DURECT Corporation Reports First Quarter 2023 Financial Results and Business Update

May 08, 2023, 16:05 ET

– Webcast of Earnings Call Today, May 8th at 4:30 p.m. ET

– Topline data from AHFIRM trial expected in 2H 2023

CUPERTINO, Calif., May 8, 2023 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced financial results for the three months ended March 31, 2023 and provided a corporate update.

“We are rapidly approaching the completion of enrollment in our Phase 2b AHFIRM trial later this quarter and remain on track to report topline data in the second half of 2023. We are preparing to file an NDA for larsucosterol in alcohol-associated hepatitis (AH) if the AHFIRM trial outcome is positive and are in the early stages of commercial launch planning in the U.S.,” statedJames E. Brown, D.V.M., President and CEO of DURECT. “If approved, larsucosterol would be the first FDA-approved treatment for AH. We also are pleased that an article describing our Phase 2a data in AH has been published online in The American Journal of Gastroenterology. This peer-reviewed publication provides further insight into the efficacy and safety of larsucosterol in AH and underscores the insufficiency of current treatment approaches for this highly lethal disease.”

Recent Business Highlights:

- **AHFIRM approaching completion** – DURECT has enrolled more than 285 patients in the AHFIRM trial to date, which exceeds 95% of the target enrollment for the 300-patient trial. We have enrolled patients at leading hospitals in the U.S., Australia, E.U. and U.K., including prominent transplant centers. We continue to expect to complete enrollment in the AHFIRM trial in the second quarter of 2023, which should enable topline data to be reported in the second half of 2023.
- **Peer-reviewed publication of Phase 2a trial of larsucosterol in AH** – Additional data from our previously completed Phase 2a trial evaluating larsucosterol in AH was recently published online by The American Journal of Gastroenterology. In addition to previously reported safety and efficacy data from the 19-patient, open label Phase 2a trial, the publication includes individual patient data and additional liver biomarker data as well as cross-study comparisons of severe AH patients from the Phase 2a trial with two matching comparison arms from a contemporaneous study conducted by the DASH (Defeat Alcoholic Steatohepatitis) Consortium.
- **Upcoming AH Key Opinion Leader (KOL) Event** – DURECT announced that it will be hosting a KOL event for investors on May 16, 2023 at 12 p.m. ET in New York City. The event will include presentations by Dr. Paul Gaglio and Dr. Brett Fortune, as well as members of our senior leadership team.

Financial Highlights for Q1 2023:

- Total revenues were $2.1 million and net loss was $12.0 million for the three months ended March 31, 2023 compared to total revenues of $1.9 million and net loss of $10.8 million for the three months ended March 31, 2022.
- At March 31, 2023, cash, cash equivalents and investments were $44.4 million, compared to $43.6 million at December 31, 2022. Debt at March 31, 2023 was $21.3 million, compared to $21.2 million at December 31, 2022.
- In February 2023, we completed a registered direct offering of common stock and warrants with a leading institutional healthcare investor and an existing institutional investor. The offering raised net proceeds from the financing of approximately $8.8 million.

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 first quarter 2023 results and provide a corporate update:

Monday, May 8 @ 4:30 p.m. Eastern Time / 1:30 p.m. Pacific Time

Toll Free:	1-877-869-3847
International:	201-689-8261
Conference ID:	13738577
Webcast:	https://event.choruscall.com/mediaframe/webcast.html?webcastid=nKLHIvLR

A live audio webcast of the presentation will be also available by accessing DURECT's homepage atwww.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 the AHFIRM Trial
Enrollment is ongoing in our Phase 2b randomized, double-blind, placebo-controlled, international, multi-center study in subjects with severe acute alcohol-associated hepatitis (AH) to evaluate saFety and effIcacy of laRsucosterol treatMent (AHFIRM). The study is comprised of three arms targeting enrollment of 300 total patients, with approximately 100 patients in each arm: (1) Placebo plus supportive care, with or without methylprednisolone capsules at the investigators' discretion; (2) larsucosterol (30 mg); and (3) larsucosterol (90 mg). Patients in the larsucosterol arms receive the same supportive care without steroids. In order to maintain blinding, patients in the two active arms receive matching placebo capsules if the investigator prescribes steroids. The primary outcome measure will be the 90-Day incidence of mortality or liver transplantation for patients treated with larsucosterol compared to those treated with placebo. The Company has enrolled patients at clinical trial sites across the U.S., EU, U.K., andAustralia. Reflecting the life-threatening nature of AH and the lack of therapeutic options, the U.S. Food and Drug Administration (FDA) has granted larsucosterol Fast Track Designation for the treatment of AH. We believe a positive outcome in the AHFIRM trial could support a New Drug Application filing. For more information, refer to ClinicalTrials.gov Identifier: NCT04563026.

