

BioDelivery Sciences International's (BDSI) CEO Mark Sirgo Presents at Morgan Stanley Healthcare Conference (Transcript)

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BioDelivery Sciences International, Inc. (NASDAQ:[BDSI](#))

Morgan Stanley Healthcare Conference

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Executives

Mark Sirgo - President and CEO

Analysts

Chris Caponetti - Morgan Stanley

Chris Caponetti - Morgan Stanley

Thanks everyone for joining the BDSI session. I am Chris Caponetti and I encourage you to please visit morganstanley.com/researchdisclosures for disclaimers. With that it's my pleasure to welcome Mark Sirgo, BDSI's President and CEO to the stage.

Let me tell you a little bit about Mark. He has over 30 years of experience in the pharmaceutical industry, including 16 years in clinical drug development, seven years in marketing, sales and business development and 12 in executive management positions. He's been with BDSI since 2004 and he also serves on the Board of Directors and is the Chairman of the Compensation Committee at Salix.

Mark thanks so much for coming out today.

Mark Sirgo

You're welcome, pleasure to be here.

Chris Caponetti - Morgan Stanley

Yes. So we'll turn over to you for some opening remarks. You had your Investor Day last Friday which I understand was very well received by investors. So if you could just provide us with an

introduction to BDSI, the progress year-to-date, talk a little bit about your upcoming drug launch and any key takeaways from last Friday's Analyst Meeting. That would be great.

Mark Sirgo

Yes thank you Chris. BDSI is a specialty pharmaceutical company. We use drug delivery to reinvent proven therapeutics. We've got two products now approved through FDA in the 10 years I have been at the company. Most recently we had BUNAVAIL approved for the treatment of opioid dependence, which is a product that will compete with Suboxone. In that particular space, we have also had two very positive Phase 3 study results for BEMA Buprenorphine chronic pain product that we've got part of a vendor pharmaceuticals first study read out in January and the second one read out in June, NDA scheduled for submission late this year hopefully no later than in January '15. And we had an interim analysis on our first Phase 3 pivotal trial for Clonidine Topical Gel which was a positive signal and we're adding a few more patients to that trial, but it should have read out sometime first quarter of next year. So we continue to focus in pain and addiction medicine using drug delivery also falling to 505(b)(2) regulatory pathway where we can reference the originating companies pre-clinical data. And I think we've done it effectively through our first two approvals.

Chris Caponetti - Morgan Stanley

That's a great introduction. So I wanted to start off on BUNAVAIL if we can. Just the commercialization plans in your marketing strategy for that product. How many sales reps, what physicians, what geographies are you targeting that sort of things?

Mark Sirgo

Sure. The nice thing about this category is that it's really consolidated geographically and in the physician base as well there is about 5,000 physicians that treat opioid addiction and 80% of the business is consolidated East to the Mississippi. And because of such small group of physicians you can cover with a small number of sales representatives. So for a company like us launching our first product, it's very manageable in terms of the commercial spends, we're going to have about 60 sales people for regional managers and two individuals, one at Quintiles because this is a contract salesforce and then David Acheson who have got sales and manage markets for us overseeing the entire effort.

So we're set to launch our national sales meeting is actually is this Friday it runs through early next week and we'll have our feet on the ground the following week. We've had five MSLs, Medical Science Liaison on individuals out in the field since last April, sort of paving the way first talking about the technology and then after the approval talking about the product itself. So we've been in some of the highest practicing offices in this space for about six months. Salesforce of course will hit the ground as I said week after next. Again about 60 people targeted 80% of these individuals would be East of the Mississippi the rest in Texas, Phoenix and West Coast.

Chris Caponetti - Morgan Stanley

Yes well those 60 sales reps, how does that compete against Reckitt-Benckiser who is there Suboxone?

Mark Sirgo

Right, we don't have any exact figure on their salesforce at this point in time it is somewhere next to certainly of 100, could be up to 150 individuals at this point. They cover a more expansive physician base, it is still that 5,000 but within that they have lot of touches on all 5,000 where ours would be more focused on the highest prescribers of that group. Having said that, I think more importantly it is the -- what we've learned about in the last year or two prior to launch in terms of the unmet need in that marketplace, so just talking a little bit about the products themselves Suboxone has done extremely well, it's been in the market for 12 years. Record has started with a sublingual tablet and they transitioned over to a sublingual film.

These products, Record products they are placed under the tongue, there is no MucoAdhesive properties so patients are instructed to place it in that sublingual cavity and for 10 minutes not to talk or to swallow which both of those things it's hard to not do in a 10 minute timeframe particularly physiologically. But having said that, you need to do that in order to get the drug absorbed and under best circumstances they get about 20% of that drug absorbed. With our product it's a transmucosal film, it fits inside the lining of the cheek, it's MucoAdhesive so it sticks and it's in place. Patient just goes about in their normal data routine, so they can talk, they can swallow, they can do whatever they'd like to do.

