DURECT Corporation Announces Second Quarter 2019 Financial Results and Update of Programs

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

CUPERTINO, Calif., Aug. 1, 2019 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced financial results for the three months ended June 30, 2019 and provided a corporate update.

- Total revenues were $4.0 million and net loss was $7.2 million for the three months ended June 30, 2019 as compared to total revenues of $3.4 million and net loss of $7.0 million for the three months ended June 30, 2018.
- At June 30, 2019, cash and investments were $38.1 million, compared to cash and investments of $34.5 million at December 31, 2018. Subsequent to the end of the quarter, in July DURECT received a $25 million payment from Gilead relating to an exclusive license agreement for DURECT's SABER® technology. Debt at June 30, 2019 was $20.8 million, which included partial accrual for the final payment of our term loan.

"The second quarter was very productive, with multiple important milestones achieved, including announcing compelling preliminary data from the first 10 alcoholic hepatitis (AH) patients, announcing that the preliminary data from the completed 90 mg severe cohort was consistent with the first 10 patients, and proceeding to the 150 mg severe cohort in the ongoing DUR-928 alcoholic hepatitis trial," stated James E. Brown, D.V.M., President and CEO of DURECT. "We also successfully submitted a full response to the POSIMIR® CRL seeking FDA approval, and received a user fee goal date for FDA response of December 27, 2019. In addition, in July we executed an exclusive license agreement with Gilead for a long-acting injectable HIV investigational product utilizing DURECT's SABER® technology, entailing an upfront fee of $25 million, up to $145 million in additional milestone payments plus royalties and an exclusive option to license additional SABER-based products directed to HIV and HBV for an additional$150 million per product in upfront and milestones plus royalties."

Update on Selected Programs and Transactions:

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 acute organ injuries such as AH and acute kidney injury (AKI), in chronic liver diseases such as non-alcoholic steatohepatitis (NASH), and in inflammatory skin disorders such as psoriasis and atopic dermatitis.

Clinical Trials

Alcoholic Hepatitis (AH)

- As reported on May 7 and 8, 2019 through a press release and key opinion leader conference call, preliminary clinical data from the first 10 AH patients dosed with DUR-928 demonstrated statistically significant reductions from baseline of serum bilirubin levels and MELD scores. Additionally, Lille scores in patients treated with DUR-928 were statistically lower than historical controls. DUR-928 was well tolerated and PK parameters were not affected by the severity of the disease.
- In June, we completed dosing the 90 mg cohort (n=4) in severe AH patients and, following approval by the Dose Escalation Committee (DEC), initiated dosing for the 150 mg cohort in severe AH patients. Preliminary data from the 90 mg severe cohort was consistent with the first 10 patients.
- We are now enrolling moderate AH patients in the 90 mg cohort and severe AH patients in the 150 mg cohort.
- About the AH Trial: DURECT is conducting a Phase 2a clinical trial with intravenously administered DUR-928 in patients with AH. This is an open label, dose escalation (30, 90 and 150 mg), multi-center U.S. study that includes patients with moderate and severe AH (as determined by initial MELD score). Dose escalation requires approval by the Dose Escalation Committee (DEC) following its review of safety and pharmacokinetic (PK) results from the prior dose level. The target number of patients for the study is 4 moderate and 4 severe per dose. The objectives of this study include assessment of safety, PK and pharmacodynamic (PD) signals, including liver chemistry, 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 03432260.

- In parallel with our ongoing trial, we are supporting Professor Craig McClain, MD (Chief of Research Affairs, Division of Gastroenterology, Hepatology and Nutrition, University of Louisville) in his efforts to initiate an NIH-funded study of DUR-928 in AH patients at the University of Louisville.
- 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 the U.S. in 2010, resulting in hospitalization costs of nearly $50,000 per patient. The cost of a liver transplant exceeds $800,000.

