

Equity Research

Irina Rivkind Koffler
212-915-1237
irivkind@cantor.com

Agile Therapeutics, Inc. (AGRX-\$8.89)

Rating: BUY

Target Price: \$20.00

4Q:14 Beat/Twirla Enrollment on Track; Maintain BUY, Raise PT to \$20 from \$17

<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	0.0E	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
<i>Prev</i>	—	—	—	(0.40)E
2015E	(0.33)E	(0.35)E	(0.37)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	(1.42)E	(1.04)E	
<i>Prev</i>	(0.89)E	(1.62)E	—	

- **Conservative spending drove the earnings beat in 4Q:14:** Agile generated no revenue in the quarter and recorded a loss per share of (\$0.37) versus FactSet consensus estimates of (\$0.43) and our estimate of (\$0.40). Management indicated that its Phase III program of the Twirla contraceptive patch remains on track to complete enrollment in 3Q:15 at the latest. We have updated our model for lower expenses, higher cash from the January private placement, and the associated increased share count. We are therefore raising our DCF-derived price target from \$17 to \$20. We reiterate our BUY rating on Agile and don't think that the stock will be negatively affected by the "biotech bubble" sector sell-off since Agile's program is a low-risk reformulation, in a large and attractive market.
- **Updates to our model:** Management noted that R&D will continue to climb gradually in 2015 but then begin to decline as patients exit the trial in mid-2016. Additionally, SG&A spend should remain generally in line with the 4Q:14 run rate, with slight upticks over time. We have updated our forecasts to reflect this thinking and now model 2015 loss per share of (\$1.42), down from (\$1.62) previously. We are not expecting the company to generate any revenue until 2017 (company is unlikely to receive an FDA approval before 1Q:17) and therefore believe that consensus revenue estimates in 2016 will need to come down. Management reiterated that it feels comfortable with its cash position, which it believes should fund operations through the end of 2016. Agile has access to another \$8.5M tranche in Hercules debt, which management indicated could fund another 1-2 quarters of operations in 2017.
- **Management is happy with Twirla trial progress:** The company confirmed that it remains on schedule to complete patient enrollment in 3Q:15 with data release in 3Q:16. Management indicated that its contract research organization continues to execute well in running the trial and that it has seen nothing concerning thus far with respect to safety or patient discontinuation rates. Additionally, patient demographics have been representative of typical contraceptive trials. We expect Agile to submit a response to its Twirla complete response letter (CRL) in 2H:16 followed by a six-month FDA review and approval and launch in early 2017.

Current Statistics

Market Cap (\$Mil)	\$197.0	Free Float (%):	18.600
Avg. Daily Trading Volume (3 mo.):	42,540		
Shares Out (Mil):	22.154		

EARNINGS SUMMARY:

We summarize 4Q:14 earnings in Exhibit 1 below.

Exhibit 1: Agile 4Q:14 Earnings

	4Q:14E	4Q:14A	% Variance	Q/Q Growth	Comments
Revenues	0.0	0.0	NM	NM	
Total Revenues	0.0	0.0	NM	NM	FactSet Consensus \$0.00
COGS	0.0	0.0	NM	NM	
Gross Profit	0.0	0.0	NM	NM	
SG&A	1.5	1.5	3.2%	7.0%	
R&D	5.5	5.0	-9.5%	8.1%	
EBIT	-7.0	-6.5	NM	NM	
Interest and Other Income	-0.4	-0.3	NM	NM	
Pre-tax income	-7.4	-6.8	NM	NM	
Income tax expense	0.0	0.0	NM	NM	
Net Income	-7.4	-6.8	NM	NM	
Diluted shares	18.6	18.6	0.2%	0.2%	
Operating EPS	(\$0.40)	(\$0.37)	NM	NM	FactSet Consensus (\$0.43)

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 (up from \$17 previously). 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 2: Agile Income Statement (dollars in millions)

