

Equity Research

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Agile Therapeutics, Inc. (AGRX-\$11.81)

Rating: BUY

Target Price: \$20.00

No Financing Overhang; Twirla Data Expected in 3Q:16; Maintain BUY and \$20 PT

<u>REV</u>	<u>1Q</u>	<u>2Q</u>	<u>3Q</u>	<u>4Q</u>
2014A	0.0A	0.0A	0.0A	0.0A
2015E	0.0A	0.0E	0.0E	0.0E
2016E	—	—	—	—
<u>EPS</u>	<u>1Q</u>	<u>2Q</u>	<u>3Q</u>	<u>4Q</u>
2014A	0.09A	(0.46)A	(0.34)A	(0.37)A
2015E	(0.40)A	(0.36)E	(0.37)E	(0.38)E
Prev	(0.33)E	(0.35)E	—	(0.36)E
2016E	—	—	—	—
<u>FY</u>	<u>2014A</u>	<u>2015E</u>	<u>2016E</u>	
REV	0.0A	0.0E	0.0E	
EPS	(1.41)A	(1.51)E	(1.06)E	
Prev	—	(1.42)E	(1.04)E	

- **Investment summary:** Agile's contraceptive patch trial remains on track to report data in 3Q:16 and the company has sufficient cash to fund operations through 2016. We continue to view Agile as an attractive takeout candidate next year. Agile recorded a 1Q:15 loss per share of (\$0.40) versus FactSet consensus estimates of (\$0.34) and our estimate of (\$0.33). We attribute the miss to a \$1.0M loss on debt extinguishment that was taken as a result of recent favorable debt refinancing (management estimates that this had a (\$0.05) impact on earnings). Management indicated that its Phase III program of the Twirla contraceptive patch remains on track to complete enrollment in 3Q:15 and report data in 3Q:16, a year later. We reiterate our BUY rating and \$20 PT on AGRX which is based on DCF valuation.
- **Management could announce its second pipeline candidate this summer:** The company is deciding between two pipeline contraceptive patch programs to advance forward. AG200-ER is a patch that allows a woman to extend the length of her cycle (or to have fewer periods) while AG200-SP is a different patch designed to provide shorter, lighter periods. Management indicated that AG200-ER would be simpler to develop but represent a smaller market opportunity, while AG200-SP is more commercially attractive but also more technically complex. Management indicated that it does not expect to finance the advancement of its pipeline this year but would need to do so at a later point.
- **Cash update:** The company has \$53.9M in cash on its balance sheet and access to another \$8.5M in debt that could be drawn from Hercules to fund operations beyond 2016. We would expect additional financing in 2016 to allow for Twirla pre-launch activities as well as pipeline advancement.

Current Statistics

Market Cap (\$Mil)	\$262.2	Free Float (%):	18.600
Avg. Daily Trading Volume (3 mo.):	79,853		
Shares Out (Mil):	22.203		

EARNINGS SUMMARY:

We summarize 1Q:15 earnings in Exhibit 1 below.

Exhibit 1: Agile 1Q:15 Earnings

	1Q:15E	1Q:15A	% Variance	Q/Q Growth	Y/Y Growth	Comments
Revenues	0.0	0.0	NM	NM	NM	
Total Revenues	0.0	0.0	NM	NM	NM	FactSet Consensus \$0.00
COGS	0.0	0.0	NM	NM	NM	
Gross Profit	0.0	0.0	NM	NM	NM	
SG&A	1.6	1.6	-0.1%	3.3%	51.8%	
R&D	5.3	5.4	1.5%	8.1%	285.8%	
EBIT	-6.9	-7.0	NM	NM	NM	
Interest and Other Income	-0.4	-1.6	NM	NM	NM	\$1M loss on debt extinguishment
Pre-tax income	-7.3	-8.5	NM	NM	NM	
Income tax expense	0.0	0.0	NM	NM	NM	
Net Income	-7.3	-8.5	NM	NM	NM	
Diluted shares	22.2	21.3	-4.1%	14.2%	119.4%	
Operating EPS	(\$0.33)	(\$0.40)	NM	NM	NM	FactSet Consensus (\$0.34)

Source: Company reports, Cantor Fitzgerald estimates, and FactSet consensus

Valuation

We value Agile Therapeutics via discounted cash flow analysis (DCF) to attain our \$20 price target. We employ a weighted average cost of capital of 13% to account for the clinical risk in the program along with a 1% terminal growth rate.

