Endo Pharmaceuticals Returns Product Rights to TRANSDUR(TM)-Sufentanil to DURECT

CUPERTINO, Calif., Feb. 27 /PRNewswire-FirstCall/ — DURECT Corporation (Nasdaq: DRRX) today reported that Endo Pharmaceuticals (Nasdaq: ENDP) has given notice that it is returning to us Endo's rights in the U.S. and Canada to develop and commercialize TRANSDUR(TM)-Sufentanil, a proprietary transdermal patch in development intended to treat chronic pain. Endo and DURECT recently completed a successful end-of-Phase II meeting with the FDA. Endo has notified us of its intention to terminate the license agreement entered into between Endo and DURECT, and has committed to assist in an orderly and rapid transition of this program back to DURECT.

(Logo: http://www.newscom.com/cgi-bin/prnh/20020717/DRRXLOGO)

"We are disappointed to lose Endo as a partner for the U.S. and Canada, but understand that the program is no longer a strategic fit for them," stated James Brown, President and CEO of DURECT. "However, we appreciate the fact that Endo substantially advanced this program such that it is now Phase III ready. With the worldwide rights to this program restored to us, we believe we have an attractive asset to partner or to progress it ourselves."

Endo recently successfully completed a Phase II program for TRANSDUR-Sufentanil in which they evaluated the conversion of patients on oral and transdermal opioids to TRANSDUR-Sufentanil. The most recent Phase II study met its primary and secondary objectives of establishing a successful dose-titration regimen and dose potency relationships, demonstrating safety and tolerability at the therapeutic dose, and achieving effective analgesic pain control. The Phase II data, extensive non-clinical data that had been generated by Endo and detailed proposed protocols for Phase III were reviewed with the FDA at an end-of-Phase II meeting on February 19, 2009. As a result of that meeting, we believe we have a clear idea of the anticipated regulatory pathway for the Phase III program and approval, which will follow a 505(b)2 pathway as discussed with FDA.

DURECT anticipates now recognizing in the fourth quarter of 2008 additional revenue as a result of accelerating the remaining amortization of the Endo upfront license fee. Correspondingly, the net loss for the fourth quarter of 2008 and for the fiscal year will be less than previously reported in DURECT's earning release on February 9, 2009. These are non-cash financial items.

About TRANSDUR-Sufentanil

TRANSDUR-Sufentanil is intended to provide continuous delivery of sufentanil for up to seven days from a single application, as compared to the three days of relief provided by currently available opioid patches. We anticipate that the small size of our sufentanil patch (potentially as small as 1/5th the size of currently marketed transdermal fentanyl patches for a therapeutically equivalent dose) and longer duration of action may offer improved convenience and compliance for patients. In addition, we believe that the improved product profile relative to existing fentanyl patches may make

these patches an attractive alternative for many patients currently on extended release oral opioids.

About DURECT Corporation

DURECT is an emerging specialty pharmaceutical company developing innovative drugs for pain and other chronic diseases, with late-stage development programs including REMOXY(R), POSIDUR(TM), ELADUR(TM), and TRANSDUR(TM)-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 http://www.www.durect.com.

NOTE: POSIDUR(TM), SABER(TM), ORADUR(TM), TRANSDUR(TM), and ELADUR(TM) 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 US Food and Drug Administration or other health authorities.

DURECT Forward-Looking Statement

The statements in this press release regarding TRANSDUR-Sufentanil, its potential attributes, its potential as an alternative to extended release opioid products, possible Phase III program, our intentions to enter into collaborations or further develop the program and anticipated regulatory pathway for this program 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, the uncertainty and costs associated with the development and commercialization of certain opioid drug products such as TRANSDUR-Sufentanil due to increased scrutiny and possible new regulations relating to risk evaluation and mitigation of these drugs, our difficulty or failure to obtain approvals from regulatory agencies with respect to TRANSDUR-Sufentanil, design, enroll, conduct and complete clinical trials, complete the design, development, and manufacturing process development of TRANSDUR-Sufentanil, consummate collaborative agreements relating to TRANSDUR-Sufentanil, manufacture and commercialize and obtain marketplace acceptance of TRANSDUR-Sufentanil, 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 dated November 4, 2008 under the heading "Risk Factors."

SOURCE DURECT Corporation

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