About Alcohol-associated Hepatitis (AH)
AH is an acute form of alcohol-associated liver disease (ALD), associated with long-term heavy intake of alcohol and often occurs after a recent period of increased alcohol consumption (i.e., a binge). AH is typically characterized by severe inflammation and destruction of liver tissue (i.e., necrosis), potentially leading to life-threatening complications including liver failure, acute kidney injury and multi-organ failure. There are no FDA approved therapies for AH and a retrospective 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. A subsequent global study published inDecember 2021, which included 85 tertiary centers in 11 countries across 3 continents, prospectively enrolled 2,581 AH patients with a median Model of End-Stage Liver Disease (MELD) score of 23.5, reported mortality at 28 and 90 days of approximately 20% and 31%, respectively. Stopping alcohol consumption is necessary, but frequently not sufficient for recovery in many moderate (defined as MELD scores of 11-20) and severe (defined as MELD scores >20) patients and the use of treatments to reduce liver inflammation, such as corticosteroids, are limited by contraindications and have not been shown to improve survival at 90 days or one year, and have demonstrated an increased risk of infection. While liver transplantation is becoming more common for ALD patients, including AH patients, the total number of such transplants is still relatively small. Average charges for a liver transplant exceed$875,000, and patients require lifelong immunosuppressive therapy to prevent organ rejection.

About Larsucosterol
Larsucosterol is an endogenous sulfated oxysterol and an epigenetic modulator. Epigenetic regulators are compounds that regulate patterns of gene expression without modifying the DNA sequence. DNA hypermethylation, an example of epigenetic dysregulation, results in transcriptomic reprogramming and cellular dysfunction, and has been found to be associated with many acute (e.g., AH) or chronic diseases (e.g., NASH). As an inhibitor of DNA methyltransferases (DNMT1, DNMT3a and3b), larsucosterol inhibits DNA methylation, which subsequently modulates expression of genes that are involved in cell signaling pathways associated with stress responses, cell death and survival, and lipid biosynthesis. This may ultimately lead to improved cell survival, reduced inflammation, and decreased lipotoxicity. As an epigenetic modulator, the proposed mechanism of action provides further scientific rationale for developing larsucosterol for the treatment of acute organ injury and certain chronic diseases.

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. Larsucosterol, DURECT's lead drug candidate, binds to and inhibits the activity of DNA methyltransferases (DNMTs), epigenetic enzymes which are elevated and associated with hypermethylation found in alcohol-associated hepatitis (AH) patients. Larsucosterol is in clinical

development for the potential treatment of AH, for which FDA has granted a Fast Track Designation; non-alcoholic steatohepatitis (NASH) is also being explored. In addition, POSIMIR® (bupivacaine solution) for infiltration use, a non-opioid analgesic utilizing the innovative SABER® platform technology, is FDA-approved and has been exclusively licensed to Innocoll Pharmaceuticals for commercialization in the United States. For more information about DURECT, please visit www.durect.com and follow us on Twitter https://twitter.com/DURECTCorp.

