

May 13, 2015

Agile Therapeutics, Inc.

First-Quarter Earnings; Twirla Phase III Trial Enrollment on Track for Completion by Third Quarter

- After the close Tuesday, May 12, Agile Therapeutics reported first-quarter earnings and more importantly provided an update on the ongoing pivotal trial for Twirla, the company's lead product for contraception. The company continues to guide to enrollment completion of its pivotal Phase III trial for Twirla in the third quarter of 2015. We continue to believe in management's ability to run a positive clinical trial, which should be completed in the third quarter of 2016 (roughly one year after enrollment of the last patient) and continue to view shares of Agile as attractive for those who can wait until the Phase III results in 2016.
- In the quarter, management focused on gaining financial flexibility to fund operations through 2016. In February, Agile Therapeutics announced that it had secured a debt facility from Hercules Technology Growth Capital (HTGC \$12.93) 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 was used for working capital. Agile also has an additional tranche of \$8.5 million based on meeting clinical milestones (although the company is not obligated to take it). This debt facility adds to the company's financial flexibility gained in January after Agile completed a private placement that resulted in net proceeds of approximately \$19.3 million, which included several high quality healthcare specialist investors.
- Agile has previously run a Phase III trial under a former management team and using a small contract research organization; the trial 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 any contraceptive products that have been approved; Pearl Index scores normally approximate 2.0 in the more recent studies. In March, the company published safety and tolerability data in *The American Journal of Obstetrics & Gynecology*. Treatment-emergent adverse events with Twirla were nasopharyngitis (5.2%), nausea (4.1%), upper respiratory infection (3.5%), headache (3.4%), sinusitis (2.9%), cervical dysplasia (2.3%), and urinary tract infection (2.1%). The proportion of women who experienced any treatment-emergent adverse event was similar among women randomized to the contraceptive patch (47.5%), the combination oral contraceptive with 20 µg of ethinyl estradiol (47.4%), or the combination oral contraceptive 30 µg of ethinyl estradiol (46.8%).
- Despite the disparity in efficacy in its previous study, we believe that Twirla has been shown to be both safe and tolerable with similar adverse event rates to several types of combination oral contraceptives. We continue to believe that Agile's last Phase III trial, which prompted a Complete Response Letter (CRL) by the agency, was flawed in many ways that should be remedied in the current trial, and that management is focused on executing a high-quality study, which is important in this category of therapies. 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 III study design.

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: \$11.81 (52-Wk.: \$5-\$13)
Market Value (mil.): \$262
Fiscal Year End: December
Long-Term EPS Growth Rate:
Dividend/Yield: None

	2014A	2015E	2016E
Estimates			
EPS Q1	\$0.02	A\$-0.40	NA
Q2	\$-0.28	\$-0.41	NA
Q3	\$-0.34	\$-0.42	NA
Q4	\$-0.37	\$-0.43	NA
FY	\$-1.41	\$-1.66	\$-1.42
CY		\$-1.66	\$-1.42
Sales (mil.)	0	0	0
Valuation			
FY P/E	NM	NM	NM
CY P/E		NM	NM

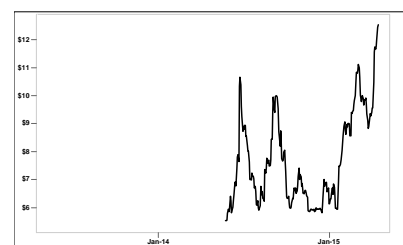
Trading Data (FactSet)

Shares Outstanding (mil.)	19
Float (mil.)	19
Average Daily Volume	67,553

Financial Data (FactSet)

