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

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

CUPERTINO, Calif., Nov. 4, 2019 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced financial results for the three months ended September 30, 2019 and provided a corporate update.

- Total revenues were $10.8 million and net loss was $2.0 million for the three months ended September 30, 2019 as compared to total revenues of $8.0 million and net loss of $2.7 million for the three months ended September 30, 2018.
- At September 30, 2019, cash and investments were $57.1 million, compared to cash and investments of $34.5 million at December 31, 2018. In September, DURECT earned a $10 million milestone under its agreement with Gilead; payment of the milestone was received in October and is therefore not reflected in the cash and investments figure as ofSeptember 30, 2019. Debt at September 30, 2019 was $21.0 million, which included partial accrual for the final payment of our term loan.

“Recent progress continues on both our proprietary and partnered clinical development programs, led by the completion of the DUR-928 Phase 2a alcoholic hepatitis study. The strength of the data from this study is underscored by its selection as an oral late-breaking presentation and for inclusion in the ‘Best of The Liver Meeting’ summary slide deck at the upcoming Liver Meeting® 2019,” stated James E. Brown, D.V.M., President and CEO of DURECT. “In addition, we completed enrollment in the DUR-928 psoriasis trial and passed the half way point for enrollment in the DUR-928 NASH trial. In September we earned a$10 million development milestone under our exclusive license agreement with Gilead for a long-acting injectable HIV investigational product utilizing DURECT’s SABER® technology.”

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 alcoholic hepatitis (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)

- We completed the Phase 2a clinical trial of DUR-928 in patients with alcoholic hepatitis (AH). The final enrollment for the trial consists of 12 severe patients (Model for End-Stage Liver Disease (MELD) 21-30) and 7 moderate patients (MELD 11-20) for a total of 19 AH patients. After being discharged on day 2, one patient did not return for the scheduled day 7 and day 28 follow up visits; therefore Lille, bilirubin and MELD data reported below are based on 18 patients. Patients treated with DUR-928 had statistically significant reductions from baseline in bilirubin (day 7 and 28) and MELD (day 28), as well as statistically significantly lower Lille scores, compared with a historical control group (n=15) from a University of Louisville (UL) AH study[1]. All 19 patients treated with DUR-928 survived the 28-day follow-up period.
- The study results have been selected for an oral presentation as part of the late-breaking session ofThe Liver Meeting® 2019. Additionally, the results have been selected for inclusion in the ‘Best of The Liver Meeting’ summary slide deck in the alcohol-related liver disease category.
- Tarek Hassanein, M.D., one of the trial’s principal investigators, will deliver the oral late-breaking presentation detailing trial results.

Oral Late-Breaking Presentation Details:	
Title:	Safety and Efficacy of DUR-928: A Potential New Therapy for Acute Alcoholic Hepatitis

Date:	Tuesday, November 12, 2019
Time:	8:30 a.m. Eastern Time
Location:	Auditorium, Hynes Convention Center
Session Title:	Late-Breaking Abstract Oral Session II
Presentation Type:	Oral, Late-Breaking Session
Publication Number:	LO9

- In a separate poster presentation, Craig McClain, M.D., will present additional comparative data from the Phase 2a clinical trial of DUR-928 and a control group from a contemporaneous AH trial conducted at University of Louisville.

Poster Presentation Details:	
Title:	DUR-928 Therapy of Acute Alcoholic Hepatitis: A Pilot Study
Date:	Sunday, November 10, 2019
Time:	12:00 – 2:00 p.m. Eastern Time
Presentation Type:	Poster Presentation
Location:	Hynes Convention Center, Hall B
Publication Number:	1376

