

## Agile Therapeutics, Inc.

### Travels With Management Highlight Confidence in Phase III Trial Progress and Market Opportunity

- We hosted investor meetings with Agile CEO Al Altomari and Director of Investor Relations Mary Coleman and came away more positive on the company's progress in its ongoing Phase III trial with its lead product, a contraceptive patch called Twirla, as well as the potential market opportunity that exists if approved. The clinical trial, known as 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 began enrollment in September 2014. The primary endpoint of the study will be the Pearl Index, the industry standard measurement of efficacy in contraception studies.
- Our conclusions from the meetings were three-fold: 1) the previous failed trials that resulted in a complete response letter from the FDA were due to correctable errors by previous management in study execution, 2) the company has received significant guidance from the FDA on trial design and the Pearl Index score needed for approval, and 3) the market opportunity for a contraceptive patch, if approved, could be large based on pricing, market size, and growth.
- Agile has previously run a Phase III trial under its former management team and using a small contract research organization, which resulted in a Pearl Index score of 5.76 for Twirla and a Pearl Index score of 6.72 for an oral contraceptive comparator, both with high confidence intervals. These rates are significantly higher than any contraceptive products that have been approved; Pearl Index scores normally come in around 2.0 in the more recent studies. However, contraceptives with higher Pearl scores have been previously approved such as Quartette, which had a Pearl Index score of 3.19, while the highest approved upper bound of the 95% confidence interval was 5.03 for Seasonale in 2003. We continue to believe that the last trial, which prompted a Complete Response Letter by the agency, was flawed in many ways that can be remedied in the current trial. We believe new clinical management is focusing on enrollment and site selection, as a concentration of unplanned pregnancies in the last trial occurred at only a few study sites (36% of on-drug pregnancies reported at 4 of 96 sites, including one site in Las Vegas that represented 15% of the randomized subject population). A disproportionately high number of subjects in higher risk groups enrolled in the last study, leading to noncompliance and pregnancy (i.e., new users had a Pearl Index score of 8.7 and minority subjects who were new users had a Pearl Index score of 16.0). From speaking with management, the company has developed a cooperative dialogue with the FDA that has resulted in the approval of the company's open-label, single-arm study design, and the use of the PHT electronic diary. As a result of our meetings, we are increasingly more confident in management's ability to conduct a sound clinical trial and achieve a Pearl Index score within the range of the approved products referenced earlier.

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

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

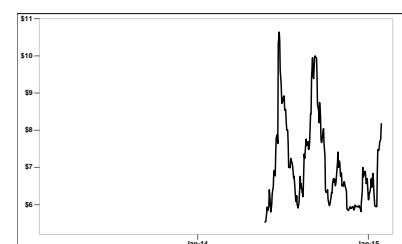
Symbol: AGRX (NASDAQ)  
Price: \$8.77 (52-Wk.: \$5-\$13)  
Market Value (mil.): \$164  
Fiscal Year End: December  
Long-Term EPS Growth Rate:  
Dividend/Yield: None

	2013A	2014E	2015E
<b>Estimates</b>			
EPS FY		\$-1.46	\$-1.58
CY		\$-1.46	\$-1.58
Sales (mil.)	NA	0	0
<b>Valuation</b>			
FY P/E	NA	NM	NM
CY P/E		NM	NM

<b>Trading Data (FactSet)</b>	
Shares Outstanding (mil.)	19
Float (mil.)	4
Average Daily Volume	29,878

<b>Financial Data (FactSet)</b>	
Long-Term Debt/Total Capital (MRQ)	0.0
Book Value Per Share (MRQ)	2.3
Return on Equity (TTM)	-340.3

