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19-Mar-2014

Horizon Pharma, Inc. (HZNP)

Acquisition of Vidara Therapeutics International Ltd and Become Horizon Pharma plc by Horizon Pharma
MANAGEMENT DISCUSSION SECTION

Operator: Good morning, ladies and gentlemen, and welcome to the Horizon Pharma Conference Call. At this time, all participants are in a listen-only mode. As a reminder, today’s conference is being recorded.

I would like to turn the conference over to your host, Mr. Bob de Vaere, Executive Vice President and Chief Financial Officer. Please go ahead, sir.

Robert J. de Vaere

Thank you. Good morning and welcome to Horizon Pharma Conference Call. This morning, we issued a press release that provides the details of the company’s acquisition of the Vidara Therapeutics International Limited through a reverse merger for stock and cash valued at approximately $660 million. During this call, we will discuss the acquisition and the financial [ph] acquisitions outlined in our press release. The press release is available on our website at www.horizonpharma.com.

Leading the call today will be, Tim Walbert, Chairman, President and Chief Executive Officer of Horizon Pharma. Also on the call this morning are Todd Smith, Chief Commercial Officer; Bob Carey, Executive Vice President and Chief Business Officer; Chris Murphy, Vice President, Business Development; and Jeff Sherman, Executive Vice President and Chief Medical Officer. During the call, we will be referring to slides, which we’ve posted in the Events section of our website. So please refer to www.horizonpharma.com.

As a reminder, during today’s call we will make certain forward-looking statements. These statements may include statements regarding our financial outlook including expected pro forma combined full-year net revenues and EBITDA, excluding one-time transaction expenses for 2014, our expectations of achieving cash flow positive operations, our sales and marketing plans, potential growth of our business, expected benefits of expanding our product portfolio, and other expected benefits and the timing of the proposed transaction with Vidara. These forward-looking statements are based on current information, assumptions, and expectations that are subject to change and involve a number of risks and uncertainties that may cause actual results to differ materially from those contained in the forward-looking statements.

These risks are described in our filings made with the SEC including our Annual Report on Form 10-K for the year ended December 31, 2013 and our current report on Form 8-K that we filed this morning. You are cautioned not to place undue reliance on these forward-looking statements, and Horizon disclaims any obligation to update such statements.

I’ll now turn the call over to Tim.

Timothy Walbert

Thank you, Bob, and good morning everyone. It’s certainly been a busy few months for us. This morning we announced the acquisition of Vidara Therapeutics Limited, a privately held profitable specialty pharmaceutical company headquartered in Dublin, Ireland. The companies have agreed to combine through a reverse merger, accelerating Horizon’s transformation to a profitable specialty pharmaceutical company with a portfolio of products currently marketed in the United States. The acquisition expands and diversifies our revenue base with the addition of ACTIMMUNE, a bioengineer form of interferon gamma 1b – a bioengineer form of interferon gamma 1b, which realized $58.9 million in net revenues in 2013.
The addition of ACTIMMUNE is complementary to our business model of focusing on targeted commercial opportunities such as RAYOS, where we can optimize the value of the product while providing affordable access to patients. This is an important next step in the execution of our growth strategy combining organic growth with product and company acquisitions.

The combined company will be named Horizon Pharma Plc and will be organized under the laws of Ireland with the company’s U.S. operations continuing to be based in Deerfield, Illinois.

The combined company will have four products marketed in the U.S., with the expected pro forma combined full year 2014 revenues of $250 million to $265 million and expected adjusted EBITDA of $65 million to $75 million, net of one-time transaction expenses. We’re including – excuse me, in one-time transaction expenses. We will acquire Vidara Therapeutics in a reverse merger for stock and cash valued at approximately $660 million, including $200 million in cash subject to certain adjustments.

At the closing of the transaction, Horizon Pharma stockholders would own approximately 74% of Horizon Pharma plc and Vidara Therapeutics shareholders would own approximately 26%. There’ll be approximately $100 million basic shares and $122 million fully diluted shares at the closing. Horizon officers and directors and funds affiliated with certain of its directors entered into voting agreements representing approximately 20% of the outstanding shares and more than 95% of [ph] Vidara shareholders agreed to vote in support of the agreement.

