DURECT Corporation Announces Fourth Quarter and Full Year 2020 Financial Results and Update of Programs

Webcast of Earnings Call Today, March 4th at 4:30 p.m. Eastern Time

CUPERTINO, Calif., March 4, 2021 /PRNewswire/ — DURECT Corporation (Nasdaq: DRRX) today announced financial results for the three months and year ended December 31, 2020 and provided a corporate update.

“We have achieved a number of important milestones over the past few months, most significantly, initiating dosing in the DUR-928 AHFIRM trial in patients with severe alcohol-associated hepatitis (AH) and obtaining Fast Track Designation for that indication,” stated James E. Brown, D.V.M., President and CEO of DURECT. “We also obtained FDA approval for POSIMIR® and took steps to strengthen our financial position, our board and our management team as we advance the development of DUR-928, a potentially life-saving therapy for patients with severe AH.”

Accomplishments since last earnings call:

- Initiated patient dosing in the Phase 2b AHFIRM clinical study of DUR-928 in severe AH
- DUR-928 was granted FDA Fast Track Designation for the treatment of AH
- FDA approval of POSIMIR in adults to produce post-surgical analgesia for up to 72 hours following Arthroscopic Subacromial Decompression
- Presented additional Safety Data and Efficacy Signals from the Phase 1b NASH trial at The Liver Meeting Digital Experience™ 2020
- Appointment of two highly experienced biopharmaceutical board members
- Sale of the LACTEL Absorbable Polymers product line to Evonik for $15 million in cash
- Further strengthened our financial position by raising $47.8 million in equity since December 31, 2020

Financial highlights for Q4 and full year 2020:

- On December 31, 2020, the Company completed the sale of its LACTEL Absorbable Polymers product line to Evonik Corporation for $15 million in cash, resulting in a gain of approximately $12.8 million which is reflected in net income and net loss for three and twelve months ended December 31, 2020, respectively. As a result of the sale, the operating results from our LACTEL product line have been excluded from continuing operations and presented as discontinued operations in the accompanying Condensed Statements of Operations and Comprehensive Income (Loss) and Condensed Balance Sheets for all periods presented.
- Total revenues were $2.2 million and net income was $4.4 million for the three months ended December 31, 2020 as compared to total revenues of $9.0 million and net loss of $4.2 million for the three months ended December 31, 2019. Total revenues were $30.1 million and net loss was $0.6 million for the year ended December 31, 2020, compared to total revenues of $25.1 million and net loss of $20.6 million for the year ended December 31, 2019.
- At December 31, 2020, cash, cash held in escrow and investments were $56.9 million, compared to cash and investments of $64.8 million at December 31, 2019. In Q1 2021, DURECT raised net proceeds of $47.8 million from an underwritten public offering and other sales of equity. Debt at December 31, 2020 was $20.8 million, compared to $20.3 million at December 31, 2019.

Major activities in 2021:

- Ramping up clinical trial sites and enrollment in the Phase 2b AHFIRM trial of DUR-928 in severe AH
- Initiating ex-US dosing in the AHFIRM trial
- Commercial partnership discussions for POSIMIR, and potential subsequent commercial launch

- Publication of the DUR-928 mechanism of action in a peer-reviewed journal
- Determining next steps in NASH
- Potential new license and collaboration agreements

Update on Selected Programs and Transactions:

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 alcohol-associated hepatitis (AH) as well as in chronic liver diseases such as non-alcoholic steatohepatitis (NASH).

Clinical Development

Alcoholic Hepatitis (AH)

- We have begun dosing 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 DUR-928 in approximately 300 patients with severe AH. The study is comprised of three arms targeting 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) DUR-928 (30 mg); and (3) DUR-928 (90 mg). Patients receive an intravenous (IV) dose of DUR-928 or placebo (sterile water) on day 1 and a second IV dose on day 4 if they are still hospitalized. The primary outcome measure is 90-day survival rate for patients treated with DUR-928 compared to those treated with placebo plus SOC. Secondary endpoints include 28-day survival, the rate of adverse events, Lille and MELD (prognostic scores), and time in the intensive care unit. We are targeting 40-50 clinical trial sites in the US, Europe and Australia.
- Given the high mortality rate in severe AH patients and the absence of an approved therapeutic, we believe demonstration of a robust survival benefit in the AHFIRM trial may support an NDA filing.
- 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.
- Reflecting the life-threatening nature of AH and the lack of therapeutic options for this devastating condition, the FDA recently granted DUR-928 Fast Track Designation for the treatment of AH. The FDA grants Fast Track Designation to facilitate development and expedite the review of therapies with the potential to treat a serious condition where there is an unmet medical need. A therapeutic that receives Fast Track Designation can benefit from early and frequent communication with the agency in addition to a rolling submission of the marketing application, with the objective of getting important new therapies to patients more quickly.
- Alcohol-associated hepatitis (also called alcoholic hepatitis or 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 a recent onset of 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 122,000 hospitalizations for patients with AH in 2017. The cost per AH 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 $875,000 per patient. An analysis of 77 studies published between 1971 and 2016, which included data from a total of 8,184 patients, showed the average overall mortality from AH was 26% at 28 days and 29% at 90 days after admission.