#### Two-Year Price Performance Chart

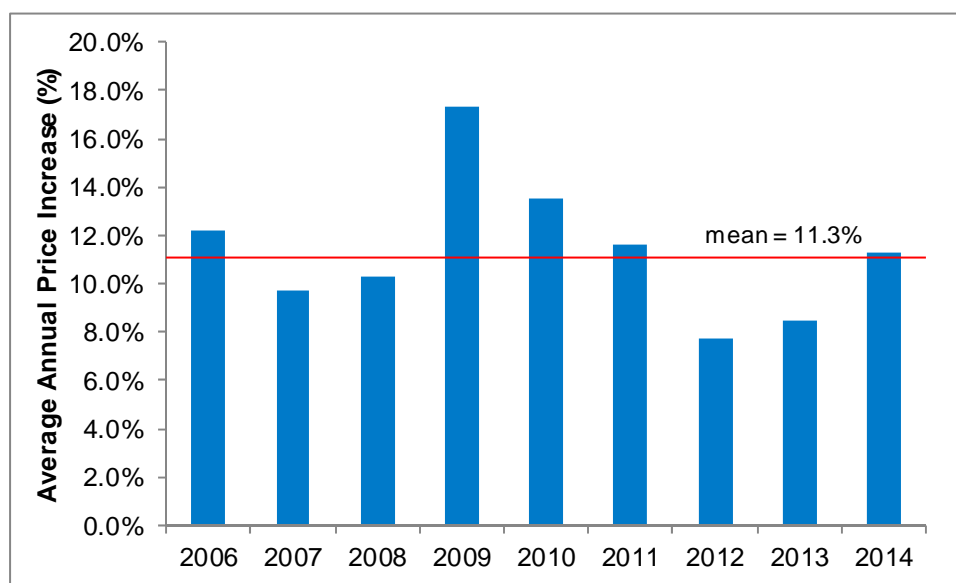


Sources: FactSet, William Blair & Company estimates

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- Lastly, the company noted the large market opportunity that exists in a growing \$4.1 billion U.S. market for combined hormonal contraceptives. As shown in exhibit 1, contraceptive pricing has grown an average of 11.3% year-over-year since 2006, making 1% TRx share equal to approximately \$126 million. A low-dose contraceptive patch, Ortho Evra, captured approximately 11% TRx market share when it was labeled at 20 µg ethinyl estradiol/day. In April 2014, Mylan (MYL \$53.22) launched Xulane, a generic equivalent to Evra priced at \$95.12 that has captured 698,890 total prescriptions in nine months (almost 1% market share), according to IMS Health (exhibit 2). This approximates to \$66.5 million in sales for the last three quarters of 2014 or about \$100 million annualized in the first 12 months after launch.
- Management continues to guide to completing patient screening for SECURE by the end of the first quarter with initiation of dosing expected to begin by early in the second quarter of 2015 and top-line results expected early in 2016. To date, 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 that it has had no pregnancies or loss of patients to follow-up. In addition to the clinical update, Agile recently 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 the company's runway comfortably through its Phase III trial and top-line data release in 2016. At the end of the third quarter of 2014, the company had \$45.7 million in cash and cash equivalents (not including the private placement) with management conveying its belief to be funded through the first quarter of 2016. We altered our model to reflect the share dilution from the private placement, updated the cash estimate, and rolled ahead our time value.
- We continue to believe that shares of Agile hold a strong risk/reward profile, given the well-defined efficacy of ethinyl estradiol/levonorgestrel products, clear pathway for approval of contraception products, the potential market opportunity, and management's significant experience in women's health. However, shareholders will likely have to be patient for several months when news flow regarding the company's main product may be scarce, as 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 current Phase III study for Twirla as achievable. We maintain our Outperform rating on Agile Therapeutics and our \$18 price target.

