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Agile Therapeutics Inc. (AGRX-NASDAQ)

AGRX: Formal Dispute Resolution Continues to Office of New Drugs…

Based on our probability adjusted DCF model that takes into account potential future revenues from Twirla®, AGRX is valued at $0.75/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 (08/09/18)	$0.28
Valuation	**$0.75**

OUTLOOK

On July 24, 2018, Agile Therapeutics, Inc. (AGRX) announced that the FDA's Office of Drug Evaluation III (ODEIII) has denied the company's appeal of the complete response letter issued for the new drug application of Twirla®. The appeal was in regard to the FDA's decision that the *in vivo* adhesion properties of Twirla® were not sufficient to support approval. The company is planning to appeal the decision of the ODEIII to the Office of New Drugs.

The company exited the second quarter of 2018 with approximately $22 million in cash and cash equivalents, which we believe is sufficient to fund current operations into the second quarter of 2019. If the company is successful in the dispute resolution it will need to raise significant additional capital in order to perform the pre-commercialization activities for Twirla®, and if approved the commercial launch of the product.

SUMMARY DATA

52-Week High	**$5.31**
52-Week Low	**$0.27**
One-Year Return (%)	**-91.14**
Beta	**1.48**
Average Daily Volume (sh)	**568,329**
Shares Outstanding (mil)	**34**
Market Capitalization ($mil)	**$10**
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 A	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	-$0.16 A	-$0.14 E	-$0.12 E	-$0.63 E
2019					-$0.66 E
2020					-$0.79 E

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WHAT'S NEW

Business Update

Office of Drug Evaluation III Denies Appeal

On July 24, 2018, Agile Therapeutics, Inc. (AGRX) announced that the FDA's Office of Drug Evaluation III (ODEIII) has denied the company's appeal of the complete response letter issued for the new drug application of Twirla®. The appeal was in regard to the FDA's decision that the *in vivo* adhesion properties of Twirla® were not sufficient to support approval. The company is planning to appeal the decision of the ODEIII to the Office of New Drugs.

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.

The next appeal for Agile will occur with the director of the Office of New Drugs. Janet Woodcock is the Acting Director of the Office of New Drugs; however, she is also the Director of the Center for Drug Evaluation and Research (CDER). Thus, since she would be meeting with Agile as the Director of CDER if the appeal process went up another level, we anticipate that she will appoint someone to meet with the company in her place for this next appeal meeting.

To help investors get a better sense of how often formal dispute resolutions are successful, we located a paper that analyzed dispute resolution outcomes for CDER for fiscal years 2003 through 2014 (Sharma *et al*., 2016). During that time period, there were 137 appeal issues received, although since sponsors can appeal the same issue more than once (and each is regarded as a unique appeal) there were a total of 173 unique appeals. Of those 173 unique appeals, 140 (81%) were accepted for review while 25 (14%) were refused and eight (5%) were withdrawn by the sponsor prior to CDER deciding whether to accept the appeal or not. Of the 140 unique appeals reviewed, 23 (16%) were granted while 117 (84%) were denied. In addition, the paper noted that over the 12-year period examined, 29 of the 137 appeal issues received were appealed to multiple management levels. During that time, there was only one case in which the appeal was granted at a higher level. Based on this data, it's difficult to come to any other conclusion than a positive outcome for Agile's dispute resolution being very unlikely.

Financial Update

On August 3, 2018, Agile announced financial results for the second quarter of 2018. As expected, the company did not record any revenues. Net loss for the quarter was $5.3 million, or $0.16 per share. R&D expenses for the second quarter of 2018 totaled $2.4 million, compared to $3.8 million for the second quarter of 2017. The decrease in R&D expenses was primarily attributable to a decrease in clinical development, regulatory, and manufacturing commercialization expenses. G&A expenses for the second quarter of 2018 totaled $2.3 million, compared to $3.2 million in the second quarter of 2017. The decrease was primarily due to a decrease in commercial development expenses.

Cash burn for the second quarter of 2018 totaled $4.2 million and the company exited the second quarter of 2018 with approximately $22.5 million in cash and cash equivalents. We believe this is sufficient to fund current operations into the second quarter of 2019, however the company will require significant additional amounts of capital in order to perform pre-commercialization activities and to launch Twirla®, if

approved. As of August 2, 2018, the company had approximately 34.4 million shares outstanding, and when factoring in stock options and warrants a fully diluted share count of approximately 40.5 million.

Conclusion

We were disappointed to hear that the ODEIII denied the company's appeal, and we will be interested to hear the outcome of the meeting with the Office of New Drugs. If the appeal is granted, the company will have to refile the NDA, which we believe will include both an Advisory Committee meeting ("AdCom") and a six-month review time. Unfortunately, based on the data presented above, we believe that a positive outcome is very unlikely, and investors should be aware that if the next appeal is denied the company may be forced to consider alternative strategies (e.g., a reverse merger). Based on what we believe to be a very low likelihood for success with the appeal process, we have lowered our valuation to $0.75.