Book Value Per Share (MRQ)	1.9
Return on Equity (TTM)	-95.1

Two-Year Price Performance Chart



Sources: FactSet, William Blair & Company estimates

- For the first quarter, net income was reported as a loss of \$8.5 million, or a loss of \$0.40 per share, less than our estimate of a loss of \$8.3 million, or \$0.40 per share, and consensus of a loss of \$7.6 million, or \$0.34 per share. During the quarter earnings were negatively affected by a one-time noncash expense associated with the debt restructuring, which artificially depressed earnings by approximately \$0.05. R&D spending was reported at \$5.378 million, lower than our estimate of \$6.4 million and consensus of \$5.7 million. SG&A expense of \$1.599 million stayed in line with both our estimate of \$1.5 million and consensus of \$1.6 million. We show reported earnings, our estimates, and consensus estimates in exhibit 1. With \$53.9 million in cash and cash equivalents at the end of the first quarter in addition to capital available to the company through its debt facility, we believe that Agile has the cash necessary to complete the Twirla Phase III study, which should be a significant value-creating event for the company.
- We continue to view Twirla as holding significant value given the large market opportunity that exists in a growing \$4.1 billion U.S. market for combined hormonal contraceptives. As shown in exhibit 2, 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 \$70.33) launched Xulane, a generic equivalent to Evra, priced at \$95.12 that captured 111,954 total prescriptions in March 2015 alone (which annualizes to well over 1 million prescriptions), according to IMS Health (exhibit 3).
- 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. We believe that previous pushbacks in study completion have come to an end and believe that maintaining the quality of patients enrolled in the SECURE trial remains a major focus for the company. 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 price target remains at \$18 given what we believe is a conservative NPV for Twirla, which would likely see upside in an acquisition scenario.

Exhibit 1
Agile Therapeutics, Inc.
First Quarter Results and Estimates

	AGRX Q1 15A	WB Q1 15E	Consensus Q1 15E	Q/Q Growth	Y/Y Growth
(\$ in thousands except EPS)					
Total Revenue	\$ -	\$ -	\$ -	NA	NA
R&D	\$ 5,378.0	\$ 6,400.0	\$ 5,700.0	8%	286%
G&A	\$ 1,599.0	\$ 1,500.0	\$ 1,600.0	3%	52%
Operating Income (loss)	\$ (6,977.0)	\$ (7,900.0)	\$ (7,200.0)	NM	NM
Net Income	\$ (8,538.0)	\$ (8,300.0)	\$ (7,600.0)	NM	NM
EPS	\$ (0.40)	\$ (0.37)	\$ (0.34)	NM	NM

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

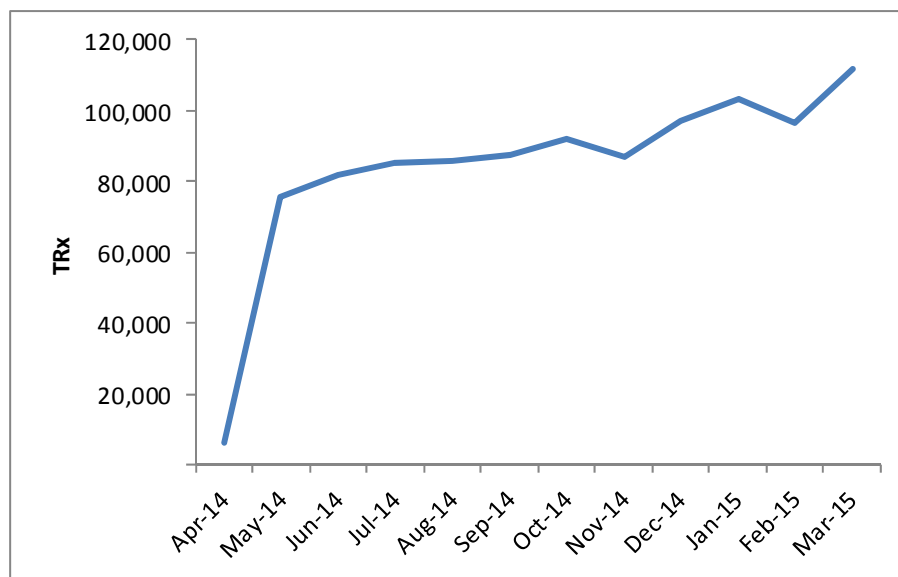
Exhibit 2
Agile Therapeutics, Inc.
Average Annual Price Increase of Contraceptives From 2006-2014*



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

Source: Agile company reports, PriceRx Select

Exhibit 3
Monthly Prescriptions of Xulane Since Launch



Source: IMS Health

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 III 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	\$ 17.85
Cash Per Share					\$ 2.22
NPV of Future Losses Per Share					\$ (2.61)
NPV Value Per Share					\$ 17.46

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 III trial and expenses needed to bring the product to market.

