

Equity Research

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Agile Therapeutics, Inc. (AGRX-\$7.36)

Rating: BUY

Target Price: \$17.00

Expense Containment & Twirla Progress; Maintain 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	0.0E	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	(0.37)E	(0.50)E
Prev	—	(0.53)E	(0.51)E	(0.64)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	(1.02)E	(1.51)E	
Prev	—	(1.70)E	—	

- **Conservative spending beats expectations in 2Q:14:** Agile generated no revenue in the quarter, and recorded a loss per share of (\$0.46) versus FactSet consensus estimates of (\$0.37) and our estimate of (\$0.53). Operating expenses were much lower than the Street anticipated, resulting in a theoretical "beat" on the net loss. However, the actual EPS loss came in above consensus due to the Street's usage of a higher pro-forma share count in calculating EPS. We like the conservative spend by management coupled with a timely trial start. As a result, we have lowered our expense estimates in 2014. Agile finished the quarter with cash and cash equivalents of \$53.5 million, which management believes is sufficient to fund operations through 1Q:16. We reiterate our BUY rating and \$17 PT, which are based on DCF analysis.
- **The clinical program is tightly managed and enrollment is expected to complete in 1Q:15:** The company confirmed it is on schedule, with enrollment of its first Twirla contraceptive patch patient expected 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). On the manufacturing front, the company is working with Corium International on commercial scale-up of manufacturing capabilities, and expects to complete validation and expansion of the manufacturing facilities by the end of 2016 (prior to launch). We expect Agile to submit its 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. Finally, management now expects to have seven Orange Book listed patents for Twirla, an increase from the five we initially contemplated in our initiation report (*Reinventing the Contraceptive Patch: Initiating Coverage with a BUY Rating and \$17 PT*, dated 6/17/14).
- **An easy story with a lot to like:** (1) Twirla will compete in a large and lucrative contraceptive market that has experienced accelerated growth due to the passage of the Affordable Care Act. (2) We believe that a contraceptive patch would generate significant patient and physician demand given that J&J's Ortho Evra quickly attained 10% market share before safety concerns about its estrogen exposure led to the brand's decline. (3) Even under conservative risk-adjusted assumptions, we believe that Twirla can attain over \$300 million in peak sales. (4) We like category pricing in contraceptives. (5) There has been significant M&A activity in women's health, which should also benefit Agile, in our view.

Current Statistics

Market Cap (\$Mil)	\$136.8	Float Shares (Mil):	18.600
Avg. Daily Trading Volume (3 mo.):	NA		
Shares Out (Mil):	18.593		

EARNINGS SUMMARY:

We summarize 2Q:14 earnings in Exhibit 1 below.

Exhibit 1: Agile 2Q:14 Earnings

	2Q:14E	2Q: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	1.80	1.10	-38.7%	4.8%	
R&D	5.00	2.39	-52.2%	71.5%	
Other	0.00	0.00	NM	NM	
EBIT	-6.80	-3.49	NM	NM	
Interest and Other Income	-0.34	-0.22	NM	NM	
Pre-tax income	-7.14	-3.72	NM	NM	
Income tax expense	0.00	0.00	NM	NM	
Net Income	-7.14	-3.72	NM	NM	
Diluted shares	13.51	8.00	-40.8%	-17.5%	
Operating EPS	(\$0.53)	(\$0.46)	NM	NM	FactSet Consensus \$(0.46)

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

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 Evoke Pharma and 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:14E	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	5.0	7.0	15.8	25.0	26.3	27.6	28.9	30.4	31.9	33.5
SG&A	5.9	3.6	1.1	1.1	1.3	1.7	5.2	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	6.3	8.7	21.3	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)	(6.3)	(8.7)	(21.3)	(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	0.7	0.2	0.3	1.0	0.0
Interest expense	(0.1)	(1.5)	0.0	(0.4)	(0.6)	(0.6)	(1.5)	(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	0.0	0.0	0.2	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)	(0.5)	(0.5)	(1.3)	(0.7)	(0.1)	0.1	(0.1)	0.1	0.7	1.0
Pretax Income	(23.3)	(14.3)	(2.8)	(3.7)	(6.8)	(9.2)	(22.6)	(35.7)	(41.4)	(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)	(6.8)	(9.2)	(19.0)	(35.7)	(41.4)	(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)	(\$0.37)	(\$0.50)	(\$1.02)	(\$1.51)	(\$1.50)	(\$1.71)	\$0.12	\$1.38	\$2.01	\$2.32

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

Exhibit 3: Agile Sales Estimates (dollars in millions)

	2012	2013	1Q:14E	2Q:14A	3Q:14E	4Q:14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E
Products														
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%
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.

