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

CUPERTINO, Calif., Aug. 1, 2016 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) announced today financial results for the second quarter of 2016. Total revenues were $3.2 million and net loss was $9.0 million for the three months ended June 30, 2016 as compared to total revenues of $4.4 million and net loss of $5.5 million for the three months ended June 30, 2015.

At June 30, 2016, we had cash and investments of $33.9 million, compared to cash and investments of $29.3 million at December 31, 2015. At June 30, 2016, we had $19.8 million in short and long term debt.

"The REMOXY® ER PDUFA date of September 25, 2016 is now less than two months away and, if approved, this would be the first pharmaceutical product in our pipeline authorized for commercialization," stated James E. Brown, D.V.M., President and CEO of DURECT. "Our first two DUR-928 patient studies are progressing in Australia and we are moving forward with preparing two INDs which are required to enable future clinical trials in the U.S. For POSIMIR®, we are in the process of amending the PERSIST Phase 3 trial in response to FDA advice while we continue enrollment in the trial."

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.

  Our first patient trial utilizing DUR-928 is an open-label single-ascending-dose safety and pharmacokinetic (PK) Phase 1b trial of DUR-928 in NASH patients and matched control subjects. This study is being 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 a higher dose. The study is being conducted in Australia, and we anticipate that we will start obtaining results from this trial in the third quarter of 2016. This study is designed to enable and inform a subsequent multi-dose study in NASH and/or other patients with other liver function impairment. We are also preparing to request in the near future a pre-IND meeting with the FDA as precursor to submitting an IND later this year which is required to enable future clinical trials in liver diseases in the U.S.

  Our second patient study with DUR-928, also being conducted in Australia, is currently screening patients with dosing expected shortly. 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 a 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. Our request for a pre-IND meeting has been granted by the FDA; we anticipate that feedback from that meeting will enable the filing of an IND later in the year which is required to enable future clinical trials in kidney diseases in the U.S.

- **REMOXY ER (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. 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.

  Pain Therapeutics (our licensee) resubmitted the NDA for REMOXY 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). In May 2016, positive data

from a REMOXY human abuse potential study was presented at the 35th Annual Scientific Meeting of the American Pain Society. Also in May 2016, the FDA informed Pain Therapeutics that there was a tentative date of August 5, 2016 for an Advisory Committee meeting to review the REMOXY NDA. In July 2016, Pain Therapeutics announced that the FDA had determined that the Advisory Committee meeting is unnecessary and would not be held on August 5. Pain Therapeutics also stated that the FDA advised them that the regulatory review remains active and is on-going, and the PDUFA date of September 25, 2016 remains unchanged.

- **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 new 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 are 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. Additionally, we are switching in Part 2 the primary efficacy endpoint (pain reduction on movement) from 0-72 hours after surgery to 0-48 hours after surgery. Assessing pain reduction on movement from 0-72 hours is now the key secondary efficacy endpoint and other efficacy endpoints, including 72-hour opioid use, remain the same. We expect to enroll approximately 264 patients in Part 2 of PERSIST, and we expect this part of the trial to take approximately one year to enroll. 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.

- **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.

- **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).

Earnings Conference Call

A live audio webcast of a conference call to discuss second quarter 2016 results will be broadcast live over the internet at4:30 p.m. Eastern Time on August 1 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® ER, addressing key unmet needs in pain management. 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, 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 regulatory matters, including the PDUFA date for REMOXY and potential FDA approval of REMOXY and our other product candidates, anticipated and 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 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 of delays in the commencement or enrollment of clinical trials, 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 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, 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 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 May 6, 2016 under the heading "Risk Factors."

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

	Three months ended June 30		Six months ended June 30	
	2016	2015	2016	2015
Collaborative research and development and other revenue	$ 371	$ 1,778	$ 790	$ 3,516
Product revenue, net	2,786	2,663	5,975	5,698
Total revenues	3,157	4,441	6,765	9,214
Operating expenses:				
Cost of product revenues	913	1,022	2,155	2,028
Research and development	7,852	5,638	14,477	11,005
Selling, general and administrative	2,888	2,724	5,950	5,544
Total operating expenses	11,653	9,384	22,582	18,577
Loss from operations	(8,496)	(4,943)	(15,817)	(9,363)
Other income (expense):				
Interest and other income (expenses)	40	23	67	151
Interest expense	(558)	(558)	(1,116)	(1,119)
Net other income (expense)	(518)	(535)	(1,049)	(968)
Net loss	$ (9,014)	$ (5,478)	$(16,866)	$(10,331)
Net loss per share				

	Basic	$ (0.07)		$ (0.05)		$ (0.13)	$ (0.09)
	Diluted	$ (0.07)		$ (0.05)		$ (0.13)	$ (0.09)
Weighted-average shares used in computing net loss per share							
	Basic	132,812		118,804		127,480	116,313
	Diluted	132,812		118,804		127,480	116,313
Total comprehensive loss		$ (9,007)		$ (5,482)		$(16,842)	$(10,420)

DURECT CORPORATION

CONDENSED BALANCE SHEETS

(in thousands)

	As of June 30, 2016 (unaudited)		As of December 31, 2015(1)
ASSETS			
Current assets:			
Cash and cash equivalents	$ 8,036		$ 3,583
Short-term investments	24,523		25,457
Short-term restricted Investments	100		–
Accounts receivable	1,855		2,222
Inventories	4,157		3,917
Prepaid expenses and other current assets	2,602		3,142
Total current assets	41,273		38,321
Property and equipment, net	1,382		1,566
Goodwill	6,399		6,399
Long-term investments	1,050		–
Long-term restricted Investments	150		250
Other long-term assets	236		236
Total assets	$ 50,490		$ 46,772
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities:			
Accounts payable	$ 1,317		$ 1,286
Accrued liabilities	4,770		4,970
Contract research liability	569		575
Deferred revenue, current portion	1,033		616
Total current liabilities	7,689		7,447
Deferred revenue, noncurrent portion	2,097		2,269
Long-term debt, net	19,752		19,684
Other long-term liabilities	1,790		2,489
Stockholders' equity	19,162		14,883
Total liabilities and stockholders' equity	$ 50,490		$ 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-second-quarter-2016-financial-results-and-update-of-programs-300307093.html

SOURCE DURECT Corporation

Matt Hogan, Chief Financial Officer, DURECT Corporation, 408-777-4936