Risks

- (1) Clinical risk in the conduct of the pivotal Phase III trial of Twirla and obtaining a Pearl Index that is acceptable to FDA for approval. We have risk-adjusted the probability of a positive outcome by 60%.
- (2) The Affordable Care Act may steer patients to generic forms of Ortho Evra rather than the Twirla patch.
- (3) The Twirla commercial ramp may be slower than expected.
- (4) Life-cycle extension programs carry clinical risk.

Exhibit 2: Agile Income Statement (dollars in millions)

	2012	2013	2014	1Q:15A	2Q:15E	3Q:15E	4Q:15E	2015E	2016E	2017E	2018E	2019E	2020E	2021E
Revenues:														
Revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	35.4	111.7	195.7	246.8	285.4
Total revenues	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	35.4	111.7	195.7	246.8	285.4
Operating expenses:														
COGS	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.5	7.9	14.1	18.4	22.1
Gross Profit	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	33.0	103.8	181.7	228.4	263.3
R&D	17.4	9.2	13.4	5.4	5.7	6.0	6.1	23.2	16.2	17.0	17.9	18.8	19.7	20.7
SG&A	5.9	3.6	5.2	1.6	1.7	1.8	1.9	6.9	10.0	55.0	68.8	79.1	87.0	95.7
Total operating expenses	23.3	12.7	18.5	7.0	7.4	7.8	8.0	30.1	26.2	72.0	86.6	97.8	106.7	116.4
Operating income (Loss)	(23.3)	(12.7)	(18.5)	(7.0)	(7.4)	(7.8)	(8.0)	(30.1)	(26.2)	(39.1)	17.2	83.8	121.7	146.9
Interest income	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.1	0.2	0.4	0.0
Interest expense	(0.1)	(1.5)	(1.6)	(0.4)	(0.6)	(0.6)	(0.6)	(2.1)	(1.3)	(1.3)	(0.3)	(0.3)	(0.3)	0.0
Change in fair value of warrant liability	0.2	(0.1)	0.3	(0.1)	0.0	0.0	0.0	(0.1)	0.0	0.0	0.0	0.0	0.0	1.0
Loss on extinguishment of debt	0.0	0.0	0.0	(1.0)	0.0	0.0	0.0	(1.0)	0.0	0.0	0.0	0.0	0.0	0.0
Other income (expense), net	0.1	(1.6)	(1.2)	(1.6)	(0.5)	(0.5)	(0.5)	(3.2)	(1.3)	(1.2)	(0.2)	(0.1)	0.1	1.0
Pretax Income	(23.3)	(14.3)	(19.7)	(8.5)	(7.9)	(8.3)	(8.5)	(33.3)	(27.5)	(40.2)	17.0	83.7	121.8	147.9
Tax Rate	NA	NA	NA	NA	NA	NA	NA	NA	0%	0%	39%	39%	39%	39%
Tax expense	0.0	0.0	(3.7)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	6.6	32.6	47.5	57.7
Beneficial conversion charge	(0.6)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net income	(23.9)	(14.3)	(16.1)	(8.5)	(7.9)	(8.3)	(8.5)	(33.3)	(27.5)	(40.2)	10.4	51.1	74.3	90.2
Weighted average common shares (diluted)	39.5	49.5	11.4	21.3	22.2	22.3	22.4	22.1	26.1	27.4	28.7	30.2	31.7	33.3
Diluted EPS	(\$0.60)	(\$0.29)	(\$1.41)	(\$0.40)	(\$0.36)	(\$0.37)	(\$0.38)	(\$1.51)	(\$1.06)	(\$1.47)	\$0.36	\$1.69	\$2.35	\$2.71
<div> <div>Consensus Revenue</div> <div>Consensus EPS</div> <div>\$0.0</div> <div>(\$0.37)</div> <div>\$0.0</div> <div>(\$0.38)</div> <div>\$0.0</div> <div>(\$0.37)</div> <div>\$0.0</div> <div>(\$1.50)</div> <div>\$0.0</div> <div>(\$1.24)</div> </div>														
Margin Analysis	2012	2013	2014	1Q:15A	2Q:15E	3Q:15E	4Q:15E	2015E	2016E	2017E	2018E	2019E	2020E	2021E
Gross Margin	-	-	-	-	-	-	-	-	-	93.1%	93.0%	92.8%	92.5%	92.3%
COGS	-	-	-	-	-	-	-	-	-	6.9%	7.0%	7.2%	7.5%	7.7%
SG&A	-	-	-	-	-	-	-	-	-	155.2%	61.5%	40.4%	35.2%	33.5%
R&D	-	-	-	-	-	-	-	-	-	48.1%	16.0%	9.6%	8.0%	7.3%
Operating Margin	-	-	-	-	-	-	-	-	-	-110.2%	15.4%	42.8%	49.3%	51.5%
Net Income Margin	-	-	-	-	-	-	-	-	-	-113.6%	9.3%	26.1%	30.1%	31.6%
Growth (Y/Y)	2012	2013	2014	1Q:15A	2Q:15E	3Q:15E	4Q:15E	2015E	2016E	2017E	2018E	2019E	2020E	2021E
Net Sales	-	-	-	-	-	-	-	-	-	-	215%	75%	26%	16%
SG&A	-	-40%	44%	52%	54%	24%	20%	35%	44%	450%	25%	15%	10%	10%
R&D	-	-47%	46%	286%	138%	30%	23%	73%	-30%	5%	5%	5%	5%	5%
EBIT	-	-45%	-	-	-	-	-	-	-	-	-	387%	45%	21%
Interest income (expense)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Tax	-	-	-	-	-	-	-	-	-	-	-	391%	46%	21%
Net Income	-	-	-	-1132%	-	-	-	-	-	-	-	391%	46%	21%
Diluted EPS	-	-	-	-571%	-	-	-	-	-	-	-	368%	39%	16%

