DURECT Corporation Reports Second Quarter 2024 Financial Results and Business Update

Aug 13, 2024, 16:01 ET

– *FDA Granted Breakthrough Therapy Designation for Larsucosterol in Alcohol-Associated Hepatitis*

– *Held Type B Meeting with FDA to Discuss Phase 3 Clinical Trial Design*

– *Seeking to Initiate Phase 3 Trial in 2024 with Topline Results Expected in 2H 2026*

– *Webcast of Earnings Call Today, August 13th at 4:30 p.m. ET*

CUPERTINO, Calif., Aug. 13, 2024 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced financial results for the three months ended June 30, 2024 and provided a business update.

“Our immediate priority is to finalize the design of our planned pivotal Phase 3 trial of larsucosterol in alcohol-associated hepatitis (AH),” stated James E. Brown, D.V.M., President and CEO of DURECT. “Recently we had a productive Type B meeting with the U.S. Food and Drug Administration (FDA) to discuss our proposed trial design and requirements to obtain approval. We are encouraged by the FDA’s feedback on our plans to advance development of larsucosterol, including its granting of Breakthrough Therapy Designation (BTD), and look forward to providing a further update on specifics of the Phase 3 design following expected communications from FDA. Assuming we obtain sufficient funds, we plan to initiate the Phase 3 study by the end of 2024 and would expect to report topline results by the second half of 2026. We are committed to advancing development of larsucosterol and bringing this potentially lifesaving therapy to patients as quickly as possible. If larsucosterol meets our expectations in Phase 3 and we are successful in gaining approval, it would likely be the first FDA-approved treatment for AH.”

Business Update:

- The FDA granted Breakthrough Therapy Designation to larsucosterol for the treatment of patients with AH. BTD is designed to expedite the development and review of therapies intended to treat a serious or life-threatening condition and whose preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on one or more clinically significant endpoints over existing available therapies.
- In July 2024, DURECT held a Type B meeting with the FDA to discuss the design of its planned Phase 3 clinical trial of larsucosterol in AH that, if successful, could support a potential NDA filing. The Company plans to provide additional details of the Phase 3 trial design following receipt of the written minutes from this meeting. DURECT’s goal is to initiate its Phase 3 trial in 2024, subject to obtaining sufficient funding, with topline results expected by the second half of 2026.
- Data from the Company’s Phase 2b AHFIRM trial, which evaluated the safety and efficacy of larsucosterol as a treatment for patients with severe AH, were featured in a late-breaking oral presentation at the European Association for the Study of the Liver (EASL) Congress 2024 on June 8, 2024 in Milan, Italy. This was the first presentation of the AHFIRM data at a medical meeting. Top line data from the study were previously announced in 2023.

Financial Highlights for Q2 2024:

- Total revenues were $2.2 million and net loss was $3.7 million for the three months ended June 30, 2024 compared to total revenues of $2.1 million and net loss of $11.2 million for the three months ended June 30, 2023.
- Cash, cash equivalents and investments were $15.8 million at June 30, 2024, compared to $29.8 million at December 31, 2023. Debt at June 30, 2024 was $12.5 million, compared to $16.7 million at December 31, 2023.

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 the second quarter

2024 results and provide a corporate update:

Tuesday, August 13 @ 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:	13747506
Webcast:	https://viavid.webcasts.com/starthere.jsp?ei=1678530&tp_key=3a937134de

Call me™: Participants can use Guest dial-in numbers above and be answered by an operator OR click the Call me™ link for instant telephone access to the event. The Call me™ link will be made active 15 minutes prior to the scheduled start time.

