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

CUPERTINO, Calif., March 2, 2015 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months ended December 31, 2014. Total revenues were $4.3 million for the three months ended December 31, 2014 and for the three months ended December 31, 2013. Net loss was $5.9 million for the three months ended December 31, 2014 as compared to a net loss of $5.1 million for the same period in 2013.

Total revenues were $19.4 million and net loss was $22.1 million for the year ended December 31, 2014, compared to total revenues of $15.3 million and net loss of $21.5 million for the year ended December 31, 2013.

At December 31, 2014, we had cash and investments of $34.9 million, compared to cash and investments of $24.4 million at December 31, 2013. At December 31, 2014, we had $19.8 million in long term debt.

“We are excited to announce today that the lead product candidate from our Epigenomic Regulator Program, the endogenous small molecule DUR-928, has achieved positive results in multiple animal models and completed a successful Phase 1 human safety study,” stated James E. Brown, D.V.M., President and CEO of DURECT. “With respect to POSIDUR™, we have submitted to the FDA a protocol synopsis for a soft tissue clinical trial designed to generate the data required to address the Complete Response Letter. Regarding REMOXY®, we are supporting Pain Therapeutics as they focus on an orderly transfer of the program back from Pfizer and finalizing a strategy around the prospect of resubmitting the NDA. Finally, our injectable programs continue to make progress as exemplified by our ophthalmic feasibility study with Santen maturing into a development agreement.”

In 2015, we look forward to:

- Supporting Pain Therapeutics as they transition the program back from Pfizer and prepare for a potential resubmission of the NDA
- Initiating a Phase 3 clinical trial for POSIDUR to address the Complete Response Letter once we have determined the study design parameters with the FDA
- Conducting additional Phase 1 studies with DUR-928 such that we can commence one or more Phase 2 studies in 2016
- Supporting Zogenix as they conduct a multi-dose clinical study with Relday™ and position the program to be Phase 3 ready in 2016
- Supporting Santen in our new ophthalmic development program
- Advancing existing feasibility projects and potentially entering into additional feasibility studies and collaborations

Highlights for DURECT in Fiscal Year 2014 and Major Potential Milestones over the Next 12-18 Months:

- **POSIDUR (SABER®-Bupivacaine) Post-Operative Pain Relief Depot**. In February 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 indicated that additional clinical safety studies would need to be conducted. We had a face-to-face meeting with the FDA in September 2014 to discuss what needs to be done to address the issues cited in the Complete Response Letter. As a result of this meeting and based on subsequent communications with the FDA, we have submitted to the FDA a protocol synopsis for a soft tissue Phase 3 clinical trial designed to generate the data required for product approval, including efficacy and safety data for POSIDUR. We are awaiting FDA feedback to that protocol synopsis.

  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 ourselves in the U.S. in the event that we

determine that is the preferred route of commercialization.

- **REMOXY (oxycodone) Extended-Release Capsules CII.** Following guidance received from the FDA in 2013 and having achieved technical milestones related to manufacturing, Pfizer announced in October 2013 that they would proceed with the additional clinical studies and other actions required to address the Complete Response Letter received in June 2011. Pfizer stated that these new clinical studies would 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. According to information posted to ClinicalTrials.gov, we understand these studies have been completed, although we have not been provided any results. Pfizer notified Pain Therapeutics in late October 2014 that Pfizer had decided to discontinue development of REMOXY. Pfizer has stated that they will return all rights, including responsibility for regulatory activities, to Pain Therapeutics. Additionally, Pfizer has stated that they will continue ongoing activities under the agreement with Pain Therapeutics until the scheduled termination date in April 2015. Pain Therapeutics has stated that it is focused on an orderly transfer of the program back from Pfizer, finalizing a strategy around the prospect of resubmitting the NDA, and seeking a new commercialization partner.

  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.

- **Epigenomic Regulator Program.** We announced today our Epigenomic Regulator Program and the successful completion of a Phase 1 clinical trial with the program's lead product candidate, DUR-928. DUR-928 is an endogenous, small molecule, new chemical entity (NCE), which may have broad applicability in several metabolic diseases such as nonalcoholic fatty liver disease (NAFLD) and nonalcoholic steatohepatitis (NASH), and in acute organ injuries such as acute kidney injury. This program is more fully described in a separate press release dated March 2, 2015.
- **ELADUR® (TRANSDUR-bupivacaine).** On January 7, 2014 we announced that we had entered into an agreement granting Impax Laboratories, Inc. (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, these positive results 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 first quarter of 2015.

  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.

- **Santen Ophthalmic Program.** In December 2014, we entered into an agreement with Santen Pharmaceutical Co., Ltd. (Santen) whereby we granted Santen an exclusive worldwide license to our proprietary SABER formulation platform and other intellectual property to develop and commercialize a sustained release product to deliver an ophthalmology drug utilizing our SABER technology. Santen controls and funds the development and commercialization program. In connection with the license agreement, Santen paid us an upfront fee of $2.0 million in cash and agreed to make contingent cash payments to the Company of up to $76.0 million upon the achievement of certain development and commercialization-based milestones. Santen will also pay for certain Company costs incurred in the development of the licensed product. If the product is commercialized, the Company would also receive a tiered royalty on annual net product sales ranging from single-digit to the low double digits, determined on a country-by-country basis.

