Zacks Small-Cap Research
Sponsored – Impartial - Comprehensive

March 23, 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: Meeting with FDA to Determine When Twirla® NDA can be Resubmitted…

Based on our probability adjusted DCF model that takes into account potential future revenues from Twirla®, AGRX is valued at $5.50/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 (03/23/18)	$2.93
Valuation	**$5.50**

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®. The company will be meeting with the FDA soon to determine the next steps to address all of the issues raised in the CRL. Once the minutes from that meeting are received the company will provide guidance on when the NDA can be resubmitted. Based on cutting back its pre-commercialization activities, we believe the company has sufficient cash to fund operations through 2018.

SUMMARY DATA

52-Week High	**$5.37**
52-Week Low	**$2.52**
One-Year Return (%)	**-1.01**
Beta	**1.91**
Average Daily Volume (sh)	**126,210**
Shares Outstanding (mil)	**34**
Market Capitalization ($mil)	**$100**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**71**
Insider Ownership (%)	**5**
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	**-4.2**
P/E using 2019 Estimate	**-5.6**

Risk Level	**High**
Type of Stock	**Small-Blend**
Industry	**Med-Drugs**

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 E	0 E	0 E	0 E	0 E
2019					7.5 E
2020					30.8 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	-$0.16 E	-$0.17 E	-$0.17 E	-$0.16 E	-$0.74 E
2019					-$0.95 E
2020					-$0.63 E

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

WHAT'S NEW

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 will be meeting with the FDA to determine what is necessary in order to refile the NDA.

Twirla® CRL

On December 22, 2017, Agile announced that the FDA issued a CRL for the company's NDA for Twirla®, the company's once-weekly low-dose hormonal contraceptive patch. The CRL identified three areas that the agency felt the company needed to address:

1) Deficiencies related to the quality adhesion test methods
2) Observations noted during an inspection of the facility of the third-party manufacturer (Corium International Inc.)
3) Questions related to the adhesive properties of Twirla® and whether there was any relationship to the results seen in the SECURE Phase 3 clinical trial.

Management provided additional information related to these issues in a conference call. First, the company developed a new validated quality adhesion test method, which took into account suggestions provided by the FDA, and the company filed an amendment to the NDA with the results of the new test on Dec. 1, 2017. However, the CRL stated that the amendment was not reviewed prior to issuance of the CRL. In addition, both Corium and Agile responded to the observations noted during the FDA's inspection of the manufacturing facility, which included deficiencies related both to Twirla® (which were related to the quality adhesion test methods) and other deficiencies not related to Twirla®. Lastly, the company does not believe there are any correlations between Twirla® adhesion and any of the results seen in the SECURE Phase 3 clinical trial, including such things as bleeding, the Pearl Index, or drop-out rate. This was the first clinical trial to have subjects measure adhesion on a daily basis and record it in a digital diary, thus there is a very large amount of data. The company believes that perhaps the FDA is not sure how to put all that data into context, and thus will work to better present that data to the agency such that it can be assured that adhesion did not play a role in any of the clinical data collected during the trial.

Agile has indicated that they have requested a Type A meeting with the FDA and that meeting should take place within 30 days of that request. Following the meeting, it will take approximately 30 days to receive the meeting minutes. Once those are received, the company will have a better sense of what will be required in order to resubmit the NDA. During the call to discuss the CRL, management indicated that it believes the agency has just about everything it needs to answer the questions it raised, however we won't know for certain until after Agile receives the official meeting minutes.

Abstract Presented at APhA 2018 Meeting

On March 14, 2018, Agile announced that an abstract was accepted for a poster presentation on the Phase 3 SECURE trial for Twirla® at the American Pharmacists Association (APhA) 2018 Annual Meeting. The poster describing the safety and efficacy results that were previously disclosed, including the bleeding and wearability/tolerability profile, was presented Saturday and Sunday, Mar. 17 and 18, 2018.

