

With the Launch of their Lead Pain Relief Product DUEXIS in the United States and a Second Product LODOTRA for Reducing Morning Symptoms in Rheumatoid Arthritis Approved in Europe and 16 Countries and Israel, Horizon Pharmaceutical, Inc. is Well Positioned to Reward Investor Confidence

**Healthcare
Drug Manufacturers - Major
(HZNP-NASDAQ)**



Timothy P. Walbert
Chairman, President and CEO
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BIO: Mr. Walbert has served as chairman of our board of directors and our president and chief executive officer since our inception in March 2010. Mr. Walbert has also served as the president and chief executive officer of Horizon Pharma USA since June 2008 and on its board of directors since July 2008. From May 2007 to June 2009, Mr. Walbert served as president, chief executive officer and director of IDM Pharma, Inc., or IDM, a biopharmaceutical company which was acquired by Takeda America Holdings, Inc., or Takeda, in June 2009. From January 2006 to May 2007, Mr. Walbert served as execu-

tive vice president, commercial operations of NeoPharm, Inc., a biopharmaceutical company. From June 2001 to August 2005, Mr. Walbert served as divisional vice president and general manager, Immunology and divisional vice president, global cardiovascular strategy at Abbott, a broad-based healthcare company. From April 1998 to June 2001, Mr. Walbert served as director, Celebrex North America and arthritis team leader, Asia Pacific, Latin America and Canada at G.D. Searle & Company, a pharmaceutical company. Mr. Walbert received his B.A. in business from Muhlenberg College, in Allentown, Pennsylvania. Mr. Walbert serves on the Board of Directors of Raptor Pharmaceuticals, Inc., XOMA Ltd., the Biotechnology Industry Organization (BIO), the Illinois Biotechnology Industry Organization (iBIO) and the Greater Chicago Arthritis Foundation.

Company Profile:

Horizon Pharma, Inc. is a biopharmaceutical company that is developing and commercializing innovative medicines to target unmet therapeutic needs in arthritis, pain and inflammatory diseases.

**Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine**

CEOCFO: Mr. Walbert, what is the focus at Horizon Pharma and why have you chosen that particular area to work on?

Mr. Walbert: We are building a specialty pharmaceutical company, focusing on areas of significant unmet

need. Our initial focus is in the area of arthritis, pain and inflammation diseases. We have two lead assets that have been proven to treat both osteoarthritis and/or rheumatoid arthritis. We are a four-year-young company that in the last seven months raised over \$160 million, built a commercial organization of over 150 people to launch our lead product DUEXIS, approved in April 2011 and have a second product pending FDA approval in July this year.

Mr. Walbert: The decision for Horizon to enter into arthritis was driven by the withdraw of Vioxx (an arthritis agent from Merck) from the U.S. market due to safety concerns. This left many patients suffering from osteoarthritis without a safe and effect agent to not only relieve their arthritis pain, but protect from the adverse events associated with pain relievers such as ibuprofen. The company was originally founded in Palo Alto, California and was initially funded by leading venture capitalists in the San Francisco Bay Area. In 2010, we acquired Nitec Pharma, based in Switzerland, to add a second arthritis product, which is RAYOS for rheumatoid arthritis. That enabled us to de-risk the company and build a franchise in a particular therapeutic area. It also allowed us to amortize all the cost, drive further top-line revenue and better be prepared to access the public markets, which we did in completing our initial public offering (IPO) in July 2011.

CEOCFO: Would you tell us about the Horizon Pharma products?

Mr. Walbert: We have two approved products. Our first product is called DUEXIS, which is a combination of ibuprofen and famotidine. It offers strong pain relief and is the most prescribed pain reliever in the U.S., with over thirty million prescriptions each year. Unfortunately, ibuprofen is a product that causes up to 40% of patients to get serious stomach ulcers, which lead to complications that unfortunately cause up to 16,000 deaths and 100,000 hospitalizations each year. Our phase 3 clinical trials have demonstrated that the benefit of combining ibuprofen with famotidine, is that famotidine is an agent that significantly reduces these serious ulcers that are caused by ibuprofen. Therefore, built it into one pill, you can get that pain relief that physicians and patients love and use on a regular basis, but protect these patients from those serious ulcers. This really offers a great solution to patients suffering from osteoarthritis.

