DURECT Corporation Announces Fourth Quarter and Full Year 2017 Financial Results and Update of Programs

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

CUPERTINO, Calif., March 1, 2018 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced financial results for the three months and year ended December 31, 2017 and provided a corporate update.

- Total revenues were $19.5 million and net profit was $8.2 million for the three months ended December 31, 2017 as compared to total revenues of $3.5 million and net loss of $8.8 million for the three months ended December 31, 2016. The revenues for the three months ended December 31, 2017 included the recognition of the remaining $15.4 million in deferred revenue from the $20 million upfront fee associated with our agreement with Sandoz; this revenue during the fourth quarter period was a non-cash item as the $20 million fee was received in the second quarter of 2017.
- Total revenues were $49.2 million and net loss was $3.7 million for the year ended December 31, 2017, compared to total revenues of $14.0 million and net loss of $34.5 million for the year ended December 31, 2016.
- At December 31, 2017, cash and investments were $36.9 million, compared to cash and investments of $25.2 million at December 31, 2016. Debt at December 31, 2017 was $19.9 million.

“We now are conducting two Phase 2 trials with DUR-928, with a third Phase 2 trial 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, Indivior’s NDA application for RBP-7000, a drug candidate for schizophrenia, has been accepted for review by the FDA with a PDUFA target action date of July 28, 2018. In addition, the NDA for REMOXY ER has been resubmitted by Pain Therapeutics and accepted by the FDA, with a PDUFA date of August 7, 2018.”

Potential milestones in 2018:

- Conducting Phase 2 clinical trials of DUR-928 in three indications, and reporting of initial Phase 2 data
- Approval of Indivior’s New Drug Application (NDA) application for RBP-7000, which would result in a milestone payment for DURECT as well as future single-digit percentage earn-out payments based on U.S. net sales
- Approval of REMOXY ER which would result in a milestone payment for DURECT as well as future royalty payments of 6 – 11.5% based on net sales
- New license and collaboration agreements

Update on Selected Programs and Transactions:

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 have initiated 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 4-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 an open label study, we expect to generate data during the course of 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 to treat patients with PSC. 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 includes 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 include 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 will receive DUR-928 by intravenous infusion, and the dose may be adjusted in Part B based on the findings from Part A. Patients will be enrolled at 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 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 data during the course of 2018.
- Alcoholic hepatitis is a syndrome of progressive inflammatory liver injury associated with long-term heavy intake of alcohol, and involves a spectrum that ranges from mild injury to severe, life threatening liver damage. The prevalence of AH has not been accurately determined; it is believed to occur in 10-35% of heavy drinkers. 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

- We developed a topical formulation of DUR-928 because of the promising results we achieved in a previous exploratory Phase 1b trial in psoriasis patients utilizing intralesional injections 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 by the FDA. 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 December 2017, Pain Therapeutics announced that they had successfully concluded a pre-NDA guidance meeting with the FDA. According to Pain Therapeutics, the purpose of a pre-NDA meeting is to acquaint FDA reviewers with the data to be submitted in the NDA, to uncover any major unresolved problems, including whether the NDA resubmission constitutes a complete response to the 2016 Complete Response Letter, and to discuss the best approach to the presentation and formatting of data in the NDA. In January 2018, Pain Therapeutics announced positive results from a human abuse potential study using nasal administration of REMOXY ER and that they had completed all studies necessary to resubmit the REMOXY ER NDA to the FDA. In February 2018, Pain Therapeutics stated that they had resubmitted the REMOXY ER NDA. On March 1, 2018, Pain Therapeutics announced that the FDA has determined that the NDA is sufficiently complete to permit a substantive review and the FDA has set a PDUFA action date of August 7, 2018. Pain Therapeutics also stated that they believe the FDA will hold an open advisory committee meeting to discuss REMOXY ER, although a date has not yet been determined.

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 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.

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 and we understand that Orient Pharma is pursuing a NDA with the Taiwan FDA for ORADUR-Methylphenidate ER. We retain rights to all other markets in the world, notably including the U.S., Europe and Japan. We have started a process of contacting potential development and commercialization partners for major markets not licensed to Orient Pharma.

Debt amendment. In February 2018, we amended our existing $20 million term loan with Oxford Finance such that principal payments now commence 9 months later than originally agreed (i.e., commencing December 1, 2018 rather than March 1, 2018).

