

Agile Therapeutics

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Agile Therapeutics preps for commercialization of contraceptive skin patch Twirla

- New Jersey-based firm seeks to provide women with contraception options beyond the birth-control pill
- Flagship product Twirla is an FDA-approved low-dose prescription skin patch contraceptive
- Amassed nearly \$94 million of capital for Twirla's commercial rollout in 4Q 2020

What Agile Therapeutics does:

Agile Therapeutics Inc (NASDAQ:AGRX) is a healthcare company dedicated to providing women with contraception options that offer them freedom from taking the pill daily.

The Princeton, New Jersey-based company has five products in its pipeline but the main focus is on lead product Twirla, also known as AG200-15, which won US Food and Drug Administration (FDA) approval in February 2020.

The low-dose prescription contraceptive is delivered through the skin via the company's proprietary patch technology called Skinfusion.

Twirla is designed for weekly application to deliver a 30 mcg daily dose of ethinyl estradiol, a type of estrogen, along with a 120 mcg daily dose of levonorgestrel, a well-known progestin. The patch can be worn on the abdomen, buttock, or upper torso (excluding the breasts).

Agile notes that Twirla is contraindicated for women who have body mass indices greater than 30 kg/m². It is also contraindicated for women over 35 who smoke.

In addition to Twirla, Agile has a pipeline of four other transdermal contraceptive products in various stages of development and testing:

- AG200-ER, a regimen that allows a woman to extend the length of her cycle
- AG200-SP, a regimen designed to provide shorter and lighter periods
- AG200-ER (SmP), a regimen to allow a woman to extend the length of her cycle while experiencing shorter and lighter periods
- AG890, a progestin-only contraceptive patch intended for use by women who are unable or unwilling to take estrogen

How is it doing:

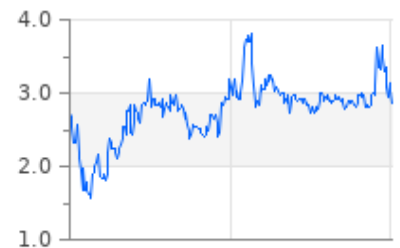
Agile has said it plans to begin the pre-validation and validation of the commercial manufacturing process for Twirla in the first half of 2020. It will manufacture three batches of Twirla and complete the validation process in the second half of 2020.

At the same time, the company will prepare to make Twirla available for commercial supply in a market estimated to be

Price: 2.87

Market Cap: \$251.41 m

1 Year Share Price Graph



February 2020 August 2020 February 2021

Share Information

Code: AGRX

Listing: NASDAQ

52 week High Low
3.885 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.

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worth \$3.7 billion and in which Agile could generate up to \$300 million in sales, by some estimates.

In the first quarter of 2020, Agile plans to target managed care and patient payors to gain market access for Twirla. In the second quarter, the company plans to begin hiring and training an initial sales team of 70 to 100 persons who will reach out to obstetricians and gynaecologists, nurse practitioners, physician assistants, and primary care providers.

In the fourth quarter of 2020, Agile intends to ship the product to wholesalers.

Many on Wall Street foresee the promise of Twirla, which means the company has been able to raise sufficient capital to expand operations and fund Twirla's manufacturing and roll-out through the end of 2021.

The company closed out its first quarter of 2020 with nearly \$94 million in cash and cash equivalents after raising more than \$68 million in debt and equity financing prompted by the FDA's decision on Twirla.

Meanwhile, Agile also broadened its board of directors with two recent appointments -- Sharon Barbari, a former CFO with Cytokinetics, InterMune and Gilead Sciences, and Dr Sandra Carso, an obstetrician and gynaecologist physician who has served on several FDA advisory committees.

The company, as it looks ahead, plans to monitor spending closely and expects operating expenses for the full year 2020 to be in the range of \$52 million to \$56 million, with general and administrative expenses accounting for about 70% of the spending as it builds out its commercial infrastructure. Net revenue in the fourth quarter of 2020, reflecting the initial launch of Twirla, is expected to be in the range of \$4 million to \$6 million.

However, the company acknowledges that the coronavirus (COVID-19) pandemic could affect its operations.

If the COVID-19 outbreak or other factors impact the company's business plan or its ability to generate revenue from the launch of Twirla, Agile has the ability to revise its commercial plans, including curtailing sales and marketing spending, to allow it to continue to fund its operations.

Inflection points:

- Plans to ship Twirla to wholesalers in the fourth quarter of 2020
- Expects to generate revenue soon after with expanded sales staff
- Broaden company's women's health portfolio to address unmet needs

What the boss says:

"The FDA's approval of Twirla will enable us to deliver on our short-term goal of establishing Agile in the contraceptive prescription market and working towards our longer-term mission to broaden our women's health portfolio, including in areas of unmet need," according to Agile CEO AI Altomari.

"We are grateful to the clinical trial patients, researchers, healthcare providers, and advocates, whose contributions helped us secure the approval of a new transdermal contraceptive option that may serve the contraceptive needs and preferences of many women. We are proud to offer this new option and look forward to bringing Twirla to women and their healthcare providers."

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