

Agile Therapeutics Inc.

(AGRX-NASDAQ)

AGRX: Numerous Catalysts in 2019...

Based on our probability adjusted DCF model that takes into account potential future revenues from Twirla®, AGRX is valued at \$4.00/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 (03/14/19) **\$1.65**
Valuation **\$4.00**

OUTLOOK

On March 12, 2019, Agile Therapeutics, Inc. (AGRX) announced financial results for the 2018 and provided a business update. Agile is set for an eventful 2019, as the company will be resubmitting the NDA for Twirla® in the second quarter of 2019, will likely have an Advisory Committee meeting in late third quarter or early fourth quarter of 2019, and a potential approval of Twirla® before the end of 2019. The company recently completed a private placement that resulted in gross proceeds of \$7.8 million and we believe the company has sufficient capital to fund operations into the fourth quarter of 2019, but will require additional capital to fund the launch and commercialization of Twirla®.

SUMMARY DATA

52-Week High **\$3.70**
52-Week Low **\$0.25**
One-Year Return (%) **-51.45**
Beta **0.36**
Average Daily Volume (sh) **915,942**

Shares Outstanding (mil) **34**
Market Capitalization (\$mil) **\$57**
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-Blend**
Industry **Med-Generic Drug**

ZACKS ESTIMATES

Revenue

(in millions of \$)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	0 A	0 A	0 A	0 A	0 A
2019	0 E	0 E	0 E	0 E	0 E
2020					7.7 E
2021					47.1 E

Earnings Per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2018	-\$0.20 A	-\$0.16 A	-\$0.11 A	-\$0.11 A	-\$0.58 A
2019	-\$0.11 E	-\$0.10 E	-\$0.08 E	-\$0.08 E	-\$0.39 E
2020					-\$0.71 E
2021					-\$0.12 E

WHAT'S NEW

Business Update

Agile Therapeutics, Inc. (AGRX) is a women's healthcare company focused on developing healthcare products to fulfill the unmet contraceptive needs of women. The company's lead candidate product, Twirla[®] (AG200-15), is a once-weekly low-dose hormonal contraceptive patch that contains the active ingredients ethinyl estradiol (EE, a synthetic estrogen) and levonorgestrel (LNG, a type of progestin). The patch utilizes the company's Skinfusion technology, which allows Twirla[®] to be the first contraceptive patch capable of delivering LNG across the skin in a reliable manner. The company has conducted a comprehensive development program for Twirla[®] that includes three Phase 3 clinical trials. Following receipt of a complete response letter (CRL) in Dec. 2017 for the new drug application (NDA) filed for Twirla[®], the company pursued a formal dispute resolution with the FDA, which the agency denied. However, the FDA provided an alternative pathway to approval by recommending the company perform a comparative wear study to compare the adhesion profile of Twirla[®] to that of Xulane[®], the generic version of the contraceptive patch Ortho Evra[®]. The company successfully completed the comparative wear study and is now prepared to refile the NDA.

Multiple Catalyst Ahead in 2019

Agile now has all the pieces in place for a path to approval for Twirla[®]:

- The NDA will be refiled in the second quarter of 2019. This will be a complete response to the CRL received in Dec. 2017 and will include results from the comparative wear study (discussed below), additional information on the company's manufacturing process, and additional analyses that were performed as a response to issues brought up in the CRL.
- We anticipate that an Advisory Committee ("AdComm") meeting will take place during the second half of 2019 to discuss the Twirla[®] NDA and will likely focus on the safety and efficacy of Twirla[®], which could include a discussion of the Pearl Index from the Phase 3 Secure trial.
- A reinspection of the third-party manufacturing facility will likely take place during the second half of 2019.
- Assuming the NDA is refiled in the second quarter of 2019, and given a six-month review period, we anticipate a PDUFA date near the end of 2019.

Adhesion Study Successful

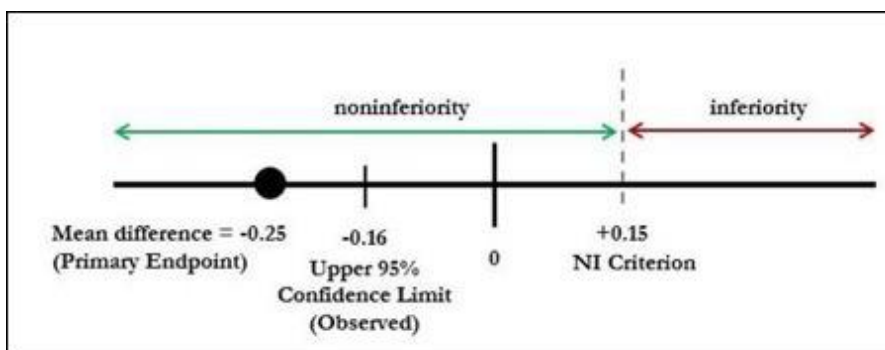
On February 11, 2019, Agile Therapeutics, Inc. (AGRX) [announced](#) positive topline results for the comparative adhesion study that tested the company's investigational low-dose once-weekly contraceptive patch (Twirla[®]) against Xulane[®], the generic version of the contraceptive patch Ortho Evra[®]. 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/m². 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.

