DURECT Corporation Announces First Quarter 2018 Financial Results and Provides Corporate Update

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

CUPERTINO, Calif., May 2, 2018 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced financial results for the three months ended March 31, 2018 and provided a corporate update.

- Total revenues were $3.5 million and net loss was $8.3 million for the three months ended March 31, 2018 as compared to total revenues of $4.6 million and net loss of $8.1 million for the three months ended March 31, 2017.
- At March 31, 2018, cash and investments were $44.3 million, compared to cash and investments of $36.9 million at December 31, 2017. Debt at March 31, 2018 was $19.8 million.

“We are very pleased with recent progress on our lead internal candidate DUR-928, with our first two Phase 2 trials in different indications now underway and a third Phase 2 trial in another indication expected to commence in the third quarter of this year,” stated James E. Brown, D.V.M., President and CEO of DURECT. “On other fronts, we have economic stakes in two drug candidates that have approaching PDUFA dates. Indivior’s NDA for RBP-7000, in development for schizophrenia, has a PDUFA target action date of July 28, 2018 and Pain Therapeutics’ REMOXY ER has a PDUFA target action date of August 7, 2018.”

Update on Selected Programs:

Epigenetic Regulator Program. DUR-928, the lead product candidate in our Epigenetic Regulator Program, is an endogenous, first-in-class small molecule, which may have broad applicability in several hepatic and renal diseases such as nonalcoholic steatohepatitis (NASH) and other disorders of the liver including primary sclerosing cholangitis (PSC), in acute organ injuries such as acute liver and kidney injury, and in inflammatory skin disorders such as psoriasis and atopic dermatitis.

Oral Administration

- We are conducting a Phase 2a trial in PSC with orally administered DUR-928. This is a randomized, open label study with two cohorts (a low dose cohort of 10 mg and a high dose cohort of 50 mg), in which patients (n = 15-20 per cohort) will receive oral dosing of DUR-928 for four weeks with follow-up for an additional four weeks. The objectives of this study include safety, pharmacokinetics (PK), and pharmacodynamic (PD) markers, including the percent change from baseline of serum alkaline phosphatase (ALP) and other biomarkers. Additional information on the trial design, including eligibility criteria and site locations, can be found at www.clinicaltrials.gov using the NCT Identifier NCT03394781. As this is an open label study, we expect to generate interim data in 2018.
- PSC is a chronic liver disease characterized by a progression of cholestasis (decrease in bile flow) with inflammation and fibrosis of bile ducts. DUR-928 has been awarded orphan drug designation for the PSC indication. We believe that data generated from this trial may be relevant to other chronic liver conditions, such as NASH.

Injectable Administration

- We are also conducting a Phase 2a trial with DUR-928 in patients with alcoholic hepatitis (AH). This is an open label, dose escalation study conducted in two parts. Part A is enrolling patients with moderate alcoholic hepatitis (as determined by the Model of End-Stage Liver Disease (MELD) scores, a common scoring system to assess the severity and prognosis of AH patients), and Part B will enroll patients with severe alcoholic hepatitis. The study is being conducted using three dose levels (30, 90 and 150 mg) in Part A, with sequential dose escalation following review of safety and PK results of the prior dose level. Patients are receiving DUR-928 by intravenous infusion, and the dose may be adjusted in Part B based on the findings from Part A. The trial will involve multiple clinical sites in the US and the target number of participants to complete the study is 24-36. The objectives of this study include safety, PK and PD signals, as determined by improvement in liver biochemistry,

MELD (Model for End-Stage Liver Disease) and Lille scores, and other biomarkers. Additional information on the trial design, including eligibility criteria and site locations, can be found at www.clinicaltrials.gov using the NCT Identifier NCT03432260. As an open label study, we expect to generate interim data in 2018.

- Alcoholic hepatitis is a syndrome of progressive inflammatory liver injury associated with long-term heavy intake of alcohol, and encompasses a spectrum that ranges from mild injury to severe, life threatening liver damage. The prevalence of AH has not been accurately determined; it is estimated to occur in 10-35% of heavy drinkers. According to an article in the Journal of Clinical Gastroenterology (2015 July; 49(6): 506-511), there were over 320,000 hospitalizations related to alcoholic hepatitis in 2010, resulting in hospitalization costs of nearly $50,000 per patient. We believe that data generated from this trial will be relevant to other liver injuries.

Topical Administration

- The promising results we achieved in a previous exploratory Phase 1b trial utilizing intralesional injections of DUR-928 in psoriasis patients led us to develop a topical formulation of DUR-928. We are working with expert advisors to finalize our study protocol for a Phase 2 proof-of-concept study with topically applied DUR-928. We have had pre-IND interactions with the FDA and are completing the last non-clinical study requested by the FDA prior to submitting the IND in the second quarter. We expect to initiate this study in the third quarter of 2018. We believe that there is a market opportunity for new topical drugs in inflammatory skin diseases such as psoriasis and atopic dermatitis.

Indivior Agreement and RBP-7000. In September 2017, we entered into a patent purchase agreement with an affiliate of Indivior PLC, whereby DURECT assigned certain of its U.S. patent rights to Indivior. This assignment may provide further intellectual property protection for RBP-7000, Indivior's investigational once-monthly injectable risperidone product for the treatment of schizophrenia. Indivior submitted an NDA for RBP-7000 to the FDA, which has been accepted for review. The PDUFA (Prescription Drug User Fee Act) target action date is July 28, 2018.

Under the terms of the agreement, Indivior has made an upfront non-refundable payment to DURECT of $12.5 million, with the potential for an additional $5 million payment based on NDA approval of RBP-7000, as well as quarterly earn-out payments that are based on a single digit percentage of U.S. net sales for certain products covered by the patent rights, including RBP-7000. The patent rights include granted patents extending through at least 2026.