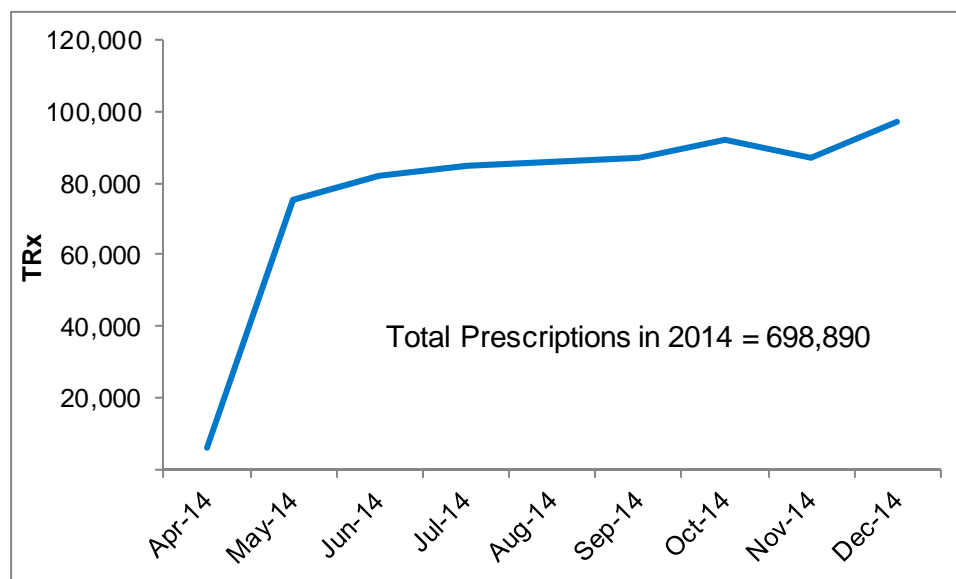
**Exhibit 1**  
**Agile Therapeutics, Inc.**  
**Average Annual Price Increase of Contraceptives From 2006-2014\***



\*Includes price increases which occurred through Dec. 15, 2014

Source: Agile company reports, PriceRx Select

**Exhibit 2**  
**Agile Therapeutics, Inc.**  
**Xulane Monthly Prescriptions Since Launch**



Source: IMS Health, Agile company reports

### Valuation

We rate Agile Therapeutics as 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.

### Sum of the Parts Valuation

	Peak Sales	Discount Rate	Probability of Success	Peak Sales	Value Per Share
Twirla	\$392	11%	75%	2021	\$ 18.75
Cash Per Share					\$ 2.73
NPV of Future Losses Per Share					\$ (3.03)
NPV Value Per Share					\$ 18.44

Source: William Blair & Company L.L.C. estimates

For per share numbers we use fully diluted share count of 22 million

### 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 the commencement of Twirla's Phase III trial and expenses needed to bring the product to market.

