DURECT Corporation Reports Second Quarter 2023 Financial Results and Business Update

09 Aug, 2023, 16:05 ET

– ***Webcast of Earnings Call Today, August 9th at 4:30 p.m. ET***

– ***Topline data from AHFIRM trial expected in Q4 2023***

CUPERTINO, Calif., Aug. 9, 2023 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced financial results for the three months ended June 30, 2023 and provided a corporate update.

“We are pleased to have completed enrollment in our Phase 2b AHFIRM trial in June and remain on track to report topline data in the fourth quarter of 2023. Assuming a positive outcome from AHFIRM, we plan to review the results with the U.S. Food and Drug Administration (FDA) in the first quarter of 2024. If approved, larsucosterol would be the first FDA-approved treatment for alcohol-associated hepatitis (AH),” stated James E. Brown, D.V.M., President and CEO of DURECT. “We are also excited to announce the expansion of our epigenetic modulator platform into oncology. In conjunction with teams of experienced chemists and biologists, our research and development team have designed new chemical entities (NCE) that are now in preclinical development for multiple oncology indications. With this achievement, DURECT is advancing its mission to be a global leader in the emerging field of epigenetic medicine.”

Recent Business Highlights:

- **AHFIRM enrollment completed** – DURECT announced on June 7, 2023 that it had met the enrollment target in the AHFIRM trial. In total, we randomized and dosed 301 patients at leading hospitals in the U.S., Australia, E.U. and U.K., including prominent transplant centers. We continue to expect to report topline data in the fourth quarter of 2023.
- **AH Key Opinion Leader (KOL) event** – DURECT hosted a KOL event for investors on May 16, 2023. The event included presentations by Dr. Paul Gaglio and Dr. Brett Fortune as part of our on-going campaign to build awareness of the mortality rate and unmet patient need in AH, and the role that larsucosterol may play in the treatment of AH.
- **Publication of Phase 2a data in AH** – Additional data from DURECT’s previously completed Phase 2a trial evaluating larsucosterol in AH were published by the peer-reviewed journal American Journal of Gastroenterology. The publication featured the previously reported safety and efficacy data from the 19-patient, open label Phase 2a trial. It also included 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.
- **Expanding pipeline with novel anti-cancer NCEs** – Building on our knowledge of epigenetic modulation, DURECT has internally developed multiple novel small molecule DNMT inhibitors that exhibit broad spectrum activity against multiple hematologic and solid tumor types. These compounds display unique and desirable physiochemical properties and pharmacokinetic profiles, as well as favorable tolerability. We intend to select a product candidate by the end of 2023 to advance into clinical trials in cancer patients. Our goal is to be prepared to initiate clinical trials for this product candidate by the end of 2024.

Financial Highlights for Q2 2023:

- Total revenues were $2.1 million and net loss was $11.2 million for the three months ended June 30, 2023 compared to total revenues of $2.1 million and net loss of $11.6 million for the three months ended June 30, 2022.
- At June 30, 2023, cash, cash equivalents and investments were $34.9 million, compared to $43.6 million at December 31, 2022. Debt at June 30, 2023 was $20.7 million, compared to $21.2 million at December 31, 2022.
- After the end of the second quarter, in July 2023, we completed a registered direct offering of common stock and warrants which raised net proceeds of approximately $13.8 million.

Earnings Conference Call

We will host a conference call and webcast today at 4:30 p.m. Eastern Time/1:30 p.m. Pacific Time to discuss second quarter 2023 results and provide a corporate update:

Wednesday, August 9 @ 4:30 p.m. Eastern Time / 1:30 p.m. Pacific Time
Toll Free: 1-877-407-0784
International: 1-201-689-8560
Conference ID: 13740526
Call me™: click here

Participants can use guest dial-in numbers above to reach an operator or they can click the Call me™ link for instant telephone access to the event (dial-out). The Call me™ link will be made active 15 minutes prior to scheduled start time.

