Citron RESEARCH

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Questcor (NASDAQ:QCOR): A Single Digit Stock in 18 Months or Less and Here's Why

Introduction

For the last two years Citron has been focusing considerable attention on the well-known problems of a group of Chinese domiciled companies trading on U.S. exchanges. But loyal Citron readers are aware that during our almost 12 years of publishing, some of our best work has focused on U.S. companies in the healthcare industry, for example:

> **Arthrocare (ARTC)** : In a series of 2007 and '08 reports, Citron exposed the accounting scheme at surgical device company Arthrocare, which ultimately sent the stock tumbling from $50 to a low of $2.
>
> **Amedisys (AMED)** : It was also a series of Citron reports in 2008 and '09 that exposed how Amedisys gamed the Medicare reimbursement system; the stock collapsed from $50 to $10 when regulators caught up and the sad truth was exposed.

So when we read Mellissa Davis's thought-provoking articles on Questcor (NASDAQ:QCOR) (here and here) in http://www.theStreetSweeper.org in January, we filed some Freedom of Information Act Requests (FOIA) to explore what other parts of the story the investing public should know … and we were stunned by what we found. There's **much** more to this story than meets the eye. Citron cannot imagine how Questcor's $3.5 billion dollar valuation has gotten so detached from the underlying reality.

Let's make one thing clear. Questcor is **not** a normal pharma company; it is exclusively a sales channel for a single high-priced drug: HP Acthar Gel; no more, no less. The company has no other pipeline, no other drug candidates, and no material R&D investment in any other pharma products. If Acthar had a sustainable future, it would be reasonable to hang a multiple on the stock. But if, as our story outlines, the glory days of its exploitive strategy are numbered, the stock valuation should reflect the many "landmines" the company has to tiptoe through, the detonation of any one of which will savage its valuation.

Therefore investors need to know:

- What Questcor's drug Acthar **actually is, and is not.**
- What is the true **competitive landscape** for this single high-priced drug.
- How the drug is marketed to doctors, compared to how it is marketed on Wall Street.

- How the company is abusing the system in ways that subject it to extreme business and regulatory risks.
- How management values the current stock as an investment, based on the patterns of its insider sales

Brief History of Questcor

ACTH, a hormone occurring naturally in humans, was originally approved by the FDA as a drug in 1952 (see FOIA file links, Point 1a below). **Yes, it is a 60 year old drug!** Acthar Gel is concentrated and purified ACTH, stabilized in a gel which gives it a longer release effect. The truth is, Questcor's "natural" ACTH is extracted from pig pituitaries in Canada, then shipped to the US where it is "purified" and concentrated. Questcor claims its specialized knowledge of this 50-year old process creates a high barrier to entry.

Questcor acquired the rights to Acthar from Aventis in 2001 for $100,000. At that time, the market for the drug was dwindling. However, in an application filed in 2007 and approved in 2010, it was able to persuade the FDA to grant Acthar orphan drug status to treat the rare condition of Infantile Spasms.

Questcor raised the price of Acthar from $1,000 a vial to $23,000 (currently over $27,000) per vial. In justifying the extreme initial price hike, then interim CEO Don Bailey commented:

> *"The goal of Questcor's new strategy is to make manufacturing and distribution of Acthar economically viable on a stand-alone basis, so that Questcor can continue to ensure the availability of Acthar for those patients who need it most, and* ***fund projects which can contribute to the growth of the company****."*
>
> - - Questcor CEO Don Bailey, August 2007

http://phx.corporate-ir.net/phoenix.zhtml?c=89528&p=irol-newsArticle&ID=1044912&highlight

- What did you expect him to say? **"We plan on using the breathtaking price increase to fund a massive hard-sell campaign, that funds us to game the system by extending Acthar sales into every conceivable tangential indication, while we pillage insurance companies and sell our stock, all in a short period of time before the government or competition catches on ... " ???**

... the unvarnished truth sometimes doesn't go over so well on Wall St. ...

Understand: neither Citron, nor, we assume, the FDA, begrudges a company a profit for selling an orphan drug at a high price; this creates an economic incentive to make a treatment available for a tiny unserved market. As expressed in CEO Bailey's own words:

> *"We have this drug at a very high price right now because, really, our principal market is infantile spasms … It's really driven by the very, very small population of patients that need the drug."*
>
> - - Questcor CEO Don Bailey, early 2009

However, Questcor used this combination of high price and orphan drug status to aggressively move to expand the use of Acthar for other indications; so much so, that the Infantile Spasms condition that induced the FDA to grant the orphan drug protection to Questcor, **now accounts for 6% - 10% of the company's revenues**.

Meanwhile, the company has aggressively expanded marketing to promote Acthar's use for other indications, at the price justified by the orphan drug designation, using the most questionable of tactics, discussed below. We believe this violates the intent of the Orphan Drug Act, and exposes the company to severe competitive risk, also discussed below. But ethics aside, the business model of claiming a niche orphan drug can be "grown" into a "multi-billion dollar opportunity" as the company claims, is a doomed strategy, as this report will document.

