

What's Next for Valeant Pharmaceuticals?

Expect an array of protracted, distracting, and expensive investigations.



Disclosure Insight™ reports provide commentary and analysis on public company interactions with investors and with the SEC. They are often reliant on our expertise with using the Freedom of Information Act.

Valeant Pharmaceuticals \$VRX

As of 30-Sep-2015, we received information from the SEC to suggest the absence of recent SEC investigative activity at Valeant. Given recent developments, including [Valeant's receipt of subpoenas from federal prosecutors](#) seeking information related to how it prices and distributes drugs; and, a recent and well-circulated Citron report¹, we expect this will change.

If they haven't already, we fully expect SEC and Canadian enforcement officials to contact the company sometime in the next 10 days or so. We base this on the timing we've seen in documents from our database on closed SEC probes of other public companies.

There's just too much going on at Valeant for these regulators to ignore. They are going to have to open inquiries, if only to sort out the conflicting arguments and claims currently circulating about the company. New FDA investigations could also begin.

¹ See, Citron Research: [Valeant — Could this be the pharmaceutical Enron?](#)

Of the many items that we know can trigger an SEC investigation, Valeant has high risk from these four –

1. Significant, negative media and/or analyst reports, especially if they move the stock price. The Citron report fits this profile.
2. An accounting or disclosure controversy.
3. Significant stock price volatility (usually more than 10%), unusual options activity, etc.
4. Referrals from other government agencies, including criminal investigations.

Given the complexity of the issues, paired with the company's very vocal proclamations of innocence, you should expect these investigations will be protracted, time-consuming, distracting, and expensive. None of that is good for investors.

[On 22-Oct-2015, a Canadian regulator was already reported to have said no formal investigation of Valeant had started](#) (quoted below). The SEC doesn't usually comment. In fact, it's highly unusual for any regulator to comment in this fashion. This is not good for Valeant.

“Quebec's securities regulator says **it hasn't launched a formal investigation into Valeant**, which has its headquarters in Laval near Montreal, but is watching the situation ‘very seriously.’ **[Emphasis added]**

This statement should not give investors comfort as it does not rule out informal inquiries. In the US, SEC investigations usually start out informally. Both formal and informal probes can be very serious. The guys from Tyco went to jail though its SEC probe was informal.

The key questions regarding any possible new SEC and/or Canadian investigation of Valeant –

1. **Will the company tell you?** Compared to other companies in our research database, Valeant has been about average when it comes to disclosing its regulatory exposures in the past. As such, yes, we expect they will tell you.

But they may not give it prominence. The recent receipt of subpoenas was only announced in a conference call with no accompanying formal SEC filing.

For those who can't wait, the company's given investors a golden opportunity to ask outright if the SEC or any other entity has started a new inquiry. Valeant management plans to hold a [conference call on Monday, 26-Oct-2015](#).

Assuming they don't beat you to the punch, here's three great questions to ask –

- What communications, if any, has Valeant had with the SEC's Division of Enforcement, the US Attorney/DOJ, or Canadian regulators, regarding any matter, in the past 30 days?
- If such communications exist, what was the purpose and date of those communications?
- Last week the company said it received a subpoena from the U.S. Attorney's Office for the District of Massachusetts and a subpoena from the U.S. Attorney's Office for the Southern District of New York.

We recommend asking when they were received, who they were sent to, and what information they seek?

2. **When will the company tell you?** Again, we expect Valeant will be contacted very soon by Canadian and SEC enforcement officials, if they have not already. Again, given its history, we do expect Valeant will eventually disclose this new SEC or Canadian probe.

Given the market sensitivity to these shares right now, we won't be surprised if Valeant announces an SEC probe either ahead of or in the opening to its conference call on Monday. Brace yourself.

3. **What will the company tell you?** Assuming disclosure of an SEC, or any other new probes are made, you should expect an array of denials paired with promises of full cooperation with investigators.

Blah, blah. We see it all the time. Details on who is investigating, when they started, and details on the issues being examined are what really matters.

If disclosure comes ahead of or during the conference call, especially if they see this report, you should also prepare for the company to, perhaps, do a preemptive move by claiming it can't discuss its investigations as "they are confidential". This is fluff.

In general, a company under investigation by the SEC can tell you whatever they want. If the SEC's already contacted them, they will already have a good idea what the SEC is investigating.

We strongly recommend investors take Valeant management to task if they try to dodge or even refuse to answer questions regarding possible or existing investigations.

