

14 Sep 2023 | News

Akili Turns Heel, Goes 'All In' On OTC Model For ADHD Digital Therapeutics

"We're taking destiny into our own hands," says CEO Eddie Martucci.

by [Barnaby Pickering](#)

The Boston, MA-based company says the pivot away from Rx will enable it to pursue a significantly larger market and remove "key friction points" that have prevented patients from accessing its game-based digital ADHD treatment. The company is targeting year-over-year cost savings of \$8m-\$18m after investments to juice up its direct digital marketing program.

It seems reimbursement headwinds ultimately proved too much for prescription digital medicine company Akili, Inc., which announced on 13 September that it would convert to a non-prescription direct-to-consumer model to get its game-based ADHD treatment into the hands of more patients.

"We've been running a prescription model that has dependencies on healthcare stakeholders who we don't solve a direct problem for. Friction here was honestly more than we anticipated. Insurers have been extremely slow-moving and are not stepping up for innovative medical products even when they're safe," said Eddie Martucci, the firm's CEO, in a next-day call with analysts.

He expanded on those remarks during the call's Q&A portion when asked how Akili's transformation reflects on the broader digital therapeutics opportunity.

"Is it just too new too soon," suggested TD Cowen analyst Charles Rhyee. "Because it would seem like in pediatrics if the first-line treatment ends up being stimulant use, you would think that parents would look at potential harm versus benefit from drug use. Why has that friction been so hard?"

Martucci replied, “I wouldn't say that every single market is exactly the same. What I would say is that what we're seeing is the friction of a prescription model, and the reticence of insurers to step up to non-drug treatments is broader than any one market.”

In three months of availability through the Apple App Store, EndeavorOTC has tallied 125,971 first-time downloads and has 4,170 active subscribers paying around \$82 each, amounting to approximately \$340,000 in billing.

Disentangled from payers and other intermediaries, Akili is confident that a non-prescription model will enable it to reach more patients and drive revenues to support growth margins of 60%-70% by late 2025. The firm says it will work with the US Food and Drug Administration to achieve OTC labeling for its treatments and expects no market disruptions in the interim.

As a result of the reset, Akili's operating costs will be lower, including a 40% workforce reduction impacting its field sales force and market access team. Based on Akili's projected operating costs for 2023 and 2024, the cuts stand to provide savings between \$8m and \$18m, offset by investments in the firm's direct digital marketing capabilities.

The Boston, MA-based company says EndeavorRX, aimed at children between the ages of 8 and 12 with attention deficit/hyperactivity disorder (ADHD), “challenges players to chase mystic creatures, race through different worlds, and use boosts to problem-solve while building their very own universe.” (Also see "[Kids, Time To Play Your Medicine: Akili Prepares Launch Of EndeavorRx Video Game For ADHD](#)" - Medtech Insight, 17 Dec, 2021.)

The program (see the [full-length trailer](#)) challenges children to multitask and ignore distractions by navigating courses, collecting targets, and avoiding obstacles. Meanwhile, an algorithm measures performance and customizes each patient's treatment in real time, according to [endeavorrx.com](#).

The non-drug cognitive treatment is meant to be played for 25 minutes, five days a week, for at least four consecutive weeks, or as prescribed. Parents can follow their child's treatment with the EndeavorRx Insight app to track daily efforts and level completion, the company says.

In June, Akili launched EndeavorOTC, built on the same technology as EndeavorRX, through the Apple App Store to the roughly 11 million US adults with ADHD. (Also see "[Akili Introduces Adult](#)

[Version Of Video Game Therapy To Lessen ADHD Symptoms](#)" - Medtech Insight, 7 Jun, 2023.) According to Martucci, the product's current pricing is around \$25 per month, or around \$130 for an annual subscription.

In three months, the digital therapy has tallied 125,971 first-time downloads and has 4,170 active subscribers paying close to \$82 each on average, amounting to approximately \$340,000 in billing. Akili reported total revenues of just \$323,000 in 2022.

Further, around 57% of subscriber sessions adhered to recommended treatment length, playing the full 25 minutes, 51% of subscribers were retained after one month, and 67% after two months, in line with other consumer health and wellness apps but at a premium price three to four times higher than industry average, Akili says.

Those stats are remarkable, Martucci said, "particularly given the fact that we took a product built for a pediatric audience and made it available to adults," and it reflects "what we believe is a willingness to pay for the clinical impact of our product and the rigor of our supporting data."

Clinical Clout

Data from Akili's pivotal trial, STARS-ADHD, were [published](#) in *The Lancet Digital Health* in February 2020. Comparing EndeavourRX against another educational game as a control, Akili and Duke University Medical Center researchers found that TOVA API, which is a composite measure of attention functioning, improved 47% for those assigned to EndeavorRX versus 32% to a digital intervention control, in a study of 348 children.

Moreover, 36% of EndeavorRX recipients versus 21% of control patients moved to the normative range, no longer showing a recognizable attention deficit.

More recently, the company published data from adult usage of Endeavour. The STARS ADHD Adult trial showed EndeavorOTC improved participants' ability to focus by an average of 85% with over one-third of participants no longer exhibiting an attention deficit following treatment. Further, 73% of participants reported quality-of-life improvements, including completing tasks on time and managing multiple tasks at once. (Also see "[Akili Introduces Adult Version Of Video Game Therapy To Lessen ADHD Symptoms](#)" - Medtech Insight, 7 Jun, 2023.)

Akili says it plans to pursue regulatory approval for over-the-counter labeling of its treatment products. The company is on track to submit adult clinical trial data later this year to the FDA for OTC authorization of EndeavorOTC, which would be the first OTC label designation for a digital treatment, and intends to submit data to the FDA to convert its switch EndeavorRX to OTC in 2024 after completing an in-process indication expansion for users 13 to 17 years old.

While revenues are trending up, Akili's 2023 operating costs are anticipated to total between

\$55m and \$60m, according to its release. The firm's share price, which started at \$10 a share following its IPO in August 2022 through a merger with a special purpose acquisition company, is now less than a dollar.

But the company has a cash runway now to extend it to the 2025 second half. According to president and chief operating officer Matt Franklin, Akili is "laser-focused" on customer acquisition and retention while scanning for organic acquisition opportunities, including partnerships in business-to-business channels.

Franklin further noted, "The technology that powers our products has been studied in clinical trials with conditions such as major depressive disorder, mild cognitive impairment, multiple sclerosis, autism spectrum disorder, lupus, and others conditions that impact a significant number of individuals in the US. Across all of these studies, we've seen consistent and similar improvement in attention function and symptom relief."

While those markets have always been part of Akili's vision for the future, it believes a non-prescription model will facilitate access to those patients without having to add specialty sales and commercial support.

Martucci's belief in Akili's digital treatments is not shaken. "This is not just another health app," he said. "This product is showing up to consumers as a sophisticated, powerful, next-generation medical product with 10 years of published clinical trials, offering consumers the same technology as the world's only FDA-approved prescription video game, but without a prescription."

The difference, he said, is that "we're taking destiny into our own hands, and the power of our products themselves are poised to be the driver of our success."