

## Agile Therapeutics, Inc.

### Second-Quarter Results a Non-event as Company Prepares to Begin Pivotal Phase III Trial

- After the close on Thursday, August 14, Agile Therapeutics announced second-quarter results. We view these financial results as a relative non-event, in relation to the company's pivotal Phase III trial for its lead product, Twirla, a contraceptive patch. The pivotal trial for Twirla is on track to begin enrollment in the third quarter, with study completion expected in the first quarter of 2016. During the second quarter of 2014, Agile continued to work with manufacturing partner Corium (CORI \$5.95) on the scale-up of Twirla and expects to complete validation and expansion by the end of 2016. Lastly, in collaboration with its third-party CRO Parexel (PRXL \$57.67; Outperform), Agile selected PHT Corporation to provide e-diaries for the trial. We view this update as important, because collecting daily use data during the Phase III will be critical and was an issue during the first pivotal trial. 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.
- Regarding second-quarter financials, the company reported a pro forma net loss of \$3.718 million, or \$0.28 per share, lower than our estimate of a loss of \$6.274 million or \$0.31 per share, as well as consensus of a loss of \$6.2 million or \$0.37 per share. R&D and G&A expenses were \$2.39 million and \$1.1 million, respectively, lower than our estimates of \$5.5 million and \$1.225 million and consensus of \$4.8 million and \$1.5 million. The company believes that its current cash and cash equivalents of \$53.5 million are sufficient to fund operations through the first quarter of 2016.
- In the second quarter, in addition to the company's IPO, Agile Therapeutics also 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 Twirla. As the patent coverage around Twirla continues to solidify, we anticipate Agile management to enroll the first patients for the company's pivotal Phase III trial for the product in the near term. Pending an 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.
- 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 trial design, execution, and conduct. 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 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

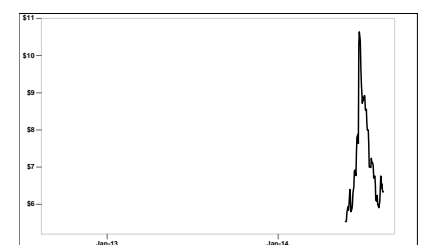
Symbol: AGRX (NASDAQ)  
Price: \$6.22 (52-Wk.: \$5-\$13)  
Market Value (mil.): \$117  
Fiscal Year End: December  
Long-Term EPS Growth Rate:  
Dividend/Yield: None

	2013A	2014E	2015E
<b>Estimates</b>			
EPS Q1	NA	A\$0.02	NA
Q2	NA	A\$-0.28	NA
Q3	NA	\$-0.57	NA
Q4	NA	\$-0.56	NA
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.)	6
Average Daily Volume	200,421

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

#### Two-Year Price Performance Chart



Sources: FactSet, William Blair & Company estimates

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- 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. In addition to a thorough screening visit, each participant will have a two-week run-in period to get accustomed to the device, and the company is anticipating a four- to six-month enrollment period to ensure patients are appropriately vetted and compliant throughout the trial period. 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.
- We continue to believe 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. After the update today, the company remains on track with previous guidance to complete the Phase III study by the first quarter of 2016. We therefore maintain our Outperform rating on shares of Agile Therapeutics and maintain our \$18 price target.

**Exhibit 1**  
**Agile Therapeutics, Inc.**  
**Second Quarter Results and Estimates**

	AGRX Q2 14A	WB Q2 14E	Consensus Q2 14E	Y/Y Growth
(\$ in thousands except EPS)				
<b>Total Revenue</b>	\$ -	\$ -	\$ -	NA
R&D	\$ 2,390.9	\$ 5,500.0	\$ 4,800.0	-1%
G&A	\$ 1,103.9	\$ 1,225.0	\$ 1,500.0	34%
Operating Income (loss)	\$ (3,494.7)	\$ (6,725.0)	\$ (6,200.0)	-8%
Net Income	\$ (3,718.4)	\$ (6,274.0)	\$ (6,200.0)	-3%
<b>EPS</b>	\$ (0.46)	\$ (0.31)	\$ (0.37)	NM
<b>Pro Forma EPS</b>	\$ (0.28)	\$ (0.31)	\$ (0.37)	NM

Source: Company reports, William Blair & Company L.L.C. estimates  
Consensus estimates reported by FactSet

## 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*

Agile Therapeutics

Earnings Model

8/14/14

(\$ in millions except EPS data)

Company Profile: Aggressive Growth

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	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
Gross Profit	-	-	-	-	-	-	-	-	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
Growth							-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
Growth		-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
growth			NA	NA	NA	NA	73%	-14%	146%	49%		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
							NM	NM	NM	NM	51%	61%
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 conversion 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						

William Blair & Company, L.L.C.

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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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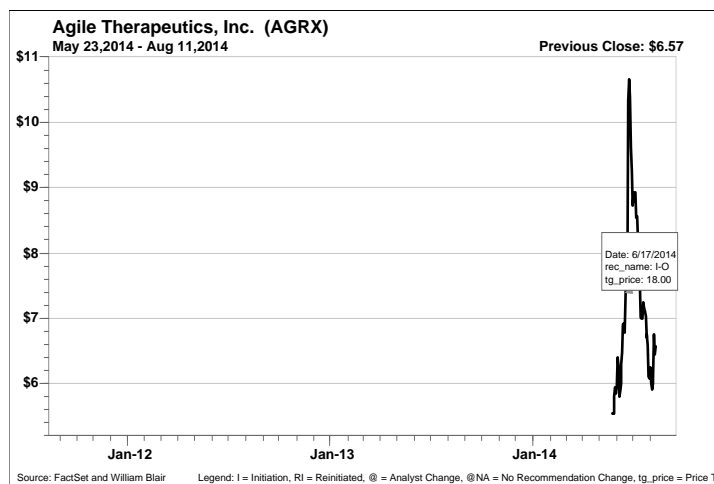
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DOW JONES: 16,713.58

S&P 500: 1,955.18

NASDAQ: 4,453.00



### **Current Rating Distribution (as of 07/31/14)**

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

\*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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