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# DURECT Is Well Positioned With Multiple Products In Late Stage Development, Collaborations With Certain Programs To Help With Development Costs Of These Drug Candidates As Well As Other Programs That Have Been Retained With An Eye On Becoming A Specialty Pharma Company

**Healthcare**
**Drug Manufacturers - Others**
**(DRRX-NASDAQ)**

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**Dr. James E. Brown D.V.M.**
**Co-Founder, President and CEO**

**BIO:**
James E. Brown, D.V.M. co-founded DURECT in February 1998 and has served as President, Chief Executive Officer and a Director since June 1998. He previously worked at ALZA Corporation as Vice President of Biopharmaceutical and Implant Research and Development from June 1995 to June 1998. Prior to that, Dr. Brown held various positions at Syntex Corporation, a pharmaceutical company, including Director of Business Development from May 1994 to May 1995, Director of Joint Ventures for Discovery Research from April 1992 to May 1995, and held a number of positions including Program Director for Syntex Research and Development from October 1985 to March 1992. Dr. Brown holds a B.A. from San Jose State University and a D.V.M. (Doctor of Veterinary Medicine) from the University of California, Davis where he also conducted post-graduate work in pharmacology and toxicology.

**Company Profile:**
DURECT Corporation is an emerging specialty pharmaceutical company focused on the development of pharmaceutical systems based on its proprietary drug delivery platform technologies focused on treating chronic and episodic diseases and conditions. The Company currently has multiple late-stage pharmaceutical products in development initially focused on significant unmet medical needs in pain management, with a number of research programs underway in a variety of other therapeutic areas.

**Interview conducted by:**
**Lynn Fosse, Senior Editor**
**CEOCFOinterviews.com**

**CEOCFO**: Dr Brown, what was your vision when you founded DURECT and where are you today?

**Dr. Brown:** "Before I begin, let me mention that I'll undoubtedly make forward-looking statements that have risks and uncertainties that may make actual results differ from my statements, so I'd like to direct all readers to review our SEC filings for a full discussion of those risk factors. Our vision was provided by my partner, Dr. Felix Theeuwes, when starting the company. Felix was the Chief Scientific Officer at ALZA during his 29-year tenure there. ALZA was really the company that pioneered what became the drug delivery industry. Felix said he wanted to recreate ALZA in 10 years. First of all, Felix liked to say he didn't have another 29 years to do it all over again! Secondly, we thought we could apply a lot of the lessons from the ALZA experience and do certain things in parallel instead of sequentially. In its early decades, ALZA focused on building a broad technology base and built a solid business by partnering essentially all their programs. In their third decade, ALZA transitioned into a specialty pharma company, selling products they had developed, finally culminating in their sale to J&J for $12 billion in 2001. Our vision was to do some partnering to help fund the company, typically in Phase II to drive better economic terms, but in parallel retain some programs that could allow us to build our own sales and marketing organization. Where we are today is a company with five products in clinical development, the first of which has successfully completed clinical trials and is very close to filing an NDA with the FDA, followed by three other products in Phase II."

**CEOCFO:** What's the common thread for your products?

**Dr. Brown:** "Our most advanced products are all in the field of pain management and each is based on applying our advanced drug delivery technologies to compounds that have been in the marketplace for some time and are known to be safe and effective. Through our drug delivery technologies, we can improve the performance or safety of these drugs. One of the criteria we set before starting a program is that we have to believe we can produce a product that is substantially better than what is on the market today or it isn't worth undertaking. The advantages of working with known chemical entities, in contrast to other companies that focus on developing new drugs de novo, is that one can still produce commercially large products but typically at about one-tenth the cost and in one-half the time."

**CEOCFO:** Tell us about your flagship products today; what they are and where you are in the process?

**Dr. Brown:** "We have four late-stage products in development that we typically spend most of our time describing. Remoxy™ is a gel cap for treating chronic pain with the added feature that it is more difficult to abuse than existing comparable products. POSIDUR™ is an injectable depot to treat post-operative pain for several days with a local agent, reducing the need for narcotics that work systemically. We have a Sufentanil patch to treat chronic pain for seven days with a single application, and then we have ELADUR™, a three-day patch to treat post-herpetic neuralgia and possibly other local pain indications. Remoxy is closest to market, having successfully completed all of its clinical trials. Remoxy contains oxycodone, the active ingredient in OxyContin® which is a product widely used by patients suffering from moderate-to-severe pain. OxyContin did about $1.6 billion last year in sales, precisely because it is so effective in treating the intended population. The major issue with OxyContin, however, is that it is widely abused, including by kids; the popular press not long ago labeled it the Hillbilly Heroin. Remoxy, because of our ORADUR™ technology, is much more difficult to abuse."