William Blair

Agile Therapeutics

Earnings Model

5/12/15

(\$ in millions except EPS data)

Company Rating: Outperform
Company Profile: Aggressive Growth

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	2012(A)	2013(A)	2014(A)	Q1(A)	Q2(E)	Q3(E)	Q4(E)	2015(E)	2016(E)	2017(E)	2018(E)	2019(E)
Product Revenue								-	-			
Twirla	-	-	-	-	-	-	-	-	-	73,587	203,592	343,408
Royalty/Milestone Revenue	-	-	-	-	-	-	-	-	-	-	-	-
Total Revenue	-	-	-	-	-	-	-	-	-	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		
incremental rev q/q												
Cost of Goods Sold	-	-	-	-	-	-	-	-	-	7,359	20,359	34,341
Gross Profit	-	-	-	-	-	-	-	-	-	66,229	183,233	309,067
SG&A	17,387	9,154	5,151	1,599	1,599	1,599	1,599	6,396	10,725	48,500	50,300	52,000
Growth			-44%					24%	24%	352%	571%	329%
R&D	5,930	3,574	13,365	5,378	6,800	7,000	7,200	26,378	21,350	15,000	17,000	21,000
Growth		-40%	274%	-	-	-	-	97%	-19%	-30%	13%	24%
Total Operating Expenses	23,317	12,728	18,515	6,977	8,399	8,599	8,799	32,774	32,075	58,875	67,300	73,000
growth			45%	185%	140%	42%	35%	77%	-2%	84%	14%	8%
Operating Income	(23,317)	(12,728)	(18,515)	(6,977)	(8,399)	(8,599)	(8,799)	(32,774)	(32,075)	7,354	115,933	236,067
EBIT Margin			NM					NM	NM	NM	57%	69%
growth y/y (%)			NM	185%	140%	42%	35%	NM	NM	NM	NM	NM
Depreciation and Amortization	-	-	1,000	250	250	250	250	1,000	1,000	1,000	1,000	1,000
EBITDA	(23,317)	(12,728)	(17,760.2)	(6,727)	(8,149)	(8,349)	(8,549)	(31,774.0)	(31,075.0)	8,354	116,933	237,067
			NM					NM	NM	NM	57%	69%
Interest expense	(140)	(1,592)	(1,563)	(424)	(400)	(400)	(400)	(1,624)	(1,600)	(1,600)	8,000	8,000
Interest income	26	-	-	-101	-	-	-	-	-	-	-	-
Change in fair value of warrants	171.0	-	348.6	-	-	-	-	-	-	-	-	-
Other	-	-	-	-1036	-	-	-	-	-	-	-	-
Income Before Taxes	(23,260)	(14,320)	(19,730)	(8,538)	(8,799)	(8,999)	(9,199)	(35,535)	(33,675)	5,754	123,933	244,067
Income Tax Provision	-	-	(3,652)	-	-	-	-	-	1,000	2,071	44,616	87,864
Effective Tax Rate	0.0%	0.0%	NM	0.0%	0.0%	0.0%	0.0%	NA	NA	36%	36%	36%
Beneficial conversino charge	(600)	-	-	-	-	-	-	-	-	-	-	-
Net Income (loss) Attributable to Common	(23,860)	(14,320)	(16,077)	(8,538)	(8,799)	(8,999)	(9,199)	(35,535)	(34,675)	3,682	79,317	156,203
Net loss per share	(845)	(405)	(16,077)	(8,538)	(8,799)	(8,999)	(9,199)	(35,535)	(33,675)	3,682	79,317	156,203
Net income to common per share (diluted)			(1.41)	(0.40)	(0.41)	(0.42)	(0.43)	(1.66)	(1.42)	0.15	2.78	5.35
Basic avg. number of shares	28	35	11,394	21,283	21,383	21,483	21,583	21,433	21,833	22,233	28,241	28,341

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DOW JONES: 18,068.23

S&P 500: 2,099.12

NASDAQ: 4,976.19



Current Rating Distribution (as of 04/30/15)

Coverage Universe	Percent	Inv. Banking Relationships*	Percent
Outperform (Buy)	65	Outperform (Buy)	14
Market Perform (Hold)	32	Market Perform (Hold)	2
Underperform (Sell)	2	Underperform (Sell)	0

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