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

Nov 02, 2022, 16:05 ET

– ***Webcast of Earnings Call Today, November 2nd at 4:30 p.m. ET***

– ***AHFIRM trial timeline continues to improve***

CUPERTINO, Calif., Nov. 2, 2022 /PRNewswire / — DURECT Corporation (Nasdaq: DRRX) today announced financial results for the three months ended September 30, 2022 and provided a corporate update.

“We are excited that we are now on track to complete enrollment of our pivotal AHFIRM trial in the second quarter of 2023, earlier than we previously estimated. We continue to make excellent progress toward our goal of bringing larsucosterol to market as the first FDA-approved treatment for alcohol-associated hepatitis,” stated James E. Brown, D.V.M., President and CEO of DURECT. “In addition, we earned $10 million in total milestone payments from our Innocoll collaboration. We are pleased that Innocoll has launched POSIMIRÂ® and look forward to following their launch progress.”

Third Quarter and Recent Business Highlights:

- **Continued progress in AHFIRM enrollment** â?? DURECT has enrolled more than 200 patients in the AHFIRM trial to date, which exceeds two-thirds 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. and are continuing to open new sites, including prominent transplant centers. We currently expect to complete enrollment in the AHFIRM trial in the second quarter of 2023, which should enable top-line results to be reported in the second half of 2023.
- **Commercial launch of POSIMIR** â?? In September 2022, Innocoll Pharmaceuticals Limited (Innocoll) commercially launched and achieved the first sales of POSIMIR in the United States, triggering a $2 million milestone for DURECT. In August 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 which was received by DURECT during the third quarter.

Financial Highlights for Q3 2022:

- Total revenues were $12.0 million and net loss was $2.5 million for the three months ended September 30, 2022 compared to total revenues of $2.2 million and net loss of $10.0 million for the three months ended September 30, 2021.
- At September 30, 2022, cash and investments were $52.0 million, compared to cash and investments of $70.0 million at December 31, 2021. Total debt at September 30, 2022 was $21.0 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 third quarter 2022 results and provide a corporate update:

Wednesday, November 2 @ 4:30 p.m. Eastern Time / 1:30 p.m. Pacific Time	
Toll Free:	1-877-869-3847
International:	201-689-8261
Conference ID:	13733742
Webcast:	https://event.choruscall.com/mediaframe/webcast.html?webcastid=FVUpzjla

A live audio webcast of the presentation will be also available by accessing DURECT’s homepage atwww.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 sa**F**ety and eff**I**cacy of la**R**sucosterol (DUR-928) treat**M**ent (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 and3b), 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, POSIMIRÂ® (bupivacaine solution) for infiltration use, a non-opioid analgesic utilizing the innovative SABERÂ® 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 theAHFIRM trial in the second quarter of 2023 and report top-line results 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 commercial launch of POSIMIR by 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, 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 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 September 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: POSIMIRÂ® is a trademark of Innocoll Pharmaceuticals, Ltd. in the U.S. and a trademark of DURECT Corporation outside of the U.S. SABERÂ® 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 BALANCE SHEETS

(in thousands)

(unaudited)

	As of September 30, 2022	As of December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 50,394	$ 49,844
Short-term investments	1,499	19,966
Accounts receivable, net	3,229	6,477
Inventories, net	2,269	1,870
Prepaid expenses and other current assets	1,955	3,580
Total current assets	59,346	81,737
Property and equipment, net	211	227
Operating lease right-of-use assets	2,340	3,446
Goodwill	6,169	6,169
Long-term restricted Investments	150	150
Other long-term assets	256	261

Total assets	$ 68,472	$ 91,990
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,139	$ 1,311
Accrued liabilities	6,240	6,799
Term loan, current portion, net	3,106	–
Deferred revenue, current portion	–	98
Operating lease liabilities, current portion	1,872	1,848
Total current liabilities	13,357	10,056
Deferred revenue, noncurrent portion	812	812
Operating lease liabilities, noncurrent portion	639	1,824
Term loan, noncurrent portion, net	17,928	20,632
Other long-term liabilities	882	884
Stockholders' equity	34,854	57,782
Total liabilities and stockholders' equity	$ 68,472	$ 91,990

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	
	2022	2021	2022	2021
Collaborative research and development and other revenue	$ 10,585	$ 443	$ 11,686	$ 1,752
Product revenue, net	1,392	1,722	4,282	4,928
Total revenues	11,977	2,165	15,968	6,680
Operating expenses:				
Cost of product revenues	345	364	1,073	1,075
Research and development	9,881	8,023	26,909	23,431
Selling, general and administrative	3,883	3,236	11,570	9,935
Total operating expenses	14,109	11,623	39,552	34,441
Loss from operations	(2,132)	(9,458)	(23,584)	(27,761)

Other income (expense):					
	Interest and other income	284	34	465	110
	Interest and other expense	(623)	(553)	(1,745)	(1,606)
Net other expense		(339)	(519)	(1,280)	(1,496)
Net loss		$ (2,471)	$ (9,977)	$ (24,864)	$ (29,257)
Net change in unrealized loss on available-for-sale securities, net of reclassification adjustments and taxes		17	3	$ 2	$ 7
Total comprehensive loss		$ (2,454)	$ (9,974)	$ (24,862)	$ (29,250)
Net loss per share					
	Basic	$ (0.01)	$ (0.04)	$ (0.11)	$ (0.13)
	Diluted	$ (0.01)	$ (0.04)	$ (0.11)	$ (0.13)
Weighted-average shares used in computing net loss per share					
	Basic	227,774	227,499	227,735	224,191
	Diluted	227,774	227,499	227,735	224,191

SOURCE DURECT Corporation