

# ZOGENIX

## Zogenix to Develop and Commercialize Proprietary Long-Acting Risperidone Formulation for Needle-Free Subcutaneous Administration Using the DosePro(R) Delivery System and DURECT's SABER(TM) Depot Technology

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### *Potential to Address \$16 Billion World-Wide Antipsychotics Market*

SAN DIEGO and CUPERTINO, Calif., July 12, 2011 (GLOBE NEWSWIRE) -- Zogenix, Inc. (Nasdaq:[ZGNX - News](#)), a pharmaceutical company commercializing and developing products for the treatment of central nervous system disorders and pain, and DURECT Corporation (Nasdaq:[DRRX - News](#)), a specialty pharmaceutical company focused on the development of pharmaceutical systems based upon its proprietary drug delivery platform technologies, announced today a development and license agreement. Under the agreement, Zogenix will be responsible for the clinical development and commercialization of a proprietary, long-acting injectable formulation of risperidone using DURECT's SABER(TM) controlled-release formulation technology in combination with Zogenix's DosePro(R) needle-free, subcutaneous drug delivery system. The Companies will also share non-clinical development responsibilities. Zogenix expects to initiate clinical studies for the new product candidate, Relday(TM), in patients with schizophrenia in early 2012 following filing of an Investigational New Drug (IND) application.

Risperidone is one of the most widely prescribed medications used to treat the symptoms of schizophrenia and bipolar I disorder in adults and teenagers 13 years of age and older. Relday will be developed to address unmet clinical needs in this large patient population.

The Companies expect that, if approved, Relday will be the first once-monthly, subcutaneous antipsychotic product available in a needle-free delivery system to enter the long-acting injectable antipsychotic market. The existing long-acting injectable risperidone product, which achieved global net sales of \$1.5 billion in 2010, requires twice monthly, 2 mL intramuscular injections with a 21 gauge or larger needle. The Companies also expect that, if approved, Relday will provide a new long-acting treatment option for patients that currently use daily oral antipsychotic products. The combined market for oral and injectable antipsychotic products is estimated at more than \$16 billion in 2010. The Companies believe the SABER controlled-release technology will allow Relday to be delivered subcutaneously without a needle on a once-monthly basis with a simplified dosing regimen, improved pharmacokinetic profile and significant reduction in injection volume. This will be enabled by DosePro's unique ability to deliver highly viscous formulations.

Roger L. Hawley, chief executive officer of Zogenix, said, "Relday is the result of a focused preclinical formulation development effort with DURECT. We believe Relday has best-in-class potential because it consists of a proven drug with improved attributes that our market research indicates are preferred by psychiatrists. The target audience of U.S. psychiatrists can be covered efficiently with a relatively small sales force. Outside the United States, we expect Relday will be of great interest to prospective commercial partners. We look forward to working with DURECT to file an IND for Relday which will enable initiation of clinical development in early 2012."

James E. Brown, D.V.M., president and chief executive officer of DURECT Corporation, said, "Consummation of this collaboration further demonstrates the flexibility and broad potential associated with our SABER depot technology platform, which we are also employing in our POSIDUR(TM) program which is in Phase III as well as with proteins and peptides in multiple feasibility projects. In conjunction with the DosePro delivery system, our goal is to develop a product that meets psychiatrists' and patients' preference for a long-acting, subcutaneous, needle-free antipsychotic medication. Zogenix has successfully developed and commercialized a CNS product, and we are pleased to work with them on this exciting opportunity with Relday."

Mr. Hawley added, "We view this licensing deal as further validation of the value that our proprietary DosePro delivery system can provide to potential product candidates. We have demonstrated that physicians and patients are attracted to the technology with the launch of our first product, SUMAVEL DosePro, and we continue to focus on identifying new opportunities to more broadly leverage the technology."

Under the terms of the agreement, Zogenix will make an upfront payment of \$2.25 million to DURECT, with the potential to pay DURECT up to an additional \$103 million in future clinical, regulatory and commercial milestone payments based upon successful achievement of certain events. Zogenix will have exclusive global rights to commercialize Relday and will pay DURECT a royalty on Relday product sales.

Zogenix will provide additional details on the agreement and the anticipated expenses associated with the development of Relday on the Company's second quarter 2011 financial results conference call.

