

## Agile Therapeutics, Inc.

### First Patients Dosed in Twirla Pivotal Phase III in Line with Guidance, Readout Expected in First Half 2016

- Before the markets opened on Monday, September 29, Agile Therapeutics announced the dosing of the first patients in its pivotal Phase III study of lead product Twirla, a once-weekly transdermal contraceptive patch. The trial, also 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 up to 70 sites in the United States for up to one year. After the update Monday, the company remains on track with previous guidance to enroll patients within the next four to six months and to complete the SECURE study by the first quarter of 2016. Exhibit 1, on page 2, shows the upcoming development milestones for the company within the next two years.
- 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. 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 new management team members, 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).
- 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 (36% of on-drug pregnancies reported at four of 96 sites, representing 15% of the randomized subject population), 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 the FDA has given the company a relatively achievable path to approval and we believe 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.

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September 29, 2014

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

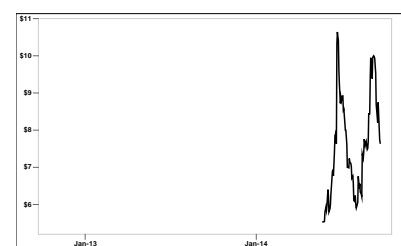
Symbol: AGRX (NASDAQ)  
Price: \$7.41 (52-Wk.: \$5-\$13)  
Market Value (mil.): \$150  
Fiscal Year End: December  
Long-Term EPS Growth Rate:  
Dividend/Yield: None

	2013A	2014E	2015E
<b>Estimates</b>			
EPS FY		\$-1.35	\$-1.32
CY		\$-1.35	\$-1.32
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.)	9
Float (mil.)	2
Average Daily Volume	148,828

<b>Financial Data (FactSet)</b>	
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

- Agile continues to work with manufacturing partner Corium (CORI \$6.34) on the scale-up of Twirla and expects to complete validation and expansion by the end of 2016. Regarding the company's IP, Agile has seven issued patents on its proprietary Skinfusion technology to list in the Orange Book upon approval with five patents expiring in 2021 and two patents expiring in 2028. Lastly, in collaboration with its third-party CRO Parexel (PRXL \$62.95; Outperform), Agile selected PHT Corporation to provide e-diaries (LogPad System) for the trial that both the FDA and investigators are familiar with. We believe that collecting daily-use data during the Phase III trial will be critical since it was an issue during 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.
- 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 current Phase III study for Twirla as achievable. As of the end of the second quarter, the company reported cash and cash equivalents of roughly \$53.5 million, which it believes is sufficient to fund operations through the first quarter of 2016 (with about \$31 million needed to conduct the Phase III trial). We therefore maintain our Outperform rating on Agile Therapeutics and our \$18 price target.

**Exhibit 1**  
**Agile Therapeutics**  
**Twirla Development Milestones**

Time	Event
3Q 2014	Study initiation, investigator's meetings, subject screening, patient enrollment
1Q 2015	Expected completion of patient enrollment
1Q 2016	Expected last patient, last visit
2Q 2016	Potential submission of Complete Response Letter response
4Q 2016	Qualification of commercial manufacturing line (expected completion of validation)

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

# William Blair & Company, L.L.C.

(\$ in millions except EPS data)

