 3.1 day in cycle 1 to 1.6 days in cycle 13. In addition, patch related irritation and itching rates were low (83% had no patch site irritation; 65% had no itching) and while patch detachment was reported by 10% of subjects in cycle 1, this was reduced to 2% by cycle 13.

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

Source: Agile Therapeutics, Inc.

With a robust data package in hand, we anticipate Agile resubmitting the new drug application (NDA) for Twirla® before the end of the second quarter of 2017. In April 2017, the company held a pre-submission meeting with the FDA, and based on the preliminary information provided, the FDA indicated that the SECURE trial results appear acceptable for resubmission, however there was no discussion on whether the results would be sufficient for approval. Based upon the data showing an increased PI in women with higher BMI, we believe there is a possibility for there to be language in the final approved label regarding the use of Twirla® in women based on weight.

Contraceptive Effectiveness and Obesity

The results obtained by Agile showing an increased PI with increased BMI are not unprecedented, but instead likely represent the inclusion of a diverse group of subjects in the SECURE trial that was not true in most prior contraceptive clinical trials. A number of studies have been published that show how obesity can affect the metabolism of combined hormonal contraceptives, including the patch, and their effectiveness:

Zieman *et al*., 2002: This was an analysis of pooled data from three pivotal studies of the contraceptive patch Ortho Evra®. The contraceptive failure rate was found to be low and uniformly distributed across the weight range for women <90 kg, however for women who were ≥90 kg, there appeared to be an increased risk of pregnancy. While those ≥90 kg made up only 3% of the study population they accounted for 33% (5/15) of the reported pregnancies. In addition, 20% of the study population was ≥74 kg and this cohort accounted for 60% (9/15) of the reported pregnancies. Body weight was a significant risk factor for pregnancy in a proportional hazards model ($P < 0.001$).

Holt *et al*., 2005: This was a case-control study that investigated the pregnancy rate among (combination oral contraceptives (COC) users and found a 60% increased risk of unintended pregnancy in COC users with BMI >27.3

kg/m^2. Among women who were consistent users (they missed no pills in the reference month), the risk of pregnancy doubled in women with BMI >27.3 kg/m^2 or >32.2 kg/m^2. Weight was also a factor, as women weighing >74.8 kg had a 70% higher risk of pregnancy compared to women weighing 74.8 kg or less.

Edelman *et al*., 2009: This study compared the effects of a COC on the hypothalamic-pituitary-ovarian axis in obese and non-obese women. Obese women were found to have a significantly larger mean area under the curve (AUC), longer LNG half-life (and thus a lower maximal LNG concentration on Cycle 2, Day 1), and a longer time to reach steady state. These factors potentially lead to a time after the placebo week when obese women would not be adequately protected from pregnancy.

Lopez *et al*., 2010: This was a Cochrane Review of 11 studies that used pregnancy as an outcome and found that women with a BMI >25 kg/m^2 were almost twice as likely to become pregnant when on COCs than normal-weight women. In addition, they found that for those using a patch contraceptive there was a significant association of pregnancy with body weight, but not with BMI, although the authors stipulate that "the field could use trials of contraceptive methods stratified by BMI" due to limited data being available.

Dinger *et al*., 2011: This study examined outcome data from over 50,000 U.S. women from a prospective, non-interventional long-term cohort study and found that women with higher BMI were more likely to get pregnant when on oral contraceptives, even after adjusting for age, parity, and education level.

Yamazaki *et al*., 2015: This was a meta-analysis conducted using individual participant data directly from Phase 3 clinical trial data of COCs and published by current and former FDA reviewers. The trials were reviewed by the FDA between 2002 and 2012 and all measured effectiveness using the PI. The pooled PI from seven clinical trials was 3.14 for obese and 2.53 for non-obese women. The overall hazard ratio for unintended pregnancy in obese women compared to non-obese women was 1.44, presenting a 44% higher pregnancy rate for obese women using COCs after adjusting for age and race.

The takeaway from all of these studies is that there does appear to be a correlation between BMI (and/or body weight) and PI for women on hormonal contraceptives, and that the results seen in the SECURE trial are not unique to Twirla® and do not represent any type of patch-specific negative attributes.

