DURECT Corporation Announces First Quarter 2016 Financial Results and Update of Programs

CUPERTINO, Calif., May 5, 2016 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the first quarter of 2016. Total revenues were $3.6 million and net loss was $7.9 million for the three months ended March 31, 2016 as compared to total revenues of $4.8 million and net loss of $4.9 million for the three months ended March 31, 2015.

At March 31, 2016, we had cash and investments of $24.3 million, compared to cash and investments of $29.3 million at December 31, 2015. Subsequent to the end of the first quarter, we raised net proceeds of approximately $17.0 million from the sale of additional shares of common stock. Including these proceeds, our pro forma cash and investments at March 31, 2016 would have been approximately $41.3 million. At March 31, 2016, we had $19.7 million in short and long term debt.

“The highlight of the quarter was undoubtedly the resubmission of the REMOXY® NDA, followed by its acceptance for review by the FDA and the establishment of a September 25, 2016 PDUFA date,” stated James E. Brown, D.V.M., President and CEO of DURECT. “With respect to DUR-928, we have progressed into our first two patient studies with results anticipated during the course of this year. For POSIMIR®, we continued the PERSIST Phase 3 trial which we are in the process of amending in response to an FDA recommendation.”

Update of Selected Programs:·

- **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.

  During the first quarter, we began our first patient trial utilizing DUR-928. This study is an open-label 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 successive cohorts evaluating single-dose levels of oral DUR-928. After a PK/safety review at each dose, the study can proceed to the next higher dose. The study is being conducted in Australia, and we anticipate that we will start obtaining results from this trial in the second quarter of 2016. This study is designed to enable and inform a subsequent multi-dose study in NASH or other patients with other liver function impairment.

  In addition, our protocol has been approved by the institutional review board for a second study in patients with DUR-928, also being conducted in Australia. This Phase 1b trial of DUR-928 is an open-label single-ascending-dose safety and pharmacokinetic study in patients with impaired kidney function and matched control subjects. This study will be conducted in successive cohorts evaluating 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. 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.

- **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. Pain Therapeutics (our licensee) resubmitted the NDA on schedule in March 2016. In April 2016, Pain Therapeutics announced that the FDA had determined that the NDA was sufficiently complete to permit a substantive review and that September 25, 2016 is the target action date under the Prescription Drug User Fee Act (PDUFA). The extended release oxycodone market is greater than $2 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.
- **POSIMIR (SABER®-Bupivacaine) Post-Operative Pain Relief Depot.** In November 2015, we began enrolling patients for PERSIST, a new POSIMIR Phase 3 clinical trial, consisting of patients undergoing laparoscopic cholecystectomy (gallbladder removal) 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 in a post hoc analysis 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 began recruiting patients for this trial with an intent to compare POSIMIR to placebo. Based on recommendations from the FDA received subsequent to the start of the trial, in April 2016 we decided to amend the PERSIST trial including by incorporating standard bupivacaine HCl as an active control. This change will add to the time and cost to complete the PERSIST trial, but we believe that a positive outcome from this trial design would result in a stronger NDA filing and potentially commercial advantages. This clinical trial 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.

- **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 (our licensee) announced that they had completed a multi-dose Phase 1b trial with results consistent with the profile of risperidone and a previous Phase 1 single-dose clinical trial. Zogenix has stated that it is seeking 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.
- **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 first quarter 2016 results will be broadcast live over the internet at4:30 p.m. Eastern Time on May 5 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 in DURECT'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.

DURECT Forward-Looking Statement

The statements in this press release regarding regulatory matters, including the PDUFA date for REMOXY and potentialFDA approval of REMOXY and our other product candidates, ongoing clinical trials (including timing and results) for POSIMIR, DUR-928, ORADUR-Methylphenidate and our other drug candidates, potential royalties from Pain Therapeutics, the potential license of POSIMIR, DUR-928, ORADUR-ADHD and other products, the potential benefits and uses of our drug candidates, potential markets for our product candidates, potential plans to commercialize POSIMIR ourselves, 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 FDA will not approve REMOXY or will delay doing so, 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 NDA resubmission or product approval, the risk that prior clinical trials (including prior trials of POSIMIR in laparoscopy patients) will not be confirmed in subsequent trials, the potential failure of clinical trials to meet their intended endpoints, the risk that Pain Therapeutics, Zogenix or Orient Pharma will discontinue development of REMOXY, Relday or ORADUR-Methylphenidate, 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 potential POSIMIR NDA submission, 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, 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 filed on March 1, 2016 under the heading "Risk Factors."

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

	Three months ended March 31	
	2016	2015
Collaborative research and development and other revenue	$ 419	$ 1,738
Product revenue, net	3,189	3,035
Total revenues	3,608	4,773
Operating expenses:		
Cost of product revenues	1,242	1,006
Research and development	6,625	5,367
Selling, general and administrative	3,062	2,820
Total operating expenses	10,929	9,193
Loss from operations	(7,321)	(4,420)
Other income (expense):		
Interest and other income	27	128
Interest expense	(558)	(561)
Net other income (expense)	(531)	(433)
Net loss	$ (7,852)	$ (4,853)
Net loss per share		
Basic	$ (0.06)	$ (0.04)
Diluted	$ (0.06)	$ (0.04)
Weighted-average shares used in computing net loss per share		
Basic	122,149	113,793
Diluted	122,149	113,793
Total comprehensive loss	$ (7,835)	$ (4,938)

DURECT CORPORATION
CONDENSED BALANCE SHEETS
(in thousands)

As of March 31, 2016 (unaudited)	As of December 31, 2015[1]

ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,853	$ 3,583
Short-term investments	20,181	25,457
Short-term restricted Investments	100	–
Accounts receivable	1,722	2,222
Inventories	4,007	3,917
Prepaid expenses and other current assets	3,074	3,142
Total current assets	32,937	38,321
Property and equipment, net	1,477	1,566
Goodwill	6,399	6,399
Long-term restricted Investments	150	250
Other long-term assets	236	236
Total assets	$ 41,199	$ 46,772
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 994	$ 1,286
Accrued liabilities	4,552	4,970
Contract research liability	454	575
Deferred revenue, current portion	464	616
Current portion of Long-term debt, net	1,826	–
Total current liabilities	8,290	7,447
Deferred revenue, noncurrent portion	2,206	2,269
Long-term debt, net	17,892	19,684
Other long-term liabilities	2,585	2,489
Stockholders' equity	10,226	14,883
Total liabilities and stockholders' equity	$ 41,199	$ 46,772

(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-2016-financial-results-and-update-of-programs-300263777.html

SOURCE DURECT Corporation

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