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# NPS Pharmaceuticals' (NPSP) CEO Francois Nader on Q1 2014 Results - Earnings Call Transcript

NPS Pharmaceuticals, Inc. (NASDAQ:NPSP)

Q1 2014 Earnings Conference Call

May 8, 2014 8:30 AM ET

**Executives**

Susan Mesco – Executive Director-Investor Relations

Francois Nader – President and Chief Executive Officer

Luke M. Beshar – Executive Vice President and Chief Financial Officer

Eric Pauwels – Senior Vice President and President-NPS Pharma International

Roger J. Garceau – Executive Vice President and Chief Medical Officer

Paul Firuta – President-US Commercial Operations

**Analysts**

Geoffrey C. Meacham - JPMorgan Securities LLC

Navdeep Singh – Goldman Sachs & Co.

David Friedman – Morgan Stanley & Co. LLC

Alan Carr – Needham & Co. LLC

Boris Peaker – Oppenheimer & Co., Inc.

David M. Nierengarten – Wedbush Securities, Inc.

Carol Werther – Summer Street Research Partners

Paul A. Matteis – Leerink Partners LLC

Graig Suvannavejh – MLV & Co. LLC

Eun K. Yang – Jefferies LLC

Navdeep Singh – Goldman Sachs & Co.



**Operator**

Good day, ladies and gentlemen, and welcome to the First Quarter 2014 Pharma Earnings Conference

Instructions) As a reminder, this call is being recorded for replay purposes.

And now I would like to turn the call over to Susan Mesco, Executive Director Investor Relations. Please proceed, ma'am.

**Susan Mesco**

Thank you, Pereta and welcome to our first quarter conference call. Before we start, let me remind you that today's call will include forward-looking statements based on current expectations. Such statements represent our judgment as of today and may involve risks and uncertainties that may cause actual results to differ from the results discussed in forward-looking statements. Please refer to our filings with the SEC, which are available from the SEC or our website for information concerning the risk factors that could affect the company.

Joining me on today's call are members of our executive management team, including Dr. Francois Nader, our President and Chief Executive Officer; Luke Beshar, our Chief Financial Officer; Eric Pauwels, President, NPS Pharma International; Roger Garceau, Chief Medical Officer and Paul Firuta, President, US Commercial Operations.

**Francois Nader**

Thank you, Susan, and good morning everyone. Thank you for joining us on today's call. 2014 continues to be an important growth year for NPS Pharma as we are focusing on our four strategic priorities: first, the continued growth of Gattex in the U.S.; second, securing the U.S. approval of Natpara; third, expanding our international business; and fourth, advancing our pipeline to drive long-term success.

I will start with Gattex in the U.S. February marked the first anniversary of the U.S. introduction of Gattex. We are very proud that the launch of Gattex has been one of the most successful ultra-orphan drug launches to date.

Last year we penetrated 6% to 10% of the estimated addressable market and delivered sales of $32 million. I am confident that we have built a great foundation for the continuing success of our Short Bowel Syndrome franchise in 2014. We achieved first quarter sales of approximately $18 million, representing sequential growth of 17%.

Physician interest in Gattex remains very high with new prescriptions in March and April higher than fourth quarter monthly averages. We are also seeing an expanding base of prescriber from GI physicians to surgeons, and we are investing in this important growth opportunity by expanding our reach to more potential prescribers in more territories.

And we are getting anecdotal feedback with stories of patients on Gattex freeing themselves from parental nutrition, while significantly decreasing the frequency of its use after being dependent for many years. All this of course is very gratifying to us as we believe we are making a real difference to patients. This being said, we faced some unique challenges early on in the year, resulting in sales that were slower than expected in January and February. It happens for two main reasons. First, delays in new dispenses along with their subsequent refills partially due to the severe winter weather.

The impact on patients and physicians included delays in scheduling and performing the tests and procedures that are recommended prior to starting Gattex. It also affected the coordination of nursing visits for new patient starts. These challenges were also compounded by the fact that given their small number, our sales representatives have to cover large geographies and suspended travel took them out of the field on all too many occasions.

The second reason has to do with an increase in discontinuations. In the first quarter we saw a small uptick in our discontinuation rate, which we anticipated would take place over time. As you may recall, last year we reported less than 10% of patients had discontinued therapy, which was better than we had expected

30%.

