Zacks Small-Cap Research

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Agile Therapeutics Inc. (AGRX-NASDAQ)

AGRX: Questions About Adhesion Leads to CRL for Twirla®…

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 (12/28/17)	$2.84
Valuation	**$5.50**

OUTLOOK

On December 22, 2017, Agile Therapeutics Inc. (AGRX) announced that the FDA issued a complete response letter (CRL) in response to the company's new drug application (NDA) for Twirla®. The deficiencies identified by the FDA have to do with the quality control tests performed to test the patch's adhesion, observations noted during an inspection of the facility of the third party manufacturer (Corium International Inc.), and whether the patch's adhesion properties have any relationship to data observed in the SECURE Phase 3 clinical trial. The company will now meet with the FDA to determine the next steps to address all of the issues raised in the CRL. Now that the commercialization activities will not be occurring, the company should have sufficient capital to perform whatever tasks are necessary to resubmit the NDA.

SUMMARY DATA

52-Week High	**$6.62**
52-Week Low	**$2.04**
One-Year Return (%)	**-53.67**
Beta	**2.03**
Average Daily Volume (sh)	**1,064,976**
Shares Outstanding (mil)	**34**
Market Capitalization ($mil)	**$97**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**73**
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 2016 Estimate	**N/A**
P/E using 2017 Estimate	**N/A**

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

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	0 A	0 A	0 A	0 A	0 A
2017	0 A	0 A	0 A	0 E	0 E
2018					0 E
2019					19.2 E

Earnings per Share
(EPS is operating earnings before non recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2016	-$0.27 A	-$0.29 A	-$0.27 A	-$0.19 A	-$1.02 A
2017	-$0.26 A	-$0.26 A	-$0.22 A	-$0.23 E	-$0.97 E
2018					-$0.79 E
2019					-$0.63 E

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WHAT'S NEW

Business Update

FDA Issues CRL for Twirla®

On December 22, 2017, Agile Therapeutics, Inc. (AGRX) announced that the U.S. Food and Drug Administration (FDA) issued a complete response letter (CRL) for the company's new drug application (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 will request a meeting with the FDA to discuss the CRL after management believes it has had sufficient time to analyze the CRL in full. Following receipt of the meeting minutes (which will be provided to Agile within 30 days of the meeting), 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.

The company had previously guided for its current cash position to be sufficient to fund operations through the second quarter of 2018. However, that took into account expected spending on commercialization activities, which are being suspended due to the CRL. Management indicated that it will give full guidance on the company's cash runway following the meeting with the FDA, which we believe will likely

Conclusion

The CRL for Twira® is certainly disappointing, but we do not think there is anything insurmountable or that can't be addressed through additional data analysis or an alternative presentation of the data. At this time we do not believe that additional clinical trials will be necessary. Importantly, the FDA did not indicate there were any issues with the safety of Twirla®. Once the company is able to meet with the FDA to get clarity on what the agency needs we will get a better sense on when a resubmission can occur.

We have decreased our valuation to $5.50 based on pushing out the launch for Twirla® by a year, which is our best guess at this point until management is able to provide additional guidance following its meeting with the FDA. Again, 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.
Income Statement

Agile Therapeutics, Inc.	2016 A	Q1 A	Q2 A	Q3 A	Q4 E	2017 E	2018 E	2019 E
Twirla	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$19.2**
YOY Growth	-	-	-	-	-	-	*#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	$19.2
YOY Growth	-	*#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	$3.0
Product Gross Margin	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*84.4%*
SG&A	$8.8	$2.4	$3.2	$3.5	$3.5	$12.6	$15.0	$30.0
% SG&A	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*156.3%*
R&D	$20.9	$4.7	$3.8	$3.2	$3.3	$15.0	$15.0	$17.0
% R&D	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*88.5%*
Operating Income	($29.7)	($7.1)	($7.0)	($6.7)	($6.8)	($27.6)	($30.0)	($30.8)
Operating Margin	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*-160.4%*
Interest Income / Net	($2.1)	($0.4)	($0.5)	($0.4)	($0.5)	($1.7)	($1.6)	($0.5)
Pre-Tax Income	($31.8)	($7.5)	($7.4)	($7.1)	($7.3)	($29.4)	($31.6)	($31.3)
Taxes	($3)	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($28.7)	($7.5)	($7.4)	($7.1)	($7.3)	($29.4)	($31.6)	($31.3)
YOY Growth	*#REF!*	-	-	-	-	*2.2%*	*7.6%*	*-0.9%*
Net Margin	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*	*-163.0%*
Reported EPS	($1.02)	($0.26)	($0.26)	($0.22)	($0.23)	($0.97)	($0.79)	($0.63)
Fully Diluted Shares	28.3	28.8	28.8	31.9	32.0	30.4	40.0	50.0

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

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