DURECT Corporation Announces Third Quarter 2020 Financial Results and Update of Programs

Webcast of Earnings Call Today, November 2nd at 4:30 p.m. ET

CUPERTINO, Calif., Nov. 2, 2020 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced financial results for the three months ended September 30, 2020 and provided a corporate update.

- Total revenues were $2.7 million and net loss was $9.3 million for the three months ended September 30, 2020 as compared to total revenues of $10.8 million and net loss of $2.0 million for the three months ended September 30, 2019.
- At September 30, 2020, cash and investments were $49.8 million, compared to cash and investments of $51.3 million at June 30, 2020 and $64.8 million at December 31, 2019. Debt at September 30, 2020 was $20.7 million, compared to $20.3 million at December 31, 2019.

“We are pleased with the progress made in our development of DUR-928 for the indications of Alcoholic Hepatitis, COVID-19 and NASH,” stated James E. Brown, D.V.M, President and CEO of DURECT. “We expect dosing to begin shortly in AHFIRM, our Phase 2b clinical trial evaluating the potential life-saving capacity of DUR-928 in patients with severe Alcoholic Hepatitis. We initiated dosing in our Phase 2a trial of DUR-928 in COVID-19 patients in September and also will be presenting additional data from our Phase 1b NASH trial at The Liver Meeting Digital Experience™ 2020 in mid-November. We have had continuing correspondence with the FDA regarding the POSIMIR NDA and believe they are making progress with their review. And last but not least, we are excited to welcome Dr. Norman Sussman as our Chief Medical Officer.”

Update on Selected Programs:

Epigenetic Regulator Program. DUR-928, the lead product candidate in the Company’s Epigenetic Regulator Program, is an endogenous, orally bioavailable, first-in-class small molecule, which may have broad applicability in acute organ injuries such as alcoholic hepatitis (AH) and coronavirus disease 2019 (COVID-19) patients with acute liver or kidney injury as well as in chronic liver diseases such as non-alcoholic steatohepatitis (NASH).

Clinical Development

Alcoholic Hepatitis (AH)

- We expect to begin dosing soon in our Phase 2b study in subjects with severe acute **A**lcoholic **H**epatitis to evaluate safety and ef**FI**cacy of DU**R**-928 treat**M**ent **(AHFIRM)**. AHFIRM is a randomized, double-blind, placebo-controlled, international, multi-center Phase 2b study to evaluate the safety and efficacy of DUR-928 in approximately 300 patients with severe AH. The study will be comprised of three arms of approximately 100 patients each: (1) DUR-928 (30 mg); (2) DUR-928 (90 mg); and (3) Placebo plus standard of care (SOC). SOC may include the use of methylprednisolone, a corticosteroid, at the discretion of the treating physician. Patients will receive an intravenous (IV) dose of DUR-928 or placebo (sterile water) on day 1 and a second IV dose on day 4 if they are still hospitalized. The primary outcome measure will be 90-day survival rate for patients treated with DUR-928 compared to those treated with placebo plus SOC. Secondary endpoints include 28-day survival, the rate of adverse events, Lille and MELD (prognostic scores) and time in the intensive care unit. The Company is targeting 40-45 clinical trial sites in the US and Europe.
- Given the high mortality rate in severe AH patients and the absence of an approved therapeutic, demonstration of a robust survival benefit in the AHFIRM trial may support an NDA filing.
- During 2019, we completed a Phase 2a clinical trial of DUR-928 in patients with AH. All 19 patients treated with DUR-928 survived the 28-day follow-up period, 74% of patients (14/19) were discharged in ? 4 days after receiving a single dose of DUR-928, and there were no drug-related serious adverse events.
- AH is an acute form of alcoholic liver disease (ALD) associated with long-term heavy intake of alcohol, and often occurs after a recent period of increased alcohol consumption. AH is typically characterized by a recent onset of jaundice and hepatic failure. According to the most recent data provided by the Agency for Healthcare Research and Quality (AHRQ), a part of the US Department of Health and Human Services

(HHS), there were over 122,000 hospitalizations for patients with AH in 2017. From a recent publication analyzing the mortality and costs associated with AH, the cost per patient is estimated at over $50,000 in the first year. ALD is one of the leading causes of liver transplants in the U.S., costing over $800,000 per patient. An analysis of 77 studies published between 1971 and 2016, which included data from a total of 8,184 patients, showed the overall mortality from AH was 26% at 28 days, 29% at 90 days and 44% at 180 days after admission.

