

Durect Is Well Positioned With Four Late Stage Products In Development, Each Of Which Address Large Market Opportunities With Differentiated Features Compared To The Products That Are Available Today

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

DURECT Corporation

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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 is an emerging specialty pharmaceutical company developing innovative drugs for pain and other chronic diseases, with late-stage development programs including REMOXY®, POSIDUR™, ELADUR™, and TRANS-DUR™-Sufentanil. DURECT's proprietary oral, transdermal and injectable depot delivery technologies may enable new indications and superior clinical/commercial attributes such as abuse deterrence, improved convenience, compliance, efficacy and safety for small molecule and biologic drugs. For more information, please visit www.durect.com.

**Interview conducted by:
Walter Banks, Publisher
CEOCFOinterviews.com**

CEOCFO: Dr. Brown, the last time we spoke was a year ago; can you tell us how and if the vision has changed for DURECT in a year?

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 these risk factors.

We have advanced several programs since we last spoke. Let me start with Remoxy, which is a controlled release, more difficult to abuse form of the widely used opioid oxycodone. In the past year, the NDA for Remoxy was filed with the FDA and it was granted an accelerated review by the FDA. Then in December of 2008, the FDA came back with a Complete Response letter that basically indicated that the FDA seemed satisfied with regard to the clinical data, but that they were asking for additional non-clinical information before the product can be approved. Our partner, King Pharmaceuticals, has announced that will be holding a meeting with the FDA in the first half of July of this year, after which they expect to be in a better position to make projections about the path forward for Remoxy. We're looking forward to the outcome of that meeting and to this product proceeding towards approval. We believe Remoxy has a major market opportunity. The overall market for extended release opioids is over \$4 billion, and OxyContin had sales in 2008 of over \$2 billion. We think Remoxy has advantages over OxyContin, in particular in that Remoxy is more difficult to tamper with and therefore abuse.

The next product that I should update on is POSIDUR, which is a product intended to treat post-operative pain. POSIDUR is a controlled released form of bupivacaine that is put in and around the wound at the time a surgeon closes and then it provides up to three days of pain control. This product has shown nice efficacy after hernia surgery. In the past year, as I look at the most significant events with regards to this program, it would be the

initiation of additional Phase IIb studies. DURECT is conducting a Phase IIb study in shoulder surgery in Australia. Our partner Nycomed has initiated two separate Phase IIb studies in the European theatre, one in shoulder surgery and one in hysterectomy. From a regulatory standpoint, we have also received feedback from the FDA with regard to the outline of what we need to do to achieve approval for POSIDUR in the United States. Armed with this input, we are now positioning ourselves with the conclusion of these Phase IIb studies to be able to start the Phase III for that program. In the past year, we have decided that we probably should partner the US rights to POSIDUR. This is a product that we have considered for a while commercializing ourselves, but looking at the size of the opportunity, and with the financial markets as they are, we've concluded that we may be better served to partner POSIDUR rather than try to develop and sell it ourselves. Armed with the right partner, we think the odds of successful development and achieving rapid market penetration are higher than if we go it alone. We are now in discussions with multiple parties with respect to US rights to POSIDUR. As a reminder, we have licensed European rights to Nycomed and in so doing, we received \$14 million up front, \$8 million as our first milestone payment triggered by Phase IIb data in hernia where we demonstrated a 30% improvement in pain control versus placebo as well as about a three-fold reduction in the use of narcotics as rescue medicine in those patients. In our relationship with Nycomed, we have \$180 million in potential milestone payments to come. They will pay us a royalty on sales where they sell the product, starting at 15% and going as high as 40%. We also get a manufacturing mark up and they pay for half of the cost of our worldwide development program, even though they have no rights in the US, Canada or Asia.

The third product worthy of update is our TRANSDUR-Sufentanil patch. Like the two previous products, TRANSDUR-Sufentanil addresses a large opportunity.