CEOCFO: Has famotidine been around a long time?

Mr. Walbert: Yes, it has.

CEOCFO: Why has this combination not been tried

before with the ibuprofen, and what is it that Horizon has figured out that allows you to make a successful combination?

Mr. Walbert: That is a very good question. As we have looked at the marketplace, there were agents called COX2, such as VIOXX and Celebrex. These agents brought great promise and \$7 billion in annual sales in 2003. They had done a great job of relieving patients' pain, while significantly reducing the serious stomach ulcers. Unfortunately, VIOXX was withdrawn from the market in September of 2004 due to safety concerns, so what we knew was there was a need now for products that can provide pain relief, but significantly reduce these serious stomach ulcers. Famotidine or Pepcid as it is known over the counter, had typically been used to treat or heal ulcers or treat reflux disease. Therefore, what we did is we took a different dose of it, so instead of it being twice a day, we took a much higher dose per day and then did it in 3-times dosing to combine it

with ibuprofen. Then, for the first time showed that you could now actually reduce those serious stomach ulcers, which had never been shown by a product such as famotidine before.

CEOCFO: Will people be able to take larger doses of the ibuprofen because of this addition?

Mr. Walbert: One of the factors that comes into play is the dose of ibuprofen is 800 milligrams in each pill taken three times a day in DUEXIS. Typically, physicians were using 400 or 600 milligrams to avoid the GI adverse events that are associated with ibuprofen. Now they can give the full therapeutic dose and relieve their patients' pain in an optimal way, because they have that built-in GI protection that is offered with DUEXIS.

CEOCFO: What about your other drug, LODOTRA?

Mr. Walbert: First, DUEXIS was launched into the United States, with

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our launch coming in January. So, we are about five weeks into the launch in the United States. We built an organization of 80 representatives, and we are doubling that to 160 representatives in the second half of this year to sell the product here in the US. Our second product is LODOTRA. This product is approved in Europe and 16 countries and Israel. We have selected Mundipharma, which is a multi-billion dollar private company with sales throughout Europe and Asia, as the company to market the product outside of the US. They are marketing it in both Europe and Asia. We announced yesterday that they will also market LODOTRA in Latin America for us. LODOTRA is designed to significantly reduce the morning symptoms that patients get from rheumatoid arthritis. If you look at the typical patient that gets rheumatoid arthritis, the first two hours in the morning are typically devastating. These patients do not have the ability to brush their teeth, their hair, or even tie their shoes. We believe LODOTRA can

offer a great benefit to these patients. One of the businesses I previously ran was the immunology/biologic division at Abbott Laboratories, where I led the development and global launch of a product called HUMIRA, which sold almost \$8 billion last year. This year it should become the biggest product in the world. The whole promise around the treatment of rheumatoid arthritis is adding accretive therapies that can slow the progression of the disease. This is measured as stopping cartilage from destructing in the joints. Additionally, we need to help patients with their symptoms such as fatigue and stiffness that do not allow them to do activities of daily living. So, the challenge we have is how do we? LODOTRA is a proprietary delivery system of low-dose prednisone, which is used in approximately half of patients with rheumatoid arthritis. The problem is associated with pro-inflammatory cytokines such as TNF-alpha and IL-6, which when there is too much of them they actually lead to the body destroying itself, such as the destruction of cartilage. LODOTRA was designed to be taken at bedtime and have none of the product released until

around two a.m. when these pro-inflammatory cytokines are peaking that cause the symptoms of RA. By blocking them when they are at the peak, you may get better reduction of these early morning severe symptoms that patients experience, such as morning stiffness, fatigue, and joint pain. We completed two clinical trials where we successfully showed that LODOTRA improves the overall signs and symptoms of RA and we have a potential FDA approval date of July 26th 2012. Our plan is to launch RAYOS with our existing sales force to 4000 rheumatologists here in the US.

