DURECT Corporation Reports Third Quarter 2024 Financial Results and Provides Business Update

Nov 13, 2024, 16:01 ET

– *Seeking to initiate Phase 3 registrational trial for larsucosterol with topline results expected within two years of initiation*

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

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

“We remain focused on preparations for the Phase 3 trial for larsucosterol in severe alcohol-associated hepatitis (AH), including discussions with U.S. clinical sites and hepatologists, to streamline the initiation process,” stated James E. Brown, D.V.M., President and CEO of DURECT. “Our goal is to begin the trial as soon as possible, subject to obtaining sufficient funding, which should enable us to report topline data within two years of trial initiation. If successful, the FDA has agreed that a single Phase 3 trial may be sufficient to support a New Drug Application (NDA). We believe the selected primary endpoint of 90-day survival is clinically meaningful and provides the greatest probability of success based on the Phase 2b AHFIRM data. We look forward to initiating the trial as soon as possible. We believe that larsucosterol, if approved, could provide physicians with a much-needed treatment that could significantly improve the current 90-day mortality rates of approximately 30%.”

Recent business highlights and updates:

- DURECT announced details on the design of its planned registrational Phase 3 trial to evaluate the safety and efficacy of larsucosterol for the treatment of patients with severe alcohol-associated hepatitis (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 we received from the U.S. FDA during a Type B meeting held under Breakthrough Therapy Designation (BTD) as well as learnings from our prior Phase 2b AHFIRM trial in AH. DURECT’s goal is to begin the trial as soon as possible, subject to obtaining sufficient funding, with topline results expected within two years of trial initiation.
- DURECT plans to deliver an oral and two poster presentations at The Liver Meeting 2024, organized by the American Association for the Study of Liver Diseases (AASLD), to be held November 15-19, 2024 in San Diego, California. These presentations will showcase additional data from the completed Phase 2b AHFIRM trial which evaluated larsucosterol for the treatment of alcohol-associated hepatitis (AH). The data further support the design of the Company’s planned Phase 3 trial of larsucosterol, including the importance of timely treatment in clinical outcomes. Top line data from AHFIRM were previously announced in November 2023.
- On November 8, 2024, DURECT received notice that Innocoll Pharmaceuticals is terminating its license agreement for POSIMIR® (bupivacaine solution), effective in May 2025. Innocoll has committed to transfer all data and know-how related to POSIMIR to DURECT, and the company is evaluating next steps with respect to the commercialization of POSIMIR.

Financial Highlights for Q3 2024:

- Total revenues were $1.9 million and net loss was $4.3 million for the three months ended September 30, 2024 compared to total revenues of $1.7 million and net loss of $3.0 million for the three months ended September 30, 2023.
- Cash, cash equivalents and investments were $10.5 million at September 30, 2024, compared to $29.8 million at December 31, 2023. Debt at September 30, 2024 was $10.5 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 Third Quarter 2024 results and provide a corporate update:

Toll Free:	1-877-407-0784

International: 1-201-689-8560

Call Me: https://callme.viavid.com/viavid/?callme=true&passcode=13740526&h=true&info=company-email&r=true&B=6

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 the scheduled start time.

Webcast: https://viavid.webcasts.com/starthere.jsp?ei=1691806&tp_key=491002eb9b

The live audio webcast of the presentation will be also available on DURECT's homepage atwww.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. 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 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. 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 and report top-line data within two years of initiation, the potential for a single Phase 3 trial of larsucosterol, if successful, to support an NDA filing, and the potential uses and benefits of larsucosterol 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 September 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 September 30		Nine months ended September 30	
	2024	2023	2024	2023
Collaborative research and development and other revenue	$ 369	$ 506	$ 1,471	$ 1,657
Product revenue, net	1,558	1,238	4,454	4,222
Total revenues	1,927	1,744	5,925	5,879
Operating expenses:				
Cost of product revenues	513	312	1,158	1,059

	Research and development	2,164	7,199	8,530	23,738
	Selling, general and administrative	3,217	3,790	9,325	11,712
Total operating expenses		5,894	11,301	19,013	36,509
Loss from operations		(3,967)	(9,557)	(13,088)	(30,630)
Other income (expense):					
	Interest and other income	163	653	711	1,681
	Interest and other expenses	(364)	(700)	(1,338)	(2,175)
	Change in fair value of warrant liabilities	(117)	7,016	(1,913)	8,601
	Issuance cost for warrants	–	(427)	–	(1,627)
	Loss on issuance of warrants	–	–	–	(2,033)
Other income (expense), net		(318)	6,542	(2,540)	4,447
Net loss		$ (4,285)	$ (3,015)	$ (15,628)	$ (26,183)
Net change in unrealized gain (loss) on available-for-sale securities, net of reclassification adjustments and taxes		$ 7	$ (6)	$ 14	$ 1
Total comprehensive loss		$ (4,278)	$ (3,021)	$ (15,614)	$ (26,182)
Net loss per share					
	Basic	$ (0.14)	$ (0.11)	$ (0.51)	$ (1.04)
	Diluted	$ (0.14)	$ (0.01)	$ (0.51)	$ (1.07)
Weighted-average shares used in computing net loss per share					
	Basic	31,039	27,211	30,906	25,175
	Diluted	31,039	27,511	30,906	25,433

DURECT CORPORATION

CONDENSED BALANCE SHEETS

(in thousands)

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

Cash and cash equivalents	$	9,086	$	28,400
Short-term Investments	1,290		1,280	
Accounts receivable, net	1,016		1,261	
Inventories, net	2,376		2,219	
Prepaid expenses and other current assets	657		1,511	
Total current assets	14,425		34,671	
Property and equipment, net	52		91	
Operating lease right-of-use assets	3,142		3,980	
Goodwill	6,169		6,169	
Long-term restricted Investments	150		150	
Other long-term assets	128		128	
Total assets	$	24,066	$	45,189
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	$	498	$	1,777
Accrued liabilities	4,798		5,966	
Term loan, current portion, net	10,466		16,663	
Operating lease liabilities, current portion	1,308		1,381	
Warrant liabilities	3,137		1,224	
Total current liabilities	20,207		27,011	
Operating lease liabilities, noncurrent portion	1,966		2,702	
Other long-term liabilities	676		693	
Stockholders' equity	1,217		14,783	
Total liabilities and stockholders' equity	$	24,066	$	45,189

(1) Derived from audited financial statements.

SOURCE DURECT Corporation