DURECT Corporation Announces Fourth Quarter and Full Year 2019 Financial Results and Update of Programs

Fourth Quarter Highlighted by Presentation of Positive DUR-928 Phase 2a Alcoholic Hepatitis Data at the Liver Meeting® 2019

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

CUPERTINO, Calif., March 3, 2020 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced financial results for the three months and year ended December 31, 2019 and provided a corporate update.

- Total revenues were $10.7 million and net loss was $4.2 million for the three months ended December 31, 2019 as compared to total revenues of $3.6 million and net loss of $7.3 million for the three months ended December 31, 2018.
- Total revenues were $29.6 million and net loss was $20.6 million for the year ended December 31, 2019, compared to total revenues of $18.6 million and net loss of $25.3 million for the year ended December 31, 2018.
- At December 31, 2019, cash and investments were $64.8 million, compared to cash and investments of $34.5 million at December 31, 2018.
  Debt at December 31, 2019 was $20.3 million, compared to $20.5 million at December 31, 2018.

“The highlight of the year for DURECT in 2019 was achieving positive results from our DUR-928 Phase 2a alcoholic hepatitis (AH) study, which were featured in multiple presentations at the Liver Meeting® 2019, including a late-breaking oral presentation by Dr. Tarek Hassanein,” stated James E. Brown, D.V.M., President and CEO of DURECT. “In addition, we have already exceeded our 60 patient enrollment target in the ongoing NASH trial, and the last patient is scheduled to begin the 28-day dosing period next week. We are on track to announce top-line NASH data mid-year. We are also making steady progress toward starting a Phase 2b AH clinical trial by mid-year. In January 2020, the FDA held an Advisory Committee meeting to discuss our POSIMIR NDA resubmission. Subsequently, we have continued to interact with FDA as they continue their review.”

Potential major milestones in 2020:

- Initiation of Phase 2b trial of DUR-928 in AH: mid-year
- Reporting top-line data from the DUR-928 one-month daily dose trial in NASH: mid-year
- POSIMIR® FDA decision
- Commercial partnership if POSIMIR is approved
- New license and collaboration agreements

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, orally bioavailable, first-in-class small molecule, which may have broad applicability in acute organ injuries such as AH, and in chronic liver diseases such as non-alcoholic steatohepatitis (NASH).

Clinical Trials

Alcoholic Hepatitis (AH)

- During 2019, we completed a Phase 2a clinical trial of DUR-928 in patients with AH. The study results were presented as a late-breaking oral presentation at The Liver Meeting® 2019 by Dr. Tarek Hassanein, one of the trial's principal investigators. In a separate poster presentation, Dr. Craig McClain presented additional comparative data from the Phase 2a clinical trial of DUR-928 and a control group of severe AH patients treated with corticosteroids in a contemporaneous AH trial conducted at University of Louisville. Additionally, the DUR-928 results were selected for inclusion in the "Best of The Liver Meeting" summary slide deck in the Alcohol-related Liver Disease category. Inclusion in this slide deck is considered a singular honor and indicates the high level with which the AASLD review committee regarded this study.
- All 19 patients treated with DUR-928 in the AH trial survived the 28-day follow-up period and there were no drug-related serious adverse events. Patients treated with DUR-928 had a statistically significant reduction from baseline in bilirubin at days 7 and 28, and model of end-stage liver disease (MELD) at day 28. Lille scores were also statistically significantly lower than those from a well-matched group of patients in a contemporary trial as well as from several published comparable historical control groups. Seventy four percent of all DUR-928 treated patients and 67% of those with severe AH were discharged from the hospital within four days of receiving a single dose of DUR-928.
- DUR-928 AH Phase 2a trial design: The open-label, dose escalation, multi-center study was designed to determine the safety, pharmacokinetics and pharmacodynamic signals of DUR-928 in AH patients following treatment. This included assessing liver biochemistry, biomarkers, and prognostic scores such as the Lille score. Final enrollment included 19 patients with moderate and severe AH, who were administered DUR-928 intravenously at three different doses. Eight patients (four moderate and four severe) were dosed at 30 mg, seven patients (three moderate and four severe) were dosed at 90 mg and four patients (all severe) were dosed at 150 mg. After being discharged on day two, one patient did not return for the scheduled day 7 and day 28 follow-up visits (this patient did survive through day 28); therefore Lille, bilirubin and MELD data reported above are based on 18 patients.
- 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. 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. 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. ALD is one of the leading causes of liver transplants in the U.S., costing over $800,000 per patient.
- We are working with the FDA and our advisors to finalize the design of a multi-center, international, randomized, double blind, placebo-controlled Phase 2b clinical trial of DUR-928 in AH patients. We are planning to initiate the trial in mid-2020. Based on our current working assumptions related to trial design, number of clinical trial sites and enrollment rates, top-line data for this trial may be available in 2022.

