

Equity Research

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Agile Therapeutics, Inc. (AGRX-\$6.90)

Rating: BUY

Target Price: \$17.00

\$20M Private Placement Provides Working Capital Runway; Reiterate BUY and \$17 PT

<u>REV</u>	<u>1Q</u>	<u>2Q</u>	<u>3Q</u>	<u>4Q</u>
2013A	—	—	—	—
2014E	0.0A	0.0A	0.0A	0.0E
2015E	—	—	—	—
<u>EPS</u>	<u>1Q</u>	<u>2Q</u>	<u>3Q</u>	<u>4Q</u>
2013A	—	—	—	—
2014E	0.09A	(0.46)A	(0.34)A	(0.40)E
2015E	—	—	—	—
<u>FY</u>	<u>2013A</u>	<u>2014E</u>	<u>2015E</u>	
REV	0.0A	0.0E	0.0E	
EPS	(0.29)A	(0.89)E	(1.62)E	
Prev	—	—	(1.51)E	

- **Agile strengthens its balance sheet:** The company announced a private placement of 3.4 million shares priced at \$5.85/share to yield expected gross proceeds of \$20 million. The shares cannot be resold without an effective registration statement and management indicated that there were no warrants or discounts to entice participating investors. We have updated our model to include the additional share count. (We were previously modeling an additional 5 million shares in 2015, so our loss estimates actually worsened due to the lower-than-expected share dilution.) We now model 2015 net loss of (\$1.62) per share versus (\$1.46) FactSet consensus. We reiterate our BUY rating and \$17 PT.
- **Uses of cash:** Management indicated that the additional cash will fund working capital rather than to advance its other birth control patch pipeline assets. Management confirmed that without this financing it would have still had sufficient cash through the unblinding of the existing Phase III Twirla trial in 2016. Management stated that it would first need to meet with FDA to discuss next steps in its pipeline development program (announcement expected mid-year) and could contemplate another financing to fund the next compound at that time. We are currently not modeling any additional share dilution in 2015.
- **Encouraging updates from the Twirla Phase III trial:** Management noted that while it is still early, it is enrolling a good mix of the "right" patients in its contraceptive patch trial, its 74 experienced sites are performing well, and its contract research organization (Parexel) is executing consistently. There have been no pregnancies or patients lost to follow-up as expected at this stage. Management expects to complete enrollment by April, and with a 12-month follow-up period, we would expect this trial to complete by mid-2016, with data in Summer 2016 and potential approval in early 2017 after a 6-month review clock. Consensus currently models revenues in 2016, but we think that this is overly aggressive at this time. We like that management can monitor enrollment in real time and analyze the baseline characteristics of trial patients, which allows it to anticipate treatment compliance (based on historical data in the space). This should minimize any unexpected trial conduct issues or data collection problems, in our view.

Current Statistics

Market Cap (\$Mil)	\$128.3	Free Float (%):	18.600
Avg. Daily Trading Volume (3 mo.):	23,306		
Shares Out (Mil):	18.593		

Valuation

We value Agile Therapeutics via discounted cash flow analysis (DCF) to attain our \$17 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.
- (5) The company may need to raise additional funds in mid-2015 to finance its pipeline program.

Exhibit 1: Agile Income Statement (dollars in millions)

