

Equity Research

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Agile Therapeutics, Inc. (AGRX-\$6.42)

Rating: BUY

Target Price: \$17.00

Earnings Beat on Conservative Spending; Twirla Enrollment on Track; Maintain BUY

<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
<i>Prev</i>	—	—	(0.37)E	(0.50)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	(1.51)E	
<i>Prev</i>	—	(1.02)E	—	

- **Conservative spending drove the earnings beat in 3Q:14:** Agile generated no revenue in the quarter and recorded a loss per share of (\$0.34) versus FactSet consensus estimates of (\$0.50) and our estimate of (\$0.37). This beat came as operating expenses were much lower than the Street anticipated. We like the conservative spend by management coupled with timely enrollment metrics in the pivotal Phase III program. Management indicated that SG&A spend should remain steady, though R&D will continue to climb in 4Q:14 and again in 1Q:15 as the bulk of the Twirla Phase III trial enrollment progresses. We have updated our forecasts to reflect this guidance and now model 2014 loss per share of (\$0.89) (previously a loss per share of \$1.02). We reiterate our BUY rating and \$17 PT, which are based on DCF analysis.
- **Twirla trial enrollment remains on track:** The company confirmed it is on schedule, with dosing of the initial Twirla contraceptive patch patients in the third quarter. Management has 50 clinical sites screening patients and is monitoring all elements of the study via an electronic dashboard on a daily basis (which allows for tighter oversight of a typical contraceptive user population relative to the first trial). The company plans to continue scaling to 70 clinical sites, but stated that the core sites are currently up and running, and the remaining additions will be mostly academic centers and KOLs. We expect Agile to submit a response to its CRL in 1H:16 followed by a 6-month FDA review and approval by year-end. We model launch in early 2017.
- **Marketing takeaways:** We went marketing with management in early October. Two new takeaways were that (1) Management feels very confident about its barriers to potential generic entrants and believes that it is the only company that is able to get levonorgestrel into a patch. Management indicated that it will have seven Orange Book-listable patents to protect Twirla, which we think should offer protection until 2028. (2) Management is exploring non-dilutive financing options to provide additional flexibility after its data release in early 2016 and remove its financing overhang. The cash burn this quarter was approximately \$7.8M, and we estimate that the company has sufficient financing through early 2016 at this burn rate. Management deferred manufacturing its validation batches closer to the Twirla launch date as a means to preserve cash.

Current Statistics

Market Cap (\$Mil)	\$119.4	Free Float (%):	18.600
Avg. Daily Trading Volume (3 mo.):	39,316		
Shares Out (Mil):	18.593		

EARNINGS SUMMARY:

We summarize 3Q:14 earnings in Exhibit 1 below.

Exhibit 1: Agile 3Q:14 Earnings

	3Q:14E	3Q:14A	% Variance	Q/Q Growth	Comments
Revenues	0.00	0.00	NM	NM	
Total Revenues	0.00	0.00	NM	NM	FactSet Consensus \$0.00
COGS	0.00	0.00	NM	NM	
Gross Profit	0.00	0.00	NM	NM	
SG&A	1.30	1.45	11.3%	31.0%	
R&D	5.00	4.60	-7.9%	92.5%	
Other	0.00	0.00	NM	NM	
EBIT	-6.30	-6.05	NM	NM	
Interest and Other Income	-0.55	-0.30	NM	NM	
Pre-tax income	-6.85	-6.35	NM	NM	
Income tax expense	0.00	0.00	NM	NM	
Net Income	-6.85	-6.35	NM	NM	
Diluted shares	18.60	18.59	0.0%	132.4%	
Operating EPS	(\$0.37)	(\$0.34)	NM	NM	FactSet Consensus (\$0.50)

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

OTHER TAKEAWAYS FROM THE CALL:

- Management is extremely pleased by the addition of its new Board member James Tursi, M.D. Dr. Tursi is an OB/GYN with extensive experience with the FDA's division of urology and gynecology. He is currently the Chief Medical Officer for Auxilium Pharmaceuticals, which is in the process of being acquired by Endo International.

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. We use similar valuation metrics in other clinical-stage companies in our universe such as Eagle Pharmaceuticals.

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 2: 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	23.6	27.6	29.0	30.4	32.0	33.5	35.2
Diluted EPS	(\$0.60)	(\$0.29)	\$0.09	(\$0.46)	(\$0.34)	(\$0.40)	(\$0.89)	(\$1.51)	(\$1.50)	(\$1.71)	\$0.12	\$1.38	\$2.01	\$2.32
<div> <div>Consensus Revenue</div> <div>Consensus EPS</div> <div> <div>\$0.0</div> <div>(\$0.52)</div> <div>\$0.0</div> <div>(\$1.27)</div> <div>\$0.0</div> <div>(\$1.09)</div> <div>\$20.9</div> <div>(\$1.40)</div> </div> </div>														
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 3: 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.