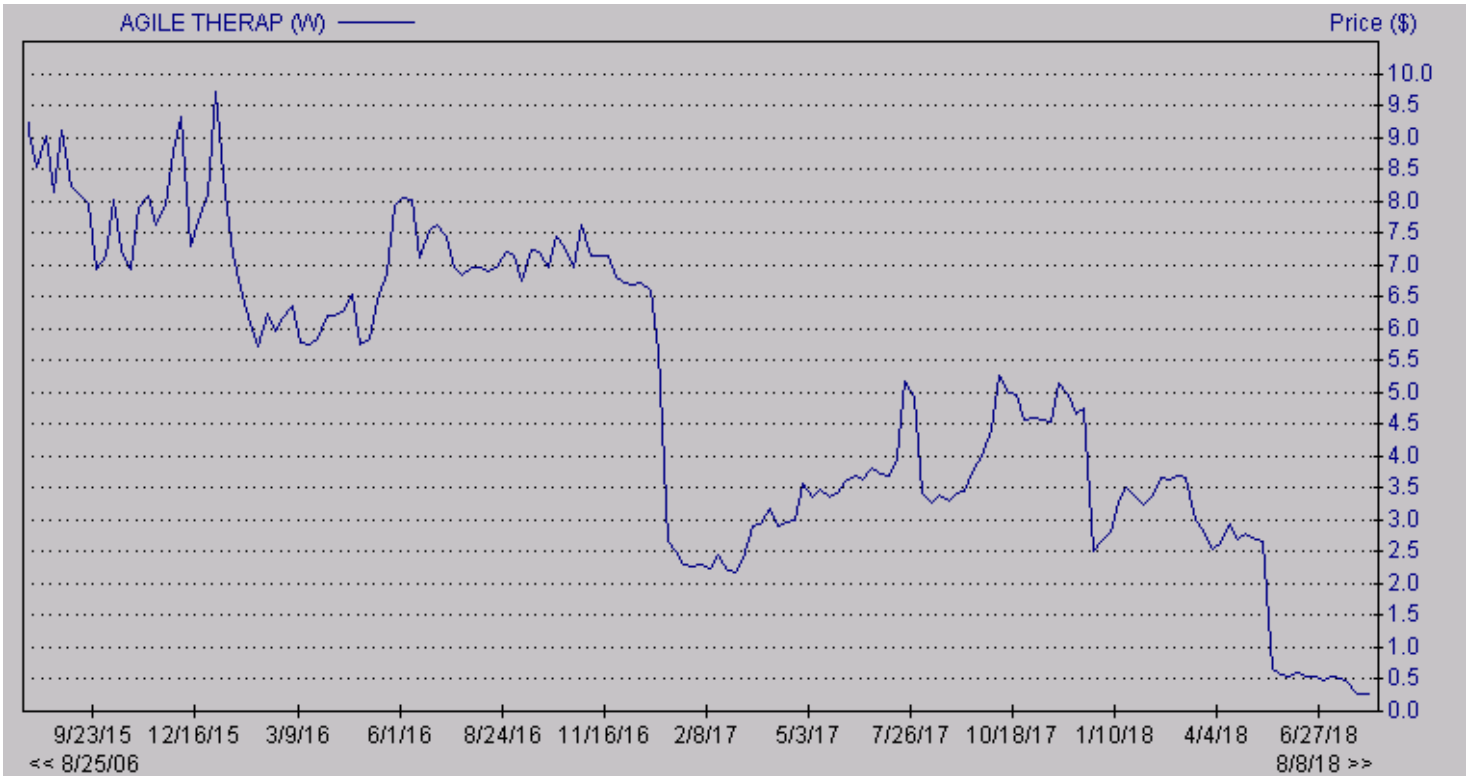
PROJECTED FINANCIALS

Agile Therapeutics, Inc.	2017 A	Q1 A	Q2 A	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**
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	$2.3	$2.3	$10.0	$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	$2.0	$1.8	$10.2	$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	$0.0	$0.0	$0.4	$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)	($4.3)	($4.1)	($20.6)	($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)	($0.4)	($0.4)	($1.6)	($0.5)	($0.5)
Pre-Tax Income	($28.3)	($7.3)	($5.3)	($4.7)	($4.5)	($22.2)	($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)	($4.7)	($4.5)	($22.2)	($31.5)	($41.3)
YOY Growth	*-1.5%*	-	-	-	-	*-21.6%*	*41.9%*	*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)	($0.14)	($0.12)	($0.63)	($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.

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