DURECT Corporation Announces Second Quarter 2013 Financial Results and Update of Programs

CUPERTINO, Calif., Aug. 5, 2013 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the second quarter of 2013. Total revenues were $3.9 million for the three months ended June 30, 2013 as compared to $4.8 million for the three months ended June 30, 2012. Net loss for the three months ended June 30, 2013 was $5.1 million, compared to a net loss of $4.3 million for the same period in 2012.

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

At June 30, 2013, we had cash and investments of $21.3 million, compared to cash and investments of $25.5 million at March 31, 2013 and $28.9 million at December 31, 2012.

“We are pleased that our New Drug Application (NDA) for POSIDUR™ has been accepted by the FDA and the PDUFA date is approximately 6 months away,” stated James E. Brown, D.V.M., President and CEO of DURECT. “Another recent positive event was the selection of a lead formulation in our ORADUR-ADHD program, enabling us to commence a proactive business development effort for that program.”

Update of Programs:

- **POSIDUR (SABER®-Bupivacaine) Post-Operative Pain Relief Depot.** In April 2013, we submitted a new drug application (NDA) as a 505(b)(2) application, which relies in part on the FDA’s findings of safety and effectiveness of a reference drug. In June 2013, we announced that our NDA submission had been accepted by the FDA, indicating that the application is sufficiently complete to permit a substantive review. The Prescription Drug User Fee Act (PDUFA) goal date (the date the FDA expects to complete its review of the NDA) is February 12, 2014.

  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 are in discussions with potential partners regarding licensing development and commercialization rights to POSIDUR, for which we hold worldwide rights.

- **REMOXY (oxycodone) Extended-Release Capsules CII.** Pfizer has efforts underway to resolve the issues raised in the REMOXY Complete Response Letter, which are primarily related to manufacturing. In May 2013, Pfizer stated that they had met with the FDA in March 2013 to discuss their plan to address the Complete Response Letter, and that they had received written guidance from the FDA in May 2013 regarding required next steps, including additional clinical studies, to address the letter. We understand from Pfizer that these additional clinical studies include, in part, a pivotal bioequivalence study with the modified formulation to bridge to the clinical data conducted with the original formulation, as well as an abuse potential study with the modified REMOXY formulation. Based on this guidance from the FDA, Pfizer stated that they are considering their options with respect to REMOXY. Further, if Pfizer elects to continue development of REMOXY, which we expect will be determined in the fall of 2013, Pfizer stated that they would not expect to resubmit the NDA, addressing the deficiencies identified in the Complete Response Letter, before mid-2015.

  REMOXY, an investigational drug, is a unique long acting oral formulation of oxycodone intended to treat moderate-to-severe pain when a continuous, around the clock opioid analgesic is needed for an extended period of time. 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.

- **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 3 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 for which we hold worldwide rights.

- **ORADUR-ADHD Program.** We recently selected a lead formulation for the lead program in our ORADUR-ADHD (Attention Deficit Hyperactivity Disorder) program, ORADUR-Methylphenidate. This formulation was chosen based on its potential for rapid onset of action, long duration with once-a-day dosing and target pharmacokinetic profile as demonstrated in a recent Phase 1 trial. In addition, this product candidate utilizes a small capsule size relative to the leading existing long acting products on the market and incorporates our ORADUR anti-tampering technology. Our licensee, Orient Pharma, is planning to meet with the Taiwan Food and Drug Administration (TFDA) later this year to discuss the Phase 3 program in that market and is developing its plans for further development in the defined Asian and South Pacific countries to which it has rights from DURECT. DURECT retains rights to all other markets in the world, notably including the U.S., Europe and Japan, and is initiating licensing discussions with other companies now that the lead formulation has been selected.
- **Relday™ (Risperidone Program).** In January 2013, Zogenix (our licensee) announced positive single-dose pharmacokinetic (PK) results from a Phase 1 clinical trial of Relday. According to Zogenix, adverse events in the Phase 1 trial in patients diagnosed with schizophrenia were generally mild to moderate and consistent with other risperidone products. The Phase 1 clinical trial for Relday was conducted as a single-center, open-label, safety and PK trial of 30 patients with chronic, stable schizophrenia or schizoaffective disorder. Per Zogenix, based on the favorable safety and PK profile demonstrated with the 25 mg and 50 mg once-monthly doses tested in the Phase 1 trial, Zogenix extended the study to include a 100 mg dose of the same formulation. In May 2013, Zogenix announced positive results with the 100 mg arm, demonstrating dose proportionality across the full dose range that would be anticipated to be used in clinical practice. According to Zogenix, the positive results from this study extension positions Zogenix to begin a multi-dose clinical trial, which would provide the required steady-state pharmacokinetic and safety data prior to initiating Phase 3 development studies, subject to Zogenix's ability to secure a development and commercialization partner prior to initiation of the multi-dose trial.

