EQUITY RESEARCH

RBC Capital Markets

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Agile Therapeutics

Twirla Phase III on track with enrollment of first subjects in 3Q2014

Our view: Following quarterly results and our discussion with management, we received status and timing updates for the upcoming Phase III study. Approval for Twirla in 2H2016 is on track, and we still see a compelling opportunity for patient investors. The quarter was a non-event, but we look forward to more patient recruitment updates into year-end, and will be hosting meetings with management in early September.

Key points:

Twirla Phase III progressing as Agile looks to enroll first subjects in 3Q2014. Agile is initiating start-up activities with PARAXEL focused on site selection and training. We expect enrollment to last 4-6 months beginning in September with the trial lasting ~12 months. The company will likely be able to respond to the FDA's CRL in 1Q2016, and assuming a 6-month review, we should see approval in 2H2016. As poor patient recruitment and loss of data were contributing factors to the prior Phase III failure, the company is being careful in patient screening and improving its data collection methods. As expected, E-diaries are also being deployed and each prospective patient will be put through a trial period before being given the drug. Management noted it may give an update on Phase III enrollment before results next quarter.

2Q spend came in as expected with Agile ending the quarter with ~ $53.5 million in cash. 2Q spend of $3.5 million was not far off of our expectations of $3.1 million. We expect R&D costs to accelerate into year-end as patient recruitment kicks into gear. Management expects cash on hand to fund operations through Phase III data. The company will complete equipment validation and expansion until after approval, and in coordination with planned commercialization activities. Corium, responsible for Twirla manufacturing, is working with the company to prepare supply for Twirla for the Phase III trial.

We still see a compelling opportunity for patient investors. Our $340 million peak sales estimate for lead product candidate Twirla reflects a 3% TRx penetration with 4% pricing increases, which are both arguably conservative - creating what we think is a very favorable upside scenario. For each 100 basis points in TRx penetration, we see roughly $114 million in additional peak sales and that translates into close to $3 in NPV per share or roughly 50% implied upside from where the stock currently trades.

Outperform
Speculative Risk
NASDAQ: AGRX; USD 6.22
Price Target USD 12.00

WHAT'S INSIDE	
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Scenario Analysis*

Downside Scenario	Current Price	Price Target	Upside Scenario
2.00	6.22	12.00	25.00
↓ 68%		↑ 93%	↑ 302%

*Implied Total Returns

Key Statistics

Shares O/S (MM):	20.0	Market Cap (MM):	124
Dividend:	0.00	Yield:	0.0%

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)
Prev.		(1.23)		
Revenue	0.0	0.0	0.0	14.8
P/AEPS	NM	NM	NM	NM

EBITDA, Adj	Q1	Q2	Q3	Q4
2014	(2.4)A	(3.5)A	(10.8)E	(10.0)E
Prev.		(3.1)E		(10.4)E
2015	(6.3)E	(4.3)E	(4.3)E	(3.3)E
EPS, Adj Diluted				
2014	0.01A	(0.28)A	(0.55)E	(0.50)E
Prev.		(0.17)E		(0.52)E
2015	(0.32)E	(0.22)E	(0.22)E	(0.13)E

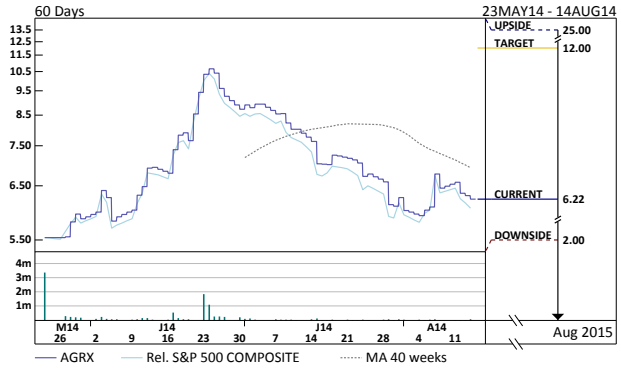
All values in USD unless otherwise noted.

Priced as of prior trading day's market close, EST (unless otherwise noted).

For Required Conflicts Disclosures, see Page 5

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 mid-single 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 take-out 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 ($ in millions)	FY2012 Actual	FY2013 Actual	Mar-14	Jun-14	Sep-14E	Dec-14E	FY2014 Est.	Mar-15E	Jun-15E	Sep-15E	Dec-15E	FY2015 Est.	FY2016 Est.	FY2017 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 it.

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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HOLD [Sector Perform]	658	41.46	159	24.16
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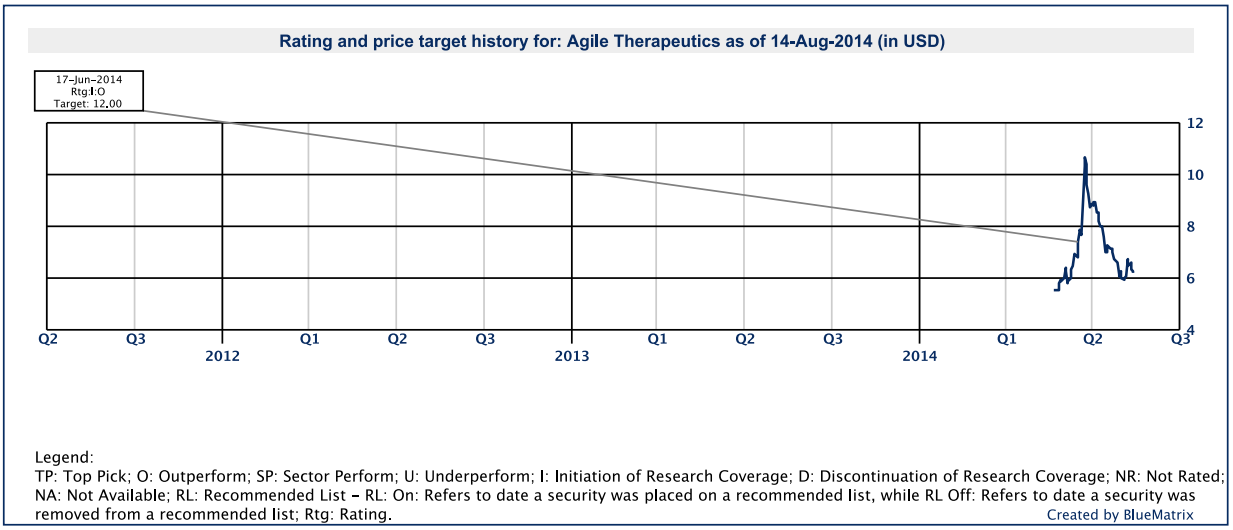

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