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

CUPERTINO, Calif., Oct. 31, 2016 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the third quarter of 2016. Total revenues were $3.7 million and net loss was $8.8 million for the three months ended September 30, 2016 as compared to total revenues of $4.7 million and net loss of $6.5 million for the three months ended September 30, 2015.

At September 30, 2016, we had cash and investments of $29.0 million, compared to cash and investments of $29.3 million at December 31, 2015. At September 30, 2016, we had $19.8 million in long term debt.

“We are pleased to have provided a separate update today on our DUR-928 program,” stated James E. Brown, D.V.M., President and CEO of DURECT. “Regarding POSIMIR®, we have switched over the majority of our active clinical trial sites in the PERSIST Phase 3 trial from Part 1 to Part 2, in which POSIMIR is compared head-to-head against bupivacaine HCL, and continue to add new sites as enrollment proceeds.”

Update of Selected Programs:

- **Epigenetic Regulator Program.** DUR-928, our Epigenetic 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 steatohepatitis (NASH), and in acute organ injuries such as acute kidney injury.

  As reported in greater detail in a separate press release today, our first Phase 1b clinical trial in patients has progressed to the second cohort with a higher dose. While this study was not designed to assess the efficacy of DUR-928 as a therapy for NASH, we are pleased to be able to report that certain biomarkers for liver function and liver injury were reduced in the first cohort 12 hours after a single dose of DUR-928 as compared to before dosing. Collectively, the reduction of these biomarkers plus results from our animal and cell culture studies suggest potential therapeutic activity of DUR-928 for patients with liver disease. However, additional studies are required to evaluate the safety and efficacy of DUR-928, and there is no assurance that these biomarker effects will be observed in a statistically significant manner, or that DUR-928 will demonstrate safety or efficacy in treating NASH or other liver diseases in larger controlled trials. We have recently requested a pre-IND meeting with the U.S. Food and Drug Administration (FDA) as precursor to submitting an IND, which is required to enable a future liver disease clinical trial in the United States.

  Our second Phase 1b clinical study with DUR-928, in patients with impaired kidney function (stage 3 and 4 chronic kidney disease), is underway in Australia. We recently held a pre-IND meeting with the Cardiovascular and Renal Products Division of the FDA; we anticipate utilizing feedback from that meeting as well as from our clinical advisors to file an IND which is required to enable a future kidney disease clinical trial in the United States.

- **POSIMIR (SABER®-Bupivacaine) Post-Operative Pain Relief Depot** POSIMIR is our investigational post-operative pain relief depot that utilizes our patented SABER technology and is intended to deliver bupivacaine to provide up to 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.

  In November 2015, we began enrolling patients for PERSIST, a POSIMIR Phase 3 clinical trial consisting of patients undergoing laparoscopic cholecystectomy (gallbladder removal) surgery. We began recruiting patients for this trial comparing 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. Starting in August 2016, we began implementing Part 2 of the PERSIST trial to evaluate POSIMIR against standard bupivacaine HCl rather than placebo as we have been doing in Part 1. We expect to enroll approximately 264 patients in Part 2 of PERSIST, and we expect this part of the trial to finish dosing patients

in the third quarter of 2017. We believe that a positive outcome from this new trial design would result in a stronger NDA resubmission and potential commercial advantages. In a previous clinical trial of 50 patients in the same surgical model (laparoscopic cholecystectomy), POSIMIR was compared with the active control bupivacaine HCl, 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) and for the first 2 days after surgery (p=0.0198), using the same statistical methodology specified for the current trial. There can be no assurance that the PERSIST trial will replicate these results.

- **REMOXY® ER (oxycodone) Extended-Release Capsules CII.** Based on our ORADUR® technology, the investigational drug REMOXY ER is a unique long-acting formulation of oxycodone designed to discourage common methods of tampering associated with opioid misuse and abuse.

  In September 2016, Pain Therapeutics (our licensee) received a Complete Response Letter from the FDA for REMOXY ER. Based on its review, the FDA has determined that the NDA cannot be approved in its present form and specifies additional actions and data that are needed for drug approval. Pain Therapeutics has stated that it is evaluating the comments raised by the FDA and is consulting with outside experts.

- **ORADUR-ADHD Program.** ORADUR-Methylphenidate is an investigational drug that has the potential for rapid onset of action, long duration with once-a-day dosing, 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 dosing the trial 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.
- **Debt Refinancing.** In July 2016, we refinanced our existing $20 million term loan with Oxford Finance into a new term loan that results in an extended maturity (to four years) and an extended interest only period (to 18 months).
- **Upcoming investor conference.** DURECT will be presenting at the Stifel Nicolaus Healthcare Conference at 4:30 pm Eastern time on November 15. The conference is being held at the New York Palace Hotel in New York. A live audio webcast of the presentation will be available by accessing http://wsw.com/webcast/stifel5/drrx. A live audio webcast of these presentations will also be 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.