Companies Mentioned:

Auxilium Pharmaceuticals, Inc. (AUXL - NASDAQ): NC

Eagle Pharmaceuticals Inc. (EGRX - NASDAQ): BUY

Endo Health Solutions Inc. (ENDP - NASDAQ): HOLD

Disclosures Appendix

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BUY: We have a positive outlook on the stock based on our expected 12 month return relative to its risk. The expected return is based on our view of the company and industry fundamentals, catalysts, and valuation. We recommend investors add to their position.

HOLD: We have a neutral outlook on the stock based on our expected 12 month return relative to its risk. The expected return is based on our view of the company and industry fundamentals, catalysts, and valuation.

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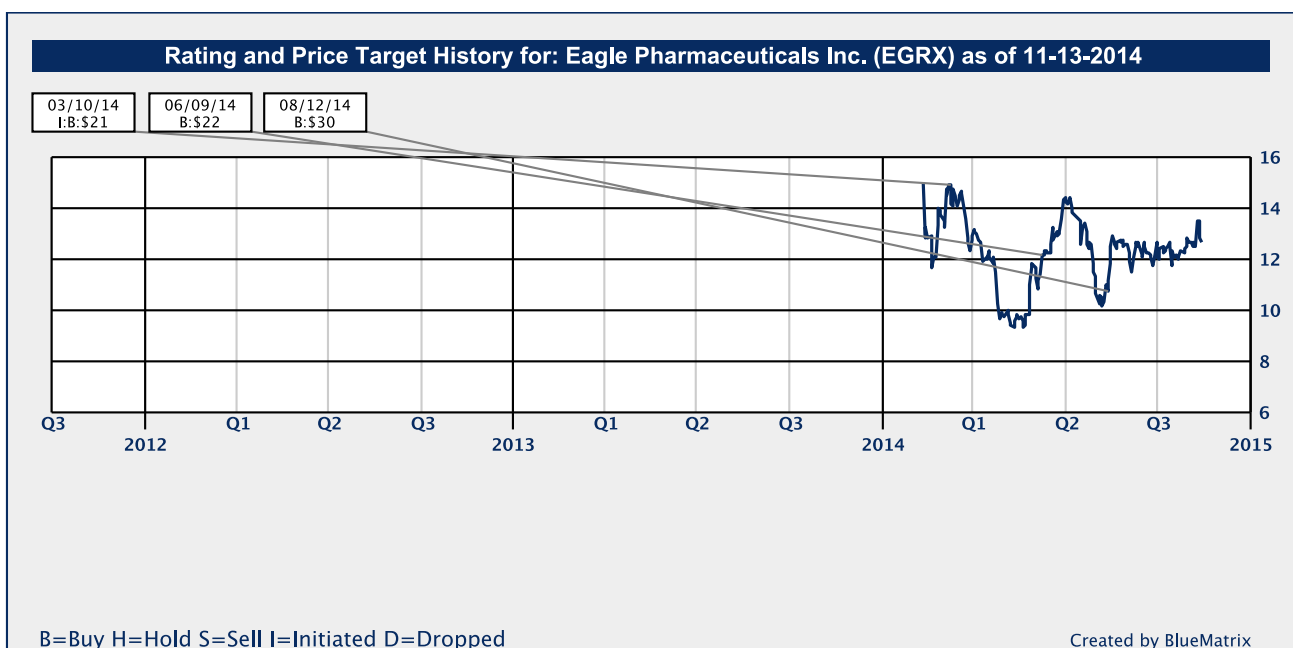
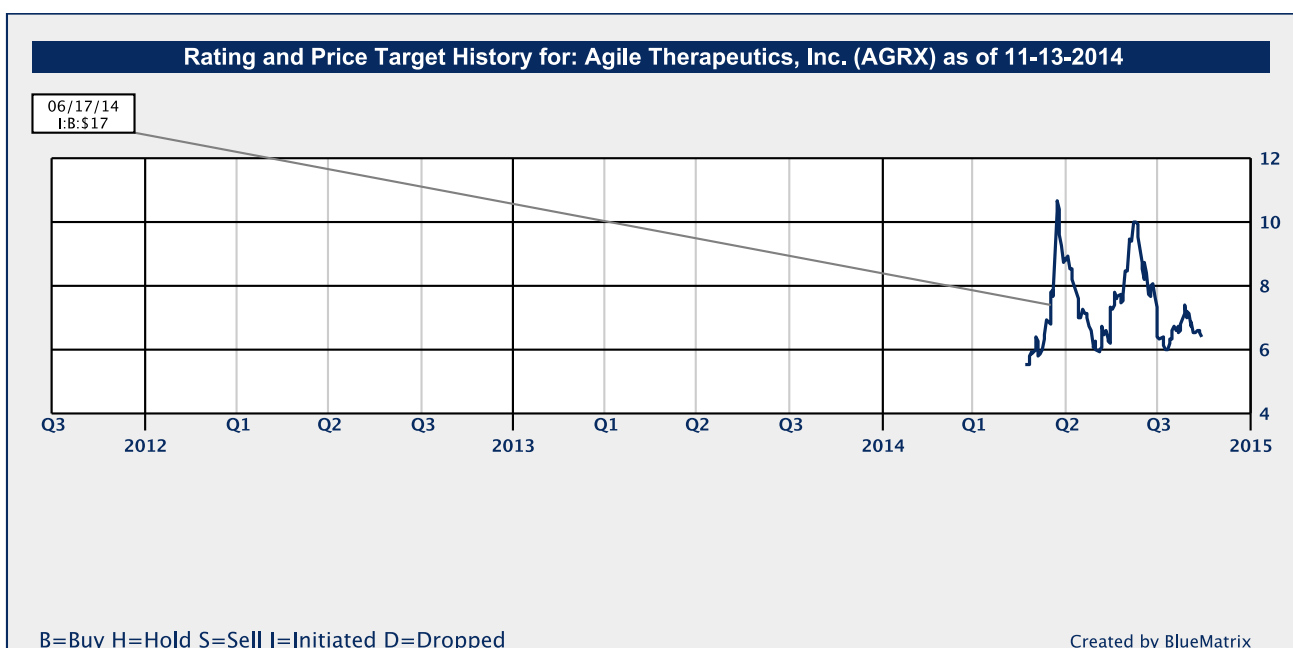
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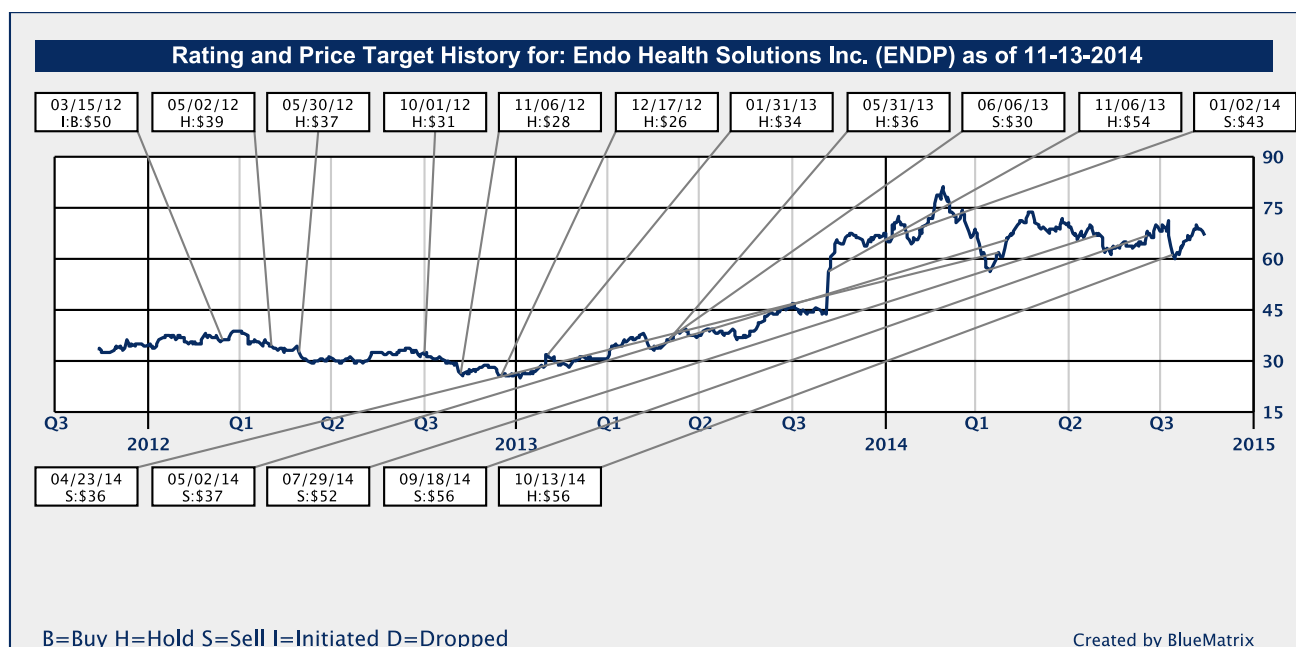
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Distribution of Ratings/Investment Banking Services (IB) as of 11/14/14

Rating	Cantor		IB Serv./Past 12 Mos.	
	Count	Percent	Count	Percent
BUY [B]	89	60.54	21	23.60
HOLD [H]	49	33.33	10	20.41
SELL [S]	9	6.12	1	11.11