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

CUPERTINO, Calif., April 30, 2015 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the first quarter of 2015. Total revenues were $4.8 million and net loss was $4.9 million for the three months ended March 31, 2015 as compared to total revenues of $6.3 million and net loss of $3.6 million for the three months ended March 31, 2014.

At March 31, 2015, we had cash and investments of $29.8 million, compared to cash and investments of $34.9 million at December 31, 2014. Subsequent to quarter-end, we raised net proceeds of $10.1 million from the sale of 5.4 million shares in the open market at an average price of $1.94 per share through use of our ATM facility. At March 31, 2015, we had $19.8 million in long term debt.

"We initiated our multiple-ascending-dose, oral administration Phase 1 study with DUR-928 in March and expect to have results in the second quarter of 2015," stated James E. Brown, D.V.M., President and CEO of DURECT. "With respect to POSIDUR™, we expect to hear back shortly from the FDA regarding our protocol synopsis for a soft tissue Phase 3 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. Last month our licensee Zogenix announced the initiation of a multi-dose Phase 1 trial of Relday™ and that they expect to have top-line results from that study in the third quarter of 2015. In addition, we understand that Orient Pharma expects to initiate an ORADUR-ADHD Phase 3 study in mid-2015 in Taiwan."

Update of Selected Programs:

- **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 efficacy and safety data required by the FDA for product approval. We anticipate receiving FDA feedback to that protocol synopsis in the near term.

  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. Simultaneous with these activities, 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.** Based on DURECT's ORADUR® technology, REMOXY is a unique long-acting formulation of oxycodone designed to discourage common methods of tampering associated with opioid misuse and abuse. Development and commercialization rights had been held by Pfizer until October of 2014, when Pfizer notified our licensee, Pain Therapeutics, that it was returning those rights. We understand that the studies required to resubmit the NDA were completed in 2014, although we have not seen the results. Pain Therapeutics has stated that it is focused on an orderly transition of the program back from Pfizer, which they expect to be substantially complete in the second quarter of 2015, finalizing a strategy around the prospect of resubmitting the NDA, and seeking a new commercial partner. The extended release oxycodone market is ~$2.5 billion in the U.S. alone, and we are eligible for a potential royalty on REMOXY of between 6.0% to 11.5% of net sales depending on sales volumes.

- **Epigenomic Regulator Program.** On March 2, 2015 we announced our Epigenomic Regulator Program and the successful completion of a single dose, oral administration 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. On March 30, 2015 we announced the initiation of a multiple-ascending-dose, oral administration Phase 1 clinical trial with DUR-928. We expect to have results from this study in the second quarter of 2015.

- **Relday (Risperidone Program).** Relday is a proprietary, long-acting, once-monthly subcutaneous injectable formulation of risperidone. 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. Zogenix commenced a multi-dose trial in the first quarter of 2015 and expects to have top-line data in the third quarter of 2015. Zogenix has also stated that it is targeting an end-of-Phase 2 meeting with the FDA by early 2016.

- **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. We understand that Orient Pharma, our licensee in defined Asian and South Pacific countries, anticipates initiating a Phase 3 study in Taiwan in mid-2015 and 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 first 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 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 first quarter 2015 results will be broadcast live over the internet at4:30 p.m. Eastern Time on April 30 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, CNS disorders, 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, controlled release, 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.

DURECT Forward-Looking Statement

The statements in this press release regarding regulatory matters, including meetings, discussions and submissions for POSIDUR, REMOXY and Relday and potential FDA approval of our product candidates, anticipated clinical trials (including timing and results) for DUR-928, Relday, ORADUR-Methylphenidate and our other drug candidates, potential royalties from Pain Therapeutics, 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, future commercialization activities for POSIDUR and other products, the potential license of POSIDUR, 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 development of REMOXY may be significantly delayed and adversely affected by Pfizer's discontinuation of its development, 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 trials of POSIDUR, requests for additional information or product non-approval or non-acceptance of our POSIDUR, 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 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-K for the fiscal year ending December 31, 2014 filed with the Securities and Exchange Commission on March 3, 2015, under the heading "Risk Factors."

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

	Three months ended March 31	
	2015	2014
Collaborative research and development and other revenue	$ 1,738	$ 3,512
Product revenue, net	3,035	2,781
Total revenues	4,773	6,293
Operating expenses:		
Cost of product revenues	1,006	1,063
Research and development	5,367	5,469
Selling, general and administrative	2,820	3,363
Total operating expenses	9,193	9,895
Income (loss) from operations	(4,420)	(3,602)
Other income (expense):		
Interest and other income (expenses)	128	3
Interest expense	(561)	(1)
Net other income (expense)	(433)	2
Net loss	$ (4,853)	$ (3,600)
Net loss per share		
Basic	$ (0.04)	$ (0.03)
Diluted	$ (0.04)	$ (0.03)
Weighted-average shares used in computing net loss per share		
Basic	113,793	110,468
Diluted	113,793	110,468
Total comprehensive loss	$ (4,938)	$ (3,596)

DURECT CORPORATION CONDENSED BALANCE SHEETS (in thousands)		
	As of March 31, 2015 (unaudited)	As of December 31, 2014[1]
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,989	$ 2,680
Short-term investments	27,026	30,016
Accounts receivable	2,243	2,122
Inventories	3,806	3,642
Prepaid expenses and other current assets	1,402	1,034
Total current assets	36,466	39,494
Property and equipment, net	1,615	1,749
Goodwill	6,399	6,399
Long-term investments	500	1,804
Long-term restricted Investments	250	350
Other long-term assets	288	288
Total assets	$ 45,518	$ 50,084
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 890	$ 1,021
Accrued liabilities	3,186	5,051
Contract research liability	307	358
Deferred revenue, current portion	1,048	538
Current portion of long-term debt, net	1,826	–
Total current liabilities	7,257	6,968
Deferred revenue, noncurrent portion	2,608	2,742
Long-term debt, net	18,017	19,824
Other long-term liabilities	2,161	2,035
Stockholders' equity	15,475	18,515
Total liabilities and stockholders' equity	$ 45,518	$ 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-first-quarter-2015-financial-results-and-update-of-programs-300075310.html

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