DURECT Corporation Announces Third Quarter 2015 Financial Results and Update of Programs

CUPERTINO, Calif., Nov. 2, 2015 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the third quarter of 2015. Total revenues were $4.7 million and net loss was $6.5 million for the three months ended September 30, 2015 as compared to total revenues of $4.3 million and net loss of $7.1 million for the three months ended September 30, 2014.

At September 30, 2015, we had cash and investments of $32.4 million, compared to cash and investments of $34.9 million at December 31, 2014. At September 30, 2015, we had $19.7 million in long term debt.

“We continued to make solid progress on multiple fronts since last quarter,” stated James E. Brown, D.V.M., President and CEO of DURECT. “We recently began recruiting patients in our POSIMIR™ pivotal Phase 3 clinical trial which is intended to provide the data necessary for a robust NDA resubmission. For DUR-928, the single-ascending-dose Phase 1 trial with our injectable formulation reported no treatment related adverse events such that we are moving on to the multiple-dose Phase 1 trial, and today we are reporting positive data from a leptin deficient rat model, which is the 8th preclinical model to demonstrate a positive effect when administering DUR-928. Regarding Relday, Zogenix reported positive results from their Phase 1b multi-dose clinical trial such that they are initiating efforts to secure a partner for Relday which is now positioned for Phase 3.”

Update of Selected Programs:

- **POSIMIR (SABER®-Bupivacaine, also previously known as POSIDUR™) Post-Operative Pain Relief Depot** We recently began recruiting patients for PERSIST, the POSIMIR pivotal Phase 3 clinical trial. PERSIST is planned to involve slightly over 300 patients undergoing laparoscopic cholecystectomy (gallbladder removal) surgery. These patients will be randomized on a one-to-one basis to receive either POSIMIR or placebo as a one-time intra-incisional instillation at the time of surgery. In a previous clinical trial of 50 patients undergoing laparascopic cholecystectomy, POSIMIR was compared with the active control bupivacaine hydrochloride, against which POSIMIR demonstrated an approximately 25% reduction in pain intensity on movement for the first 3 days after surgery (p=0.024), using the same statistical methodology specified for the current trial. We believe that PERSIST represents the first pivotal efficacy trial in this category in a laparoscopic procedure. We expect that it will take approximately one year to complete patient enrollment in PERSIST. This clinical trial is based on multiple interactions with the FDA and is designed to generate data necessary to support an NDA resubmission.

  POSIMIR is our investigational post-operative pain relief depot that utilizes our patented SABER technology and is intended to deliver bupivacaine to provide 3 days of pain relief after surgery. We are in discussions with potential partners regarding licensing development and commercialization rights to POSIMIR, for which we hold worldwide rights. We are also continuing to evaluate the requirements for commercializing POSIMIR on our own in the U.S., in the event that we determine that to be the preferred route of commercialization.

- **Epigenomic Regulator Program.** DUR-928, our Epigenomic Regulator Program’s lead product candidate, 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.

  Previously we communicated that the biological activity of DUR-928 has been demonstrated in 7 different animal disease models involving three animal species. Four of these models represent acute organ injury (endotoxin shock, kidney, liver and brain) and three represent chronic disorders of hepatic lipid accumulation and dysfunction (e.g., NAFLD and NASH). Today we are reporting that DUR-928 reduced lipid accumulation in the liver in a leptin deficient Zucker rat model. In this study, 3 weeks of daily treatment by oral administration of DUR-928 significantly reduced hepatic triglyceride, total cholesterol as well as free fatty acids levels. Liver morphology and lipidosis were also noticeably improved, consistent with biochemical changes. The data from this model provides further support to our other animal models and is suggestive of DUR-928’s potential use in chronic metabolic disorders.

In addition, in August 2015 we commenced a Phase 1 single-site, randomized, double-blinded, placebo-controlled, single-ascending-dose study that evaluated the safety, tolerability and pharmacokinetics of DUR-928 when administered by injection. The 18-subject study evaluated DUR-928 in three cohorts of healthy volunteers receiving DUR-928 at escalating doses that resulted in peak plasma concentrations at least 100-fold higher than endogenous levels. DUR-928 was well-tolerated at all dose levels, with no treatment-related adverse events reported. DURECT is now moving on to a multiple-dose Phase 1 trial with the injectable formulation. Assuming no adverse safety results from this trial, DURECT would then be positioned to commence patient trials in 2016 with an injectable formulation as well as with an oral formulation.

- **REMOXY (oxycodone) Extended-Release Capsules CII.** Based on our ORADUR® technology, REMOXY is a unique long-acting formulation of oxycodone designed to discourage common methods of tampering associated with opioid misuse and abuse. In May 2015, Pain Therapeutics (our licensee) stated that the transition of REMOXY back from Pfizer was substantially complete, and in July 2015 they stated that they expect to resubmit the NDA in the first quarter of 2016. The extended release oxycodone market is ~$2.4 billion in the U.S. alone, and we are eligible for a potential royalty on REMOXY between 6.0% to 11.5% of net sales depending on sales volumes.

- **Relday (Risperidone Program).** Relday is a proprietary, long-acting, once-monthly subcutaneous injectable formulation of risperidone for the treatment of schizophrenia. To provide context, an existing long-acting injectable risperidone product that achieved $1.2 billion in global net sales in 2014 requires drug reconstitution prior to use and twice-monthly, intramuscular injections. Zogenix (our licensee) has previously announced positive results from a single-dose Phase 1 clinical trial of Relday at the full dose range anticipated to be used in clinical practice. In September 2015, Zogenix announced positive top-line results from a Phase 1b multi-dose parallel group clinical trial that enrolled 60 subjects. According to Zogenix, the trial results for Relday demonstrated that risperidone plasma concentrations in the therapeutic range were achieved on the first day of dosing, reached steady state levels following the second dose and consistently maintained therapeutic levels throughout the four-month period. Also according to Zogenix, Relday was generally safe and well-tolerated, with results consistent with the profile of risperidone and the previous Phase 1 single-dose clinical trial. Zogenix further stated that it has now initiated efforts to secure a development and commercialization partner for Relday, and that Relday is well-positioned to begin a Phase 3 program once a partner is secured.