Source: Company reports, Cantor Fitzgerald estimates, and FactSet Consensus

Exhibit 3: Agile Sales Estimates (dollars in millions)

Products	2012	2013	2014E	1Q:15A	2Q:15E	3Q:15E	4Q:15E	2015E	2016E	2017E	2018E	2019E	2020E	2021E
Twirla														
Sales	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	59.1	186.2	326.2	411.4	475.6
Growth											215%	75%	26%	16%
Risk Adjustment = 60%	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%	60%
Risk-Adjusted Twirla Sales	0.0	0.0	0.0					0.0	0.0	35.4	111.7	195.7	246.8	285.4
Pipeline														
AG200-ER														
Sales	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
AG200-SP														
Sales	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
AG890														
Sales	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total Agile Revenues	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	35.4	111.7	195.7	246.8	285.4
Growth											215%	75%	26%	16%
COGS														
Product Sales	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	35.4	111.7	195.7	246.8	285.4
COGS Estimate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	6.9%	7.0%	7.2%	7.5%	7.7%
Total COGS	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	2.5	7.9	14.1	18.4	22.1

Source: Company reports, and Cantor Fitzgerald estimates

Company Description

Agile is a development-stage specialty pharmaceutical company focused on the women's contraceptive market. The company's lead pipeline product is Twirla, a low-dose, estrogen contraceptive patch that is expected to launch in 2017.

Disclosures Appendix

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Rating	Cantor		IB Serv./Past 12 Mos.	
	Count	Percent	Count	Percent
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HOLD [H]	52	33.55	8	15.38
SELL [S]	7	4.52	1	14.29