	2012	2013	1Q:14A	2Q:14A	3Q:14A	4Q:14A	2014	1Q:15E	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	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	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	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	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	5.0	13.4	5.3	5.7	6.0	5.7	22.7	15.9	16.7	17.5	18.4	19.3	20.3
SG&A	5.9	3.6	1.1	1.1	1.4	1.5	5.2	1.6	1.7	1.8	1.9	7.0	10.0	55.0	68.8	79.1	87.0	95.7
Total operating expenses	23.3	12.7	2.45	3.5	6.0	6.5	18.5	6.9	7.4	7.8	7.5	29.6	25.9	71.7	86.2	97.4	106.3	115.9
Operating income (Loss)	(23.3)	(12.7)	(2.4)	(3.5)	(6.0)	(6.5)	(18.5)	(6.9)	(7.4)	(7.8)	(7.5)	(29.6)	(25.9)	(38.7)	17.6	84.2	122.2	147.4
Interest income	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.1	0.2	0.4	0.0
Interest expense	(0.1)	(1.5)	(0.4)	(0.4)	(0.4)	(0.4)	(1.6)	(0.4)	(0.4)	(0.4)	(0.4)	(1.8)	(1.3)	(1.3)	(0.3)	(0.3)	(0.3)	0.0
Change in fair value of warrant liability	0.2	(0.1)	0.0	0.2	0.1	0.1	0.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.0
Other income (expense), net	0.1	(1.6)	(0.4)	(0.2)	(0.3)	(0.3)	(1.2)	(0.4)	(0.4)	(0.4)	(0.4)	(1.8)	(1.3)	(1.2)	(0.2)	(0.1)	0.1	1.0
Pretax Income	(23.3)	(14.3)	(2.8)	(3.7)	(6.4)	(6.8)	(19.7)	(7.3)	(7.8)	(8.2)	(8.0)	(31.4)	(27.1)	(39.9)	17.4	84.1	122.3	146.4
Tax Rate	NA	NA	NA	NA	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	0.0	0.0	0.0	0.0	6.8	32.8	47.7	57.9
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	0.0	0.0	0.0	0.0
Net income	(23.9)	(14.3)	0.8	(3.7)	(6.4)	(6.8)	(16.1)	(7.3)	(7.8)	(8.2)	(8.0)	(31.4)	(27.1)	(39.9)	10.6	51.3	74.6	90.5
Weighted average common shares (diluted)	39.5	49.5	9.7	8.0	18.6	18.6	11.4	22.2	22.2	22.2	22.2	22.2	26.2	27.5	28.8	30.3	31.8	33.4
Diluted EPS	(\$0.60)	(\$0.29)	\$0.09	(\$0.46)	(\$0.34)	(\$0.37)	(\$1.41)	(\$0.33)	(\$0.35)	(\$0.37)	(\$0.36)	(\$1.42)	(\$1.04)	(\$1.45)	\$0.37	\$1.70	\$2.35	\$2.71
Consensus Revenue													\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$12.3
Consensus EPS													(\$0.48)	(\$0.34)	(\$0.30)	(\$0.27)	(\$1.49)	(\$1.50)
Margin Analysis	2012	2013	1Q:14A	2Q:14A	3Q:14A	4Q:14A	2014	1Q:15E	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	-	-	-	-	-	-	-	-	-	-	-	-	-	47.0%	15.7%	9.4%	7.8%	7.1%
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-109.2%	15.8%	43.0%	49.5%	51.6%
Net Income Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-112.5%	9.5%	26.2%	30.2%	31.7%
Growth (Y/Y)	2012	2013	1Q:14A	2Q:14A	3Q:14A	4Q:14A	2014	1Q:15E	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%	280%	138%	30%	14%	70%	-30%	5%	5%	5%	5%	5%
EBIT	-	-45%	-	-	-	-	-	-	-	-	-	-	-	-	-	378%	45%	21%
Interest income (expense)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Tax	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	382%	45%	21%
Net Income	-	-	-	-	-	-	-	-988%	-	-	-	-	-	-	-	382%	45%	21%
Diluted EPS	-	-	-	-	-	-	-	-489%	-	-	-	-	-	-	-	359%	38%	16%

