Zacks Small-Cap Research

Sponsored – Impartial - Comprehensive

May 22, 2018
David Bautz, PhD
312-265-9471
dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Agile Therapeutics Inc. (AGRX-NASDAQ)

AGRX: Determining a Path Forward Following Receipt of Meeting Minutes…

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 (05/22/18)	$0.69
Valuation	**$1.50**

OUTLOOK

Agile Therapeutics Inc. (AGRX) is developing Twirla®, a once-weekly low–dose combination hormonal contraceptive patch that has completed three Phase 3 clinical trials. In Dec. 2017, the company received a complete response letter (CRL) in response to the company's new drug application (NDA) for Twirla®. On May 18, 2018, the company provided an update on the content of the official minutes from the Type A meeting with the FDA. The FDA continues to have significant concerns with the adhesion properties of Twirla®, which the agency doesn't believe can be addressed with the currently available data. The company will likely pursue formal dispute resolution and has indicated that the current cash position should be sufficient to fund that process.

SUMMARY DATA

52-Week High	**$5.37**
52-Week Low	**$0.69**
One-Year Return (%)	**-79.34**
Beta	**2.12**
Average Daily Volume (sh)	**803,601**
Shares Outstanding (mil)	**34**
Market Capitalization ($mil)	**$24**
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	-$0.17 E	-$0.16 E	-$0.80 E
2019					-$0.95 E
2020					-$0.63 E

© Copyright 2018, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Business Update

Disclosure of Meeting Minutes

On May 18, 2018, Agile Therapeutics, Inc. (AGRX) announced the content of the official meeting minutes following the Type A meeting with the FDA. According to the minutes, the FDA continues to have significant concerns regarding the adhesion properties of Twirla®, which the agency does not believe can be addressed by the currently available data. The FDA stated that in order to address the concerns the company would need to reformulate the transdermal patch and conduct a formal adhesion study with the new formulation. Following that, a bioequivalence study would need to be performed between the old formulation and new formulation, and if bioequivalence was not shown a new Phase 3 study would need to be conducted with the new formulation. If bioequivalence was shown, the agency anticipated an advisory committee meeting taking place to obtain input on whether the benefits outweigh the risks for Twirla®.

During the conference call, management stated that they disagreed with the agency's conclusion and they believe that they have submitted all the data necessary to show that adhesion is not a major issue for Twirla®. In addition, the company has planned compliance and patient education programs that should satisfy the issues raised by the FDA. Management also stated that it likely does not make sense to reformulate or redesign the product, and that even if they were to do that a bioequivalence study for a patch is inherently difficult thus it would likely result in another Phase 3 trial being required.

While not official yet, the likely course of action for the company is going to be a formal dispute resolution with the FDA. 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.

We anticipate the company providing additional updates once a path forward is determined. As of March 31, 2018, the company had approximately $28 million in cash and cash equivalents, which we believe will allow them to fund operations for the dispute resolution as management has indicated that essentially all other activities for the company have been put on hold as a result of the feedback from the FDA.

Conclusion

The news from the FDA regarding Twirla® was not what we had anticipated and we will look for additional updates from the company regarding the path forward. Given the uncertainty surrounding Twirla's® regulatory pathway we have decreased our probability of approval to 50% and pushed out approval to 2020, although this could change based upon future company guidance. In addition, we believe the company will require more funding than initially thought as the company's current cash total will likely be used for the dispute resolution. Our current valuation is $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**
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	$3.0	$6.0	$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	$3.1	$2.7	$2.5	$11.4	$30.0	$40.0
% SG&A	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*519.5%*
R&D	$14.4	$4.0	$2.3	$2.0	$1.8	$10.1	$11.0	$12.5
% R&D	*#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)	($24.4)	($47.0)	($50.8)
Operating Margin	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*-659.7%*
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)	($26.0)	($47.5)	($51.3)
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)	($5.8)	($5.1)	($4.7)	($26.0)	($47.5)	($51.3)
YOY Growth	*-1.5%*	-	-	-	-	*-8.0%*	*82.4%*	*8.0%*
Net Margin	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*-666.2%*
Reported EPS	($0.91)	($0.20)	($0.17)	($0.15)	($0.13)	($0.75)	($0.99)	($0.99)
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.

© Copyright 2018, Zacks Investment Research. All Rights Reserved.

HISTORICAL STOCK PRICE



© Copyright 2018, Zacks Investment Research. All Rights Reserved.

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, David Bautz, PhD, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.