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

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

CUPERTINO, Calif., Nov. 1, 2017 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced financial results for the three months ended September 30, 2017 and provided a corporate update.

- Executed a patent purchase agreement with Indivior relevant to Indivior's RBP-7000, yielding DURECT a $12.5 million upfront payment, as well as a potential $5 million milestone payment and potential earn-out payments. Indivior submitted a NDA for RBP-7000 to the U.S. FDA on September 28, 2017.
- Including the $12.5 million described above, total revenues were $20.7 million and net income was $6.1 million for the three months ended September 30, 2017 as compared to total revenues of $3.7 million and net loss of $8.8 million for the three months ended September 30, 2016.
- At September 30, 2017, cash and investments were $41.8 million, compared to cash and investments of $25.2 million at December 31, 2016.

"The top-line results from the Phase 3 clinical trial of POSIMIR did not meet expectations, trending in favor of POSIMIR but not reaching statistically significance. We will be working to understand the trial results more fully in the coming weeks," statedJames E. Brown, D.V.M., President and CEO of DURECT. "On other fronts, positive highlights of the third quarter included reaching an agreement with Indivior which resulted in a meaningful upfront payment to DURECT as well the potential for further payments based on the progress of RBP-7000, a drug candidate for schizophrenia for which Indivior has submitted an NDA to the FDA. We are also making significant progress towards initiating multiple Phase 2 studies with DUR-928."

Update on Selected Programs and Transactions:

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 over the first 48 hours after surgery as compared to standard bupivacaine HCl. While results trended in favor of POSIMIR versus the comparator, they did not achieve statistical significance. We andSandoz, our licensee for commercialization rights for POSIMIR in the United States, will be working to understand the trial results more fully in the coming weeks.

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 liver and/or kidney injury, and in autoimmune/inflammatory skin disorders such as psoriasis and atopic dermatitis.

Oral Administration

- We are actively working towards initiating a Phase 2 trial in primary sclerosing cholangitis (PSC) with orally administered DUR-928. Our protocol has been reviewed by the FDA and our IND is now open. Clinical trial site preparation is underway, and we are targeting dosing our first patient by the end of 2017. PSC is a chronic liver disease characterized by a progression of cholestasis (decrease in bile flow) with inflammation and fibrosis of bile ducts. We have received orphan drug designation for DUR-928 to treat patients with PSC. We believe that data generated from this trial will be relevant to other chronic liver conditions, such as NASH.

Injectable Administration

- We now have an open IND for an initial Phase 2 trial with an injectable formulation of DUR-928. We are currently finalizing the protocol based on detailed input received in October 2017 from our expert advisors during The Liver Meeting® (the annual meeting of the American Association for the Study of Liver Diseases or AASLD). This first study will be conducted in patients with moderate and severe acute liver function impairment to assess the safety and pharmacokinetics of several doses of DUR-928.
- At AASLD, a poster was presented by Dr. Shunlin Ren of Virginia Commonwealth University / McGuire VA Medical Center which included newly disclosed data from animal studies with DUR-928 in various acute organ injuries. One of the new disclosures was the dose-dependent effect of DUR-928 in stabilizing mitochondrial membranes, which is an important factor in cell viability and prevention of cell death. Previous results had been reported with DUR-928 in an acute animal model where the toxicity was caused by lipopolysaccharide (LPS); in this poster, similar results (i.e., 90% survival with DUR-928 vs. 10% survival on placebo) were shown when the toxicity was caused by injected acetaminophen. This poster also demonstrated the pharmacological effect of DUR-928 in animal models of both endotoxin and drug induced multiple organ injuries, including the liver, the kidney and the lungs. This poster is available at www.www.durect.com under Science and Technologies, Papers.

Topical Administration

- Based on promising results from a previous exploratory Phase 1b trial in psoriasis utilizing intralesional micro injections of DUR-928, we have developed topical formulations of DUR-928 and have recently completed GLP skin irritation / sensitization studies with the lead formulations in two species. We have had pre-IND interactions with the FDA and are incorporating FDA's comments in our upcoming IND while we are actively working with expert advisors to finalize our study protocol for a Phase 2 proof-of-concept study with topically applied DUR-928. We expect to initiate this study in the first half of 2018. We believe that there is a large market opportunity for new topical drugs for inflammatory skin diseases such as psoriasis and atopic dermatitis.