Companies Mentioned:

Corium International, Inc. (CORI - NASDAQ): NC

Eagle Pharmaceuticals Inc. (EGRX - NASDAQ): BUY

Evoke Pharma, Inc. (EVOK - NASDAQ): BUY

Johnson & Johnson (JNJ - NYSE): NC

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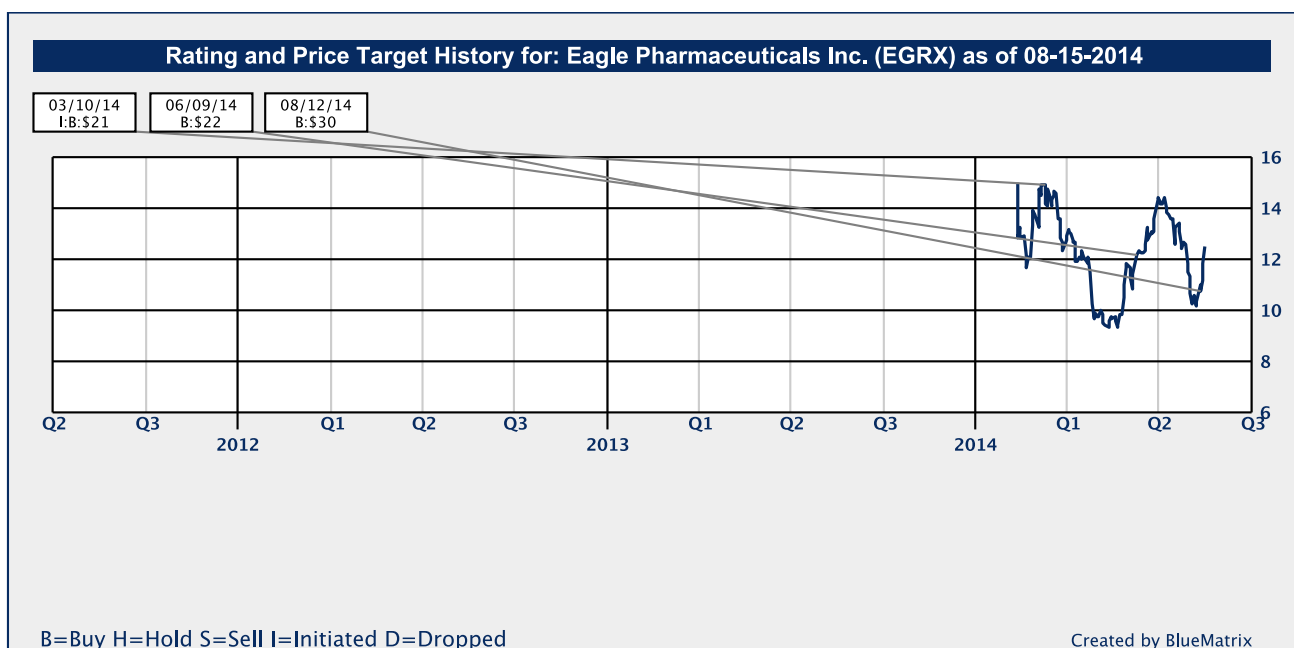
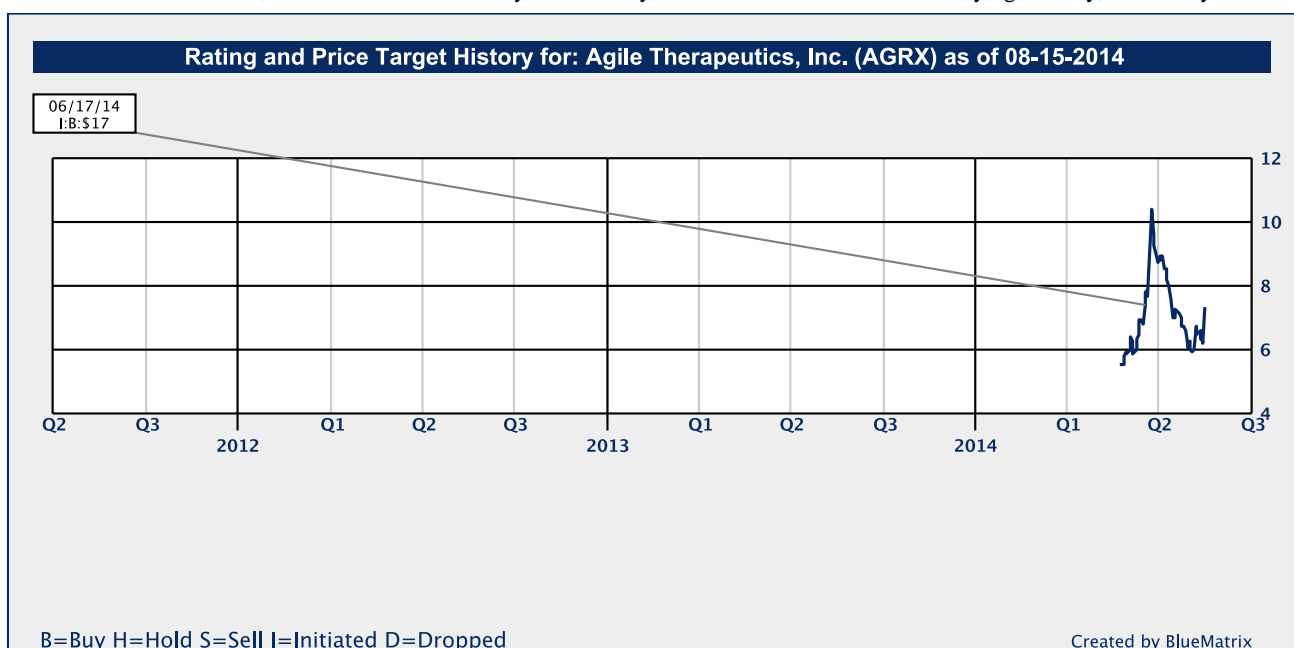
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Distribution of Ratings/Investment Banking Services (IB) as of 08/18/14

Rating	Cantor		IB Serv./Past 12 Mos.	
	Count	Percent	Count	Percent
BUY [B]	81	59.56	22	27.16
HOLD [H]	45	33.09	7	15.56
SELL [S]	10	7.35	1	10.00