DURECT Corporation Reports First Quarter 2025 Financial Results and Provides Business Update

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Planning a registrational Phase 3 trial for larsucosterol in alcohol-associated hepatitis (AH) with topline results expected within two years of trial initiation

Larsucosterol Phase 2b AHFIRM trial results published in NEJM Evidence in January 2025

CUPERTINO, Calif., May 13, 2025 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced financial results for the first quarter ended March 31, 2025 and provided a business update.

“Our primary focus continues to be initiating the Phase 3 trial of larsucosterol for severe AH, contingent on securing sufficient funding,” stated James E. Brown, D.V.M., President and CEO of DURECT. “We continue to be engaged in active dialogue to explore all options for funding the continued development of larsucosterol, including potential business development and financing transactions. Additionally, the publication of the results of our Phase 2b AHFIRM trial in January 2025 in *NEJM Evidence* provides important validation of the potential value of larsucosterol as a treatment for AH and supports our planned Phase 3 trial design.”

Recent business highlights and updates:

- DURECT is planning a registrational Phase 3 trial to evaluate the safety and efficacy of larsucosterol for the treatment of patients with severe AH. The trial will be a randomized, double-blind, placebo-controlled, multi-center study conducted in the U.S. The primary endpoint will be 90-day survival. The trial design incorporates feedback received from the U.S. Food and Drug Administration (FDA) during a Type B meeting that took place in 2024 under Breakthrough Therapy Designation (BTD) as well as learnings from the prior Phase 2b AHFIRM trial in AH. DURECT’s goal is to begin the trial in 2025, subject to obtaining sufficient funding, with topline results expected within two years of trial initiation.
- Results from the AHFIRM Phase 2b trial were published in *NEJM Evidence* in January 2025. In addition to highlighting the key findings from this study, the article also included new trial data, including subgroup analyses that explain regional differences in patient populations and in AH treatment regimens. Variations in time from hospitalization to first dose highlighted the importance of timely treatment in patients with severe AH. Top line data from AHFIRM were previously announced in November 2023.
- On May 6, 2025, Innocoll Pharmaceuticals Limited (Innocoll) transferred all data and know-how related to POSIMIR to us upon termination of the licensing agreement between us and Innocoll. We are evaluating next steps with respect to finding a new partner to commercialize POSIMIR.

Financial Highlights for the First Quarter 2025:

- Total revenues were $0.3 million and net loss was $4.2 million for the three months ended March 31, 2025 compared to total revenues of $0.5 million and net loss of $7.6 million for the three months ended March 31, 2024.
- As of March 31, 2025, cash, cash equivalents and investments were $8.4 million, compared to cash, cash equivalents and investments of $12.0 million at December 31, 2024.

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 consisted 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. 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 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. Larsucosterol, DURECT's lead drug candidate, binds to and inhibits the activity of DNA methyltransferases, epigenetic enzymes that are elevated and associated with hypermethylation found in AH patients. Larsucosterol is in clinical development for the potential treatment of AH, for which the FDA has granted a Fast Track and a Breakthrough Therapy designation; MASH has also been explored. 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: our plans regarding finding a new partner to commercialize POSIMIR, our plans to conduct a Phase 3 clinical trial of larsucosterol, the ability of the Phase 3 trial to be successful and, if successful, to support a New Drug Application filing, the sufficiency of our capital requirements and our ability to secure sufficient funding for a Phase 3 trial of larsucosterol, our expectations for timing of topline results from a Phase trial of larsucosterol and the potential uses of larsucosterol to treat 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 risk that 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 we do not raise sufficient capital to commence or complete the Phase 3 clinical trial of larsucosterol in patients with AH or continue to fund our operations, the risk that the FDA or other government agencies may experience disruptions due to departmental funding shortages or require additional clinical trials for larsucosterol before approving larsucosterol for the treatment of AH, the risk that Breakthrough Therapy designation does not expedite the process for FDA approval and that larsucosterol may never be approved; and risks related to the sufficiency of our cash resources, our anticipated capital requirements, our ability to regain the minimum bid price for continued listing on Nasdaq, 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 filings, including its annual report on Form 10-K for the year ended December 31, 2024 and quarterly report on Form 10-Q for the quarter ended March 31, 2025, 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 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: 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	
	2025	2024
Collaborative research and development and other revenue	$ 321	$ 496
Total revenues	321	496
Operating expenses:		
Research and development	1,883	4,119
Selling, general and administrative	2,577	2,681
Total operating expenses	4,460	6,800
Loss from operations	(4,139)	(6,304)
Other income (expense):		
Interest and other income	95	321
Change in fair value of warrant liabilities	(119)	(1,718)
Other expense, net	(24)	(1,397)
Loss from continuing operations	(4,163)	(7,701)
Income (loss) from discontinued operations	(69)	58
Net loss	$ (4,232)	$ (7,643)
Net change in unrealized gain on available-for-sale securities, net of reclassification adjustments and taxes	$ –	$ 4
Total comprehensive loss	$ (4,232)	$ (7,639)
Net loss per share, basic		

	Loss from continuing operations	$ (0.13)	$ (0.25)
	Income (loss) from discontinued operations	$ –	$ –
	Net loss per common share	$ (0.13)	$ (0.25)
Net loss per share, diluted			
	Loss from continuing operations	$ (0.13)	$ (0.25)
	Income (loss) from discontinued operations	$ –	$ –
	Net loss per common share	$ (0.13)	$ (0.25)
Weighted-average shares used in computing net income (loss) per share			
	Basic	31,042	30,637
	Diluted	31,042	30,637

DURECT CORPORATION

CONDENSED BALANCE SHEETS

(in thousands)

	As of March 31, 2025 (unaudited)	As of December 31, 2024 [1]
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,963	$ 11,011
Short-term Investments	297	792
Accounts receivable, net	330	453
Inventories, net	85	106
Prepaid expenses and other current assets	737	813
Total current assets	9,412	13,175
Property and equipment, net	38	41
Operating lease right-of-use assets	1,912	2,135
Goodwill	2,725	2,725
Long-term restricted Investments	150	150
Other long-term assets	123	123
Total assets	$ 14,360	$ 18,349
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		

Accounts payable	$	313	$	309
Accrued liabilities	4,603		4,771	
Operating lease liabilities, current portion	1,090		1,082	
Warrant liabilities	1,667		1,548	
Total current liabilities	7,673		7,710	
Operating lease liabilities, noncurrent portion	893		1,124	
Other long-term liabilities	443		384	
Stockholders' equity	5,351		9,131	
Total liabilities and stockholders' equity	$	14,360	$	18,349

(1) Derived from audited financial statements.

SOURCE DURECT Corporation