



# DURECT Corporation Announces Third Quarter 2012 Financial Results and Update of Programs

CUPERTINO, Calif., Nov. 5, 2012 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months ended September 30, 2012. Total revenues were \$3.8 million for the three months ended September 30, 2012 as compared to \$8.1 million for the three months ended September 30, 2011. Net loss for the three months ended September 30, 2012 was \$4.8 million, compared to a net loss of \$5.0 million for the same period in 2011.

(Logo: <http://photos.prnewswire.com/prnh/20020717/DRRXLOGO>)

At September 30, 2012, we had cash and investments of \$21.0 million, compared to cash and investments of \$23.7 million at June 30, 2012 and \$30.8 million at December 31, 2011. We have no debt obligations, other than normal liabilities associated with running our business.

“Following our pre-NDA communications with the FDA this summer, we are preparing to submit a new drug application for POSIDUR in the first quarter of 2013,” stated James E. Brown, D.V.M., President and CEO of DURECT. “Pfizer has initiated a confirmatory bioavailability study to assess the pharmacokinetic profile of modified REMOXY formulation compositions, with a data read out expected early in 2013. We also are pleased that Zogenix has been actively enrolling in the Phase I clinical trial for Relday.”

## Update of Programs:

- **REMOXY<sup>®</sup> (oxycodone) Extended-Release Capsules CII** Pfizer has efforts underway to resolve the issues raised in the REMOXY Complete Response Letter and stated in their quarterly earnings call on November 1, 2012 that they have initiated a confirmatory bioavailability study to assess the pharmacokinetic profile of modified REMOXY formulation compositions, with data expected in early 2013. Pfizer expects that the results of this study will provide greater clarity on Pfizer’s ability to adequately address the questions raised in the Complete Response Letter, and Pfizer is targeting a meeting with the FDA in late March to discuss these outputs. Based on feedback Pfizer receives from the FDA at the meeting, Pfizer will subsequently determine the next steps and/or required timing to respond to the Complete Response Letter.

REMOXY, an investigational drug, is a unique long acting oral formulation of oxycodone intended to treat moderate to severe pain. Based on DURECT’s ORADUR<sup>®</sup> technology, which is covered by issued patents and pending patent applications owned by us, REMOXY is designed to discourage common methods of tampering associated with prescription opioid analgesic misuse and abuse.

- **POSIDUR<sup>™</sup> (SABER<sup>®</sup>-Bupivacaine) Post-Operative Pain Relief Depot** Following our pre-NDA communications during the summer with the FDA regarding POSIDUR, we intend to submit a new drug application (NDA) under 505(b)(2) with the FDA in the first quarter of 2013.

POSIDUR is our investigational post-operative pain relief depot that utilizes our patented SABER technology to deliver bupivacaine to provide up to three days of pain relief after surgery. We currently hold worldwide commercialization rights to POSIDUR.

- **Transdermal Development Candidates.** DURECT has two transdermal products that are in mid- to late-stage development with features that may be superior to currently available patches. TRANSDUR<sup>™</sup>-Sufentanil is our proprietary



transdermal patch intended to deliver sufentanil to chronic pain sufferers for a period of up to 7 days from a single application; this compares favorably against existing fentanyl patches which are substantially larger and typically effective for 2-3 days. ELADUR, for topical neuropathic conditions such as post-herpetic neuralgia (PHN), is our proprietary transdermal patch intended to deliver bupivacaine for a period of up to three days from a single application; existing lidocaine patches for this condition can be worn for 12 hours with a rest period of 12 hours during which time many patients experience breakthrough pain. We are in discussions with potential partners regarding licensing development and commercialization rights to these two transdermal programs to which we hold worldwide rights.