The article Questcor CEO Don Bailey DOES NOT WANT YOU TO READ:

Before we introduce our thesis, all readers should read the article from BioPharm Insight **linked here**. (also available online at the time of posting here) It extensively quotes numerous experts in their medical specialty fields, Questcor CEO Don Bailey in rebuttal, and no shortsellers. No complaints about stock wheeler-dealers or Wall Street shenanigans. Refreshingly, it's all about the practice of medicine.

We will be referencing this article extensively in this piece. Before proceeding, readers are encouraged to Google the qualifications of the physicians quoted in the piece.

Dr. Aaron Miller: http://www.mountsinai.org/profiles/aaron-miller

- Member of the Board of Directors of the American Academy of Neurology
- Chairman of the Clinical Advisory Committee, New York Multiple Sclerosis Society

> "I think there's no demonstrated advantage of Acthar gel over IV or high dose methylprednisolone … Whether the drug has other advantages, hasn't been clearly demonstrated … We don't know yet if patients who failed on steroids would respond to Acthar gel. That's not adequately investigated at this point … I don't think there's currently much indication to use that…"

Dr. David Snyder: http://www.nynapc.com/doctors/detail.php?ID=2

- Practiced in the First Comprehensive Multiple Sclerosis Centers in the country
- Director of Neurology, Director of Comprehensive MS Center at NY Hospital Queens
- Member and former chair, Clinical Advisory Committee of NYC Chapter of National MS Society

> "I talked to the drug reps. They tell me there are neurologists that use a fair amount of Acthar. It's difficult for me to figure out why. Essentially, it's just another way of ensuring an increased level of steroids, ... I think frankly, Questcor sees a future in Acthar in other areas and not in MS. There's no benefit, unless patients have a problem with IV steroids."

Dr. Nan Hsien Kuo: http://www.arthritisnewyork.com/dr-nan-hsien-kuo.html
Fellowship in Rheumatology, National Institutes of Health, Bethesda Maryland
Faculty staff of NY Hospital Queens, specializing in autoimmune diseases
Board certified in internal medicine, member American College of Rheumatology

> "Corticotropin is part of a hormone injection, and it's not something we do routinely .,, Steroid injections are given more frequently and work further downstream compared to Acthar ... As far as I can see, I don't see a market for this [in rheumatology]," said Kuo.

When these leading name experts in their biggest market, Multiple Sclerosis finds no use for the drug, regardless of price consideration, it can't be discounted by any analyst or investor. You can't dismiss it like Don Bailey's pathetic attempt at a rebuttal.

Overview: Short lifespan, unsustainable business model

In Citron's opinion, Questcor is a scheme, not a business. The difference? Schemes operate business models with very limited lifespans. Typically, they create the appearance of enduring value, while dumping stock valued at inflated P/E multiples.

For the reasons enumerated in this report, it is Citron's assessment that Questcor's sales strategy is self-defeating. The more it trumpets its "multi-billion dollar strategy", the more it exposes its vulnerability to competition from generics, synthetics, insurance company clampdowns on reimbursement, and better drugs. Meanwhile, as insiders feast on compensation via cheap options, the company uses stock buybacks deceptively to keep the game going.

Citron is convinced this stock is headed back to single digits as the story of its meteoric rise unravels in the light of the truth.

Citron's opinion on Questcor is based on the following points :

Contents: (click to jump to each section's details)

Each of these points is material to investors' assessment of the company's risks, rewards and valuation; Citron examines each in detail below.

Of the above points, 1a), 1b), 2), 3) and 4) are primary qualitative weaknesses of Questcor's business model and represent major vulnerabilities to the company's sustainability.

Points 5), 6), and 7) identify specific actions which profile a management running the company by short term stock-boosting tactics rather than long-term sustainability. They know best what they have.

Point 8) describes how and why momentum investors are left unaware of the risks.

... and we round out with Point 9) a few observations about analysts who are asleep at the switch and playing deaf, dumb and blind in the face of the obvious risks.

1) Highly vulnerable to, but in apparent denial of competitive threats from:

1a) Generic Equivalent Competition

In a 2008 speech denouncing price gouging in the U.S. pharmaceuticals marketplace, Senator Amy Klobuchar stated:

> "According to a study published in the Rand Journal of Economics, the market size for a drug has to be **about $32 million**, that's 2007 dollars adjusted for inflation, to ensure entry of a generic into the market."
>
> http://klobuchar.senate.gov/multimediagallery_detail.cfm?id=301410&

The reality of the competitive drug industry in the US is that generic competitors enter any market where the revenues exceed $50 to $100 million a year. That estimate places the current revenues for Acthar at **over four to ten times beyond the levels** where generic competitors see opportunity. How long is the illusion of exclusivity going to last? And is there any real barrier to entry at all ?

As our research details, numerous generic ACTH drugs were in the marketplace as long as 60 years ago. They left the market because there was insufficient demand to support the drug. If in fact there is a market, there is nothing to prevent their return now.

From examination of the files released to Citron by the FDA under **Freedom of Information Act**, you can see for yourself that the original label for generic ACTH was the source from which Acthar's label was derived. Acthar was granted a new label in 2007; if you examine the language carefully, it is evident that Questcor's Acthar label simply copies the language of the previously approved generic product label for ACTH – no sign of the "secret sauce" the company's misleading language suggests. There was no new drug trial conducted or submitted; the approval was based on the same prior science as the generic ACTH injection products.