Non-Alcoholic Steatohepatitis (NASH)

- We have exceeded our 60 patient enrollment target in the ongoing NASH trial, and the last patient is scheduled to begin the 28-day dosing period next week. The trial is a Phase 1b randomized and open-label clinical study being 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 MRI and ultrasonic imaging, respectively) 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 or more patients per dose group for a total of over 60 patients in the trial.
- We expect all patients to complete their dosing and follow up visits in the first half of 2020 and expect to announce top-line study results mid-year.
- 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.

Psoriasis

- In January 2020, we announced the results from a Phase 2a clinical trial of DUR-928 in patients with mild to moderate plaque psoriasis. Twenty-two patients completed the study, applying DUR-928 topically to the plaque on one arm and the vehicle (placebo) to a similar plaque on the other arm daily for 28 days. DUR-928 did not demonstrate a benefit over vehicle (placebo) based on Investigator's Global Assessment (IGA), or in any of the secondary analyses, including Local Psoriasis Severity Index (LPSI). However, at the end of the 4-week daily application period, plaques in both the DUR-928 and vehicle treatment groups were significantly improved over baseline with respect to both IGA and LPSI scores. In fact, 90% of plaques in both groups had at least a 1 point reduction in LPSI score after the 4-week daily application period as compared to baseline. Daily topical application of DUR-928 was well tolerated with no meaningful differences in adverse events between the treatment and vehicle (placebo) groups. Based on the top-line data, we do not plan to continue development of topical DUR-928 in psoriasis at this time and will focus our near- term development activities on AH and NASH.

POSIMIR® (bupivacaine extended-release solution) Post-Operative Pain Relief Depot. POSIMIR is the Company'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.

- 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 response to the CRL in June 2019. The FDA initially assigned a user fee goal date of December 27, 2019, but subsequently scheduled a meeting of the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) for January 16, 2020; a new user fee goal date has not been assigned. At the meeting, six Advisory Committee members voted to recommend that the efficacy, safety, and overall risk-benefit profile of POSIMIR support approval, while six did not recommend approval based on the information presented. Although the FDA considers the recommendations of the Advisory Committee, the recommendations by the panel are non-binding.
- Since the Advisory Committee meeting, we have continued to interact with the FDA as they continue their review.
- The efforts to evaluate the program, develop a strategy for filing the response, and preparing the response, have been under the direction of Dr. Lee Simon, who was formerly the FDA's Division Director of Analgesic, Anti-inflammatory and Ophthalmologic Drug Products. Dr. Simon also led our preparation efforts for the Advisory Committee meeting.
- 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 Collaboration. The investigational long-acting injectable HIV product using DURECT's SABER technology under development with Gilead is currently being re-formulated and will undergo additional pre-clinical development work.

Debt Amendment. In December 2019, the Company amended its existing $20 million term loan with Oxford Finance such that principal payments will commence 18 months later than previously scheduled (i.e., commencing December 1, 2021 rather than June 1, 2020) and the final maturity date has been moved back by 18 months (i.e., from November 1, 2022 to May 1, 2024). The interest rate and final payment remain unchanged, and the Company paid Oxford Finance an amendment fee of $825,000.

