

BUSINESS INSIDER

The Valeant executive who could've saved Bill Ackman's investment just walked out the door



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MAR. 3, 2016, 11:20 AM

Hedge fund billionaire Bill Ackman has one big reason for staying in the center of a storm.

That storm is Valeant



Activist investor Bill Ackman on the floor of the New York Stock Exchange on November 10.

REUTERS/Brendan McDermid

Pharmaceuticals, a stock that has seen its price fall 70% in the past six months. As Ackman's largest position in the market, it blew a giant hole in his fund's portfolio at the end of 2015.

But Ackman is sticking by the company, and here's why:

"We expect that much of the uncertainty will be resolved in the relative short term, hopefully in a few weeks or so when we expect the company to issue results, update guidance, and file its 10-K," according to a statement read on CNBC on Wednesday.

"Based on publicly available information it appears that Valeant's core franchises remain strong."

That's where Ackman could be wrong.

The reality is that, regardless of whether you believe Valeant has been transparent and fair with investors, the company's top two drugs face some serious risks. Forget the multiple federal and state investigations, forget scrutiny from Congress over the company's pricing practices, and forget the delayed quarterly and annual reports.

ACPLIX DDS PTY LTD. et al

Lets just focus on those "core franchises."

Jublia

Valeant's two hottest drugs are Xifaxan, a remedy for irritable-bowel syndrome, and Jublia, a \$1,000 drug to treat toe fungus.

We'll start with Jublia, because its challenges are more straightforward. Jublia is Valeant's No. 2 drug by revenue, pulling in \$106 million for the company in the third quarter of 2015.

Here's the problem: Toe fungus can probably be treated for a lot less than \$1,000, and people are figuring this out.

CVS, the massive drugstore chain, said in February that it was going to require that **customers try and fail** to be cured by less expensive drugs before it would sell them Jublia. It was a big development that was overshadowed by all the other news about Valeant's financial restatements.



Consider this from a conversation [Bloomberg's Robert Langreth](#) had with CVS's chief medical officer:

Older nail-fungus medicines are "much more efficacious" than Jublia and cost far less, said Brennan. "It is a circumstance where we can go to clients and say, this is just waste we are eliminating."

On the internet, there's something of a **debate raging** about **Jublia's effectiveness**. Some even argue that **Vicks Vapor Rub is just as effective**. But we'll leave that to the people with toe fungus to decide.

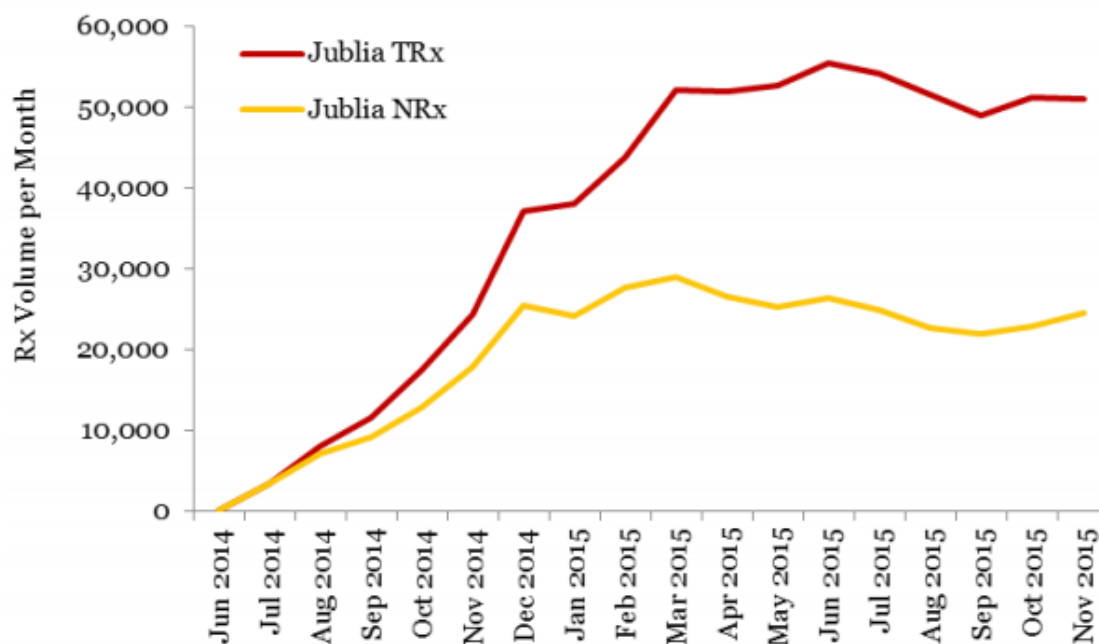
Then there's this, from Wells Fargo analysts earlier this month, about how Valeant's defunct pharmacy Philidor might have been propping up Jublia sales (emphasis ours):

We believe that a substantial portion of **Jublia's growth was fueled by Philidor and anticipate a significant negative impact to Jublia from the termination of Philidor and shift to Walgreens**. While Jublia has patent protection into 2030, its exclusivity ends in 2019, and we believe competitors may be keen on introducing a less expensive version of the drug.

