DURECT Corporation Announces Fourth Quarter and Year End 2011 Financial Results

CUPERTINO, Calif., March 1, 2012 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months and year ended December 31, 2011. Total revenues were $8.9 million for the three months ended December 31, 2011, up from $8.5 million for the three months ended December 31, 2010. Net loss for the three months ended December 31, 2011 was $2.1 million, down from a net loss of $5.3 million for the same period in 2010.

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

For the fiscal year ended December 31, 2011, total revenues were $33.5 million, up from $31.6 million for the same period in 2010. Net loss for the year ended December 31, 2011 was $18.8 million, down from a net loss of $22.9 million for the same period in 2010.

At December 31, 2011, DURECT had cash and investments of $30.8 million, compared to cash and investments of $49.6 million at December 31, 2010. The Company has no debt obligations, other than normal liabilities associated with running our business.

“Our most advanced development programs are REMOXY® and POSIDUR™. We continue to support an experienced team at Pfizer in resolving the remaining issues related to REMOXY as Pfizer executes specific activities in preparation for a meeting with the FDA,” stated James E. Brown, D.V.M., President and CEO of DURECT. “For POSIDUR, we are currently preparing the integrated summary of safety and efficacy for the overall program in anticipation of a pre-NDA meeting which we expect to hold in mid-year. Financially, we have recently taken steps to reduce our anticipated cash burn rate in 2012 from the$15-17 million range stated in November 2011 to our current guidance of approximately $12 million, which assumes no new collaborations and no milestone payments.”

In 2012, we look forward to:

- Pfizer conducting a meeting with the FDA to discuss the REMOXY resubmission
- Conducting of a pre-NDA meeting with the FDA for POSIDUR, with a potential NDA submission in 2012
- Supporting Zogenix as they initiate a Phase I study with Relday™
- Selecting a formulation based on our Phase I studies to take forward in our ORADUR-ADHD program
- Potentially entering into additional feasibility studies and collaborations

Highlights for DURECT in Fiscal Year 2011 and Major Potential Milestones over the Next 12-18 Months:

- **REMOXY.** On June 23, 2011, Pfizer received a Complete Response Letter from the U.S. Food and Drug Administration (FDA) for the REMOXY NDA which had been resubmitted in December 2010 by King Pharmaceuticals (acquired by Pfizer in February 2011). The FDA’s Complete Response Letter raised concerns related to, among other matters, the Chemistry, Manufacturing, and Controls (CMC) section of the NDA for REMOXY. Pfizer has efforts underway to resolve these issues and stated in its last earnings call on January 31, 2012 that it expects to conduct two bioavailability studies in the second quarter of 2012 and then meet with the FDA in the third quarter to discuss next steps.

  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® technology, which is covered by issued patents and pending patent applications owned by us, REMOXY is designed to resist common methods of prescription drug misuse and abuse. DURECT is eligible for a potential royalty on REMOXY of between 6.0% to 11.5% of net sales depending on the sales volumes. In addition, we supply to Pfizer two of the key excipients used in the manufacture of REMOXY for which we are paid our manufacturing cost plus a specified percentage mark-up.

- **POSIDUR (SABER™-Bupivacaine) Post-Operative Pain Relief Depot**. After preparation of integrated safety and efficacy summaries combining our previous well controlled studies with data from the BESST trial, we intend to hold a pre-NDA meeting with the FDA in mid-2012, with a potential NDA submission later in the year. The BESST trial supplemented our safety database with an additional 305 patients, each of whom agreed to extensive cardiac monitoring. While the results trended positive for both pain reduction and reduction of supplemental opioid use in the first three days after surgery, they did not reach statistical significance for the selected primary endpoints. Previous well controlled Phase II studies for hernia and shoulder surgery demonstrated positive efficacy results compared to placebo for both pain reduction and reduction of supplemental opioid use in the first three days after surgery.

POSIDUR is our 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. POSIDUR is licensed to Hospira for commercialization in the U.S. and Canada. We retain commercialization rights in all other countries.

- **ORADUR-ADHD Program.** We and Orient Pharma have completed several Phase I pharmacokinetic studies with multiple formulations. Based on information from those studies, we are continuing to evaluate our lead formulations. Orient Pharma is our licensee for certain Asian and South Pacific countries.
- **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. Zogenix expects to initiate clinical studies for Relday in patients with schizophrenia in 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.

- **ELADUR (TRANSDUR®-Bupivacaine).** In February 2012, Pfizer notified us that they are returning their worldwide development and commercialization rights to ELADUR. Pfizer has committed to assist in an orderly and rapid transition of program data back to DURECT. We intend to initiate discussions with other potential partners regarding licensing development and commercialization rights to this program.

