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

Form 8-K

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

August 3, 2020
Date of Report
(Date of earliest event reported)

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

Delaware	**000-31615**	**94-3297098**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(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	**Trading Symbol**	**Name of Each Exchange on Which Registered**
Common Stock $0.0001 par value per share **Preferred Share Purchase Rights**	**DRRX**	**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. ☐

Item 2.02. Results of Operations and Financial Condition.

On August 3, 2020, DURECT Corporation, a Delaware corporation ("DURECT"), announced its second quarter 2020 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 August 3, 2020

DURECT CORPORATION

INDEX TO EXHIBITS

Exhibit Number	Description
99.1	Press Release of DURECT Corporation dated August 3, 2020

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.

DURECT Corporation

Date: August 3, 2020

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

Exhibit 99.1

DURECT Corporation Announces Second Quarter 2020 Financial Results and Update of Programs

Live Webcast of Earnings Call Today, August 3rd at 4:30 p.m. ET

CUPERTINO, Calif., August 3, 2020/PRNewswire/ -- DURECT Corporation (Nasdaq: DRRX) today announced financial results for the three months ended June 30, 2020 and provided a corporate update.

- Total revenues were $25.8 million and net income was $14.3 million for the three months ended June 30, 2020 as compared to total revenues of $4.0 million and net loss of $7.2 million for the three months ended June 30, 2019. Revenues for the three months ended June 30, 2020 included the recognition of $23.1 million in deferred revenue from the $35 million upfront fee and initial milestone payment associated with the termination notice of our agreement with Gilead. This $23.1 million in revenue is non-recurring and has no cash flow impact.
- At June 30, 2020, cash and investments were $51.3 million, compared to cash and investments of $64.8 million at December 31, 2019. Debt at June 30, 2020 was $20.5 million, compared to $20.3 million at December 31, 2019.

“We continued to make progress in our clinical programs investigating DUR-928, our lead epigenetic regulator, during the second quarter. We were pleased to report positive topline data from our Phase 1b NASH trial and we look forward to presenting additional data from the trial at a future scientific meeting,” stated James E. Brown, D.V.M., President and CEO of DURECT. “We also initiated a Phase 2 trial of DUR-928 in COVID-19 patients with acute liver or kidney injury and are finalizing our preparations to initiate the Phase 2b trial with DUR-928 in alcoholic hepatitis in the upcoming months. The review of our New Drug Application (NDA) for POSIMIR is also ongoing and we continue to respond to the Agency’s requests for information.”

Update on Selected Programs:

Epigenetic Regulator Program. DUR-928, the lead product candidate in the Company’s Epigenetic Regulator Program, is an endogenous, orally bioavailable, first-in-class small molecule, which may have broad applicability in acute organ injuries such as alcoholic hepatitis (AH) and coronavirus disease 2019 (COVID-19) patients with acute liver or kidney injury as well as in chronic liver diseases such as non-alcoholic steatohepatitis (NASH).

Clinical Development

Alcoholic Hepatitis (AH)

- We are working with the FDA and our advisors to finalize the design of a multi-center, international, randomized, double-blind, placebo-controlled Phase 2b clinical trial of DUR-928 in severe AH patients. Patients in the trial will be randomized to receive 30 mg of DUR-928, 90 mg of DUR-928 or placebo. The primary endpoint will be survival rate for patients treated with DUR-928 compared to those treated with placebo. Further details of the trial design, including the size of the trial and other trial parameters will be provided at a future date. We expect to initiate this trial in the second half of 2020.
- During 2019, we completed a Phase 2a clinical trial of DUR-928 in patients with AH. All 19 patients treated with DUR-928 survived the 28-day follow-up period, 74% of patients (14/19) were discharged in ≤ 4 days after receiving a single dose of DUR-928, and there were no drug-related serious adverse events. These results show the potential of DUR-928 as a life-saving therapy for AH patients which currently have an overall historical mortality rate of 26% at 28 days, according to an analysis of 77 studies published between 1971 and 2016, which included data from a total of 8,184 patients.
- AH is an acute form of alcoholic liver disease (ALD) associated with long-term heavy intake of alcohol, and often occurs after a recent period of increased alcohol consumption. AH is typically characterized by recent onset jaundice and hepatic failure. According to the most recent data provided by the Agency for Healthcare Research and Quality (AHRQ), a part of the US Department of Health and Human Services (HHS), there were over 117,000 hospitalizations for patients with AH in 2016. From a recent publication analyzing the mortality and costs associated

with AH, the cost per patient is estimated at over $50,000 in the first year. ALD is one of the leading causes of liver transplants in the U.S., costing over $800,000 per patient.

