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Why one FDA snag is moving Valeant Pharmaceuticals investors more than two successes

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Even when the majority of news about Valeant Pharmaceuticals International Inc. is good, this week showed that investor confidence in the company remains shaky, and can be easily rattled by even minor setbacks.

Early Friday morning the Laval, Que.-based drugmaker announced the U.S. Food and Drug Administration has not yet approved the experimental glaucoma treatment Vesneo, due to “manufacturing deficiencies” at a Bausch and Lomb facility in Tampa, Fla.

This disappointing news for the beleaguered company pushed its stock down 6.24 per cent to \$30.03 in Toronto on Friday, knocking off most of the gains made after two other drugs passed FDA approval with flying colours earlier this week.

On Tuesday, the FDA unanimously approved brodalumab, a drug for moderate-to-severe plaque psoriasis, and the same day gave the OK to a supplemental New Drug Application for the oral form of the opioid-induced constipation treatment Relistor.

“We think going forward they should be able to gradually crawl their way back into the market’s good graces,” said Raghuram Selvaraju, an analyst at Rodman & Renshaw, a unit of H.C. Wainwright & Co.

Selvaraju says because the issue with Vesneo is only with the production — not the safety of the drug itself — he expects the delay will be minor, with the approval only pushed back as far as October.

“What we expect to be a short delay doesn’t compromise the drug’s relative advantages versus existing marketed products, which it handily beat, or for that matter it’s positioning versus other drugs that are currently in development,” said Selvaraju who continues to rate Valeant as a “Buy” with a \$90 target price.

Selvaraju says he believes Vesneo and Relistor have the potential to be blockbusters, with over US\$1 billion in annual sales, while brodalumab could reach a peak of US\$500 million in annual sales.

But other analysts have doubts about the multi-billion dollar potential of the drugs in Valeant’s pipeline.

“I think those (estimates) are widely optimistic,” said **Dimitry Khmelnitsky**, an analyst at **Veritas Investment Research**.

Khmelnitsky says he does not believe new drugs will replace the roughly 20 to 25 per cent EBITDA that could be lost as some of Valeant’s own medications become generic over the next 30 months.

Valeant was briefly the largest company by market cap on the Toronto Stock Exchange in July 2015, but the stock has since lost about 90 per cent of its value a result of an ongoing drug-pricing scandal and the severing of ties with mail-order pharmacy Philidor Rx Services.

“I would argue that Valeant faces a lot of headwinds,” said **Khmelnitsky**. “Those headwinds are the inability to take price increases, but more importantly the relationship with payers and access and reimbursement restrictions on Valeant medicines, slowdown in key growth segments, regulatory investigations and media scrutiny.”

Although Valeant has admitted to problems with its once aggressive business model, their strategy — acquiring companies with late-stage drug programs and then cutting research and development — is still under debate.

“People have mischaracterized Valeant’s R&D programs,” Bill Ackman, whose Pershing Square Capital Management LP is one of the drugmaker’s biggest holders, said Wednesday on a conference call with investors. “This company has one of the most productive R&D programs of any pharmaceutical company in the country.”

Khmelnitsky says the billions of dollars that Valeant spent on acquiring companies with pipeline drugs has to be accounted for in measuring success.

In May, the U.S. Securities and Exchange Commission sent Valeant multiple letters questioning the practice of stripping away acquisition-related expenses from its “non-GAAP” earnings reports, given that until recently the drugmaker had been fuelling growth through frenzied deal making.

“Once that’s factored in, I’m not quite convinced Valeant’s R&D is that much more effective than the industry’s,” **Khmelnitsky** said.

Selvaraju says he believes that despite the deluge of negative news about Valeant over the past months, the company's R&D strategy remains sound.

For instance, he says Valeant could end up paying AstraZeneca PLC less than US\$445 million for the exclusive license to brodalumab, a drug that cost "billions" to develop and has the potential to be a big seller.

"Other large-cap pharma companies are woefully inefficient, and that was Valeant's mantra for a long time," Selvaraju said. "That viewpoint is still valid."

He says in order to get back in the good graces of investors Valeant cannot have any further downward revisions on earnings guidance, must shed some of its non-performing assets and actually get these late-stage drugs to market.

Valeant is reporting its second quarter 2016 results on August 9.