Indivior Agreement. 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 a New Drug Application (NDA) for RBP-7000 to the U.S. Food and Drug Administration (FDA) on September 28, 2017.

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 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 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 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. In October 2017, Pain Therapeutics announced that there is a pre-NDA guidance meeting with the FDA planned for November 14, 2017 and Pain Therapeutics is planning an NDA resubmission in the first quarter of 2018.

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 have started a process of contacting potential development and commercialization partners for major markets not licensed to Orient Pharma.

Upcoming investor conference. DURECT will be presenting at the Stifel 2017 Healthcare Conference at 11:45 am Eastern time on November 15. 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/stifel10/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 2017 results and provide a corporate update will be broadcast live over the internet at 4:30 p.m. Eastern Time on November 1 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 developing 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 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 and injectable delivery technologies are designed to enable new indications and enhanced attributes for small-molecule and biologic drugs. One 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 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 of Indivior's RBP-7000 investigational drug for schizophrenia, for which Indivior submitted an NDA on September 28, 2017. 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, RBP-7000, 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 potential future payments from Indivior, clinical trial plans for DUR-928, including the potential commencement of clinical trials in primary sclerosing cholangitis, moderate and severe acute liver function impairment, and psoriasis, 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, the potential use of RBP-7000 to treat schizophrenia, and the potential use of ORADUR-Methylphenidate ER to treat ADHD, potential markets for our product candidates, Indivior's plans for RBP-7000, 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 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 POSIMIR, or REMOXY ER, 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 inDURECT's Form 10-Q filed on August 9, 2017 under the heading "Risk Factors."

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

	Three months ended September 30		Nine months ended September 30	
	2017	2016	2017	2016
Collaborative research and development and other revenue	$ 5,602	$ 352	$ 7,304	$ 1,142
Product revenue, net	2,644	3,391	9,828	9,366
Revenue from sale of intellectual property rights	12,500	–	12,500	–
Total revenues	20,746	3,743	29,632	10,508
Operating expenses:				
Cost of product revenues	3,105	2,180	5,572	4,335
Research and development	8,378	6,805	25,005	21,282
Selling, general and administrative	3,138	3,043	9,862	8,993
Total operating expenses	14,621	12,028	40,439	34,610
Income (Loss) from operations	6,125	(8,285)	(10,807)	(24,102)
Other income (expense):				
Interest and other income	605	45	680	112
Interest and other expense	(619)	(592)	(1,803)	(1,708)
Net other expense	(14)	(547)	(1,123)	(1,596)
Net income (loss)	$ 6,111	$ (8,832)	$(11,930)	$(25,698)
Net income (loss) per share				
Basic	$ 0.04	$ (0.06)	$ (0.08)	$ (0.20)
Diluted	$ 0.04	$ (0.06)	$ (0.08)	$ (0.20)
Weighted-average shares used in computing net income (loss) per share				
Basic	147,213	137,933	143,873	130,990
Diluted	151,885	137,933	143,873	130,990
Total comprehensive income (loss)	$ 6,114	$ (8,836)	$(11,927)	$(25,678)

DURECT CORPORATION
CONDENSED BALANCE SHEETS
(in thousands)

	As of September 30, 2017 (unaudited)	As of December 31, 2016[1]
ASSETS		
Current assets:		
Cash and cash equivalents	$ 35,287	$ 5,404
Short-term investments	6,379	19,600
Accounts receivable	2,180	1,154
Inventories, net	3,155	3,782
Prepaid expenses and other current assets	2,877	2,486
Total current assets	49,878	32,426
Property and equipment, net	1,045	1,297
Goodwill	6,399	6,399
Long-term restricted Investments	150	150
Other long-term assets	282	236
Total assets	$ 57,754	$ 40,508
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		

Accounts payable	$ 2,058		$ 2,086
Accrued liabilities	5,718		5,060
Contract research liability	728		783
Deferred revenue, current portion	16,002		968
Term loan, current portion, net	5,276		19,853
Total current liabilities	29,782		28,750
Deferred revenue, noncurrent portion	1,140		1,879
Term loan, noncurrent portion, net	14,623		–
Other long-term liabilities	2,170		1,541
Stockholders' equity	10,039		8,338
Total liabilities and stockholders' equity	$ 57,754		$ 40,508

(1) Derived from audited financial statements.

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SOURCE DURECT Corporation

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