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

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

CUPERTINO, Calif., May 10, 2017 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced financial results for the three months ended March 31, 2017 and provided a corporate update.

- Total revenues were $4.6 million and net loss was $8.1 million for the three months ended March 31, 2017 as compared to total revenues of $3.6 million and net loss of $7.8 million for the three months ended March 31, 2016.
- Subsequent to the end of the first quarter, we signed an agreement with Sandoz AG pursuant to which we anticipate receiving a $20 million upfront license payment.
- At March 31, 2017, cash and investments were $16.8 million, compared to cash and investments of $25.2 million at December 31, 2016. Including the upfront license fee from Sandoz less a fee owed to an advisory firm, our pro forma cash and investments at March 31, 2017 would have been approximately $36.1 million. Debt at March 31, 2017 was $19.9 million.

“We are very pleased to have a company with the market presence and resources of Sandoz to commercialize POSIMIR® in the United States,” stated James E. Brown, D.V.M., President and CEO of DURECT. “Recent enrollment rates for PERSIST, the POSIMIR pivotal Phase 3 clinical trial in post-operative pain, are ahead of schedule and support completion of dosing in the second quarter of 2017, which would position us to announce top-line results in the fourth quarter of this year. We were also pleased to present at a major scientific meeting the results from our Phase 1b NASH study in which we observed promising decreases in certain cell death markers, an improvement of a key biomarker of liver function, and decreases in certain biomarkers associated with inflammation, in each case from a single oral dose of DUR-928, the lead molecule in our Epigenetic Regulator Program.”

Update on Selected Programs:

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 intended to deliver bupivacaine to provide up to 3 days of pain relief after surgery.

- In May 2017, we signed a development and commercialization agreement with Sandoz AG covering the United States. Under the terms of the agreement, Sandoz will make an upfront payment to DURECT of $20 million, with the potential for up to an additional $43 million in development and regulatory milestones, up to an additional $230 million in sales-based milestones, as well as a tiered double digit royalty on product sales in the United States. DURECT will remain responsible for the completion of the ongoing PERSIST Phase 3 clinical trial for POSIMIR as well as FDA interactions through approval. Closing of the transaction is anticipated to occur in the second quarter of 2017 and is contingent solely on the expiration or termination of the applicable waiting period under the Hart-Scott-Rodino (HSR) Antitrust Improvements Act of 1976.
- We expect to finish dosing patients in PERSIST, a POSIMIR Phase 3 clinical trial consisting of patients undergoing laparoscopic cholecystectomy (gallbladder removal) surgery, in the second quarter of 2017 and to have top-line results in the fourth quarter of this year.
- In a previous clinical trial of 50 patients in the same surgical model (laparoscopic cholecystectomy), POSIMIR was compared with the active control bupivacaine HCl, against which POSIMIR demonstrated in a post hoc analysis an approximately 25% reduction in pain intensity on movement for the first 3 days after surgery (p=0.024) and for the first 2 days after surgery (p=0.0198), using the same statistical methodology specified for the current trial. There can be no assurance that the PERSIST trial will replicate these results.

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 kidney injury, and in autoimmune/inflammatory skin disorders such as psoriasis.