In Business Insider's discussions with Philidor employees last year, Jublia was brought up time and time again as one of their biggest sellers. Patients would pay a \$0 copay, and insurance companies could be charged \$535 to \$1,500 for Jublia. Jublia was also mentioned in a Philidor employee manual. [From Bloomberg](#):

The manual instructed employees to submit claims under different pharmacy identification numbers if an insurer rejected Philidor's request for reimbursement — to essentially shop around for one that would be accepted.

Now Philidor is no more, and with CVS being uncooperative, 2016 is already looking very different from 2015 for Jublia.

Exhibit 28. Jublia TRx and NRx, Monthly (June 2014 to November 2015)

Source: IMS Health and Wells Fargo Securities, LLC

You'll also note that Jublia sales have started leveling off.

Wells Fargo

Xifaxan

Valeant picked up Xifaxan in its \$11 billion acquisition of Salix Pharmaceuticals (an acquisition now under investigation by both the US attorney's office for the Southern District of New York and the Securities and Exchange Commission).

Since then, Xifaxan has been huge for Valeant. The company thinks it may make \$1 billion in 2016, and it generated \$220 million in Q3 2015 alone. It also has FDA approval for an irritable-bowel-syndrome indication, which means that it is the go-to treatment for IBS. (Actavis Pharmaceuticals' Viberzi is also approved for an IBS indication.)

All of this is great, but it won't last forever. In fact, it won't last 10 years (so watch your DCF models, Wall Street).

Valeant was just informed that the FDA approved an abbreviated new drug application, or ANDA, for a generic version of Xifaxan in December. The application was filed by [Allergan Pharmaceuticals](#), a company Valeant unsuccessfully tried to acquire in 2014.

Xifaxan has what's called "Orange Book exclusivity." To file the ANDA, Allergan first had to file what is called a P-IV certification. That means Allergan is challenging Xifaxan's exclusivity because it's invalid, not infringed, or unenforceable.

To counter and stop the generic from coming to market, Valeant will sue Allergan. If it sues within 45 days, it can get a 30-month stay. To get around the 30-month stay, Allergan can file an inter partes review against the patents, which could kill exclusivity within 18 months.

In the best-case scenario for Valeant, Allergan will slug it out in court for three to four years before its drug is able to get to market. The best case.

Either way, Xifaxan's billion-dollar days are numbered. Valeant has yet to respond to Business Insider's request

for comment on this story.

You thought that was it?

On Monday night Valeant announced that the head of US dermatology and gastrointestinal, Deb Jorn, was **resigning effective immediately**. Jorn was responsible for both Jublia and Xifaxan.

Solodyn (another of Valeant's top 10 brands) was also under her purview.

This is supposed to be a year of transition for Valeant: The company has committed to lowering prices across the board and paying down its \$30 billion debt load.

It also said it wouldn't be doing any mergers-and-acquisitions deals, which is how the company acquired drugs in the model it says it is now leaving behind.

So that means the resilience of potential blockbuster drugs like Jublia and Xifaxan is all the more important.

But with those stars already fading, Valeant will have to prove that it has products in the pipeline that can shine as brightly as the previous ones did. That's not an easy task in good times. It's a horror show in times like Valeant's.

Q3 2015 Top 30 Brands (1/3)
(\$M)

Product	Q3 2014	Q4 2014	Q1 2015	Q2 2015	Q3 2015
1) Xifaxan	-	-	-	148	220
2) Jublia	13	53	62	102	106
3) Wellbutrin XL*	80	82	68	67	92
4) SofLens*	95	89	81	84	84
5) Xenazine	56	52	57	66	73
6) Provenge	-	-	30	74	69
7) Solodyn	54	61	57	65	66
8) Ocuvite / Preservision*	62	62	60	59	57
9) ReNu*	59	60	53	59	54
10) Glumetza	-	-	-	26	53

Top 30 represent 54% of total company revenue

* Sales depressed on 12 of top 30 products due to FX impact

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