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

CUPERTINO, Calif., May 2, 2013 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the first quarter of 2013. Total revenues were $4.2 million and net loss was $5.2 million for the three months ended March 31, 2013. For comparison, total GAAP revenue was $41.2 million and net income was $30.8 million for the three months ended March 31, 2012. The revenue for the first quarter of 2012 included the accelerated recognition of $35.4 million in deferred revenue associated with upfront fees previously received under terminated collaboration agreements; this revenue was non-recurring and had no cash flow impact. Adjusting for this non-recurring revenue, revenue for the first three months ended March 31, 2012 would have been $5.8 million and net loss would have been $4.6 million.

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

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

“We were pleased to announce on April 16 that we had submitted the New Drug Application (NDA) for POSIDUR™ and look forward to the FDA‘s review,” stated James E. Brown, D.V.M., President and CEO of DURECT. “The FDA’s recent decisions to allow updated labeling for opioids that demonstrate abuse-deterrent properties and not to allow generics against the original OxyContin® are positive developments for REMOXY®. Pfizer recently stated that they had a productive meeting with the FDA in late March and we note the recent additional patent issuance extending coverage of REMOXY in the U.S. to at least 2031. Another positive event during the first quarter was our collaborator Zogenix reporting positive results from the Relday™ Phase 1 study and rapid expansion of that study to include a higher dose, which today also reported positive results.”

Update of Programs:

- **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. Pfizer held a meeting with the FDA in late March 2013 to discuss their proposed resubmission plan for REMOXY. On April 30, Pfizer stated that they had a productive meeting with the FDA and received guidance that is helping to inform the next steps in addressing the issues raised by the FDA in the Complete Response Letter. In 2013, we received issuance of an additional ORADUR® patent that would protect REMOXY in the U.S. until at least 2031.

  On April 16, 2013, the FDA announced two actions relevant to abuse-deterrent opioids. First, after reviewing the available science, the FDA will allow the label for opioids to describe abuse-deterrent properties. Second, the FDA will not accept or approve any generic forms of the original OxyContin ER.

  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.

- **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. We expect that the FDA will notify us whether our NDA submission has been accepted for filing in June 2013. If accepted for filing, the FDA would be expected to assign a Prescription Drug User Fee Act (PDUFA) target date (the date the FDA expects to complete its review of the POSIDUR NDA) in the first quarter of 2014.

  DURECT will be presenting a poster on POSIDUR at the American Pain Society Meeting on May 9 from 9:30 to 11:00 a.m. in New Orleans. This poster will summarize results from a well controlled shoulder surgery trial. After the meeting, DURECT

will make the poster available through our website www.www.durect.com.

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.

- **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 for 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 optimize 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 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.

  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 first 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-ADHD (territories outside certain Asian and South Pacific markets), as well as various internal programs which we have not described publicly in detail.
- **Upcoming Investor Presentation.** DURECT will be presenting at the Marcum 2013 MicroCap Conference in New York City on Thursday, May 30 at 10:30 a.m. Eastern time at the Grand Hyatt Hotel. A live webcast of the presentation will be available by accessing http://wsw.com/webcast/marcum/drrx/ or 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.

Earnings Conference Call

A live audio webcast of a conference call to discuss first quarter 2013 results will be broadcast live over the internet at 4:30 p.m. Eastern Time on May 2 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 Statements

The statements in this press release regarding the potential regulatory meetings and submissions for REMOXY and POSIDUR, potential regulatory approvals of REMOXY AND POSIDUR, 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 requests for additional information or product non-approval or non-acceptance 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, 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 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-K for the fiscal year ending on December 31, 2012 under the heading "Risk Factors."

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

	Three months ended March 31,	
	2013	2012
Collaborative research and development and other revenue	$ 913	$38,328
Product revenue, net	3,240	2,857
Total revenues	4,153	41,185
Operating expenses:		
Cost of product revenues	1,658	1,461
Research and development	4,789	5,634
Selling, general and administrative	2,901	3,280
Total operating expenses	9,348	10,375
Income (loss) from operations	(5,195)	30,810
Other income (expense):		
Interest and other income	14	21
Interest and other expense	(2)	(2)
Net other income	12	19
Net Income (loss)	$ (5,183)	$30,829
Net income (loss) per share		
Basic	$ (0.05)	$ 0.35
Diluted	$ (0.05)	$ 0.35
Weighted-average shares used in computing net income (loss) per share		
Basic	101,881	87,547

Diluted	101,881	87,568
Total comprehensive income (loss)	$ (5,181)	$30,826

DURECT CORPORATION
CONDENSED BALANCE SHEETS
(in thousands)

	As of March 31, 2013 (unaudited)	As of December 31, 2012(1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 8,250	$ 11,195
Short-term investments	16,261	17,337
Accounts receivable	1,567	2,166
Inventories	3,058	3,399
Prepaid expenses and other current assets	1,949	2,258
Total current assets	31,085	36,355
Property and equipment, net	2,229	2,457
Goodwill	6,399	6,399
Intangible assets, net	31	36
Long-term investments	716	–
Long-term restricted Investments	300	400
Other long-term assets	148	288
Total assets	$ 40,908	$ 45,935
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 833	$ 1,785
Accrued liabilities	3,591	3,997
Contract research liability	423	483
Deferred revenue, current portion	255	662
Total current liabilities	5,102	6,927
Deferred revenue, noncurrent portion	1,487	1,480
Other long-term liabilities	791	1,197
Stockholders' equity	33,528	36,331
Total liabilities and stockholders' equity	$ 40,908	$ 45,935

(1) Derived from audited financial statements.

SOURCE DURECT Corporation

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