**CEOCFO:** Why is it more difficult to abuse?

**Dr. Brown:** "Our ORADUR technology includes a substance that makes it very difficult to extract the drug. The most common way that oxycodone is abused today is that an addict will crush the tablet and then snort or inject the powder, or an addict will try to extract the drug with alcohol. If you were to take one of our gel caps and crush it, the substance inside looks like Vaseline. It's very sticky and so the drug can't be physically abused by snorting or injecting. If one tries to take alcohol or some other solvent to try and extract the drug, very little is released quickly. We can't make the product abuse-proof, but we can make it far more difficult to abuse. Just as the body has to be able extract the drug and make use of it or it wouldn't be effective, a professional chemist will figure out ways to extract the drug and unfortunately post it on the Web. What we will do, however, is take it out of the party scene and make it much more difficult to abuse."

**CEOCFO:** What were some of the results of your clinical studies?

**Dr. Brown:** "At the end of December 2007, we finished the last of the Phase III work under the Special Protocol Assessment Process by the FDA. These studies met all of their endpoints and there were no drug related safety issues. All the data is being pulled together for the New Drug Application, which we expect will be filed in the second quarter of this year. Upon approval by the FDA, Remoxy will be commercialized by King Pharmaceuticals and we will receive a royalty on sales that starts at 6% and then goes to 11.5% based on sales levels. We also receive a small manufacturing mark-up from King Pharmaceuticals as we will produce some of the key components of Remoxy."

**CEOCFO:** Do you expect partnerships to commercialize all of your products?

**Dr. Brown:** "We strive to maintain a balanced business model. Certain programs have been licensed to strong commercialization partners – Nycomed, Endo Pharmaceuticals and King Pharmaceuticals – on attractive terms. This has provided financial, developmental and commercialization resources to us. For other programs, we've retained worldwide or territorial rights. This gives us the basis for future partnering and financing of product development as well as a pathway for us to build our own specialty pharma business in North America to capture the full value of these product candidates."

**CEOCFO:** What's the next product on the agenda?

**Dr. Brown:** "POSIDUR is actually the first product that we would look forward to possibly selling ourselves. It requires a specialty pharmaceutical sales force because it is a product that will be used by surgeons in a surgical suite. Therefore, this is a market that we feel can be covered with a relatively small sales force, somewhere in the range of about 100 to 150 sales reps for the U.S. We've licensed POSIDUR to Nycomed so that they can commercialize it in Europe and several other countries where they have a meaningful presence, but we retained the rights to the US, Canada and Asia for ourselves. I might note that we received a $14 million fee from Nycomed upon sign-

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**- Dr. James E. Brown D.V.M.**

ing this collaboration, received $8 million by achieving a development milestone in 2007, and are eligible to receive a blended royalty of 15-40% on Nycomed's sales. Nycomed also pays 50% of our joint US/European development program costs. These terms speak to the potential value of this product.

Bupivacaine and lidocaine and other sodium channel blockers are used frequently by surgeons today as they close the incision in order to control pain for typically three to four hours. Our SABER technology is able to take bupivacaine and release it in a controlled fashion around the wound for up to three days. The opportunity here is to reduce the use of other post-operative pain medicines, in particular narcotics. Narcotics have a number of associated side effects such as constipation, vomiting and somnolence. Therefore, the strategy here is to control pain locally rather than numbing the patient's head, allowing patients to move about more rapidly and hopefully saving on health care costs by virtue of getting a patient up and about sooner while reducing complications associated with narcotics. This product is in Phase II.

Last year we completed a large Phase IIb study in 122 hernia patients. In this study, we were able to demonstrate a significant reduction in post-operative pain while at the same time significantly reducing the use of narcotics. In fact what we saw in this trial was about 30% less pain on day one, day two and day three when we compared the POSIDUR high dose group versus placebo. We also saw about three times less narcotics were taken by the POSIDUR group. The really astounding and exciting thing about this study was showing both 30% better pain control and three times less narcotics being taken."

**CEOCFO:** Is there much competition in the areas that you are developing?
**Dr. Brown:** "Of course. We're working in large markets that remain underserved and there are many other pharmaceutical companies trying to develop improved therapeutics. One way we compete is by having multiple advanced drug delivery technologies, ranging from SABER injectible depots to ORADUR oral gel caps to TRANSDUR™ transdermal patches. We then apply these technologies to develop truly differentiated products. For example, Oxycodone is an effective agent but the existing product gets widely abused. Our product, Remoxy, should be similarly effective in controlling pain but now it is much more difficult to abuse. Similarly, bupivicaine is commonly used by surgeons today but only lasts for 3-4 hours. We have put it in our SABER technology with POSIDUR and now it lasts for three days, enabling improved pain control and a reduction in narcotic use. Naturally we are also aggressive in filing patents around our technologies and products to protect them."

**CEOCFO:** Please touch on your other two main products.
**Dr. Brown:** "TRANSDUR-Sufentanil is a seven day patch for chronic pain sufferers. We have licensed this product in the US and Canada to Endo Pharmaceuticals (Nasdaq: ENDP). In this case, Endo is paying all of the development costs and we are eligible for $35 million in milestone payments as well as future royalties on sales. We've retained the rights to this drug candidate in Europe and Asia, and expect to partner these territories as well. This product is currently in Phase II.

