

Agile Therapeutics

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Agile Therapeutics has productive 2Q, on track to seek approval for Twirla contraceptive patch

Agile Therapeutics Inc (NASDAQ:AGRX) chairman and chief executive officer Al Altomari said Thursday that the second quarter was "very productive" for the company and it is on track to seek approval for its lead product candidate Twirla.

The company said executives will meet with the US Food and Drug Administration's advisory committee on October 30 to review the company's New Drug Application (NDA) for Twirla, a low-dose prescription contraceptive delivered through the skin via the company's proprietary patch.

The Princeton, New Jersey-based women's health-care company announced last month that the FDA had accepted for review the NDA resubmission for Twirla. The company had originally submitted an application for FDA approval in June 2017, but the agency asked for more data.

READ: Agile Therapeutics to meet FDA committee in October to review NDA for Twirla

Agile resubmitted the NDA for Twirla (AG200-15) on May 16, 2019 and the FDA has assigned a Prescription Drug User Fee Act action date of November 16, 2019 for the completion of its review.

Altomari said: "Between the resubmission and acceptance of our Twirla NDA as well as the announcement of the advisory committee meeting, we believe we are on track to seek the approval of Twirla."

Research firm Oppenheimer predicts the Twirla contraceptive patch could drive sales of \$250 million to \$300 million.

Currently there is only one US government-approved contraceptive patch available to women - Xulane, which is produced by Mylan Pharmaceuticals Inc (NASDAQ:MYL).

Important contraception option

"We continue to believe that Twirla, if approved, will provide women with an important contraception option they do not currently have — a once-weekly contraceptive patch designed to deliver a low dose of estrogen," said Altomari.

Analysts expect Twirla to have safety advantages to Xulane, given the latter's issues with high estrogen levels. They also think women will find Twirla more user-friendly than Xulane, which had gross sales of \$271 million in 2018.

Twirla is designed to be applied once weekly for three weeks, followed by a week without a patch. The company has eight patents covering Twirla. Its active ingredients are ethinyl estradiol, a type of synthetic estrogen, and levonorgestrel, a type of progestin.

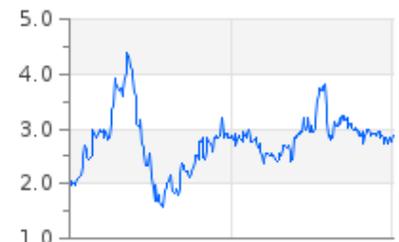
Sufficient cash reserves

For the second quarter ended June 30, Agile posted a smaller loss of \$3.5 million, or \$0.08 per share, compared to a

Price: 3

Market Cap: \$267.55 m

1 Year Share Price Graph



December 2019 June 2020 December 20

Share Information

Code: AGRX

Listing: NASDAQ

52 week	High	Low
	4.75	1.36

Sector: Pharma & Biotech

Website: www.agiletherapeutics.com

Company Synopsis:

Agile Therapeutics is a forward-thinking women's healthcare company dedicated to fulfilling the unmet health needs of today's women. Our current product candidates are designed to provide women with contraceptive options that offer freedom from taking a daily pill, without committing to a longer-acting method.

action@proactiveinvestors.com.au

loss of \$5.3 million, or \$0.16 per share in the same period a year earlier.

As of June 30, Agile had \$10.6 million in cash and cash equivalents, compared to \$7.8 million on December 31, 2018. During the second quarter, the company raised approximately \$1.4 million from the sale of 992,072 shares.

In its statement, the company said it believes its cash reserves will "be sufficient to meet its projected operating requirements" through to the end of the year.

R&D expenses shrunk to \$1.8 million for the quarter compared to \$2.4 million for the same period a year earlier.

Contact Uttara Choudhury at uttara@proactiveinvestors.com

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