Citron RESEARCH

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FTC Investigates Questcor:
Serious Jeopardy for Synacthen Deal

Analysts Comments tell you Everything You (and FTC investigators) Need to Know

On June 11, Questcor (NASDAQ:QCOR) surprised the investment community with news that it had acquired rights to Synacthen for the United States and up to 40 countries from Novartis. Within weeks the stock had doubled on that news, adding 1.75 billion in market cap. Why?

Simple. Synacthen is a synthetic version of ACTH, the sole labeled active ingredient in Acthar, which is Questcor's only source of revenue. Synacthen has been prescribed in Europe for well over a decade for the same general spectrum of indications that Acthar is labeled for in the US – but at 1/1000th the price.

So when Questcor, which previously had no drug pipeline, no serious investigational efforts, and no significant double-blind studies proving efficacy of Acthar vs Synacthen, acquired these rights, the analyst community went all giddy – fawning all over how this move protected Questcor's barrier to competition with regard to the pricing of Acthar. Questcor postured the deal as if they bought Synacthen just because they wanted to acquire a new drug, but anyone with half a brain knew that was bullshit.

And thank God the FTC has more than half a brain … sorry, Questcor.

Here's how the New York Times called it:

> "The most obvious threat to Questcor's business was the possibility of someone bringing Synacthen to the United States. Synacthen is a synthetic fragment of the hormone in Acthar."

http://www.nytimes.com/2013/06/15/business/questcor-pays-135-million-for-rights-to-competitors-drug.html

Enter the FTC

Regulatory newsletter The Capital Forum [**http://www.thecapitolforum.com/antitrust.html**] has been following the potential for antitrust investigations regarding Questcor and Synacthen. Friday they reported from several sources that the FTC has launched a non-public investigation into Questcor's acquisition of US rights to Synacthen. It opines that this investigation will likely move on an accelerated timeline. FTC's Mergers I team is leading the investigation.

In particular, the report states the investigation was requested by Senator Amy Klobuchar, who already understands Questcor's pricing gambit well; she is head of the Senate's Anti-Trust Subcommittee. The Capitol Forum Report deems her "the most influential member of Congress on anti-trust issues", which is why the probe may well earn accelerated action. Recently appointed FTC's Bureau of Competition chairperson, Deborah Feinstein has significant experience in pharmaceutical mergers and acquisitions.
http://www.mondaq.com/unitedstates/x/275640/Antitrust+Competition/PayForDelay+To+Stay+FTCs+Top+Priority

While we have a copy of the Capitol Forum report, we will respect its copyright, and just recommend all interested investors subscribe to the Capitol Forum for the full piece.

This acquisition has different dynamics because the deal with Novartis was purposely structured to fall below the FTC's "reportable" threshold – however, that **does not** exempt it from being scrutinized as anti-competitive. The report calls the antitrust effects of the acquisition "compelling", and deems the economic benefits Questcor receives from Acthar as "monopoly profits".

Note that the FTC's mission is specifically stated to thwart anti-competitive and monopolistic actions of corporations, and to enforce the Sherman and Clayton acts. And Citron notes the FTC states it frequently works together with the **Department of Justice** to support their competitive analyses.
http://www.ftc.gov/bc/antitrust/factsheets/antitrustlawsguide.pdf

Under these market conditions, it is obvious that it is in Questcor's economic interests to thwart Synacthen's availability in the US for as long as possible; to send its approval process down every conceivable blind alley of non-relevant indications; to work to prevent importation of Synacthen from European sources (currently allowed under FDA's "compassionate-use" program, although there is no documented clinical benefit for Acthar over Synacthen other than an extreme cost differential.)

What is most amazing is that the analyst community couldn't give two shits about the law or about the sustainability of the U.S. healthcare system -- they were so tone-deaf they actually cheered Questcor for eliminating all potential generic competition.

