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Agile Therapeutics Inc. (AGRX-NASDAQ)

AGRX: Positive Results for Twirla® Adhesion Study; NDA Resubmission in 2Q19…

Based on our probability adjusted DCF model that takes into account potential future revenues from Twirla®, AGRX is valued at $3.00/share. This model is highly dependent upon Twirla® attaining regulatory approval and its commercial success and will be adjusted accordingly based upon regulatory and commercial outcomes.

Current Price (02/12/19)	$0.91
Valuation	**$3.00**

OUTLOOK

On February 11, 2019, Agile Therapeutics, Inc. (AGRX) announced positive topline results for the comparative adhesion study between Twirla® and Xulane®, the generic version of the contraceptive patch Ortho Evra®. Results showed a mean adhesion score of 0.14 and 0.39 for Twirla® and Xulane®, respectively, with a mean difference of -0.25 and upper 95% confidence limit of -0.16. Twirla® was to be deemed statistically non-inferior if the upper 95% confidence limit was less than +0.15, thus the study met that definition. The company will now work to get the NDA for Twirla® refiled during the second quarter of 2019 and then, assuming the NDA is accepted for review, prepare for an Advisory Committee meeting sometime in the second half of 2019, with approval possible before the end of 2019.

SUMMARY DATA

52-Week High	**$3.83**
52-Week Low	**$0.25**
One-Year Return (%)	**-73.38**
Beta	**0.32**
Average Daily Volume (sh)	**292,756**
Shares Outstanding (mil)	**34**
Market Capitalization ($mil)	**$31**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**42**
Insider Ownership (%)	**7**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**-1.0**
P/E using 2019 Estimate	**-1.0**

Risk Level	**High**
Type of Stock	**Small-Value**
Industry	**Med-Generic Drug**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	0 A	0 A	0 A	0 A	0 A
2018	0 A	0 A	0 A	0 E	0 E
2019					0 E
2020					7.7 E

Earnings Per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2017	-$0.26 A	-$0.26 A	-$0.22 A	-$0.18 A	-$0.91 A
2018	-$0.20 A	-$0.16 A	-$0.11 A	-$0.11 E	-$0.61 E
2019					-$0.66 E
2020					-$0.79 E

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WHAT'S NEW

Business Update

Adhesion Study Successful

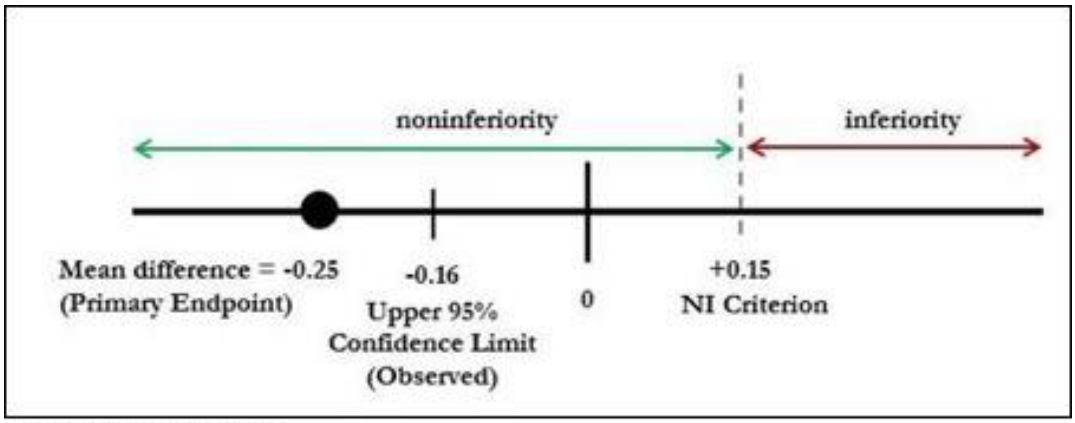
On February 11, 2019, Agile Therapeutics, Inc. (AGRX) announced positive topline results for the comparative adhesion study that tested the company's investigational low-dose once-weekly contraceptive patch (Twirla®) against Xulane®, the generic version of the contraceptive patch Ortho Evra®. The trial was designed to show non-inferiority in adhesion between Twirla® and Xulane®. It was a randomized, open label, crossover adhesion study that randomized a total of 83 women between the ages of 18-35 years and a body mass index (BMI) <35 kg/m^2. Seventy-nine subjects completed the study and 77 were included in the per protocol population for the primary analysis. Study subjects were randomized to wear either Twirla® or Xulane® for one week and then switch to the other patch for the second week. Adhesion of each patch was quantified daily through the following scale:

0 = ≥ 90% adhered (essentially no lift off the skin)
1 = ≥ 75% to < 90% adhered (only some edges lift off the skin)
2 = ≥ 50% to < 75% adhered (less than half is lifted off the skin
3 = > 0% to < 50% adhered (not detached, but more than half lifts off the skin)
4 = 0% adhered (detached and completely off the skin)

Results showed that the mean adhesion score difference between Twirla® and Xulane® was -0.25 with the upper bound of the 95% confidence limit for the mean difference of -0.16. Following discussion with the FDA in December 2018, it was decided that Twirla® would be considered statistically non-inferior to Xulane® if the upper 95% confidence limit of the mean difference was less than +0.15, thus Twirla® met the definition of non-inferiority. The negative value for the difference in mean adhesion score indicates that the mean score for Xulane® was higher than the mean score for Twirla®. The results are summarized below.

	Twirla		Xulane		Difference (Twirla - Xulane)		
	N	Mean (SD)	N	Mean (SD)	Mean (SD)	One-sided upper 95% CI	Non-inferior?
Adhesion Score	77	0.14 (0.28)	77	0.39 (0.40)	-0.25 (0.23)	-0.16	Yes

Source: Agile Therapeutics, Inc. / Zacks SCR



Source: Agile Therapeutics, Inc.

The company will now turn its full attention to getting the New Drug Application (NDA) resubmitted, which we expect to be completed during the first half of 2019. We anticipate an Advisory Committee ("AdComm") taking place to discuss the Pearl Index values from the Phase 3 trial. In addition, we anticipate an inspection of the third-party manufacturer's facility taking place prior to approval. If the NDA is submitted in the first half of 2019, with a six-month review period Twirla® could be approved before the end of 2019.

Conclusion

We are glad to see that the adhesion study for Twirla® was a success and the company can now fully focus on getting the NDA resubmitted before the end of the first half of 2019. We currently estimate that the company has sufficient capital to fund operations through the second quarter of 2019, but will require additional capital to fund operations beyond that, including any pre-commercialization activities and the commercial launch of Twirla®, if approved. Based on the successful results of the adhesion study we have slightly increased the probability of approval for Twirla®, which has increased our valuation to $3.00.

PROJECTED FINANCIALS

Agile Therapeutics, Inc.	2017 A	Q1 A	Q2 A	Q3 A	Q4 E	2018 E	2019 E	2020 E
Twirla	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$7.7**
YOY Growth	-	-	-	-	-	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*
Licensing / Development	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
Total Revenues	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$7.7
YOY Growth	*#DIV/0!*	*#REF!*	*#REF!*	*#REF!*	*#REF!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*
Cost of Goods Sold	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$6.0
Product Gross Margin	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*22.1%*
SG&A	$12.4	$3.1	$2.3	$1.8	$2.0	$9.2	$20.0	$30.0
% SG&A	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*389.6%*
R&D	$14.4	$4.0	$2.4	$1.5	$1.8	$9.7	$11.0	$12.5
% R&D	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*162.3%*
Other Exp.	$0	$0.0	$0.4	$0.3	$0.0	$0.7	$0.0	$0.0
% Other	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*0.0%*
Operating Income	($26.8)	($7.0)	($5.1)	($3.6)	($3.8)	($19.6)	($31.0)	($40.8)
Operating Margin	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*-529.9%*
Interest Income / Net	($1.5)	($0.3)	($0.2)	($0.2)	($0.4)	($1.6)	($0.5)	($0.5)
Pre-Tax Income	($28.3)	($7.3)	($5.3)	($3.8)	($4.2)	($21.2)	($31.5)	($41.3)
Taxes	$0	($0)	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($28.3)	($6.8)	($5.3)	($3.8)	($4.2)	($21.2)	($31.5)	($41.3)
YOY Growth	*-1.5%*	-	-	-	-	*-25.1%*	*48.5%*	*31.1%*
Net Margin	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*-536.4%*
Reported EPS	($0.91)	($0.20)	($0.16)	($0.11)	($0.11)	($0.61)	($0.66)	($0.79)
Fully Diluted Shares	30.9	34.2	34.3	34.4	37.0	35.0	48.0	52.0

Source: David Bautz, PhD - Zacks Investment Research, Inc.

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