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. In this 65-patient study, reductions from baseline (pre-treatment) levels were seen in liver enzymes, liver stiffness as measured by imaging, serum lipids and biomarkers. Many of these reductions were statistically significant and DUR-928 was well tolerated at all three doses evaluated.
- Additional results, including biomarker data, were presented through a poster at The Liver Meeting Digital Experience™ 2020 held November 13-16, 2020.

COVID-19

Since we initiated our clinical trial of DUR-928 in patients with COVID-19, several vaccines and therapeutics for COVID-19 have been approved and are being deployed worldwide. Treatment regimens for patients with COVID-19 have also evolved, the disease landscape has changed and additional therapies have entered clinical trials. Consequently, there have been a limited number of patients eligible or willing to enroll in our trial, and we have elected to discontinue the trial. The people and resources that were supporting the COVID-19 trial are now being redirected to support the AHFIRM trial.

POSIMIR® (bupivacaine solution)

- In February 2021, POSIMIR was granted U.S. FDA approval in adults for administration into the subacromial space under direct arthroscopic visualization to produce post-surgical analgesia for up to 72 hours following arthroscopic subacromial decompression. POSIMIR is the only approved sustained-release bupivacaine product indicated for up to 72 hours of post-surgical analgesia from a single application.
- The approval was based on positive data from a randomized, multicenter, assessor-blinded, placebo–controlled clinical trial in patients undergoing arthroscopic subacromial decompression surgery with an intact rotator cuff. The primary outcome measures were mean pain intensity and total opioid rescue analgesia administered, both evaluated over the first 72 hours after surgery versus placebo. POSIMIR demonstrated a statistically significant improvement in both primary outcome measures: a 1.3 point, or 20%, reduction in mean pain intensity on a 0-10 point pain scale (p=0.01), and a 67% reduction in I.V. morphine-equivalent rescue opioid use, from a median of 12 mg in the placebo group to 4 mg in the POSIMIR group (p=0.01). In connection with this approval, the Company or its licensee, will be required to conduct two postmarketing non-clinical studies. Full Prescribing Information, including the Boxed Warning, is available at www.POSIMIR.com
- DURECT is in discussions with potential partners regarding the licensing of commercialization rights to POSIMIR, for which DURECT currently holds worldwide rights.
- Subacromial decompression is a type of shoulder surgery used to treat impingement syndrome, a common repetitive-use injury that causes pain when the arm is raised over the head. The procedure is typically performed arthroscopically, meaning that several small incisions are made in the skin and muscle of the shoulder through which a camera lens (arthroscope) and surgical instruments are inserted during surgery. Arthroscopic subacromial decompression is generally considered outpatient surgery, and most patients go home within a few hours of surgery. The recovery period may extend from weeks to months, but the most intense pain typically occurs during the first 3 days after surgery and is often managed with oral opioids. There are over 600,000 surgeries involving arthroscopic subacromial decompression performed each year in the U.S.

Sale of LACTEL Absorbable Polymers product line

- In December 2020, we sold our LACTEL product line to Evonik for $15 million in cash. The gain from this sale was approximately $12.8 million. This transaction is part of our effort to focus on epigenetic regulation and the development of DUR-928.
- The $15 million of cash was held in escrow as of December 31, 2020 and was released to DURECT's bank account in January 2021.

Important additions to our team

- In November 2020, we appointed Dr. Norman Sussman as our Chief Medical Officer. Dr. Sussman is a renowned hepatologist with extensive clinical experience and expertise in the liver disease field. He brings over 30 years of clinical research and development experience in academia and industry and a proven track record in clinical research of liver diseases.
- In January 2021, we appointed two new members to our board of directors. Gail J. Maderis, MBA, and Mohammad Azab, MD, MSc, MBA, are industry veterans with extensive drug development, clinical research and medical affairs experience.