Thus, any generic entrant would need to show only bioactivity and purity of ACTH, and could get the same label as Acthar, except for the Infantile Spasms indication protected by the Orphan Drug designation, now just 6% - 10% of its revenues.

The FDA's FOIA Files on Cortitotropin approvals:

Questcor Acthar Label Approval 2010

Carter-Glogau / Steris Approval 1984

Nordic / Duracton Approval 1962

Organon Approval 1955

Armour Pharmaceutical Approval 1952 File #963 from 1952

Armour Pharmaceutical Approval 1952 File #975 from 1951

Parke Davis #400 from 1952

You can see for yourself all the approvals are based on "corticotrophin / ACTH" – the human body's hormone, and not any additional "secret sauce" whatsoever. This is the ugly fact Questcor does not want you to see.

Whenever they talk about the drug they mislead the investing public by creating the illusion that they have constructed a huge barrier to entry.

That is the big lie.

The actual approved indications for Acthar Gel:

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2697107/table/t1-ptj34_5p250/

The company of course claims that producing highly purified ACTH (which is extracted from pig pituitaries) is difficult to impossible, and the process is a highly protected trade secret.

It's the lack of credible barrier to entry that has Questcor's CEO Don Bailey's posturing his "its snake oil" argument for Wall Street, He's caught in a bizarre contradiction, as seen in **the above-referenced BioPharmInsight article and also below.**

On the one hand, the only recognized active ingredient in the product HP (Highly Purified) Acthar Gel, is the human hormone ACTH. He can't make any medical claims for the drug that aren't backed by scientific studies – and other than the study used to grant Orphan Drug status for Infantaile Spasms, there are none. On the other hand, investors want to know about barrier to entry, so he is forced into making claims that venture into "snake oil salesman" territory.

Below are his own words about Acthar Gel, as filed with the SEC :

""I'd like to go through the barriers to entry because this is the key question most investors have with respect to the longevity of this unusual asset. The first barrier to entry is the formulation. Acthar is a biologic. Acthar is an extraction of porcine pituitaries. It's an ***undisclosed composition, so that's a trade secret****. The manufacturing process is also a trade secret. It's complex, it's unique, and we own all elements of the manufacturing process. We have exclusive worldwide rights to Acthar, so we own it lock, stock and barrel. We have no partners. The composition of Acthar that comes out of the manufacturing process is tied to the process,* ***so if you don't know the process you can't figure out what's actually in Acthar****. Acthar is technically a polypeptide,* ***but there are probably multiple active ingredients and there are multiple peptides within Acthar, and they're undisclosed. "***

■ **Investor presentation Aug 22, 2011, filed as an 8-K with the SEC**

- - Questcor CEO Don Bailey, early 2009

There are nearly two years worth of further statements from investor presentations, also filed with the SEC, which **cannot legally be made** in conjunction with the actual marketing and sales of Acthar Gel. Over the last two years, Bailey has continuously described HP Acthar Gel in filings using terms such terms as " Undisclosed composition", "Process complex, unique and proprietary", "Difficult/Impossible to reverse engineer", "Complex pharmacology", "Not well characterized", "Generic pathway unlikely", "Biosimilar pathway unlikely" …

We especially like this phrase: "other active peptides are in Acthar as well" … so let's get this straight – HP Acthar is "Highly Purified", but there are other active ingredients in it anyway? Those would be … impurities, right?

It is simply **illegal to market medicinals** on the basis of "undisclosed active ingredients" or "trade secrets" in the United States. It has been 106 years since Theodore Roosevelt signed the Food and Drug Act which prohibited **"the sale of any drug the active ingredient of which was not either stated clearly on the label or listed in the *United States Pharmacopoeia* or the *National Formulary.*"**

That's what makes the linked BioPharmInsight article so astounding. He states

> "There **are many more active ingredients than ACTH in Acthar**, according to Bailey. With Achtar, the mechanism of action might be related to something else, he noted. Acthar is not well understood because money has not been spent on the science…"

The simple, irrefutable fact is that there is not one shred of scientific evidence substantiating that there exists anything of therapeutic value in Acthar except ACTH. Period. End of story…The rest is snake oil.

How about the production of a generic natural ACTH drug? First of all, the drug was produced as early as 1952 – 60 years ago -- by several companies. This was certainly after the invention of chromatography, but well before modern tech including computer controlled chromatographic processing and an avalanche of other biotech advancements over the last 60 years. ACTH is a well-studied, 39 amino acid chain. Are we to believe that Questcor's "multi-billion dollar market opportunity" is invulnerable to any generic pharma company figuring out how to process ACTH from a natural source? It is Citron's opinion that Questcor's claims simply do not pass the "reasonable man test".

Remember, Questcor own disclosure states it has **no intellectual property protection** with regard to Acthar. (see point 4 below)

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1b) Synthetic ACTH (Novartis' Synacthen Depot) is already in the market in Europe.

On the synthetic side, there is a well known, cheap synthetic ACTH, available in Europe for over a decade. In fact, patients in need of the drug here in the U.S. often import it individually, under a policy in which the FDA tolerates individuals bringing in an unavailable drug authorized elsewhere for their own use under its "compassionate-use" policy.