ELADUR is our proprietary transdermal patch intended to deliver bupivacaine for a period of up to three days from a single application. ELADUR demonstrated a positive efficacy trend in a Phase 2a study for post-herpetic neuralgia (PHN); a poster describing this study was presented at the 27th Annual Scientific Meeting of the American Pain Society on May 8, 2008 and is accessible on DURECT's website at www.www.durect.com/wt/durect/page_name/Publications.

- **TRANSDUR-Sufentanil.** We continue discussions with potential partners regarding licensing development and commercialization rights to this program to which we hold worldwide rights.

TRANSDUR-Sufentanil is our proprietary transdermal patch intended to deliver sufentanil to chronic pain sufferers for a period of up to seven days from a single application.

- **Feasibility Projects and Other Activities.** During 2011, 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.
- **Financial Guidance.** Our net cash consumption is influenced by the timing and structure of new corporate collaborations, the achievement of milestones under existing collaborations, and the extent to which we choose to fund unpartnered programs. While we anticipate entering into new collaborations in the future, assuming current funding plans for our R&D programs, no new collaborations and no milestone payments, we currently anticipate our net cash consumption in 2012 will be approximately $12 million.
- **Business Development Activities.** We have multiple programs that may potentially be partnered over the next 12-18 months. These include POSIDUR for Japan and other territories outside the U.S. and Canada, TRANSDUR-Sufentanil worldwide rights, ELADUR worldwide rights, ORADUR-ADHD for territories outside certain Asian and South Pacific markets, as well as various internal programs which we have not described publicly in detail.

Earnings Conference Call

A live audio webcast of a conference call to discuss 2011 results will be broadcast over the internet at 4:30 p.m. Eastern Time on March 1 and is available by accessing DURECT's homepage at www.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.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 action on REMOXY by the FDA, our anticipated net cash consumption, potential regulatory meetings and submissions for POSIDUR, anticipated clinical trials (including timing and results) for TRANSDUR-Sufentanil, ELADUR, ORADUR-ADHD, 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 of adverse decisions by regulatory agencies, including rejection of meeting requests 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 November 7, 2011 under the heading "Risk Factors."

DURECT CORPORATION
STATEMENTS OF OPERATIONS DATA
(in thousands, except per share amounts)
(unaudited)

	Three months ended December 31,		Year ended December 31,	
	2011	2010	2011	2010
Collaborative research and development and other revenue	$ 6,454	$ 5,929	$ 22,360	$ 20,091
Product revenue, net	2,481	2,567	11,127	11,500
Total revenues	8,935	8,496	33,487	31,591
Operating expenses:				
Cost of revenues (1)	927	1,177	4,713	4,275
Research and development (1)	7,013	9,447	34,053	36,214
Selling, general and administrative (1)	3,154	4,045	13,574	14,937
Total operating expenses	11,094	14,669	52,340	55,426
Loss from operations	(2,159)	(6,173)	(18,853)	(23,835)
Other income (expense):				
Interest and other income	25	838	134	943
Interest and other expense	(4)	19	(46)	(6)
Net other income (expense)	21	857	88	937
Net loss	$ (2,138)	$ (5,316)	$ (18,765)	$ (22,898)
Net loss per share, basic and diluted	$ (0.02)	$ (0.06)	$ (0.21)	$ (0.26)
Shares used in computing basic and diluted net loss per share	87,514	86,976	87,410	86,868
(1) Includes stock-based compensation related to the following:				
Cost of revenues	$ 81	$ 88	$ 328	$ 341
Research and development	904	1,223	4,181	4,941
Selling, general and administrative	389	497	2,132	2,520
Total stock-based compensation	$ 1,374	$ 1,808	$ 6,641	$ 7,802

DURECT CORPORATION
BALANCE SHEET DATA
(in thousands)

	As of December 31, 2011 (unaudited)	As of December 31, 2010 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 8,896	$ 10,437
Short-term investments	19,535	35,005
Short-term restricted investments	367	66
Accounts receivable	3,448	3,716
Inventories	3,252	2,836
Prepaid expenses and other current assets	1,803	2,785
Total current assets	37,301	54,845
Property and equipment, net	3,124	1,776
Goodwill	6,399	6,399
Intangible assets, net	53	71
Long-term investments	1,530	3,197
Long-term restricted Investments	501	867
Other long-term assets	288	405
Total assets	$ 49,196	$ 67,560
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,274	$ 981
Accrued liabilities	4,884	6,740

Contract research liability	1,361	2,109
Deferred revenue, current portion	7,372	8,079
Total current liabilities	14,891	17,909
Deferred revenue, noncurrent portion	30,090	34,849
Other long-term liabilities	738	315
Stockholders' equity	3,477	14,487
Total liabilities and stockholders' equity	$ 49,196	$ 67,560

(1) Derived from audited financial statements.

SOURCE DURECT Corporation

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