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

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

CUPERTINO, Calif., Nov. 7, 2018 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced financial results for the three months ended September 30, 2018 and provided a corporate update.

- Total revenues were $8.0 million and net loss was $2.7 million for the three months ended September 30, 2018 as compared to total revenues of $20.7 million and net income of $6.1 million for the three months ended September 30, 2017. The third quarter of 2018 included a $5 million milestone payment from Indivior related to the FDA approval of PERSERIS™ (risperidone). The third quarter of 2017 included $12.5 million in revenues from the upfront payment related to a patent purchase agreement with Indivior.
- At September 30, 2018, cash and investments were $41.5 million, compared to cash and investments of $36.9 million at December 31, 2017. Debt at September 30, 2018 was $19.9 million.

“During the third quarter, we benefited from two product approvals through corporate relationships, most notably U.S.FDA approval of Indivior’s PERSERIS to treat adults with schizophrenia, as well as the Taiwan Ministry of Health and Welfare’s approval of Orient Pharma’s Methydur Sustained Release Capsules to treat patients with ADHD,” stated James E. Brown, D.V.M., President and CEO of DURECT. “We expect anticipated earn-outs and royalties from these approvals to begin providing cash flow, starting next year, that will help finance the development of our proprietary pipeline, including DUR-928, which we are currently evaluating in two Phase 2a clinical trials in alcoholic hepatitis (AH) and primary sclerosing cholangitis (PSC). We are planning to accelerate enrollment in the AH trial by enrolling both moderate and severe AH patients simultaneously going forward. In addition, we plan to initiate a Phase 2a clinical trial of topical DUR-928 in patients suffering from psoriasis in the first quarter of 2019, and a trial in nonalcoholic steatohepatitis (NASH) patients in the first half of 2019.”

Update on Selected Programs:

Epigenetic Regulator Program. DUR-928, the lead product candidate in the Company’s Epigenetic Regulator Program, is an endogenous, first-in-class small molecule, which may have broad applicability in several hepatic and renal diseases such as NASH and PSC, in acute organ injuries such as AH and acute kidney injury (AKI), and in inflammatory skin disorders such as psoriasis and atopic dermatitis.

Ongoing Clinical Trials

Alcoholic Hepatitis (AH)

- DURECT is conducting a Phase 2a clinical trial with intravenously administered DUR-928 in patients with AH. This is an open label, dose escalation, multi-center U.S. study, originally designed to be conducted in two sequential parts. Part A includes patients with moderate AH (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 includes patients with severe AH. Three dose levels (30, 90 and 150 mg) are planned for testing in Part A. Dose escalation occurs following review of safety and pharmacokinetic (PK) results of the prior dose level by a Dose Escalation Committee (DEC). The target number of patients for the study is 4-6 per dose group. The objectives of this study include safety, PK and pharmacodynamic (PD) signals, including liver biochemistry and 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.
- The Company recently completed dosing for the low-dose 30 mg cohort (n=4) of Part A (moderate AH patients). After completing the safety and PK review by the DEC, DURECT plans to commence the 90 mg cohort in Part A.
- The Company has amended the protocol so that after the DEC completes its review, DURECT can begin enrolling Part B

(severe AH patients), starting with the low dose, while it simultaneously continues enrolling Part A (moderate AH patients). The Company believes enrolling Part A and B simultaneously will accelerate the overall timeline for the trial. Over the course of the trial, the clinical sites have encountered many severe AH patients who may have qualified for Part B but were deemed screen failures due to their MELD scores being too high for Part A.

- AH 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 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.

Primary Sclerosing Cholangitis (PSC)

- The Company is currently conducting a Phase 2a clinical trial in PSC with orally administered DUR-928. This is a randomized, open label, multi-center study with two cohorts (10 mg and 50 mg), in which patients (n = 15-20 per cohort) receive daily oral dosing of DUR-928 for four weeks with follow-up for an additional four weeks. The objectives of this study include safety, PK and PD signals, 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. To date, five PSC patients have been dosed, and as such the Company is not able to provide meaningful interim data at this time. The Company plans to continue enrolling patients and will provide an update when enrollment has reached a critical mass for data analysis.
- 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.