	2012(A)	2013(A)	Q1(A)	Q2(A)	Q3(A)	Q4(E)	2014(E)	2015(E)	2016(E)	2017(E)	2018(E)	2019(E)
Product Revenue												
Twirla	-	-	-	-	-	-	-	-	-	117,740	228,121	343,408
Royalty/Milestone Revenue	-	-	-	-	-	-	-	-	-	-	-	-
<b>Total Revenue</b>	-	-	-	-	-	-	-	-	-	117,739.8	228,120.8	343,407.7
yr/yr growth	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	93.8%	50.5%
q/q growth	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
incremental rev q/q												
<b>Cost of Goods Sold</b>	-	-	-	-	-	-	-	-	-	11,774	22,812	34,341
<i>Gross Profit</i>	-	-	-	-	-	-	-	-	-	105,966	205,309	309,067
<b>SG&amp;A</b>	17,387	9,154	1,053	1,104	1,446	1,470	4,900	6,500	18,250	48,500	50,300	52,000
<i>Growth</i>							-46%	33%	181%	166%	315%	329%
<b>R&amp;D</b>	5,930	3,574	1,394	2,391	4,603	5,600	13,988	24,200	23,300	15,000	17,000	21,000
<i>Growth</i>		-40%	-	-	-	-	291%	73%	-4%	-36%	13%	24%
<b>Total Operating Expenses</b>	23,317	12,728	2,448	3,495	6,049	7,070	19,061	30,700	41,550	63,500	67,300	73,000
<i>growth</i>			NA	NA	NA	NA	50%	61%	35%	53%	6%	8%
Operating Income	(23,317)	(12,728)	(2,448)	(3,495)	(6,049)	(7,070)	(19,061)	(30,700)	(41,550)	42,466	138,009	236,067
EBIT Margin							NM	NM	NM	NM	60%	69%
growth y/y (%)			NA	NA	NA	NA	NM	NM	NM	NM	NM	NM
Depreciation and Amortization	-	-	250	5	250	250	1,000	1,000	1,000	1,000	1,000	1,000
EBITDA	(23,317)	(12,728)	(2,198)	(3,490)	(5,799)	(6,820)	(18,306.2)	(29,700.0)	(40,550.0)	43,466	139,009	237,067
Interest expense	(140)	(1,592)	(378)	(403.5)	(392)	(300)	(1,474)	2,000	1,500	1,500	8,000	8,000
Interest income	26	-	0	0.1	1.3	1.0						
Change in fair value of warrants	171.0	-	13	179.7	86.2	70.0						
Other	-	-										
Income Before Taxes	(23,260)	(14,320)	(2,813)	(3,718)	(6,353)	(7,370)	(20,255)	(28,700)	(40,050)	43,966	146,009	244,067
Income Tax Provision	-	-	(3,652)	-	-	-	(3,652)	1,000	1,000	15,828	52,563	87,864
Effective Tax Rate	0.0%	0.0%	NA	NA	NA	NA	NM	NA	NA	36%	36%	36%
Beneficial conversino charge	(600)	-										
Net Income (loss) Attributable to Common	(23,860)	(14,320)	839	(3,718)	(6,353)	(7,370)	(16,602)	(29,700)	(41,050)	28,138	93,446	156,203
Net loss per share	(845)	(405)	839	(3,718)	(6,353)	(7,370)	(16,602)	(29,700)	(41,050)	28,138	93,446	156,203
Net income to common per share (diluted)			5.62	(0.46)	(0.34)	(0.40)	(1.46)	(1.58)	(1.94)	1.31	3.60	5.87
Basic avg. number of shares	28	35	149	8,000	18,592	18,600	11,335	18,850	19,250	19,650	25,658	25,758
<b>Key Ratios (GAAP unless noted)</b>												
Gross Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	90.0%	90.0%	90.0%
R&D (% Total Rev.)	NM	NM	NM	NM	NM	NM	NM	NM	NM	12.7%	7.5%	6.1%
SG&A (% Total Rev.)	NM	NM	NM	NM	NM	NM	NM	NM	NM	41.2%	22.0%	15.1%
Operating Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	36.1%	60.5%	68.7%
Net Income Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	23.9%	41.0%	45.5%
<b>Revenue Growth</b>												
Growth Yr/Yr	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	94%	51%
Growth Q/Q	NM		NM	NM	NM	NM						
<b>SG&amp;A Growth</b>												
Growth Yr/Yr	NM	-47%	NM	NM	NM	NM	-46%	33%	181%	166%	4%	3%
Growth Q/Q	NM		NM	NM	NM	NM						
<b>R&amp;D Growth</b>												
Growth Yr/Yr	NM	-40%	NM	NM	NM	NM	291%	73%	-4%	-36%	13%	24%
Growth Q/Q	NM		NM	NM	NM	NM						

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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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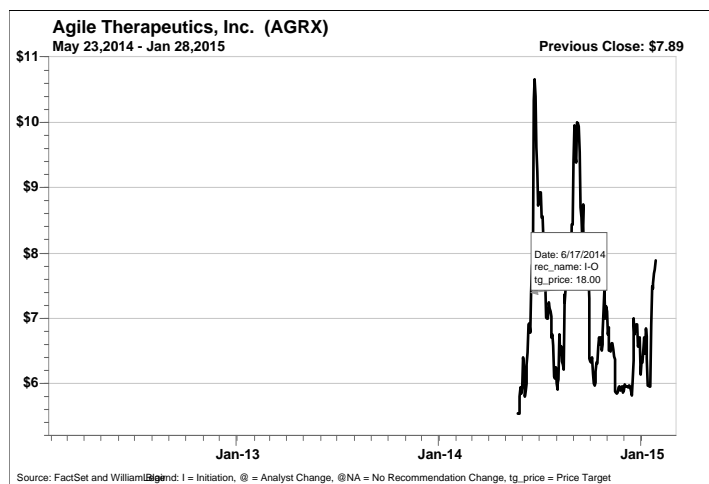
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DOW JONES: 17,673.02

S&P 500: 2,041.51

NASDAQ: 4,716.70



### **Current Rating Distribution (as of 01/31/15)**

Coverage Universe	Percent	Inv. Banking Relationships*	Percent
Outperform (Buy)	64	Outperform (Buy)	16
Market Perform (Hold)	32	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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