# Zacks Small-Cap Research

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## Agile Therapeutics Inc. (AGRX-NASDAQ)

### *AGRX: Awaiting Details of Adhesion Study for Twirla®…*

Based on our probability adjusted DCF model that takes into account potential future revenues from Twirla®, AGRX is valued at $2.50/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 (11/05/18) | $1.05 |
| **Valuation** | **$2.50** |

## OUTLOOK

Agile Therapeutics, Inc. (AGRX) is developing Twirla®, a once-weekly low dose hormonal contraceptive patch. Following receipt of a complete response letter (CRL) in 2017, the company initiated a formal dispute resolution process with the U.S. FDA, which concluded in October 2018. The agency denied the company's appeal, however the FDA's Office of New Drugs (OND) provided the company with a potential path forward to allow an NDA resubmission without having to conduct extensive additional studies. Instead, OND suggested that Agile perform an adhesion similarity study comparing Twirla® and Xulane®, the generic version of the contraceptive patch Ortho Evra®. If that study is successful, Agile would be able to respond to the CRL, which would also allow the FDA to review the safety and efficacy of Twirla® and would likely include an advisory committee meeting. Once the company has had a chance to design the adhesion study we anticipate learning additional details and timelines for filing the NDA.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$5.17** |
| **52-Week Low** | **$0.25** |
| **One-Year Return (%)** | **-79.50** |
| **Beta** | **-0.95** |
| **Average Daily Volume (sh)** | **9,211,406** |
| **Shares Outstanding (mil)** | **34** |
| **Market Capitalization ($mil)** | **$32** |
| **Short Interest Ratio (days)** | **N/A** |
| **Institutional Ownership (%)** | **52** |
| **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 A | 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 | -$0.11 A | -$0.11 E | -$0.61 E |
| 2019 | | | | | -$0.66 E |
| 2020 | | | | | -$0.79 E |


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## WHAT'S NEW

### Business Update

*Office of New Drugs Provides Potential Path to NDA Resubmission*

On October 9, 2018, Agile Therapeutics, Inc. (AGRX) announced that the company has concluded the formal dispute resolution with the U.S. Food and Drug Administration (FDA) regarding the complete response letter (CRL) issued for the new drug application (NDA) of Twirla®. While the FDA's Office of New Drugs (OND) denied the company's appeal, the agency did provide the company with a potential path to an NDA resubmission that would not include reformulating Twirla® or doing any type of bridging studies. Instead, OND suggested that Agile perform an adhesion comparison study between Twirla® and Xulane®, the generic version of the contraceptive patch Ortho Evra®. Since Xulane® is considered to have an acceptable adhesion profile by the FDA, demonstrating equivalent adhesive properties between Twirla® and Xulane® would be sufficient to show that Twirla® has adequate adhesion.

The company still needs to meet with the FDA's Division of Bone, Reproductive and Urological Products (DBRUP) in order to come to an agreement about what the adhesion trial would look like. Following this meeting the company will release additional details about the trial, however at this point we estimate that the trial will likely be completed by the end of the first quarter of 2019. Regardless of the path forward, Agile is going to likely need two additional rounds of funding: one to take the company to an NDA resubmission and another for launching Twirla®, if approved.

If the adhesion properties of Twirla® are adequately addressed, the FDA will still need to review its safety and efficacy following resubmission of the NDA. This will likely include an Advisory Committee ("AdComm") meeting, at which time such issues as the Pearl Index will be discussed.

### Financial Update

On November 1, 2018, Agile announced financial results for the third quarter of 2018. As expected, the company did not report any revenues. Net loss for the third quarter of 2018 was $3.8 million, or $0.11 per share, compared to a net loss of $7.1 million, or $0.22 per share, for the third quarter of 2017. R&D expenses for the third quarter of 2018 were $1.6 million compared to $3.2 million for the third quarter of 2017. The decrease in expenses was due to decreased manufacturing and commercialization expenses as a result of the CRL received in 2017. G&A expenses totaled $1.8 million for the third quarter of 2018 compared to $3.5 million for the third quarter of 2017. The decrease was due to the suspension of pre-commercialization activities as a result of the CRL received in 2017.

Cash burn for the third quarter of 2018 totaled $3.2 million and the company exited the third quarter of 2018 with approximately $16.9 million in cash and cash equivalents. We estimate this is sufficient to fund operations in to the second quarter of 2019, however the company will require significant additional amounts of capital in order to fund the adhesion study, preparing for the Advisory Committee meeting, performing pre-commercialization activities, and to launch Twirla®, if approved. As of Nov. 1, 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

Even though the FDA denied the company's formal appeal, the details disclosed by the company regarding a potential path forward to an NDA resubmission are a clear positive and should be considered a "win". We look forward to hearing additional details about the adhesion study and particularly the anticipated timelines to an NDA resubmission. Now that there is a much clearer path to market we have increased the probability of approval for Twirla® to 70%, however investors should be aware that additional financings will likely be forthcoming to fund the company through the NDA resubmission and potentially for commercialization. Our valuation currently stands at $2.50.