The Truth – In the Analysts' Own Words

Sorry Questcor, your true motives for acquiring Synacthen were beyond transparent. While your statements characterized Synacthen as a "severely neglected" drug, the reality is that at least one other company had gone through the entire negotiation process with Novartis, and had offered up a significant sum for licensing before you swooped in with more cash. Your only incentive was to protect the pricing for Acthar. Your analysts' coverage bragged about your abuse of the market to Wall Street, offering it up as the reason why investors should buy your stock.

Now those same words become the engraved invitation for the FTC's investigation:

From Jefferies:

QCOR Acquires Rights to Synacthen and Removes Overhang Of Potential Competitor

"Synacthen/ Synacthen Depot have been a key concern among investors as a potential competitive threat to Acthar in the U.S. in indications that are revenue drivers for QCOR (MS, IS, NS, and rheumatology). We have always maintained that Synacthen / Synacthen Depot would likely need to demonstrate efficacy/safety in clinical trials in the U.S. for those indications, and therefore viewed the likelihood of it being a competitive threat as unlikely. Now that Synacthen's rights are held by QCOR, a key overhang is removed."

From Oppenheimer:

The recently announced deal to acquire Synacthen rights from Novartis removes a significant overhang, in our view. There had been fears that another company could attempt to bring Synacthen to the US (it is currently approved in Europe) and compete with Acthar. With Questcor now in the process of obtaining Synacthen rights, this important overhang appears to be resolved…

From Janney:

• Elimination of potential competitor. With Acthar's success in the last few years, the introduction of Synacthen and Synacthen Depoto the US market has been on the minds of investors as a potential threat given the overlap in indications, especially in QCOR's growth driver of rheumatology. Though not an immediate threat, in our opinion as certain safety and efficacy trials would have to be completed, it would have laid a timeline out for QCOR and Acthar. With this acquisition, that potential threat has been absorbed and eliminated.
• **What is Synacthen and Synacthen Depo:** Synacthen (tetracosactide) and Synacthen Depo are a 100% synthetic 24 amino acid analogue of natural ACTH which acts as a melnaocortin receptor agonist similar to QCOR's naturally derived Acthar gel. Currently, Synacthen and Synacthen Depo are approved in 40+ countries for certain autoimmune and inflammatory indications such as rheumatoid arthritis, ulcerative colitis, chronic skin conditions responsive to corticosteroids, nephritic syndrome and acute flare-ups in MS patients and retrobulbar neuritis. Though there is obvious overlap in indications between Acthar and Synacthen, QCOR management did not clarify which indications it plans to develop.

So What's the Threat to Questcor Worth?

It must be understood that the United States is the **only country in the world** that has sales of HP Acthar Gel. That is because we have the only healthcare system **so broken** that it makes insurers reimburse $28,000 for a 65-year old drug when there is a well-known synthetic/generic equivalency already available in the market.

The FTC can be assured that if Questcor owns acquires the rights to Synacthen, the one study the medical community really needs will be **the very one Questcor will NEVER produce**: a straight double-armed blinded clinical trial putting Synacthen up against Acthar for the major indications currently generating Acthar sales volumes – as of now, MS exascerbations, and some rheumatology and nephrology conditions for patients untreatable with corticosteroid therapies.

Upon any realistic timeline for Synacthen entering the market, a terminating date has to be placed on the revenue stream Questcor derives from Acthar. Whether you think it's two years, four years, or even six years, the end of the corporate gravy train becomes a certainty, and only the date would remain in question. Whatever date investors pick, a double digit EPS is suicidal –a single digit multiple is all the stock is worth -- the net present value until its market is decimated by inexpensive competition.

In a complete other story to follow within weeks, we will explain why we believe the U.S. Attorney's Office of the Southern District of New York is involved, and why we believe Questcor management will be doing "perp walks" – yes criminal. In our next report, we will describe a network of illegal insider trading amongst Questcor insiders, as well as the fraud behind the now infamous Chronic Disease Fund.

Please stay tuned. Citron will take great pleasure in detailing the fraud and abuses of the system fostered by Questcor and its management … while they continue to disgorge insider sales in massive quantities.

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