DURECT Corporation Announces Second Quarter 2017 Financial Results and Provides Corporate Update

Live Webcast of Earnings Call Today at 4:30 p.m. Eastern Time

CUPERTINO, Calif., Aug. 8, 2017 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced financial results for the three months ended June 30, 2017 and provided a corporate update.

- Executed a U.S. commercialization agreement with Sandoz for POSIMIR®, including a $20 million upfront payment, as well as milestone payments and double digit royalties.
- Total revenues were $4.3 million and net loss was $9.9 million for the three months ended June 30, 2017 as compared to total revenues of $3.2 million and net loss of $9.0 million for the three months ended June 30, 2016.
- At June 30, 2017, cash and investments were $33.6 million, compared to cash and investments of $25.2 million at December 31, 2016. Cash and investments increased during the quarter primarily as a result of the upfront payment received from Sandoz in connection with our POSIMIR agreement. Debt at June 30, 2017 was $19.9 million.

“Highlights of the second quarter included reaching agreement with Sandoz to commercialize POSIMIR in the United States and completing ahead of schedule the enrollment of PERSIST, the POSIMIR pivotal Phase 3 clinical trial in post-operative pain,” stated James E. Brown, D.V.M., President and CEO of DURECT. “We completed drug-drug interaction studies with DUR-928, the lead molecule in our Epigenetic Regulator Program, and found no evidence of likely drug interactions. We also completed a second Phase 1b study in which we observed that DUR-928 was well tolerated in moderate to severe kidney function impaired patients and that the pharmacokinetics were comparable among the patients and matched control subjects. In addition, we were pleased that Orient Pharma, our licensee in certain Asian and South Pacific countries, has achieved positive top-line results from a Phase 3 clinical study of ORADUR-Methylphenidate ER conducted in Taiwan.”

Update on Selected Programs:

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 designed to deliver bupivacaine to provide up to 3 days of pain relief after surgery.

- In May 2017, we signed a development and commercialization agreement with Sandoz AG covering the United States. Under the terms of the agreement, Sandoz has made an upfront payment to DURECT of $20 million, with the potential for up to an additional $43 million in development and regulatory milestones, up to an additional $230 million in sales-based milestones, as well as a tiered double digit royalty on product sales in the United States. DURECT will remain responsible for the completion of the PERSIST Phase 3 clinical trial for POSIMIR as well as FDA interactions through approval.
- In June 2017, we completed enrolling 296 patients in Part 2 of PERSIST, a POSIMIR Phase 3 clinical trial consisting of patients undergoing laparoscopic cholecystectomy (gallbladder removal) surgery. We expect to complete patient follow-up visits in the third quarter and to announce top-line results from PERSIST in the fourth quarter of this year.

Epigenetic Regulator Program. DUR-928, the lead product candidate in our Epigenetic Regulator Program, is an endogenous, small molecule, new chemical entity (NCE), which may have broad applicability in several metabolic diseases such as nonalcoholic steatohepatitis (NASH) and other disorders of the liver, in acute organ injuries such as acute kidney injury, and in autoimmune/inflammatory skin disorders such as psoriasis.

Oral Administration

- We recently conducted *in vivo* drug-drug interaction (DDI) studies with both orally administered and IV injected DUR-928. The results demonstrate that DUR-928 did not have effects on the safety and pharmacokinetics (PK) of midazolam, a drug

used for detecting drug-drug interactions via the enzyme CYP3A4. This enzyme is commonly associated with causing many clinically relevant drug-drug interactions. These data will be included in upcoming INDs submitted to the FDA.
- We are actively working towards initiating a Phase 2 trial in primary sclerosing cholangitis (PSC), with orally administered DUR-928. PSC is a chronic liver disease characterized by a progression of cholestasis (decrease in bile flow) with inflammation and fibrosis of bile ducts. We recently applied for and have received orphan drug designation for PSC with DUR-928.

Injectable Administration

- We recently completed a Phase 1b study in Australia with DUR-928. This was an open-label, single-ascending-dose study investigating safety and PK in patients with impaired kidney function (stage 3 and 4 chronic kidney disease) and matched control subjects.
- This study was conducted in successive cohorts evaluating single-dose levels (first a low dose and then a high dose which was four times larger than the low dose cohort) of DUR-928 administered by intramuscular injection. The low dose cohort enrolled 6 kidney function impaired patients and 3 matched control subjects, and the high dose cohort enrolled 5 kidney function impaired patients and 3 matched control subjects.
- In this trial, DUR-928 was well tolerated among all subjects and the PK parameters between the kidney function impaired patients and the matched control subjects were comparable.
- We are working closely with expert advisors to design Phase 2 trials in one or more indications with an injectable formulation of DUR-928.

Topical Administration

- As previously disclosed, we completed an exploratory Phase 1b trial in psoriasis patients (n = 9 evaluable patients) utilizing intralesional micro injections of DUR-928; promising activity was observed which we believe warrants further investigation.
- In the first half of 2017, we developed several topical formulations of DUR-928 that we expect to utilize in a future topical application psoriasis trial. We believe that there is a large unmet medical need for new topical drugs for inflammatory skin diseases such as psoriasis and atopic dermatitis.