The efficiency of our system is also important because we actually give half the amount of drug you get the same plasma concentration. So less drug exposure has been a very positive thing with physicians. Even though Buprenorphine is an highly abused opioid it's not that patients aren't going to attempt to do that. So less drug better for us for available for diversion and so on. The other thing about having less drugs available is that less so that Buprenorphine is swallowed on a daily basis and we all know that one of the primary side effects of Buprenorphine is or any opioid is constipation and largely a topical phenomena in GI track with these receptors are present. So we've actually seen in our safety study. So FDA required us to do a 250 patient safety study where we converted these patients over from Suboxone on to our product and followed them for three months. We asked a lot of questions as they came off of Suboxone, one of which was the issue of constipation. 41% of them indicated they actually were suffering from constipation.

After three months on BUNAVAIL, two-thirds of those patients had resolution. So it dropped from 41% to 13%. This is not a well-controlled study I am not suggesting that it is, but intuitively knowing how opioids work on the GI track the less that goes down there the better. So I think we have a product because it's more efficient in its delivery for giving less count on the GI track you are going to see certain types of side effects particularly constipation. So that was another important I think finding. And then just the ease of use and we collected that information in that particular study as well and patients found the product extremely easy to use particularly given the ritual they have to go through every day on Suboxone. That's a little bit of a flavor for how the products actually differ.

Chris Caponetti - Morgan Stanley

And in your slide deck, you have a hypothetical illustration of how you got to \$250 million in sales for BUNAVAIL. Is that a reasonable target? Walk us through how we get there to the 250. And then is that a reasonable target for your guys?

Mark Sirgo

Well I think it's very reasonable. And the way we get there, we use like most people market researched it to arrive at that information. But having said that a large sample a quantitative sample of addiction medicine specialists. As we look at this entire category and we are looking out now over five years to reach peak which is that number. We're suggesting that the generic piece in the market is going to be roughly 40%. I mean right now it's about 18% and there is no real good visibility and as to why it's going to get to 40% at this point but that's what we are allowing for us with maybe a bit conservative. That leaves 60% on the branded side which translates into about 1.5 billion. And our expectation based on our market research is what we described is profile that I've just explain, it suggests we will get between 20% and 25% of that 1.5 branded business.

Chris Caponetti - Morgan Stanley

And of that 1.5 billion, so we have Orexo, they have their own product that's recently launched, that's annualizing about 36 million according to IMS. You think Record has some life cycle management. So out five years what does branded market looked like and then what do you make of the Orexo launch trends and is that a fair comparison for BUNAVAIL, how does your product differ?

Mark Sirgo

Right, so looking at the market out that far I mean there is no reason I believe that Suboxone will still be the primary product in this space and they will manage the majority the 1.5 million we should be second. And when you consider recent launch with Orexo and when I criticize but I think it's not a differentiated product, it's a sublingual tablet, so they are really competing with the sublingual generic tablets in many respects. So it's tough to enter a market where you've got a competitor like Suboxone where you don't really have any differentiating features. I think the other thing is Record did an outstanding job of converting people from their sublingual tablet to their sublingual film and it convinced physicians that it's a better product, it's something that patients prefer. Just about every powerful attribute I think that they convinced physicians that is just better overall than tablets. And I think that is also heard Orexo is opportunity in this particular space.

So I don't think it's a good proxy now, I think you need to differentiate a product and I am hopeful by the way I will describe BUNAVAIL you can see that we have that and certainly on market research that we are conducted supports that. And we had a great Analyst Day last week. In the last Investor Day two addiction specialists speak at the meeting and I think in a very unbiased fashion they just talked about the opportunities that existed in the space for novel ways

to deliver Buprenorphine in these patients and they're convinced that we meet that. And again we're not suggesting we're going to overtake Record here. They have done a very good job they're entrenched in the space right now, but we have a better product and that's why we think we can achieve that 20%-25% market share.

Chris Caponetti - Morgan Stanley

That's great and just to wrap-up on BUNAVAIL, what's the IP look like for that product?

Mark Sirgo

Well, we think it's quite strong, we've got a series of patents overtime, it is supported but the most important one is the most recent one that we had in branded and which we call the dual PH patent and it runs through 2032. We create a PH environment in the film and the way we construct that film for this product at least as having Buprenorphine in the MucoAdhesive layer, the naloxone is in the backing layer. There is PH environment in each of those it is unique to the product and that's the under fittings really of that patent. So I think it's very, very strong IP very difficult I mean to try to design around that following on those PH ranges you would never be able to show bioequivalence. So either infringe it or given the marketplace basically as we would look at it.

Chris Caponetti - Morgan Stanley

That's great and audience before we switch to BEMA any final questions on BUNAVAIL? Yes, she is running up with the mic so we can get you on the webcast sorry about that. Thank you.

Unidentified Analyst

I probably should know this, but just talk about the relative pricing in the space at this pointing time?

Mark Sirgo

Yes, the relative pricing in the space right, it's published now so we priced it fairly in the Suboxone film. The most utilized strength is their 8 milligram which is our 4 milligram which is around \$7 per film. Well, 16 milligrams is the average dose so it would be two films.

Unidentified Analyst

Orexo price in the generic?

Mark Sirgo

Orexo price pretty much the same price point.

Chris Caponetti - Morgan Stanley

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