- **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. Orient Pharma, our licensee in defined Asian and South Pacific countries, has initiated a Phase 3 study in Taiwan and anticipates completing it in 2016. 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.

- **Feasibility Projects and Other Activities.** During the third quarter of 2015, 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 ophthalmic program 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 POSIMIR, 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 third quarter 2015 results will be broadcast live over the internet at 4:30 p.m. Eastern Time on November 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 biopharmaceutical company focused on two areas of active drug development: new therapeutics based on its proprietary drug delivery platforms and new chemical entities derived from its Epigenomic Regulator Program. Its drug development expertise is being applied primarily to the fields of pain management, CNS disorders, acute organ injury and metabolic diseases such as NAFLD/NASH. 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 POSIMIR (SABER-Bupivacaine) and REMOXY (ORADUR-oxycodone). DURECT's Epigenomic Regulator Program includes the lead molecule DUR-928 in Phase 1 development. DUR-928 is an endogenous small molecule that modulates lipid homeostasis, inflammation and cell survival. For more information, please visit www.www.durect.com.

NOTE: POSIMIR™, SABER®, ORADUR®, and TRANSDUR® are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners. POSIMIR, REMOXY, ELADUR, ORADUR-Methylphenidate, Relday and DUR-928 are investigational drugs under development and have not been approved for sale by the U.S. Food and Drug Administration or other health authorities.

DURECT Forward-Looking Statement

The statements in this press release regarding regulatory matters, including anticipated meetings and submissions for POSIMIR, REMOXY and Relday and potential FDA approval of our product candidates, anticipated clinical trials (including timing and results) for POSIMIR, DUR-928, Relday, ORADUR-Methylphenidate and our other drug candidates, potential royalties from Pain Therapeutics, the potential benefits and uses of our drug candidates, potential markets for our product candidates, the potential license of POSIMIR, DUR-928, ORADUR-ADHD and other products and other 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 the clinical trial of POSIMIR will take longer to conduct than anticipated or result in data that will not support a successful resubmission, the risk that Pain Therapeutics will discontinue development of REMOXY or be delayed in development or regulatory submissions, the risk of adverse decisions by regulatory agencies, including requests for additional information or product non-approval or non-acceptance of our POSIMIR, REMOXY or other NDA submissions, delays and additional costs due to requirements imposed by regulatory agencies, additional time and resources that may be required for development, testing and regulatory approval of our Epigenomic Regulatory Program, potential adverse effects arising from the testing or use of our drug candidates, the risk that prior clinical trials will not be confirmed in subsequent trials, 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 for the quarter ending June 30, 2015 filed with the Securities and Exchange Commission on August 3, 2015, under the heading "Risk Factors."

DURECT CORPORATION

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

	Three months ended September 30		Nine months ended September 30	
	2015	2014	2015	2014
Collaborative research and development and other revenue	$ 2,052	$ 1,752	$ 5,568	$ 6,999
Product revenue, net	2,691	2,506	8,389	8,133
Total revenues	4,743	4,258	13,957	15,132
Operating expenses:				
Cost of product revenues	884	2,337	2,912	4,491
Research and development	6,654	5,463	17,659	17,020
Selling, general and administrative	3,177	3,051	8,721	9,264
Total operating expenses	10,715	10,851	29,292	30,775

Income (loss) from operations	(5,972)	(6,593)	(15,335)	(15,643)
Other income (expense):				
Interest and other income (expenses)	43	60	194	66
Interest expense	(558)	(559)	(1,677)	(593)
Net other income (expense)	(515)	(499)	(1,483)	(527)
Net loss	$ (6,487)	$ (7,092)	$(16,818)	$(16,170)
Net loss per share				
Basic	$ (0.05)	$ (0.06)	$ (0.14)	$ (0.15)
Diluted	$ (0.05)	$ (0.06)	$ (0.14)	$ (0.15)
Weighted-average shares used in computing net loss per share				
Basic	120,483	111,882	117,718	110,978
Diluted	120,483	111,882	117,718	110,978
Total comprehensive loss	$ (6,481)	$ (7,013)	$(16,901)	$(16,089)

DURECT CORPORATION

CONDENSED BALANCE SHEETS
(in thousands)

	As of September 30, 2015 (unaudited)	As of December 31, 2014(1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,389	$ 2,680
Short-term investments	26,805	30,016
Accounts receivable	2,269	2,122
Inventories	3,972	3,642
Prepaid expenses and other current assets	1,391	1,034
Total current assets	39,826	39,494
Property and equipment, net	1,602	1,749
Goodwill	6,399	6,399
Long-term investments	–	1,804
Long-term restricted Investments	250	350
Other long-term assets	236	288
Total assets	$ 48,313	$ 50,084
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 798	$ 1,021
Accrued liabilities	4,690	5,051
Contract research liability	630	358
Deferred revenue, current portion	616	538
Total current liabilities	6,734	6,968
Deferred revenue, noncurrent portion	2,338	2,742
Long-term debt, net	19,650	19,824
Other long-term liabilities	2,378	2,035
Stockholders' equity	17,213	18,515
Total liabilities and stockholders' equity	$ 48,313	$ 50,084

(1) Derived from audited financial statements.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/durect-corporation-announces-third-quarter-2015-financial-results-and-update-of-programs-300170479.html

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