

## Agile Therapeutics, Inc.

### Weather Affects SECURE; Now Expected to Complete Enrollment During Third Quarter as Company Gains Runway Through 2016

- After the close on Tuesday, February 24, Agile Therapeutics announced that it had secured a debt facility from Hercules Technology Growth Capital of up to \$25 million, with the first tranche of \$16.5 million funded upon execution with no principal payments due until July 2016. Of that \$16.5 million, \$15.5 million was used to repay Agile's existing term loan, and the rest for working capital. Agile also has an additional tranche of \$8.5 million available, which provides the company the financial runway to fund operations through 2016. Prior to this agreement, the company's cash was only sufficient to bring the company through mid-2016, the previous estimate of top-line data release.
- In connection with the secured debt facility, the company also used provided an update on its ongoing Phase 3 clinical trial, SECURE. The company stated that enrollment in recent weeks has been slower than anticipated, and management now expects the completion of enrollment in the third quarter of 2015. This one-quarter delay pushes the timeline for completion of the study to the third quarter of 2016 (one year after enrollment of the last patient). After speaking with management, we believe that the delay is due to the weather on the East Coast inhibiting the face-to-face interaction that is necessary for the screening process in the study. The company has also stated that it has a significant number of clinical sites in the areas that have been particularly affected in recent months.
- Agile previously ran a Phase 3 trial under a former management team and used 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 were significantly higher than for any of the contraceptive products that have been approved, for which Pearl Index scores normally come in around 2.0 in the more recent studies. This was particularly concerning in the oral contraceptive comparator, where the approved product had received an approvable Pearl Index score in the registered clinical trial. We continue to believe that Agile's last Phase 3 trial, which prompted a complete response letter (CRL) by the agency, was flawed in many ways, which can be remedied in the current trial, and that the company is executing with study quality as its main priority. From our previous conversations with management, we also believe that the company has developed a cooperative dialogue with the FDA that has resulted in a relatively achievable open-label, single-arm Phase 3 study design.

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

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February 24, 2015

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

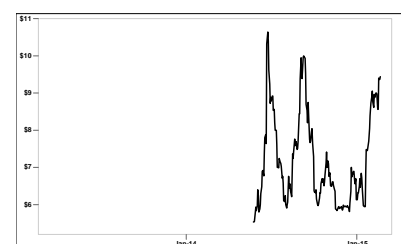
Symbol: AGRX (NASDAQ)  
Price: \$9.82 (52-Wk.: \$5-\$13)  
Market Value (mil.): \$181  
Fiscal Year End: December  
Long-Term EPS Growth Rate:  
Dividend/Yield: None

	2013A	2014E	2015E
<b>Estimates</b>			
EPS FY		\$-1.46	\$-1.63
CY		\$-1.46	\$-1.63
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	29,153

<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

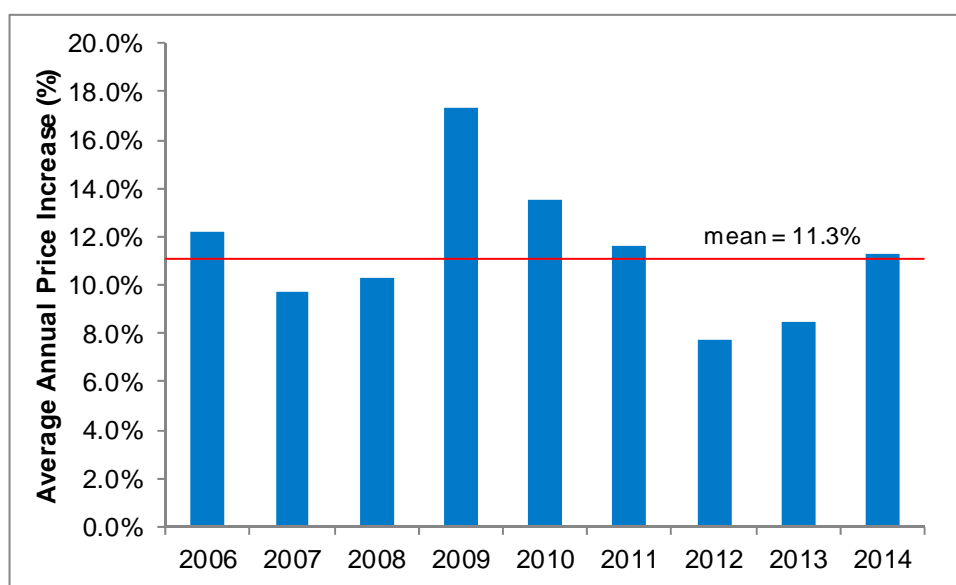
#### Two-Year Price Performance Chart



Sources: FactSet, William Blair & Company estimates

- While we now must wait over a year until top-line data, the large market opportunity 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 about \$126 million. A low-dose contraceptive patch, Ortho Evra, captured about 11% TRx market share when it was labeled at 20 µg ethinyl estradiol/day. In April 2014, Mylan (MYL \$57.22) launched Xulane, a generic equivalent to Evra, priced at \$95.12 that captured 97,404 total prescriptions in December alone (which annualizes to over one million prescriptions), according to IMS Health (IMS \$26.45; Outperform).
- We continue to believe that shares of Agile hold a strong risk/reward profile, given the well-defined efficacy of ethinyl estradiol-levonorgestrel products, the clear pathway for approval of contraception products, the potential market opportunity, and management's significant experience in women's health. Although we are somewhat frustrated in further delaying study completion, maintaining the quality of patients enrolled in the SECURE trial is well worth a one- to two-quarter delay. 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 3 study for Twirla as achievable. We maintain our Outperform rating on Agile Therapeutics, and our price target remains at \$18, due to the refinanced debt schedule that offsets the quarter delay in the clinical program.