The Horizon Board of Directors will remain the same with Virinder Nohria – Dr. Virinder Nohria, President and Chief Medical Officer of Vidara also joining the Board. I’ll remain Chairman, President and CEO of Horizon Pharma plc, and the rest of Horizon management will remain in place with Vidara executives joining Horizon in leadership roles.

We’ll tell you a little bit more about Vidara. This Ireland-based company is focused on meeting needs of orphan indications and diseases with high unmet needs. ACTIMMUNE, which is a biologic for chronic granulomatous disease also known as CGD and severe malignant osteopetrosis or SMO is sold through especially sales force with orphan and biologic experience. Investments have been made to support the growth of ACTIMMUNE through increasing diagnosis and improving patient compliance. This private company of 24 employees, as I mentioned earlier, had sales of $58.9 million in 2013.

Vidara’s lead product ACTIMMUNE is approved in the U.S. for two indications, which I’ll share more about in a minute, with significant growth in the product. We position [indiscernible] potential additional indications, where we see great growth potential with U.S. Patent Protection out to 2022. Vidara has commercial rights to ACTIMMUNE in the United States, Canada, Japan, in certain Latin American, Asian and other territories.

Chronic granulomatous disease or CGD is a disease of the immune system. It is described as primary immunodeficiency disorder because primary means it’s not caused by some other disease or disorder. In people who have CGD, a type of white blood cell called phagocyte is affected. These defective phagocytes cannot generate superoxide leading to an inability to do harm for microorganisms such as bacteria and fungi. As a result, the immune system is weakened and people with CGD are more likely to have certain [indiscernible] recurrent, severe bacterial and fungal infections and chronic inflammatory conditions.

These patients are prone to developing masses called granulomas, which can occur repeatedly in organs throughout the body and cause a variety of problems. ACTIMMUNE is also approved by the FDA to slow the
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worsening of severe malignant osteopetrosis, also called SMO. This genetic disorder affects normal bone formation. There are several different forms of osteopetrosis, not to be confused with the more common osteoporosis, a very different condition, which are determined by the pattern of genetic inheritance and characteristics, all forms of osteopetrosis are characterized by the abnormal increase in bone density. Severe malignant osteopetrosis is one form of osteopetrosis, and it’s sometimes referred to as the marble bone disease or malignant infantile osteoporosis, because it occurs in very young children. While exact numbers are not known, it’s been estimated that one out of 250,000 children are born with severe malignant osteopetrosis.

ACTIMMUNE delays the time to disease progression and benefits patients by increasing red blood cell production and bone resorption – or reabsorption, excuse me. Beyond the current approved indications for ACTIMMUNE, there are several additional growth opportunities. There have been over 200 studies listed including investigator initiated trials, most of which have not been supported by the company. The most advanced trials 12 patients-study being conducted by the Friedreich’s Ataxia Research Alliance. In addition, early work in eczema herpeticum, which is being linked to atopic dermatitis is being pursued with investigators. Over the coming months, we’ll fully assess these opportunities and determine the path forward.

The acquisition helps diversify a revenue base with a portfolio of products across primary care, specialty markets, and rheumatology. ACTIMMUNE complements our business model of targeted promotions, specialists, and primary care physicians. This transaction is expected to be accretive to Horizon Pharma 2014 GAAP, non-GAAP earnings per share in a pro-forma full year basis. No operating cost synergies are assumed in the transaction. The tax rate of Horizon Pharma, Plc is expected to be in the low 20 percentile or lower compared to Horizon’s expected future tax rate in the high 30%. We also announced today committed capital from Deerfield Management Company of $215 million, pending execution of company’s final financing plans.

