Citron RESEARCH

February 28, 2014

Questcor has Responded to Citron's Report on the Independent Laboratory Studies of Acthar

Citron says: "Astonishing"

With regard to Questcor (NASDAQ:QCOR) Citron has obviously often been skeptical, we've certainly been inquisitive, and we've even been righteously indignant at times.

But now we're utterly astonished. Just read what the company said in response to our report yesterday.

In what Citron expects will likely unfold as one of the biggest pharmaceutical stories of 2014, a statement from Steve Cartt to Bloomberg confirms the laboratory findings Citron reported yesterday:

February 27, 2014 (Bloomberg) -- Questcor Pharmaceuticals COO Steve Cartt email quoted by Bloomberg First Word:

"Each Acthar lot meets FDA-mandated specifications which have not changed over several decades." He continues, Acthar is "naturally derived, complex peptide formulation that is not yet fully understood". He states Questcor's research program is "working to develop a more comprehensive understanding of the individual components in Acthar".

Notice what **he did not say**: "Highly Purified ACTH **IS** the main ingredient in Acthar Gel."

So not only is pure ACTH **not** the active ingredient in Acthar, but **it might not even be present in the drug at all**.

While the company stands by the premise "This is the way we've always done it…", that **does not protect them** from either the civil or criminal consequences of a mislabeled drug.

They're banking their entire company on the statement: "**each batch meets FDA-mandated specifications**". But at the same time, they explicitly admit to not knowing what's in it. So how do those purported manufacturing specifications protect the public with regard to efficacy, or correct dosing?

If the primary active ingredient in Acthar Gel is indeed deamidated ACTH, as detected in the tests presented to the FDA, where are the clinical studies of deamidated ACTH proving efficacy of that substance? There is no such science.

How can they make any justifiable label statement about the dosing of deamidated ACTH?

Meanwhile, Questcor has sold the drug for 9 years, with a billion dollar run rate, marketed directly to very ill patients. **Where have they made the investment to determine what's actually in the vials?**

Submitted to an independent lab, a great deal was learned in just a few weeks. Has it occurred to anybody that **maybe Questcor has never wanted to know?** That knowing the composition of Acthar would threaten their entire business model?

Questcor has not completed a single modern clinical trial proving efficacy for any condition on its label. In fact, even for the orphan drug designation they obtained for infantile spasms, there are only the smallest of trials, with conflicting results in current published research.

Meanwhile, insiders have sold hundreds of million dollars in stock, the amount of which dwarfs Questcor's total cumulative R&D expenditures by multiples. In fact, the company has spent more money marketing the product at Olive Gardens and Red Lobsters around the country than they've spent on research to understand it.

And to what standard is this quote held to in regard to corporate accountability for pharmaceutical companies?

"Coca-Cola is not going to tell you what Coke contains, either," Mr. Bailey says.

Mr. Bailey, Coca Cola knows what their formula is. While you insist you don't know what is in Acthar, yet each batch is purportedly produced to FDA specifications.

The risks to Questcor of these revelations are breathtaking. What standards is Acthar actually being produced to? By what rationale can a physician ever prescribe it for a patient?

Realistically, what are the chances the FDA looks at this statement and concludes:

> **"OK, no harm no foul. Business as usual. Just keep expanding the number of sales people, indications, and informational dinners. No problem…."**

Will the insurance companies (let alone Medicare and Tricare) passively continue to reimburse for a $30,000 drug that is improperly labeled, as admitted by the company?

Lest we not forget, the study that Questcor used for medical justification of its expansion into nephrology (now approaching 40% of revenues), actually was done with **Synacthen** … This study was posted on Questcor's own website until they pulled it down. Then there's the looming competitive reality of inexpensive synthetic ACTH, which, given these findings, cannot be kept off the market for long, regardless of Questcor's untenable Synacthen rights acquisition.

If Questcor cannot stand by the Acthar label, which states unequivocally that the sole active ingredient in Acthar is pure ACTH, then this story is a lot bigger than the stock market. The focus must be on the real needs of the patients, the ability of physicians to prescribe, confident in their knowledge of what medicine the patient is being treated with, and of course a system that provides affordable health care.

Meanwhile, everyone familiar with Questcor knows that long-time officer David Medeiros was the brains behind the drug manufacturing process at Questcor. Finally we can confidently state that his recent abrupt transfer out of his roles, without a succession plan, is not just smoke in the story; now it's fire.

For too long Questcor has been able to tell one story to the medical community and the FDA, while spinning a completely different story to Wall Street. Citron will now step aside and let the FDA join with the SEC, and other Federal regulators in the long-overdue process of correcting Questcor's abuses of both the medical community and the investment community.

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