

RBC Capital Markets

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Agile Therapeutics

We continue to see an attractive upside case post management meetings

Our view: We spent two days on the road with AGRX management and met separately with CORI who is the company's third party manufacturer. Overall, we remain confident in the early Twirla Phase III progress and timelines and continue to see a potentially significant upside case in the stock for investors who can be patient.

Key points:

Patient recruitment efforts going well as management takes added precautions for data compliance and patient population mix. Enrollment is expected to take 4-6 months and management focus here is appropriately high. We continue to have confidence that precautions taken with PAREXEL, site selection, experience of investigators, electronic diary implementation and patient screening will lead to a better efficacy result.

Competitive dynamics remain favorable and largely unchanged. This continues to be an area of focus for investors and we continue to see what could be potentially material upside to our forecasts. Other than Ortho-Evra, we see little branded competition for Twirla and MYL's generic (Xulane) has now taken close to 80% share of the brand at a very modest generic discount.

Our model still bridges AGRX cash through to Phase III data read. Agile ended Q2 with \$53.5 million in cash and we think that can carry the company through to early 2016 on the current strategic path. At that point we think AGRX could be a logical takeout target possibly creating an attractive exit for investors should management choose not to commercialize it itself.

How we are thinking about this stock - very attractive upside case for those willing to be patient. We think this is an interesting small cap opportunity for investors who can look to a time horizon into early 2016. Our peak sales forecast is arguably conservative at \$340 million (net) and if we were to un-risk adjust our model and lower our WACC to 10% we could argue for DCF value >\$25 with upside to our peak forecasts and possible strategic takeout value possibly adding further to that.

Twirla updates will keep the story in front of investors. Potential periodic status updates include: (1) Sept 2014: first patient is expected to begin dosing (2) mid-Nov 2014: update on enrollment status (3) Jan-Mar 2015: completion of patient enrollment (4) mid-2015: updates on pipeline (5) 1H 2016: Phase III results and CRL response and (7) 2H 2016 approval.

Outperform **Speculative Risk**

NASDAQ: AGRX; USD 9.39

Price Target USD 12.00

WHAT'S INSIDE	
☐ Rating/Risk Change	☐ Price Target Change
☐ In-Depth Report	☐ Est. Change
□ Preview	✓ News Analysis

Scenario Analysis*

4	Downside Scenario	Current Price	Price Target	Upside Scenario	
	2.00	9.39	12.00	25.00	
	↓ 79%		† 28%	1 66%	

*Implied Total Returns

Key Statistics

Shares O/S (MM):	20.0	Market Cap (MM):	188
Dividend:	0.00	Yield:	0.0%
		Aug Daily Valumas	47.640

RBC Estimates

FY Dec	2013A	2014E	2015E	2016E
EBITDA, Adj		(26.8)	(18.4)	(25.0)
EPS, Adj Diluted		(1.32)	(0.87)	(1.14)
Revenue	0.0	0.0	0.0	14.8
P/AEPS	NM	NM	NM	NM
EBITDA, Adj	Q1	Q2	Q3	Q4
EBITDA, Adj 2014	Q1 (2.4)A	Q2 (3.5)A	Q3 (10.8)E	Q4 (10.0)E
2014	(2.4)A	(3.5)A	(10.8)E	(10.0)E
2014 2015	(2.4)A	(3.5)A	(10.8)E	(10.0)E
2014 2015 EPS, Adj Diluted	(2.4)A (6.3)E	(3.5)A (4.3)E	(10.8)E (4.3)E	(10.0)E (3.3)E

Target/Upside/Downside Scenarios

Exhibit 1: Agile Therapeutics



Source: Bloomberg and RBC Capital Markets estimates for Upside/Downside/Target

Target price/ base case

Our base case scenario sees a \$12 share price on the following assumptions:

- Progress toward successful Phase III results and expected commercial launch by Agile in US H2/16.
- Peak US sales potential of \$340 million for Twirla reflecting 3% share of the CHC market on 4% annual pricing increases.
- Risk adjustment of 70% in our DCF while our Twirla NPV assumes a 23% discount rate on un-risk adjusted sales.
- No revenue contribution from the remainder of the pipeline and only modest benefit from existing NOLs.

Upside scenario

Our upside case scenario sees a \$25 share price on the following assumptions:

- Progress toward successful Phase III results and expected commercial launch by Agile in US H2/16.
- Peak US sales of \$617 million for Twirla reflecting 5% share of the CHC market and 5% annual pricing increases.
- Risk adjustment of 70% in our DCF while our Twirla NPV assumes a 23% discount rate on un-risk adjusted sales as the Phase III data read is expected in late 2015 (> 12 months).
- No revenue contribution from the remainder of the pipeline and only modest benefit from existing NOLs.

Downside scenario

Our downside case scenario sees a \$2 share price on an early unexpected halt to the Phase III study. In this scenario we assume modest value for platform technology, cash on hand, and existing NOLs.

