

Agile Therapeutics Inc.

(AGRX-NASDAQ)

AGRX: Files Formal Dispute Resolution with the FDA...

Based on our probability adjusted DCF model that takes into account potential future revenues from Twirla®, AGRX is valued at \$1.50/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 (06/08/18) \$0.60
Valuation \$1.50

OUTLOOK

On June 7, 2018, Agile Therapeutics, Inc. (AGRX) announced that the company has filed a formal dispute resolution request with the FDA in regards to Twirla®, the company's once-weekly low-dose combination hormonal contraceptive patch that has completed three Phase 3 clinical trials. Following receipt of a CRL in Dec. 2017, the company conducted a Type A meeting with the FDA and the minutes from that meeting stated that the FDA still had significant concerns regarding the adhesion properties of Twirla® that could not be addressed through the company's proposed patient compliance program. A meeting with the Office Director will take place within 30 days, after which the Director will provide a decision within 30 days.

In addition, the company announced a 30% reduction in workforce such that the company's cash and cash equivalents are now expected to fund operations into 2Q19.

SUMMARY DATA

52-Week High \$5.37
52-Week Low \$0.54
One-Year Return (%) -84.69
Beta 1.79
Average Daily Volume (sh) 1,277,917

Shares Outstanding (mil) 34
Market Capitalization (\$mil) \$20
Short Interest Ratio (days) N/A
Institutional Ownership (%) 72
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 E	0 E	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	-\$0.17 E	-\$0.15 E	-\$0.13 E	-\$0.66 E
2019					-\$0.66 E
2020					-\$0.79 E

WHAT'S NEW

Business Update

Formal Dispute Resolution Request Filed with FDA

On June 7, 2018, Agile Therapeutics, Inc. (AGRX) [announced](#) that the company has filed a formal dispute resolution request with the FDA in regards to Twirla[®], the company's once-weekly low-dose combination hormonal contraceptive patch that has completed three Phase 3 clinical trials. As a reminder, Agile filed an NDA for Twirla[®] in the first half of 2017 and received a complete response letter in Dec. 2017. Following a Type A meeting with the FDA, the official meeting minutes stated that the agency still had significant concerns regarding the adhesion properties of Twirla[®] that could not be addressed through the company's proposed patient compliance program. Agile disagreed with this assessment and thus has begun formal dispute resolution proceedings.

We believe the dispute will be reviewed by the Office of Drug Evaluation II and that the company will have a meeting with the Office Director. This meeting is supposed to take place within 30 days of the dispute resolution request. Following the meeting, the Director will have 30 days to provide a decision.

FDA regulations for dispute resolution are governed by [21 CFR 10.75](#), which provides a mechanism whereby an applicant can obtain formal review of any FDA decision by the employee's supervisor. Regulation [21 CFR 314.103](#) governs dispute resolution as they pertain to NDA filings, specifically scientific or medical disputes, which are first handled by the Division Director, then the Office Director, and finally with the Center Director if the matter is still unresolved. For each step of the process, the FDA has 30 days in which to conduct a meeting with the company once its requested, after which it has 30 days to issue a formal response.

Financial Update

In addition to announcing the submission of the formal dispute resolution request with the FDA, the company also announced that it is reducing its workforce by approximately 30%, primarily from commercial and clinical operations, as a means to conserve cash during the resolution process. We now anticipate the company's current cash reserves will fund operations into the second quarter of 2019.

Conclusion

We will be very interested to hear the outcome of the meeting with the Office Director regarding Twirla[®] and based on the 60-day turnaround for the meeting and response we believe the company should be able to provide an update before the end of the third quarter of 2018. While unfortunate, the reduction in workforce will provide the company with additional time to work through the resolution process, which is very difficult to predict the outcome of at this point. Our valuation remains at \$1.50.

PROJECTED FINANCIALS

Agile Therapeutics, Inc.	2017 A	Q1 A	Q2 E	Q3 E	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	\$3.1	\$2.7	\$2.5	\$11.4	\$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	\$2.3	\$2.0	\$1.8	\$10.1	\$11.0	\$12.5
<i>% R&D</i>	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	#DIV/0!	162.3%
Operating Income	(\$26.8)	(\$7.0)	(\$5.4)	(\$4.7)	(\$4.3)	(\$21.4)	(\$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)	(\$0.4)	(\$0.4)	(\$0.4)	(\$1.6)	(\$0.5)	(\$0.5)
Pre-Tax Income	(\$28.3)	(\$7.3)	(\$5.8)	(\$5.1)	(\$4.7)	(\$23.0)	(\$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)	(\$5.8)	(\$5.1)	(\$4.7)	(\$23.0)	(\$31.5)	(\$41.3)
<i>YOY Growth</i>	-1.5%	-	-	-	-	-18.6%	36.7%	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)	(\$0.17)	(\$0.15)	(\$0.13)	(\$0.66)	(\$0.66)	(\$0.79)
Fully Diluted Shares	30.9	34.2	34.3	34.3	37.0	35.0	48.0	52.0

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

HISTORICAL STOCK PRICE



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