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

CUPERTINO, Calif., Aug. 6, 2012 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months ended June 30, 2012. Total revenues were $4.8 million for the three months ended June 30, 2012 as compared to $7.8 million for the three months ended June 30, 2011. Net loss for the three months ended June 30, 2012 was $4.3 million, compared to a net loss of $5.2 million for the same period in 2011.

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

At June 30, 2012, we had cash and investments of $23.7 million, compared to cash and investments of $26.4 million at March 31, 2012 and $30.8 million at December 31, 2011. We have no debt obligations, other than normal liabilities associated with running our business.

“Based on our recent pre-NDA communications with the FDA, we intend to submit a new drug application for POSIDUR in late 2012 or early 2013,” stated James E. Brown, D.V.M., President and CEO of DURECT. “We are also pleased that Pfizer continues to move forward with their efforts to prepare for an FDA interaction later this year with respect to REMOXY and that Zogenix has commenced a Phase I clinical trial for Relday.”

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 their earnings call on July 31, 2012 that they are analyzing preliminary results from two bioavailability studies and hoping to meet with the FDA in the fourth quarter. 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.** Based on recent pre-NDA communications with the FDA regarding POSIDUR, we intend to finish preparing and submit a new drug application (NDA) under 505(b)(2) with the FDA in late 2012 or early 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™-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. Zogenix expects that study results will be available 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 second 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 second quarter 2012 results will be broadcast live over the internet at 4:30 p.m. Eastern Time on August 6 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-Q on May 4, 2012 under the heading "Risk Factors."

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

	Three months ended June 30,		Six months ended June 30,	
	2012	2011	2012	2011
Collaborative research and development and other revenue	$ 2,227	$ 5,188	$40,555	$ 10,700
Product revenue, net	2,569	2,645	5,426	5,737
Total revenues	4,796	7,833	45,981	16,437
Operating expenses:				
Cost of product revenues	1,118	1,085	2,579	2,486
Research and development	4,982	8,708	10,616	18,588
Selling, general and administrative	3,049	3,327	6,329	7,043
Total operating expenses	9,149	13,120	19,524	28,117
Income (loss) from operations	(4,353)	(5,287)	26,457	(11,680)
Other income (expense):				
Interest and other income	27	43	49	83
Interest expense	(2)	(1)	(4)	(5)
Net other income	25	42	45	78
Net Income (loss)	$(4,328)	$(5,245)	$26,502	$(11,602)
Net income (loss) per share				
Basic	$ (0.05)	$ (0.06)	$ 0.30	$ (0.13)
Diluted	$ (0.05)	$ (0.06)	$ 0.30	$ (0.13)
Weighted-average shares used in computing net income (loss) per share				
Basic	87,602	87,404	87,575	87,338
Diluted	87,602	87,404	87,593	87,338
Total comprehensive income (loss)	$(4,330)	$(5,242)	$26,496	$(11,585)

DURECT CORPORATION
BALANCE SHEET DATA
(in thousands)

	As of June 30, 2012 (unaudited)	As of December 31, 2011[1]
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,156	$ 8,896
Short-term investments	14,878	19,535
Short-term restricted investments	–	367
Accounts receivable	2,598	3,448
Inventories	3,177	3,252
Prepaid expenses and other current assets	1,225	1,803
Total current assets	26,034	37,301
Property and equipment, net	2,766	3,124
Goodwill	6,399	6,399
Intangible assets, net	44	53
Long-term investments	4,299	1,530
Long-term restricted Investments	400	501
Other long-term assets	288	288
Total assets	$ 40,230	$ 49,196
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 703	$ 1,274
Accrued liabilities	3,704	4,884
Contract research liability	429	1,361
Deferred revenue, current portion	312	7,372
Total current liabilities	5,148	14,891
Deferred revenue, noncurrent portion	1,636	30,090
Other long-term liabilities	689	738
Stockholders' equity	32,757	3,477
Total liabilities and stockholders' equity	$ 40,230	$ 49,196

(1) Derived from audited financial statements.

SOURCE DURECT Corporation

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