Despite the bounce back in March and April, it is unlikely that this will compensate for the first quarter shortfall. Therefore, we are revising our full year guidance for 2014 to a range $100 million to $110 million from our prior guidance of $110 million to $120 million. However, this revision has to be put in perspective recognizing that the 2014 outlook represents 200% year-over-year growth, which would be a tremendous second year for any product launch.

As we remain very bullish on the long-term outlook for Gattex, we decided to invest in maximizing the full market potential for Gattex by deploying the following new commercial initiatives. First, we have added more firepower to the U.S. Commercial leadership team. We are very happy to welcome Paul Firuta to NSP Pharma. Paul joined us in March to lead our U.S. Commercial Operations.

He is a seasoned commercial executive with extensive experience launching and commercializing biologics. Most recently Paul led the ViroPharma's commercial operations for the Americas where he directed the launch of Cinryze, one of the most successful orphan drug launches to date in the U.S. With both the appointments, Eric Pauwels, who has led the successful launch for Gattex in the U.S., will now focus on growing our international business.

Our second initiative is that after our first year of commercial experience we are also learning that Gattex is promotionally sensitive and we will be capitalizing on this opportunity by adding 11 new representatives to our sales organization. One of the reasons for this expansion is that while GI specialists remain our primary focus, we have seen a meaningful percentage of prescriptions coming from colorectal surgeons and our surgical specialists. Consequently, our expanded field-based team would allow us to begin calling on these new targets.

In addition, we are significantly increasing awareness of Short Bowel Syndrome through programs like patient and physician education, peer-to-peer targeting and outreach through patient advocacy to make sure we are educating physicians and patients on Short Bowel Syndrome and Gattex in the U.S.

Now let me turn to Natpara, our second strategic priority which is securing the U.S. approval of Natpara. As you know, our U.S. BLA is currently under FDA review and our PDUFA action date is October 24. FDA is actively engaged and our interactions with the agency are ongoing. During our mid-cycle discussion FDA confirmed they intent to review Natpara at an Advisory Committee Meeting, which is tentatively scheduled for July 24.

As we did successfully with Gattex, we are working with distinguished outside experts including former FDA reviewers and panel members to prepare for the outcome. Our European strategy for Natpara, which will be the brand name for Natpara in Europe, is proceeding according to plan and we expect to file the NAA this year.

As you know, patients with hyperparathyroidism face a significant burden of disease given the multitude of physical, cognitive, and emotional systems associated with this disorder. And when approved, Natpara would provide hyperparathyroidism in patients with the first exact replica replacement therapy to treat their condition.

We have geared up our pre-launch activities to lay the groundwork for the successful introduction of Natpara in the U.S. Our pre-launch activities focus on education and generating awareness on the burden of hypoparathyroidism through three key strategies. First, educating patients, so far we have generated significant awareness through our unbranded Web site hypoparathyroidismanswers.com, where patients can register and opt in to receive information and updates on hypoparathyroidism. We have also created a very large online community for hypoparathyroidism.

Second, educating physicians. We're in the process of profiling centers of excellence and prioritizing our targeted endocrinologists in the U.S. We will also began a disease awareness campaign with physicians.

long-term risks.

We have been very active preparing for a successful launch. Our team is making excellent progress and we look forward to making this important treatment available to hypoparathyroidism patients as quickly as possible. We've continue to provide more and more details as we get closure to the launch.

Our third strategic corporate therapy I would like to cover today is our international expansion, and at this time I would like to invite Eric Pauwels to provide you with a brief update. Eric?

**Eric Pauwels**

Thank you, Francois and good morning to all joining today's call. The international expansion of our orphan disease franchise continue to advance. We have made important progress since we last we spoke. Our international management team is now largely in place as well as the local and regional management physicians.

We are very pleased with the caliber and experience of the individuals who joined us as many came to NPS Pharma from the leadership roles at highly viewed biopharmaceutical companies with specific expertise in successfully launching orphan products.

Based on our expectation for securing our target pricing and reimbursement we expect that our international roll out will start with our first commercial launch in Germany followed by the U.K. and then Nordic countries. As Germany is a key reference for international pricing, we have decided to take advantage of the new long-term data that speaks to real life post marketing experience such as parenteral support medium data from U.S. centers of excellence to strengthen our (indiscernible) investigation.

For this reason, we decided to slightly delay our German filings from mid-year to the fall to leverage stronger robust and value proposition that supports similar pricing quarter.

We are also making good progress in the UK working with KOLs and centers of excellence. In parallel, we continue to build Short Bowel Syndrome awareness in international markets. We had conducted meetings with leading SBS experts in Europe, Japan, and Latin America. These initiatives are generating significant interest in our efforts.

