# DURECT Corporation Reports Third Quarter 2021 Financial Results and Update of Programs

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

**-Expanded number of AHFIRM study sites**

**-Opened first ex-US AHFIRM study sites**

**-Advanced POSIMIR licensing process**

CUPERTINO, Calif., Nov. 2, 2021 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced financial results for the three months ended September 30, 2021 and provided a corporate update.

“I am proud of the progress we have made in expanding clinical trial sites and the pace of enrollment in the AHFIRM study, particularly given the challenges faced by many of the hospitals where our study is being conducted in dealing with the Delta variant surge.” stated James E. Brown, DVM, President and CEO of DURECT. “I am also pleased with the progress made in our POSIMIR licensing process.”

**Third Quarter and Recent Business Highlights:**

**Continued progress in clinical study site openings** – DURECT has increased the total number of planned sites for the Phase 2b AHFIRM study to 60+. Since the last earnings call, the Company has opened an additional 10 clinical trial sites. There are now 36 global AHFIRM study sites open, more than 50% of the planned locations.

**Opening of first ex-US sites** – DURECT also recently opened the first ex-US study sites in Australia. This marks the beginning of the ex-US expansion of the AHFIRM study.

**USAN Council name approved** – The United States Adopted Names (USAN) Council has approved ‘larsucosterol’ as the nonproprietary (generic) name for DUR-928.

**Progress with POSIMIR partnering** – POSIMIR licensing negotiations continue to advance.

**Upcoming Key Milestones:**

DURECT is focused on advancing DUR-928 (larsucosterol) for the treatment of AH

- At the AASLD Liver Meeting November 12-15, Suthat Liangpunsakul, M.D. will present a poster reporting the growing prevalence of AH hospitalizations in the U.S., highlighting the growing unmet need for these patients.
- With strong interest from hepatologists to join the study, we plan to continue to expand the AHFIRM study to more than 60 total clinical trial sites across the U.S., E.U., U.K., and Australia.
- We expect to initiate ex-US dosing in the AHFIRM study in the coming weeks.
- We are on track to complete a POSIMIR license deal with a U.S. partner who would subsequently launch the product.
- We will determine next steps for larsucosterol in non-alcoholic steatohepatitis (NASH).

**Financial highlights for Q3 2021:**

- Total revenues were $2.2 million and net loss was $10.0 million for the three months ended September 30, 2021, compared to total revenues of $1.8 million and net loss of $9.3 million for the three months ended September 30, 2020.

- At September 30, 2021, cash and investments were $80.9 million, compared to cash, cash held in escrow and investments of $56.9 million at December 31, 2020. Debt at September 30, 2021 was $20.5 million, compared to $20.8 million at December 31, 2020

**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 2021 results and provide a corporate update:

***Tuesday, November 2 @ 4:30 p.m. Eastern Time / 1:30 p.m. Pacific Time***

| | |
|---|---|
| Toll Free: | 877-869-3847 |
| International: | 201-689-8261 |
| Conference ID: | 13724352 |
| Webcast: | Click Here for Webcast |

The conference call will also be available by webcast on DURECT's homepage at www.www.durect.com under the "Investors" tab. If you are unable to participate during the 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 study in subjects with severe acute **AH** to evaluate sa**F**ety and eff**I**cacy of DU**R**-928 treat**M**ent **(AHFIRM)**. AHFIRM is a randomized, double-blind, placebo-controlled, international, multi-center Phase 2b study to evaluate the safety and efficacy of larsucosterol (also known as DUR-928) in approximately 300 patients with severe AH. The study is comprised of three arms targeting enrollment of approximately 100 patients each: (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., E.U., U.K., and Australia. Reflecting the life-threatening nature of AH and the lack of therapeutic options for this devastating condition, the 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.

**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), the Company'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 AH patients. Larsucosterol is in clinical development for the potential treatment of alcohol-associated hepatitis (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. Full prescribing information about POSIMIR, including the Boxed Warning, can be found at www.posimir.com. 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 the potential for larsucosterol (also known as DUR-928) to treat patients with AH and NASH, clinical trial enrollment and plans, plans to complete a commercial license for POSIMIR and for its commercial launch, the potential benefits of Fast Track Designation, the potential for the AHFIRM trial to support an NDA filing for larsucosterol in AH, and plans to develop larsucosterol in NASH 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, the risk that the AHFIRM trial, even if successful, may not be sufficient alone to support an NDA filing for larsucosterol in AH, the risk that Fast Track designation for larsucosterol in AH may not actually lead to faster FDA review or an approval, risks that biomarker data in earlier trials of larsucosterol may not predict clinical efficacy, risks that we may not enter a commercial license for POSIMIR on favorable terms, if at all, risks that a licensee may not commercialize POSIMIR successfully, if at all, and risks related to entering into new agreements or 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 filed on March 5, 2021 and in our Form 10-Q for the quarter ended September 30, 2021 when filed with the Securities and Exchange Commission under the heading "Risk Factors."