- Lille scores are used in clinical practice to help determine the prognosis and response for AH patients after 7 days of treatment. The lower the Lille score, the better the prognosis is for the AH patient. Patients with a Lille score below 0.45 have a 6-month survival rate of 85% vs. those with Lille scores of above 0.45, who have only a 25% 6-month survival rate (Louvet A et al. Hepatology 2007; 45: 1348-54). In our study, the median Lille score for the AH patients treated with DUR-928 was 0.10. 89% (16/18) had a Lille score below 0.45. The median Lille score among the UL cohort of 15 patients treated with either supportive care or supportive care with corticosteroids was 0.41, with 53% (8/15) having a Lille score below 0.45.
- DUR-928 was well tolerated in all patients, with no drug-related serious adverse events reported at any dose level. Drug exposures were dose proportional and were not affected by the severity of the disease.
- About the AH trial: Patients with moderate and severe AH were treated with intravenously administered DUR-928 in this open label, dose escalation multi-center U.S., Phase 2a clinical trial. Final enrollment was 19 patients comprised of: 8 patients (4 moderate and 4 severe) dosed at 30 mg, 7 patients (3 moderate and 4 severe) dosed at 90 mg and 4 patients (4 severe) dosed at 150 mg. The objectives of this study included assessment of safety, PK and pharmacodynamic (PD) signals, including liver biochemistry, biomarkers, and prognostic scores, including the Lille score, following DUR-928 treatment.
- 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 recent onset jaundice and hepatic failure (*Journal of Hepatology 2019, vol. 70; 314-318*). 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 (*PLOS ONE | https://doi.org/10.1371/journal.pone.0192393, February 14, 2018*). 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 117,000 hospitalizations for patients with alcoholic hepatitis in 2016. From a recent publication analyzing the mortality and costs associated with alcoholic hepatitis, the cost per patient is estimated at over $50,000 in the first year (*Alcohol 2018:71:57-63).* ALD is one of the leading causes of liver transplants in the US, each of which cost over $800,000.

Non-Alcoholic Steatohepatitis (NASH)

- We have enrolled over half of the expected 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 (targeting 15 evaluable) for a total of approximately 60 patients in the trial.
- Key endpoints include safety, PK, and signals of biological activities, including clinical chemistry and biomarkers as well as liver fat content by imaging.
- We expect to complete the study in the first half of 2020 and announce top-line study results following completion of the trial.

Psoriasis

- We have completed enrollment in 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. Over twenty patients have been enrolled with the goal of obtaining approximately 15 evaluable patients. Each patient serves as their own control, applying DUR-928 to the plaque on one arm and the vehicle (placebo) 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 the vehicle-treated plaques.
- We expect to announce top line data from this study by the end of 2019.

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.

- In July 2019, the FDA agreed to file the submitted response to the Complete Response Letter (CRL) as a complete Class 2 Resubmission and initially assigned a user fee goal date of December 27, 2019. The FDA subsequently has tentatively scheduled an Advisory Committee meeting for January 16, 2020; a new user fee goal date has not been assigned.
- The effort to evaluate the program, develop a strategy for filing the response, and preparing 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. Dr. Simon is also leading our preparation efforts for the Advisory Committee meeting.

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. In September 2019, we earned the first $10 million milestone payment under this program, which was received in the fourth quarter of 2019. 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.

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 third quarter 2019 results and provide a corporate update:

Toll Free:	877-407-0784
International:	201-689-8560
Conference ID:	13695661
Webcast:	http://public.viavid.com/index.php?id=136610

A live audio webcast of the presentation will also be 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 andproprietary drug delivery platforms. DUR?928, a new chemical entity in Phase 2 development, is the lead candidate inDURECT'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 AH and acute kidney injury (AKI), chronic hepatic diseases such as 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, and a long-acting injectable SABER-based HIV investigational product being developed with Gilead. For more information about DURECT, please visit www.www.durect.com.