Planned Clinical Trials

Psoriasis

- The Company is planning to conduct a Phase 2a proof-of-concept trial with topical DUR-928 in patients with mild to moderate plaque psoriasis beginning in the first quarter of 2019. This will be a multicenter, randomized, double-blind, vehicle-controlled clinical trial conducted in the U.S. Approximately 20 subjects will be enrolled to obtain about 15 evaluable subjects in the study. DUR-928 will be applied topically once-daily for four weeks. Patients will serve as their own controls, as each patient will have similar contralateral plaques. DUR-928 will be applied to one plaque and the vehicle control will be applied to the contralateral plaque daily for four weeks. Patients will be followed for an additional four weeks and the primary efficacy endpoint will be improvement in local psoriasis scores in the DUR-928-treated plaque compared to the vehicle-treated plaque.
- The Company observed activity of DUR-928 in a previous exploratory Phase 1b trial utilizing intralesional injections of DUR-928 in psoriasis patients. In support of the upcoming study, it has completed multiple non-clinical safety studies for topically applied DUR-928.
- Skin inflammatory disorders, such as psoriasis and atopic dermatitis, affect approximately 7.5 million and 32 million Americans, respectively. Most currently available topical treatments, typically as first line therapy, either slow down excessive skin cell proliferation or reduce inflammation. Steroids are the most commonly used topical anti-inflammatory agents because they reduce the swelling and redness of lesions.

Non-Alcoholic Steatohepatitis (NASH)

- DURECT is planning to conduct a clinical trial in NASH patients with orally-administered DUR-928 beginning in the first half of 2019. Further details on study design and timing will be provided as the Company gets closer to initiation. In the Company's previous Phase 1b NASH study, reported at the European Association for the Study of the Liver (EASL) in April 2017, a reduction of certain biomarkers after a single oral dose of DUR-928 was observed. Exploratory biomarker analysis indicated that a single oral dose of DUR-928 in NASH patients resulted in statistically significant reductions from baseline of both full-length and cleaved cytokeratin-18 (CK-18), bilirubin, hsCRP and IL-18.

Indivior Agreement and PERSERIS. In September 2017, the Company entered into a patent purchase agreement with an affiliate of Indivior PLC, whereby the Company 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 the Company of $12.5 million. Indivior also agreed to make an additional $5 million payment to the Company 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. In July 2018, the FDA approved the NDA for PERSERIS and the Company received the $5 million milestone payment in August 2018. On November 1, 2018, Indivior stated that they are preparing a full promotional launch of PERSERIS with a field force of 40 to 60 representatives, contingent upon the preliminary injunction against Dr. Reddy's Laboratories being upheld by the U.S. Court of Appeals for the Federal Circuit. Indivior further stated that they will be making PERSERIS available in the U.S. in Q4 2018 to begin generating product awareness and trial. For more information on PERSERIS, please see Indivior's earnings press release dated November 1, 2018. U.S. sales of long acting injectables to treat schizophrenia were in excess of $3 billion in 2017.

POSIMIR® (SABER®-Bupivacaine) Post-Operative Pain Relief Depot. POSIMIR is the Company's investigational post-operative pain relief depot that utilizes the Company's patented SABER technology and is designed to deliver bupivacaine to provide up to 3 days of pain relief after surgery.

In October 2017, the Company 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, the Company amended its 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. DURECT continues to evaluate and consider potential next steps with the program.

Methydur Sustained Release Capsules (ORADUR®-methylphenidate ER Capsules). In September 2018, Orient Pharma informed DURECT that it had obtained marketing authorization from the Ministry of Health and Welfare in Taiwan for Methydur Sustained Release Capsules. This product is indicated for the treatment of attention deficit hyperactivity disorder (ADHD) and will be available in three strengths (22 mg, 33 mg and 44 mg) in Taiwan. Orient Pharma also has stated that it expects to make Methydur Sustained Release Capsules commercially available in Taiwan in 2019, while seeking a partner in China and pursuing regulatory approvals in selected other countries where it has commercialization rights and a commercial presence.

In August 2009, DURECT entered into a development and license agreement with Orient Pharma Co., Ltd., a diversified multinational pharmaceutical, healthcare and consumer products company with headquarters in Taiwan. In this agreement, DURECT granted to Orient Pharma the development and commercialization rights to ORADUR-Methylphenidate ER Capsules (Methydur Sustained Released Capsules) in certain defined Asian and South Pacific countries. DURECT retains rights to North America, Europe, Japan and all other countries not specifically licensed to Orient Pharma. DURECT is entitled to receive a royalty on sales of Methydur Sustained Release Capsules by Orient Pharma. Orient Pharma has also committed to supply a portion of the commercial requirements in territories other than the United States for Methydur Sustained Release Capsules.

Debt amendment. In November 2018, the Company amended its existing $20 million term loan with Oxford Finance such that principal payments now commence 18 months later than previously scheduled (i.e., commencing June 1, 2020 rather than December 1, 2018) and the final maturity date is moved back by 30 months (i.e., from August 1, 2020 to November 1, 2022). The interest rate and final payment remain unchanged, and the Company paid Oxford Finance an amendment fee of $900,000.

Upcoming investor conference. DURECT will be presenting at the Stifel 2018 Healthcare Conference at 11:45 am Eastern time on Wednesday, November 14. The conference is being held at the Lotte New York Palace Hotel. A live audio webcast of the presentation will be available by accessing http://wsw.com/webcast/stifel14/drrx . A live audio webcast of these presentations will also be 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.