Non-Alcoholic Steatohepatitis (NASH)

- In May 2020, we reported positive topline results from a Phase 1b randomized and open-label clinical study conducted in the U.S. to evaluate safety, pharmacokinetics and signals of biological activity (including clinical chemistry and biomarkers as well as liver fat content and liver stiffness by imaging) of DUR-928 in NASH patients with stage 1-3 fibrosis. A total of 65 patients completed the study. DUR-928 was orally administered daily at 50 mg (n=23), 150 mg (n=21), or 600 mg (300 mg BID (n=21)). Patients in this trial were dosed daily for 4 weeks and followed up for an additional 4 weeks.
- As shown in the table below, significant reductions from baseline (pre-treatment) levels were seen in liver enzymes, liver stiffness as measured by imaging and serum lipids. The Company believes that this demonstration of multiple important liver enzymes, plasma lipids and imaging results moving in the same direction, especially given the short treatment course of four weeks, is a promising indication of DUR-928's potential in NASH.

Median at Day 28 **** p < 0.05*** ***** p < 0.01*** ****** p < 0.001***		**All Subjects**			**Patients with ≥ 10% Reduction in MRI-PDFF**		
		50 mg QD *(n=21-23)*	**150 mg QD** *(n=20-21)*	**300 mg BID** *(n=20-21)*	**50 mg QD** *(n=9)*	**150 mg QD** *(n=8)*	**300 mg BID** *(n=9)*
Liver Enzymes	**ALT**	**-16%***	-10%	**-17%*****	**-21%****	**-19%***	**-32%*****
	AST	-14%	-9%	**-18%****	**-24%****	-21%	**-39%*****
	GGT	-6%	-1%	**-8%***	**-13%*****	**-16%***	-14%
Imaging	**MRI-PDFF**	-7%	-7%	-4%	**-18%*****	**-19%*****	**-23%*****
	FibroScan	**-10%****	-9%	-1%	-7%	**-9%****	-9%
Serum Lipids	**LDL-C**	-6%	**-11%***	-7%	-7%	-11%	**-8%***
	Non-HDL-C	-8%	-5%	-1%	-10%	**-8%***	**-12%***
	Triglycerides	**-13%***	-3%	-2%	-9%	0%	-8%
	24% reduction in serum triglycerides in patients with elevated baseline triglycerides (≥200 mg/dL; n=16) across all dose groups at day 28 from baseline (p <0.01)						

ALT *(alanine aminotransferase);* ***AST*** *(aspartate aminotransferase);* ***GGT*** *(gamma-glutamyl transferase);* ***LDL-C*** *(Low-Density Lipoprotein – Cholesterol);* ***Non-HDL-C*** *(Total cholesterol excluding High-Density Lipoprotein-Cholesterol);* ***QD*** *(once a day);* ***BID*** *(twice a day);* ***MRI-PDFF*** *(Magnetic Resonance Imaging - Proton Density Fat Fraction) is a non-invasive measure of the proportion of liver tissue which is composed of fat;* ***FibroScan*** *is a specialized ultrasound machine that measures the stiffness of liver tissue.*

- DUR-928 was well tolerated at all three doses evaluated. There were no serious adverse events reported during the study. Pharmacokinetic (PK) parameters after repeat dosing were comparable to those after a single dose (from a prior study), indicating no accumulation after repeat dosing.
- Results, including biomarker data, are still being analyzed. DURECT plans to present additional results and data analyses at a future scientific meeting.
- Non-alcoholic fatty liver disease (NAFLD) is the most common form of chronic liver disease in both children and adults. It is estimated that NAFLD affects approximately 30% to 40% of adults and 10% of children in the United States. NASH, a more severe and progressive form of NAFLD, is one of the most common chronic liver diseases worldwide, with an estimated prevalence of 3-5% globally. No drug is currently approved for NAFLD or NASH.

COVID-19

- We have begun to recruit patients for a randomized, double-blind, placebo-controlled, multi-center Phase 2 study to evaluate the safety and efficacy of DUR-928 in hospitalized COVID-19 infected patients with acute liver or kidney injury.