CEOCFO: So you are really moving along!

Mr. Walbert: Yes, it is two launches for a small company in about seven months, and typically small companies do one and try to grow from there. Single products do not make companies. We need multiple products and therapeutic focus so that we

can leverage our expense base and drive the revenue that is needed to pay our public shareholders back.

CEOCFO: On both of the products, has the medical community been paying attention?

Mr. Walbert: I think so. I actually just spent my first day out riding with a representative in New York City yesterday and talking to rheumatologists, orthopedic surgeons, and primary care physicians who clearly see the benefit that DUEXIS can offer. Many of them are adopting it at a great rate because they see the benefit of relieving pain and preventing many of these serious stomach ulcers and GI adverse events. So, we see good uptake at this point. We have launched with DUEXIS and we have positive expectations coming forward for RAYOS as well. We are also seeing positive signs with the launch of LODOTRA in Europe where Mundipharma, Ltd. has done a good job launching LODOTRA in Italy and launching into Germany in the second half of last year. We are seeing strong early adoption of LODOTRA in these European markets. Then there is the promise of RAYOS doing the same here in the US markets.

CEOCFO: Will Horizon Pharma be taking it to consumers?

Mr. Walbert: That is a good question, as there has been a general credibility challenge with products like Celebrex and Vioxx, which did enormous Direct-to-consumer promotion. I was involved in the marketing of Celebrex in the United States and both Searle (Celebrex) and Merck (Vioxx) spent a considerable hundreds of millions of dollars making sure, everyone saw Dorothy Hamill and many different people espousing the great benefits of Vioxx and Celebrex. There is a real credibility gap in this category around the promise that a product can offer, especially when later on down the road they heard about such adverse events with Vioxx. As a small company, we just do not have the capital to take that broad approach. Our focus is to go after a subset of physicians. We are calling on 30,000 physicians in the US and these 30,000 physicians collectively write 36 million prescriptions for pain relievers such

as ibuprofen. Therefore, we think we can take that targeted approach and drive significant uptake on a relative scale. Obviously, if we had the 5,000 representatives we had launching Celebrex, we would have much different expectations with DUEXIS. However, we believe that with our targeted approach, we can deliver significant value to our public shareholders.

CEOCFO: Will Horizon continue to go it alone?

Mr. Walbert: We are looking at really two strategies. As far as partnering, we are looking at specific specialties. If the company has a focus on calling on the 8,000 orthopedic surgeons, then we will look at reaching out and having someone who really is an expert in that field promote DUEXIS and maximize him in that space. Or it may be someone who might call on podiatrists who are also big users of pain relievers. When it comes to the primary effort, with my experience and the team's experience, where we have collectively launched 14 pain products into the United States, we believe we have the expertise to do it. In the last seven months, we have raised \$160 million, so we have the capital now to execute our strategy. We believe our near-term focus on these two lead products will allow us to drive success, but more importantly demonstrate that we can be a company that can bring additional assets in, drive them successfully and build a better organization.

CEOCFO: Horizon has a few other products in the pipeline; are you involved anywhere else?

Mr. Walbert: We have two other products but at this point, given that we are a microcap company our focus is on maximizing our lead assets. We are not spending any money on our pipeline at this point in time. It is a real sign of the times, with limited capital and the high cost of capital today for small companies. We just did a \$60 million debt note at about 17% interest, whereas if I am running a multibillion-dollar business, I can borrow money at 2% interest. So, the cost of capital for small companies is extremely high and you need to focus that capital on your lead assets, drive

success and then you are afforded the ability to build behind it. Our real strategy is to leverage our stock and financial position as we become successful to bring in incremental assets that are already developed to minimize that initial capital outlay until we have further success.