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 hormonal contraceptive market.

According to EvaluatePharma, the worldwide hormonal contraceptive market (including both combination and progestin-only products) totaled approximately $6.5 billion in 2016, while the U.S. market totaled approximately $3.7 billion. The top selling products are shown in the following table.

Product	Type	Active Ingredient(s)	Company	2016 WW Sales ($millions)	2016 US Sales ($millions)
Mirena	IUD	levonorgestrel	Bayer	$1,154	$776
Nuvaring	Vaginal ring	ethinyl estradiol; etonogestrel	Merck	$777	$576
Yasmin	Combination Pill	drospirenone; ethinyl estadiol	Bayer	$750	$142
Nexplanon	Implant	etonogestrel	Merck	$606	$420
Lo Loestrin	Combination Pill	ethinyl estradiol; norethindrone acetate	Allergan	$404	$404
			Total	$3,691	$2,318

Source: EvaluatePharma / Zacks SCR

There has been little to no growth as measured by prescription volume over the past ten years in the hormonal contraceptive market, except for a 4.8% increase in 2013 compared to 2012. This was a one-time boost in prescriptions due to the enactment of the Patient Protection and Affordable Care Act (ACA), which required all health care plans to offer preventative services to women with no deductible, co-insurance, or co-payments. The preventative services include all FDA approved contraceptive methods.

Following enactment of the ACA, generic oral contraceptives showed the highest growth, likely due to the fact that most health insurance companies were offering generics as a no cost-sharing option (i.e., no deductible, co-pay, or co-insurance). In May 2015, several U.S. government agencies clarified the requirements for the contraceptive coverage under the ACA. These requirements include at least one form of contraception in each of the 18 current methods the FDA lists in the Birth Control Chart must be offered with no cost-sharing. Since the patch is listed among the 18 current contraceptive methods, at least one patch product must be offered to patients with no cost-sharing. Recently, there has been much talk about repealing certain parts of the ACA, however at this point nothing has occurred and the requirements in regards to contraceptive coverage are still in effect.

Contraceptive Patch Experience

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 pharmacokinetic 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. 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.

Bayer is developing what we believe to be the only other combined hormonal contraceptive patch, which uses EE and a third generation progestin (gestodene, which has not been approved by the U.S. FDA). Bayer completed a Phase 3 efficacy trial in the U.S. in 2011, however the company never submitted a NDA to the FDA for the gestodene patch and no longer lists it with the pipeline.

Twirla® Commercialization Plan and Market Research

It approved, Agile plans on building a sales and marketing force for Twirla® that will initially focus on OBGyns, Nurse Practitioners, Physician Assistants, and Primary Care Physicians who are the top prescribers of contraceptives in the U.S. The company plans to utilize a sales force of 70-100 representatives that could reach the approximately 22,000 prescribers responsible for 80% of branded CHC products.

As opposed to a traditional direct-to-consumer advertising campaign that includes television ads, Agile plans to rely mostly on social media to reach its target demographic of women age 18-34 years. Most women of that age get their information through social networks, with text messaging being the preferred method of communication. A targeted advertising campaign that utilizes social media and blogs, combined with some traditional outlets such as magazines, are likely to create sufficient brand awareness of Twirla® while at the same time being a cost-effective approach.

Agile has performed market research with over 800 healthcare professionals and 3,300 consumers to gain insight into Twirla® and the contraceptive market. Some important points from this data include:

- Healthcare practitioners have a large influence on which hormonal contraceptive their patients ultimately choose. Most present oral contraceptives first due to its long history and familiarity.

- The PI is not an important factor given that most consumers are not going to understand it, thus healthcare practitioners place very little emphasis on it. Given a choice between products with comparable PIs, which product has the lower PI is not going to be a deciding factor as efficacy is assumed for all approved CHC products.

- Many consumers lose excitement for oral contraceptives after realizing the difficulty of remembering to take one every day.

- Approximately 15% of women surveyed indicated they would be “extremely likely” to ask their doctor for a prescription for Twirla®.