### **About Zogenix**

Zogenix, Inc. (Nasdaq:[ZGNX - News](#)), with offices in San Diego and Emeryville, California, is a pharmaceutical company commercializing and developing products for the treatment of central nervous system disorders and pain. Zogenix's first commercial product, SUMAVEL DosePro (sumatriptan injection) Needle-free Delivery System, was launched in January 2010 for the acute treatment of migraine and cluster headache. Zogenix's lead product candidate, Zohydro (hydrocodone bitartrate), is a novel, oral, single-entity extended-release capsule formulation currently in Phase 3 clinical trials for the treatment of moderate to severe chronic pain in patients requiring around-the-clock opioid therapy.

For additional information, please visit [www.zogenix.com](http://www.zogenix.com).

Relday and Zohydro are trademarks and SUMAVEL(R) and DosePro(R) are registered trademarks of Zogenix, Inc.

### **About DURECT Corporation**

DURECT is a specialty pharmaceutical company developing innovative drugs for pain and chronic diseases, with late-stage development programs including REMOXY(R), POSIDUR(TM), ELADUR(R), and TRANSDUR(R)-Sufentanil. DURECT's proprietary oral, transdermal and injectable depot delivery technologies 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](http://www.durect.com).

NOTE: POSIDUR(TM), SABER(TM), ORADUR(R), TRANSDUR(R), ELADUR(R), and DURIN(R) are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners. REMOXY, POSIDUR, ELADUR and TRANSDUR-Sufentanil are drug candidates under development and have not been approved for commercialization by the U.S. Food and Drug Administration or other health authorities.

### **Zogenix Forward Looking Statements**

Zogenix cautions you that statements included in this press release that are not a description of historical facts are forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "indicates," "will," "intends," "potential," "suggests," "assuming," "designed" and similar expressions are intended to identify forward-looking statements. These statements are based on the company's current beliefs and expectations. These forward-looking statements include statements regarding the development and commercialization of a commercially successful product, the timing of filing an IND, the ability of such product to address the global anti-psychotic market, the ability to develop a once-monthly injectable product with improved pharmacokinetics and significant reduction in injection volume, ability to achieve first-in-class status, coverage of the target physician audience with a small sales force, partnering opportunities for Relday outside the United States, and leveraging the DosePro technology. The inclusion of forward-looking statements should not be regarded as a representation by Zogenix that any of its plans will be achieved. Actual results may differ from those set forth in this presentation due to the risk and uncertainties inherent in Zogenix's business, including, without limitation: the uncertainties associated with the clinical development and regulatory approval of product candidates such as Relday, the ability of Zogenix and DURECT to obtain, maintain and successfully enforce adequate patent and other intellectual property protection of Relday and the ability to operate its business without infringing the intellectual property rights of others; the market potential for anti-psychotics, and Zogenix's ability to compete within that market; inadequate therapeutic efficacy or unexpected adverse side effects relating to Relday that could prevent its development or commercialization, or that could result in recalls or product liability claims; Zogenix's dependence on its collaboration with DURECT to develop Relday; the ability of Zogenix to field a targeted sales force which successfully markets Relday; and other risks described in Zogenix's filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Zogenix undertakes no obligation to revise or update this presentation to reflect events or circumstances after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement. This caution is made under the safe harbor provisions of Section 21E of the Private Securities Litigation Reform Act of 1995.

#### **DURECT Forward Looking Statement**

The statements in this press release regarding the potential uses, benefits, commercial opportunity and possible market of Relday, expected timing of filing of an IND and initiation of clinical trials for Relday, expected returns to DURECT from commercialization of Relday, anticipated interest in Relday from possible commercialization collaborators outside the U.S. and potential milestone payments and royalties receivable from Zogenix for the development and commercialization of Relday are forward-looking statements involving risks and uncertainties that can cause actual results to differ materially from those in such forward-looking statements. Potential risks and uncertainties include, but are not limited to, DURECT's and Zogenix's difficulty or failure to obtain approvals from regulatory agencies with respect to its clinical trials and other development activities, or their respective abilities to design, enroll, conduct and complete clinical trials, failure of such clinical trials to produce intended results, failure to achieve the performance milestones or commercial sales that trigger the referenced payments or royalties, possible adverse events associated with the use of Relday, delays and costs due to additional work or other requirements imposed by regulatory agencies for continued development, approval or sale of Relday, our ability to complete the design, development, and manufacturing process development of Relday, and to manufacture, commercialize and obtain marketplace acceptance of Relday, and avoid infringing patents held by other parties and secure and defend patents of our own, and manage and obtain capital to fund our growth, operations and expenses. Further information regarding these and other risks is included in DURECT's Form 10-Q filed on May 6, 2011 under the heading "Risk Factors."



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