As you know Japan represents a key orphan drug market opportunity outside the U.S. Recently Japan's Ministry of Health, Labor, and Welfare selected Gattex as one of 10 high priority drugs for an unmet medical need. This is critical step in locating a positive regulatory pathway. We also preparing to file for orphan drug status in Japan later this year and we have scheduled a meeting this summer with Japan's pharmaceutical and medical device agency to discuss our regulatory path.

So to summarize, we are making terrific progress with our international build out, which is a top organizational priority, and we remained highly confident that the foundation we are putting in place will deliver significant growth in 2015 and for many years beyond.

With that I'll turn the call over back to Francois.

**Francois Nader**

Thank you, Eric. The four strategic corporate priorities covered today is the pipeline we are building to drive our long-term growth. Our team reached an important milestone this quarter with the filing of an IND for NPSP795 in autosomal dominant hypocalcemia. We are on target to initiate our Phase 2a proof-of-concept study by Nadir.

As a reminder ADH is a lifelong genetic disorder that is caused by mutations of the calcium-sensing receptor, which plays a major role in calcium-homeostasis. Patients with ADH continue to excrete calcium in their urine because their receptor always senses that there serum calcium is too high. ADH can prevent immediately post birth with severe hypocalcemia, which can cause life threatening neonatal complications

In adults, ADH is typically characterized by hypocalcemia with low concentrations of PTH and high levels of urine calcium. Clinically there is a significant increase risk for renal complications including nephrocalcinosis and impaired renal function. There is no approved treatment for ADH and NPSP792 is antagonist of calcium-sensing receptor and could be first treatment specifically targeting the mutation.

We are also expanding our Short bowel syndrome franchise with our pediatric clinical program. Gattex could answer a significant unmet medical need for children with Short Bowel Syndrome given the comorbidities and daily living challenges associated with life long parenteral support along with a significant healthcare burden to society.

Our global study of Gattex in pediatric Short Bowel Syndrome is progressing and have completed enrollment of the first cohort.

So in summary, we are focused on achieving our vision of becoming the world's premier orphan drug business. We are very confident in the growth prospects of Gattex investors, we are actively building our international presence. We are preparing for the launch of our second orphan product Natpara and behind these programs we are advancing our clinical pipeline to drive long-term success

With that, I'll turn the call to Luke for his financial reports. Luke?

**Luke M. Beshar**

Thanks, Francois and again good morning. From a financial perspective, NPS Pharma continues to be in terrific shape. Despite some weather related challenges we achieved approximately $18 million in sale of the Gattex and we feel very good about delivering our revised full year guidance of $100 million to $110 million of net global sales for Gattex or Revestive.

Our Sensipar royalties are an important driver in the first quarter bringing in more than $23 million of revenue. To remind you, under the repayment terms of our royalty advance from Amgen. On May 15, we'll receive a $15 million cash payment, in the Amgen we withhold the remaining $8 million to repay interest and principal. We continue to anticipate that we will fully repay the remaining advance of $48 million by the end of the third quarter of next year.

Get to that we will receive 100% of our Sensipar royalties through March 28 in the U.S. and through the end of 2018 for the rest of the world. With annual sales of Sensipar now exceeding $1 billion our revenues from Sensipar provides some tremendous financial flexibility for NPS for the coming years. We also receive a cash royalty from Janssen sales for NUCYNTA, which for the quarter was approximately $600,000.

Moving to the expense side of the P&L, cost of sale were $2 million, roughly 11% of sales consisting primarily of royalties and packaging costs. As you may recall, the product currently being used to support the introduction of Gattex was manufactured (indiscernible) and therefore expense to R&D. During the first few years of sales, this will result in the benefit to our gross margin. And while the pre-approval product is consumed we expect the gross margin on Gattex to normalize to approximately 80%.

First quarter research and development expenses was $21 million representing an increase of approximately $5 million from the same quarter last year. The primary driver of these brands was a credit in 2013 from the close out of certain clinical trials, and to a lesser extend an increase in regulatory activities in Natpara in 2014.

For the first quarter, SG&A expenses were $25 million versus approximately $14 million last year. This increase is attributable to the activities to support the launch of Gattex, pre-launch initiatives for Natpara and the build up of our international business. We continue to maintain a strong financial position and ended the quarter with approximately $176 million in cash, which leaves us very well capitalized to globally commercialize both Gattex and Natpara and to advance new pipeline of opportunities for growth.

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