- **ORADUR-ADHD Program.** We are developing a drug candidate (ORADUR-ADHD) based on DURECT's ORADUR Technology for the treatment of Attention Deficit Hyperactivity Disorder. This drug candidate is intended to provide once-a-day dosing with added tamper resistant characteristics to address common methods of abuse and misuse of these types of drugs. We and Orient Pharma have completed several Phase I pharmacokinetic studies with multiple formulations, and we are continuing to refine our lead formulations. Orient Pharma is our licensee for certain Asian and South Pacific countries, while we retain the rights to the rest of the world.
- **Relday™ (Risperidone Program).** In July 2011, we signed a development and license agreement with Zogenix to develop Relday, a product candidate targeting the antipsychotic market. In July 2012, Zogenix announced that it had initiated its first Phase I clinical trial for Relday in patients. This study is a single-center, open-label, safety and pharmacokinetic (PK) trial that will enroll 30 patients with chronic, stable schizophrenia or schizoaffective disorder. We understand that Zogenix expects that the study will be completed by the end of 2012. Relday is a proprietary, long-acting (once-monthly) injectable formulation of 0.5 mL of risperidone using DURECT's SABER controlled-release formulation technology in combination with Zogenix's DosePro® needle-free, subcutaneous drug delivery system. The existing long-acting injectable risperidone product, which achieved \$1.6 billion in global net sales in 2011, requires twice-monthly, 2 mL intramuscular injections with a 21 gauge or larger needle.
- **Feasibility Projects and Other Activities.** During the third quarter of 2012, we continued work on several feasibility projects as a means of demonstrating that our technologies can achieve the drug delivery objectives set forth by our collaborators and are worthy of further development. The Zogenix program, described above, was one such project which has matured into a development and license agreement.
- **Business Development Activities.** We have multiple programs that may potentially be licensed over the next 12-18 months. These include POSIDUR, TRANSDUR-Sufentanil, ELADUR, ORADUR-ADHD (territories outside certain Asian and South Pacific markets), as well as various other programs which we have not described publicly in detail.

## Earnings Conference Call

A live audio webcast of a conference call to discuss third quarter 2012 results will be broadcast live over the internet at 4:30 p.m. Eastern Time on November 5 and is available by accessing DURECT's homepage at [www.durect.com](http://www.durect.com) and clicking "Investor Relations." If you are unable to participate during the live webcast, the call will be archived on DURECT's website under Audio Archive in the "Investor Relations" section.

## About DURECT Corporation

DURECT is a specialty pharmaceutical company developing innovative drugs for pain and chronic diseases, with late-stage development programs including REMOXY®, POSIDUR™, ELADUR®, and TRANSDUR®-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™, SABER®, ORADUR®, TRANSDUR® and ELADUR® are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners. REMOXY, POSIDUR, ELADUR, TRANSDUR-Sufentanil and Relday are drug candidates under development and have not been approved for commercialization by the U.S. Food and Drug Administration or other health authorities.

## DURECT Forward-Looking Statement

The statements in this press release regarding the potential bioavailability study for REMOXY, potential regulatory meetings and submissions for REMOXY and POSIDUR, anticipated clinical trials (including timing and results) for Relday and our other drug candidates, the potential benefits and uses of our drug candidates, collaborations with third parties and potential business development activities 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 risk



that Pfizer will discontinue development of Remoxy, the risk of adverse decisions by regulatory agencies, including rejection of meeting requests, requests for additional information or product non-approval, delays and additional costs due to requirements imposed by regulatory agencies, potential adverse effects arising from the testing or use of our drug candidates, the potential failure of our clinical trials to meet their intended endpoints, our potential failure to maintain our collaborative agreements with third parties or consummate new collaborations and DURECT's (and that of its third party collaborators where applicable) difficulty or failure to obtain approvals from regulatory agencies with respect to its development activities and products, or ability to design, enroll, conduct and complete clinical trials, complete the design, development, and manufacturing process development of the referenced product candidates, manufacture and commercialize the referenced product candidates, obtain marketplace acceptance of the referenced product candidates, avoid infringing patents held by other parties and secure and defend patents of our own, and manage and obtain capital to fund operations and expenses. Further information regarding these and other risks is included in DURECT's Form 10-Q on August 7, 2012 under the heading "Risk Factors."