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

Exhibit 3: Agile Sales Estimates (dollars in millions)

	2012	2013	1Q:14E	2Q:14A	3Q:14A	4Q:14A	2014E	1Q:15E	2Q:15A	3Q:15A	4Q:15E	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	0.0	0.0	0.0	0.0	59.1	186.2	326.2	411.4	475.8
Growth															215%	75%	26%	16%
Risk Adjustment = 60%	60%	60%	60%	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	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	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	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	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	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	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%	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	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

Analyst Certification

The analyst primarily responsible for this research report, and whose name appears on the front cover, certifies that: (i) all of the views expressed in this research report accurately reflects his or her personal views about any and all of the subject securities or issuers featured in this report; and (ii) no part of any of the research analyst's compensation was, is, or will be, directly or indirectly related to the specific recommendations or views expressed by the research analyst in this report.

Legal Disclosures

Lead or Co-manager: Cantor Fitzgerald and/or its affiliates, has acted as lead or co-manager in a public offering of equity and/or debt securities for Agile Therapeutics, Inc. within the last 12 months

Investment banking (last 12 months): Cantor Fitzgerald and/or its affiliates has received compensation for investment banking services in the last 12 months from Agile Therapeutics, Inc..

Investment banking (next 3 months): Cantor Fitzgerald and/or its affiliates, expect to receive, or intend to seek, compensation for investment banking services within the next three months from all of the companies referenced within this report.

Cantor Fitzgerald and/or its affiliates is a market maker in Agile Therapeutics, Inc..

Cantor Fitzgerald's rating system

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.

SELL: We have a negative 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 reduce their position.

NC: Not Covered. Cantor Fitzgerald does not provide an investment opinion or does not provide research coverage on this stock.

Prior to September 12, 2006, Cantor Fitzgerald had the below ratings:

BUY - denotes stocks that we expect will provide a total return (price appreciation plus yield) of 15% or more over a 12-month period. A BUY rated stock is expected to outperform the total average return of analyst's industry coverage universe on a risk adjusted basis.

HOLD - denotes stocks that we suggest will provide a total return or total negative return of up to 15% over 12-month period. A HOLD rated stock is expected to perform in-line with the total average return of the analyst's industry coverage universe on a risk adjusted basis.

SELL - denotes stocks that we expect to provide a total negative return of more than 15% over a 12 month period. A SELL rated stock is expected to underperform the total average return of the analyst's industry coverage universe on a risk adjusted basis.

NC - Not Covered. Cantor Fitzgerald does not provide research coverage on this company.

Other Disclosures

This report is for informational purposes only and is based on publicly available data believed to be reliable, but no representation is made that such data are accurate or complete. Opinions and projections contained herein reflect our opinion as of the date of this report and are subject to change. Pursuant to Cantor Fitzgerald's policy, the author of this report does not own shares in any company he/she covers.

