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

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

*– **Adding new clinical sites and patient dosing progressing in the AHFIRM trial***

CUPERTINO, Calif., May 4, 2022 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced financial results for the three months ended March 31, 2022 and provided a corporate update.

“Progress continues in the larsucosterol (DUR-928) AHFIRM trial, with more patients dosed in the first quarter of 2022 than in any prior quarter, reflecting the opening of additional clinical trial sites and our ongoing efforts to work with existing sites to recruit more patients with severe alcohol-associated hepatitis (AH) that meet our enrollment criteria,” stated James E. Brown, D.V.M., President and CEO of DURECT.

First Quarter and Recent Business Highlights:

- **Continued progress in AHFIRM enrollment** – DURECT has now dosed the first patients in Australia, France and Belgium, with 57 AHFIRM study sites now open at leading hospitals in the U.S., Australia, E.U. and U.K., a net increase of 6 sites in the two months since our last earnings call. At the pace of enrollment achieved in the first quarter of 2022, we would complete dosing the last patient in the AHFIRM trial in mid-2023; we expect the pace of enrollment should improve through our clinical site expansion, clinical trial engagement activities and the potential lessening of the impact of COVID on the hospitals participating in AHFIRM.
- **Engaging thought leaders and increasing awareness of AH** – DURECT’s medical affairs team has been substantially increasing our AH market outreach and education efforts to amplify larsucosterol awareness and facilitate AHFIRM enrollment efforts. We have recently hosted the first of multiple regional AHFIRM study update meetings with our investigators and study site coordinators, sponsored and exhibited at three liver-focused congresses in person, and retained a medical communications agency to broaden awareness of AH, the AHFIRM trial and larsucosterol.
- **Approaching U.S. launch of POSIMIR by our licensee** – DURECT signed an exclusive U.S. licensing agreement for POSIMIR® with Innocoll Pharmaceuticals in December 2021. Under the agreement, DURECT will earn low to mid double-digit royalties from net sales of POSIMIR and is eligible to receive up to $136 million in upfront and milestone payments, including the $4 million upfront license fee received in January 2022, and a $2 million milestone payment upon the first commercial sale of POSIMIR, which is anticipated in Q2 2022.

Financial highlights for Q1 2022:

- Total revenues were $1.9 million and net loss was $10.8 million for the three months ended March 31, 2022 compared to total revenues of $2.2 million and net loss of $10.1 million for the three months ended March 31, 2021.
- At March 31, 2022, cash and investments were $64.4 million, compared to cash and investments of $70.0 million at December 31, 2021. Debt at March 31, 2022 was $20.8 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 first quarter 2022 results and provide a corporate update:

Wednesday, May 4 @ 4:30pm Eastern Time / 1:30 p.m. Pacific Time

Toll Free:	1-800-285-6670
International:	713-481-1320
Conference ID:	13729654
Webcast:	https://event.choruscall.com/mediaframe/webcast.html?webcastid=6RVdxB8I

A live audio webcast of the presentation will be also available by accessing DURECT’s homepage at www.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 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 standard of care (SOC) which may include the use of methylprednisolone, a corticosteroid, at the discretion of the treating physician; (2) larsucosterol (30 mg); and (3) larsucosterol (90 mg). All patients in the trial receive supportive care. The primary outcome measure is 90-Day survival rate for patients treated with larsucosterol compared to those treated with placebo plus SOC. The Company is targeting 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 demonstration of a robust survival benefit in the AHFIRM trial would support an NDA 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 an 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 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 and severe 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 alcoholic liver disease patients, including AH patients, the procedure involves a long waiting period, a burdensome selection process, and costs more than $875,000 on average.

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 development and commercialization in the United States. For more information about DURECT, please visit www.www.durect.com and follow us on Twitter https://twitter.com/DURECTCorp.

DURECT Forward-Looking Statement
The statements in this press release regarding plans to complete enrollment of the AHFIRM trial in mid-2023, plans to increase the number of clinical trial sites in the AHFIRM trial, the expected commercial launch of POSIMIR by Innocoll and potential future payments we may receive from Innocoll, and the potential to develop larsucosterol for NASH or other indications are forward-looking statements involving risks and uncertainties that can cause actual results to differ materially from those in such forward-looking statements. Potential risks and uncertainties include, but are not limited to, 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 or the life-saving potential of larsucosterol in a statistically significant manner, risks that Innocoll may not commercialize POSIMIR successfully, if at all, 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 Form 10-K for the year ended December 31, 2021 and Form 10-Q for the quarter ended March 31, 2022 when filed with the Securities and Exchange Commission under the heading "Risk Factors." These reports are available on our website www.www.durect.com under the "Investors" tab.

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 March 31, 2022	
	2022	2021
Collaborative research and development and other revenue	$ 495	$ 574
Product revenue, net	1,420	1,638
Total revenues	1,915	2,212
Operating expenses:		
Cost of product revenues	335	352
Research and development	8,211	7,975
Selling, general and administrative	3,735	3,531
Total operating expenses	12,281	11,858
Loss from operations	(10,366)	(9,646)
Other income (expense):		
Interest and other income	54	37
Interest and other expense	(530)	(525)
Net other expense	(476)	(488)
Net loss	$ (10,842)	$ (10,134)
Net change in unrealized loss on available-for-sale securities, net of reclassification adjustments and taxes	(19)	(9)
Total comprehensive loss	$ (10,861)	$ (10,143)
Net loss per share		
Basic	$ (0.05)	$ (0.05)
Diluted	$ (0.05)	$ (0.05)
Weighted-average shares used in computing net loss per share		
Basic	227,688	217,537
Diluted	227,688	217,537

DURECT CORPORATION
CONDENSED BALANCE SHEETS
(in thousands)
(unaudited)

	As of March 31, 2022	As of December 31, 2021
ASSETS		

Current assets:					
Cash and cash equivalents	$	49,440		$	49,844
Short-term investments	14,761			19,966	
Accounts receivable, net	960			6,477	
Inventories, net	2,076			1,870	
Prepaid expenses and other current assets	3,398			3,580	
Total current assets	70,635			81,737	
Property and equipment, net	226			227	
Operating lease right-of-use assets	3,090			3,446	
Goodwill	6,169			6,169	
Long-term restricted Investments	150			150	
Other long-term assets	261			261	
Total assets	$	80,531		$	91,990
LIABILITIES AND STOCKHOLDERS' EQUITY					
Current liabilities:					
Accounts payable	$	2,269		$	1,311
Accrued liabilities	4,892			6,799	
Deferred revenue, current portion	–			98	
Operating lease liabilities, current portion	1,862			1,848	
Total current liabilities	9,023			10,056	
Deferred revenue, noncurrent portion	812			812	
Operating lease liabilities, noncurrent portion	1,442			1,824	
Term loan, noncurrent portion, net	20,765			20,632	
Other long-term liabilities	882			884	
Stockholders' equity	47,607			57,782	
Total liabilities and stockholders' equity	$	80,531		$	91,990

View original content:https://www.prnewswire.com/news-releases/durect-corporation-reports-first-quarter-2022-financial-results-and-update-of-programs-301539986.html

SOURCE DURECT Corporation

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