| DURECT CORPORATION  |                    |            |  |                   |             |  |
|---|--------------------|------------|--|-------------------|-------------|--|
| STATEMENTS OF COMPREHENSIVE INCOME (LOSS)                             |                    |            |  |                   |             |  |
| (in thousands, except per share amounts)                              |                    |            |  |                   |             |  |
| (unaudited)   |                    |            |  |                   |             |  |
|   | Three months ended |            |  | Nine months ended |             |  |
|   | September 30,      |            |  | September 30,     |             |  |
|   | 2012               | 2011       |  | 2012              | 2011        |  |
| Collaborative research and development and other revenue              | \$ 1,126           | \$ 5,206   |  | \$ 41,681         | \$ 15,906   |  |
| Product revenue, net  | 2,702              | 2,909      |  | 8,127             | 8,646       |  |
| Total revenues  | 3,828              | 8,115      |  | 49,808            | 24,552      |  |
| Operating expenses:   |                    |            |  |                   |             |  |
| Cost of product revenues  | 1,037              | 1,300      |  | 3,616             | 3,786       |  |
| Research and development  | 4,745              | 8,452      |  | 15,361            | 27,040      |  |
| Selling, general and administrative                                   | 2,854              | 3,377      |  | 9,183             | 10,420      |  |
| Total operating expenses  | 8,636              | 13,129     |  | 28,160            | 41,246      |  |
| Income (loss) from operations   | (4,808)            | (5,014)    |  | 21,648            | (16,694)    |  |
| Other income (expense):   |                    |            |  |                   |             |  |
| Interest and other income   | 17                 | 31         |  | 66                | 109         |  |
| Interest expense  | (12)               | (42)       |  | (15)              | (42)        |  |
| Net other income  | 5                  | (11)       |  | 51                | 67          |  |
| Net Income (loss)   | \$ (4,803)         | \$ (5,025) |  | \$ 21,699         | \$ (16,627) |  |
| Net income (loss) per share   |                    |            |  |                   |             |  |
| Basic   | \$ (0.05)          | \$ (0.06)  |  | \$ 0.25           | \$ (0.19)   |  |
| Diluted   | \$ (0.05)          | \$ (0.06)  |  | \$ 0.25           | \$ (0.19)   |  |
| Weighted-average shares used in computing net income (loss) per share |                    |            |  |                   |             |  |
| Basic   | 87,671             | 87,450     |  | 87,607            | 87,375      |  |
| Diluted   | 87,671             | 87,450     |  | 87,726            | 87,375      |  |
| Total comprehensive income (loss)                                     | \$ (4,796)         | \$ (5,037) |  | \$ 21,700         | \$ (16,622) |  |

| DURECT CORPORATION                |                    |        |                                  |
|-----------------------------------|--------------------|--------|----------------------------------|
| BALANCE SHEET DATA                |                    |        |                                  |
| (in thousands)                    |                    |        |                                  |
|                                   | As of              |        | As of                            |
|                                   | September 30, 2012 |        | December 31, 2011 <sup>(1)</sup> |
| (unaudited)                       |                    |        |                                  |
| <b>ASSETS</b>                     |                    |        |                                  |
| Current assets:                   |                    |        |                                  |
| Cash and cash equivalents         | \$                 | 6,285  | \$ 8,896                         |
| Short-term investments            |                    | 12,193 | 19,535                           |
| Short-term restricted investments |                    | -      | 367                              |
| Accounts receivable               |                    | 2,082  | 3,448                            |



|  |  |           |  |           |
|--|--|-----------|--|-----------|
| Inventories                                    |  | 3,291     |  | 3,252     |
| Prepaid expenses and other current assets      |  | 935       |  | 1,803     |
| Total current assets                           |  | 24,786    |  | 37,301    |
| Property and equipment, net                    |  | 2,559     |  | 3,124     |
| Goodwill                                       |  | 6,399     |  | 6,399     |
| Intangible assets, net                         |  | 40        |  | 53        |
| Long-term investments                          |  | 2,141     |  | 1,530     |
| Long-term restricted Investments               |  | 400       |  | 501       |
| Other long-term assets                         |  | 288       |  | 288       |
| Total assets                                   |  | \$ 36,613 |  | \$ 49,196 |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>    |  |           |  |           |
| Current liabilities:                           |  |           |  |           |
| Accounts payable                               |  | \$ 785    |  | \$ 1,274  |
| Accrued liabilities                            |  | 3,760     |  | 4,884     |
| Contract research liability                    |  | 472       |  | 1,361     |
| Deferred revenue, current portion              |  | 312       |  | 7,372     |
| Total current liabilities                      |  | 5,329     |  | 14,891    |
| Deferred revenue, noncurrent portion           |  | 1,558     |  | 30,090    |
| Other long-term liabilities                    |  | 662       |  | 738       |
| Stockholders' equity                           |  | 29,064    |  | 3,477     |
| Total liabilities and stockholders' equity     |  | \$ 36,613 |  | \$ 49,196 |
| (1) Derived from audited financial statements. |  |           |  |           |

SOURCE DURECT Corporation

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