Oral Administration

- Our first patient trial utilizing DUR-928 was an open-label, single-ascending-dose safety and pharmacokinetic (PK) Phase 1b trial in liver function impaired (NASH) patients and matched control subjects. This study was conducted in Australia, evaluating single-dose levels (first a low dose and then a high dose) of orally administered DUR-928 in successive cohorts. Twenty subjects with NASH and 12 matched control subjects received DUR-928.
- A poster reporting results from this study was presented at the International Liver Congress™ 2017 organized by the European Association for the Study of the Liver (EASL) in Amsterdam on April 22, 2017.
- Although this study was not designed to assess efficacy, we observed a dose dependent reduction of certain biomarkers after a single oral dose of DUR-928. There can be no assurance these results will be confirmed in larger controlled studies.
    - The mean decrease of full-length CK-18 (a generalized cell death marker) at 12 hours after dosing was 33% in the NASH patients in the low dose cohort and 41% in the high dose cohort.
    - The mean decrease of cleaved CK-18 (a cell apoptosis marker) at 12 hours was 37% in the NASH patients in the low dose cohort and 47% in the high dose cohort.
    - The mean decrease in total bilirubin (a liver function marker) at 12 hours in the NASH patients was 27% in the low dose cohort and 31% in the high dose cohort.
    - High sensitivity C-Reactive Protein (hsCRP), a marker of inflammation, trended higher at 12 hours in the NASH patients by 3% on average in the low dose cohort but trended lower by 12% on average in the high dose cohort.
    - IL-18, an inflammatory mediator implicated in both liver and kidney diseases, trended lower at 12 hours by 5% on average in both the low dose cohort and in the high dose cohort.
- A poster describing results from two STAM™ NASH mouse model studies was presented at the AASLD Emerging Trends Conference 2017: Emerging Trends in Non-alcoholic Fatty Liver Disease in Washington, DC on March 17, 2017.
- We are actively working towards a Phase 2 trial in primary sclerosing cholangitis (PSC), with orally administered DUR-928. PSC is a chronic liver disease characterized by a progression of cholestasis (decrease in bile flow) with inflammation and fibrosis of bile ducts. It is an orphan medical condition for which there is no established medical treatment.

Injectable Administration

- Our second Phase 1b study with DUR-928, also being conducted in Australia, is an open-label, single-ascending-dose safety and pharmacokinetic study in patients with impaired kidney function (stage 3 and 4 chronic kidney disease) and matched control subjects.
- This study is being conducted in successive cohorts evaluating single-dose levels (first a low dose and then a high dose) of DUR-928 administered by intramuscular injection. The low dose cohort consisted of 6 kidney function impaired patients and 3 matched control subjects.
- Data from the low dose cohort showed the PK parameters between the kidney function impaired patients and the matched control subjects were comparable. After a PK/safety review of this cohort, patients are now being enrolled in the high dose cohort, utilizing a dose four times larger than the low dose cohort. We expect to complete this study shortly.
- We are working closely with expert advisors to design Phase 2 trials in one or more indications with an injectable formulation of DUR-928.

Topical Administration

- As previously disclosed, we completed an exploratory Phase 1b trial in psoriasis patients (n = 9 evaluable patients) utilizing intradermal micro injections of DUR-928; promising activity was observed which we believe warrant further investigation.
- In the first quarter of 2017, we developed several topical formulations of DUR-928 that we are evaluating for a topical application microplaque psoriasis trial. We believe that there is a large unmet medical need for new topical drugs for inflammatory skin diseases such as psoriasis or atopic dermatitis for use prior to systemic biologic treatments which often have significant associated side effects.

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 September 2016, Pain Therapeutics (our licensee) received a Complete Response Letter from the FDA for REMOXY ER. Based on its review, the FDA has determined that the NDA cannot be approved in its present form and specifies additional actions and data that are needed for drug approval.
- 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 recent 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, after which it intends to have a pre-NDA meeting with the FDA followed by resubmission of the REMOXY NDA.

ORADUR-ADHD Program. ORADUR-Methylphenidate 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 completed dosing a Phase 3 study in Taiwan and anticipates obtaining top-line results from that study in the second quarter of 2017. We retain rights to all other markets in the world, notably including the U.S., Europe and Japan.

