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

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

CUPERTINO, Calif., Aug. 1, 2018 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced financial results for the three months ended June 30, 2018 and provided a corporate update.

- Total revenues were $3.4 million and net loss was $7.0 million for the three months ended June 30, 2018 as compared to total revenues of $4.3 million and net loss of $9.9 million for the three months ended June 30, 2017.
- At June 30, 2018, cash and investments were $42.5 million, compared to cash and investments of $36.9 million at December 31, 2017. Debt at June 30, 2018 was $19.9 million.

“We are pleased that Indivior has received FDA approval for PERSERIS™, triggering a $5 million milestone payment to DURECT and future earn-out payments based on U.S. net sales,” stated James E. Brown, D.V.M., President and CEO of DURECT. “Enrollment is underway in our DUR-928 Phase 2a trials with PSC and alcoholic hepatitis patients, and we expect to initiate a Phase 2 trial with DUR-928 in psoriasis patients this quarter.”

Update on Selected Programs:

Indivior Agreement and PERSERIS. 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 PERSERIS (risperidone) extended-release injectable suspension for the treatment of schizophrenia in adults.

Under the terms of the agreement, Indivior made an upfront non-refundable payment to DURECT of $12.5 million. Indivior also agreed to make an additional $5 million payment to DURECT based on NDA approval of PERSERIS, 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 PERSERIS. The patent rights include granted patents extending through at least 2026. On July 27, 2018, Indivior announced that the FDA had approved the NDA for PERSERIS. On July 30, 2018, Indivior stated that they commit to providing the launch timing for PERSERIS as soon as reasonably practicable, but no later than when its Q3 2018 results are announced which is currently scheduled for November 1, 2018. U.S. sales of long acting injectables to treat schizophrenia were in excess of $2 billion in 2017.

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 alcoholic hepatitis (AH) and acute kidney injury (AKI), and in inflammatory skin disorders such as psoriasis and atopic dermatitis.

Oral Administration

- We are conducting a Phase 2a clinical trial in PSC with orally administered DUR-928. This is a randomized, open label study with two cohorts (a cohort of 10 mg and a 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.

Injectable Administration

- We are also conducting a Phase 2a clinical 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 this is 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.

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 have had pre-IND interactions with the FDA and recently completed the last non-clinical study requested by the FDA prior to submitting the IND for a Phase 2 proof-of-concept study with topically applied DUR-928. We expect to initiate this study in the third quarter of 2018.

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. The REMOXY ER NDA was resubmitted to the FDA by Pain Therapeutics in February 2018. On June 26, 2018, a joint meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and Drug Safety and Risk Management Advisory Committee of the FDA voted 14 to 3 against the approval of REMOXY ER for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. The PDUFA date for completion of the review is August 7, 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. In May 2018, we amended our U.S. licensing agreement with Sandoz, pursuant to which DURECT is now eligible for up to $30 million in milestone payments based on NDA approval, and remains eligible for up to an additional $230 million in sales-based milestones. Each party, pursuant to the Amendment, is also permitted to develop or commercialize competing products. The Amendment also includes modifications to DURECT's development obligations and to both parties' termination provisions, including a right for DURECT to terminate for

convenience prior to NDA approval. There is also a new termination fee payable to DURECT in the event that Sandoz terminates the agreement for convenience. The agreement between the two companies remains in full force and effect, except as expressly covered in the Amendment. We continue to evaluate and consider potential next steps with the program.

Earnings Conference Call

A live audio webcast of a conference call to discuss second quarter 2018 results and provide a corporate update will be broadcast live over the internet at 4:30 p.m. Eastern Time on August 1 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 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, hepatic and renal diseases such as nonalcoholic steatohepatitis (NASH) and primary sclerosing cholangitis (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 will receive a milestone payment upon NDA approval and single digit sales-based earn-out payments from U.S. net sales of Indivior's PERSERIS™ drug for schizophrenia, which was approved by the FDA in July 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 and POSIMIR 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 Sandoz, 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 generation 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 (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, take longer to conduct than 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 REMOXY ER, the risk that Indivior will not launch PERSERIS or that it will obtain marketplace acceptance, the risk of obtaining marketplace acceptance of REMOXY ER, if approved, the risk that Sandoz 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 will discontinue plans to commercialize REMOXY ER, or be delayed in commercialization if such product receives 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-Q filed on May 9, 2018 under the heading "Risk Factors."

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

	Three months ended June 30		Six months ended June 30	
	2018	2017	2018	2017
Collaborative research and development and other revenue	$ 645	$ 1,268	$ 1,741	$ 1,702
Product revenue, net	2,768	3,051	5,160	7,184
Total revenues	3,413	4,319	6,901	8,886
Operating expenses:				
Cost of product revenues	1,084	924	2,258	2,467
Research and development	6,120	9,079	13,072	16,627
Selling, general and administrative	2,816	3,681	6,010	6,724
Total operating expenses	10,020	13,684	21,340	25,818
Loss from operations	(6,607)	(9,365)	(14,439)	(16,932)
Other income (expense):				
Interest and other income	240	39	398	75
Interest and other expense	(644)	(601)	(1,267)	(1,184)
Net other expense	(404)	(562)	(869)	(1,109)
Net loss	$ (7,011)	$ (9,927)	$(15,308)	$(18,041)
Net loss per share				
Basic	$ (0.04)	$ (0.07)	$ (0.10)	$ (0.13)
Diluted	$ (0.04)	$ (0.07)	$ (0.10)	$ (0.13)
Weighted-average shares used in computing net loss per share				
Basic	161,621	142,532	157,612	142,176
Diluted	161,621	142,532	157,612	142,176
Total comprehensive loss	$ (7,010)	$ (9,925)	$(15,307)	$(18,041)

DURECT CORPORATION
CONDENSED BALANCE SHEETS
(in thousands)

	As of June 30, 2018 (unaudited)	As of December 31, 2017[1]
ASSETS		
Current assets:		
Cash and cash equivalents	$ 37,338	$ 29,375
Short-term investments	5,061	7,384
Accounts receivable	1,465	2,376
Inventories, net	3,263	3,163
Prepaid expenses and other current assets	2,691	3,060
Total current assets	49,818	45,358
Property and equipment, net	749	929
Goodwill	6,399	6,399
Long-term restricted Investments	150	150
Other long-term assets	282	277
Total assets	$ 57,398	$ 53,113
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 895	$ 1,520
Accrued liabilities	4,520	5,511
Contract research liability	710	834
Deferred revenue, current portion	203	682
Term loan, current portion, net	7,520	7,281
Total current liabilities	13,848	15,828
Deferred revenue, noncurrent portion	623	1,093
Term loan, noncurrent portion, net	12,341	12,634

Other long-term liabilities		2,317		2,070
Stockholders' equity		28,269		21,488
Total liabilities and stockholders' equity		$ 57,398		$ 53,113
(1) Derived from audited financial statements.				

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