Webcast: https://viavid.webcasts.com/starthere.jsp?ei=1628151&tp_key=ba103a2a9b

A live audio webcast of the presentation will be also available by accessing DURECT's homepage at www.durect.com on the "Events" page, under the "Investors" tab. If you are unable to participate during the live webcast, the call will be archived on DURECT's website under "Events" in the "Investors" section.

About the AHFIRM Trial
Enrollment was completed in June 2023 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, and 301 total patients were randomized and dosed, 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., and Australia. 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 in December 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 therapies that reduce liver inflammation, such as corticosteroids, are limited by contraindications, 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 and 3b), 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 that 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 report topline data in the fourth quarter of 2023, our plans to meet with the FDA to review results of AHFIRM in the first quarter of 2024, 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, our NCE program for oncology and plans to initiate clinical trials related to this program, 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 does not confirm the results from earlier clinical or pre-clinical trials, or does 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 June 30, 2023 when filed under the heading "Risk Factors." These reports are available on our website www.durect.com under 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 June 30		Six months ended June 30	
	2023	2022	2023	2022
Collaborative research and development and other revenue	$ 508	$ 606	$ 1,151	$ 1,101
Product revenue, net	1,573	1,470	2,984	2,890
Total revenues	2,081	2,076	4,135	3,991
Operating expenses:				
Cost of product revenues	359	393	747	728
Research and development	7,946	8,817	16,539	17,028
Selling, general and administrative	3,827	3,952	7,922	7,687
Total operating expenses	12,132	13,162	25,208	25,443
Loss from operations	(10,051)	(11,086)	(21,073)	(21,452)
Other income (expense):				
Interest and other income	511	127	1,028	181
Change in fair value of warrant liabilities	(892)	–	1,585	–
Interest and other expenses	(749)	(592)	(1,475)	(1,122)
Issuance cost for warrants	–	–	(1,200)	–
Loss on issuance of warrants	–	–	(2,033)	–
Other income (expense), net	(1,130)	(465)	(2,095)	(941)
Net loss	$(11,181)	$(11,551)	$(23,168)	$(22,393)
Net change in unrealized loss on available-for-sale securities, net of reclassification adjustments and taxes	$ 1	$ 4	$ 7	$ (15)
Total comprehensive loss	$(11,180)	$(11,547)	$(23,161)	$(22,408)
Net loss per share				
Basic	$ (0.46)	$ (0.51)	$ (0.96)	$ (0.98)
Diluted	$ (0.46)	$ (0.51)	$ (0.96)	$ (0.98)
Weighted-average shares used in computing net loss per share				
Basic	24,508	22,774	24,140	22,771
Diluted	24,508	22,774	24,377	22,771

DURECT CORPORATION

CONDENSED BALANCE SHEETS

(in thousands)

(unaudited)

	As of June 30, 2023 (unaudited)	As of December 31, 2022 [1]
ASSETS		
Current assets:		
Cash and cash equivalents	$ 31,760	$ 43,483
Short-term investments	2,985	–
Short-term restricted Investments	150	–
Accounts receivable, net	1,304	3,423
Inventories, net	2,262	2,113
Prepaid expenses and other current assets	1,829	2,375
Total current assets	40,290	51,394
Property and equipment, net	149	188
Operating lease right-of-use assets	2,043	1,943
Goodwill	6,169	6,169
Long-term restricted Investments	–	150
Other long-term assets	6	256
Total assets	$ 48,657	$ 60,100
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 980	$ 3,106
Accrued liabilities	7,779	7,896
Term loan, current portion, net	20,721	21,170
Deferred revenue, current portion	178	–
Operating lease liabilities, current portion	1,324	1,832
Warrant liabilities	10,448	–
Total current liabilities	41,430	34,004
Operating lease liabilities, noncurrent portion	803	260
Other long-term liabilities	924	851

Stockholders' equity	5,500	24,985
Total liabilities and stockholders' equity	$ 48,657	$ 60,100

(1) Derived from audited financial statements.

SOURCE DURECT Corporation