Non-Alcoholic Steatohepatitis (NASH)

- In May 2020, we reported positive topline results from a Phase 1b randomized and open-label clinical study conducted in the U.S. to evaluate safety, pharmacokinetics and signals of biological activity (including clinical chemistry and biomarkers as well as liver fat content and liver stiffness by imaging) of DUR-928 in NASH patients with stage 1-3 fibrosis. A total of 65 patients completed the study. DUR-928 was orally administered daily at 50 mg (n=23), 150 mg (n=21), or 600 mg (300 mg BID (n=21)) for 4 weeks. At the end of dosing, patients were followed up for an additional 4 weeks.
- Reductions from baseline (pre-treatment) levels were seen in liver enzymes, liver stiffness as measured by imaging, and serum lipids. Many of these reductions were statistically significant. The Company believes that these results , i.e., multiple important parameters moving in the same desirable direction, especially given the short treatment course of four weeks, is a promising indication of DUR-928's potential in NASH.
- DUR-928 was well tolerated at all three doses evaluated. There were no serious adverse events reported during the study. Pharmacokinetic (PK) parameters after repeat dosing were comparable to those after a single dose (from a prior study), indicating no accumulation after repeat dosing.
- Additional results, including biomarker data, will be presented through a poster at The Liver Meeting Digital Experience™ 2020 being held November 13-16, 2020.
- 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 approximately 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 3-5% globally. No drug is currently approved for NAFLD or NASH.

COVID-19

- We have initiated dosing in a randomized, double-blind, placebo-controlled, multi-center Phase 2 study to evaluate the safety and efficacy of DUR-928 in hospitalized COVID-19 patients with acute liver or kidney injury.
- A total of approximately 80 patients are planned to be enrolled into two study treatment groups in a 3:1 (DUR-928: placebo) ratio. Patients will receive a dose of 150 mg of DUR-928 or placebo by intravenous infusion on day 1 and day 4 in combination with standard of care therapy, which will be determined by the principal investigator (PI) at each clinical trial site. The primary efficacy endpoint is a composite of survival and being free of acute organ failure (free of mechanical ventilation, free of liver failure events and free of renal replacement therapy) at day 28. Patients will be followed for 60 days. Any drug product(s) determined by the FDA to be safe and effective for the treatment of COVID-19 while the trial is ongoing may be offered, at each PI's discretion, to any remaining and future patients in this trial.
- COVID-19 is an infectious disease caused by severe acute respiratory syndrome coronavirus (SARS-COV-2). The rapid spread of the disease has resulted in a pandemic with millions of confirmed cases and over one million deaths worldwide. While most cases result in mild symptoms, including fever, cough and shortness of breath, some rapidly progress into acute respiratory distress syndrome (ARDS), multi-organ failure, and death. Many of these patients experience severe systemic inflammation that results in acute injuries in multiple organs including the liver and/or the kidney. Organ injury may also occur in hospitalized COVID-19 patients as the result of other complications of the viral infection. In a study of 1,059 adult cases of confirmed hospitalized COVID-19, 62% of patients presented with at least one elevated liver enzyme. In another study, 36.6% of 5,449 patients admitted with COVID-19 had or developed acute kidney injury (AKI).

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

- We have continued to communicate with the FDA regarding their review of the POSIMIR NDA and believe they are making progress on their review.

Methydur® Sustained Release Capsules (ORADUR®-Methylphenidate). Our partner, Orient Pharma, has informed us that they launched Methydur Sustained Release Capsules commercially in Taiwan in September 2020.

Conference Call
We will host a conference call today at 4:30 p.m. Eastern Time / 1:30 p.m. Pacific Time to discuss third quarter 2020 results and provide a corporate update:

Monday, November 2 @ 4:30 p.m. Eastern Time / 1:30 p.m. Pacific Time

Toll Free:	877-407-0784
International:	201-689-8560
Conference ID:	13706541
Webcast:	http://public.viavid.com/index.php?id=140595

The conference call will also be available by webcast on DURECT's homepage at www.www.durect.com under the "Investors" tab. If you are unable to participate during the 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 committed to transforming the treatment of acute organ injury and chronic liver diseases by advancing novel and potentially lifesaving therapies based on its endogenous epigenetic regulator program. DURECT's lead candidate, DUR-928 is an endogenous sulfated oxysterol and an epigenetic regulator. It represents a new class of therapeutics with a unique mechanism of action. DUR-928 epigenetically modulates the expression of multiple clusters of master genes that are involved in many important cell signaling pathways, through which it stabilizes mitochondria, reduces lipotoxicity, regulates inflammatory or stress responses, and promotes cell survival. This drug candidate is currently in Phase 2 development for the treatment of alcoholic hepatitis (AH) and the treatment of COVID-19 patients with acute liver or kidney injury as well as Phase 1 development for the treatment of nonalcoholic steatohepatitis (NASH). DURECT's proprietary drug 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® (bupivacaine extended-release solution), an investigational locally-acting, non-opioid analgesic intended to provide up to three days of continuous pain relief after surgery. For more information aboutDURECT, please visit www.www.durect.com.