CEOCFO: You mentioned a bit about your background; what about the team in general and why it is so important to have the commercialization expertise in addition to the right product?

Mr. Walbert: In today's times the complexity of bringing products into the US is at an all-time high. We have known Europe and its pricing model and the difficulties in Europe for a number of years, but now when you bring a product into the US you have hurdles that many people have not ever faced. Therefore, you need a commercial organization that has lived through the complexity of not only helping physicians understand your product and become convinced and prescribe it, but you have to have next an equal decision-maker in the process, which is the payer. Payers today have significant influence in the use of new products, as they often do not reimburse them for the first six to twelve months, if at all. So, you have that initial challenge of not only convincing a physician to write your product, you now have to convince the payer to cover your product and pay for it. Then the third process that comes into play now is you have to do it at a co-pay to the patient that they can afford, because payers are passing, and companies in many forms are passing an increasing amount of the risk and cost of healthcare to their employees and patients. Therefore, patients are playing more of an active role in covering the costs. For instance, for an average branded product to relieve pain, the co-pay to the patient is anywhere from \$45 to \$55 per patient, per month. What we also know when we look at the actual number of prescriptions that are paid for, most patients will not pay for the prescription at the pharmacy when there is a co-pay above \$35. They will leave it at the pharmacy and this is something that is occurring at an increasing level throughout the United

States. We put in place a program that allows each patient to have a co-pay of approximately \$20, because we know that based on the data, \$20 is a price they are willing to pay to get their medication. You have a complexity in today's times that requires people of significant commercial experience. Todd Smith, who runs our sales, marketing and business development arena, has launched ten products into the US, with small and large pharmaceutical companies. He also been at Fenwal, which is a private equity backed company that was spun out of Baxter. He has broad experience from a business, marketing, and sales perspective. He has to understand all of those aspects of sales, marketing, and the reimbursement arena as well as the business development. Secondly, Mike Adatto runs our managed care organization, and our commercial sales operations group, has had significant experience working with me at a company called Searle, where we launched Celebrex. He was also involved in managed care for Takata for the last five years, so he built a great deal of experience in understanding payers and what drives their behavior. He understands how to best get the right price for your product and the right coverage. I have

found that the success that I have had over the years is primarily driven by my ability to hire the right people who have the requisite experience to drive our business.

CEOCFO: There are many companies to choose from in your sector; why should investors pay attention to Horizon Pharma today?

Mr. Walbert: What we offer is a company that is a microcap company at a reasonable share price at this time. We are significantly undervalued based on the opportunity for our lead assets. We are a company with a proven management team that has built products/business selling as much as \$8 billion a year and we are de-risked with two approved products. Many small companies have significant risk as they only have one product/asset to garner returns from, which brings great risk if something negative occurs. We have two lead products that are approved with a team that has done it before. We believe that this combination and the significant quarter-over-quarter growth and year-over-year growth that we hope to drive over the next several years will provide great incentive for our existing shareholders as well as potential new shareholders.

CEOCFO: Final thoughts, what should people remember most about Horizon Pharma?

Mr. Walbert: When you look at a small company like ours, a real sign of success comes from the type of investors you have and the willingness of them to continue to invest in the company. We went public in July of last year (2011), where we raised \$50 million from existing investors like Essex Woodlands Healthcare Ventures, Atlas Ventures, TVM Capital, Scale Ventures and Sutter Hill Ventures, as well as new institutional investors such as Fidelity and Columbia Wanger. Subsequent to that initial public offering in July of 2011, in February 22nd we raised \$60 million in senior debt, and on February 29th we completed a private placement of equity and raised \$51 million. Over the last seven months we raised over \$160 million, which shows that investors believe in the team and our opportunity, believe in the opportunity ahead and they are putting their money behind it.

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