



March 26, 2015

Agile Therapeutics

Twirla Phase 3 study still on track for full enrollment in 3Q 2015

Our view: Per the 4Q update and our follow-up discussion with management, Twirla's Phase III study remains on track with funding in place through Phase 3 data. Spend came in below expectations from slower 4Q recruitment and is expected to ramp into 2015, but recent funding in 1Q puts Agile on a steady financial foothold. We continue to see an attractive upside case in AGRX shares.

Key points:

Management reiterated confidence in full enrollment for Twirla's Phase III study in 3Q2015. Enrollment began in September 2014 and is expected to complete by 3Q15, which means topline data will be available 2H2016. The company continues to focus on diligent patient screening and data collection methods with the deployment of E-diaries, and we believe that precautions taken through patient screening will lead to a positive efficacy result in-line with currently approved contraceptives. Recall that subpar patient recruitment and loss of data were contributing factors to the prior Phase III trial that led to the CRL.

4Q spend came in lighter than expected though will trend higher as enrollment ramps; following recent funding, we expect cash on hand to fund Agile through Phase 3 data in 2H2016. R&D costs for the Twirla trial are likely to increase into 2015 from \$4.98 million in 4Q and level off before declining in 2016 as patients complete the study. Management expects cash on hand to fund operations through end of 2016, with optionality for an additional \$8.5 million in debt from Hercules if Phase 3 data is positive which would provide further funding into 2017. Beyond that, we could see additional capital needs should AGRX pursue commercial infrastructure build.

AGRX remains a compelling opportunity for patient investors with small cap appetite; take-out post positive Phase 3 data is a realistic possibility. Our \$340 million peak sales estimate for lead product candidate Twirla reflects a 3% TRx penetration and a relatively modest pricing assumption; both are 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. Additionally, we still think AGRX could be a logical takeout target possibly creating an attractive exit for investors should management choose not to commercialize Twirla itself. We think interest here could be high on a de-risked outlook with potential interest from a host of companies participating in the branded contraceptive space which include ACT, TEVA, MYLAN and others.

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Sector: Pharmaceuticals/Specialty

Outperform

Speculative Risk

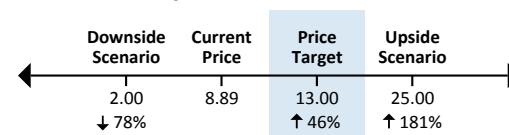
NASDAQ: AGRX; USD 8.89

Price Target USD 13.00

WHAT'S INSIDE

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Scenario Analysis*



*Implied Total Returns

Key Statistics

Shares O/S (MM):	20.0	Market Cap (MM):	178
Dividend:	0.00	Yield:	0.0%
		Avg. Daily Volume:	44,638

RBC Estimates

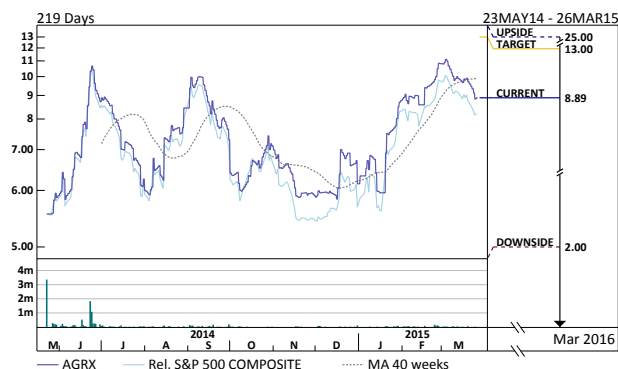
FY Dec	2013A	2014E	2015E	2016E
EBITDA, Adj		(18.5)	(26.8)	(21.9)
Prev.		(22.1)	(23.4)	(27.0)
EPS, Adj Diluted		(0.98)	(1.29)	(0.93)
Prev.		(1.11)	(1.23)	(1.39)
Revenue	0.0	0.0	0.0	0.0
Prev.				14.8
P/AEPS	NM	NM	NM	NM
EBITDA, Adj	Q1	Q2	Q3	Q4
2014	(2.4)A	(3.5)A	(6.0)A	(6.5)A
Prev.				(10.2)E
2015	(6.7)E	(6.8)E	(6.7)E	(6.7)E
Prev.	(10.3)E	(5.0)E	(4.0)E	(4.1)E
EPS, Adj Diluted				
2014	0.01A	(0.28)A	(0.34)A	(0.37)A
Prev.			(0.32)A	(0.52)E
2015	(0.33)E	(0.33)E	(0.32)E	(0.32)E
Prev.	(0.53)E	(0.27)E	(0.22)E	(0.22)E