- A total of approximately 80 patients are planned to be enrolled into two study treatment groups in a 3:1 (DUR-928: placebo) ratio. Patients will receive a dose of 150 mg of DUR-928 or placebo by intravenous infusion on day 1 and day 4 in combination with standard of care therapy, which will be determined by the principal investigator (PI) at each clinical trial site. The primary efficacy endpoint is a composite of survival and being free of acute organ failure (free of mechanical ventilation, free of liver failure events and free of renal replacement therapy) at day 28. Patients will be followed for 60 days. Should any drug product be determined by the FDA to be safe and effective for the treatment of COVID-19 while the trial is ongoing, such treatments may be offered, at each PI's discretion, to any remaining and future patients in this trial.

- COVID-19 is an infectious disease caused by severe acute respiratory syndrome coronavirus (SARS-COV-2). The rapid spread of the disease has resulted in a pandemic with millions of confirmed cases and hundreds of thousands of deaths worldwide. While most cases result in mild symptoms, including fever, cough and shortness of breath, some rapidly progress into acute respiratory distress syndrome (ARDS), multi-organ failure, and death. Many of these patients experience a rapid elevation of inflammation-inducing signaling molecules (cytokine storm) that trigger acute injuries in multiple organs including the liver and the kidney. Organ injury may also occur in hospitalized COVID-19 patients as the result of other complications of the viral infection. In a study of 1,059 adult cases of confirmed hospitalized COVID-19, 62% of patients presented with at least one elevated liver enzyme. In another study, 36.6% of 5,449 patients admitted with COVID-19 had or developed acute kidney injury (AKI).

- The reasons for investigating DUR-928 in this patient population include:
    - DUR-928 has demonstrated, both *in vitro* and *in vivo*, its ability to stabilize mitochondria, modulate inflammatory responses, and promote cell survival and tissue regeneration, which may render it to be effective in preventing or treating acute organ injury.
    - Patients with severe COVID-19 can develop multi-organ injury, including acute kidney, liver and/or cardiac injury, in addition to lung injury and ARDS. Therefore, preventing or successfully treating acute organ injury by alleviating acute cell injury, regulating inflammation, promoting cell survival, and stimulating tissue regeneration could potentially save lives of those hospitalized patients with COVID-19.
    - Most relevant to COVID-19 patients with acute liver or kidney injury are results from the recently completed Phase 2a study in AH patients (see above). As in AH patients, COVID-19 patients, especially those with acute liver or kidney injury, are at risk of septic shock and eventually multi organ failure and death. All 19 AH patients dosed with DUR-928 survived the 28-day study, while the historical 28-day mortality rate in AH patients is 26% on average.

POSIMIR® (bupivacaine extended-release solution) Post-Operative Pain Relief Depot. POSIMIR is DURECT's investigational post-operative pain relief depot that uses the Company's patented SABER technology and is designed to deliver bupivacaine to provide up to 3 days of pain relief after surgery.

- Since the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) meeting on January 16, 2020, we have continued to interact with the FDA, including answering information requests, as they continue their review of the POSIMIR NDA.

Conference Call
We will host a conference call today at 4:30 p.m. Eastern Time / 1:30 p.m. Pacific Time to discuss second quarter 2020 results and provide a corporate update:

Monday, August 3 @ 4:30 p.m. Eastern Time / 1:30 p.m. Pacific Time
Toll Free: 877-407-0784

International: 201-689-8560
Conference ID: 13706541
Webcast: http://public.viavid.com/index.php?id=140595

A live audio webcast of the presentation will also be available by accessing DURECT's homepage at 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 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. DURECT's lead candidate, DUR-928 is an endogenous sulfated oxysterol and an epigenetic regulator. It represents a new class of therapeutics with a unique mechanism of action. DUR-928 epigenetically modulates the expression of multiple clusters of master genes that are involved in many important cell signaling pathways, through which it stabilizes mitochondria, reduces lipotoxicity, regulates inflammatory or stress responses, and promotes cell survival. This drug candidate is currently in Phase 2 development for the treatment of alcoholic hepatitis (AH) and the treatment of COVID-19 patients with acute liver or kidney injury as well as Phase 1 development for the treatment of nonalcoholic steatohepatitis (NASH). DURECT's proprietary drug delivery technologies are designed to enable new indications and enhanced attributes for small-molecule and biologic drugs. One late-stage product candidate in this category is POSIMIR® (bupivacaine extended-release solution), an investigational locally-acting, non-opioid analgesic intended to provide up to three days of continuous pain relief after surgery. For more information about DURECT, please visit www.durect.com.