Upcoming investor conference. DURECT will be presenting at the H.C. Wainwright NASH Investor Conference on March 19, 2018 at 11:40 am Eastern Time. The conference is being held at the St. Regis Hotel in New York City. A live audio webcast of the presentation will be available by accessing http://wsw.com/webcast/hcw3/drrx/ and also on the Investor Relations section of DURECT's homepage (www.www.durect.com). The call will be also archived on DURECT's website.

Earnings Conference Call
A live audio webcast of a conference call to discuss fourth quarter 2017 results and provide a corporate update will be broadcast live over the internet at 4:30 p.m. Eastern Time on March 1 and is available by accessing DURECT's homepage at www.www.durect.com and clicking "Investor Relations." A replay of 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. 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 ofIndivior'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, RBP-7000, 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 Pain Therapeutics, clinical trial plans for DUR-928, including the conducting of clinical 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, the potential regulatory approval of REMOXY ER and RBP-7000 (including the timing thereof), Orient Pharma's plans to obtain regulatory approval of ORADUR-Methylphenidate 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 are not started when anticipated or do not demonstrate the safety or efficacy of DUR-928 in a statistically significant manner, 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 that FDA may not grant regulatory approval of RBP-7000, REMOXY ER or POSIMIR, the risks of obtaining marketplace acceptance of POSIMIR, RBP-7000 or 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, Indivior or Orient Pharma will discontinue development of REMOXY ER, RBP-7000 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 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 November 2, 2017 under the heading "Risk Factors."

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

	Three months ended December 31		Twelve months ended December 31	
	2017	2016	2017	2016
Collaborative research and development and other revenue	$16,273	$ 738	$23,577	$ 1,880
Product revenue, net	3,265	2,779	13,093	12,145
Revenue from sale of intellectual property rights	–	–	12,500	–
Total revenues	19,538	3,517	49,170	14,025
Operating expenses:				
Cost of product revenues	1,061	955	6,633	5,290
Research and development	6,604	7,992	31,609	29,274
Selling, general and administrative	3,303	2,832	13,165	11,825
Total operating expenses	10,968	11,779	51,407	46,389
Income (Loss) from operations	8,570	(8,262)	(2,237)	(32,364)
Other income (expense):				
Interest and other income	287	31	967	143
Interest and other expense	(622)	(580)	(2,425)	(2,288)
Net other expense	(335)	(549)	(1,458)	(2,145)
Net income (loss)	$ 8,235	$ (8,811)	$ (3,695)	$(34,509)
Net income (loss) per share				
Basic	$ 0.06	$ (0.06)	$ (0.03)	$ (0.26)
Diluted	$ 0.05	$ (0.06)	$ (0.03)	$ (0.26)
Weighted-average shares used in computing net income (loss) per share				
Basic	149,428	137,933	145,273	133,163
Diluted	150,759	137,933	145,273	133,163
Total comprehensive income (loss)	$ 8,234	$ (8,819)	$ (3,693)	$(34,498)

DURECT CORPORATION
CONDENSED BALANCE SHEETS
(in thousands)

	As of	As of

	December 31, 2017 (unaudited)	December 31, 2016[1]
ASSETS		
Current assets:		
Cash and cash equivalents	$ 29,375	$ 5,404
Short-term investments	7,384	19,600
Accounts receivable	2,376	1,154
Inventories, net	3,163	3,782
Prepaid expenses and other current assets	3,060	2,486
Total current assets	45,358	32,426
Property and equipment, net	929	1,297
Goodwill	6,399	6,399
Long-term restricted Investments	150	150
Other long-term assets	277	236
Total assets	$ 53,113	$ 40,508
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,520	$ 2,086
Accrued liabilities	5,511	5,060
Contract research liability	834	783
Deferred revenue, current portion	682	968
Term loan, current portion, net	7,281	19,853
Total current liabilities	15,828	28,750
Deferred revenue, noncurrent portion	1,093	1,879
Term loan, noncurrent portion, net	12,634	–
Other long-term liabilities	2,070	1,541
Stockholders' equity	21,488	8,338
Total liabilities and stockholders' equity	$ 53,113	$ 40,508

(1) Derived from audited financial statements.

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SOURCE DURECT Corporation

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