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

January 5, 2021 (December 31, 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 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On January 5, 2021, DURECT Corporation ("DURECT") announced that the Board of Directors of DURECT (the "Board"), has appointed, effective as of January 4, 2021 (the "Effective Date"), Ms. Gail Maderis as a Class I director of DURECT with a term to expire at the 2022 Annual Meeting of Stockholders and Dr. Mohammed Azab as a Class III director of DURECT with a term to expire at the 2021 Annual Meeting of Stockholders. In connection with the appointments, the Board approved an increase in the size of the Board, from eight to ten members, effective as of the Effective Date.

Ms. Gail Maderis, 63 years old, has served as the President, Chief Executive Officer and a board member of Antiva BioSciences, Inc., a privately held biopharmaceutical company focused on developing topical therapeutics for HPV-based diseases, since July 2015. Prior to that, Ms. Maderis served as the President and Chief Executive Officer of BayBio, an independent, non-profit trade association serving the life sciences industry in Northern California, from 2009 until its merger with the California Healthcare Institute in early 2015. From 2003 to 2009, Ms. Maderis was President and Chief Executive Officer of FivePrime Therapeutics, Inc., a biotechnology company focused on the discovery and development of innovative protein and antibody drugs, and prior to that, she held general management positions at Genzyme Corporation, including Founder and President of Genzyme Molecular Oncology, a publicly traded division of Genzyme Corporation, and Corporate Vice President of Genzyme Corporation from 1997 to 2003. Ms. Maderis has been a member of several private company boards of directors, and she previously served as a director of Opexa Therapeutics, Inc. Ms. Maderis received a B.S. degree in Business Administration from the University of California at Berkeley and an M.B.A. from Harvard Business School. The Board believes that Ms. Maderis' operational, industry and leadership experience in the biopharmaceutical industry as CEO of FivePrime Therapeutics, Inc., President of Genzyme Molecular Oncology and her current position at Antiva, and her insight into business and policy trends impacting the biopharma industry qualify her to serve as a director of DURECT.

Dr. Azab, 65 years old, served as President and Chief Medical Officer of Astex Pharmaceuticals, Inc., ("Astex"), a pharmaceutical company focused on the discovery and development of drugs in oncology and other areas from January 2014 to November 2020, and prior to that, he had served as Astex's Chief Medical Officer from July 2009 to January 2014. Since his retirement, in November 2020, from his management role, Dr. Azab has served as the Chair of the Board of Directors for Astex, which is now a wholly owned subsidiary of Otsuka Pharmaceuticals. Previously, Dr. Azab served as President and CEO of Intradigm Corporation, a developer of siRNA cancer therapeutics. Prior to this, Dr. Azab served as Executive Vice President of Research and Development, and Chief Medical Officer of QLT Inc., and in several leadership positions at Astra Zeneca in the United Kingdom and Sanofi Pharmaceuticals in France. Dr. Azab holds his medical degree (MB ChB) from Cairo University and an M.B.A. from the Richard Ivey School of Business, University of Western Ontario. He received post-graduate training and degrees in oncology research from the University of Paris-Sud and biostatistics from the University of Pierre et Marie Curie in Paris, France. Dr. Azab has more than 30 years of experience in clinical research, global drug development, and business management and led the global development of several drugs currently approved in oncology and other therapeutic areas. He also serves on the board of directors of Xenon Pharmaceuticals Inc. The Board believes Dr. Azab's scientific background including his senior management experience in the pharmaceutical industry and as a board member of a publicly traded company, qualify him to serve on the Board.

Neither Ms. Maderis nor Dr. Azab has any family relationships with any of DURECT's directors or executive officers and none is a party to any transactions of the type listed in Item 404(a) of Regulation S-K.

Ms. Maderis and Dr. Azab will each receive cash and equity compensation in accordance with DURECT's current compensation practices for non-employee directors. In addition, each will receive a stock option grant at the Company's 2021 annual stockholder meeting in an amount consistent with annual grants awarded to other non-employee directors and pro-rated to reflecting a partial year of service prior to the annual meeting. Each will also enter into an indemnification agreement with DURECT consistent with the form agreement executed with each of DURECT's current directors.

A copy of the press release announcing these appointments is attached hereto as Exhibit 99.1.

Item 8.01. Other Events.