Non-Alcoholic Steatohepatitis (NASH)

- In March 2019, we began enrolling patients in a Phase 1b randomized and open-label clinical study being conducted in the U.S. to evaluate safety, pharmacokinetics and signals of biological activity of DUR-928 in NASH patients with stage 1-3 fibrosis. DUR-928 (at doses of 50 mg QD, 150 mg QD or 300 mg BID) is administered orally for 28 consecutive days with approximately 20 patients per dose group for a total of approximately 60 patients in the trial.
- Key endpoints include safety and PK, clinical chemistry and biomarkers (e.g., bilirubin, lipids, liver enzymes, CK-18s, and inflammatory cytokines) as well as liver imaging (e.g., MRI-PDFF).
- We expect to announce initial data from this study in the second half of 2019.
- In the Company's previous Phase 1b NASH study, reported at the European Association for the Study of the Liver (EASL) in April 2017, an exploratory biomarker analysis demonstrated that a single oral dose of DUR-928 in NASH patients, at both dose levels tested (50 mg and 200 mg), resulted in statistically significant reductions from baseline of both full-length and cleaved cytokeratin-18 (CK-18), bilirubin, hsCRP and IL-18.
- Non-alcoholic fatty liver disease (NAFLD) is the most common form of chronic liver disease in both children and adults. It is estimated that NAFLD affects about 30% to 40% of adults and 10% of children in the United States. NASH, a more severe and progressive form of NAFLD, is one of the most common chronic liver diseases worldwide, with an estimated prevalence of more than 10% of adults in the United States, Europe, Japan and other developed countries. No drug is currently approved for NAFLD or NASH.

Psoriasis

- We are conducting a Phase 2a, randomized, double-blind, vehicle-controlled proof-of-concept clinical trial, in which DUR-928 is applied topically once-daily for four weeks in patients with mild to moderate plaque psoriasis. The trial is being conducted at multiple clinical sites in the U.S. Twenty patients are planned to be enrolled to obtain approximately 15 evaluable patients. Patients serve as their own controls, applying DUR-928 to the plaque on one arm and the vehicle to a similar plaque on the other arm. After the treatment period, patients are followed for an additional four weeks. The primary efficacy endpoint is the change in local psoriasis scores from baseline in the DUR-928-treated plaques compared to that in the vehicle-treated plaques. Additional information on the trial design, including eligibility criteria and site locations, can be found at www.clinicaltrials.gov using the NCT Identifier 03837743.
- We began enrolling patients in March of 2019 and expect to announce top line data from this study in the second half of 2019.
- We previously conducted an exploratory Phase 1b trial in psoriasis patients (9 evaluable patients) in Australia. The trial was randomized, double-blinded, placebo and self-controlled, using a micro-plaque assay with intralesional injections of DUR-928. The results were encouraging and warranted advancing into the current proof-of-concept trial with topically applied DUR-928. In support of the Phase 2a study, we have completed multiple non-clinical safety studies for topically applied DUR-928.
- Psoriasis is an inflammatory skin disease and an immune-mediated condition that causes the body to make new skin cells in days rather than weeks. Psoriasis affects an estimated 7.5 million Americans. According to the International Federation of Psoriasis Associations (IFPA), nearly 3% of the world's population, or about 125 million people, has some form of psoriasis. Psoriasis causes itchiness and irritation and may be painful. There is no cure, but currently approved treatment can ease symptoms. Approximately 80% of patients with psoriasis have localized disease, which can be treated with topical therapies. As such, topical agents remain the mainstay of psoriasis treatment.

POSIMIR® (bupivacaine extended-release solution) 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.

- After a comprehensive review of the POSIMIR program in light of the issues raised by the FDA in our communications with them, including the Complete Response Letter (CRL), we prepared and submitted a full response to the CRL in late June 2019 intending to address the issues raised in the CRL and seeking FDA approval of POSIMIR.
- The FDA has agreed to file the submitted response to the CRL as a complete Class 2 Resubmission and assigned a user fee goal date of December 27, 2019.
- The effort to evaluate the program, develop a strategy for filing the response, and the actual writing of key sections of the response, has been under the direction of Dr. Lee Simon, who was formerly FDA's Division Director of Analgesic, Anti-inflammatory and Ophthalmologic Drug Products.
- We believe that the completed inguinal hernia and subacromial decompression (shoulder) clinical trials support the efficacy of POSIMIR in post-operative pain and meet the requirements to be considered as adequate and well-controlled pivotal clinical trials. Both trials demonstrated a significant decrease in pain and opioid use over the 0-72 hour period following surgery as compared to placebo.
- We have completed 16 clinical trials in the POSIMIR program, involving over 1,400 patients, over 850 of whom received POSIMIR with the remainder in control groups. We believe this is a sufficiently sized safety database. We believe that, with the PERSIST safety data from over 380 patients included, we now have sufficient data to address FDA's issues raised in the CRL and that the data package meets the requirements for FDA approval.
- POSIMIR has not been approved by the FDA for marketing in the U.S. for any indication and there can be no assurance that FDA will approve the planned submission described above.

