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

CUPERTINO, Calif., Feb. 29, 2016 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the three months ended December 31, 2015. Total revenues were $5.2 million for the three months ended December 31, 2015 and $4.3 million for the three months ended December 31, 2014. Net loss was $5.8 million for the three months ended December 31, 2015, compared to a net loss of $5.9 million for the same period in 2014.

Total revenues were $19.1 million and net loss was $22.7 million for the year ended December 31, 2015, compared to total revenues of $19.4 million and net loss of $22.1 million for the year ended December 31, 2014.

At December 31, 2015, we had cash and investments of $29.3 million, compared to cash and investments of $34.9 million at December 31, 2014. At December 31, 2015, we had $19.7 million in long term debt.

“2015 was a transformative year for DURECT as our most mature programs advanced in meaningful ways and we announced and made rapid progress with our Epigenomics Regulator Program,” stated James E. Brown, D.V.M., President and CEO of DURECT. “For DUR-928, in 2015 we completed five Phase 1 clinical trials, dosed over 75 healthy volunteers with either our oral or injectable formulations, and saw no serious or treatment-related adverse events, enabling us to start 2016 by initiating our first DUR-928 patient trial. In November 2015, we began recruiting patients in PERSIST, our POSIMIR™ pivotal Phase 3 clinical trial which is designed to generate the data required for a resubmission of the NDA. In addition, we understand that Pain Therapeutics is in the later stages of completing the resubmission of the REMOXY® NDA, which should lead to a 6 month review by the FDA.”

In 2016, we look forward to:

- Completing a Phase 1b patient study with DUR-928 for patients with nonalcoholic steatohepatitis (NASH) with our oral formulation, enabling and informing subsequent patient studies
- Initiating a multi-dose study with our oral formulation of DUR-928 in patients with NASH or other liver function impairment
- Completing a Phase 1b patient study with DUR-928 for patients with renal impaired kidney function with our injectable formulation, enabling and informing subsequent patient studies
- Initiating at least one study designed to evaluate an initial indication of potential efficacy in one or more medical conditions
- Completing enrollment in the Phase 3 POSIMIR clinical trial in patients undergoing laparoscopic gall bladder removal
- Potential FDA approval for REMOXY
- Completion of the Phase 3 trial with ORADUR®-Methylphenidate in Taiwan by our partner Orient Pharma
- Supporting Zogenix as they seek a development and commercialization partner for Relday™
- Advancing existing feasibility projects and potentially entering into additional feasibility studies and collaborations

Highlights for DURECT in Fiscal Year 2015 and Major Potential Milestones over the Next 12-18 Months:

- **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 NASH, and in acute organ injuries such as acute kidney injury.

  During 2015 more than 75 healthy volunteers in our five Phase 1 studies received DUR-928 given either orally or through injection at varying doses substantially in excess of endogenous levels, with no serious treatment-related adverse events reported.

  Building on our learnings from 8 animal models that were previously reported and multiple Phase 1 trials, in January 2016 we began our first patient trial utilizing DUR-928. This study is a single-ascending-dose safety and pharmacokinetic Phase 1b trial of DUR-928 in NASH patients and matched control subjects. This study will be conducted in three successive cohorts

evaluating three single-dose levels of oral DUR-928. After a PK/safety review at each dose, the study can proceed to the next higher dose. Assuming all three cohorts are dosed, the study will comprise approximately 48 subjects, of which approximately 30 will have received DUR-928. The study is being conducted in Australia, and we anticipate that we will obtain results from this trial in the first half of 2016. This study is designed to enable and inform a subsequent multi-dose study in NASH or other chronic metabolic disease.

We are planning to shortly commence a second study in patients with DUR-928, also to be conducted in Australia. This Phase 1b trial of DUR-928 will be a single-ascending-dose safety and pharmacokinetic study of DUR-928 in patients with impaired kidney function and matched control subjects. This study will be conducted in three successive cohorts evaluating three single-dose levels of DUR-928 administered by injection. After a PK/safety review at each dose, the study can proceed to the next higher dose. Assuming all three cohorts are dosed, the study will comprise approximately 45 subjects, of which approximately 30 will have received DUR-928. We anticipate that this study will be completed in 2016, and that this study will enable and inform subsequent trials for patients with either acute kidney injury or other kidney function impairment.

