William Blair

Agile Therapeutics, Inc.

September 16, 2014

Twirla Phase III Study SECURE Initiated; Results Expected in First Half 2016

Before the markets opened Tuesday, September 16, Agile Therapeutics announced the initiation of its Phase III trial entitled SECURE (Study to Evaluate Contraceptive Use, Reliability, and Effectiveness). The pivotal trial initiation for Twirla, a low-dose combined hormonal contraceptive patch that delivers ethinyl estradiol and levonorgestrel, puts the study on track for completion in first quarter 2016, which is consistent with previous guidance. The trial is expected to enroll about 2,100 female subjects for use of Twirla up to one year in an open-label, single-arm study. In addition to a thorough screening visit, each participant will have a two-week run-in period to get accustomed to an e-diary as well as education on using the patch itself. The company anticipates a four- to six-month enrollment period to ensure that patients are appropriately vetted and compliant throughout the trial period, which we believe is important since noncompliance significantly complicates the standard primary endpoint used in contraception studies.

The Phase III trial will assess the efficacy of Twirla in preventing pregnancy using the widely accepted Pearl Index as the primary endpoint. The Pearl Index is defined as the number of contraceptive failures per 100 women divided by exposure. The numerator in the index is the number of pregnancies, and the denominator is the cumulative number of months or cycles of exposure from the start of the method until the completion of the study, discontinuation of the method, or pregnancy. As shown in exhibit 1, on the following page, in the past decade, some oral contraceptive products have been approved with overall Pearl rates of about 2.0, while the highest approved upper bound of the 95% confidence interval was 5.03 for Seasonale in 2003. In addition, the most recent approval of a contraceptive was Quartette, which had a Pearl rate of 3.19. We believe that new management, including new Chief Medical Officer Elizabeth Garner, M.D., who came to Agile with an impressive women's health background, should be able to run a trial focused on achieving an approvable Pearl Index score of less than 3.19 (or lower).

Recall that Agile had previously conducted a Phase III clinical program for Twirla and filed an NDA with the FDA in April 2012. The FDA issued a complete response letter (CRL) in February 2013 and requested additional clinical data, quality control information, and manufacturing/control information. The company analyzed the data from the program and determined several flaws in trial design, execution, and conduct. The Pearl Index for Twirla was 5.76 pooling both Phase III trials; however, the combined oral contraceptive control in the Phase III studies yielded a Pearl Index score of 6.72. The flaws that resulted in high Pearl Index scores included poor subject compliance, a concentration of unplanned pregnancies at a few study sites, and a disproportionately high number of subjects at higher risk of noncompliance and pregnancy. Agile will use the results from SECURE to address issues raised in the agency's CRL, and we believe that the FDA has given the company a relatively achievable path to approval and that the company is on track for a regulatory decision in late 2016 and launch in 2017.

Agile Therapeutics, based in Princeton, New Jersey, is a developer of therapeutics for the women's health setting.

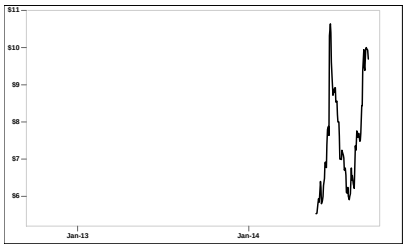
Stock Rating:	**Outperform**
Company Profile:	**Aggressive Growth**
Price Target:	$18.00
Symbol:	AGRX (NASDAQ)
Price:	$8.70 (52-Wk.: $5-$13)
Market Value (mil.):	$162
Fiscal Year End:	December
Long-Term EPS Growth Rate:	
Dividend/Yield:	None

	2013A	2014E	2015E
Estimates			
EPS Q1	NA	A$0.02	NA
Q2	NA	A$-0.28	NA
Q3	NA	$-0.57	NA
Q4	NA	$-0.56	NA
FY		$-1.35	$-1.32
CY		$-1.35	$-1.32
Sales (mil.)	NA	0	0
Valuation			
FY P/E	NA	NM	NM
CY P/E		NM	NM

Trading Data (FactSet)	
Shares Outstanding (mil.)	9
Float (mil.)	2
Average Daily Volume	160,058

Financial Data (FactSet)	
Long-Term Debt/Total Capital (MRQ)	0.2
Book Value Per Share (MRQ)	0.0
Return on Equity (TTM)	-340.3

Two-Year Price Performance Chart



Sources: FactSet, William Blair & Company estimates

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During second quarter 2014, Agile continued to work with manufacturing partner Corium (CORI $6.95) on the scale-up of Twirla and expects to complete validation and expansion by the end of 2016. Lastly, in collaboration with its third-party CRO Parexel (PRXL $60.97; Outperform), Agile selected PHT Corporation to provide e-diaries for the trial. The company reported that patient screening is underway and the first subjects have been enrolled in the study run-in period using the e-diary. We believe that collecting daily use data during the Phase III trial will be critical since it was an issue during its previous Phase III trials. During this Phase III study, an easy-to-use electronic application should enable increased compliance rates throughout the trial, leading to less missing data and potentially an improved Pearl score.

In addition, in the second quarter the company also announced that it was issued U.S. patent 8,747,888 as a continuation of its prior patent (U.S. 8,246,978) for a "dermal delivery device with reduced loss of its volatile components." The patent is a continuation of the '978 patent and will provide coverage into 2028 for Twirla. As the patent coverage relating to Twirla continues to solidify, pending an approval and successful development of Twirla, the company will look to list in the Orange Book patent '888 as well as five other issued patents.