See https://braininstitute.mch.com/wiki/ACTH_for_infantile_spasms for details, especially note the price comparison of $615 vs. $74,000 to treat an average case of Infantile Spasms.

> **"Synacthen Depot, a long-acting synthetic b1-24-corticotropin, exhibits the same activity as natural ACTH with regard to all its biological activities."**

http://www.rxmed.com/b.main/b2.pharmaceutical/b2.1.monographs/CPS-%20Monographs/CPS-%20%28General%20Monographs-%20S%29/SYNACTHEN.html

Experts interviewed by Citron believe the path to market in the US for this formulation is relatively short, simple, and not particularly costly.

Synacthen Depot contains only the first 23 of the 39 amino acids **of natural ACTH but is generally believed to have entirely the same biological function.** **http://en.wikipedia.org/wiki/Cosyntropin**. **http://en.wikipedia.org/wiki/Synacthen**

This drug sells for 1/30th or less than the price of Acthar Gel.

Ironically, one of the very studies published by Questcor to justify the use of Acthar for nephrotic syndrome **actually used the synthetic form of the drug in the drug trial.**

> "This trial used a long-acting synthetic, truncated analogue of ACTH (Synacthen Depot, tetracosactide, ACTH1-24). The compositions of Acthar and synthetic, truncated ACTH analogues are not identical and data evaluating dose and therapeutic, mechanistic, and safety equivalence are limited. "

http://www.acthar.com/nshcp/acthar-effectively-lowers-proteinuria-nephrotic-syndrome

Hmmm: At the very same time, Questcor, self-servingly and with no scientific basis, insists elsewhere that synthetic ACTH is **not** bio-equivalent to Acthar. Which is it?

It is Citron's understanding and belief that Novartis is currently taking steps to bring Synacthen Depot to the U.S. market. Further, Citron believes that its inevitable entry to the US market could be devastating to sales and revenues for Acthar due to the extreme price differential. Qualified parties are encouraged to contact Novartis for details.

The path for a synthetic version of a naturally occurring hormone to gain approval is well known and neither overly complex nor costly. Questcor has been consistently misleading Wall Street by under-reporting this looming competitive threat. Here is but one recent example, from Questcor's last conference call:

> **David Amsellem – Piper Jaffray, Inc.>:** "Okay. That's helpful. And then on the competitive landscape, what's your sense of how long it could take **Novartis** to bring its synthetic corticotropin to the U.S. market if that's what they're doing? **And also to what extent is their usage of it right now in the U.S. on, I guess, a** compassionate use basis? Thanks."
>
> **<A – David Young – Questcor Pharmaceuticals, Inc.>:** "Yes, thanks. It really depends on what the product is. They could try to bring a generic or a biosimilar, which would be almost impossible, given the guidances. If they try to bring in a different molecule, like

> the **Novartis** product, which is a completely different peptide, then that also would be difficult, because it wouldn't compete with us in terms of being equal to us. So it's – we don't have a great idea of anything coming in now, but even if something was to come in soon, it would take many, many years before it gets approved. "

Investors are **strongly encouraged** to review Acthar's labeling in the FOIA file, and in particular compare the wording to the ACTH labeling it is based upon from the prior generic manufacturers. Then, judge for yourself the truth of the company's statement above, before you "bet the house" on it.

How do the analysts miss this obvious vulnerability? Are they performing any analysis, or just taking the company's word for it? Piper 's analyst says :

> "...Synacthen, that is a different chemical entity (and can never be a substitutable generic)..."

This is not the relevant question investors need to be informed about, but rather just loose investor-relations-speak, an exercise in intellectual dishonesty. The important question is simply this: does a generic path to market exist for an ACTH drug with a label that rivals HP Acthar Gel? Citron believes the answer is conclusively yes.

It is Citron's opinion, that once Synacthen Depot is approved in the US, while **pharmacists** will not be free to swap it as a "generic ACTH" until its bioidentity is established by clinical trial, **physicians will immediately be free to prescribe it for all ACTH label indications except for Infantile Spasms.** And at two orders of magnitude less costly, insurance companies, already toughening policies for Acthar Gel reimbursement (see Point 3 below) will insist that the less costly alternative be the preferred treatment option, and approve Acthar Gel reimbursement only in cases where synthetic ACTH fails or causes adverse reactions. However, Citron is not aware of any documented cases of medical divergence between synthetic and "natural" ACTH in the literature.
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2) Desperate and Unscientific Basis for Expanding Markets

As part of Questcor's search for new markets and new uses of Acthar, on June 11 the company put on the full PR blitz for a June 14 conference call to disclose its expansion into rheumatology. On the conference call, we learned that the company is basing its "medical decision" to hire a new sales force on a **retrospective, 5-patient, unblinded, open label "study" with no control arm**. This tactic harkens back to Questcor's penny-stock roots; it is simply not credible scientific practice for a real pharma company.

Here are the comments of one industry analyst interviewed by Citron :

> "That was perhaps the most egregious conference call I have ever heard in the history of my 23 year run in this industry. Not even hard-up, cash-strapped, smallcap biotechs would ever hold a conference call to discuss a five patient retrospective case study!! Its beyond embarrassing, it's shameful."