Investment summary

Agile's lead product Twirla offers a low-dose once-weekly contraceptive patch that we believe fills an established unmet need in the market. Twirla offers both convenience and compliance benefits that we think would appeal to a core patient base once approved. Our thesis rests on four main points:

- 1) We believe Twirla can capture 3% TRx share in the sizable \$4.2 billion CHC market that is growing annually in the midsingle digits given the unique benefits that a CHC patch product without a black box safety warning could bring.
- 2) We see a clear path to market for Twirla and expect positive Phase III data in 1Q2016 followed by approval in H2/16.
- 3) There could be additional value from the existing pipeline and platform technology that we have not ascribed value to.
- 4) We see Agile as a logical takeout candidate by an established player in contraceptives with significant marketing resources and an established specialty sales force.

Potential Catalysts to focus on: 1) Phase III data readout in 1Q2016, 2) NDA approval in 2H2016, and 3) Potential acquisition that could be possible post positive Phase III data.

Risks to our thesis: 1) New phase III data for Twirla is insufficient for an NDA filing, 2) Additional regulatory or execution delays to launch, 3) Potential for greater than expected financing needs, and 4) Lack of commercial uptake or adoption below expectations



Exhibit 2: AGRX PNL 2012 to 2017E

Agile - Income Statement	FY2012	FY2013					FY2014					EV2015	FY2016	FY2017	
(\$ in millions)	Actual	Actual	Mar-14	Jun-14	Sep-14E	Dec-14E		Mar-15E	Jun-15E	Sep-15E	Dec-15E	Est.	Est.	Est.	Comments
Revenue	·														
Twirla	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	14.8	68.0	Assume a 2H2016 launch - no generics through '22E
Other	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	Pipeline potential for lifecycle and upside
Total 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	14.8	68.0	Each 100 bps Twirla share ~\$100M in revenue
Cost of goods sold	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.1	5.6	
Total 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	13.6	62.4	GM 90-92% - no royalty commitments
Research and development (R&D)	17.4	9.2	1.4	2.4	9.5	8.7	22.0	5.0	3.0	3.0	2.0	13.0	7.0	3.9	
General and administrative (G&A)	5.9	3.6	1.1	1.1	1.3	1.3	4.8	1.2	1.2	1.2	1.2	4.9	5.1	5.2	Should be relatively stable
Sales and marketing (S&M)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.1	0.1	0.5	26.5	37.8	Based on 90 reps, promo, social media, ad spend
Operating income (adjusted)	(23.3)	(12.7)	(2.4)	(3.5)	(10.8)	(10.1)	(26.8)	(6.4)	(4.4)	(4.4)	(3.4)	(18.4)	(25.0)	15.5	
Interest expense & other	(0.7)	(1.5)	(0.4)	(0.4)	(0.2)	0.1	(0.9)	(0.1)	(0.1)	(0.1)	(0.1)	(0.4)	(0.2)	0.0	
Interest income and other income (expense)	0.2	(0.1)	0.0	0.2	0.0	(0.2)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Total interest & other	(0.5)	(1.6)	(0.4)	(0.2)	(0.2)	(0.1)	(0.9)	(0.1)	(0.1)	(0.1)	(0.1)	(0.4)	(0.2)	0.0	
Earnings before income taxes (adj)	(23.9)	(14.3)	(2.8)	(3.7)	(11.0)	(10.1)	(27.7)	(6.4)	(4.4)	(4.4)	(3.4)	(18.8)	(25.1)	15.5	
Income tax (adjusted)	0.0	0.0	(3.7)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
Net earnings to Agile	(23.9)	(14.3)	0.8	(3.7)	(11.0)	(10.1)	(27.7)	(6.4)	(4.4)	(4.4)	(3.4)	(18.8)	(25.1)	15.5	
EPS (pro-forma), diluted	(\$603.8)	(\$289.4)	\$0.01	(\$0.28)	(\$0.55)	(\$0.50)	(\$1.32)	(\$0.32)	(\$0.22)	(\$0.22)	(\$0.13)	(\$0.87)	(\$1.14)	\$0.70	
Diluted shares outstanding	0.0	0.0	9.7	13.2	20.1	20.2	15.8	20.3	20.4	20.5	25.6	21.7	22.0	22.3	
EBITDA	(23.3)	(12.7)	(2.4)	(3.5)	(10.8)	(10.0)	(26.8)	(6.3)	(4.3)	(4.3)	(3.3)	(18.4)	(25.0)	15.5	
EBITDA margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	22.8%	
Growth analysis Y-O-Y	FY2012	FY2013					FY2014					FY2015	FY2016	FY2017	
Revenue	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	361%	We assume 2H16 launch with peak year 2021
COGS	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	400%	
Gross profit	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	358%	
Research and development (R&D)	NM	NM	NM	NM	NM	NM	140%	259%	25%	-68%	-77%	-41%	-46%	-44%	
General and administrative (G&A)	NM	NM	NM	NM	NM	NM	34%	17%	12%	-5%	-8%	3%	3%	2%	
Sales and marketing (S&M)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	5206%	43%	
Operating income (adjusted)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	-162%	
Net earning (adjusted)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	-162%	
EPS (adjusted)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	
Margin analysis	FY2012	FY2013		_			FY2014			_		FY2015	FY2016	FY2017	
Gross margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	92%	92%	
R&D	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	47%	6%	R&D growth could be higher - depends on pipeline
SG&A	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	35%	8%	
Sales and marketing (S&M)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	180%	56%	
Operating income (adjusted)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	-169%	23%	
Interest expense	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	-1%	0%	
Interest income and other income (expense)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	0%	0%	
Tax rate	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	0%	0%	0%	NOLs could reduce tax burden
Net earnings (adjusted)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	-170%	23%	

