Valeant Pharmaceuticals Intl Inc. (TSX:VRX) Recovery Hits a Roadblock

Description

Earlier this year, **Valeant Pharmaceuticals Intl Inc.** (TSX:VRX)(NYSE:VRX) announced what it refers to as the *Significant Seven* — a group of upcoming products from which the company could realize sizable and sustainable revenue growth of US$1 billion over the next few years.

The Significant Seven was a key step of Valeant's much-hyped turnaround plan, which was beginning to gain traction with both investors as well as with the stock price, which is still up nearly 20% year to date. Last month, Valeant even announced it would adopt a new name to leave its troubled past behind.

That positive outlook took a hit this week.

FDA fails to approve Duobrii

This week, the FDA announced that it would not be granting approval for Duobrii just yet. Duobrii is one of three plaque psoriasis-related drugs that make up the Significant Seven, and a delay or an outright rejection of the drug could spell re-evaluating the company's proposed revenue growth from its new drugs.

As it stands now, a potential release of Duobrii in 2018 seems unlikely, and a 2019 release could also be optimistic, given that a series of meetings and reviews are likely to follow, and additional information from the FDA could trickle in over the course of the next six months.

One positive takeaway is that FDA didn't cite any issues with either the manufacturing or the clinical profile of the drug, so an eventual approval could still be forthcoming.

To try to expedite the process and maintain some hope of coming close to its targets, Valeant is seeking out a meeting with the agency to address any concerns and work towards bringing Duobrii to market.

What this means for Valeant and investors

Long-time investors and followers of Valeant will recall that the company's former business model was reliant on cheap loans that were used to acquire drugs that Valeant could then hike prices on and move on to the next drug with more cheap loans.

While we're all familiar with the epic collapse of Valeant's stock price that followed, there's a key point to be made about that period in time and the current environment.

The Significant Seven represents Valeant's shift to a more traditional research-and-development (R&D) approach over the acquire-and-market stance of the past, and that traditional R&D method often comes with delays and setbacks, such as this one from the FDA.

Valeant still has two more outstanding regulatory decisions for two other drugs that are expected to be decided on in August and then in October.

Current and prospective investors in Valeant need not be reminded that Valeant is still a work in progress and that the company was never intended to have speedy recovery or return to its former glory as the darling of the market.

In other words, investing in Valeant requires a certain appetite for risk and a long-term commitment. A 25% increase in Valeant's dermatology sales force announced earlier this year will reap rewards, as will Valeant's impressive work to chew away at the mountain of debt the company still has.

The results and growth will come — just not this week or as a result of this announcement.

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Date
2025/07/08
Date Created
2018/06/20
Author
dafxentiou