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 January 2018, Pain Therapeutics announced positive results from a human abuse potential study using nasal administration of REMOXY ER and stated that all studies necessary to resubmit the REMOXY ER NDA to the FDA had been completed. The REMOXY ER NDA was resubmitted to the NDA by Pain Therapeutics in February 2018 and this was followed by an announcement on March 1 that the FDA had determined that the NDA was sufficiently complete to permit a substantive review. A PDUFA target action date has been set for August 7, 2018. The FDA plans to hold an Advisory Committee Meeting to discuss the NDA for REMOXY ER, and the tentative date for this meeting is June 26, 2018.

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 October 2017, we reported that PERSIST, a Phase 3 clinical trial for POSIMIR did not meet its primary efficacy endpoint of reduction in pain on movement as compared to standard bupivacaine HCl over the first 48 hours after surgery. While the efficacy results trended in favor of POSIMIR versus the comparator, they did not achieve statistical significance. We are working together with Sandoz, our U.S. commercial licensee for POSIMIR, to consider potential next steps.

Earnings Conference Call

A live audio webcast of a conference call to discuss first quarter 2018 results and provide a corporate update will be broadcast live over the internet at 4:30 p.m. Eastern Time on May 2 and will be available by accessing DURECT's homepage at www.www.durect.com and clicking "Investor Relations." If you are unable to participate in 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 2 development, is the lead candidate inDURECT'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, hepatic and renal diseases such as nonalcoholic steatohepatitis (NASH) and PSC, and inflammatory skin conditions such as psoriasis and atopic dermatitis. DURECT's advanced oral and injectable 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 which the FDA has set a PDUFA target action date of August 7, 2018. In addition, for the assignment of certain patent rights, DURECT may receive a milestone payment upon NDA approval and single digit sales-based earn-out payments from U.S. net sales of Indivior's RBP-7000 investigational drug for schizophrenia, for which Indivior has submitted an NDA and for which the FDA has set a PDUFA target action date of July 28, 2018. 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. DUR-928, REMOXY ER, POSIMIR and RBP-7000 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 potential future payments from Indivior and Pain Therapeutics, clinical trial plans for DUR-928, including the Phase 2a trials in primary sclerosing cholangitis and alcoholic hepatitis, and the potential commencement of a clinical trial in psoriasis, the potential disclosure of Phase 2 data in 2018, the potential benefits and uses of our drug candidates, including the potential use of DUR-928 to treat PSC, alcoholic hepatitis, other disorders of the liver, kidney diseases, acute organ injuries, psoriasis, atopic dermatitis or other inflammatory conditions, our plans for POSIMIR, and the potential regulatory approval of REMOXY ER and RBP-7000 (including the timing thereof) 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 are not started when anticipated or do not demonstrate the safety or efficacy of DUR-928 in a statistically significant manner, the risk that FDA may not grant regulatory approval of RBP-7000 or REMOXY ER, the risks of obtaining marketplace acceptance of RBP-7000 or REMOXY ER, if approved, the risk thatSandoz may terminate our agreement with them and discontinue plans to commercialize POSIMIR, the risk that prior clinical trials (including prior 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 Indivior will discontinue plans to commercialize REMOXY ER or RBP-7000, respectively, or be delayed in commercialization if such products receive FDA approval, the risk that additional time and resources that may be required for development, testing and regulatory approval of POSIMIR or 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-K filed on March 8, 2018 under the heading "Risk Factors."

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

		Three months ended March 31		
		2018		2017
Collaborative research and development and other revenue		$ 1,096		$ 434
Product revenue, net		2,392		4,133
	Total revenues	3,488		4,567
Operating expenses:				
	Cost of product revenues	1,174		1,543
	Research and development	6,952		7,548
	Selling, general and administrative	3,194		3,043
Total operating expenses		11,320		12,134

Loss from operations		(7,832)		(7,567)
Other income (expense):				
	Interest and other income	158		36
	Interest and other expense	(623)		(583)
Net other expense		(465)		(547)
Net loss		$ (8,297)		$ (8,114)
Net loss per share				
	Basic	$ (0.05)		$ (0.06)
	Diluted	$ (0.05)		$ (0.06)
Weighted-average shares used in computing net loss per share				
	Basic	153,558		141,815
	Diluted	153,558		141,815
Total comprehensive loss		$ (8,297)		$ (8,116)

DURECT CORPORATION
CONDENSED BALANCE SHEETS
(in thousands)

	As of March 31, 2018 (unaudited)		As of December 31, 2017[1]
ASSETS			
Current assets:			
Cash and cash equivalents	$ 39,325		$ 29,375
Short-term investments	4,809		7,384
Accounts receivable	1,819		2,376
Inventories, net	3,254		3,163
Prepaid expenses and other current assets	2,801		3,060
Total current assets	52,008		45,358
Property and equipment, net	845		929
Goodwill	6,399		6,399
Long-term restricted Investments	150		150
Other long-term assets	277		277
Total assets	$ 59,679		$ 53,113
LIABILITIES AND STOCKHOLDERS' EQUITY			
Current liabilities:			
Accounts payable	$ 791		$ 1,520
Accrued liabilities	4,923		5,511
Contract research liability	720		834
Deferred revenue, current portion	203		682
Term loan, current portion, net	4,655		7,281
Total current liabilities	11,292		15,828
Deferred revenue, noncurrent portion	623		1,093
Term loan, noncurrent portion, net	15,178		12,634
Other long-term liabilities	2,191		2,070
Stockholders' equity	30,395		21,488
Total liabilities and stockholders' equity	$ 59,679		$ 53,113

(1) Derived from audited financial statements.

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