Source: Company data, RBC Capital Markets Research

Valuation

Our \$12 price target is based equally on our DCF and NPV valuation. Given that the primary value of Agile comes from its lead product candidate Twirla, we think that taking a blended approach is warranted.

Our DCF valuation of \$12 per share reflects our risk adjusted forecasts in the US for Twirla. Our Twirla NPV has expected sales and marketing expenses for commercialization, R&D spending to support expected pipeline studies, and the full organizational cost structure applied against

Our NPV reflects full US sales for Twirla in the US. Our \$12 value is based on a 14% WACC and an explicit forecast through 2022 beyond which we assume a terminal growth rate of -30% assuming generic threats in that time period.

Price target impediments

1) New Phase III study results may still show unacceptable efficacy with high Pearl Index levels, 2) Other potential deficiencies that may block an NDA submission, 3) low market acceptance and product uptake at commercialization, 4) Potential need for additional financing, and 5) Competitive risks from other branded or generic contraceptives.

Company description

Agile Therapeutics (AGRX) is development-stage women's health specialty pharmaceutical company focused on branded contraceptive patches. The company is based in Princeton, New Jersey, and, as of May 20, 2014, employed 11 full-time employees. Agile's lead product candidate, Twirla™ (AG200-15), is a once-weekly prescription contraceptive patch currently in Phase 3 clinical development. Twirla is a combination hormonal contraceptive patch that contains ethinyl estradiol (EE), a synthetic estrogen, and levonorgestrel (LNG), a progestin, which have established records of efficacy and safety in existing contraceptives. Twirla is designed to consistently deliver the hormones over a seven-day period at levels comparable to currently available oral contraceptives. Agile expects Phase III data by 1Q 2016, and approval in H2/16. Additional pipeline products include: 1) AG200-ER, an extended cycle regimen patch, 2) AG200-SP, a 28-day regimen that includes a shortened hormone-free interval, and 3) a progestin-only candidate, AG890, for women unable or unwilling to take estrogen.



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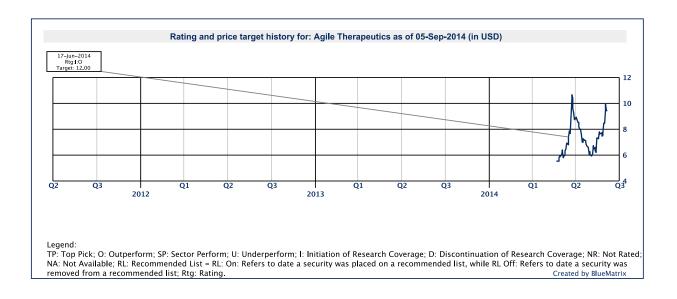
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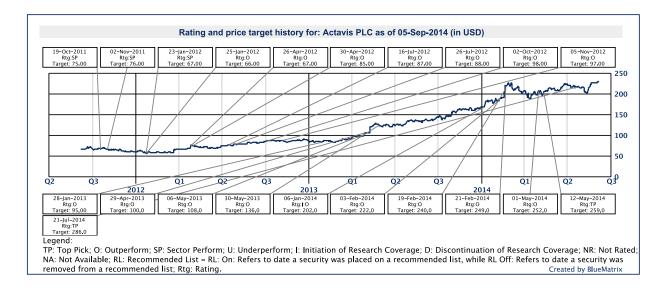


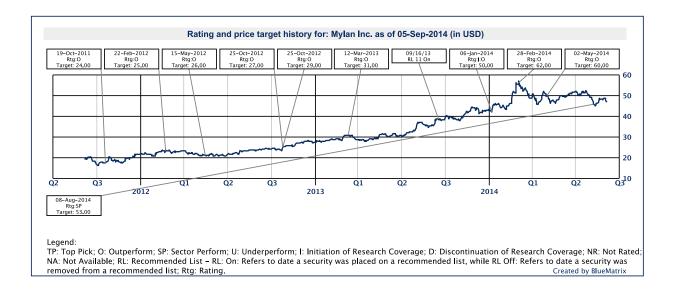
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	As of 30-J	Jun-2014			
			Investment Banking Serv./Past 12 Mos.		
Rating	Count	Percent	Count	Percent	
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HOLD [Sector Perform]	658	41.46	159	24.16	
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