Gilead Agreement. In July 2019, we entered into an agreement with Gilead Sciences, Inc. (Gilead) granting Gilead the exclusive worldwide rights to develop and commercialize a long-acting injectable HIV investigational product utilizing our SABER technology. Gilead also received exclusive access to the SABER platform for HIV and Hepatitis B Virus (HBV) and the exclusive option to license additional SABER-based products directed to HIV and HBV. Under the terms of the agreement, Gilead made an upfront payment to us of $25 million, with the potential for up to an additional $75 million in development and regulatory milestones, up to an additional $70 million in sales based milestones, as well as tiered royalties on product sales. Gilead has the exclusive option to license additional SABER-based products directed to HIV and HBV for an additional $150 million per product in upfront, development, regulatory and sales based milestones as well as tiered royalties on sales. The parties will collaborate on specified development activities with Gilead controlling and funding the development programs.

Indivior Agreement and PERSERIS™. In September 2017, we entered into a patent purchase agreement with an affiliate of Indivior PLC, whereby we assigned certain of our U.S. patent rights to Indivior. Under the terms of the agreement, Indivior paid us $12.5 million upfront and a $5 million milestone based on NDA approval of PERSERIS (risperidone) extended-release injectable suspension for the treatment of schizophrenia in adults. We also receive quarterly earn-out payments 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 into at least 2026.

- According to its public disclosures, Indivior has stated that:
  - The PERSERIS commercial launch took place in the last week of February 2019 with a field force of 50 representatives.
  - As of Indivior's July 31, 2019 update on the first half of 2019:
    - Net revenue was consistent with Indivior's expectations
    - Managed care coverage is over 70% nationally, which is at parity with established LAIs
    - Sales key performance indicators (KPIs) (reach and frequency) are on target
    - Continued positive patient and HCP feedback
  - Indivior previously announced a peak annual net revenue goal for PERSERIS of $200 to $300 million.
- U.S. sales of long acting injectables to treat schizophrenia were in excess of $3 billion in 2017.
- Full prescribing information for PERSERIS, including BOXED WARNING, and Medication Guide can be found at www.perseris.com.

Financing. In June 2019, we raised net proceeds of approximately $15.0 million in a registered offering of the Company's common stock.

Earnings Conference Call

We will host a conference call today at 4:30 p.m. Eastern Time/1:30 p.m. Pacific Time to discuss second quarter 2019 results and provide a corporate update:

Toll Free:	877-407-0784
International:	201-689-8560
Conference ID:	13692344
Webcast:	http://public.viavid.com/index.php?id=135202

A live audio webcast of the presentation will be also available by accessing DURECT's homepage at www.www.durect.com and clicking "Investors." If you are unable to participate during the live webcast, the call will be archived on DURECT's website under "Event Calendar" in the "Investors" 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) and acute kidney injury (AKI), chronic hepatic diseases such as nonalcoholic steatohepatitis (NASH), 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. Key product candidates in this category include POSIMIR® (bupivacaine extended-release solution), an investigational locally-acting, non-opioid analgesic intended to provide up to 3 days of continuous pain relief after surgery, a long-acting injectable SABER-based HIV investigational product being developed with Gilead, and ORADUR™-Methylphenidate ER Capsules, approved as Methydur Sustained Release Capsules in Taiwan, where it is indicated for the treatment of attention deficit hyperactivity disorder (ADHD). In addition, for the assignment of certain patent rights, DURECT receives single digit sales-based earn-out payments from U.S. net sales of Indivior's PERSERIS™ (risperidone) drug for schizophrenia, which was commercially launched in February 2019. In July 2019 we executed an exclusive license agreement with Gilead for a long-acting injectable HIV investigational product utilizing DURECT's SABER® technology, entailing an upfront fee of $25 million, up to $145 in additional milestone payments plus tiered royalties and an exclusive option to license additional SABER-based products directed to HIV and HBV for an additional $150 million per product in upfront and milestones plus royalties. For more information about DURECT, 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 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 the potential benefits and uses of DURECT's drug candidates, including, but not limited to, the potential use of DUR-928 to treat alcoholic hepatitis, hepatic and renal diseases such as NASH, and inflammatory skin conditions such as psoriasis and atopic dermatitis, the potential use of POSIMIR to treat post-operative pain, the potential of the long-acting injectable SABER-based investigational product being developed with Gilead to treat HIV, the potential use of ORADUR-Methylphenidate to treat ADHD, the potential for sales-based earn-out payments from the sale of Indivior's PERSERIS to treat schizophrenia, and the potential development of a long-acting injectable SABER-based HIV product with Gilead and associated potential payments to DURECT 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 possibility that studies of DUR-928 will not replicate results from earlier preclinical or clinical trials, the risks that PERSERIS will not obtain market acceptance and meaningful sales, as well as possible adverse events associated with the use of PERSERIS, POSIMIR, ORADUR-Methylphenidate, the long-acting injectable SABER-based HIV investigational product being developed with Gilead, and DUR-928, and delays and costs due to additional work or other requirements imposed by regulatory agencies for continued development, approval or sale of POSIMIR, the long-acting injectable SABER-based HIV investigational product being developed with Gilead, ORADUR-Methylphenidate and DUR-928. Further information regarding these and other risks related to DURECT is included in DURECT's Form 10-Q filed on May 8, 2019 under the heading "Risk Factors."

