DURECT Corporation Announces Second Quarter 2014 Financial Results and Update of Programs

CUPERTINO, Calif., Aug. 7, 2014 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the second quarter of 2014. Total revenues were $4.6 million and net loss was $5.5 million for the three months ended June 30, 2014 as compared to total revenues of $3.9 million and net loss of $5.1 million for the three months ended June 30, 2013.

DURECT Corporation (www.www.durect.com) is pioneering the development and commercialization of pharma

At June 30, 2014, we had cash and investments of $37.3 million, compared to cash and investments of $21.8 million at March 31, 2014 and $24.4 million at December 31, 2013. At June 30, 2014, we had $19.8 million in long term debt.

“In the near future we expect to send to the FDA the POSIDUR™ briefing package for our face-to-face meeting scheduled for late September. This meeting is intended to gain more clarity on the next steps that would be required to address the issues cited in the Complete Response Letter,” stated James E. Brown, D.V.M., President and CEO of DURECT. “Regarding REMOXY®, Pfizer has five studies currently posted on Clintrials.gov, with one that was recently completed. Our licensee, Pain Therapeutics, announced recently that they expect to start a Phase 1 clinical trial with ORADUR®-Hydromorphone shortly with an expectation of starting a Phase 3 trial for this product candidate in 2015. Other programs, some of which are partnered and some of which are currently unpartnered, are progressing as well.”

Update of Programs and Activities:

- **REMOXY (oxycodone) Extended-Release Capsules CII.** Pfizer has efforts underway to resolve the issues raised in the Complete Response Letter for REMOXY, which primarily relate to manufacturing. Following guidance received from the FDA in 2013, Pfizer announced that they will proceed with the additional clinical studies and other actions required to address the Complete Response Letter received in June 2011. These new clinical studies will include, in part, a pivotal bioequivalence study with the modified REMOXY formulation to bridge to the clinical data related to the original REMOXY formulation, and an abuse-potential study with the modified formulation. As previously disclosed, the complete response submission is not expected to occur prior to mid-2015.

  REMOXY, an investigational drug, is a unique long acting oral formulation of oxycodone intended to treat pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. 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.** On February 12, 2014 we received a Complete Response Letter from the FDA. Based on its review, the FDA has determined that they cannot approve the NDA in its present form, stating the NDA does not contain sufficient information to demonstrate that POSIDUR is safe when used in the manner described in the proposed label, and the FDA has indicated that additional clinical safety studies need to be conducted. We have been evaluating the issues and recommendations described in the Complete Response Letter and plan to have further discussions with the FDA around them at a face-to-face meeting at the FDA which is scheduled for late September.

  POSIDUR is our investigational post-operative pain relief depot that utilizes our patented SABER technology and is intended 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, while at the same time we are preparing to be in a position to commercialize POSIDUR ourself in the U.S. in the event that we determine that is the preferred route of commercialization.

- **ELADUR® (TRANSDUR-bupivacaine).** On January 7, 2014 we announced that we had entered into an agreement granting Impax the exclusive worldwide rights to develop and commercialize ELADUR. Under the terms of the agreement, Impax paid DURECT an upfront fee of $2 million, with possible additional payments of up to $61 million upon the achievement of predefined development and commercialization milestones. If ELADUR is commercialized, DURECT would also receive a tiered royalty on product sales. Impax will control and fund the development program.

  ELADUR, for the treatment of pain associated with 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.

- **Relday™ (Risperidone Program).** In 2013, Zogenix (our licensee) announced positive single-dose pharmacokinetic (PK) results from a Phase 1 clinical trial of Relday at 25 mg, 50 mg and 100 mg once-monthly doses, representing the full dose range that would be anticipated to be used in clinical practice. According to Zogenix, the positive results from this study extension position 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, and Zogenix plans to commence this multi-dose trial in the fourth quarter of 2014.

  Relday is a proprietary, once-monthly subcutaneous injectable formulation of risperidone with immediate onset of action using DURECT's SABER controlled-release formulation technology. An existing long-acting injectable risperidone product, which achieved $1.3 billion in global net sales in 2013, requires twice-monthly, intramuscular injections and drug reconstitution prior to use.