- **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 1 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 2014, we conducted research and development activities on these programs under approved workplans with Pain Therapeutics. In 2015, Pain Therapeutics informed us that they intend to return to us all of Pain Therapeutics' rights and obligations under our license agreement to develop and commercialize ORADUR-based formulations of oxymorphone and hydrocodone but without impacting the rights and obligations of the two parties with respect to REMOXY and hydromorphone.
- **Feasibility Projects and Other Activities.** During 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 and the Santen program, described above, are two such projects which have matured into development and license agreements.
- **Business Development Activities.** We have multiple programs that may potentially be licensed over the next 12-18 months. These include POSIDUR, DUR-928, 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 2014 results will be broadcast live over the internet at 4:30 p.m. Eastern Time on March 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 pharmaceuticals company with expertise in drug discovery, drug delivery and drug development, applying those skills primarily to therapeutics in the fields of pain management, acute organ injury and metabolic diseases. DURECT's proprietary oral, transdermal and injectable depot delivery technologies enable new indications and superior clinical/commercial attributes such as improved abuse deterrence, convenience, adherence, efficacy and safety for small molecule and biologic drugs. Late stage development programs of this nature include REMOXY® and POSIDUR™. DURECT's Epigenomic Regulator Program includes the lead molecule DUR-928 in Phase 1. DUR-928 is an endogenous small molecule that is an epigenomic modulator of cellular activities involved in lipid homeostasis, metabolic disease, inflammation and cell survival. 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, POSIDUR, ELADUR, ORADUR-Methylphenidate, Relday and DUR-928 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 DUR-928, Relday, ORADUR-Methylphenidate and our other drug candidates, potential royalties or milestone payments from Impax and Santen, the potential benefits and uses of our drug candidates, including and commencing new feasibility projects, collaborations with third parties, including the transition of REMOXY from Pfizer to Pain Therapeutics and the ophthalmic development program with Santen, future commercialization activities for POSIDUR and other products 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 Pain Therapeutics 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 4, 2014 under the heading "Risk Factors."

DURECT CORPORATION

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

	Three months ended December 31		Twelve months ended December 31	
	2014	2013	2014	2013
Collaborative research and development and other revenue	$ 1,257	$ 1,414	$ 8,256	$ 3,590
Product revenue, net	3,012	2,875	11,145	11,736
Total revenues	4,269	4,289	19,401	15,326
Operating expenses:				
Cost of product revenues	1,195	1,033	5,686	4,837
Research and development	5,409	4,850	22,429	18,945
Selling, general and administrative	3,020	3,498	12,284	12,706
Total operating expenses	9,624	9,381	40,399	36,488
Income (loss) from operations	(5,355)	(5,092)	(20,998)	(21,162)
Other income (expense):				
Interest and other income (expenses)	(27)	(6)	39	(284)
Interest expense	(558)	(2)	(1,151)	(6)
Net other income (expense)	(585)	(8)	(1,112)	(290)
Net loss	$ (5,940)	$ (5,100)	$(22,110)	$(21,452)
Net loss per share				
Basic	$ (0.05)	$ (0.05)	$ (0.20)	$ (0.21)
Diluted	$ (0.05)	$ (0.05)	$ (0.20)	$ (0.21)
Weighted-average shares used in computing net loss per share				
Basic	113,656	106,416	111,666	103,078
Diluted	113,656	106,416	111,666	103,078
Total comprehensive loss	$ (5,935)	$ (5,101)	$(22,024)	$(21,457)

DURECT CORPORATION
CONDENSED BALANCE SHEETS
(in thousands)

	As of December 31, 2014 (unaudited)	As of December 31, 2013[1]
ASSETS		
Current assets:		
Cash and cash equivalents	$ 2,680	$ 7,836
Short-term investments	30,016	12,753
Accounts receivable	2,122	2,349
Inventories	3,642	3,502
Prepaid expenses and other current assets	1,034	1,888
Total current assets	39,494	28,328
Property and equipment, net	1,749	1,985
Goodwill	6,399	6,399
Intangible assets, net	–	18
Long-term investments	1,804	3,352
Long-term restricted Investments	350	450
Other long-term assets	288	288

Total assets	$	50,084	$	40,820
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	$	1,021	$	736
Accrued liabilities		5,051		5,865
Contract research liability		358		329
Deferred revenue, current portion		538		255
Total current liabilities		6,968		7,185
Deferred revenue, noncurrent portion		2,742		1,296
Long-term debt, net		19,824		–
Other long-term liabilities		2,035		1,618
Stockholders' equity		18,515		30,721
Total liabilities and stockholders' equity	$	50,084	$	40,820

(1) Derived from audited financial statements.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/durect-corporation-announces-fourth-quarter-2014-financial-results-and-update-of-programs-300043748.html

SOURCE DURECT Corporation

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