NOTE: 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 the potential benefits and uses of DURECT's drug candidates, including, but not limited to, the potential use of DUR-928 to treat AH, hepatic and renal diseases such as NASH and AKI, and inflammatory skin conditions such as psoriasis and atopic dermatitis, the potential use of POSIMIR to treat post-operative pain, planned clinical trial announcements for the Phase 2a trial of DUR-928 in psoriasis in 2019 or for the Phase 1b trial in patients with NASH following anticipated trial completion in 2020, 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 risk of delays in clinical trials or adverse safety events from patients administered with DUR-928, the risk that the ongoing clinical trials of DUR-928 in NASH or psoriasis do not successfully achieve their endpoints, the risk that placebo controlled studies of DUR-928 required for regulatory approval will not replicate results from open label clinical trials or trials with small numbers of patients or historical controls, the risks that the long-acting injectable SABER-based HIV investigational product being developed with Gilead will not succeed or that Gilead will abandon this program, the risk that theFDA Advisory Committee will not recommend approval of POSIMIR or that the FDA will not approve POSIMIR, and the risk of delays and costs due to additional work or other requirements imposed by regulatory agencies for continued development, approval or sale of any of our product candidates. Further information regarding these and other risks related to DURECT is included in DURECT's Form 10-Q filed on August 2, 2019 under the heading "Risk Factors" and in subsequent reports that we file with the Securities and Exchange Commission.

[1] Our advisor, Dr. Craig McClain from the University of Louisville (UL), shared anonymized data from his study, in which 15 AH patients with initial MELD scores ranging from 15-30 received either supportive care alone (n=8) or supportive care with corticosteroids (n=7).

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

	Three months ended September 30		Nine months ended September 30	
	2019	2018	2019	2018
Collaborative research and development and other revenue	$ 7,741	$ 5,691	$ 10,880	$ 7,432
Product revenue, net	3,022	2,345	7,999	7,505
Total revenues	10,763	8,036	18,879	14,937
Operating expenses:				
Cost of product revenues	731	912	2,746	3,170
Research and development	7,906	6,542	20,755	19,614
Selling, general and administrative	3,837	2,870	10,569	8,880
Total operating expenses	12,474	10,324	34,070	31,664
Loss from operations	(1,711)	(2,288)	(15,191)	(16,727)
Other income (expense):				
Interest and other income	350	234	736	632

	Interest and other expense	(629)	(661)	(1,892)	(1,928)
Net other expense		(279)	(427)	(1,156)	(1,296)
Net loss		$ (1,990)	$ (2,715)	$(16,347)	$(18,023)
Net loss per share					
	Basic	$ (0.01)	$ (0.02)	$ (0.09)	$ (0.11)
	Diluted	$ (0.01)	$ (0.02)	$ (0.09)	$ (0.11)
Weighted-average shares used in computing net loss per share					
	Basic	192,039	162,002	172,939	159,091
	Diluted	192,039	162,002	172,939	159,091
Total comprehensive loss		$ (1,981)	$ (2,715)	$(16,345)	$(18,022)

DURECT CORPORATION
CONDENSED BALANCE SHEETS
(in thousands)

	As of September 30, 2019 (unaudited)	As of December 31, 2018(1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 39,726	$ 31,644
Short-term investments	17,235	2,671
Accounts receivable	12,193	1,757
Inventories, net	3,618	3,421
Prepaid expenses and other current assets	970	2,247
Total current assets	73,742	41,740
Property and equipment, net	462	605
Operating lease right-of-use assets	6,397	–
Goodwill	6,399	6,399
Long-term restricted Investments	150	150
Other long-term assets	1,107	1,105
Total assets	$ 88,257	$ 49,999
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,501	$ 1,589
Accrued liabilities	4,512	4,668
Contract research liability	2,089	1,405
Deferred revenue, current portion	27,582	–
Term loan, current portion, net	2,981	–
Operating lease liabilities, current portion	2,028	–
Total current liabilities	40,693	7,662
Deferred revenue, noncurrent portion	2,033	812
Operating lease liabilities, noncurrent portion	4,836	–
Term loan, noncurrent portion, net	17,970	20,533
Other long-term liabilities	719	992
Stockholders' equity	22,006	20,000
Total liabilities and stockholders' equity	$ 88,257	$ 49,999

(1) Derived from audited financial statements.

View original content:http://www.prnewswire.com/news-releases/durect-corporation-announces-third-quarter-2019-financial-results-and-update-of-programs-300950989.html

SOURCE DURECT Corporation

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