Financial Update

On March 12, 2018, Agile announced financial results for the fourth quarter and full year 2017. As expected, the company did not report any revenues. Net loss for the fourth quarter of 2017 was $6.2 million, or $0.18 per share, compared to a net loss of $5.2 million, or $0.18 per share, for the fourth quarter of 2016. R&D expenses in the fourth quarter of 2017 were $2.7 million compared to $5.5 million in the fourth quarter of 2016. G&A expenses in the fourth quarter of 2017 were $3.3 million compared to $2.3 million in the fourth quarter of 2016.

Net loss for 2017 was $28.3 million, or $0.91 per share, compared to a net loss of $28.7 million, or $1.02 per share, for 2016. R&D expenses in 2017 were $14.4 million compared to $20.9 million in 2016. The decrease in R&D expenses were due to decreased clinical trial costs partially offset by increased expenses associated with commercial manufacturing activities. G&A expenses $12.4 million in 2017 compared to $8.8 million in 2016. The increase in expenses was due to increased pre-commercialization activities.

As of Dec. 31, 2017, the company had approximately $35.9 million in cash and cash equivalents. Based on suspending the pre-commercialization activities for Twirla® we believe this will be sufficient to fund operations to the end of 2018, however the company will need to raise additional capital in order to commercialize Twirla®, if approved. As of March 9, 2018, the company had approximately 34.3 million shares outstanding and when factoring in stock options and warrants a fully diluted share count of approximately 38.6 million.

Conclusion

We will be very interested to hear the conclusions of the Type A meeting with the FDA and when the company believes it will be able to resubmit the Twirla® NDA. Importantly, the FDA did not indicate there were any issues with the safety of Twirla® in the CRL. At this time, we do not believe that additional clinical trials will be necessary. Once resubmitted, we anticipate the NDA will receive a 6-month review.

Our valuation is currently $5.50 based on launching Twirla® in 2019, which is our best guess at this point until management is able to provide additional guidance following its meeting with the FDA. We believe that management has given the FDA everything that they requested, and now it's just a matter of the agency having the time to go through all of the new information. We do not believe there are any inherent deficiencies with Twirla® or the data package compiled from the SECURE trial, and that the CRL is mostly a timing issue that will ultimately be resolved and lead to approval.

PROJECTED FINANCIALS

Agile Therapeutics, Inc.	2017 A	Q1 E	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**	**$7.5**	**$30.8**
YOY Growth	-	-	-	-	-	*#DIV/0!*	*#DIV/0!*	*310.7%*
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	$7.5	$30.8
YOY Growth	*#DIV/0!*	*#REF!*	*#REF!*	*#REF!*	*#REF!*	*#DIV/0!*	*#DIV/0!*	*310.7%*
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!*	*20.0%*	*80.5%*
SG&A	$12.4	$3.0	$3.1	$3.1	$3.1	$12.3	$30.0	$40.0
% SG&A	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*400.0%*	*129.9%*
R&D	$14.4	$2.2	$2.3	$2.3	$2.3	$9.1	$11.0	$12.5
% R&D	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*146.7%*	*40.6%*
Operating Income	($26.8)	($5.2)	($5.4)	($5.4)	($5.4)	($24.4)	($39.5)	($27.7)
Operating Margin	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*-526.7%*	*-89.9%*
Interest Income / Net	($1.5)	($0.4)	($0.4)	($0.4)	($0.4)	($1.6)	($0.5)	($0.5)
Pre-Tax Income	($28.3)	($5.6)	($5.8)	($5.8)	($5.8)	($26.0)	($40.0)	($28.2)
Taxes	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($28.3)	($5.6)	($5.8)	($5.8)	($5.8)	($26.0)	($40.0)	($28.2)
YOY Growth	*-1.5%*	-	-	-	-	*-8.1%*	*53.8%*	*-29.5%*
Net Margin	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*-533.3%*	*-91.6%*
Reported EPS	($0.91)	($0.16)	($0.17)	($0.17)	($0.16)	($0.74)	($0.95)	($0.63)
Fully Diluted Shares	30.9	34.2	34.3	34.3	37.0	35.0	42.0	45.0

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.