- **POSIMIR (SABER®-Bupivacaine) Post-Operative Pain Relief Depot.** In November 2015, we began enrolling 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 laparoscopic 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 designed to generate additional 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.

- **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 July 2015, Pain Therapeutics (our licensee) has 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. 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 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 fourth 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 fourth quarter 2015 results will be broadcast live over the internet at4:30 p.m. Eastern Time on February 29 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 actively developing new therapeutics based on its Epigenomic Regulator Program and proprietary drug delivery platforms. DUR?928, a new chemical entity in Phase 1 development, is the lead candidate inDURECT's Epigenomic Regulator Program. An endogenous, orally bioavailable small molecule, DUR-928 plays an important regulatory role in lipid homeostasis, inflammation, and cell survival, and may have applications related to acute organ injury and chronic metabolic disease, notably nonalcoholic fatty liver disease (NAFLD) and nonalcoholic steatohepatitis (NASH). DURECT's advanced oral, injectable, and transdermal delivery technologies enable new indications and enhanced attributes, such as abuse deterrence, extended dosing intervals, and superior safety and efficacy, for small-molecule and biologic drugs. Late-stage development programs in this category include POSIMIR™ and REMOXY®, addressing key unmet needs in pain management. 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. REMOXY, POSIMIR, ELADUR, ORADUR-Methylphenidate, Relday and DUR-928 are drug candidates under development and have not been approved for commercialization by theU.S. Food and Drug Administration or other health authorities.

DURECT Forward-Looking Statement

The statements in this press release regarding regulatory matters, including the anticipated NDA resubmission REMOXY and potential FDA approval of REMOXY and our other product candidates, anticipated clinical trials (including timing and results) for POSIMIR, DUR-928, ORADUR-Methylphenidate and our other drug candidates, potential royalties fromPain 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, advancing and commencing new feasibility projects, collaborations with third parties, including Pain Therapeutics' plans for REMOXY and Zogenix's plans for Relday, 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 or Zogenix will discontinue development of REMOXY or Relday, respectively, 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 DUR-928, 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 on November 3, 2015 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	
	2015	2014	2015	2014
Collaborative research and development and other revenue	$ 2,264	$ 1,257	$ 7,832	$ 8,256
Product revenue, net	2,903	3,012	11,292	11,145
Total revenues	5,167	4,269	19,124	19,401
Operating expenses:				
Cost of product revenues	993	1,195	3,905	5,686
Research and development	6,658	5,409	24,317	22,429
Selling, general and administrative	2,845	3,020	11,566	12,284
Total operating expenses	10,496	9,624	39,788	40,399
Loss from operations	(5,329)	(5,355)	(20,664)	(20,998)
Other income (expense):				
Interest and other income (expenses)	43	(27)	237	39
Interest expense	(559)	(558)	(2,236)	(1,151)
Net other income (expense)	(516)	(585)	(1,999)	(1,112)
Net loss	$ (5,845)	$ (5,940)	$ (22,663)	$ (22,110)
Net loss per share				
Basic	$ (0.05)	$ (0.05)	$ (0.19)	$ (0.20)
Diluted	$ (0.05)	$ (0.05)	$ (0.19)	$ (0.20)
Weighted-average shares used in computing net loss per share				
Basic	120,483	111,882	118,523	111,666
Diluted	120,483	111,882	118,523	111,666
Total comprehensive loss	$ (5,925)	$ (5,935)	$ (22,764)	$ (22,024)

DURECT CORPORATION
CONDENSED BALANCE SHEETS
(in thousands)

	As of December 31, 2015 (unaudited)	As of December 31, 2014[1]
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,583	$ 2,680
Short-term investments	25,457	30,016
Accounts receivable	2,222	2,122
Inventories	3,917	3,642
Prepaid expenses and other current assets	3,142	1,034
Total current assets	38,321	39,494
Property and equipment, net	1,566	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	$ 46,772	$ 50,084
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,286	$ 1,021
Accrued liabilities	4,970	5,051
Contract research liability	575	358
Deferred revenue, current portion	616	538
Total current liabilities	7,447	6,968
Deferred revenue, noncurrent portion	2,269	2,742
Long-term debt, net	19,684	19,824
Other long-term liabilities	2,489	2,035
Stockholders' equity	14,883	18,515

Total liabilities and stockholders' equity	$ 46,772	$ 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-fourth-quarter-2015-financial-results-and-update-of-programs-300227848.html

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