	2012	2013	1Q:14A	2Q:14A	3Q:14A	4Q:14E	2014E	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	1.4	2.4	4.6	5.5	13.9	25.0	26.3	27.6	28.9	30.4	31.9	33.5
SG&A	5.9	3.6	1.1	1.1	1.4	1.5	5.1	10.0	15.0	55.0	68.8	79.1	87.0	95.7
Other	0.0	0.0	0.4	0.0	0.0	0.0	0.4	0.0	0.0	0.0	0.0	0.0	0.0	1.0
Total operating expenses	23.3	12.7	2.81	3.5	6.0	7.0	19.4	35.0	41.3	82.6	97.7	109.5	118.9	130.2
Operating income (Loss)	(23.3)	(12.7)	(2.8)	(3.5)	(6.0)	(7.0)	(19.4)	(35.0)	(41.3)	(49.6)	6.2	72.2	109.6	133.1
Interest income	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.4	0.6	0.8	0.2	0.3	1.0	0.0
Interest expense	(0.1)	(1.5)	0.0	(0.4)	(0.4)	(0.4)	(1.2)	(1.1)	(0.7)	(0.7)	(0.2)	(0.2)	(0.2)	0.0
Change in fair value of warrant liability	0.2	(0.1)	0.0	0.2	0.1	0.0	0.3	0.0	0.0	0.0	0.0	0.0	0.0	1.0
Other income (expense), net	0.1	(1.6)	0.0	(0.2)	(0.3)	(0.4)	(0.9)	(0.7)	(0.1)	0.1	(0.0)	0.1	0.8	1.0
Pretax Income	(23.3)	(14.3)	(2.8)	(3.7)	(6.4)	(7.4)	(20.3)	(35.7)	(41.3)	(49.5)	6.1	72.3	110.3	134.1
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	(3.7)	0.0	0.0	0.0	2.4	28.2	43.0	52.3
Beneficial conversion charge	(0.6)	0.0	0.0	0.0										
Net income	(23.9)	(14.3)	0.8	(3.7)	(6.4)	(7.4)	(16.6)	(35.7)	(41.3)	(49.5)	3.7	44.1	67.3	81.8
Weighted average common shares (diluted)	39.5	49.5	9.7	8.0	18.6	18.6	18.6	22.0	26.0	27.3	28.7	30.1	31.6	33.2
Diluted EPS	(\$0.60)	(\$0.29)	\$0.09	(\$0.46)	(\$0.34)	(\$0.40)	(\$0.89)	(\$1.62)	(\$1.59)	(\$1.81)	\$0.13	\$1.47	\$2.13	\$2.47
Consensus Revenue							\$0.0	\$0.0	\$0.0	\$12.3				
Consensus EPS							(\$0.43)	(\$1.18)	(\$1.46)	(\$1.47)				
Margin Analysis	2012	2013	1Q:14A	2Q:14A	3Q:14A	4Q:14E	2014E	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	-	-	-	-	-	-	-	-	-	77.8%	25.9%	15.5%	12.9%	11.7%
Operating Margin	-	-	-	-	-	-	-	-	-	-139.9%	5.5%	36.9%	44.4%	46.7%
Net Income Margin	-	-	-	-	-	-	-	-	-	-139.7%	3.3%	22.5%	27.3%	28.7%
Growth (Y/Y)	2012	2013	1Q:14A	2Q:14A	3Q:14A	4Q:14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E
Net Sales	-	-	-	-	-	-	-	-	-	-	215%	75%	26%	16%
SG&A	-	-40%	-	-	-	-	43%	96%	50%	267%	25%	15%	10%	10%
R&D	-	-47%	-	-	-	-	52%	80%	5%	5%	5%	5%	5%	5%
EBIT	-	-45%	-	-	-	-	-	-	-	-	-	1072%	52%	22%
Interest income (expense)	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Tax	-	-	-	-	-	-	-	-	-	-	-	1079%	53%	22%
Net Income	-	-	-	-	-	-	-	-	-	-	-	1079%	53%	22%
Diluted EPS	-	-	-	-	-	-	-	-	-	-	-	1023%	45%	16%

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

Exhibit 2: Agile Sales Estimates (dollars in millions)

Products	2012	2013	1Q:14E	2Q:14A	3Q:14A	4Q:14E	2014E	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	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%

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.

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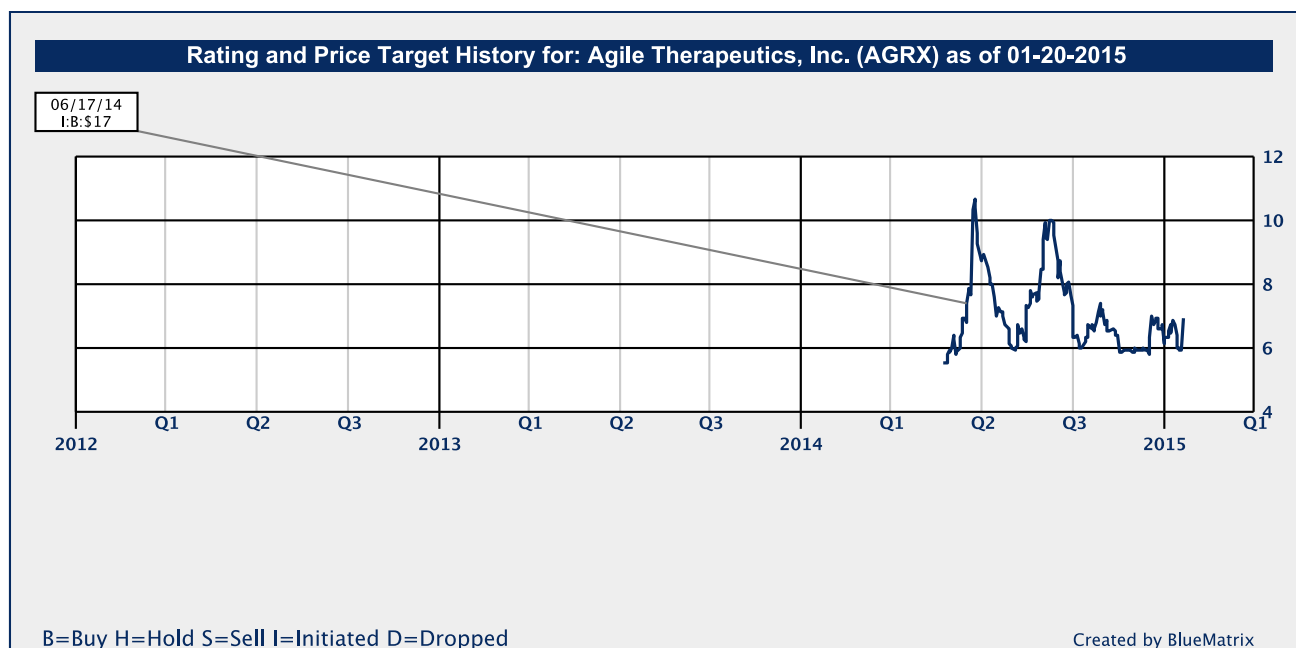
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			Count	Percent
BUY [B]	92	61.33	23	25.00
HOLD [H]	49	32.67	10	20.41
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