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Perrigo's Pivot To Building Brand Market Share Boosted With Opill OTC Oral Contraceptive Approval

by Malcolm Spicer

Year after acquiring HRA, Perrigo makes preparations to launch arguably the most anticipated OTC switch in US pharma history, Opill with 0.075-mg norgestel. Analysts estimate $100m annual market for OTC birth control.

Perrigo Company PLC has made notable progress before in its pivot from focusing its US OTC drug business on providing generic copies of OTC national brands to making and marketing national brands.

The transition's biggest step to date came on 13 July with the Food and Drug Administration's approval of the application its subsidiary HRA Pharma submitted for the first nonprescription oral contraceptive available OTC in the US.

A little more than a year after it acquired Paris-based HRA and a year after HRA, after working with women's health and reproductive rights advocacy group Ibis Reproductive Health on OTC studies, submitted a supplemental new drug application for 0.075-mg norgestrel branded Opill, Perrigo is making preparations to launch arguably the most anticipated OTC switch in US pharma history.

The FDA approved HRA's sNDA as a full switch of 0.075-mg norgestrel for sales without age restrictions *(see related story)*.

"Opill has the potential to radically transform women's access to contraception," said president and CEO David Lockwood-Taylor in a statement following the FDA announcement, less than two weeks after he took Perrigo's helm.

Investors drove a brief surge in Perrigo's share price after the FDA approval was announced, moving from a previous close of $33.08 to $34.83 at 9:45 a.m. ET, its highest point since $37.62 on 1 May. But while trading remained heavy at roughly five times average volume the remainder of the day, the price settled to close up slightly, 0.16%, at $33.24.

Progestin-Only Pills 2% Of Oral Contraceptive Sales

Market analysts also noted the size of the potential Opill market.

"We believe this is a major development for [Perrigo] as the company will be the first to be able to market and sell an OTC birth control pill in the US," said Canaccord Genuity Capital Markets analysts in a research note posted soon after the FDA announcement.

They referenced market research estimating the all-Rx US oral contraceptive market at around $4.8bn in 2022, with the vast majority, around 98%, of the sales on combined-ingredients oral contraceptives, unlike progestin-only Opill.

Other progestin-only contraceptive pills (POPs), also all Rx, accounted for the remaining roughly 2% of the total market. Sales of POPs have waned as combination ingredient oral contraceptives have claimed dominant market share; HRA discontinued marketing its 0.075-mg norgestel Rx pill in 2005.

"This implies around $100Mm [total addressable market] for Opill in the current state. However, we believe demand for POPs will significantly grow due to Opill being OTC," the Canaccord analysts said.

They also referenced 2022 research showing that 77% of reproductive-age females would favor taking birth control if it was available OTC. "This gives us confidence that consumers will adopt [Perrigo's] Opill either as first-time users or by switching from Rx to OTC."

First OTC Birth Control Pill Approved In US Will Launch With Three-Year Market Exclusivity

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FDA approval of Perrigo subsidiary HRA's application comes 60 years after Rx birth control was approved in the US, one year after the application was submitted, and 13 months after the Supreme Court's Dobbs ruling. Perrigo plans to launch sales in 2024 first quarter.

Read the full article here

Perrigo's 'Opportunity' More Long Term

At JP Morgan, North America Equity Research analysts estimate the US OTC daily birth control market as a $100m "opportunity." Sales primarily will come from uninsured consumers, around 10% of women between 15 and 49 years old, those without access to a doctor.

The JP Morgan analysts added, though, that they don't expect the opportunity will pan out rapidly for Perrigo, which has yet to schedule announcing its second-quarter results.

"We see today's update as an incremental positive for the story with approval already broadly anticipated following" an FDA advisory panel's unanimous vote in May to recommend approval, they said.

After the planned launch of sales in the 2024 first quarter will come "a year where we do not expect meaningful profit contribution given early stages of the launch" before having positive contribution on operating margin and earnings per share starts in 2025, according to the JP Morgan note.

The analysts don't anticipate Lockwood-Taylor to announce "any large revamp/change in strategy/reset to near-term earnings" with Perrigo's second-quarter results.

For the longer-term, they said, "while it will likely take several quarters of consistent performance for Perrigo's valuation to normalize, we see a very achievable path for earnings to recover over the next couple years."

Second Switch In A Year

Lockwood-Taylor, making his first earnings presentation with Perrigo's second-quarter results, leads the firm as it continues the transformation started by his predecessor, Murray Kessler. (Also see "*Perrigo's Next CEO Has Long OTC Brands History*" - HBW Insight, 8 Jun, 2023.)

The Dublin-based firm opened its transition from providing generic copies provided to retailers and distributors as private label and store brand products to also marketing national brands in 2019 when it acquired from *GSK plc* US rights to OTC proton pump inhibitor Prevacid 24HR (lansoprazole, 15 mg). (Also see "*Perrigo Prioritizes Innovating First After Following OTC Brands To Market*" - HBW Insight, 10 Sep, 2019.)

But its acquisition of HRA, in a €1.8bn ($2.1bn) deal which closed in April 2022, put Perrigo squarely in the OTC switch race. (Also see "*Room Available In US Pharma Industry For OTC Switch Leader: Has Perrigo Made A Reservation?*" - HBW Insight, 9 Sep, 2021.)

More than in the race, Perrigo could've moved to the front. Its competitors in the OTC space, longtime sponsors of applications to make additional ingredients available nonprescription, have prioritized reorganizing their consumer health businesses over expanding their product portfolios and confidence in success for switch applications has faded under current FDA regulations.

Its first OTC switch, Nasonex 24HR (5-mg mometasone furoate) allergy nasal spray, was

approved the following month in 2022. It acquired exclusive US rights from *Merck & Co., Inc.* in 2018 to develop and market an OTC version of Nasonex. (Also see "*Perrigo's First National Brand, Nasonex OTC Switch, Will Have Familiar Buzz In Advertising*" - HBW Insight, 21 Mar, 2022.)

It also has marketed branded consumer health products as well as private label and store brands in Europe since acquiring Omega Pharma NV in a deal that closed in 2015. (Also see "*Omega Marks The Alpha Of Perrigo's OTC Brand Play*" - Pink Sheet, 19 Mar, 2015.)