

Agile Therapeutics Inc.

(AGRX-NASDAQ)

AGRX: Twirla® Adhesion Study Underway; NDA Resubmission in 2Q19...

Based on our probability adjusted DCF model that takes into account potential future revenues from Twirla®, AGRX is valued at \$2.50/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 (01/11/19) **\$0.79**
Valuation **\$2.50**

OUTLOOK

Agile Therapeutics, Inc. (AGRX) recently conducted a meeting with the FDA's Division of Bone, Reproductive, and Urologic Products (DBRUP) in regards to the comparative adhesion study between Twirla® and Xulane®, the generic version of the contraceptive patch Ortho Evra®. Following receipt of the official meeting minutes, the company announced the adhesion study is now underway. It will be crossover wear study in approximately 80 women with a body mass index (BMI) < 35 kg/m². Subjects will wear Twirla® or Xulane® for the first week and switch to the other patch for the second week. We believe the study will complete in the first quarter of 2019, leaving Agile in a position to resubmit the NDA in the second quarter of 2019 and potentially receive approval before the end of 2019.

SUMMARY DATA

52-Week High **\$3.83**
52-Week Low **\$0.25**
One-Year Return (%) **-75.54**
Beta **-0.16**
Average Daily Volume (sh) **318,485**

Shares Outstanding (mil) **34**
Market Capitalization (\$mil) **\$27**
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

WHAT'S NEW

Business Update

Comparative Adhesion Study Underway

On January 10, 2018, Agile Therapeutics, Inc. (AGRX) [announced](#) receipt of the official meeting minutes from its Dec. 11, 2018 meeting with the U.S. Food and Drug Administration (FDA) Division of Bone, Reproductive and Urological Products (DBRUP). The meeting was held to discuss the company's comparative wear study between Twirla[®] and Xulane[®], the generic version of the contraceptive patch Ortho Evra[®], including the specific design and success criteria. The trial is designed to show non-inferiority in adhesion between Twirla[®] and Xulane[®]. Following receipt of the official meeting minutes, Agile has initiated the adhesion study in approximately 80 healthy women with a body mass index (BMI) <35 kg/m². Study subjects will wear either Twirla[®] or Xulane[®] for one week and then switch to the other patch for the second week. Adhesion of each patch will be quantified daily. Quantification of adhesion will be assessed through the following scale, which assigns a score based on the adhered surface area:

- 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)

The primary endpoint of the study will be the mean adhesion score. We anticipate the study completing in the first quarter of 2019.

Assuming the comparative adhesion study completes in the first quarter of 2019, we believe Agile will be able to resubmit the NDA for Twirla[®] in the second quarter 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 Agile has initiated the comparative wear study and we look forward to the results later in the first quarter of 2019. The study design is straight forward and we are confident that the trial will be a success. We currently estimate that the company has sufficient capital to fund operations through the second quarter of 2019 (which includes completion of the adhesion study), but will require additional capital to fund operations beyond that, including any pre-commercialization activities and the commercial launch of Twirla[®], if approved. Our current valuation is \$2.50.

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
<i>YOY Growth</i>	-	-	-	-	-	#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
<i>YOY Growth</i>	#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
<i>Product Gross Margin</i>	#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
<i>% SG&A</i>	#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
<i>% R&D</i>	#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
<i>% Other</i>	#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)
<i>Operating Margin</i>	#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
<i>Tax Rate</i>	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)
<i>YOY Growth</i>	-1.5%	-	-	-	-	-25.1%	48.5%	31.1%
<i>Net Margin</i>	#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.

HISTORICAL STOCK PRICE



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