NOTE: POSIMIR® and SABER® are trademarks 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. Full prescribing information for POSIMIR, including its Boxed Warning, can be found at www.posimir.com.

**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 | |
|---|---|---|---|---|
| | 2021 | 2020 | 2021 | 2020 |
| Collaborative research and development and other revenue | $ 443 | $ 306 | $ 1,752 | $ 23,623 |
| Product revenue, net | 1,722 | 1,504 | 4,928 | 4,280 |
| Total revenues | 2,165 | 1,810 | 6,680 | 27,903 |
| Operating expenses: | | | | |
| Cost of product revenues | 364 | 339 | 1,075 | 988 |
| Research and development | 8,023 | 6,870 | 23,431 | 21,024 |
| Selling, general and administrative | 3,236 | 3,429 | 9,935 | 10,197 |
| Total operating expenses | 11,623 | 10,638 | 34,441 | 32,209 |
| Loss from operations | (9,458) | (8,828) | (27,761) | (4,306) |
| Other income (expense): | | | | |
| Interest and other income | 34 | 84 | 110 | 477 |
| Interest and other expense | (553) | (546) | (1,606) | (1,690) |
| Net other expense | (519) | (462) | (1,496) | (1,213) |
| Loss from continuing operations | (9,977) | (9,290) | (29,257) | (5,519) |
| (Loss) income from discontinued operations | – | (42) | – | 577 |
| Net loss | $ (9,977) | $ (9,332) | $ (29,257) | $ (4,942) |
| Net (loss) income per share | | | | |
| Basic and Diluted | | | | |
| Loss from Continuing operations | $ (0.04) | $ (0.05) | $ (0.13) | $ (0.03) |
| (Loss) income from discontinued operations | $ – | $ (0.00) | $ – | $ 0.00 |
| Net loss per common share, basic and diluted | $ (0.04) | $ (0.05) | $ (0.13) | $ (0.02) |
| Weighted-average shares used in computing net (loss) income per share | | | | |
| Basic and Diluted | 227,499 | 201,877 | 224,191 | 198,176 |
| Total comprehensive loss | $ (9,974) | $ (9,385) | $ (29,250) | $ (4,921) |

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

| | As of September 30, 2021 (unaudited) | As of December 31, 2020(1) |
|---|---|---|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | $ 55,412 | $ 21,312 |
| Cash held in escrow | – | 14,979 |
| Short-term investments | 25,384 | 19,421 |
| Accounts receivable | 946 | 940 |
| Inventories | 2,270 | 1,864 |
| Prepaid expenses and other current assets | 3,238 | 4,545 |
| Total current assets | 87,250 | 63,061 |
| Property and equipment, net | 343 | 251 |
| Operating lease right-of-use assets | 3,789 | 4,749 |

| | | | | |
|---|---|---|---|---|
| Goodwill | 6,169 | | 6,169 | |
| Long-term investments | – | | 1,000 | |
| Long-term restricted Investments | 150 | | 150 | |
| Other long-term assets | 261 | | 261 | |
| Total assets | $ | 97,962 | $ | 75,641 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | | | |
| Current liabilities: | | | | |
| Accounts payable | $ | 1,894 | $ | 1,678 |
| Accrued liabilities | 5,741 | | 5,801 | |
| Contract research liability | 95 | | 545 | |
| Term loan, current portion, net | – | | 884 | |
| Operating lease liabilities, current portion | 1,835 | | 1,795 | |
| Total current liabilities | 9,565 | | 10,703 | |
| Deferred revenue, noncurrent portion | 812 | | 812 | |
| Operating lease liabilities, noncurrent portion | 2,190 | | 3,202 | |
| Term loan, noncurrent portion, net | 20,496 | | 19,936 | |
| Other long-term liabilities | 872 | | 873 | |
| Stockholders' equity | 64,027 | | 40,115 | |
| Total liabilities and stockholders' equity | $ | 97,962 | $ | 75,641 |

(1) Derived from audited financial statements.

View original content:https://www.prnewswire.com/news-releases/durect-corporation-reports-third-quarter-2021-financial-results-and-update-of-programs-301414508.html

SOURCE DURECT Corporation

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