

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**Form 8-K**

**Current Report**  
**Pursuant to Section 13 or 15(d)**  
**of the Securities Exchange Act of 1934**

**November 2, 2021**

**Date of Report**

**(Date of earliest event reported)**

**DURECT CORPORATION**  
**(Exact name of Registrant as specified in its charter)**

**Delaware**  
**(State or other jurisdiction of**  
**incorporation or organization)**

**000-31615**  
**(Commission**  
**File Number)**

**94-3297098**  
**(I.R.S. Employer**  
**Identification No.)**

**10260 Bubb Road**  
**Cupertino, CA 95014**  
**(Address of principal executive offices) (Zip code)**

**(408) 777-1417**  
**(Registrant's telephone number, including area code)**

**(Former name or former address, if changed since last report)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

**Title of Each Class**  
**Common Stock \$0.0001 par value per share**  
**Preferred Share Purchase Rights**

**Trading Symbol**  
**DRRX**

**Name of Each Exchange on Which Registered**  
**The NASDAQ Stock Market LLC**  
**(The Nasdaq Capital Market)**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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**Item 2.02. Results of Operations and Financial Condition.**

On November 2, 2021, DURECT Corporation, a Delaware corporation (“DURECT”), announced its third quarter 2021 financial results. This Current Report is filed to disclose nonpublic information required to be disclosed by Regulation FD. A copy of DURECT’s press release is attached as Exhibit 99.1 hereto and incorporated by reference herein.

The information concerning financial results in this Form 8-K and in Exhibit 99.1 shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section. The information concerning financial results in this Form 8-K and in Exhibit 99.1 shall not be incorporated into any registration statement or other document filed with the Securities and Exchange Commission by the company, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific reference in such filing.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

99.1 [Press Release of DURECT Corporation dated November 2, 2021](#)

104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 2, 2021

**DURECT Corporation**

By: /s/ Michael H. Arenberg  
Michael H. Arenberg  
Chief Financial Officer

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

*-Earnings Call and Webcast Today, November 2<sup>nd</sup> 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., November 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:**

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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

[Click Here for Webcast](#)

Conference ID: 13724352

Webcast:

The conference call will also be available by webcast on DURECT's homepage at [www.durect.com](http://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 safety and efficacy of DUR-928 treatment (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](http://www.posimir.com). For more information about DURECT, please visit [www.durect.com](http://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."

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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](http://www.posimir.com).

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**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	<u>2,165</u>	<u>1,810</u>	<u>6,680</u>	<u>27,903</u>
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	<u>11,623</u>	<u>10,638</u>	<u>34,441</u>	<u>32,209</u>
Loss from operations	(9,458)	(8,828)	(27,761)	(4,306)
Other income (expense):				
Interest and other income	34	84	110	477
Interest expense	(553)	(546)	(1,606)	(1,690)
Net other expense	<u>(519)</u>	<u>(462)</u>	<u>(1,496)</u>	<u>(1,213)</u>
Loss from continuing operations	(9,977)	(9,290)	(29,257)	(5,519)
(Loss) income from discontinued operations	—	(42)	—	577
Net loss	<u>\$ (9,977)</u>	<u>\$ (9,332)</u>	<u>\$ (29,257)</u>	<u>\$ (4,942)</u>
Net (loss) income per share				
Basic and diluted				
Loss from Continuing operations	<u>\$ (0.04)</u>	<u>\$ (0.05)</u>	<u>\$ (0.13)</u>	<u>\$ (0.03)</u>
(Loss) income from discontinued operations	<u>\$ —</u>	<u>\$ (0.00)</u>	<u>\$ —</u>	<u>\$ 0.00</u>
Net loss per common shares, basic and diluted	<u>\$ (0.04)</u>	<u>\$ (0.05)</u>	<u>\$ (0.13)</u>	<u>\$ (0.02)</u>
Weighted-average shares used in computing net income (loss) per share				
Basic and diluted	<u>227,499</u>	<u>201,877</u>	<u>224,191</u>	<u>198,176</u>
Total comprehensive loss	<u>\$ (9,974)</u>	<u>\$ (9,385)</u>	<u>\$ (29,250)</u>	<u>\$ (4,921)</u>

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

	As of September 30, 2021 (unaudited)	As of December 31, 2020 (1)
<b>ASSETS</b>		
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
<b>Total current assets</b>	<b>87,250</b>	<b>63,061</b>
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
<b>Total assets</b>	<b>\$ 97,962</b>	<b>\$ 75,641</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
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
<b>Total current liabilities</b>	<b>9,565</b>	<b>10,703</b>
Deferred revenue, noncurrent portion	812	812
Operating lease liabilities, non-current 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
<b>Total liabilities and stockholders' equity</b>	<b>\$ 97,962</b>	<b>\$ 75,641</b>

(1) Derived from audited financial statements.

SOURCE: DURECT Corporation

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