- The prescription contraceptive market is not a high priority for payers and knowledge of individual products is low. Payers indicated a willingness to work with a manufacturer to make one product preferred (i.e., $0

co-pay) in a contraceptive category, although preferred status may not preclude other products in that category from having a $0 co-pay.

Currently, the company does not have plans to commercialize Twirla® outside the U.S., however if that were to occur it would be through a partnership with another pharmaceutical company.

Financials and Capital Structure

On May 8, 2017, Agile released financial results for the first quarter of 2017. As expected, the company did not report any revenues. Net loss for the quarter was $7.5 million, or $0.26 per share. R&D expenses for the first quarter of 2017 totaled $4.7 million, compared to $4.9 million for the first quarter of 2016. The decrease was due to a decrease in clinical development expenses partially offset by increases in manufacturing, regulatory, and personnel expenses. G&A expenses for the first quarter of 2017 were $2.4 million, compared to $2.1 million for the first quarter of 2016. The increase was due to increased commercial development expenses and professional fees.

Cash burn for the first quarter of 2017 totaled approximately $6.0 million, and the company exited the first quarter of 2017 with approximately $41.7 million in cash and cash equivalents. We believe this is sufficient to fund operations into the second quarter of 2018, however the company will require additional capital for the commercial launch of Twirla®.

In February 2015, the company entered into a loan and security agreement with Hercules Capital, Inc. for a term loan of up to $25.0 million. A first tranche of $16.5 million was funded upon execution of the loan, and the company recently extended the period during which it may draw an additional tranche of $8.5 million until January 31, 2018. The loan accrues interest at a rate of the greater of 9.0% or 9.0% plus Prime minus 4.25%. Principal is due in 23 consecutive monthly installments beginning on February 1, 2017 and ending on Dec. 1, 2018.

As of May 5, 2017, Agile had approximately 28.8 million shares of common stock outstanding. In addition, the company has approximately 3.7 million stock options, 0.2 million warrants, and 0.2 million unvested restricted stock units for a fully diluted share count of approximately 32.9 million.

Valuation

We value Agile using a probability adjusted discounted cash flow model that takes into account potential future revenues for Twirla®. Now that the NDA has been refilled, we believe the FDA will perform a 6-month review, which should lead to a PDUFA date before the end of 2017.

Even with a PI 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 PI is higher than previously seen in other hormonal contraceptive trials based on a correlation between BMI and the PI. 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 PI than the SECURE trial. Once approved, we don't believe the slightly higher PI will have an adverse impact on peak revenues. We base this on market research presented by the company showing that clinicians do not discuss PI 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 in late 2017.

According to EvaluatePharma, the U.S. hormonal contraceptive market (including both combination and progestin-only products) totaled $3.7 billion. 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 80% probability of approval we value Twirla® at $258 million. When taking into account estimated capital requirements for the launch of Twirla® of $35 million, and dividing by the fully diluted share count of 32.9 million share, this leads to a valuation of approximately $7.00 per share.