DURECT Forward-Looking Statement

The statements in this press release regarding clinical development and plans for DUR-928, including plans to begin dosing soon in our Phase 2b study in subjects with acute Alcoholic Hepatitis, announce further data from the Phase 1b NASH trial, and to enroll patents in a Phase 2 study in hospitalized COVID-19 infected patients with acute liver or kidney injury, potential regulatory approval of POSIMIR, and the potential benefits and uses of our drug candidates, including the potential use of DUR-928 to treat acute organ injuries such as AH, COVID-19 patients with acute liver or kidney injury as well as chronic liver diseases such as NASH, 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, do not generate similar positive results as generated in earlier clinical or pre-clinical trials, or do not demonstrate the safety or efficacy of DUR-928 in a statistically significant manner, the risk that the AHFIRM trial does not support NDA filing, the risk that the FDA will not approve POSIMIR or will require a commercially limiting label, the risk of disruptions to our business operations resulting from the COVID-19 pandemic, the risk that additional time and resources 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 4, 2020 under the heading "Risk Factors."

NOTE: POSIMIR® and SABER® are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners. DUR-928 and POSIMIR are investigational drug candidates under development and have not been approved for commercialization by the U.S. Food and Drug Administration or other health authorities for any indication. Methydur Sustained Release Capsules have not been approved for commercialization by the U.S. Food and Drug Administration or other health authorities other than in Taiwan for any indication.

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

	Three months ended September 30		Nine months ended September 30	
	2020	2019	2020	2019
Collaborative research and development and other revenue	$ 306	$ 7,741	$23,623	$ 10,880
Product revenue, net	2,377	3,022	7,679	7,999
Total revenues	2,683	10,763	31,302	18,879
Operating expenses:				
Cost of product revenues	1,065	731	3,261	2,746
Research and development	7,009	7,906	21,412	20,755
Selling, general and administrative	3,479	3,837	10,358	10,569
Total operating expenses	11,553	12,474	35,031	34,070
Loss from operations	(8,870)	(1,711)	(3,729)	(15,191)
Other income (expense):				
Interest and other income	84	350	477	736
Interest and other expense	(546)	(629)	(1,690)	(1,892)
Net other expense	(462)	(279)	(1,213)	(1,156)
Net loss	$ (9,332)	$ (1,990)	$ (4,942)	$(16,347)
Net loss per share				
Basic	$ (0.05)	$ (0.01)	$ (0.02)	$ (0.09)
Diluted	$ (0.05)	$ (0.01)	$ (0.02)	$ (0.09)
Weighted-average shares used in computing net loss per share				
Basic	201,877	192,039	198,176	172,939
Diluted	201,877	192,039	198,176	172,939
Total comprehensive loss	$ (9,385)	$ (1,981)	$ (4,921)	$(16,345)

DURECT CORPORATION
CONDENSED BALANCE SHEETS
(in thousands)

	As of September 30, 2020 (unaudited)	As of December 31, 2019[1]
ASSETS		
Current assets:		
Cash and cash equivalents	$ 18,670	$ 34,924
Short-term investments	29,943	29,750
Accounts receivable	1,492	2,313
Inventories, net	3,628	3,383
Prepaid expenses and other current assets	3,134	1,459
Total current assets	56,867	71,829
Property and equipment, net	430	469
Operating lease right-of-use assets	5,048	6,066
Goodwill	6,399	6,399
Long-term investments	1,000	–
Long-term restricted Investments	150	150
Other long-term assets	261	1,107
Total assets	$ 70,155	$ 86,020
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,106	$ 2,109
Accrued liabilities	4,665	6,284

Contract research liability	1,746	3,653
Deferred revenue, current portion	–	22,679
Operating lease liabilities, current portion	2,039	2,043
Total current liabilities	9,556	36,768
Deferred revenue, noncurrent portion	812	812
Operating lease liabilities, noncurrent portion	3,508	4,517
Term loan, noncurrent portion, net	20,679	20,262
Other long-term liabilities	902	801
Stockholders' equity	34,698	22,860
Total liabilities and stockholders' equity	$ 70,155	$ 86,020

(1) Derived from audited financial statements.

View original content:http://www.prnewswire.com/news-releases/durect-corporation-announces-third-quarter-2020-financial-results-and-update-of-programs-301165195.html

SOURCE DURECT Corporation

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