To complete this transaction, I’ll go through an outline and steps we need to take. First, we will follow preliminary proxy statement and Vidara must file an S-4 registration statement. Closing will then be subject to customary closing conditions and regulatory approvals including Horizon stockholder approval. The S-4 registration being declared effective by the SEC and antitrust clearance. Once all conditions of closing are met, we expect to close by midyear 2014. We also expect this transaction to be taxable to Horizon’s U.S. shareholders.

The combined companies’ strategy will be to continue to leverage the assets we have growing organically and to continue to identify new opportunities. We’ll focus on driving penetration of our existing products such as DUEXIS, VIMOVO and RAYOS, and now focusing on increasing the penetration of ACTIMMUNE and looking to explore additional indications.

We’ll continue to explore new business development opportunities looking for products with targeted approaches regardless of therapeutic area and leveraging our tax efficient corporate structure. We’ll maintain our ex-U.S. partnerships and continue to protect our exclusivity.

In closing, we’re very excited about the addition of ACTIMMUNE, product well suited for our commercial portfolio and the acquisition of Vidara Therapeutics, which we believe will accelerate our transformation until profitable specialty pharmaceutical company.

Following a year of strong execution by Horizon on DUEXIS and RAYOS and our great start with VIMOVO so far this year, we remain confident as we head into the remainder of the year with three promoted products, and then later in the year with the addition of ACTIMMUNE following the closing. We’re well-positioned to drive revenue and increase value for our shareholders and we’ll continue to seek additional acquisition opportunities to further leverage our business model and maximize our commercial infrastructure.
We thank you for your continued interest and support of our company, and we’re now happy to open the call up for questions.

**QUESTION AND ANSWER SECTION**

**Operator:** Thank you. [Operator Instructions] Our first question comes from the line of Annabel Samimy of Stifel. Your line is open.

Annabel Samimy

Q

Hi. Thanks for taking my questions and congratulations on the deal. I had several questions. I just wonder if there is a bit of change in your strategy. I think originally you’re focused on trying to leverage your primary care platform and looks like you’re going more the specialty angle now. So, is this the changing strategy that you’re going after specialties and orphan drug indications and just can you help us understand that approach please?

A

Thanks, Annabel. No, we’ve always been focused on target assets, primarily on primary care with the addition of VIMOVO. And as we’ve said, we continue to look at targeted assets like we have with RAYOS. So we think ACTIMMUNE fits nicely in there. It’s a targeted approach and very efficient commercial model with 24 total employees, and really leverages our past experience in biologics and orphan diseases.

Annabel Samimy

Q

Okay. And can you help us understand how you’re going to be selling these products? Is there any leverage that you can get from your current sales force with RAYOS at all or is it a completely different sales force? And can you talk little bit about the margins on the product?

A

Sure. So there is a current sales force of high single digits selling ACTIMMUNE by the Vidara organization. So, we expect to continue that. There is a significant amount of under diagnosis of CGD and several of the other potential indications as we seek them. So, we do think there is an opportunity to enhance the education through our primary care sales force, but the primary focus will be on the targeted promotion by that commercial organization. Bob, I think margins are in the low 90%, I think roughly?

Bob J. de Vaere

A

Yeah. I mean, it’s a biologic and we really haven’t provided that level of detailed yet, but obviously it’s biologic and we’ll be providing incremental financials as we go through this process over the next month or so, as we file the S4 as well.
Annabel Samimy

Okay. The 24 employees in Vidara, that’s all. I guess, you said, sales force of high single-digits sees kind of contract sales at all?

A

No.

Annabel Samimy

For this product?

A

This is all high level experienced biologic and orphan drug sales specialists who are really working at a high scientific level. There are several medical science liaisons, a significant efficacy effort as you would expect in these type of therapeutic areas and orphan disease and very experienced management team that will continue to work with us.

Annabel Samimy

Okay. And if I can ask you a question on I guess the pipeline, you mentioned that they have a number of different indications that they’re investigating right now, can you help us understand how that’s going to take your R&D going forward?