We continue to believe that shares of Agile hold a strong risk/reward profile, given the well-defined efficacy of ethinyl estradiol/levonorgestrel products and the clear pathway for approval of contraception products. However, shareholders will likely have to be patient for several months when news flow regarding the company's main product may be scarce, and share prices of development-stage therapeutics companies tend to trade in line with the markets until a clear catalyst approaches. Ultimately, we believe in the strong management at Agile and view the Phase III study for Twirla as very achievable. After the update Tuesday, the company remains on track with previous guidance to complete the SECURE study by first quarter 2016. As of the end of the second quarter, the company reported cash and cash equivalents of about $53.5 million, which it believes is sufficient to fund operations through first quarter 2016. We therefore maintain our Outperform rating and $18 price target on shares of Agile.

Exhibit 1
Agile Therapeutics, Inc.
FDA-Approved Combined Hormonal Oral Contraceptives,
Clinical Trial Length, Pearl Index Score

Year Approved	Product Name	Study Length	Pearl Index
2013	Quartette	1 year	3.19
2010	Natazia	Up to 2.2 years	1.64 (US), 1.04 (EU)
2008	LoSeasonique	1 year	2.74
2007	Lybrel	Up to 1 year	2.38
2007	Yaz	1 year	1.41
2006	Seasonique	1 year	1.34
2006	Loestrin 24 Fe	6 cycles	1.82
2003	Seasonale	1 year	1.98
2001	Yasmin	2 years	<1.00
1998	Levlite	6 cycles	0.29
1997	Alesse	13 cycles	0.84

Sources: Company reports and William Blair & Company, L.L.C.

Valuation

Our price target of $18 is based on a net present value (NPV) analysis of the company's lead development program, Twirla. In this calculation, we assume a launch of Twirla in mid-2016, after Agile responds to the agency's CRL with data provided from the SECURE Phase III trial. We assume Twirla peak sales will approach $400 million, which we project as only 5.0% penetration into the total prescription contraception market. Exhibit 2 details our sum-of-the-parts valuation of Agile.

Exhibit 2
Agile Therapeutics, Inc.
Sum-of-the-Parts Valuation

	Peak Sales	Discount Rate	Probability of Success	Peak Sales	Value Per Share
Twirla	$392	11%	75%	2021	$ 18.32
Cash Per Share					$ 2.44
NPV of Future Losses Per Share					$ (2.86)
NPV Value					$ 358.02
NPV Value Per Share					$ 17.90

Note: For per share numbers we use fully diluted share count of 20.7 million
Source: William Blair & Company L.L.C. estimates

Risks

An investment in shares of Agile involves clinical, regulatory, and financial risks that are typical of development-stage biopharmaceutical companies. In addition, Agile may face manufacturing, intellectual property, and competitive risks. We estimate that Agile will incur losses through 2017, given the commencement of Twirla's Phase III trial and expenses needed to bring the product to market.

IMPORTANT DISCLOSURES

William Blair was a manager or co-manager of a public offering of equity securities for Agile Therapeutics, Inc. within the prior 12 months.

William Blair is a market maker in the security of Agile Therapeutics, Inc. and may have a long or short position.

William Blair intends to seek investment banking compensation in the next three months from Agile Therapeutics, Inc.

Within the past 12 months William Blair has provided or is providing investment banking services to or has an investment services relationship with Agile Therapeutics, Inc.

Additional information is available upon request.

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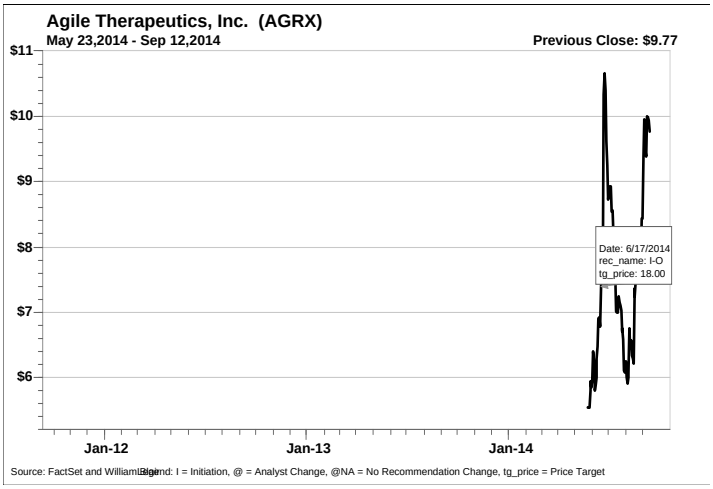
DOW JONES: 17,031.14
S&P 500: 1,984.13
NASDAQ: 4,518.90



Current Rating Distribution (as of 08/31/14)

Coverage Universe	Percent	Inv. Banking Relationships*	Percent
Outperform (Buy)	66	Outperform (Buy)	16
Market Perform (Hold)	31	Market Perform (Hold)	3
Underperform (Sell)	1	Underperform (Sell)	0

*Percentage of companies in each rating category that are investment banking clients, defined as companies for which William Blair has received compensation for investment banking services within the past 12 months.

The compensation of the research analyst is based on a variety of factors, including performance of his or her stock recommendations; contributions to all of the firm's departments, including asset management, corporate finance, institutional sales, and retail brokerage; firm profitability; and competitive factors.

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