Not only is the 5-patient study ridiculous, but Bailey now admits (in yet another humiliating quote from the same BioPharmInsight story linked at the top) Questcor has spoken to only **five** rheumatologists prior to calling the press conference to announce Questcor's entry into rheumatology indications.

> "Frankly, we've only talked to 10 doctors, five of who are rheumatologists," [Bailey] said in response to why rheumatologists have never heard of Acthar.

More comments Questcor Does Not Want You To Hear

Two days before the announcement of this five-person study, Summer Street Research held a conference call with Dr. Eric Matteson, **Chairman of the Division of Rheumatology at the Mayo Clinic**. When asked about the expansion of indications for Achtar use in rheumatology , this highly credentialed professional stated:

> **"Limited to no attractiveness in rheumatology"**
>
> **"Enthusiasm is low"**
>
> **"Very little if any role for an ACTH product in rheumotatic diseases, I don't see it."**

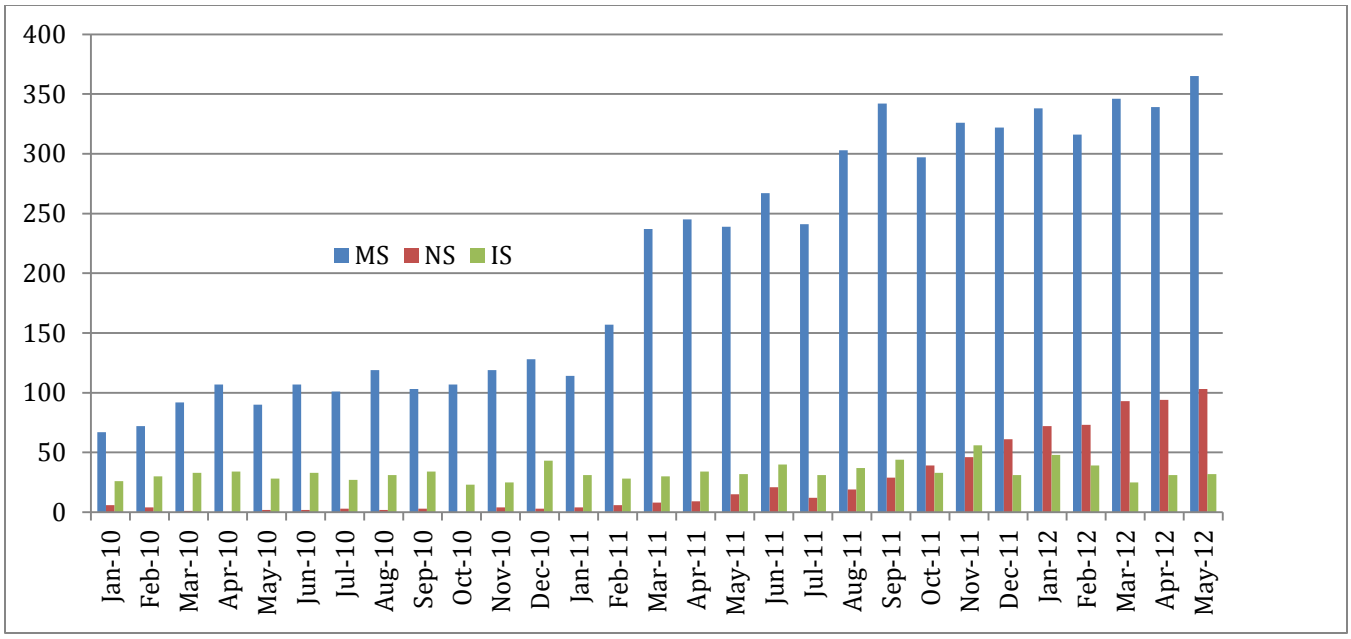
And his most insightful comment into Questcor's place in the system:

> **"If they catch any doctors it would be the result of an inefficiency in the system."**

And that is precisely what Questcor is hoping for, and its sales force is creating … more "inefficiencies" in the system so they can sell more Acthar – a drug whose adoption is driven not by the best interests of patients, but by its extreme pricing model.

One way of understanding this desperate tactic is that, as Questcor's stock price runs higher, Wall Street demands that they generate increasing numbers of prescriptions, forcing them to enter new markets. After 60 years of ACTH's availability, management now believes it can drive its sales machine into the uncharted territory of rheumatologic symptoms. Citron wonders whether their most recent move tips their hand that the MS market is topping out, forcing them to reach farther and farther for "growth".

Look at the chart of prescription trends:



Infantile Spasms (green) is a no-growth market, and Multiple Sclerosis (currently 75% of prescriptions) is showing scant real growth in nearly a year. The Nephrotic Syndrome indication is being sold based on a **study actually performed with synthetic ACTH.**
So where will the future growth come from?

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3) Insurance Industry Pushback

Most Acthar prescriptions appear to be a one-off arrangement. The company goes to great pains to report that the average prescriptions per physician is appx 1.5. (This is the context of our questions about where the non-salary marketing expense goes – see point 5) below.)

However, our interviews at major MS treatment centers indicate that Acthar has no presence. So the pattern seems to be the sales force fans out to reach individual physician practices far away from clinical centers of expertise, paying doctors handsomely to conduct "free lunch" sessions, often with small groups of doctors and/or patients. Since almost 100% of the company's revenue is insurance company reimbursement, their policies are decisively material to Questcor's revenue model. (Questcor must rebate 100% of Acthar costs to Medicare; so private insurers are footing virtually the entirety of Questcor's revenues.)