Earnings Conference Call

A live audio webcast of a conference call to discuss third quarter 2016 results will be broadcast live over the internet at 4:30 p.m. Eastern Time on October 31 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 Epigenetic Regulator Program and proprietary drug delivery platforms. DUR?928, a new chemical entity in Phase 1 development, is the lead candidate in DURECT's Epigenetic Regulator Program. An endogenous, orally bioavailable small molecule, DUR-928 has been shown in preclinical studies to play an important regulatory role in lipid homeostasis, inflammation, and cell survival. Human applications may include acute organ injury and chronic metabolic diseases such as nonalcoholic fatty liver disease (NAFLD) and nonalcoholic steatohepatitis (NASH). DURECT's advanced oral, injectable, and transdermal delivery technologies are designed to enable new indications and enhanced attributes for small-molecule and biologic drugs. One late-stage development program in this category is POSIMIR® (SABER®-Bupivacaine), an investigational analgesic product intended to address key unmet needs in postoperative pain management. Another is REMOXY ER (oxycodone), an investigational new drug based on DURECT's ORADUR technology. For more information, please visit www.www.durect.com.

NOTE: POSIMIR®, SABER®, and ORADUR® are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners. REMOXY ER, POSIMIR, DUR-928 and ORADUR-Methylphenidate 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 benefits and uses of our drug candidates, including the potential use of DUR-928 to treat NASH, other liver disease or kidney disease, the potential use of POSIMIR to treat pain, the potential abuse deterrent properties of REMOXY ER and the potential use of ORADUR-ADHD to treat ADHD, clinical trial plans for DUR-928, POSIMIR and our other product candidates (including timing and potential results), potential regulatory approvals of POSIMIR and REMOXY ER, potential markets for our product candidates, potential plans to commercialize POSIMIR ourselves, collaborations with third parties, including Pain Therapeutics' plans for REMOXY ER, 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 risks that future clinical trials of DUR-928 do not demonstrate the safety or efficacy of DUR-928 in a statistically significant manner, that the PERSIST 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, that Pain Therapeutics may not be able to adequately address all of FDA's concerns regarding the REMOXY ER NDA or there could be a delay in addressing such concerns and the potential that FDA may not grant regulatory approval of REMOXY ER, the risks of obtaining marketplace acceptance of REMOXY ER, the risk of delays in the commencement, enrollment or completion of other clinical trials, the risk that prior clinical trials (including prior trials of POSIMIR in laparoscopic cholecystectomy patients) will not be confirmed in subsequent trials, the potential failure of clinical trials to meet their intended endpoints, the risk that Pain Therapeutics or Orient Pharma will discontinue development of REMOXY, or ORADUR-Methylphenidate, respectively, or be delayed in development or regulatory submissions, the risk of adverse decisions by regulatory agencies or 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 ability to obtain capital to fund operations and expenses. Further information regarding these and other risks is included in DURECT's Form 10-Q filed on August 2, 2016 under the heading "Risk Factors."

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

	Three months ended September 30		Nine months ended September 30	
	2016	2015	2016	2015
Collaborative research and development and other revenue	$ 352	$ 2,052	$ 1,142	$ 5,568
Product revenue, net	3,391	2,691	9,366	8,389
Total revenues	3,743	4,743	10,508	13,957
Operating expenses:				
Cost of product revenues	2,180	884	4,335	2,912
Research and development	6,805	6,654	21,282	17,659
Selling, general and administrative	3,043	3,177	8,993	8,721
Total operating expenses	12,028	10,715	34,610	29,292
Loss from operations	(8,285)	(5,972)	(24,102)	(15,335)
Other income (expense):				
Interest and other income	45	43	112	194
Interest and other expense	(592)	(558)	(1,708)	(1,677)
Net other income (expense)	(547)	(515)	(1,596)	(1,483)
Net loss	$ (8,832)	$ (6,487)	$(25,698)	$(16,818)
Net loss per share				
Basic	$ (0.06)	$ (0.05)	$ (0.20)	$ (0.14)
Diluted	$ (0.06)	$ (0.05)	$ (0.20)	$ (0.14)
Weighted-average shares used in computing net loss per share				
Basic	137,933	120,483	130,990	117,718

	Diluted	137,933		120,483		130,990	117,718
Total comprehensive loss		$ (8,836)		$ (6,481)		$(25,678)	$(16,901)

DURECT CORPORATION
CONDENSED BALANCE SHEETS
(in thousands)

	As of September 30, 2016 (unaudited)	As of December 31, 2015[1]
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,363	$ 3,583
Short-term investments	22,403	25,457
Short-term restricted Investments	100	–
Accounts receivable	1,249	2,222
Inventories	3,641	3,917
Prepaid expenses and other current assets	1,744	3,142
Total current assets	34,500	38,321
Property and equipment, net	1,290	1,566
Goodwill	6,399	6,399
Long-term investments	1,000	–
Long-term restricted Investments	150	250
Other long-term assets	236	236
Total assets	$ 43,575	$ 46,772
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,494	$ 1,286
Accrued liabilities	4,092	4,970
Contract research liability	555	575
Deferred revenue, current portion	989	616
Total current liabilities	7,130	7,447
Deferred revenue, noncurrent portion	1,988	2,269
Long-term debt, net	19,838	19,684
Other long-term liabilities	1,676	2,489
Stockholders' equity	12,943	14,883
Total liabilities and stockholders' equity	$ 43,575	$ 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-third-quarter-2016-financial-results-and-update-of-programs-300354253.html

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