

Agile Therapeutics, Inc.

Issued '888 Patent Provides Additional Exclusivity to Proprietary Skinfusion Technology

- On Friday, June 20, Agile Therapeutics 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 its lead program, the contraceptive patch Twirla. As the patent coverage around Twirla continues to solidify, we anticipate Agile management will enroll the first patients for the company's pivotal Phase III trial for the product in the near term.
- In our model, we had previously assumed 10 years of exclusivity, in line with the exclusivity of the Ortho Evra product; however, this additional patent gives us more comfort in the tail value of Twirla, which would lead to upside to our current \$18 price target. Pending 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.
- Exhibit 1 shows the composition of the Twirla patch, which uses the Skinfusion technology, and highlights the complexity of the product, which we believe sets a high hurdle for generics. The product includes the two well-characterized active ingredients ethinyl estradiol and levonorgestrel as well as inactive ingredients dimethyl-sulfoxide, ethyl lactate, capric acid, lauryl lactate, and other adhesives. The inner matrix patch responsible for hormone delivery sits inside an outer portion that contains only adhesives and provides a physical barrier to prevent migration. In total, there are six layers of the patch, which integrates the safety of hormonal delivery over a seven-day period with an additional focus on flexibility and patient comfort. In addition, the company has tested the active ingredient delivery in various conditions (including heat, humidity, exercise, and exposure to water in various settings) and the results have shown that the patch was safe, efficacious, and well tolerated under all conditions (Archer et al. *Contraception* 2013, Foegh et al. *Contraception* 2013).
- Agile had previously conducted Phase III clinical trials for Twirla and filed an NDA with the FDA in April 2012. The FDA issued a complete response letter 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 the trial design, execution, and conduct, which led to a regulatory submission that was not approved. We believe these flaws 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 upcoming pivotal Phase III study to address issues raised in the agency's complete response letter, and we believe the agency has given the company a relatively achievable path to approval. The upcoming pivotal trial will be an open-label, single-arm study, enrolling roughly 2,000 women, with the primary endpoint being the standard measure for pregnancy risk in contraception studies: the Pearl Index. We believe 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 score of less than 3.16 (or lower) through attention to trial conduct and enrollment.

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

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June 20, 2014

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

Symbol: AGRX (NASDAQ)
Price: \$7.63 (52-Wk.: \$5-\$8)
Market Value (mil.): \$147
Fiscal Year End: December
Long-Term EPS Growth Rate:
Dividend/Yield: None

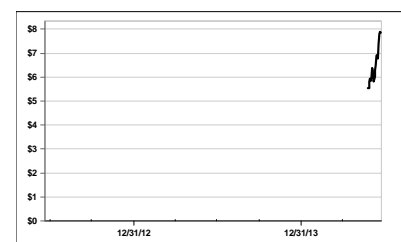
	2013A	2014E	2015E
Estimates			
EPS FY		\$-1.02	\$-0.88
CY		\$-1.02	\$-0.88

Valuation			
FY P/E	NA	NM	NM
CY P/E		NM	NM

Trading Data (FactSet)	
Shares Outstanding (mil.)	9
Float (mil.)	6
Average Daily Volume	323,145

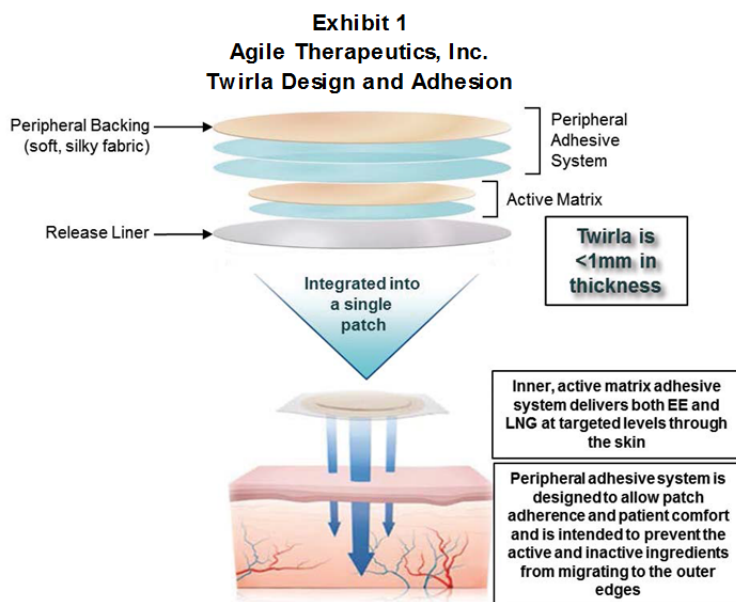
Financial Data (FactSet)	
Long-Term Debt/Total Capital (MRQ)	0.7
Book Value Per Share (MRQ)	0.0
Return on Equity (TTM)	-340.3

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. We ultimately believe in the strong management at Agile and view the current Phase III study for Twirla as very achievable. We therefore maintain our Outperform rating on shares of Agile Therapeutics and our \$18 price target.



Source: Agile Therapeutics S-1

Valuation

We rate shares of 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 complete response letter with data provided by the upcoming Phase III study. We assume Twirla peak sales will approach \$400 million, which we project as only a 5.0% penetration into the total prescription contraception market. Exhibit 2 details our sum-of-the-parts valuation of Agile Therapeutics.

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 Therapeutics 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 preparations for the Twirla Phase III trial and expenses needed to bring the product to market.

William Blair & Company, L.L.C.

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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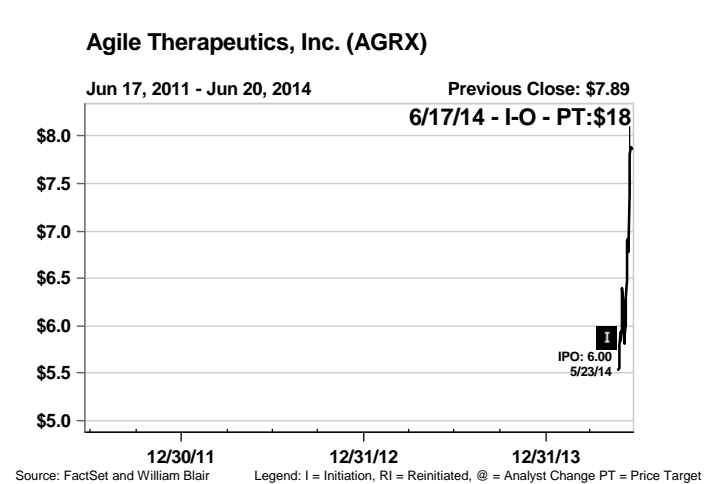
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DOW JONES: 16,921.46

S&P 500: 1,959.48

NASDAQ: 4,359.32



Current Rating Distribution (as of 05/31/14)

Coverage Universe	Percent	Inv. Banking Relationships*	Percent
Outperform (Buy)	67	Outperform (Buy)	15
Market Perform (Hold)	30	Market Perform (Hold)	2
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.

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