Not surprisingly, as the volume of Acthar prescriptions grows, insurance companies are applying increasing scrutiny to Acthar prescriptions. **Within the last week**, two health insurance companies issued highly detailed and restrictive "clinical policy" statements detailing the conditions under which they will reimburse Acthar claims. While being required to follow the

label indications closely, both Blue Cross / Blue Shield of North Carolina and UnitedHealthcare/Oxford Health lay out conditions for reimbursement in strict detail.

What these policies have in common is that for **all** indications except Infantile Spasms:

1) Aside from Infantile Spasms, Acthar is definitively ruled out as the first line treatment -- failure and/or severe reaction to (much cheaper) steroids is a medical prerequisite, and
2) The insurer has a right to review the patient's detailed medical records to verify qualification – a letter from a medical professional is insufficient.

Clearly this reflects a policy of increasing scrutiny.

http://www.bcbsnc.com/assets/services/public/pdfs/formulary/acthar_um_criteria.pdf

https://www.oxhp.com/secure/policy/hp_acthar_gel.pdf

These findings follow on the Prime Therapeutics poster of 4/20/2012 at the Academy of Managed Care Pharmacy conference, in which you'll see the same conclusions. Money could be saved by limiting reimbursement to patients documenting the rigorously requirement of first-line therapy failure. (Prime is the largest Pharmacy Benefits Manager in the US.)

http://www.primetherapeutics.com/PDF/AMCPPosterRxClass.pdf

After reviewing this data with industry professionals, our conclusions are:

A) These organizations had no prior policy with regard to Acthar; therefore their scrutiny is intensifying.
B) To the extent these policies are shared with other Blue C/S plans and/or the BCBSA Physician Executive committee level, increasing scrutiny of Acthar reimbursement will spread through the industry.

It is Citron's opinion that insurers' scrutiny could soon be causing sales of Acthar Gel to top out. Thus the company's push into new indications despite poor scientific justification.

Questcor's disclosure with regard to insurance company reimbursement policy is terse:

> "Insurance coverage continued to remain favorable for Acthar during June 2012."
>
> - - Questcor 8-K, filed 7/8/2012

When a company defends a "multi-billion dollar market opportunity" entirely dependent on insurance reimbursement on a month-to-month frame of reference, it reveals how fragile the business model truly is.

In the above referenced article, insurance companies should be taking note of how CEO Bailey contradicts himself when commenting on positioning Acthar. First he says: [Commenting on steroid failure,]. "There are patients who take steroids, who often don't do very well. Those are the patients that doctors use Acthar in." But then he follows with "the current data really isn't to position Acthar as a second-line therapy for patients who fail on steroid use."

So which is it ? Note to Bailey: There is no current data.

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4) Lack of Intellectual Property Protection for HP Acthar Gel

In order to believe in the Questcor story's long term potential, an investor would have to believe that Acthar, a **60 year old drug,**

- Is not subject to price elasticity
- Can continuously be expanded to new markets
- Cannot be synthetized
- Cannot be manufactured as a generic
- Will never face competition
- All of this without government (FDA or DOJ) or insurance industry scrutiny

This goes against every normal protocol in the pharmaceutical industry and everything we know about business as a whole.

The reality is admitted in their current 10-K. (Note: This sweeping, unqualified language is new in 2011):

> **"The patent for Acthar has expired and we have no intellectual property-based market exclusivity with respect to any indication or condition we might target."**
>
> - - Questcor 2011 10-K, filed 2/22/2012

This is why the company keeps harping on how this 60 year old drug is so difficult to produce, and how a synthetic "just isn't the same". Could they be expected to say anything else?

Citron's favorite line is:

> "When we acquired Acthar, we knew that we would have to spend millions of dollars transferring the manufacturing of the drug to contract manufacturers, and that we might fail in doing so **due to the tremendous complexities of the process."**

So let us get this straight -- the manufacturing process hasn't changed since the 1950's, (it couldn't have or there would be a new CMC section in the IS submission and we didn't see one) but for some reason after 60 years of experience, all of a sudden, it is **tremendously complex** to grind up pig pituitaries?

That is the mantra of Questcor — suddenly, it has become overwhelmingly complex to accomplish something that companies were doing 60 years ago. Suddenly we figured out how to magically accelerate sales of a 60 year old drug without any new clinical data. Suddenly a 60 year old drug has brand new effects that nobody knew about ... Suddenly ... Yeah, that happens all the time. Just can't think of another example … can any analyst or shareholder think of any other comparable situation in the entire pharma industry?

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5) Marketing Expenses = Utter Abuse of the System

The sales and marketing for HP Acthar Gel is now up to $6,100 a vial…**more than 5 X the original price of the drug before Questcor became involved.**

Generally speaking, sales and marketing is entirely unnecessary for an orphan drug. Patients and doctors involved in rare conditions typically know what drugs they need and how to find them. Typically, there would be one person answering a phone in a call center. It is obvious that Questcor is consuming healthcare expense money that should be flowing through our healthcare system to incent new discoveries, not to juice a high-priced marketing campaign for an antique drug at a new and astronomical price, with no new science to justify it.