A

We haven’t given guidance at this point in time and one of the things as I mentioned during my remarks is that, we’re going to be stepping back, Jeff Sherman, our Chief Medical Officer, in the team will be working with the Vidara team to map out what are the potential indications scientifically and mechanistically make sense. And we’ll be developing that plan and updating as we have future calls. So, no guidance from an R&D perspective other than the overall guidance that we provided on revenues and EBITDA.

Annabel Samimy

Okay. Great. Thank you.

A

Thanks, Annabel.
**Operator:** Our next question comes from the line of Edward Nash of Cowen and Company. Your line is open.

Edward Nash

**Q**

Great. Congratulations, guys. Fantastic deals announced this morning. Just – so want to get some clarity. This drug is obviously famous for having been developed or tried to be developed on IPG by InterMune, which was obviously a significant indication for them and where a lot of the off label usage was coming from. Can you give us an idea of with regards to CGD and osteopetrosis, the chronic osteopetrosis, what you guys are thinking the size of that market is on a dollar basis? And then also the additional indications what additionally do you think that could add to the overall size of the market?

**A**

All good questions, Edward. Thanks relative to the broader market opportunity and at this point we’re focusing on our near-term guidance on revenue and EBITDA. And as we finalize long-term plans relative to CGD, osteopetrosis, and looking at Friedreich’s Ataxia, and some of these others at that point, we’ll give some further color relative to those market opportunities.

Edward Nash

**Q**

Okay. And then maybe with regard to IP, so, if I’m not mistaken, the CGD indication was originally approved in 1991. So, I’m assuming that that’s not protected. But osteopetrosis rather [indiscernible] in 2000, so is that way we’re getting the 2022 additional patents they’re carrying out the protection – I assume it also protects the CGD indication?

**A**

Yes. There is a broad composition product patents after 2022. Certainly, as we pursue other indications, we’ll be seeking opportunities for orphan exclusivity. But at this point in time, we feel very confident in the existing broad patents after 2012.

Edward Nash

**Q**

Okay. So just to be clear, so anybody who’s going after – so there is no one that right now you’re still protected for anyone who would try to go after just CGD alone and not osteopetrosis.

**A**

Yes. We think this covers both products, both indications sufficiently.

Edward Nash

**Q**

Okay. Great. And the last question I had was just – so now you’ve been in the field and you guys did a fantastic job with regard to the capital structure and getting VIMOVO in. So now, how long do you think it will be before you’re
going to be able to delever yourself to be able to kind of focus on additional acquisitions to be able to continue to grow that bottom line since – where pretty much everyone is actually you kind of [indiscernible] profitable company this quarter?

Very good question. And Bob Carey has been here a week, so he has got a lot of work to do from that perspective since joining us. But as far as our capital structure, we think we’re in a good place. If you look at our convertible note that $150 million convert that was done at – I think approaching 450 and we did kept call hedge up to 671. And certainly that’s essentially acting as equity. So we’re going to continue to pursue opportunity to delever, but really focus on driving EBITDA and continuing to look for additional opportunities and as those come, we think there is opportunities to finding some in a manner that’s needed.

Edward Nash

Great. Thank you so much and again congratulations. I think this was a great acquisition for you guys.

Operator: Our next question comes from the line of Liisa Bayko of JMP Securities. Your line is open.

Liisa Bayko

And I want to add my congratulations.

Thanks, Liisa.

Liisa Bayko

Can you talk about what your current thoughts are with regards to price of ACTIMMUNE and then just give us a sense of COGS currently?

So, we haven’t given guidance on COGS at this point in time but the margins were set in the 90%. From the standpoint of pricing, I think if you look at a annualized pricing in the average patient it’s about 280,000 at the current time, the typical patient is paying about $50 out of pocket. So our plan over the next several months is to analyze that fully and make the best decisions moving forward. Certainly we think that at some point, there might be some potential opportunities from a price standpoint but we’ve not completed that analysis at this point in time.
Liisa Bayko

And could you maybe give us some indication of where you think your longer term tax rate will be now that you have this Irish.

Timothy Walbert

What I said in the remarks is below 20% or lower as we move forward.