**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

## 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 now assume a launch of Twirla in the first half of 2017, after Agile responds to the agency's CRL with data provided from the SECURE Phase 3 trial in the third quarter of 2016. We assume Twirla peak sales will approach \$400 million, which we project as only 4.0% 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	\$ 17.82
Cash Per Share					\$ 2.73
NPV of Future Losses Per Share					\$ (2.87)
NPV Value Per Share					\$ 17.68

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

For per share numbers we use fully diluted share count of 22.1 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 3 trial and expenses needed to bring the product to market.

Our model is included on the following page.

*William Blair*

Agile Therapeutics

Earnings Model

2/24/15

(\$ in millions except EPS data)

Company Rating: Outperform

Company Profile: Aggressive Growth

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	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	-	-	-	-	-	-	-	-	-	73,587	203,592	343,408
Royalty/Milestone Revenue	-	-	-	-	-	-	-	-	-	-	-	-
<b>Total Revenue</b>	-	-	-	-	-	-	-	-	-	73,587.4	203,591.7	343,407.7
yr/yr growth	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	176.7%	68.7%
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>	-	-	-	-	-	-	-	-	-	7,359	20,359	34,341
Gross Profit	-	-	-	-	-	-	-	-	-	66,229	183,233	309,067
<b>SG&amp;A</b>	17,387	9,154	1,053	1,104	1,446	1,470	5,074	4,900	11,575	48,500	50,300	52,000
Growth							-45%	-3%	136%	319%	571%	329%
<b>R&amp;D</b>	5,930	3,574	1,394	2,391	4,603	5,600	13,988	23,200	21,800	15,000	17,000	21,000
Growth		-40%	-	-	-	-	291%	66%	-6%	-31%	13%	24%
<b>Total Operating Expenses</b>	23,317	12,728	2,448	3,495	6,049	7,070	19,061	28,100	33,375	58,875	67,300	73,000
growth			NA	NA	NA	NA	50%	47%	19%	76%	14%	8%
Operating Income	(23,317)	(12,728)	(2,448)	(3,495)	(6,049)	(7,070)	(19,061)	(28,100)	(33,375)	7,354	115,933	236,067
EBIT Margin							NM	NM	NM	NM	57%	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)	(27,100.0)	(32,375.0)	8,354	116,933	237,067
Interest expense	(140)	(1,592)	(378)	(403.5)	(392)	(300)	(1,474)	(1,600)	(1,600)	(1,600)	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)	(29,700)	(34,975)	5,754	123,933	244,067
Income Tax Provision	-	-	(3,652)	-	-	-	(3,652)	1,000	1,000	2,071	44,616	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)	(30,700)	(35,975)	3,682	79,317	156,203
Net loss per share	(845)	(405)	839	(3,718)	(6,353)	(7,370)	(16,602)	(30,700)	(35,975)	3,682	79,317	156,203
Net income to common per share (diluted)			5.62	(0.46)	(0.34)	(0.40)	(1.46)	(1.63)	(1.70)	0.17	3.06	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

**Key Ratios (GAAP unless noted)**

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	20.4%	8.4%	6.1%
SG&A (% Total Rev.)	NM	NM	NM	NM	NM	NM	NM	NM	NM	65.9%	24.7%	15.1%
Operating Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	10.0%	56.9%	68.7%
Net Income Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	5.0%	39.0%	45.5%
<b>Revenue Growth</b>												
Growth Yr/Yr	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	177%	69%
Growth Q/Q	NM		NM	NM	NM	NM						
<b>SG&amp;A Growth</b>												
Growth Yr/Yr	NM	-47%	NM	NM	NM	NM	-45%	-3%	136%	319%	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%	66%	-6%	-31%	13%	24%
Growth Q/Q	NM		NM	NM	NM	NM						

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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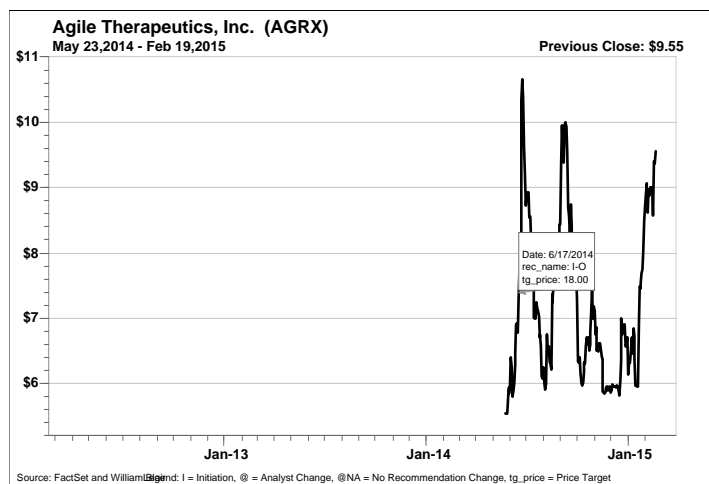
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DOW JONES: 18,116.84

S&P 500: 2,109.66

NASDAQ: 4,960.97



### **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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