Disclosures for UK investors

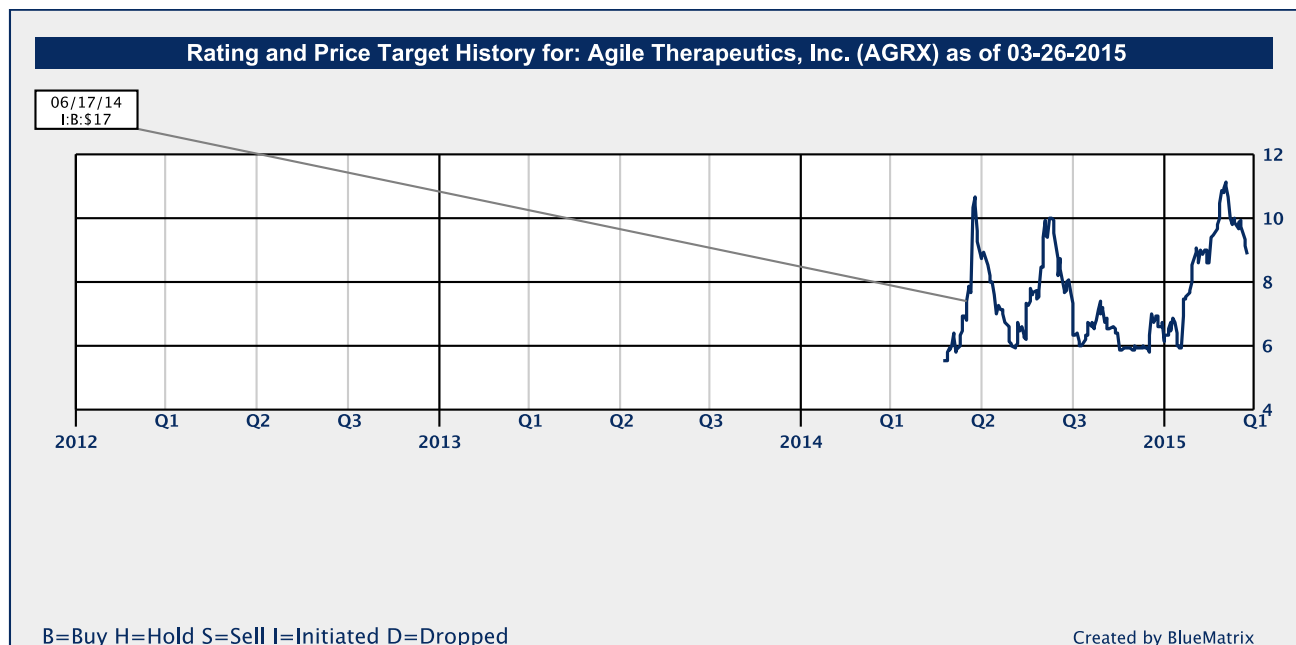
This material is approved for distribution in the United Kingdom by Cantor Fitzgerald Europe ("CFE"). CFE is authorised and regulated by the Financial Conduct Authority ("FCA"). While we believe this information and the materials upon which this information was based is accurate, except for any obligations under the rules of the FCA, we do not guarantee its accuracy. This material is only intended for use by eligible counterparties or professional clients who fall within articles 19 or 49 of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2001 and not the general investing public. None of the investments or investment services mentioned or described herein are available to other persons in the U.K and in particular are not available to "retail clients" as defined by the rules of the FCA.

Disclosure for Canadian Institutional Investors

This research report was prepared by analysts of Cantor Fitzgerald & Co. and not by Cantor Fitzgerald Canada Corporation. As a result, this report has not been prepared subject to Canadian Disclosure requirements. Cantor Fitzgerald Canada may distribute research reports prepared by its affiliates.

Risks

The financial instruments discussed in this report may not be suitable for all investors and investors must make their own investment decisions based on their specific investment objectives. Past performance should not be taken as an indication or guarantee of future performance. The price, value of and income from, any of the financial instruments featured in this report can rise as well as fall and be affected by changes in economic, financial and political factors. If a financial instrument is denominated in a currency other than the investor's currency, a change in exchange rates may adversely affect the price or value of, or income derived from, the financial instrument, and such investors effectively assume currency risk. In addition, investors in securities such as ADRs, whose value is affected by the currency of the home market of the underlying security, effectively assume currency risk.



Distribution of Ratings/Investment Banking Services (IB) as of 03/27/15

Rating	Cantor		IB Serv./Past 12 Mos.	
	Count	Percent	Count	Percent
BUY [B]	90	64.29	25	27.78
HOLD [H]	45	32.14	8	17.78
SELL [S]	5	3.57	1	20.00