From: "Wayne Holman" <[redacted]>
To: "Jeffrey Epstein" <jeevacation@gmail.com>
Subject: RE: please respond
Date: Mon, 01 Nov 2010 14:07:42 +0000

Hi Jeffrey,
I am not sure where to start but one way to look at this is to examine the way they answer some of these questions with statements that cant possibly be true because the answers are not knowable by them or are so outlandish that they render any other statements they make suspect. When I get people telling me things as fact that are actually assumptions or forecasts it makes me very nervous.

Examples:
1) The drug is 18 months away from approval. They cant know that. Even if this were a simple generic drug the review process alone averages 18 months. This is a protein biologic (much more complicated) and it has just started human trials.
2) "Human clinicals trials have just begun, but risk is a nonissue since this is a generic" This is a classic - the old there is no risk. Drug development is as risky as it gets. I cant believe someone would actually say this who has worked in drug development for 1 day.
3) "The current head of the FDA has proclaimed AB rating will likely be granted for this drug and that a bold statement about US biologics will be made with this approval." So I am supposed to believe the "current head of FDA" made this statement about a drug that hasnt been filed with the FDA and has produced no human data yet. Does that make any sense to you? It is absurd.

I could go on and on but I am sure you get the point.
One other thing to always watch out for is an over reliance on the resume of the people they have as researchers etc. They always tout some great people from big pharma as the reason this or that will be a big success. There are literally tens of thousands of big pharma people running around and as you can tell from looking at the stock charts of big pharma over the last decade they havent really knocked the cover off the ball in their old jobs and every biotech venture has a few and most biotech ventures fail.

From: Jeffrey Epstein [mailto:jeevacation@gmail.com]
Sent: Monday, November 01, 2010 9:29 AM
To: Wayne Holman
Subject: Fwd: please respond

response

---------- Forwarded message ----------
From: **Matthew Harriton** <[redacted]>
Date: Mon, Nov 1, 2010 at 9:22 AM
Subject: Re: please respond
To: Jeffrey Epstein <jeevacation@gmail.com>
Cc: Anthony Georgiou <[redacted]>

Jeffrey:

Please see responses to your questions below. Please let us know if there is a basis for further discussion.

This looks extremely high risk and without any real possibility of high reward even based on this very limited information.

1) Insulin market is very competitive with many very well funded players looking at biosimilar and bio-same insulin

a. There are 3 major players who control the insulin market on a branded basis, and only one real competitor generically (but that competitor is not a true generic in the sense of substitutability). All those involved have had issue with manufacturing cost particularly in less developed territories in the world where pricing elasticity erodes margins. Our technology allows for favorable margins. In less developed territories, the cost of the pen is not the issue since vials are often not afforded or widely distributed where countries do not think it is economically feasible. We also aaddress the issue of manufacturing facilities and plant costs, reducing the burden 10x. Thus we have patent protection for our true generic process leading to the first economically feasible generic insulin without supply constraints. Thus, we are not entering a crowded market since this is not a commoditized product. Ultimately, we believe there will be 3 major brands and 2 major generics in the market of which we will be best in class on both a branded and generic basis (based on purity of drug). With better pricing, we should be a clear winner.

2) This is very early - recent IND approval from US FDA means they are not in human trials yet or just started very recently though I suspect if they had actually started human trials they would jhave mentioned it here.

a. The drug is 18 months away from approval and it goes through CDER and not CBER (not the biologics division because of grandfather issues). The product is designed by the group that developed the first biosynthetic insulin and the FDA regulator that approved it. The former head of R&D of the big pharma at the time of approval is also involved. The current head of the FDA has proclaimed AB rating will likely be granted for this drug and that a bold statement about US biologics will be made with this approval. Human clinicals trials have just begun, but risk is a nonissue since this is a generic and approval in less developed parts of the world have already lead to preliminary discussions of approval in 6-12 months on a named patient basis and full-blown commercial sale.

3) These guys dont seem to have US rights but seem to have rights in low value geographies - you arent going to make much money selling their product in Iraq, Algeria and Libya etc.

a. Sorry if it was not clear from the materials. Elona holds global rights to this technology, we (Tony, myself and our partner) have acquired the exclusive right to the technology in the territories described. Additionally we have acquired 25% of Elona itself. According to the World Health Organization, the territories we own represent approximately 58% of the world's population of diabetics today and will represent approximately 63% in 2030. While standards of care and availability of insulin differ in various regions/countries our model takes these factors into account.

The less developed parts of the world have real opportunity because affordable insulin has never been a priority by the big 3 and they also have to contend with re-importation if sold in excess in territories where there is significant discounts. The original product has increased 3x in price over 10 years well over the cost of inflation and at the high end of average pharma price increases. Pharma companies have been trying to preserve margin and control supply to sustain profitability. What most people miss is their stake in the oral markets that are much larger. It behooves them to make available affordable insulin without supply constraints only to stave off the oral market. Thus when properly introduced, we believe the less developed countries will have widespread adoption of generic insulin. This was the impetus in Pfizer's recent purchase of Bioconn. The opportunity for the broader set of insulin properties is vast. The Lantus product is key and growth rates are notable. We can provide a truly affordable version and safely compete in the market. The key is to understand that these less

developed countries have not been presented by a suite of true generics. Even Biocon has been mismanaged in many ways that we are aware of per direct contacts to the CEO.

4) Even if they had global rights it is extremely difficult to get AB rated bio-same approval for proteins and it would be extremely difficult to get comfortable with them achieving that down the road regardless of how much due diligence you could do now.

a) AB rating only applies to US and would earmark the first true generic and force convert $1bn of product in the US alone. Outside of the US, there is no such rating but the drug would be viewed as a biosame and not biosimilar. There is also an increasing trend in this direction as new legislation is passed and reimbursement starts to not just favor but force less expensive alternatives.

5) Insulin competition isnt about manufacturing cost of the active pharmaceutical ingredient but it is based on the delivery device.

a. Insulin costs are based on API as well as delivery, but also in the grand scheme of margins relative to the effective size of the organization. Pharma companies including now even recently partnered Biocon control the market and they need billions in profitability to move the needle. Pre-filled syringes, vials and pens are commodities that can be acquired at cost, but reducing overall price of the drug to a huge discount is not only a function of cost of goods, but also financial needs of the supplier. We can absorb thinner margins and still have significant profitability while being able to scale up in size without any concern of supply constraints or capital requirement to get facilities up and running for large-scale production. This technology is well-covered through a patent portfolio and should not be underestimated for broader implications.

6) No information is given on oral insulin but many have tried for decades and failed and I suspect the lack of information means they are not in human trials and have not proven any concept. **They actually say here the low cost of their insulin is what opens up the possibility of oral insulin - that is totally false. The lack of oral insulin products today is based on technical and scientific hurdles of delivering it intact to the bloodstream through the GI tract - not cost.**

a. This point is incorrect in the sense that bioavailability has not been overcome because no one has reasonably considered to pack so much insulin in a few tablets that would effectively require an insulin city to meet demand. We have the bioavailability data and 2 year toxicty. The individual that will lead this effort spent 16 years of his life working on it and when he saw the solution resolved he committed all delivery IP to the effort. This was spurred by a conversation with a big pharma CEO who accepted the technical merits of the proposal and went to his Board to get the approval for billions of dollars in commitment for an insulin city so to speak. Now that it is no longer required, we will soon come to an appropriate collaboration.

On Sat, Oct 30, 2010 at 5:14 AM, Jeffrey Epstein <jeevacation@gmail.com> wrote:

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Matthew L.Harriton
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