- **ORADUR-ADHD Program.** In 2013, we selected a 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 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, has met with the Taiwan Food and Drug Administration (TFDA) 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 us. We retain rights to all other markets in the world, notably including the U.S., Europe and Japan, and are engaged in licensing discussions with other companies.
- **Other ORADUR-based Opioids.** We have licensed three other ORADUR-based opioids (hydrocodone, hydromorphone and oxymorphone) to Pain Therapeutics. Phase I clinical trials have been conducted for ORADUR-hydrocodone and ORADUR-hydromorphone, and an Investigational New Drug (IND) application has been accepted by the FDA for ORADUR-oxymorphone. During the second quarter of 2014, we conducted research and development activities on these programs under approved workplans with Pain Therapeutics. Our licensee, Pain Therapeutics, announced recently that they expect to start a Phase 1 clinical trial with ORADUR-Hydromorphone shortly with an expectation of starting a Phase 3 trial for this product candidate in 2015.
- **Feasibility Projects and Other Activities.** During the second quarter of 2014, we continued work on several feasibility projects and have multiple discussions underway with other parties about new feasibility projects which are designed to demonstrate that our technologies can achieve the drug delivery objectives set forth by our collaborators and are worthy of further development. The Relday 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, ORADUR-ADHD, as well as various other programs which we have not described publicly in detail.
- **Debt Financing.** On June 26, 2014, we entered into a $20 million term loan agreement with Oxford Finance. The loan has a fixed interest rate of 7.95% per annum with interest only payments for the first 18 months and repayment of all principal and interest by July 1, 2018. In addition, DURECT paid a $150,000 facility fee at closing and, at maturity or earlier termination, we must pay Oxford an additional one-time payment equal to 8% of the initial principal amount of the term loan.

The term loan gives us more flexibility to advance our pipeline of products in development.

Earnings Conference Call

A live audio webcast of a conference call to discuss second quarter 2014 results will be broadcast live over the internet at4:30 p.m. Eastern Time on August 7 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®, and TRANSDUR® are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners. REMOXY and other ORADUR-based programs, 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 discussions and submissions for REMOXY and POSIDUR, potential FDA approval of REMOXY, POSIDUR, or any of our other product candidates, commercialization plans for POSIDUR, if approved, anticipated studies and clinical trials (including timing and results) for REMOXY, Relday, ORADUR-Methylphenidate, ORADUR-Hydromorphone and our other drug candidates, potential royalties or milestone payments fromImpax, our obligations to Oxford Finance, the potential benefits and uses of our drug candidates, collaborations with third parties and potential business development, licensing and commercialization 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 rejection of meeting requests, 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 clinical trials to meet their intended endpoints, our potential failure to maintain our collaborative agreements with third parties or consummate new collaborations, the risk that we will not be able to repay our obligations to Oxford Finance, and risks related to our (and our third party collaborators where applicable) ability to design, commence, 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 Annual Report on Form 10-Q for the quarter ending March 31, 2014 under the heading "Risk Factors."

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

	Three months ended June 30		Six months ended June 30	
	2014	2013	2014	2013
Collaborative research and development and other revenue	$ 1,735	$ 905	$ 5,247	$ 1,818
Product revenue, net	2,846	3,013	5,627	6,253
Total revenues	4,581	3,918	10,874	8,071
Operating expenses:				
Cost of product revenues	1,091	1,032	2,154	2,690
Research and development	6,088	4,833	11,557	9,622
Selling, general and administrative	2,850	3,210	6,213	6,111

Total operating expenses		10,029		9,075		19,924	18,423
Income (loss) from operations		(5,448)		(5,157)		(9,050)	(10,352)
Other income (expense):							
	Interest and other income (expenses)	3		13		6	27
	Interest expense	(33)		(1)		(34)	(3)
Net other income (expense)		(30)		12		(28)	24
Net loss		$ (5,478)		$ (5,145)		$ (9,078)	$(10,328)
Net loss per share							
	Basic	$ (0.05)		$ (0.05)		$ (0.08)	$ (0.10)
	Diluted	$ (0.05)		$ (0.05)		$ (0.08)	$ (0.10)
Weighted-average shares used in computing net loss per share							
	Basic	110,570		101,954		110,519	101,918
	Diluted	110,570		101,954		110,519	101,918
Total comprehensive loss		$ (5,481)		$ (5,146)		$ (9,077)	$(10,331)

DURECT CORPORATION
CONDENSED BALANCE SHEETS
(in thousands)

	As of June 30, 2014 (unaudited)	As of December 31, 2013[1]
ASSETS		
Current assets:		
Cash and cash equivalents	$ 18,674	$ 7,836
Short-term investments	14,299	12,753
Accounts receivable	2,276	2,349
Inventories	4,554	3,502
Prepaid expenses and other current assets	751	1,888
Total current assets	40,554	28,328
Property and equipment, net	1,826	1,985
Goodwill	6,399	6,399
Intangible assets, net	9	18
Long-term investments	4,012	3,352
Long-term restricted Investments	350	450
Other long-term assets	288	288
Total assets	$ 53,438	$ 40,820
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 666	$ 736
Accrued liabilities	4,687	5,865
Contract research liability	169	329
Deferred revenue, current portion	255	255
Total current liabilities	5,777	7,185
Deferred revenue, noncurrent portion	1,169	1,296
Long-term debt, net	19,786	–
Other long-term liabilities	1,641	1,618
Stockholders' equity	25,065	30,721
Total liabilities and stockholders' equity	$ 53,438	$ 40,820

(1) Derived from audited financial statements.

Logo – http://photos.prnewswire.com/prnh/20020717/DRRXLOGO

SOURCE DURECT Corporation

Matt Hogan, Chief Financial Officer, DURECT Corporation, 408-777-4936