4. **What will the SEC make of the Citron report?** We know from experience the SEC routinely receives tips from hedge funds and other sources with "dirt" on public companies. Like any arms-length investigator, they consider the source, its agenda, and the overall quality of the data/research presented.

Like us, Citron is not new at what it does. Also like us, Citron is well-known to the SEC. Finally, and like routinely happens to us, Citron is being accused of trying to manipulate the market. No such accusation has ever stuck to us. We expect Mr. Left of Citron has his ducks lined up in this regard as well.

According to an article from the [Wall Street Journal](#), dated 22-Oct-2015, "A Wall Street Journal analysis of 111 Citron short-sale reports published from 2001 to 2014 shows an average share-price decline of 42% in the year after a Citron report was released."

Valeant shares would not have reacted as negatively as they did to the Citron report if investors viewed the source as anything less-than-credible. The SEC knows this as well.

5. **Is there any tie-in between what SEC/DOJ investigators are learning at Valeant's Salix unit?**

Some of the language in the Salix and Salix-related disclosures sound somewhat similar to allegations circulating in the market today regarding Valeant.

Regardless of overlap, the mere fact Valeant felt compelled to disclose the ongoing DOJ/SEC probes of Salix means Valeant management judges the exposure potentially material to the entire company. This is despite the fact that probe is supposedly confined to an acquired unit.

6. **What did SEC investigators learn about Valeant and its management the many times they've investigated the company in the past?** Below we

include excerpts from earlier disclosures of investigative activity at Valeant. They show a wide array of lengthy civil and criminal investigations.

Back in Apr-2013, the SEC informed us 54 boxes (roughly 162,000 pages) of records were potentially available regarding an earlier SEC investigation of Valeant. Though no other information concerning that investigation was provided to us, the sheer volume of records suggests SEC enforcement officials have a reasonable sense of what type of people are running Valeant. If they sized them up as dirtballs, then the going this time around won't be pleasant for the company or, ultimately, investors.

7. **Who else could investigate?** Regulators and enforcement officials routinely share information with each other. This opens the possibility for new criminal probes, both here and in Canada.

In addition, Valeant reports it has periodically received inquiries in the Office of Prescription Drug Promotion of the FDA in the past. These concerned compliance with marketing and other regulations. It's not hard to imagine new inquiries showing up from the FDA again.

The remainder of this report summarizes our own research findings paired with notable excerpts from company filings. This section is instructive, if only to give perspective of Valeant's "frequent flyer" status with law enforcement.

We've filed three FOIA requests on Valeant since March 2013. On 01-Apr-2014, the SEC informed us there were no records found that would suggest an investigation involving Valeant Pharmaceuticals. As cited above, they gave us that same response on 30-Sep-2015.

Valeant was involved in a multi-year SEC investigation that ended in early 2013. This is consistent with an excerpt from the 10-K filed in 2010, which we include below.

Valeant's latest 10-Q filed on 28-Jul-2015, speaks of an SEC investigation into Salix, which became a wholly owned subsidiary of Valeant on 01-Apr-2015.

Going back in time provides a sense of the wide array of investigations Valeant has dealt with in the past.

From the Valeant 10-K filed 26-Feb-2010 –

In July 2003, the Company received a subpoena from the U.S. Attorney's Office ("USAO") for the District of Massachusetts requesting information **related to the promotional and marketing activities** surrounding the commercial launch of Cardizem® LA. In particular, the subpoena sought information relating to the Cardizem® LA Clinical Experience Program, titled P.L.A.C.E. (Proving L.A. Through Clinical Experience). In October 2007, the Company received an additional related subpoena.

On May 16, 2008, Biovail Pharmaceuticals, Inc., the Company's former subsidiary, entered into a written plea agreement with the USAO whereby it agreed to plead guilty to violating the U.S. Anti-Kickback Statute and pay a fine of \$22.2 million.

In addition, on May 16, 2008, Biovail Corporation entered into a non-prosecution agreement with the USAO whereby the USAO agreed to decline prosecution of Biovail Corporation in exchange for Biovail Corporation's continuing cooperation and in exchange for its agreement to finalize a civil settlement agreement and pay a civil penalty of \$2.4 million. The civil settlement agreement has now been signed and the related fine has been paid. A hearing before the U.S. District Court in Boston took place on September 14, 2009 and the plea was approved.

In addition, as part of the overall settlement, the Company entered into a CIA with the Office of the Inspector General and the Department of Health and Human Services on September 11, 2009. The CIA requires us to have a compliance program in place and to undertake a set of defined corporate integrity obligations for a five-year term. The CIA also includes requirements for an independent review of these obligations. Failure to comply with the obligations under the CIA could result in financial penalties.