This is a seven-day patch to treat chronic pain using sufentanil, a relative of fentanyl. Fentanyl is the active agent that is used in Duragesic®, which is a very successful pain patch from J&J, with sales in 2008 of about \$1 billion. Duragesic is a patch about the size of a credit card that is worn for 2-3 days, after which one applies a new patch typically on another skin site so that the skin can recover. TRANSDUR-Sufentanil patch is about the size of a postage stamp and it can be worn for a full week. By offering a smaller surface area, patients should experience less skin irritation. Another point we're excited about is that there are some medical publications by others that suggest that sufentanil may have a wider therapeutic index than fentanyl. Therefore, we may have a safer agent as well as a more patient-friendly patch. This is a product that has completed a successful

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

end-of-Phase II meeting with the FDA. About 300 patients have been dosed with TRANSDUR-Sufentanil in 10 different clinical trials and our sufentanil patch is now poised to enter Phase III. There's a very large market opportunity here. We are actively talking to potential partners on a worldwide basis in regard to the development and commercialization rights to this product.

The last product I will update on is ELADUR. This is a three-day patch which would compete with the Endo Pharmaceuticals product LIDODERM®, which did about \$750 million in revenue last year. LIDODERM has to be worn for 12 hours and then you take it off for 12 hours to let the skin recover. Our patch is much thinner than LIDODERM and can be worn for 3 days straight. In fact, one can wear it while exercising, taking a shower or swimming. We think it could be a very nice product opportunity and

late last year we signed up Alpharma as our development and commercialization partner. In that deal, we received \$20 million upfront and are eligible for another \$93 million in development milestones and \$150 million in potential sales and marketing milestones. We also get a solid royalty on sales for this product. After completing a 60 patient Phase IIa study, our ELADUR product is poised to start Phase IIb. Late last year, King Pharmaceuticals bought Alpharma and now King is taking this product forward and we looking forward to starting the Phase IIb work with them.”

CEOCFO: What are you doing that is different with these products?

Dr. Brown: “In all cases, the active agent in these products have already been approved by the FDA and are sold by other companies for use in treating pain. In

every case, we have taken that active agent, whether it is oxycodone, bupivacaine or sufentanil, and packaged it in a new drug delivery system to enhance the safety and/or efficacy of the drug. Before starting a new program, we do an opportunity assessment process evaluating where we can best utilize our technologies to save healthcare costs and to be able

to create products where we think will make a difference to patients, to the healthcare system, to society, to ourselves, and to our potential partners.”

CEOCFO: What are your forms of delivery for the various products?

Dr. Brown: “We have two transdermal patch products. We also have an injectable product, POSIDUR. And we have oral gel caps, which provide controlled released while also reducing the ability of abusers to quickly and easily extract the drug.”

CEOCFO: Can you give us a brief synopsis on why this is an improvement on these products and why they should take to the market in a big way?

Dr. Brown: “Starting with Remoxy, we will go up against the very successful chronic pain product OxyContin, which is sold by Purdue Frederick. OxyContin had \$2 billion in sales in 2008 and fur-

ther growth is expected in 2009. The issues associated with OxyContin are that it typically needs to be dosed three times a day and it is easily and widely abused through snorting, injecting or by mixing with a variety of common drinks in order to get a quick release of the drug. Pain relievers, including OxyCodone, are now more abused in the US than marijuana or cocaine. Remoxy has the same active agent, oxycodone, and it is a true twice a day formulation. In addition, it is much harder for abusers to tamper with. If one were to take our gel caps and crush it, you physically can't snort or inject it due to the viscosity of our ORADUR™ technology which is thick like Vaseline. If you try to extract Remoxy with alcohol in a drink, only about 1/5 of the drug comes out of Remoxy in that first hour or two as compared to OxyContin. These are all things that reduce the abuse potential of the product.

We believe POSIDUR has the potential to save healthcare costs by reducing pain after surgery with bupivacaine as opposed to taking narcotics, which commonly have side-effects. In this case, what the surgeon does is place POSIDUR in and around the wound, at the time of closing after surgery. Bupivacaine is a widely used local anesthetic. The advantage then is instead of having to numb the head, which is what you have to do with the morphine-type products, you just numb the wound locally. You have the potential to avoid the side-effects of narcotics, which include constipation, dizziness, nausea, vomiting, and respiratory suppression. In reviewing the results of our 120 patient Phase IIb hernia trial, we looked at some metrics related to the dischargeability of patients from the hospital. That analysis suggested the potential to discharge a number of patients on POSIDUR more quickly than those using placebo, which translated into savings of about \$600 per procedure on average. There are over 70 million procedures in the US every year. Our market research, which includes talking to over 300 doctors, suggests that about half of those procedures might benefit from a product like POSIDUR and if we then further haircut the market to just 30%, then we still have an available market of roughly 9 million procedures per year. Our pricing

studies have suggested we may be able to charge from \$250 to \$400 per procedure, so it sets up certainly a big market opportunity for this product.