Liisa Bayko

Thanks a lot, Tim.

Timothy Walbert

Thanks, Liisa.

Operator: Thank you. And our final question comes from the line of Difei Yang. My apologize. Our next question comes from the line of Difei Yang of R.F. Lafferty. Your line is open.

Difei Yang

Good morning. Congratulations. Just a couple of quick questions. So ACTIMMUNE, could you give us a little bit of the breakdown between the two indications as well as whether the $58 million, $59 million revenue primarily coming from U.S. or is there international?

All U.S.

Difei Yang

All U.S.

It’s all U.S. revenue.
Difei Yang
Okay.

And we don't breakdown the indication.

Difei Yang
Okay. Thanks.

You're welcome. And there is early access program. So the patients through EAP programs or -- patient [indiscernible] programs in Canada, but primary effort is in the U.S.

Operator: Our next question comes from the line of Charles Duncan of Piper Jaffray. Your line is open.

Charles Duncan
Good morning, guys. Thanks for taking the question and congratulations on getting this deal done.

Thanks, Charles.

First question and you may have covered this, because I hopped on the call a little bit late. But tell me if you would, what really drove the timing of this field. We're little bit surprised, pleased with how quick it came together, but tend to thought that this should be a yearend transaction.

Well, when we look at transactions, as the opportunity presents itself, we execute upon it. So really hard to guide on why now, why now because it was available and we moved aggressively to close the transaction, and not really much more to say to that.
Charles Duncan

Q

Do you believe that you have capacity to complete additional transactions this year in terms of maybe prior to acquisitions?

A

At this point in time, we’re not going to guide on specific timing. We built our organization of [indiscernible] and Chris Murphy joining us recently. So, it’s certainly a focus to continue to and now leverage the international platform that we’re establishing with Horizon Pharma plc. So, it’s definitely going to be a longer driving organic growth, our second core strategy. So, aggressively pursuing it, but not guiding to any specific number or timing of acquisitions.

Charles Duncan

Q

And then, final question Tim is how quickly can we start to [indiscernible] the lower tax rate? When does that take effect?

A

Bob?

Robert J. de Vaere

A

Yeah. Well, clearly, we have to go through the steps that Tim’s outlined at a high level and complete the transaction. We expect that to close mid-year, depending on SEC review and things like that, but a mid-year close that will affect the – some of the changes in the organization and a more efficient tax structure post closing.

Charles Duncan

Q

Okay. So, from about mid-year on or so?

A

Robert J. de Vaere

Yeah. I mean, again, assuming a mid-year close.

Charles Duncan

Q


A
Thanks, Charles.

**Operator**: Thank you. And we have a follow-up question from the line of Edward Nash of Cowen and Company. Your line is open.

Edward Nash  

_Q_  
Hi. Just sorry. Just had one more quick question, just since we do know what the I guess I could kind of back into this a little bit, but we know what the cost of the drug is and what the revenue was for 2013. But just wanted to see if you noticed most recently, if you guys had any clarity on the number of patients out there who are actively at – who are on ACTIMMUNE right now for the two approved indications?

_A_  
We haven’t guided to that specific number. I think as we finish our analysis of what the opportunity is and get a better understanding of the opportunity, pricing, then we’ll probably start looking at providing patient numbers.

Edward Nash  

_Q_  
Okay, great. Thank you.

_A_  
Thanks, Edward.

**Operator**: And I’d like to turn the conference back to management for closing remarks.

Robert J. de Vaere  

Thank you very much. Again, I appreciate taking the time to join us today. We’re very excited about the opportunity, given the acquisition of Vidara Therapeutics. But our core focus is to drive the organic growth with DUEXIS, RAYOS, and very excited by the outstanding performance so far with VIMOVO and excited to work with Vidara team to get this to close and bring ACTIMMUNE into our commercial organization. So thank you very much for the time and have a nice day.

**Operator**: Ladies and gentlemen, this concludes our conference. You may now disconnect. Everyone have a wonderful day.
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