

Agile Therapeutics

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Agile Therapeutics has productive 3Q as it lays the ground for commercialization of Twirla contraceptive patch

Agile Therapeutics Inc (NASDAQ:AGRX) CEO Al Altomari said Monday that the women's healthcare company was preparing for commercialization in the event that its lead product candidate, Twirla, an investigational prescription contraceptive is approved.

In a statement accompanying the Princeton, New Jersey-based women's healthcare company's latest numbers, Altomari said: "The third quarter of 2019 was another productive quarter for the company. We raised much needed cash to fund our business and allow us to reactivate Corium to prepare for commercialization in the event that Twirla is approved and to accomplish other precommercial activities."

Corium has the right to manufacture Twirla. Since September, Corium has been working with Agile to prepare facilities and equipment at its Grand Rapids manufacturing site for the commercial production of Twirla. It plans to kick off pre-validation work and Agile's goal is to manufacture three validation batches of Twirla. The Agile Therapeutics boss said the FDA has completed Corium's facility pre-inspection.

"Our team has been preparing to present the case for NDA (new drug application) approval of Twirla at the advisory committee meeting. We continue to believe that Twirla, if approved, will provide women with a new, important contraception option they do not currently have," said Altomari.

Executives from the company are expected to meet with the FDA's advisory committee on October 30 to review the NDA for Twirla, a low-dose prescription contraceptive delivered through the skin via the company's proprietary patch.

In parallel, Agile plans to work with managed care and patient payers to gain market access for Twirla in the first quarter of 2020.

"In the second quarter of 2020, the company plans to hire and train an initial sales team, which it estimates will be in the range of 50 to 90 persons," said the company.

Agile expects to ship product to wholesalers and start its commercial launch in the fourth quarter of 2020. The company's marketing efforts will initially focus on obstetrician-gynecologists in the US, and it plans to use a significant number of samples in the early stage of commercial launch to gain patient trial and acceptance.

Sufficient cash reserves

Agile said that as of September 30, it had \$18.4 million in cash and equivalents, compared to \$7.8 million in cash and equivalents on December 31, 2018. During the third quarter, the company boosted its cash position by raising \$12.7 million mainly from a sale of 14,526,315 shares through a public offering in August.

The company said it has enough cash on hand to meet its projected operating requirements through the end of the first

Price: 1.85

Market Cap: \$161.06 m

1 Year Share Price Graph



Share Information

Code: AGRX

Listing: NASDAQ

52 week High Low
4.75 0.35

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

quarter of 2020. Agile will require additional capital to fund operating needs for the rest of 2020 and beyond, which will primarily be used for the completion of its commercial plan for Twirla.

For the third quarter ended September 30, the forward-thinking women's healthcare company posted a loss of \$4.4 million, or \$0.08 per share, compared to a net loss of \$3.8 million, or \$0.11 per share, in the same period a year earlier.

The company said research and development expenses were \$2.4 million for the third quarter, compared to \$1.5 million for the same period of 2018. The company explained that the rise in R&D expenses was linked to consulting fees paid to prep for the upcoming FDA advisory committee meeting later this month.

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

Contact Uttara Choudhury at uttara@proactiveinvestors.com

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Contact us +44 (0)207 989 0813 action@proactiveinvestors.com

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