All values in USD unless otherwise noted.



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 \$13 share price on the following assumptions:

- 40% M&A reflecting a 40% premium to fundamental price target
- Progress toward successful Phase III results and expected commercial launch by Agile in US H2/17.
- 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 H2/17.
- 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.
- Potential M&A takeout

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 is 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 2H2016, followed by approval in mid-2017.
- 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 1H2016; 2) NDA approval in mid-2017; 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-14	Dec-14	FY2014 Actual	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	0.0	36.3	Assume a mid-2017 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	0.0	36.3	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	0.0	2.8	
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	0.0	33.5	GM 90-92% - no royalty commitments
Research and development (R&D)	17.4	9.2	1.4	2.4	4.6	5.0	13.4	5.2	5.2	5.1	5.1	20.6	15.4	3.1	
General and administrative (G&A)	5.9	3.6	1.1	1.1	1.4	1.5	5.1	1.6	1.6	1.6	1.6	6.3	6.5	6.6	Should be relatively stable
Sales and marketing (S&M)	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	21.2	Based on 90 reps, promo, social media, ad spend
Operating income (adjusted)	(23.3)	(12.7)	(2.4)	(3.5)	(6.0)	(6.5)	(18.5)	(6.8)	(6.8)	(6.7)	(6.7)	(26.9)	(21.9)	2.6	
Interest expense & other	(0.7)	(1.5)	(0.4)	(0.4)	(0.4)	(0.4)	(1.6)	(0.5)	(0.5)	(0.5)	(0.5)	(2.2)	(2.2)	(2.2)	
Interest income and other income (expense)	0.2	(0.1)	0.0	0.2	0.1	0.1	0.3	0.1	0.1	0.1	0.1	0.4	0.2	0.0	
Total interest & other	(0.5)	(1.6)	(0.4)	(0.2)	(0.3)	(0.3)	(1.2)	(0.4)	(0.4)	(0.4)	(0.4)	(1.8)	(2.0)	(2.2)	
Earnings before income taxes (adj)	(23.9)	(14.3)	(2.8)	(3.7)	(6.4)	(6.8)	(19.7)	(7.2)	(7.2)	(7.1)	(7.1)	(28.7)	(23.8)	0.4	
Income tax (adjusted)	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	
Net earnings to Agile	(23.9)	(14.3)	0.8	(3.7)	(6.4)	(6.8)	(16.1)	(7.2)	(7.2)	(7.1)	(7.1)	(28.7)	(23.8)	0.4	
EPS (pro-forma), diluted	(\$603.8)	(\$289.4)	\$0.01	(\$0.28)	(\$0.34)	(\$0.37)	(\$0.98)	(\$0.33)	(\$0.33)	(\$0.32)	(\$0.32)	(\$1.29)	(\$0.93)	\$0.02	
Diluted shares outstanding	0.0	0.0	9.7	13.2	18.6	18.6	15.0	22.1	22.2	22.3	22.4	22.2	25.6	25.9	
EBITDA	(23.3)	(12.7)	(2.4)	(3.5)	(6.0)	(6.5)	(18.5)	(6.7)	(6.8)	(6.7)	(6.7)	(26.8)	(21.9)	2.6	
EBITDA margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	7.1%	
Growth analysis Y-O-Y	FY2012	FY2013	Mar-14	Jun-14	Sep-14	Dec-14	FY2014	Mar-15E	Jun-15E	Sep-15E	Dec-15E	FY2015	FY2016	FY2017	
Revenue	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	We assume mid-2017 launch with peak year 2021
COGS	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	
Gross profit	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	
Research and development (R&D)	NM	NM	NM	NM	NM	NM	46%	273%	117%	11%	2%	54%	-25%	-80%	
General and administrative (G&A)	NM	NM	NM	NM	NM	NM	44%	48%	42%	9%	3%	22%	3%	2%	
Sales and marketing (S&M)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	
Operating income (adjusted)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	-112%	
Net earning (adjusted)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	-102%	
EPS (adjusted)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	
Margin analysis	FY2012	FY2013	Mar-14	Jun-14	Sep-14	Dec-14	FY2014	Mar-15E	Jun-15E	Sep-15E	Dec-15E	FY2015	FY2016	FY2017	
Gross margin	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	92%	
R&D	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	9%	R&D growth could be higher - depends on pipeline
SG&A	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	18%	
Sales and marketing (S&M)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	58%	
Operating income (adjusted)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	7%	
Interest expense	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	-6%	
Interest income and other income (expense)	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	NM	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	NM	1%	