	2012(A)	2013(A)	Q1(A)	Q2(A)	Q3(E)	Q4(E)	2014(E)	2015(E)	2016(E)	2017(E)	2018(E)	2019(E)
Product Revenue												
Twirla	-	-	-	-	-	-	-	-	26,982	130,004	228,121	343,408
Royalty/Milestone Revenue	-	-	-	-	-	-	-	-	-	-	-	-
<b>Total Revenue</b>	-	-	-	-	-	-	-	-	26,982	130,004.3	228,120.8	343,407.7
yr/yr growth	NA	NA	NA	NA	NA	NA	NA	NA	NA	381.8%	75.5%	50.5%
q/q growth	NA	NA	NA	NA	NA	NA	NA	NA	NA			
incremental rev q/q												
<b>Cost of Goods Sold</b>	-	-	-	-	-	-	-	-	2,698	13,000	22,812	34,341
<i>Gross Profit</i>	-	-	-	-	-	-	-	-	24,284	117,004	205,309	309,067
<b>SG&amp;A</b>	17,387	9,154	1,053	1,104	1,470	1,470	4,900	6,500	39,000	48,500	50,300	52,000
<i>Growth</i>							-46%	33%	40%	20%	10%	15%
<b>R&amp;D</b>	5,930	3,574	1,394	2,391	6,600	6,600	22,000	12,500	7,800	21,000	39,000	48,000
<i>Growth</i>		-40%	-	-	-	-	516%	-43%	-38%	15%	10%	15%
<b>Total Operating Expenses</b>	23,317	12,728	2,447	3,495	8,070	8,070	22,082	19,000	46,800	69,500	89,300	100,000
<i>growth</i>			NA	NA	NA	NA	73%	-14%	146%	49%	28%	12%
Operating Income	(23,317)	(12,728)	(2,447)	(3,495)	(8,070)	(8,070)	(22,082)	(19,000)	(22,516)	47,504	116,009	209,067
EBIT Margin							NM	NM	NM	NM	51%	61%
growth y/y (%)			NA	NA	NA	NA	NM	NM	NM	NM	NM	NM
Depreciation and Amortization	-		250	250	250	250	1,000	1,000	1,000	1,000	1,000	1,000
EBITDA	(23,317)	(12,728)	(2,197)	(3,245)	(7,820)	(7,820)	(21,081.8)	(18,000.0)	(21,516.2)	48,504	117,009	210,067
Interest expense	(140)	(1,592)	(366)	-403.5	750.0	750.0	3,000	2,000	1,500	1,500	8,000	8,000
Interest income	26	-		0.1								
Change in fair value of warrants	171.0	-		179.7								
Other	-											
Income Before Taxes	(23,260)	(14,320)	(2,813)	(3,718)	(7,320)	(7,320)	(21,171)	(17,000)	(21,016)	49,004	124,009	217,067
Income Tax Provision	-	-	(3,652)	-	225	225	(3,202)	1,000	1,000	17,641	44,643	78,144
Effective Tax Rate	0.0%	0.0%	NA	5.0%	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)	(7,545)	(7,545)	(17,969)	(18,000)	(22,016)	31,363	79,366	138,923
Net income to common (basic)	(845)	(405)	839	(3,718)	(7,545)	(7,545)	(17,969)	(18,000)	(22,016)	31,363	79,366	138,923
Net loss per share (diluted)	(845)	(405)	839	(3,718)	(7,545)	(7,545)	(17,969)	(18,000)	(22,016)	31,363	79,366	138,923
Net income to common per share (diluted)			0.02	(0.28)	(0.57)	(0.56)	(1.35)	(1.32)	(1.57)	2.17	4.21	7.16
Basic avg. number of shares used in computing net income	28	35	75,953	13,197	13,297	13,397	13,297	13,647	14,047	14,447	18,547	18,547
Diluted avg. number of shares used in computing net income	28	35	587,270	13,197	13,297	13,397	13,297	13,647	14,047	14,447	18,847	19,391
<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	16.2%	17.1%	14.0%
SG&A (% Total Rev.)	NM	NM	NM	NM	NM	NM	NM	NM	NM	37.3%	22.0%	15.1%
Operating Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	36.5%	50.9%	60.9%
Net Income Margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	24.1%	34.8%	40.5%
<b>Revenue Growth</b>												
Growth Yr/Yr	NM	#DIV/0!	NM	NM	NM	NM	NM	NM	NM	382%	75%	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%	500%	24%	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	516%	-43%	-38%	169%	86%	23%
Growth Q/Q	NM		NM	NM	NM	NM						

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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.

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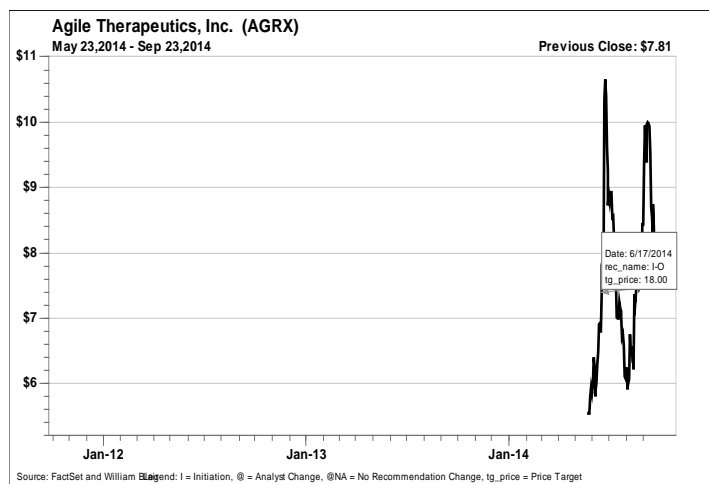
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DOW JONES: 17,113.15

S&P 500: 1,982.85

NASDAQ: 4,512.20



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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

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