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

About the AHFIRM Trial
AHFIRM was a Phase 2b randomized, double-blind, placebo-controlled, international, multi-center study conducted in subjects with severe alcohol-associated hepatitis (**AH**) to evaluate the sa**F**ety and eff**I**cacy of la**R**sucosterol treat**M**ent (AHFIRM). The study was comprised of three arms and enrolled 307 patients, with approximately 100 patients in each arm: (1) Placebo, which consists of standard of care, with or without methylprednisolone capsules at the investigators' discretion; (2) larsucosterol (30 mg); and (3) larsucosterol (90 mg). Patients in the larsucosterol arms received the same supportive care without steroids. The primary outcome measure was the 90-Day incidence of mortality or liver transplantation for patients treated with larsucosterol compared to those treated with placebo, and the key secondary endpoint was 90-Day survival. The Company enrolled patients at clinical trial sites across the U.S., EU, U.K., and Australia. In November 2023, the Company announced topline data for the AHFIRM Trial. 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 and Breakthrough Therapy Designation for the treatment of AH. 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 alcohol intake, often following a recent period of increased consumption (i.e., a binge). AH is typically characterized by severe inflammation and liver cell damage, 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 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, and limited by organ availability. 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 reported in many acute (e.g., AH) and chronic diseases (e.g., MASH). 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 late-stage biopharmaceutical company pioneering the development of epigenetic therapies that target dysregulated DNA methylation to transform the treatment of serious and life-threatening conditions, including acute organ injury and cancer. 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 the FDA has granted Fast Track and Breakthrough Therapy designation; metabolic dysfunction-associated steatohepatitis (MASH) 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 is exclusively licensed to Innocoll Pharmaceuticals for sale and distribution in the United States. For more information about DURECT, please visit www.durect.com and follow us on X (formerly Twitter) at https://x.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: the Company's ability to commence a Phase 3 trial of larsucosterol in 2024 and report top-line data by the second half of 2026, the potential for a single Phase 3 trial of larsucosterol, if successful, to support an NDA filing, and the potential uses and benefits of laruscosterol in patients with AH and potentially other indications. 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 Company is unable to raise sufficient capital to commence the Phase 3 trial of larsucosterol in AH, trial enrollment or completion takes longer than anticipated, future clinical trials of larsucosterol are delayed or do not confirm the results from subset analyses of the AHFIRM trial, including geographic or other segmentation, or of 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 larsucosterol for the treatment of AH, and that larsucosterol may never be approved; and risks related to the sufficiency of our cash resources, our anticipated capital requirements, our need or desire for additional financing, our ability to continue to meet the minimum bid price for continued listing on Nasdaq, 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, 2023 and quarterly report on Form 10-Q for the quarter ended June 30, 2024, 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	
	2024	2023	2024	2023
Collaborative research and development and other revenue	$ 606	$ 508	$ 1,102	$ 1,151
Product revenue, net	1,565	1,573	2,896	2,984
Total revenues	2,171	2,081	3,998	4,135

Operating expenses:					
	Cost of product revenues	356	359	645	747
	Research and development	2,247	7,946	6,366	16,539
	Selling, general and administrative	2,972	3,827	6,108	7,922
Total operating expenses		5,575	12,132	13,119	25,208
Loss from operations		(3,404)	(10,051)	(9,121)	(21,073)
Other income (expense):					
	Interest and other income	227	511	548	1,028
	Interest and other expenses	(445)	(749)	(974)	(1,475)
	Change in fair value of warrant liabilities	(78)	(892)	(1,796)	1,585
	Issuance cost for warrants	–	–	–	(1,200)
	Loss on issuance of warrants	–	–	–	(2,033)
Other income (expense), net		(296)	(1,130)	(2,222)	(2,095)
Net loss		$ (3,700)	$ (11,181)	$ (11,343)	$ (23,168)
Net change in unrealized loss on available-for-sale securities, net of reclassification adjustments and taxes		$ 3	$ 1	$ 7	$ 7
Total comprehensive loss		$ (3,697)	$ (11,180)	$ (11,336)	$ (23,161)
Net loss per share					
	Basic	$ (0.12)	$ (0.46)	$ (0.37)	$ (0.96)
	Diluted	$ (0.12)	$ (0.46)	$ (0.37)	$ (0.96)
Weighted-average shares used in computing net loss per share					
	Basic	31,038	24,508	30,838	24,140
	Diluted	31,038	24,508	30,838	24,377

DURECT CORPORATION

CONDENSED BALANCE SHEETS

(in thousands)

	As of June 30, 2024 (unaudited)	As of December 31, 2023 [1]
ASSETS		
Current assets:		

Cash and cash equivalents	$	15,646	$	28,400
Short-term Investments	–		1,280	
Accounts receivable, net	1,012		1,261	
Inventories, net	2,474		2,219	
Prepaid expenses and other current assets	818		1,511	
Total current assets	19,950		34,671	
Property and equipment, net	67		91	
Operating lease right-of-use assets	3,390		3,980	
Goodwill	6,169		6,169	
Long-term restricted Investments	150		150	
Other long-term assets	128		128	
Total assets	$	29,854	$	45,189
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	$	394	$	1,777
Accrued liabilities	4,670		5,966	
Term loan, current portion, net	12,545		16,663	
Operating lease liabilities, current portion	1,299		1,381	
Warrant liabilities	3,020		1,224	
Total current liabilities	21,928		27,011	
Operating lease liabilities, noncurrent portion	2,220		2,702	
Other long-term liabilities	669		693	
Stockholders' equity	5,037		14,783	
Total liabilities and stockholders' equity	$	29,854	$	45,189

(1) Derived from audited financial statements.

SOURCE DURECT Corporation