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 March 2017, Pain Therapeutics announced that it plans to resubmit the REMOXY ER NDA after completing two additional studies regarding REMOXY ER based on guidance obtained in a recent meeting with the FDA. The two studies are a clinical abuse potential study via the intranasal route of abuse and a non-clinical abuse potential study using household solvents. Pain Therapeutics stated that it expects to complete these studies by year end 2017, after which it intends to have a pre-NDA meeting with the FDA followed by resubmission of the REMOXY NDA.

ORADUR-ADHD Program. ORADUR-Methylphenidate ER is an investigational drug that has the potential for rapid onset of action and 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 reported that a Phase 3 study conducted in Taiwan has achieved positive results. We retain rights to all other markets in the world, notably including the U.S., Europe and Japan. We intend to reach out with these Phase 3 data to potential development and commercialization partners for major markets not licensed to Orient Pharma.

Earnings Conference Call

A live audio webcast of a conference call to discuss second quarter 2017 results and provide a corporate update will be broadcast live over the internet at 4:30 p.m. Eastern Time on August 8 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, chronic metabolic diseases such as primary sclerosing cholangitis (PSC), nonalcoholic fatty liver disease (NAFLD), nonalcoholic steatohepatitis (NASH) and other liver diseases with both broad and orphan populations, and inflammatory skin conditions such as psoriasis. 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 product candidate in this category is POSIMIR® (SABER®-Bupivacaine), an investigational locally-acting, non-opioid analgesic intended to provide up to 3 days of continuous pain relief after surgery. Another late stage product candidate is REMOXY® ER (oxycodone), an investigational pain control 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. POSIMIR, DUR-928, REMOXY ER and ORADUR-Methylphenidate ER 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 PSC, other disorders of the liver, kidney diseases, acute organ injuries, or psoriasis or other inflammatory conditions, the potential use of POSIMIR to treat pain, the potential abuse deterrent properties of REMOXY ER and the potential use of ORADUR-Methylphenidate ER to treat ADHD, our clinical trial plans for DUR-928 and potential reporting of Phase 3 results for POSIMIR, potential regulatory approvals of POSIMIR and REMOXY ER, potential markets for our product candidates, potential payments under the Sandoz agreement, Pain Therapeutics' plans for REMOXY ER and our plans to seek a licensee for ORADUR-Methylphenidate ER 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 analyze and report 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 that there could be a delay in addressing such concerns, the potential thatFDA may not grant regulatory approval of POSIMIR or REMOXY ER, the risks of obtaining marketplace acceptance of POSIMIR or REMOXY ER, if approved, the risk that Sandoz will not achieve milestones triggering payments, the risk that prior clinical trials (including prior trials of POSIMIR in laparoscopic cholecystectomy patients and Phase 1b trials of DUR-928) 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 ER or ORADUR-Methylphenidate ER, respectively, or be delayed in development or regulatory submissions, the risk that 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 10, 2017 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	
	2017	2016	2017	2016
Collaborative research and development and other revenue	$ 1,268	$ 371	$ 1,702	$ 790
Product revenue, net	3,051	2,786	7,184	5,975
Total revenues	4,319	3,157	8,886	6,765
Operating expenses:				
Cost of product revenues	924	913	2,467	2,155
Research and development	9,079	7,852	16,627	14,477
Selling, general and administrative	3,681	2,888	6,724	5,950
Total operating expenses	13,684	11,653	25,818	22,582
Loss from operations	(9,365)	(8,496)	(16,932)	(15,817)
Other income (expense):				

Interest and other income	39	40	75	67
Interest and other expense	(601)	(558)	(1,184)	(1,116)
Net other income (expense)	(562)	(518)	(1,109)	(1,049)
Net loss	$ (9,927)	$ (9,014)	$ (18,041)	$ (16,866)
Net loss per share				
Basic	$ (0.07)	$ (0.07)	$ (0.13)	$ (0.13)
Diluted	$ (0.07)	$ (0.07)	$ (0.13)	$ (0.13)
Weighted-average shares used in computing net loss per share				
Basic	142,532	132,812	142,176	127,480
Diluted	142,532	132,812	142,176	127,480
Total comprehensive loss	$ (9,925)	$ (9,007)	$ (18,041)	$ (16,842)

DURECT CORPORATION
CONDENSED BALANCE SHEETS
(in thousands)

	As of June 30, 2017	As of December 31, 2016(1)
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 30,405	$ 5,404
Short-term investments	3,055	19,600
Accounts receivable	1,385	1,154
Inventories	3,714	3,782
Prepaid expenses and other current assets	3,454	2,486
Total current assets	42,013	32,426
Property and equipment, net	1,089	1,297
Goodwill	6,399	6,399
Long-term restricted Investments	150	150
Other long-term assets	282	236
Total assets	$ 49,933	$ 40,508
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 1,783	$ 2,086
Accrued liabilities	4,103	5,060
Contract research liability	2,131	783
Deferred revenue, current portion	16,207	968
Term loan, current portion, net	3,273	19,853
Total current liabilities	27,497	28,750
Deferred revenue, noncurrent portion	5,617	1,879
Term loan, noncurrent portion, net	16,611	–
Other long-term liabilities	2,046	1,541
Stockholders' equity (deficit)	(1,838)	8,338
Total liabilities and stockholders' equity (deficit)	$ 49,933	$ 40,508

(1) Derived from audited financial statements.

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SOURCE DURECT Corporation

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