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 fourth quarter 2019 results and provide a corporate update:

Toll Free:	877-407-0784
International:	201-689-8560
Conference ID:	13698601
Webcast:	http://public.viavid.com/index.php?id=137885

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 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, has demonstrated the ability to regulate the expression of genes involved in lipid metabolism, inflammatory responses and cell survival. This drug candidate is currently in Phase 2 development for the treatment of alcoholic hepatitis (AH) and 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. A key 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. DURECT has also entered into an agreement with Gilead Sciences to develop and commercialize a long-acting injectable HIV investigational product using DURECT's SABER® technology. For more information about DURECT, 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 announce top-line data from the Phase 1b NASH trial by mid-year, and initiate a Phase 2b trial of DUR-928 in AH by mid-year, potential regulatory approval of POSIMIR, potential commercial relationships for POSIMIR if approved or other license and collaboration agreements, 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 and chronic liver diseases such as NASH
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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 replicate the results from 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 FDA will not approve POSIMIR,
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 successfully re-formulate the
investigational long-acting injectable HIV product under development with Gilead, 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 November 5, 2019 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.

DURECT CORPORATION

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except per share amounts)

(unaudited)

	Three months ended December 31		Twelve months ended December 31	
	2019	2018	2019	2018
Collaborative research and development and other revenue	$ 7,249	$ 775	$ 18,129	$ 8,207
Product revenue, net	3,436	2,852	11,435	10,357

	Total revenues	10,685	3,627	29,564	18,564
Operating expenses:					
	Cost of product revenues	1,397	1,093	4,143	4,263
	Research and development	9,454	5,887	30,209	25,501
	Selling, general and administrative	3,794	3,539	14,363	12,419
Total operating expenses		14,645	10,519	48,715	42,183
Loss from operations		(3,960)	(6,892)	(19,151)	(23,619)
Other income (expense):					
	Interest and other income	338	238	1,074	870
	Interest and other expense	(609)	(645)	(2,501)	(2,573)
Net other expense		(271)	(407)	(1,427)	(1,703)
Net loss		$ (4,231)	$ (7,299)	$(20,578)	$(25,322)
Net loss per share					
	Basic	$ (0.02)	$ (0.05)	$ (0.12)	$ (0.16)
	Diluted	$ (0.02)	$ (0.05)	$ (0.12)	$ (0.16)
Weighted-average shares used in computing net loss per share					
	Basic	193,181	162,040	178,042	159,834
	Diluted	193,181	162,040	178,042	159,834
Total comprehensive loss		$ (4,236)	$ (7,299)	$(20,581)	$(25,321)

DURECT CORPORATION

CONDENSED BALANCE SHEETS

(in thousands)

	As of December 31, 2019 (unaudited)	As of December 31, 2018[1]
ASSETS		
Current assets:		
Cash and cash equivalents	$ 34,924	$ 31,644
Short-term investments	29,750	2,671
Accounts receivable	2,313	1,757
Inventories, net	3,383	3,421
Prepaid expenses and other current assets	1,459	2,247
Total current assets	71,829	41,740
Property and equipment, net	469	605
Operating lease right-of-use assets	6,066	–
Goodwill	6,399	6,399
Long-term restricted Investments	150	150
Other long-term assets	1,107	1,105
Total assets	$ 86,020	$ 49,999
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,109	$ 1,589
Accrued liabilities	6,284	4,668
Contract research liability	3,653	1,405
Deferred revenue, current portion	22,679	–
Operating lease liabilities, current portion	2,043	–
Total current liabilities	36,768	7,662
Deferred revenue, noncurrent portion	812	812
Operating lease liabilities, noncurrent portion	4,517	–
Term loan, noncurrent portion, net	20,262	20,533
Other long-term liabilities	801	992
Stockholders' equity	22,860	20,000
Total liabilities and stockholders' equity	$ 86,020	$ 49,999

(1) Derived from audited financial statements.

View original content:http://www.prnewswire.com/news-releases/durect-corporation-announces-fourth-quarter-and-full-year-2019-financial-results-and-update-of-programs-301015704.html

SOURCE DURECT Corporation

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