

Biotechnology

Agile Therapeutics, Inc.

(AGRX) - BUY

Price: **\$8.70**
Fair Value Estimate: \$18.00
52-Week Range: \$5.05-\$12.55
Market Cap (MM): \$162
Shr.O/S-Diluted (mm): 18.6
Average Daily Volume: 114,927

FYE: Dec	2013E	2014E	2015E
EPS:	(1.59)E	(0.73)E	(0.99)E
Prior EPS:	NC	NC	NC
P/E:	NA	NA	NA

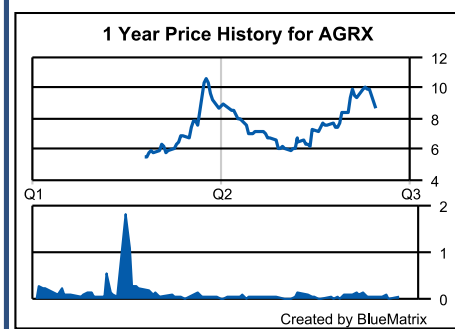
Quarterly EPS:

	Q1	Q2	Q3	Q4
2013E	--	0.09E	--	--
2014E	--	(0.46)E	--	--
2015E	--	(0.19)E	--	--
2016E	--	(0.19)E	--	--

FYE: Dec	2013E	2014E	2015E
Revenue (M):	0.0E	0.0E	0.0E

Quarterly Revenue (M):

	Q1	Q2	Q3	Q4
2013E	--	0.0E	--	--
2014E	--	0.0E	--	--
2015E	--	0.0E	--	--
2016E	--	0.0E	--	--



Equity Research
FLASH Note

AGRX: Initiation of Phase III Twirla Study; In Line With Our Expectations

KEY POINTS:

- **What's new? Phase III Twirla study initiated. Timing and study design in line with expectations.** This morning, AGRX announced the initiation of a Phase III registration study for Twirla. Timing was in line with expectations. The 2,100-patient registration study is a single-arm, open-label, multicenter study that will examine the efficacy and safety of the patch in preventing pregnancy.
- **Timelines for the Twirla program.** The company anticipates completion of patient enrollment within four to six months. As patients will be dosed for up to one year, we continue to expect top-line Phase III data in 1Q16, which remains consistent with the company's previous update to us in June.
- **Potential blockbuster drug.** Management has indicated that it expects the Twirla launch to be a steady one given its market research. In addition, the company's internal estimate for peak Twirla sales of \$900+ million assumes conservative pricing below that of Mylan's Xulane, a generic CHC patch. We conservatively estimate Twirla's market share at 9% with drug pricing at a slight discount to a generic patch and currently branded oral contraceptives, which translates into \$1.0 billion in peak sales. By comparison, Ortho Evra, the first contraceptive patch, garnered 10% market share 1.5 years after its launch and peaked at 11% share when it received a black box warning. Based on its distinguished profile, we believe Twirla can command greater market share and premium pricing to Xulane, which we view as upside to our estimates.
- **Robust balance sheet.** As of 2Q, the company had approximately \$53.5 million in cash, which we estimate should support the release of top-line Phase III data, expected in 1Q16. AGRX's strong balance sheet positions the company well to complete the Twirla program but we anticipate the need for additional cash inflows prior to commercial launch.
- **Maintaining a long term approach to investing in AGRX shares.** We do not expect any major catalysts for the rest of this year and believe investors should have a longer term investment horizon. We anticipate several important catalysts in 2015-2016 that should drive shares, namely Phase III Twirla data by 1Q16 followed by submission of a complete response in 1H16. We continue to expect a potentially favorable Phase III outcome as the regulatory pathway has been de-risked with a straightforward and simple study design, robust powering, an experienced clinical research organization and improved study conduct.
- **Reiterate Buy rating and \$18 fair value estimate.** We consider AGRX a compelling investment based on its proprietary transdermal technology, its differentiated and burgeoning pipeline, an experienced management team and attractive valuation. Our \$18 fair value estimate is based on a DCF analysis that examines free cash flow through 2022.

Research Analyst Certifications and Important Disclosures
are on pages 2 - 3 of this report

IMPORTANT DISCLOSURES

Research Analyst Certification

I, Kimberly Lee, the Primarily Responsible Analyst for this research report, hereby certify that all of the views expressed in this research report accurately reflect my personal views about any and all of the subject securities or issuers. No part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views I expressed in this research report.

Janney Montgomery Scott LLC ("Janney") Equity Research Disclosure Legend

Agile Therapeutics, Inc. currently is, or during the past 12 months was, a Janney Montgomery Scott LLC client. Janney Montgomery Scott LLC, provided investment banking related services.

Janney Montgomery Scott LLC currently acts as a market-maker in the securities of Agile Therapeutics, Inc..

Janney Montgomery Scott LLC managed or co-managed a public offering of securities for Agile Therapeutics, Inc. in the past 12 months.

Janney Montgomery Scott LLC received compensation for investment banking services from Agile Therapeutics, Inc. in the past 12 months.

Janney Montgomery Scott LLC intends to seek or expects to receive compensation for investment banking services from Agile Therapeutics, Inc. in the next three months.

The research analyst is compensated based on, in part, Janney Montgomery Scott's profitability, which includes its investment banking revenues.

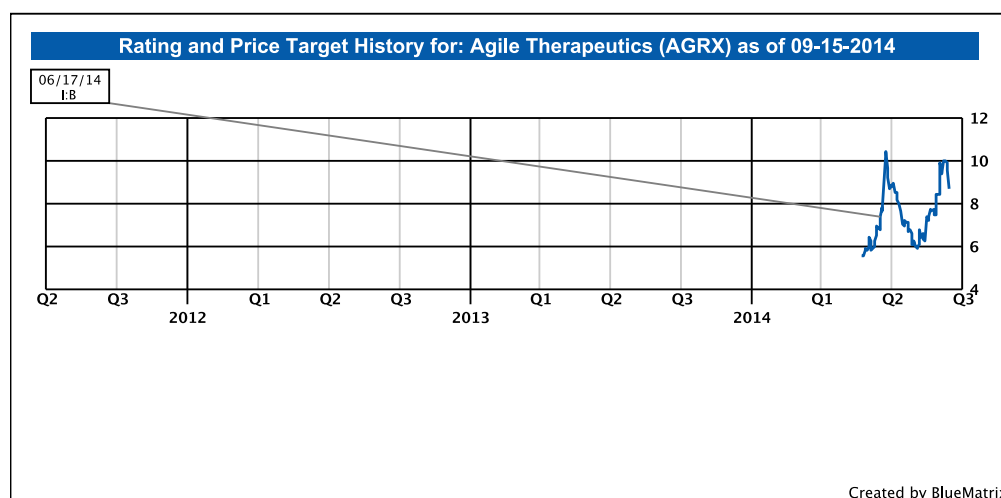
Definition of Ratings

BUY: Janney expects that the subject company will appreciate in value. Additionally, we expect that the subject company will outperform comparable companies within its sector.

NEUTRAL: Janney believes that the subject company is fairly valued and will perform in line with comparable companies within its sector. Investors may add to current positions on short-term weakness and sell on strength as the valuations or fundamentals become more or less attractive.

SELL: Janney expects that the subject company will likely decline in value and will underperform comparable companies within its sector.

Price Charts



Janney Montgomery Scott Ratings Distribution as of 6/30/14

Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY [B]	207	53.80	53	25.60
NEUTRAL [N]	176	45.70	28	15.90
SELL [S]	2	0.50	0	0.00

***Percentages of each rating category where Janney has performed Investment Banking services over the past 12 months.**

Other Disclosures

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