Earnings Conference Call

A live audio webcast of a conference call to discuss third quarter 2018 results and provide a corporate update will be broadcast live over the internet at 4:30 p.m. Eastern Time on November 7 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 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 such as Alcoholic Hepatitis (AH), 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. Late stage product candidates in this category include POSIMIR® (Extended Release Bupivacaine), an investigational locally-acting, non-opioid analgesic intended to provide up to 3 days of continuous pain relief after surgery, and ORADUR®-Methylphenidate ER Capsules, approved in Taiwan as Methydur Sustained Release Capsules, where it is indicated for the treatment of attention deficit hyperactivity disorder (ADHD). In addition, for the assignment of certain patent rights, DURECT will receive single digit sales-based earn-out payments from U.S. net sales of Indivior's PERSERIS™ (risperidone) drug for schizophrenia, which was approved in July 2018. For more information, please visit www.www.durect.com.

NOTE: ORADUR®, POSIMIR® and SABER® are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners. DUR-928 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 clinical development plans for DUR-928, including potential acceleration of the Phase 2a trial in AH, the initiation of a Phase 2a trial in psoriasis, plans for a clinical trial in patients with NASH, and the disclosure of data from the Phase 2a trial in PSC, potential future payments from Indivior, Orient Pharma and Sandoz, and the potential benefits and uses of our drug candidates, including the potential use of DUR-928 to treat PSC, AH, other disorders of the liver, kidney diseases, acute organ injuries, psoriasis, atopic dermatitis or other inflammatory conditions, and our plans for POSIMIR 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 Indivior will not launch PERSERIS or that it will obtain marketplace acceptance, the risk that Orient Pharma will not launch sales of Methydur Sustained Release Capsules as planned, 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 additional time and resources that may be required for development, testing and regulatory approval of DUR-928 or POSIMIR, 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 August 2, 2018 under the heading "Risk Factors."

DURECT CORPORATION

CONDENSED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands, except per share amounts)

(unaudited)

	Three months ended September 30		Nine months ended September 30	
	2018	2017	2018	2017

Collaborative research and development and other revenue		$ 5,691	$ 5,602	$ 7,432	$ 7,304
Product revenue, net		2,345	2,644	7,505	9,828
Revenue from sale of intellectual property rights		–	12,500	–	12,500
	Total revenues	8,036	20,746	14,937	29,632
Operating expenses:					
	Cost of product revenues	912	3,105	3,170	5,572
	Research and development	6,542	8,378	19,614	25,005
	Selling, general and administrative	2,870	3,138	8,880	9,862
Total operating expenses		10,324	14,621	31,664	40,439
Income (Loss) from operations		(2,288)	6,125	(16,727)	(10,807)
Other income (expense):					
	Interest and other income	234	605	632	680
	Interest and other expense	(661)	(619)	(1,928)	(1,803)
Net other expense		(427)	(14)	(1,296)	(1,123)
Net income (loss)		$ (2,715)	$ 6,111	$(18,023)	$(11,930)
Net income (loss) per share					
	Basic	$ (0.02)	$ 0.04	$ (0.11)	$ (0.08)
	Diluted	$ (0.02)	$ 0.04	$ (0.11)	$ (0.08)
Weighted-average shares used in computing net income (loss) per share					
	Basic	162,002	147,213	159,091	143,873
	Diluted	162,002	151,885	159,091	143,873
Total comprehensive income (loss)		$ (2,715)	$ 6,114	$(18,022)	$(11,927)

DURECT CORPORATION

CONDENSED BALANCE SHEETS

(in thousands)

	As of September 30, 2018 (unaudited)	As of December 31, 2017[1]
ASSETS		
Current assets:		
Cash and cash equivalents	$ 38,217	$ 29,375
Short-term investments	3,090	7,384
Accounts receivable	1,606	2,376
Inventories, net	3,485	3,163
Prepaid expenses and other current assets	2,870	3,060
Total current assets	49,268	45,358
Property and equipment, net	677	929
Goodwill	6,399	6,399
Long-term restricted Investments	150	150
Other long-term assets	366	277
Total assets	$ 56,860	$ 53,113
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,152	$ 1,520
Accrued liabilities	5,200	5,511
Contract research liability	1,375	834
Deferred revenue, current portion	13	682
Term loan, current portion, net	10,390	7,281
Total current liabilities	18,130	15,828
Deferred revenue, noncurrent portion	812	1,093
Term loan, noncurrent portion, net	9,500	12,634
Other long-term liabilities	2,324	2,070
Stockholders' equity	26,094	21,488

Total liabilities and stockholders' equity	$ 56,860	$ 53,113

(1) Derived from audited financial statements.

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SOURCE DURECT Corporation

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