## PROJECTED FINANCIALS

| Agile Therapeutics, Inc. | 2017 A | Q1 A | Q2 A | Q3 A | 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 | $1.8 | $2.0 | $9.2 | $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 | $1.5 | $1.8 | $9.7 | $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 | $0.3 | $0.0 | $0.7 | $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) | ($3.6) | ($3.8) | ($19.6) | ($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) | ($0.2) | ($0.4) | ($1.6) | ($0.5) | ($0.5) |
| Pre-Tax Income | ($28.3) | ($7.3) | ($5.3) | ($3.8) | ($4.2) | ($21.2) | ($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) | ($3.8) | ($4.2) | ($21.2) | ($31.5) | ($41.3) |
| *YOY Growth* | *-1.5%* | - | - | - | - | *-25.1%* | *48.5%* | *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) | ($0.11) | ($0.11) | ($0.61) | ($0.66) | ($0.79) |
| Fully Diluted Shares | 30.9 | 34.2 | 34.3 | 34.4 | 37.0 | 35.0 | 48.0 | 52.0 |

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

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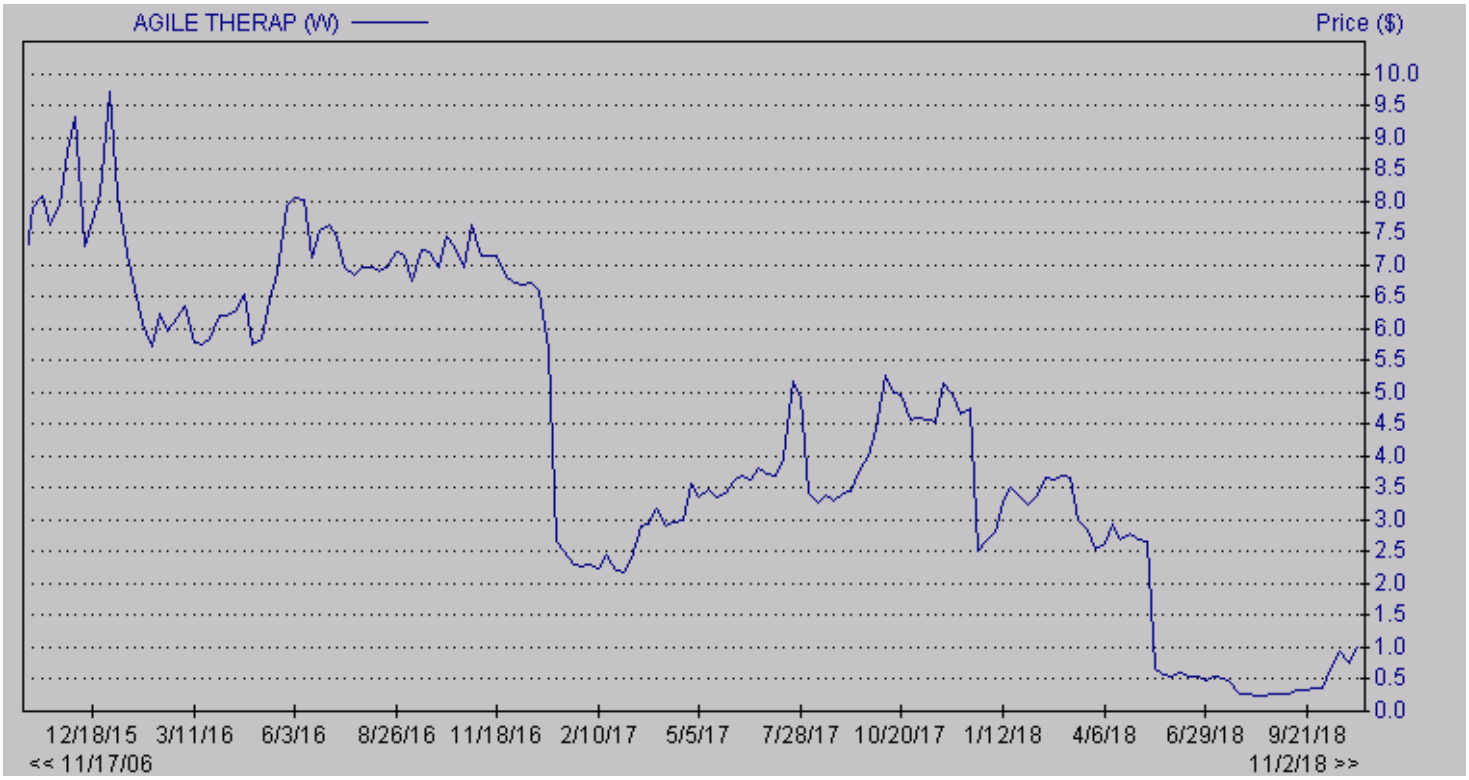
## HISTORICAL STOCK PRICE

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