  Relday is a proprietary, long-acting, once-monthly subcutaneous injectable formulation of risperidone using DURECT's SABER controlled-release formulation technology. An existing long-acting injectable risperidone product, which achieved $1.4 billion in global net sales in 2012, requires twice-monthly, intramuscular injections and drug reconstitution prior to use.

- **Feasibility Projects and Other Activities.** During the second quarter of 2013, 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-Methylphenidate (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 2013 results will be broadcast live over the internet at 4:30 p.m. Eastern Time on August 5 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.

Methylphenidate 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 Statements

The statements in this press release regarding the potential regulatory submissions and FDA actions for REMOXY and POSIDUR, potential regulatory approvals of REMOXY and POSIDUR, the potential benefits and uses of our drug candidates, clinical trials and product development plans by our collaborators, potential 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 or that Pfizer may take longer to decide as to whether to continue development of REMOXY than anticipated, the risk of adverse decisions by regulatory agencies, including requests for additional information or product non-approval of our POSIDUR or other NDA submissions, delays and additional costs due to requirements imposed by regulatory agencies, potential adverse effects arising from the testing or use of our drug candidates, our potential failure to maintain our collaborative agreements with third parties or consummate new collaborations and risks related to our (and our third party collaborators where applicable) difficulty or failure to obtain approvals from regulatory agencies with respect to our development activities and products, or ability to design, enroll, conduct and complete clinical trials, complete the design, development, and manufacturing process development of product candidates, manufacture and commercialize product candidates, obtain marketplace acceptance of 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 for the quarter ending March 31, 2013 under the heading "Risk Factors."

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

	Three months ended June 30,		Six months ended June 30,	
	2013	2012	2013	2012[1]
Collaborative research and development and other revenue	$ 905	$ 2,227	$ 1,818	$40,555
Product revenue, net	3,013	2,569	6,253	5,426
Total revenues	3,918	4,796	8,071	45,981
Operating expenses:				
Cost of product revenues	1,032	1,118	2,690	2,579
Research and development	4,833	4,982	9,622	10,616
Selling, general and administrative	3,210	3,049	6,111	6,329
Total operating expenses	9,075	9,149	18,423	19,524
Income (loss) from operations	(5,157)	(4,353)	(10,352)	26,457
Other income (expense):				
Interest and other income	13	27	27	49
Interest and other expense	(1)	(2)	(3)	(4)
Net other income	12	25	24	45
Net Income (loss)	$ (5,145)	$(4,328)	$(10,328)	$26,502
Net income (loss) per share				
Basic	$ (0.05)	$ (0.05)	$ (0.10)	$ 0.30
Diluted	$ (0.05)	$ (0.05)	$ (0.10)	$ 0.30
Weighted-average shares used in computing net income (loss) per share				
Basic	101,954	87,602	101,918	87,575
Diluted	101,954	87,602	101,918	87,593
Total comprehensive income (loss)	$ (5,146)	$(4,330)	$(10,331)	$26,496

(1) Derived from audited financial statements.

DURECT CORPORATION
CONDENSED BALANCE SHEETS
(in thousands)

	As of June 30, 2013 (unaudited)	As of December 31, 2012[1]
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,989	$ 11,195
Short-term investments	13,024	17,337
Accounts receivable	2,012	2,166
Inventories	3,151	3,399
Prepaid expenses and other current assets	1,584	2,258
Total current assets	27,760	36,355
Property and equipment, net	2,006	2,457
Goodwill	6,399	6,399
Intangible assets, net	27	36
Long-term restricted Investments	300	400
Other long-term assets	148	288
Total assets	$ 36,640	$ 45,935
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 771	$ 1,785
Accrued liabilities	3,958	3,997
Contract research liability	140	483
Deferred revenue, current portion	255	662
Total current liabilities	5,124	6,927
Deferred revenue, noncurrent portion	1,424	1,480
Other long-term liabilities	775	1,197
Stockholders' equity	29,317	36,331
Total liabilities and stockholders' equity	$ 36,640	$ 45,935

(1) Derived from audited financial statements.

SOURCE DURECT Corporation

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