TRANSDUR-Sufentanil should compete with a product that chronic pain sufferers widely utilize called Duragesic. Duragesic was actually developed by several of my DURECT colleagues back when they worked at ALZA. Duragesic sold about $1.2 billion in 2007.

Our patch seeks to provide 7 days of pain relief versus existing patches like Duragesic that deliver medication for 3 days, which enhances patient compliance and convenience and entails a lower manufacturing cost over a comparable one month treatment cycle. Existing fentanyl patches (like Duragesic) are about the size of a dollar bill folded in half, which means that during a month, a patient has to find 10 rather large spots on the body to rotate the patches around. In contrast, our patch is about 1/5 the size of Duragesic (about the size of a postage stamp) and during a month only about 4 small sites are required. We think our patch has the potential for less skin irritation and sensitization.

The last product that I will describe is called ELADUR. In this case we are developing a product that would compete with Endo's patch called Lidoderm. Lidocaine is the active agent in Lidoderm, which sold over $700 million last year. Lidoderm is approved for treating post-herpetic neuralgia or post-shingles pain, although physicians also prescribe it for sprains and other conditions. Lidoderm is a fairly thick patch that can be worn for 12 hours, after which a patient is to take the patch off for the next 12 hours to let the skin rest and recover. During this time when the patch is off, many patients experience a recurrence of pain. ELADUR is different from the Lidoderm patch in that we utilize bupivacaine, which is a more potent agent than lidocaine. This allows us to put less drug in our patch, and having to drive less drug and other materials through the skin is one of the major sources of skin irritation. Our ELADUR patch is about as thick as a piece of paper. In fact it feels like an old cotton t-shirt with breathable backing and you put it on for 3 straight days. You can take a shower with it and exercise with it, the types of things you can't do with a Lidoderm patch. At the end of last year we completed a Phase IIa study with 60 post-herpetic neuralgia patients in which we saw very nice delivery and the patches were well tolerated by the skin."

**CFOCEO:** Please tell us a little bit more about the financial situation for you today?
**Dr. Brown:** "You can imagine it can be quite expensive if we were paying for all these products by ourselves. The collaborations we have established have us to conserve our cash. We consumed less than $38 million of our own cash over the last three years. We have over $200 million in potential milestones coming from our partners over the coming years. We started the year with about $62 million in cash. We have the potential for future partnerships which enable us to make our cash last much longer and to develop new products as we move forward. We are talking to other companies right now about potential collaborations on a regional basis or a worldwide basis for the

ELADUR product, which requires a larger sales force. We are talking to potential partners in Europe and Japan about TRANSDUR-Sufentanil, and to potential partners in Japan about POSIDUR. We also have several feasibility studies underway with pharmaceutical and biotechnology companies that could blossom into larger development deals. So, we have multiple programs under discussions with other companies to supplement our existing financials and to accelerate development of these programs."

**CEOCFO:** Does the investment community recognize your potential?

**Dr. Brown: "**There certainly are some that do and some that don't. Over time, as we do more things such as our interview with you, the word will get out to those that may never have heard of us. There are a lot of smart institutional investors out there who have done varying levels of due diligence on us and I'm confident that if we can continue to hit on our development milestones, our potential will be recognized."

**CEOCFO:** Why should potential investors be interested and pick DURECT out of the crowd and what might they miss at first glance?

**Dr. Brown:** "DURECT is an emerging specialty pharma company with 5 products in development, including the first NDA on the verge of filing and 3 more in Phase II. Each of these drug candidates that we are developing are addressing large market opportunities ranging from $700 million to over $1 billion. We have differentiated features in each of these products which are protected by patents and which are able to make a difference in the healthcare industry by reducing healthcare costs, compared to products out there today. In addition, we have a maturing pipeline. We expect to file the first NDA based on our technology, Remoxy, by the middle of this year so in about a year or so we should start receiving royalty checks. We also have other products moving from Phase II to Phase III, so over the next 12 to 18 months we expect to have three additional products in Phase III. We have undisclosed programs that we don't talk about yet, but which should serve as the basis for additions to our product pipeline.

Lastly, we have a balanced business model whereby certain programs are licensed to strong partners on attractive terms, thereby providing financial, developmental and commercialization resources. Other programs have been retained by DURECT, either to be the basis for future collaborations or, as in the case of POSIDUR, to give us a pathway to building our specialty pharma business and allowing us to capture the full value of our drug candidates."

**CEOCFO:** Final thoughts: what should people remember most DURECT?

**Dr. Brown:** "What they should remember most is that we have a lot of shots on goal, a solid financial position, and a lot of near term milestones that will be demonstrative of our progress."

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DURECT

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