On November 20, 2003, the Company received notification from the SEC indicating that the SEC would be conducting an informal inquiry relating to the Company's accounting and disclosure practices for the fiscal year 2003. These issues included whether or not the Company had improperly recognized revenue and expenses for accounting purposes in relation to its financial statements in certain periods, disclosure related to those statements, and whether it provided misleading disclosure concerning the reasons for its forecast of a revenue shortfall in respect of the three-month period ended September 30, 2003, and certain transactions associated with a corporate entity that the Company acquired in 2002. On March 3, 2005, the Company received a subpoena from the SEC reflecting the fact that the SEC had entered a formal order of investigation. The subpoena sought information about the Company's financial reporting for the fiscal year 2003. Also, the scope of the investigation became broader than initially thought, and the period under review was extended to encompass the period January 1, 2001 to May 2004.

On March 24, 2008, the SEC filed a civil complaint against the Company, Eugene Melnyk, the Company's former Chairman and Chief Executive Officer ("CEO"), Brian Crombie, the Company's former Chief Financial Officer ("CFO"), and two former officers, Kenneth Howling and John Miszuk, related to the matters investigated by the SEC. The Company has entered into a Consent Decree with the SEC in which it has not admitted to the civil charges contained in the complaint but has paid \$10.0 million to the SEC to fully settle the matter. As part of the settlement, the Company has also agreed to an examination of its accounting and related functions by an independent consultant. The settlement does not include the four individuals although the Company understands Mr. Howling has

also reached a settlement with the SEC. The matter is proceeding as against former officers Mr. Melnyk, Mr. Crombie and Mr. Miszuk in the ordinary course and no hearing date has been set. The Company is indemnifying these individuals for their legal costs.

In the Spring of 2007, the Company was contacted by the USAO for the Eastern District of New York ("EDNY"), which informed the Company that the office is conducting an investigation into the same matters that the SEC is investigating. The USAO for the EDNY conducted interviews of several of the Company's current or former employees and requested documents related to fiscal years 2002 and 2003. The Company cooperated with this request and has not been contacted further. The Company cannot predict the outcome or timing of when this matter may be resolved.

Over the last few years, the Company received a number of communications from the Ontario Securities Commission (the "OSC") relating to its disclosure, and/or seeking information pertaining to certain financial periods. Similar to the SEC, the OSC advised the Company that it had **investigated whether the Company improperly recognized revenue** for accounting purposes in relation to the interim financial statements filed by the Company for each of the four quarters in 2001, 2002 and 2003, and the first quarter of 2004, and related disclosure issues. The OSC also investigated whether the Company provided misleading disclosure concerning the reasons for its forecast of a revenue shortfall in respect of the three-month period ending September 30, 2003, and certain transactions associated with a corporate entity that the Company acquired in 2002, as well as issues relating to trading in its common shares. These issues included whether the Company's insiders complied with insider reporting requirements, whether persons in a special relationship with the Company may have traded in its common shares with knowledge of undisclosed material information, whether certain transactions may have resulted in, or contributed to, a misleading appearance of trading activity in the Company's securities during 2003 and 2004 and whether certain registrants (who are the Company's former directors) may have had conflicts of interest in relation to the trading of the Company's common shares. **[Emphasis added]**

From the Valeant 10-K filed on 28-Feb-2013 –

Valeant is the subject of a Formal Order of Investigation with respect to events and circumstances surrounding trading in its common stock, the public release of data from its first pivotal Phase III trial for taribavirin in March 2006, statements made in connection with the public release of data and matters regarding its stock option grants since January 1, 2000 and its restatement of certain historical financial statements announced in March 2008. In September 2006, Valeant's board of directors established a Special Committee to review its historical stock option practices and related accounting, and informed the U.S. Securities and Exchange Commission ("SEC") of these efforts. Valeant has cooperated fully and will continue to cooperate with the SEC in its investigation. The Company cannot predict the outcome of the investigation.

We found no disclosure of an SEC investigation by Valeant, aside from Salix-related probes cited below, since the 10-K filed in Feb-2013.

Investigations of Salix –

Valeant's latest 10-Q filed on 28-Jul-2015 has the following details regarding an SEC investigation into Salix, which was became a wholly-owned subsidiary of Valeant on 01-Apr-2015 –

Salix DOJ Subpoena

On February 1, 2013, Salix received a subpoena from the U.S. Attorney's Office for the Southern District of New York requesting documents regarding sales and promotional practices for its Xifaxan®, Relistor® and Apriso® products. Salix and the Company are continuing to respond to the subpoena and are cooperating fully with the subpoena and related government investigation.

