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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: Waiting on Meeting Minutes from FDA; Planning for 2Q18 Twirla® NDA Resubmission…

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 (05/14/18)	$2.68
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 is currently awaiting the meeting minutes from the Type A meeting conducted with the FDA, after which it will provide an update on when the Twirla® NDA resubmission will occur. Based on cutting back its pre-commercialization activities, we believe the company has sufficient cash to fund operations through 2018, which also assumes a 2Q18 NDA resubmission and resumption of prelaunch commercialization activities following approval.

SUMMARY DATA

52-Week High	**$5.37**
52-Week Low	**$2.42**
One-Year Return (%)	**-23.65**
Beta	**2.12**
Average Daily Volume (sh)	**98,781**
Shares Outstanding (mil)	**34**
Market Capitalization ($mil)	**$92**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**71**
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	**-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 A	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	-$0.20 A	-$0.17 E	-$0.17 E	-$0.16 E	-$0.80 E
2019					-$0.95 E
2020					-$0.63 E

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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 held a Type A meeting with the FDA to determine what is necessary in order to refile the NDA. As soon as the minutes from that meeting are received the company will better be able to guide when the NDA resubmission will occur, however we currently believe it will be in the second quarter of 2018.

Financial Update

On May 7, 2018, Agile announced financial results for the first quarter of 2018. As expected, the company did not report any revenues. Net loss for the first quarter of 2018 was $6.8 million, or $0.20 per share, compared to a net loss of $7.5 million, or $0.26 per share, for the first quarter of 2017. R&D expenses in the first quarter of 2018 were $4.0 million compared to $4.7 million in the first quarter of 2017. The decrease was due to decreased clinical development expenses for the Phase 3 SECURE trial that was completed in 2017. G&A expenses in the first quarter of 2018 were $3.1 million compared to $2.4 million in the first quarter of 2017. The increase was primarily due to increased pre-commercialization activities in preparation for the launch of Twirla®, if approved.

As of Mar. 31, 2018, the company had approximately $28.3 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 May 4, 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.

Business Update

Waiting on Minutes from Type A FDA Meeting

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 at the time the CRL was issued. 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 held a Type A meeting with the FDA and is currently waiting 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. Right now, we anticipate the company being able to resubmit the NDA in the second quarter of 2018, however that won't be confirmed until the company gives an update once the meeting minutes are in hand.

Conclusion

We will be very interested to hear the conclusions of the Type A meeting with the FDA and to get confirmation on 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, thus if the company is able to resubmit in the second quarter of 2018 Twirla® could be approved before the end of 2018.

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 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**	**$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	$3.1	$3.1	$3.1	$3.1	$12.4	$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	$4.0	$2.3	$2.3	$2.3	$10.9	$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)	($7.0)	($5.4)	($5.4)	($5.4)	($26.2)	($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)	($0.3)	($0.4)	($0.4)	($0.4)	($1.6)	($0.5)	($0.5)
Pre-Tax Income	($28.3)	($7.3)	($5.8)	($5.8)	($5.8)	($27.8)	($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)	($6.8)	($5.8)	($5.8)	($5.8)	($27.8)	($40.0)	($28.2)
YOY Growth	*-1.5%*	-	-	-	-	*-1.6%*	*43.6%*	*-29.5%*
Net Margin	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*-533.3%*	*-91.6%*
Reported EPS	($0.91)	($0.20)	($0.17)	($0.17)	($0.16)	($0.80)	($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.

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