



DURECT Corporation Reports Fourth Quarter and Full Year 2022 Financial Results and AHFIRM Trial Update

Mar 07, 2023, 16:05 ET

- **Webcast of Earnings Call Today, March 7th at 4:30 p.m. ET**
- **Topline data from AHFIRM trial expected in 2023**

CUPERTINO, Calif., March 7, 2023 /PRNewswire / — [DURECT Corporation](#) (Nasdaq: [DRRX](#)) today announced financial results for the three months and year ended December 31, 2022 and provided a corporate update.

“We are poised to complete enrollment in our potentially pivotal AHFIRM trial in the second quarter of 2023 and report topline data in the second half of 2023. If the AHFIRM trial outcome is positive, we intend to have discussions with the FDA and other regulatory authorities regarding a possible NDA filing,” stated James E. Brown, D.V.M., President and CEO of DURECT. “Larsucosterol has the potential to be the first FDA-approved treatment for alcohol-associated hepatitis, representing a significant step forward in treating patients afflicted with this highly lethal condition.”

AHFIRM Trial Update:

DURECT has enrolled more than 260 patients in the AHFIRM trial to date, which exceeds 85% of the target enrollment for the 300-patient trial. We have over 60 AHFIRM study sites open 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.

Financial Highlights for Q4 and Full Year 2022:

- Total revenues were \$3.3 million and net loss was \$10.5 million for the three months ended December 31, 2022 compared to total revenues of \$7.3 million and net loss of \$7.0 million for the three months ended December 31, 2021. Total revenues were \$19.3 million and net loss was \$35.3 million for the year ended December 31, 2022, compared to total revenues of \$14.0 million and net loss of \$36.3 million for the year ended December 31, 2021.
- At December 31, 2022, cash, cash equivalents and investments were \$43.6 million, compared to cash, cash equivalents and investments of \$70.0 million at December 31, 2021. Debt at December 31, 2022 was \$21.2 million, compared to \$20.6 million at December 31, 2021.
- In February 2023, we completed a \$10.0 million registered direct offering of common stock and warrants with a leading institutional healthcare investor and an existing institutional investor. Net proceeds from the financing were approximately \$8.8 million excluding the proceeds, if any, from the exercise of the warrants issued in the offering.

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 and 2022 results and provide a corporate update:

Tuesday, March 7 @ 4:30 p.m. Eastern Time / 1:30 p.m. Pacific Time

Toll Free: 1-877-869-3847

International: 201-689-8261

Conference ID: 13736560



Webcast: <https://event.choruscall.com/mediaframe/webcast.html?webcastid=Do9m0bih>

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. DURECT 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 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 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 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 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, 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, 2021 and quarterly report on Form 10-Q for the quarter ended September 30, 2022 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		Twelve months ended	
	December 31		December 31	
	2022	2021	2022	2021 ⁽¹⁾
Collaborative research and development and other revenue	\$ 1,518	\$ 4,579	\$ 13,204	\$ 6,331
Product revenue, net	1,797	2,718	6,079	7,646



Total revenues	3,315	7,297	19,283	13,977
Operating expenses:				
Cost of product revenues	515	880	1,588	1,955
Research and development	9,953	8,415	36,862	31,846
Selling, general and administrative	4,345	4,514	15,915	14,449
Total operating expenses	14,813	13,809	54,365	48,250
Loss from operations	(11,498)	(6,512)	(35,082)	(34,273)
Other income (expense):				
Interest and other income	1,683	46	2,148	156
Interest and other expense	(654)	(542)	(2,399)	(2,148)
Net other expense	1,029	(496)	(251)	(1,992)
Net loss	\$ (10,469)	\$ (7,008)	\$ (35,333)	\$ (36,265)
Net change in unrealized loss on available-for-sale securities, net of reclassification adjustments and taxes	(5)	(12)	\$ (3)	\$ (5)
Total comprehensive loss	\$ (10,474)	\$ (7,020)	\$ (35,336)	\$ (36,270)
Net loss per share				
Basic	\$ (0.46)	\$ (0.31)	\$ (1.55)	\$ (1.61)
Diluted	\$ (0.46)	\$ (0.31)	\$ (1.55)	\$ (1.61)
Weighted-average shares used in computing net loss per share				
Basic	22,784	22,759	22,777	22,505
Diluted	22,784	22,759	22,777	22,505

(1) Derived from audited financial statements.

DURECT CORPORATION

CONDENSED BALANCE SHEETS

(in thousands)

As of

December 31, 2022

(unaudited)

As of

December 31, 2021 (1)

ASSETS

Current assets:



Cash and cash equivalents	\$	43,483	\$	49,844
Short-term investments	–		19,966	
Accounts receivable, net	3,423		6,477	
Inventories, net	2,113		1,870	
Prepaid expenses and other current assets	2,375		3,580	
Total current assets	51,394		81,737	
Property and equipment, net	188		227	
Operating lease right-of-use assets	1,943		3,446	
Goodwill	6,169		6,169	
Long-term restricted Investments	150		150	
Other long-term assets	256		261	
Total assets	\$	60,100	\$	91,990
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	\$	3,106	\$	1,311
Accrued liabilities	7,896		6,799	
Term loan, current portion, net	5,275		–	
Deferred revenue, current portion	–		98	
Operating lease liabilities, current portion	1,832		1,848	
Total current liabilities	18,109		10,056	
Deferred revenue, noncurrent portion	–		812	
Operating lease liabilities, noncurrent portion	260		1,824	
Term loan, noncurrent portion, net	15,895		20,632	
Other long-term liabilities	851		884	
Stockholders' equity	24,985		57,782	
Total liabilities and stockholders' equity	\$	60,100	\$	91,990

(1) Derived from audited financial statements.

SOURCE DURECT Corporation