Source: Company data, RBC Capital Markets Research



Valuation

Our \$13 price target is based on (1) 30% M&A reflecting a 40% premium to fundamental price target and (2) 35% DCF and (3) 35% 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 DCF value is based on a 14% WACC and an explicit forecast through 2022 beyond which we assume a terminal growth rate of -25% assuming generic threats in that time period.

Price target impediments

Price target impediments include but are not limited to: 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; 5) competitive risks from other branded or generic contraceptives and (6) M&A takeout by a strategic acquirer

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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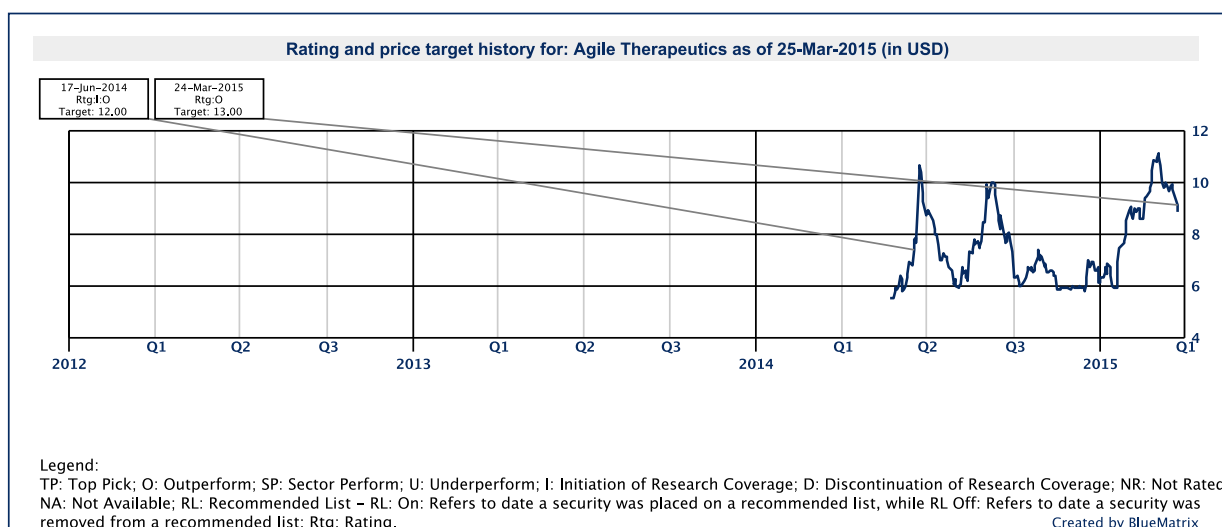
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			Count	Percent
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