Earnings Conference Call

A live audio webcast of a conference call to discuss first quarter 2017 results and provide a corporate update will be broadcast live over the internet at 4:30 p.m. Eastern Time on May 10 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 actively developing new 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, injectable, and transdermal 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 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, REMOXY ER and ORADUR-Methylphenidate 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 the potential benefits and uses of our drug candidates, including the potential use of DUR-928 to treat NASH, other disorders of the liver, kidney diseases or psoriasis or other inflammatory conditions, the potential use of POSIMIR to treat pain, the potential abuse deterrent properties of REMOXY ER and the potential use of ORADUR-ADHD to treat ADHD, clinical trial plans for DUR-928, POSIMIR and our other product candidates (including timing and potential results), potential reporting of Phase 3 results for POSIMIR and ORADUR-methylphenidate, potential regulatory approvals of POSIMIR and REMOXY ER, potential markets for our product candidates, potential closing of the agreement with Sandoz for POSIMIR and potential payments under that agreement, and Pain Therapeutics' plans for REMOXY 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 do not demonstrate the safety or efficacy of DUR-928 in a statistically significant manner, that the PERSIST clinical trial of POSIMIR will take longer to conduct than anticipated or result in data that will not support a successful NDA resubmission or product approval, 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 or REMOXY ER, if approved, the risk of delays in the commencement, enrollment or completion of other

clinical trials, the risk that prior clinical trials (including prior trials of POSIMIR in laparoscopic cholecystectomy patients and 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 Orient Pharma will discontinue development of REMOXY ER or ORADUR-Methylphenidate, respectively, or be delayed in development or regulatory submissions, the risk that the Sandoz agreement for POSIMIR will not close or that future milestones under that agreement will not be achieved, the risk of adverse decisions by regulatory agencies or delays and additional costs due to requirements imposed by regulatory agencies, additional time and resources that may be required for development, testing and regulatory approval of 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 29, 2017 under the heading "Risk Factors."

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

	Three months ended March 31	
	2017	2016
Collaborative research and development and other revenue	$ 434	$ 419
Product revenue, net	4,133	3,189
Total revenues	4,567	3,608
Operating expenses:		
Cost of product revenues	1,543	1,242
Research and development	7,548	6,625
Selling, general and administrative	3,043	3,062
Total operating expenses	12,134	10,929
Loss from operations	(7,567)	(7,321)
Other income (expense):		
Interest and other income	36	27
Interest and other expense	(583)	(558)
Net other income (expense)	(547)	(531)
Net loss	$ (8,114)	$ (7,852)
Net loss per share		
Basic	$ (0.06)	$ (0.06)
Diluted	$ (0.06)	$ (0.06)
Weighted-average shares used in computing net loss per share		
Basic	141,815	122,149
Diluted	141,815	122,149
Total comprehensive loss	$ (8,116)	$ (7,835)

DURECT CORPORATION
CONDENSED BALANCE SHEETS
(in thousands)

	As of March 31, 2017 (unaudited)	As of December 31, 2016[1]
ASSETS		
Current assets:		
Cash and cash equivalents	$ 4,272	$ 5,404
Short-term investments	12,406	19,600
Accounts receivable	2,076	1,154
Inventories	3,462	3,782
Prepaid expenses and other current assets	2,905	2,486
Total current assets	25,121	32,426
Property and equipment, net	1,191	1,297
Goodwill	6,399	6,399
Long-term restricted Investments	150	150
Other long-term assets	236	236
Total assets	$ 33,097	$ 40,508
LIABILITIES AND STOCKHOLDERS' EQUITY		

Current liabilities:		
Accounts payable	$ 1,138	$ 2,086
Accrued liabilities	3,289	5,060
Contract research liability	787	783
Deferred revenue, current portion	1,016	968
Term loan, current portion, net	1,272	19,853
Total current liabilities	7,502	28,750
Deferred revenue, noncurrent portion	1,822	1,879
Term loan, noncurrent portion, net	18,597	–
Other long-term liabilities	1,929	1,541
Stockholders' equity	3,247	8,338
Total liabilities and stockholders' equity	$ 33,097	$ 40,508

(1) Derived from audited financial statements.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/durect-corporation-announces-first-quarter-2017-financial-results-and-provides-corporate-update-300455343.html

SOURCE DURECT Corporation

Matt Hogan, Chief Financial Officer, DURECT Corporation, 408-777-4936 or Matthew Duffy, Managing Director, LifeSci Advisors, 212-915-0685