DURECT Corporation Announces First Quarter 2012 Financial Results and Update of Programs

CUPERTINO, Calif., May 3, 2012 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months ended March 31, 2012. Excluding the accelerated recognition of deferred revenue described below, DURECT's reported revenues would have been $5.8 million for the three months ended March 31, 2012 (as compared to $8.6 million for the same period in 2011) and reported net loss would have been $4.6 million for the three months ended March 31, 2012 (as compared to a net loss of $6.4 million for the same period in 2011). Total revenues as reported under GAAP were $41.2 million and net income as reported under GAAP was $30.8 million for the three months ended March 31, 2012; these figures include the accelerated recognition of $35.4 million in deferred revenue associated with upfront fees previously received under terminated collaboration agreements. This $35.4 million in revenue is non-recurring and has no cash flow impact for the quarter.

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

At March 31, 2012, we had cash and investments of $26.4 million, compared to cash and investments of $30.8 million at December 31, 2011.

"This quarter was dominated by the POSIDUR™ clinical trial results and partnership terminations. However, we continued to make progress with our development programs and we have recently reinforced the protection of our pipeline through 13 patent issuances and 2 patent allowances involving major and/or partnered programs that extend patent protection in large market jurisdictions to 2025 or beyond," stated James E. Brown, D.V.M., President and CEO of DURECT. "In particular, we now have issued U.S. patents covering REMOXY® and our other ORADUR®-based opioid programs that extend to at least 2025 as well as an issued European patent providing coverage to at least 2023."

Update of Programs:

- **REMOXY (oxycodone) Extended-Release Capsules CII.** Pfizer has efforts underway to resolve the issues raised in the REMOXY Complete Response Letter and stated in its 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. The issues raised in the Complete Response Letter relate primarily to manufacturing.

  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 discourage common methods of tampering associated with prescription opioid analgesic misuse and abuse.

- **POSIDUR (SABER®-Bupivacaine) Post-Operative Pain Relief Depot.** Preparation of our briefing package is well underway for our scheduled pre-NDA meeting with the FDA in the summer of 2012, with a potential NDA submission later in the year, depending on FDA feedback.

  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. We currently hold worldwide commercialization rights to POSIDUR following the notice given in the first quarter of 2012 by Hospira and Nycomed to terminate their collaborations related to the program.

- **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-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. Pfizer's termination of the ELADUR collaboration in the first quarter of 2012 returns to DURECT the rights to develop and commercialize ELADUR worldwide. 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. 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, 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. 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. 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 first 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 internal programs which we have not described publicly in detail.

Earnings Conference Call

A live audio webcast of a conference call to discuss first quarter 2012 results will be broadcast live over the internet at 4:30 p.m. Eastern Time on May 3 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 bioavailability studies 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 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-K on March 2, 2012 under the heading "Risk Factors."

DURECT CORPORATION
STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(in thousands, except per share amounts)
(Unaudited)

	Three months ended March 31,	
	2012	2011
Collaborative research and development and other revenue	$38,328	$ 5,512
Product revenue, net	2,857	3,092
Total revenues	41,185	8,604
Operating expenses:		
Cost of product revenues	1,461	1,401
Research and development	5,634	9,880
Selling, general and administrative	3,280	3,716
Total operating expenses	10,375	14,997
Income (loss) from operations	30,810	(6,393)
Other income (expense):		
Interest and other income	21	40
Interest expense	(2)	(4)
Net other income	19	36
Net Income (loss)	$30,829	$(6,357)
Net income (loss) per share		
Basic	$ 0.35	$ (0.07)
Diluted	$ 0.35	$ (0.07)
Weighted-average shares used in computing net income (loss) per share		
Basic	87,547	87,270
Diluted	87,568	87,270
Total comprehensive income (loss)	$30,826	$(6,343)

DURECT CORPORATION
CONDENSED BALANCE SHEETS
(in thousands)

	As of March 31, 2012 (unaudited)	As of December 31, 2011(1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,537	$ 8,896
Short-term investments	15,128	19,535
Short-term restricted investments	–	367
Accounts receivable	2,915	3,448
Inventories	3,233	3,252
Prepaid expenses and other current assets	1,488	1,803
Total current assets	30,301	37,301
Property and equipment, net	2,941	3,124
Goodwill	6,399	6,399
Intangible assets, net	49	53
Long-term investments	3,224	1,530
Long-term restricted Investments	501	501

Other long-term assets	288	288
Total assets	$ 43,703	$ 49,196
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 615	$ 1,274
Accrued liabilities	3,708	4,884
Contract research liability	665	1,361
Deferred revenue, current portion	312	7,372
Total current liabilities	5,300	14,891
Deferred revenue, noncurrent portion	1,714	30,090
Other long-term liabilities	715	738
Stockholders' equity	35,974	3,477
Total liabilities and stockholders' equity	$ 43,703	$ 49,196

(1) Derived from audited financial statements.

SOURCE DURECT Corporation

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