DURECT Forward-Looking Statements

This press release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, relating to: our plans to complete enrollment of the AHFIRM trial in the second quarter of 2023 and report topline data in the second half of 2023, the potential FDA approval of larsucosterol for the treatment of AH, the ability of a positive outcome in the AHFIRM trial to support a New Drug Application filing, our plans to commercialize larsucosterol if approved, the commercialization of POSIMIR by Innocoll, the potential to develop larsucosterol for AH, NASH or other indications, and the potential benefits, if any, of our product candidates. Actual results may differ materially from those contained in the forward-looking statements contained in this press release, and reported results should not be considered as an indication of future performance. The potential risks and uncertainties that could cause actual results to differ from those projected include, among other things, the risks that the AHFIRM trial takes longer to conduct than anticipated due to COVID-19 or other factors, the risk that ongoing and future clinical trials of larsucosterol do not confirm the results from earlier clinical or pre-clinical trials, or do not demonstrate the safety or efficacy of larsucosterol in a statistically significant manner, the risk that the FDA or other government agencies may require additional clinical trials for larsucosterol before approving it for the treatment of AH even if the results of the AHFIRM trial are successful, risks that Innocoll may not commercialize POSIMIR successfully, and risks related to the sufficiency of our cash resources, our anticipated capital requirements and capital expenditures, our need or desire for additional financing, our ability to obtain capital to fund our operations and expenses and our ability to continue to operate as a going concern. Further information regarding these and other risks is included in DURECT's most recent Securities and Exchange Commission (SEC) filings, including its annual report on Form 10-K for the year ended December 31, 2022 and quarterly report on Form 10-Q for the quarter ended March 31, 2023 when filed under the heading "Risk Factors." These reports are available on our website www.durect.comunder the "Investors" tab and on the SEC's website at www.sec.gov. All information provided in this press release and in the attachments is based on information available to DURECT as of the date hereof, and DURECT assumes no obligation to update this information as a result of future events or developments, except as required by law.

NOTE: POSIMIR® is a trademark of Innocoll Pharmaceuticals, Ltd. in the U.S. and a trademark of DURECT Corporation outside of the U.S. SABER® is a trademark of DURECT Corporation. Other referenced trademarks belong to their respective owners. Larsucosterol is an investigational drug candidate under development and has 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 March 31	
	2023	2022
Collaborative research and development and other revenue	$ 643	$ 495
Product revenue, net	1,411	1,420
Total revenues	2,054	1,915
Operating expenses:		
Cost of product revenues	388	335

	Research and development	8,593	8,211
	Selling, general and administrative	4,095	3,735
Total operating expenses		13,076	12,281
Loss from operations		(11,022)	(10,366)
Other income (expense):			
	Interest and other income	517	54
	Change in fair value of warrant liabilities	2,477	–
	Interest and other expenses	(726)	(530)
	Issuance cost for warrants	(1,200)	–
	Loss on issuance of warrants	(2,033)	–
Other income (expense), net		(965)	(476)
Net loss		$ (11,987)	$ (10,842)
Net change in unrealized loss on available-for-sale securities, net of reclassification adjustments and taxes		$ 6	$ (19)
Total comprehensive loss		$ (11,981)	$ (10,861)
Net loss per share			
	Basic	$ (0.50)	$ (0.48)
	Diluted	$ (0.52)	$ (0.48)
Weighted-average shares used in computing net loss per share			
	Basic	23,767	22,768
	Diluted	23,940	22,768

DURECT CORPORATION

CONDENSED BALANCE SHEETS

(in thousands)

	As of March 31, 2023 (unaudited)	As of December 31, 2022 [1]
ASSETS		
Current assets:		
Cash and cash equivalents	$ 39,296	$ 43,483

Short-term investments	4,924		–	
Short-term restricted Investments	150		–	
Accounts receivable, net	1,401		3,423	
Inventories, net	2,211		2,113	
Prepaid expenses and other current assets	2,522		2,375	
Total current assets	50,504		51,394	
Property and equipment, net	144		188	
Operating lease right-of-use assets	1,532		1,943	
Goodwill	6,169		6,169	
Long-term restricted Investments	–		150	
Other long-term assets	–		256	
Total assets	$	58,349	$	60,100
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	$	2,006	$	3,106
Accrued liabilities	7,388		7,896	
Term loan, current portion, net	21,303		21,170	
Deferred revenue, current portion	178		–	
Operating lease liabilities, current portion	1,655		1,832	
Warrant liabilities	9,556		–	
Total current liabilities	42,086		34,004	
Operating lease liabilities, noncurrent portion	–		260	
Other long-term liabilities	921		851	
Stockholders' equity	15,342		24,985	
Total liabilities and stockholders' equity	$	58,349	$	60,100

(1) Derived from audited financial statements.

SOURCE DURECT Corporation