Financial Update

On March 12, 2019, Agile [reported](#) financial results for the fourth quarter and full year 2018. As expected, the company did not report any revenues for the fourth quarter of full year 2018. Net loss for the fourth quarter of 2018 was \$3.8 million, or \$0.11 per share, compared to a net loss of \$6.2 million, or \$0.18 per share, for the fourth quarter of 2017. R&D expenses in the fourth quarter of 2018 were \$1.9 million compared to \$2.7 million for the fourth quarter of 2017. G&A expenses in the fourth quarter of 2018 were \$1.6 million compared to \$3.3 million for the corresponding time period in 2017.

Net loss for 2018 was \$19.8 million, or \$0.58 per share, compared to a net loss of \$28.3 million, or \$0.91 per share, in 2017. R&D expenses in 2018 were \$9.8 million compared to \$14.4 million in 2017. The decrease in R&D expenses is primarily due to a decrease in manufacturing expenses, clinical development expenses, and regulatory expenses. G&A expenses in 2018 were \$8.7 million compared to \$12.4 million in 2017. The decrease was primarily due to decreased commercial development expenses and professional fees partially offset by an increase in personnel costs.

As of Dec. 31, 2018, Agile had approximately \$7.9 million in cash and cash equivalents. In March 2018, the company [announced](#) a private placement of approximately 8.4 million shares at \$0.93 per share for gross proceeds of \$7.8 million. We estimate that the company currently has sufficient capital to fund operations into the fourth quarter of 2018, however it will require additional funds for the launch and commercialization of Twirla®, if approved.

Conclusion

Agile is set up for an exciting 2019, as all the pieces are in place for the resubmission of the Twirla® NDA and its potential approval in late 2019. The stock has had a nice run recently following the news of the positive adhesion study and the private placement, however we see additional upside in the shares ahead of all the catalysts to come in 2019. We believe the third time will be the charm and Twirla® will be approved in late 2019 with a commercial launch in 2020. We estimate peak sales of \$400 million in 2027 and applying a 13% discount rate our discounted cash flow model yields a current valuation of \$4 per share.

PROJECTED FINANCIALS

Agile Therapeutics, Inc.	2018 A	Q1 E	Q2 E	Q3 E	Q4 E	2019 E	2020 E	2021 E
Twirla	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$7.7	\$47.1
<i>YOY Growth</i>	-	-	-	-	-	-	#DIV/0!	511.7%
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	\$7.7	\$47.1
<i>YOY Growth</i>	-	-	-	-	-	-	-	511.7%
Cost of Goods Sold	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$6.0	\$6.0
<i>Product Gross Margin</i>	-	-	-	-	-	-	22.1%	87.3%
SG&A	\$8.7	\$1.8	\$2.0	\$2.1	\$2.3	\$8.2	\$30.0	\$35.0
<i>% SG&A</i>	-	-	-	-	-	-	389.6%	74.3%
R&D	\$9.8	\$3.3	\$2.1	\$1.5	\$1.7	\$8.6	\$10.0	\$12.5
<i>% R&D</i>	-	-	-	-	-	-	129.9%	26.5%
Other Exp.	\$1.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0	\$0.0
<i>% Other</i>	-	-	-	-	-	-	0.0%	0.0%
Operating Income	(\$19.5)	(\$5.1)	(\$4.1)	(\$3.6)	(\$4.0)	(\$16.8)	(\$38.3)	(\$6.4)
<i>Operating Margin</i>	-	-	-	-	-	-	-497.4%	-13.6%
Interest Income / Net	(\$0.7)	(\$0.3)	(\$0.2)	(\$0.2)	\$0.1	(\$0.5)	(\$0.5)	(\$0.5)
Pre-Tax Income	(\$20.3)	(\$5.4)	(\$4.3)	(\$3.8)	(\$3.9)	(\$17.3)	(\$38.8)	(\$6.9)
Taxes	(\$0)	(\$0)	\$0	\$0	\$0	\$0	\$0	\$0
<i>Tax Rate</i>	0%	0%	0%	0%	0%	0%	0%	0%
Net Income	(\$19.8)	(\$4.9)	(\$4.3)	(\$3.8)	(\$3.9)	(\$17.3)	(\$38.8)	(\$6.9)
<i>YOY Growth</i>	-30.1%	-	-	-	-	-12.5%	124.3%	-82.2%
Reported EPS	(\$0.58)	(\$0.11)	(\$0.10)	(\$0.08)	(\$0.08)	(\$0.39)	(\$0.71)	(\$0.12)
Fully Diluted Shares	34.3	43.0	44.0	45.0	46.0	44.5	55.0	60.0

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

HISTORICAL STOCK PRICE



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