Strengthening our financial position

In Q1 2021, DURECT raised net proceeds of $47.8 million from an underwritten public offering and other sales of equity.

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 fourth quarter 2020 results and

provide a corporate update:

Thursday, March 4 @ 4:30pm Eastern Time / 1:30 p.m. Pacific Time

Toll Free:	877-407-0784
International:	201-689-8560
Conference ID:	13715968
Webcast:	**http://public.viavid.com/index.php?id=143367**

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 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. DUR-928, the company's lead drug candidate 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 now 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 DUR-928 to treat patients with AH and NASH, plans to ramp up clinical trial sites and enrollment and initiate ex-US trial sites in the Phase 2b AHFIRM trial, plans to seek a commercialization partner for POSIMIR and its commercial launch, and to enter into additional license and commercialization agreements 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 DUR-928 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 DUR-928 in a statistically significant manner, risks that we may not enter a commercialization partnership for POSIMIR on favorable terms, if at all, risks that we or a third-party collaborator 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-Q filed on November 3, 2020 and in our annual report on Form 10-K for the year ended December 31, 2020 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® and SABER® are trademarks of DURECT Corporation. Other referenced trademarks belong to their respective owners. 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 INCOME (LOSS)
(in thousands, except per share amounts)
(unaudited)

	Three months ended December 31		Twelve months ended December 31	
	2020	2019	2020	2019
Collaborative research and development and other revenue	$ 317	$ 7,249	$ 23,941	$ 18,129
Product revenue, net	1,890	1,746	6,170	6,945
Total revenues	2,207	8,995	30,111	25,074
Operating expenses:				
Cost of product revenues	418	463	1,406	1,263
Research and development	6,682	9,295	27,709	29,640
Selling, general and administrative	3,413	3,705	13,611	14,115
Total operating expenses	10,513	13,463	42,726	45,018
Loss from operations	(8,306)	(4,468)	(12,615)	(19,944)
Other income (expense):				
Interest and other income	40	338	517	1,074

Interest and other expense	(547)	(610)	(2,237)	(2,501)
Net other expense	(507)	(272)	(1,720)	(1,427)
Loss from continuing operations	(8,813)	(4,740)	(14,335)	(21,371)
Income from discontinued operations	13,173	509	13,753	793
Net income (loss)	$ 4,360	$ (4,231)	$ (582)	$ (20,578)
Net income (loss) per share				
Basic and diluted				
Continuing operations	$ (0.04)	$ (0.02)	$ (0.07)	$ (0.12)
Discontinued operations	$ 0.06	$ 0.00	$ 0.07	$ 0.00
Net income (loss) per common share, basic and diluted	$ 0.02	$ (0.02)	$ (0.00)	$ (0.12)
Weighted-average shares used in computing net income (loss) per share				
Basic	203,272	193,181	199,457	178,042
Diluted	211,497	193,181	199,457	178,042
Total comprehensive income (loss)	$ 4,337	$ (4,236)	$ (584)	$ (20,581)

DURECT CORPORATION
CONDENSED BALANCE SHEETS
(in thousands)

	As of December 31, 2020 (unaudited)	As of December 31, 2019[1]
ASSETS		
Current assets:		
Cash and cash equivalents	$ 21,312	$ 34,924
Cash held in escrow	14,979	–
Short-term investments	19,421	29,750
Accounts receivable	940	1,516
Inventories, net	1,864	1,919
Prepaid expenses and other current assets	4,545	1,424
Discontinued operations, current portion	–	2,296
Total current assets	63,061	71,829
Property and equipment, net	251	159
Operating lease right-of-use assets	4,749	5,866
Goodwill	6,169	6,399
Long-term investments	1,000	–
Long-term restricted Investments	150	150
Other long-term assets	261	1,085
Discontinued operations, non-current portion	–	532
Total assets	$ 75,641	$ 86,020
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,678	$ 1,982
Accrued liabilities	5,801	5,940
Contract research liability	545	3,653
Deferred revenue, current portion	–	22,679
Term loan, current portion, net	884	–
Operating lease liabilities, current portion	1,795	1,742
Discontinued operations, current portion	–	772
Total current liabilities	10,703	36,768
Deferred revenue, noncurrent portion	812	812
Operating lease liabilities, noncurrent portion	3,202	4,356
Term loan, noncurrent portion, net	19,936	20,262
Other long-term liabilities	873	705
Discontinued operations, non-current portion	–	257
Stockholders' equity	40,115	22,860
Total liabilities and stockholders' equity	$ 75,641	$ 86,020

(1) Derived from audited financial statements.

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SOURCE DURECT Corporation

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