DURECT Forward-Looking Statement

The statements in this press release regarding clinical development and plans for DUR-928, including announcing further data from the Phase 1b NASH trial, initiating a Phase 2b trial of DUR-928 in AH in the second half of 2020, plans to enroll patents in a Phase 2 study in hospitalized COVID-19 infected patients with acute liver or kidney injury, potential regulatory approval of POSIMIR, and the potential benefits and uses of our drug candidates, including the potential use of DUR-928 to treat acute organ injuries such as AH and COVID-19 patients with acute liver or kidney injury as well as chronic liver diseases such as 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 future clinical trials of DUR-928 are not started when anticipated, take longer to conduct than anticipated, do not generate similar positive results as generated in earlier clinical or pre-clinical trials, or do not demonstrate the safety or efficacy of DUR-928 in a statistically significant manner, the risk that the FDA will not approve POSIMIR, the risk of disruptions to our business operations resulting from the COVID-19 pandemic, the risk that additional time and resources may be required for development, testing and regulatory approval of DUR-928 or POSIMIR, potential adverse effects arising from the testing or use of our drug candidates, our potential failure to maintain our collaborative agreements with third parties or consummate new collaborations 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-Q filed on May 11, 2020 under the heading "Risk Factors."

NOTE: POSIMIR® and SABER® are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners. DUR-928 and POSIMIR are investigational drug candidates under development and have 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 INCOME (LOSS)
(in thousands, except per share amounts)
(Unaudited)

	Three months ended June 30		Six months ended June 30	
	2020	2019	2020	2019
Collaborative research and development and other revenue	$ 23,347	$ 1,639	$ 23,317	$ 3,139
Product revenue, net	2,497	2,346	5,302	4,977
Total revenues	25,844	3,985	28,619	8,116
Operating expenses:				
Cost of product revenues	964	879	2,196	2,015
Research and development	6,686	6,598	14,403	12,849
Selling, general and administrative	3,439	3,278	6,879	6,732
Total operating expenses	11,089	10,755	23,478	21,596
Income (Loss) from operations	14,755	(6,770)	5,141	(13,480)
Other income (expense):				
Interest and other income	135	177	393	386
Interest expense	(552)	(634)	(1,144)	(1,263)
Net other expense	(417)	(457)	(751)	(877)
Net income (loss)	$ 14,338	$ (7,227)	$ 4,390	$ (14,357)
Net income (loss) per share				
Basic	$ 0.07	$ (0.04)	$ 0.02	$ (0.09)
Diluted	$ 0.07	$ (0.04)	$ 0.02	$ (0.09)
Weighted-average shares used in computing income (loss) per share				
Basic	196,866	164,359	196,306	163,219
Diluted	207,477	164,359	206,111	163,219
Total comprehensive income (loss)	$ 14,427	$ (7,230)	$ 4,464	$ (14,364)

DURECT CORPORATION

CONDENSED BALANCE SHEETS
(in thousands)

	As of June 30, 2020 (unaudited)	As of December 31, 2019 (1)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 18,446	$ 34,924
Short-term investments	32,699	29,750
Accounts receivable	1,997	2,313
Inventories	3,460	3,383
Prepaid expenses and other current assets	3,481	1,459
Total current assets	60,083	71,829
Property and equipment, net	476	469
Operating lease right-of-use assets	5,372	6,066
Goodwill	6,399	6,399
Long-term restricted Investments	150	150
Other long-term assets	283	1,107
Total assets	$ 72,763	$ 86,020
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 2,015	$ 2,109
Accrued liabilities	3,692	6,284
Contract research liability	2,572	3,653
Deferred revenue, current portion	—	22,679
Operating lease liabilities, current portion	2,073	2,043
Total current liabilities	10,352	36,768
Deferred revenue, noncurrent portion	812	812
Operating lease liabilities, non-current portion	3,827	4,517
Term loan, noncurrent portion, net	20,539	20,262
Other long-term liabilities	891	801
Stockholders' equity	36,342	22,860
Total liabilities and stockholders' equity	$ 72,763	$ 86,020

(1) Derived from audited financial statements.

SOURCE: DURECT Corporation

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