Salix SEC Investigation

The SEC is conducting an investigation into possible securities law violations by Salix relating to disclosures by Salix of **inventory amounts in the distribution channel** and related issues in press releases, on analyst calls and in Salix's various SEC filings, as well as related accounting issues. Salix and

the Company are cooperating with the SEC in its investigation, including through the production of documents to the SEC Enforcement Staff. We cannot predict the outcome or the duration of the SEC investigation or any other legal proceedings or any enforcement actions or other remedies that may be imposed on Salix or the Company arising out of the SEC investigation.

Going back in time, we get a better sense of history on this probe. You can see the FDA, DOJ, and SEC were referenced in investigation-related disclosures made by Salix.

The following excerpts are each taken from the final 10-K filed by Salix on 02-Mar-2015 –The FDA –

In addition, we periodically receive inquiries from authorities, including specifically the **Office of Prescription Drug Promotion of the FDA, regarding compliance with marketing and other regulations**. Responding to inquiries from authorities can be costly and divert the time and attention of our senior management from our business operations and result in increased legal expenses. The laws and regulations regarding off-label promotion and the authorities' interpretation of them might increase our expenses, impair our ability to effectively market our products, and limit our revenue.

The DOJ/US Attorney (that's a criminal probe) –

On February 1, 2013, we received a subpoena from the U.S. Attorney's Office for the Southern District of New York requesting documents regarding our sales and promotional practices for Xifaxan, Relistor and Apriso. The Company is in the process of responding to the subpoena and intends to cooperate fully with the subpoena and related government investigation, which has and will continue to increase our legal expenses, and might require management time and attention. Currently, we cannot predict or determine the timing or outcome of this inquiry or its impact on our financial condition or results of operations.

The SEC –

The SEC is conducting an investigation into possible

securities law violations, which may adversely affect our financial condition, results of operations and the price of our common stock.

The Audit Committee of the Board of Directors of the Company has retained outside counsel and is conducting an internal investigation of disclosures of inventory amounts in the distribution channel

and related issues in press releases, on analyst calls, and in the Company's various SEC filings. That investigation includes certain accounting issues identified during the course of the investigation, including returns of Giazo, **marketing fees paid to a wholesaler, and the Company's practices for recognizing revenue for shipments made to another wholesaler** on or after October 1, 2013, and resulted in our restating our financial results for 2013 and the first three quarters of 2014. The Audit Committee has notified the SEC Enforcement Staff that it is conducting this investigation, and has had meetings with the SEC Enforcement Staff with respect to the Audit Committee's investigation. Moreover, counsel to the Audit Committee has voluntarily provided relevant documents to the SEC Enforcement Staff, and is cooperating with the SEC Enforcement Staff in the SEC's investigation. The Company has received information requests from the SEC and the Company expects to receive subpoenas for documents and testimony during the course of the SEC's investigation.

We cannot predict the outcome or the duration of the SEC investigation or any other legal proceedings or enforcement that may arise out of the SEC investigation. We also could be subjected to other

lawsuits and could become the subject of other regulatory inquiries or investigations in addition to the SEC investigation now underway. If we are subject to adverse findings in any proceedings, we may be required to incur costs, or pay damages or penalties or have other remedies imposed upon us which could have a material adverse effect on our financial condition and results of operations.

Responding to the SEC investigation could divert management's attention from managing our day-to-day operations. Additionally, expenses that may arise from responding to the SEC investigation, management's review of responsive materials, any related litigation or other associated activities may be significant. Current and former employees, officers and directors may seek indemnification, advancement or reimbursement of expenses from us, including attorneys' fees, with respect to the current investigation or future proceedings related to this matter, if any such investigation or proceeding involves such employees, officers and directors personally. In addition, the SEC investigation may adversely affect our ability to obtain, or increase the cost of obtaining, directors' and officers' liability and other types of insurance. These events could adversely affect our financial condition, results of operations and the price of our common stock. **[Emphasis added]**

– Probes Reporter

[To learn more on our process and what our findings mean, click here](#)

Notes: The SEC did not disclose the details on investigations referenced above. The SEC reminds us that its assertion of the law enforcement exemption should not be construed as an indication by the Commission or its staff that any violations of law have occurred with respect to any person, entity, or security. New SEC investigative activity could theoretically begin or end after the date covered by this latest information which would not be reflected here.

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