



DURECT Corporation Reports Second Quarter 2022 Financial Results and Update of Programs

Aug 04, 2022, 16:05 ET

- **Webcast of Earnings Call Today, August 4th at 4:30 p.m. ET**
- **Enrollment accelerating in the AHFIRM trial**

CUPERTINO, Calif., Aug. 4, 2022 /PRNewswire/ — [DURECT Corporation](#) (Nasdaq: [DRRX](#)) today announced financial results for the three months ended June 30, 2022 and provided a corporate update.

“We continue to see enrollment accelerating in the larsucosterol (DUR-928) AHFIRM trial and are pleased to announce that we have enrolled 170 patients to date. The second quarter continued the recent positive enrollment trend, with more patients dosed than in any prior quarter, reflecting the opening of additional clinical trial sites and our ongoing efforts to work with existing sites to recruit more patients with severe alcohol-associated hepatitis (AH) that meet our enrollment criteria,” stated James E. Brown, D.V.M., President and CEO of DURECT.

Second Quarter and Recent Business Highlights:

- **Continued progress in AHFIRM enrollment** – DURECT has enrolled 170 patients in the AHFIRM trial to date, which exceeds 50% of the target enrollment for the 300-patient trial. We now have over 60 AHFIRM study sites open at leading hospitals in the U.S., Australia, E.U. and U.K. We continue to expect to enroll the last patient in the AHFIRM trial in mid-2023, which should enable top-line results to be reported in the second half of 2023.
- **FDA agreement on modified primary endpoint to include liver transplant in addition to mortality** – Through a Type C meeting with the U.S. Food and Drug Administration (FDA), FDA has concurred with DURECT’s proposal to amend the primary endpoint of the ongoing AHFIRM trial to be the reduction in mortality or liver transplant at 90 days. A liver transplant represents a serious and expensive medical event for patients and we believe that including transplanted patients as well as mortality in the primary endpoint better reflects the current state of care for AH patients.
- **Recent Patent Issuance covering POSIMIR** – On August 2, 2022, DURECT was issued a new patent by the US Patent Office, extending US patent coverage for POSIMIR to at least 2041. This event triggered an \$8 million milestone payment due to DURECT under our license agreement with Innocoll Pharmaceuticals Limited (Innocoll). This payment is in addition to the \$4 million upfront license fee received in January 2022, and a \$2 million milestone payment to be received upon the first commercial sale of POSIMIR in the United States.

Financial Highlights for Q2 2022:

- Total revenues were \$2.1 million and net loss was \$11.6 million for the three months ended June 30, 2022 compared to total revenues of \$2.3 million and net loss of \$9.1 million for the three months ended June 30, 2021.
- At June 30, 2022, cash and investments were \$54.3 million, compared to cash and investments of \$70.0 million at December 31, 2021. Total debt at June 30, 2022 was \$20.9 million, compared to \$20.6 million at December 31, 2021.

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 second quarter 2022 results and provide a corporate update:

Thursday, August 4 @ 4:30 p.m. Eastern Time / 1:30 p.m. Pacific Time	
Toll Free:	1-800-285-6670



International:	713-481-1320
Conference ID:	13729654
Webcast:	https://event.choruscall.com/mediaframe/webcast.html?webcastid=6RVdxB8l

A live audio webcast of the presentation will be also available by accessing DURECT's homepage at 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 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 (DUR-928) 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 is enrolling patients at more than 60 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 a life-threatening acute alcohol-associated liver disease (ALD) often caused by chronic heavy alcohol use and a recent period of increased alcohol consumption (i.e., a binge). It is characterized by severe inflammation and destruction of liver tissue (i.e., necrosis), potentially leading to life-threatening complications including liver failure, acute renal 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 20% and 31%, respectively. Stopping alcohol consumption is 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 been shown to provide no survival benefit at 90 days or 1 year. While liver transplantation is becoming more common for ALD patients, including AH patients, the procedure often involves a long waiting period, a burdensome selection process, costs exceeding \$875,000 on average, and patients requiring lifelong immunosuppressive therapy to prevent organ rejection.

About Larsucosterol (DUR-928)

Larsucosterol is an endogenous sulfated oxysterol and an epigenetic regulator. 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 regulates 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 regulator, 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 (also



known as DUR-928), 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 development and 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 mid-2023 and report top-line results in the second half of 2023, the expected commercial launch of POSIMIR by Innocoll and potential future payments we may receive from Innocoll, the potential to develop larsucosterol for 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, risks that Innocoll may not commercialize POSIMIR successfully, if at all, 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 most recent Securities and Exchange Commission (SEC) filings, including its annual report on Form 10-K for the year ended December 31, 2021 and quarterly report on Form 10-Q for the quarter ended June 30, 2022 when filed with the SEC 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 (DUR-928) 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		Six months ended	
	June 30		June 30	
	2022	2021	2022	2021
Collaborative research and development and other revenue	\$ 606	\$ 735	\$ 1,101	\$ 1,309
Product revenue, net	1,470	1,568	2,890	3,206
Total revenues	2,076	2,303	3,991	4,515
Operating expenses:				
Cost of product revenues	393	359	728	711



Research and development	8,817	7,433	17,028	15,408
Selling, general and administrative	3,952	3,168	7,687	6,699
Total operating expenses	13,162	10,960	25,443	22,818
Loss from operations	(11,086)	(8,657)	(21,452)	(18,303)
Other income (expense):				
Interest and other income	127	39	181	76
Interest and other expense	(592)	(528)	(1,122)	(1,053)
Net other expense	(465)	(489)	(941)	(977)
Net loss	\$ (11,551)	\$ (9,146)	\$ (22,393)	\$ (19,280)
Net change in unrealized loss on available-for-sale securities, net of reclassification adjustments and taxes	4	13	\$ (15)	\$ 4
Total comprehensive loss	\$ (11,547)	\$ (9,133)	\$ (22,408)	\$ (19,276)
Net loss per share				
Basic	\$ (0.05)	\$ (0.04)	\$ (0.10)	\$ (0.09)
Diluted	\$ (0.05)	\$ (0.04)	\$ (0.10)	\$ (0.09)
Weighted-average shares used in computing net loss per share				
Basic	227,742	227,428	227,715	222,510
Diluted	227,742	227,428	227,715	222,510

DURECT CORPORATION

CONDENSED BALANCE SHEETS

(in thousands)

(unaudited)

	As of	As of
	June 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 47,135	\$ 49,844
Short-term investments	6,977	19,966



Accounts receivable, net	1,204	6,477
Inventories, net	2,133	1,870
Prepaid expenses and other current assets	3,006	3,580
Total current assets	60,455	81,737
Property and equipment, net	222	227
Operating lease right-of-use assets	2,722	3,446
Goodwill	6,169	6,169
Long-term restricted Investments	150	150
Other long-term assets	261	261
Total assets	\$ 69,979	\$ 91,990

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:

Accounts payable	\$ 3,230	\$ 1,311
Accrued liabilities	4,537	6,799
Deferred revenue, current portion	—	98
Term loan, current portion, net	950	—
Operating lease liabilities, current portion	1,876	1,848
Total current liabilities	10,593	10,056
Deferred revenue, noncurrent portion	812	812
Operating lease liabilities, noncurrent portion	1,039	1,824
Term loan, noncurrent portion, net	19,949	20,632
Other long-term liabilities	882	884
Stockholders' equity	36,704	57,782
Total liabilities and stockholders' equity	\$ 69,979	\$ 91,990

SOURCE DURECT Corporation

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