

Agile Therapeutics, Inc.

Clinical Update Positive Although Early as Company Lengthens Runway With Capital Raise

- Before the markets opened on Tuesday, January 20, Agile Therapeutics provided a brief clinical update on its ongoing Phase III open-label study (also known as SECURE) for the company's once-weekly contraceptive patch, Twirla. Management continues to guide to completing patient screening for SECURE by the end of the first quarter, with enrollment expected to complete early in second quarter 2015 and top-line results expected early in 2016. The company has selected and trained 74 sites consistent with its strategy to enroll high-quality clinical trial sites with experience in clinical trials in the women's health sector. While still early in the trial, management noted no pregnancies or loss of patients to follow-up to date.
- SECURE is a single-arm, open-label, multicenter trial that will assess the safety and efficacy of Twirla in roughly 2,100 female subjects in the United States for up to one year; the trial enrolled its first patient in September 2014. The Phase III trial will assess the efficacy of Twirla in preventing pregnancy using the widely accepted Pearl Index as the primary endpoint. In the past decade, some oral contraceptive products have been approved with overall Pearl rates of about 2.0; the most recent approval of a contraceptive was Quartette, which had a Pearl rate of 3.19, while the highest approved upper bound of the 95% confidence interval was 5.03 for Seasonale in 2003.
- We believe that the clinical update presented Tuesday is particularly important because of Agile's previously conducted Phase III clinical program for Twirla that led to a complete response letter (CRL). We believe the ongoing SECURE trial, designed by the company's new chief medical officer, Dr. Elizabeth Garner, addresses many of the shortcomings of the company's first Phase III study, namely enrolling many patients in low-quality sites. In that study, 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 (36% of on-drug pregnancies reported at 4 of 96 sites, representing 15% of the randomized subject population), and a disproportionately high number of subjects at higher risk of noncompliance and pregnancy. While Tuesday's clinical update is still early days in the program, we believe the company has a relatively achievable path to approval in late 2016 with launch in 2017 if Agile continues to execute a high-quality program.
- In addition to the clinical update, Agile reported a \$20 million private placement led by RA Capital Management, a high-quality healthcare specialist, with participation by several existing investors. We believe the additional cash lengthens Agile's runway through its Phase III study enrollment and top-line data release in 2016. At the end of third quarter 2014, the company had \$45.7 million in cash and cash equivalents, with management conveying its belief to be funded through first quarter 2016.

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

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January 20, 2015

Stock Rating: **Outperform**
Company Profile: **Aggressive Growth**
Price Target: **\$18.00**

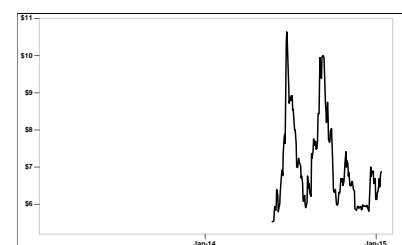
Symbol: AGRX (NASDAQ)
Price: \$6.90 (52-Wk.: \$5-\$13)
Market Value (mil.): \$111
Fiscal Year End: December
Long-Term EPS Growth Rate: NA
Dividend/Yield: None

	2013A	2014E	2015E
Estimates			
EPS Q1	NA	A\$0.02	NA
Q2	NA	A\$-0.28	NA
Q3	NA	A\$-0.34	NA
Q4	NA	\$-0.40	NA
FY		\$-1.46	\$-1.58
CY		\$-1.46	\$-1.58
Sales (mil.)	NA	0	0
Valuation			
FY P/E	NA	NM	NM
CY P/E		NM	NM

Trading Data (FactSet)	
Shares Outstanding (mil.)	19
Float (mil.)	6
Average Daily Volume	30,086

Financial Data (FactSet)	
Long-Term Debt/Total Capital (MRQ)	0.0
Book Value Per Share (MRQ)	2.3
Return on Equity (TTM)	NM

Two-Year Price Performance Chart



Sources: FactSet, William Blair & Company estimates

- 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 achievable. We maintain our Outperform rating on Agile and our \$18 price target, which we will revisit after the company reports fourth-quarter earnings.

Valuation

We rate Agile Therapeutics Outperform with a price target of \$18, based on an NPV 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.

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.

William Blair & Company, L.L.C.

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William Blair is a market maker in the security of Agile Therapeutics, Inc.

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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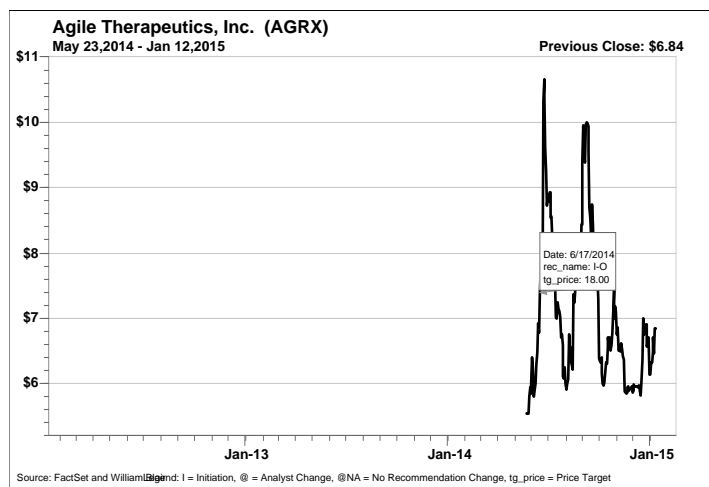
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DOW JONES: 17,511.57

S&P 500: 2,019.42

NASDAQ: 4,634.38



Current Rating Distribution (as of 12/31/14)

Coverage Universe	Percent	Inv. Banking Relationships*	Percent
Outperform (Buy)	64	Outperform (Buy)	15
Market Perform (Hold)	31	Market Perform (Hold)	2
Underperform (Sell)	2	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.

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