Is this money going to its speakers bureau, golf outings, sample products, or extravagant gifts? We do not know. We would like Questcor to provide a detailed answer.

But here's what we **do** know. In its most recent quarter Questcor reported $21,716,000 in Sales and Marketing expense. Management claimed 105 reps were employed. During the Q2 call for 2010, when asked about sales rep expenses, Don Bailey disclosed the following:

> "It should run approximately a total of $300,000 a rep and that includes the management. So if we rounded it to 40 reps that's $12 million or $3 million a quarter and have a full quarter's worth of expenses in Q3, but we would in Q4, maybe a couple of million in Q3 and $3 million in Q4."

So let's get this straight…

Sales reps companywide:	105 (77 for MS, 28 for NS, none for IS)
X cost per rep and management:	$300,000
Yearly cost of the sales team:	$31,500,000
/4 = Qtrly cost of the sales team:	$7,900,000
Qtrly Sales and Mktg Expense:	$21,716,000
Subtract to calc Other Mktg Expense	$13,800,000
Cost per vial (all 4,110 shipped)	$3,357 (in addition to the sales team cost)
Cost per vial (paid for appx 3,554)	$3,883 (in addition to the sales team cost)

That's comes to $3,357 or $3,883 per vial in unexplained marketing. That's a lot of cash to dole around to heavy prescription writers, i.e. speaking engagements, lunches, etc.

If you back out Infantile Spasms, which shouldn't require any subsidy at all, (IS was 112 scripts last quarter times 4.5 vials per prescription, appx, 504 vials can be removed from the base, the resulting marketing cost per vial goes **even 15% higher** than the above figures.) That is a **huge** amount of money sloshing around unaccounted for …

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6) Absence of meaningful R&D

Just the insider selling over the last year represents more cash than Questcor has spent on research and development over its entire lifespan.

Year	Questcor R & D Expense ($ in millions)
2011	16.8
2010	10.9
2009	9.7
2008	10.6
2007	4.8

Meanwhile, the only study that we are aware of paid for by Questcor designed to demonstrate Acthar's efficacy in treating MS was **terminated**, **by the company, with no explanation.** This is one that neither patients, doctors, nor investors will receive benefit of of Questcor's R&D from.

http://clinicaltrials.gov/ct2/show/NCT00947895

And back to the article which references this study.

> "The trial wasn't enrolling very well anyway. It isn't something we're particularly interested in," Bailey said, adding that defining patients for that type of study is very difficult.

Sorry, this excuse is worse than "the dog ate my homework". Questcor knows every MS patient out there. They couldn't get enrollment of enough patients? With the $27,000 miracle drug offered for free?

It's not every day that a pharma company gets to invest in a study of its own drug's efficacy, peek at the results, and then terminate the study while continuing right on marketing the drug anyway!

It is Citron's opinion that this data point is a giant lawsuit magnet, once the inevitable comes to light.

So in the meantime, we'll have to live with the science to date, and ". It isn't something we're particularly interested in" … and the following :

> **"multiple head-to-head clinical studies have shown no difference between the effectiveness of IV steroids and ACTH"**

http://msassociation.org/about_multiple_sclerosis/medications/types/acthar_gel.asp?ver=print

That's the state of R&D, folks. Not much science, but in the last 12 months alone insiders have sold close to 2.2 million shares with only 1500 shares being purchased. **At today's market price, that would be worth more than $120 million dollars – more than 5 years worth of R&D expense at Questcor.**

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7) Conflict of interest between purported stock buybacks and insider selling

It is through the lens of management's actions that investors can see that Questcor's brass has been acting as if their business could be terminated any day. The egregious price hike of HP Achtar Gel took place in 2007 when the stock was under $1. The price hike was responsible for the company turning profitable. In the first half of 2008, management immediately sold 1.7 million shares at an average of $5 a share. In the second half of the year insiders sold another 1.4 million shares at $7 to $9 per share. The large and consistent amount of insider selling then and since suggests that management never anticipated or valued the run beyond the limited sales to

the Infantile Spasm indication, which was the original Orphan Drug designation, and never thought the stock would get out of single digits.

As a short seller, Citron is frequently asked what are the key indicators of a "red flag" condition in the investment thesis in a company. Amongst others, whenever we see **large insider selling at the same time the company is buying back large amounts of stock**, it is commonly an ominous sign.

In these cases, when the company asserts "we are repurchasing shares", the truth is: **NO YOU ARE NOT**! **Shareholders are repurchasing shares. You (management) are selling shares.**

As a public company, Questcor's flow of options exercise and insiders' stock transactions have become a direct reflection of the same management who has never built a pipeline of drugs or made any significant investment in R&D to develop a sustainable business model.

What continues to the present day is management consistently granting itself large quantities of options, and selling them as soon as they vest. The officers and directors holdings table and outstanding share count remains remarkably consistent from year to year, regardless of which numbers you benchmark. (We've used several, stretching back to 2005.) The company stamps out about 2.5 million options a year, and the insiders sell them. The outstanding share count has barely moved – with the exception of last quarter's spend of over half the corporate cash, to inflect the needle 5%. But on an annual basis, as the table below shows, options seem to keep the share count mostly hovering.