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

	Three months ended June 30		Six months ended June 30	
	2019	2018	2019	2018
Collaborative research and development and other revenue	$ 1,639	$ 645	$ 3,139	$ 1,741
Product revenue, net	2,346	2,768	4,977	5,160

	Total revenues	3,985	3,413	8,116	6,901
Operating expenses:					
	Cost of product revenues	879	1,084	2,015	2,258
	Research and development	6,598	6,120	12,849	13,072
	Selling, general and administrative	3,278	2,816	6,732	6,010
Total operating expenses		10,755	10,020	21,596	21,340
Loss from operations		(6,770)	(6,607)	(13,480)	(14,439)
Other income (expense):					
	Interest and other income	177	240	386	398
	Interest and other expense	(634)	(644)	(1,263)	(1,267)
Net other expense		(457)	(404)	(877)	(869)
Net loss		$ (7,227)	$ (7,011)	$ (14,357)	$ (15,308)
Net loss per share					
	Basic	$ (0.04)	$ (0.04)	$ (0.09)	$ (0.10)
	Diluted	$ (0.04)	$ (0.04)	$ (0.09)	$ (0.10)
Weighted-average shares used in computing net loss per share					
	Basic	164,359	161,621	163,219	157,612
	Diluted	164,359	161,621	163,219	157,612
Total comprehensive loss		$ (7,230)	$ (7,010)	$ (14,364)	$ (15,307)

DURECT CORPORATION
CONDENSED BALANCE SHEETS
(in thousands)

	As of June 30, 2019 (unaudited)	As of December 31, 2018[1]
ASSETS		
Current assets:		
Cash and cash equivalents	$ 36,943	$ 31,644
Short-term investments	996	2,671
Accounts receivable	2,142	1,757
Inventories, net	3,665	3,421
Prepaid expenses and other current assets	1,336	2,247
Total current assets	45,082	41,740
Property and equipment, net	533	605
Operating lease right-of-use assets	6,717	–
Goodwill	6,399	6,399
Long-term restricted Investments	150	150
Other long-term assets	1,106	1,105
Total assets	$ 59,987	$ 49,999
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,012	$ 1,589
Accrued liabilities	4,377	4,668
Contract research liability	1,204	1,405
Term loan, current portion, net	972	–
Operating lease liabilities, current portion	2,014	–
Total current liabilities	10,579	7,662
Deferred revenue, noncurrent portion	812	812
Operating lease liabilities, noncurrent portion	5,143	–
Term loan, noncurrent portion, net	19,838	20,533
Other long-term liabilities	721	992
Stockholders' equity	22,894	20,000
Total liabilities and stockholders' equity	$ 59,987	$ 49,999

(1) Derived from audited financial statements.

View original content:http://www.prnewswire.com/news-releases/durect-corporation-announces-second-quarter-2019-financial-results-and-update-of-programs-300895291.html

SOURCE DURECT Corporation

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