Our Sufentanil patch is clearly more patient friendly. The duration of seven days versus 2-3 days for fentanyl patches, and a size that is about 20% of these alternative patches are clear benefits. Just to flesh out one more advantage of the seven day duration, imagine a nursing home patient with chronic pain. In our case, the care givers would have to put one patch on per week or roughly four patches a month. That is four entries in a computer and one only has to make sure the patient has his pain meds 4 times a month in this case. In contrast, a patient on OxyContin would have to get a pill two or three times a day, and thus 60-90 pills per month would have to be tracked on the computer. That is a lot of pills that have to be tracked including ensuring there is no diversion and making sure the medication is given at the appropriate time. A once a week patch reduces the paperwork and administrative costs. Our patch may also have a wider therapeutic index, so it might be a safer drug as well with less skin irritation.

ELADUR is similar. ELADUR is a three day patch used to treat intermittent pain circumstances such as the pain associated with post-herpetic neuralgia and possibly also eventually strains and sprains and back pain. The patch can be worn for three days vs. the competitive product, which is 12 hours. The design of the patch affords an opportunity to put a patch on a patient that allows them to take a shower, go swimming, and just free up their lifestyle."

CEOCFO: You have relationships with King Pharmaceuticals and Nycomed; how did they come about and is it strictly in the clinical research end of it or do they have commercialization rights as well?

Dr. Brown: "In these cases, they are both our development and commercial partners, so they will be the party that sell our products. Every deal is a little different, but typically we have a list of the usual suspects that should be interested in a particular program and we approach them to assess their interest. If appropri-

ate, we allow a smaller list of parties to review the opportunity under confidentiality. We always try to get multiple parties interested so that there is competition for the asset. Sometimes we can be surprised in the process. For example, in the case of ELADUR, Alpharma wasn't on our original contact list and they entered the process a little later than many, but then they moved very quickly and aggressively to catch up and close."

CEOCFO: Product development is expensive; can you give us an idea of the financial picture today for DURECT?

Dr. Brown: "A big part of our business model is in fact entering into these collaborations with other companies and the outcome is that they wind up paying for a good portion of the development that has to occur. Over the last four years, on average, our cash burn rate has averaged about \$12 million a year, which is not really that much considering the pipeline that we've been developing. By leveraging ourselves with partners, we can undertake far more programs than we could possibly fund on our own and a big part of success in our industry is having lots of shots on goal. We ended the first quarter with about \$47 million in cash and we have essentially no debt. Like most companies these days, we're quite mindful of how much we're spending and we're very active seeking partners for TRANSDUR-Sufentanil, POSIDUR and other programs that we haven't necessarily highlighted yet."

CEOCFO: In closing, why should the investment community take an interest in DURECT Corporation?

Dr. Brown: "If you take a look at our company, we have multiple drug candidates that are in late stage development, which is somewhat unique for a small emerging company. Remoxy has an NDA filed with the FDA, we have three other products behind that which are in Phase II and two products that are in Phase I. Each of these products addresses large market opportunities and we would submit have differentiated product features versus what exists today. We believe we have a very productive R&D group. The senior scientists at the company have done it before at other companies, and we believe we have a number of undisclosed

pre-clinical programs that will in the future yield additional drug candidates. Lastly, we have a balanced business model. We're not just swinging for the fences by ourselves. We have certain pro-

grams that are licensed to strong partners on attractive terms, which give us financial, development, and commercialization resources while moderating our cash burn. At the same time, we've kept the

rights to several other programs which could be the basis for future partnering. Therefore, DURECT represents a diversified opportunity to invest in an emerging specialty pharmaceutical company."



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