> **"We have an overhang of common stock due to a low average exercise price of employee stock options. The future exercise of employee stock options could cause dilution, which may negatively affect the market price of our shares. "**
>
> - - Questcor 2011 10-K, filed 2/22/2012

Meanwhile, Questcor's "Share Buyback" program is one of the company's major investment inducements to prospective investors. The carrot of share buybacks "returning profits to shareholders" is a part of **every version of Questcor's shareholder presentation**. In fact, this policy is mentioned in no less than **20 SEC filings** since May 2010.

The reality is that share buybacks are essentially barely keeping pace with the company's option program, which is quite effectively enriching insiders.

Much of the company's oft-promoted historical total expenditure of $263.6 million on share buybacks – 87% of its operating cash flow -- can be traced almost entirely to the pockets of

management and insiders who continue to pound out their option sales. They are essentially cashed out on an ongoing basis by the buybacks, while the public stands exposed to the risk that the share price will drop catastrophically the moment any of the competitive factors enumerated in this report materialize.

(Per Proxy Statements 2005-2012)			(Per 10-Ks and recent filings)	
Year	Shares Outstanding (per proxy statement)	Options Grants to Insiders (*incl warrants)	Basic Shares Outstanding	Fully Diluted Outstanding
2005	61,271,879	2,829,802	52,477	53,323
2006	56,999,245	2,601,384	56,732	56,732
2007	71,196,997	2,788,719	69,113	70,915
2008	69,403,636	2,757,277	67,671	71,350
2009	64,610,130	2,494,368	64,196	66,257
2010	62,040,454	2,389,103	62,112	64,741
2011	61,654,574	3,256,115	62,498	66,010
2012	63,677,031	2,526,623	63,491	66,471
8-K: 7/8/12			59,700	62,700

As of today, there is scant visible long term impact of three years of heavily hyped stock buybacks. The outstanding share count simply doesn't fall materially, it just displaces option grants.

The funny thing is that, in all fairness to management, if you know your stock is terminal, this is exactly the right strategy to execute. When the axe falls, there's limited cash on hand, no inventory, and the company disclosed all along it had no IP protection.

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8) A Note about the IBD "Top 50 Stocks" list

Citron believes that much of the recent price movement in Questcor is due to its position as the #1 stock in the "IBD Top 50" list, having worked its way to the top over the last several months. While good for measuring price momentum, the IBD list methodology is notoriously vulnerable to failing to detect unsustainable business models. In fact, IBD is exclusively quantitative measurements, and **none** of the material earnings quality / sustainability issues as raised in this report are ever reflected in its rankings. In the past 3 years two of the highest percentage collapse stocks covered by Citron were IBD #1 stocks at the time reported … Bidz.com (NASDAQ:BIDZ) and Sky-Mobi (NASDAQ:MOBI).

The primary threat is that their orphan drug protection, which applies only to Infantile Spasms, is now only 6% - 10% of their revenues. The entire balance of their revenue stream, both current and projected, **is extremely vulnerable to competition** from two distinct directions as described above, headwinds from insurance company pushback, and the utter lack of intellectual property protection. None of this is reflected in a stock's "Relative Price Strength". Buyer beware.

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9) Finally, the Analyst "Community" – watch the excuses and defenses pour forth

Why do none of analysts even mention these competitive risks? What about the ominous quotes from top subject matter experts in their specialties? Is there nothing left of the discipline of actually performing analysis, rather than just repeating company propaganda?

It's not like Questcor is a "cheap stock" if its projections all pan out, either. To stretch targets in the face of the stock's current momentum run, analysts are now forced to hang a 20 P/E on 2015 earnings projections.

(For example, one says: We have upped our Price Target on QCOR shares to $61 (from $55), which we arrive at **by applying a 20x multiple on our 2015 EPS forecast of $4.04, discounted back three years at 10%.)**

There is plenty of evidence presented here to document the serious risk factors that loom over the assumption that Questcor can make it to 2015 unscathed, let alone 20 years beyond.

Citron believes the current share price for Questcor and the analyst targets completely ignore the risk of a catastrophic share price fall **the moment** a credible competitor for synthetic or generic ACTH appears on the landscape, or the MS market falls to insurance company scrutiny or competitor drugs. We haven't mentioned several highly promising drug candidates for Multiple Sclerosis treatment making their way toward FDA approval in q4 2012 – but neither do the analysts.

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Conclusion

Citron predicts that one day in the near future, a seismic shift in Questcor's competitive landscape will surface, and the effect on Questcor's stock will be catastrophic. The risk is an immediate cut by half or more, and ultimately a retreat to single digits, as the stock returns to the value of its five-year market protection for infantile spasms, a minor sliver of its current revenue base.

And there will be nobody to sue. The company has already disclosed this vulnerability in its filings. Whether it be generics, synthetics, regulation, insurance pushback, new MS drugs or a combination of all – every one of which is a timely threat, when it does blow, the hit will be fatal – not for the insiders, but for the shareholders.

Citron believes all shareholders – both long term holders and speculators -- should consider the strong evidence that they are playing with a stock that will end where it began – in the single digits.

Cautious investing to all.