PROJECTED FINANCIALS

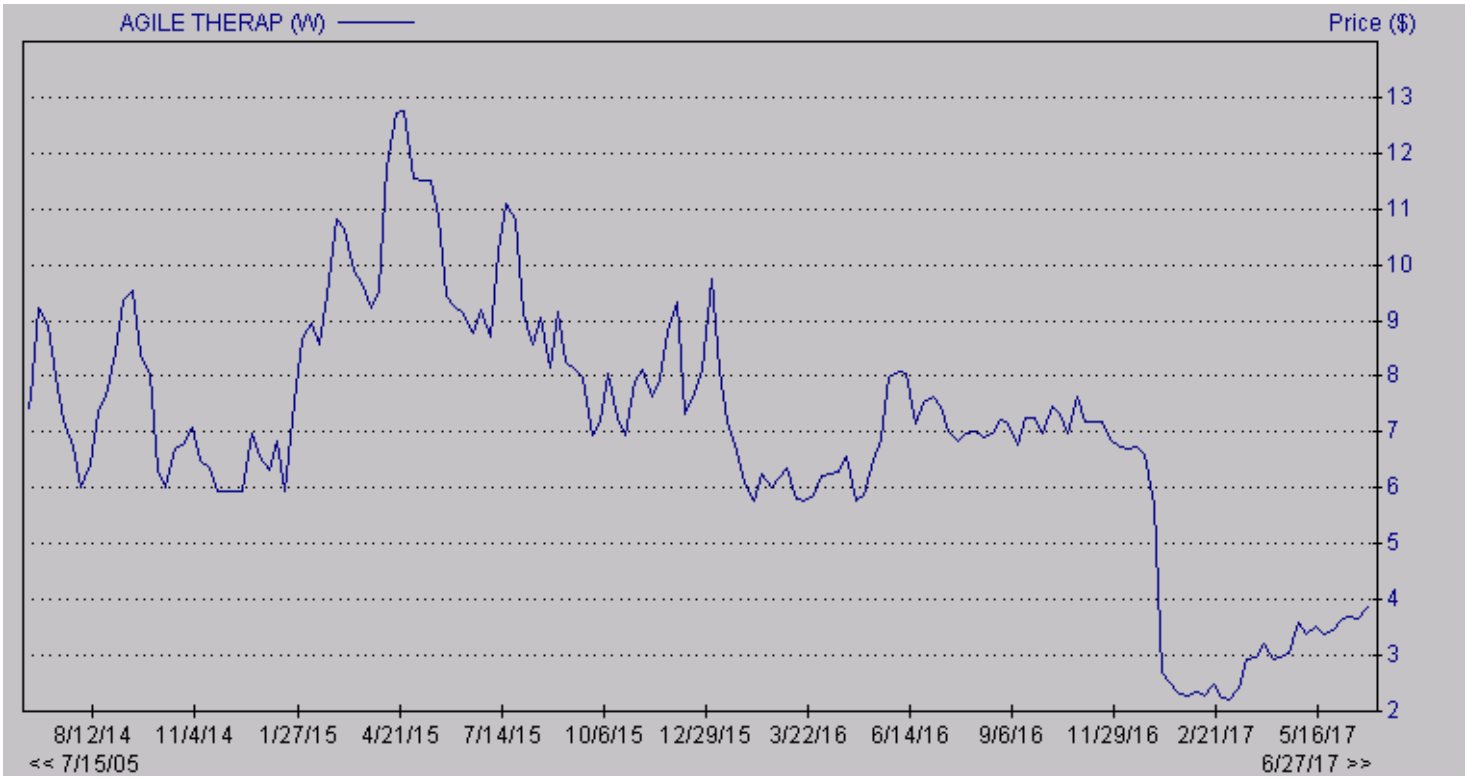
Agile Therapeutics, Inc.
Income Statement

Agile Therapeutics, Inc.	2016 A	Q1 A	Q2 E	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!*	*-100.0%*	*#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	$2.3	$2.3	$2.4	$9.4	$25.0	$30.0
% SG&A	*137310.6%*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*132.3%*	*77.9%*
R&D	$20.9	$4.7	$4.5	$4.5	$4.6	$18.3	$18.0	$17.0
% R&D	*326862.4%*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*95.2%*	*44.2%*
Operating Income	($29.7)	($7.1)	($6.8)	($6.8)	($7.0)	($27.7)	($27.1)	($14.5)
Operating Margin	*-464073.0%*	*#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)	($1.9)	($1.6)	($0.5)
Pre-Tax Income	($31.8)	($7.5)	($7.3)	($7.3)	($7.5)	($29.6)	($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)	($7.3)	($7.3)	($7.5)	($29.6)	($28.7)	($15.0)
YOY Growth	*#REF!*	-	-	-	-	*3.1%*	*-3.1%*	*-47.7%*
Net Margin	*-448767.7%*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*-151.9%*	*-39.0%*
Reported EPS	($1.02)	($0.26)	($0.25)	($0.25)	($0.26)	($1.03)	($0.72)	($0.30)
Fully Diluted Shares	28.3	28.8	28.8	28.9	29.0	28.9	40.0	50.0

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

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