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

CUPERTINO, Calif., Feb. 27, 2014 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months ended December 31, 2013. Total revenues were $4.3 million for the three months ended December 31, 2013 as compared to $3.3 million for the three months ended December 31, 2012. Net loss was $5.1 million for the three months ended December 31, 2013 as compared to a net loss of $5.5 million for the same period in 2012.

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

Total revenues were $15.3 million and net loss was $21.5 million for the year ended December 31, 2013 as compared to total revenues of $53.1 million and net income of $16.2 million for the year ended December 31, 2012. The 2012 figures include the accelerated recognition in the first quarter of 2012 of $35.4 million in deferred revenue associated with upfront fees previously received under terminated collaboration agreements. This $35.4 million in revenue was non-recurring and had no cash flow impact for the year. Excluding the accelerated recognition of deferred revenue, DURECT's reported revenues would have been $17.7 million for the year ended December 31, 2012 and reported net loss would have been $19.2 million for the year ended December 31 , 2012.

At December 31, 2013, we had cash and investments of $24.4 million, compared to cash and investments of $28.9 million at December 31, 2012. We have no debt obligations, other than normal liabilities associated with running our business.

"Our team is hard at work preparing to meet with the FDA to gain more clarity on the next steps that would be required to address the issues cited in the recent Complete Response Letter for **POSIDUR**â?¢," stated James E. Brown, D.V.M., President and CEO of DURECT. "Meanwhile, Pfizer has recently posted an additional study for **REMOXY**Â®, indicating that that late-stage program is moving forward. We also are pleased to have started 2014 by establishing a collaboration with Impax whereby **ELADUR**Â® is now back in development for post-herpetic neuralgia (PHN), the indication for which it was originally designed."

In 2014, we look forward to:

- Pfizer conducting the required studies for REMOXY to support an NDA resubmission in mid-2015
- Meeting with the FDA to clarify the next steps that would be required to address the issues raised in the POSIDUR Complete Response Letter
- Supporting Zogenix as they commence a multi-dose clinical study with Relday â?¢ in the second half of 2014
- Supporting Impax as they develop ELADUR for PHN
- Advancing existing feasibility projects and potentially entering into additional feasibility studies and collaborations

Highlights for DURECT in Fiscal Year 2013 and Major Potential Milestones over the Next 12-18 Months:

- **POSIDUR (SABERÂ®-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. 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 are evaluating the issues and recommendations described in the Complete Response Letter and plans to have further discussions with the FDA around them.

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 October 2013, Pfizer stated that, having achieved technical milestones related to manufacturing, they will continue the development program for REMOXY. Following guidance received from the FDA earlier 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$^{Â®}$ 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.

- **Other ORADUR-based Opioids.** We have licensed three other ORADUR-based opioids to Pain Therapeutics, which has recently regained all rights from Pfizer with respect to these drug candidates (hydrocodone, hydromorphone and oxymorphone). Pain Therapeutics is now free to develop and commercialize these product candidates on its own or with a licensee. 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. Pain Therapeutics has stated that they have not yet made a decision to develop or out-license the three product candidates.
- **ELADUR$^{Â®}$ (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 has 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 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.

- **Relday$^{â?¢}$ (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, and Zogenix plans to commence this multi-dose trial in the second half of 2014.

  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 $1.3 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 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 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 have initiated licensing discussions with other companies now that the lead formulation has been selected.

- **Feasibility Projects and Other Activities.** During the fourth quarter of 2013, we continued work on several feasibility projects and signed new 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, ORADUR-ADHD (territories outside certain Asian and South Pacific markets), as well as various other programs which we have not described publicly in detail.

Earnings Conference Call

A live audio webcast of a conference call to discuss fourth quarter 2013 results will be broadcast live over the internet at4:30 p.m. Eastern Time on February 27 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 REMOXYÂ®, POSIDURâ?¢, ELADURÂ®, and TRANSDURÂ®-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: POSIDURâ?¢, SABERÂ®, ORADURÂ®, TRANSDURÂ® and ELADURÂ® are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners. REMOXY, POSIDUR, ELADUR, TRANSDUR-Sufentanil, ORADUR-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 Statement

The statements in this press release regarding the potential regulatory meetings and submissions for REMOXY and POSIDUR, anticipated clinical trials (including timing and results) for Relday, ORADUR-Methylphenidate and our other drug candidates, potential milestone payments from Impax, 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 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 and risks related to our (and our third party collaborators where applicable) 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 on November 5, 2013 under the heading "Risk Factors."

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

	December 31,		December 31,	
	2013	2012	2013	2012[1]
Collaborative research and development and other revenue	$ 1,414	$ 813	$ 3,590	$42,494
Product revenue, net	2,875	2,449	11,736	10,576
Total revenues	4,289	3,262	15,326	53,070
Operating expenses:				
Cost of product revenues	1,033	1,038	4,837	4,654
Research and development	4,850	4,904	18,945	20,265
Selling, general and administrative	3,498	2,911	12,706	12,095
Total operating expenses	9,381	8,853	36,488	37,014
Income (loss) from operations	(5,092)	(5,591)	(21,162)	16,056
Other income (expense):				
Interest and other income (expenses)	(7)	95	(284)	151
Interest expense	(1)	(2)	(6)	(7)
Net other income (expense)	(8)	93	(290)	144
Net Income (loss)	$ (5,100)	$(5,498)	$(21,452)	$16,200
Net income (loss) per share				
Basic	$ (0.05)	$ (0.06)	$ (0.21)	$ 0.18
Diluted	$ (0.05)	$ (0.06)	$ (0.21)	$ 0.18
Weighted-average shares used in computing net income (loss) per share				
Basic	106,416	90,881	103,078	88,433
Diluted	106,416	90,881	103,078	88,589
Total comprehensive income (loss)	$ (5,101)	$(5,498)	$(21,457)	$16,201

(1) Derived from audited financial statements.

DURECT CORPORATION
CONDENSED BALANCE SHEETS
(in thousands)

	As of December 31, 2013 (unaudited)	As of December 31, 2012[1]
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,836	$ 11,195
Short-term investments	12,753	17,337
Accounts receivable	2,349	2,166
Inventories	3,502	3,399
Prepaid expenses and other current assets	1,888	2,258
Total current assets	28,328	36,355
Property and equipment, net	1,985	2,457
Goodwill	6,399	6,399
Intangible assets, net	18	36
Long-term investments	3,352	–
Long-term restricted Investments	450	400
Other long-term assets	288	288
Total assets	$ 40,820	$ 45,935
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 736	$ 1,785
Accrued liabilities	5,865	3,997
Contract research liability	329	483
Deferred revenue, current portion	255	662
Total current liabilities	7,185	6,927
Deferred revenue, noncurrent portion	1,296	1,480

Other long-term liabilities		1,618		1,197
Stockholders' equity		30,721		36,331
Total liabilities and stockholders' equity		$ 40,820		$ 45,935

(1) Derived from audited financial statements.

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SOURCE DURECT Corporation

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