On January 4, 2021, DURECT announced the closing of the previously disclosed sale of the Lactel® Absorbable Polymer Product Line to Evonik and receipt of $15 million, effective December 31, 2020. A copy of the press release is attached hereto as Exhibit 99.2.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

99.1 Press Release of DURECT Corporation dated January 5, 2021

99.2 Press Release of DURECT Corporation dated January 4, 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.

DURECT Corporation

Date: January 5, 2021

By: /s/ James E. Brown
James E. Brown
President and Chief Executive Officer

Exhibit 99.1

DURECT Corporation Appoints Two New Board Members

CUPERTINO, Calif., January 05, 2021/PRNewswire/ -- DURECT Corporation (Nasdaq: DRRX) today announced the appointment of two new members to its board of directors, Gail J. Maderis, MBA and Mohammad Azab, M.D., M. Sc., MBA, two senior industry veterans with extensive drug development, clinical research and medical affairs experience.

"We are pleased to welcome Ms. Maderis and Dr. Azab to our board as we continue to enhance our board in line with our maturing company," stated James E. Brown, D.V.M., President and Chief Executive Officer of DURECT. “Their extensive expertise will be valuable as we continue to advance our clinical pipeline and create value for our shareholders, in particular as we advance the Phase 2b AHFIRM study of our lead candidate DUR-928 for the treatment of alcohol-associated hepatitis (AH) and plan for other indications with DUR-928.”

Ms. Maderis stated, "Clinical data from DURECT’s lead clinical asset DUR-928 in AH and non-alcoholic steatohepatitis (NASH) look very promising and show the potential of DUR-928 for the treatment of multiple organ injury and chronic liver diseases. I am eager to work with the DURECT board and management team to bring additional perspective as the company advances its clinical pipeline and explores additional opportunities for DUR-928 to fulfill unmet needs.”

Dr. Azab added, “I am excited to be joining the DURECT board as the company advances DUR-928 in the AHFIRM trial and gets closer to potentially offering a life-saving therapy to people affected by this life-threating condition. I look forward to working with the team and providing guidance as DURECT continues to advance DUR-928 through development and eventually, to potential approval and commercialization.”

Gail Maderis has served as President and CEO of Antiva Biosciences, a venture funded biopharma company developing topical therapies to treat the pre-cancerous lesions caused by HPV, since 2015. From 2009 to 2015, she led BayBio, the industry organization representing and supporting Northern California’s life science community. From 2003 to 2009, she served as President and CEO of Five Prime Therapeutics, Inc., a protein discovery and development company. Prior to FivePrime, Ms. Maderis held senior executive positions at Genzyme Corporation, including founder and president of Genzyme Molecular Oncology. She also practiced management and strategy consulting with Bain & Co. She serves on the corporate boards of Allarity Therapeutics and Valitor, Inc., as well as on the non-profit boards of BIO (Emerging Company and Health Sections), CLSI, The Termeer Foundation and the University of California Berkeley Foundation Board of Trustees. She received a BS in business from UC Berkeley and an MBA from Harvard Business School.

Dr. Mohammad Azab served as President and Chief Medical Officer of Astex Pharmaceuticals, Inc. since 2014 after holding the position of Chief Medical Officer there since 2009. As of November 2020, upon retirement from his management role, Dr. Azab has served as the Chair of the Board of Directors for Astex Pharmaceuticals, Inc, which is a wholly owned subsidiary of Otsuka Pharmaceuticals, focused on the discovery and development of drugs in oncology and other therapeutic areas. Previously, Dr. Azab served as President and CEO of Intradigm Corporation, a developer of siRNA cancer therapeutics. Prior to this, Dr. Azab served as Executive Vice President of Research and Development, and Chief Medical Officer of QLT Inc., and in several drug development leadership positions at Astra Zeneca in the United Kingdom and Sanofi Pharmaceuticals in France. During his carrier he has led or has been involved with the development of 8 approved drugs, 7 in Oncology and one in Ophthalmology. Dr. Azab holds his

medical degree (MB ChB) from Cairo University and an M.B.A. from the Richard Ivey School of Business, University of Western Ontario. He received post-graduate training and degrees in oncology research from the University of Paris-Sud and biostatistics from the University of Pierre et Marie Curie in Paris, France. Dr. Azab has more than 30 years of experience in clinical research, global drug development, and business management and led the global development of several drugs currently approved in oncology and other therapeutic areas. Currently, he also serves on the board of directors of Xenon Pharmaceuticals Inc.

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, COVID-19 patients with acute liver or kidney injury, and non-alcoholic 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 sustained-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 and follow us on Twitter https://twitter.com/DURECTCorp.

DURECT Forward-Looking Statement

The statements in this press release regarding clinical development plans for DUR-928, including the potential use of DUR-928 to treat AH and other acute organ injuries, including in COVID-19 patients, as well as chronic liver diseases, such as NASH, and the potential use of POSIMIR to provide pain relief after surgery 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 start of the AHFIRM trial or other trials will be delayed due to COVID-19 or other factors, that the AHFIRM trial will take longer than expected and may not replicate results from earlier trials, that the clinical trial of DUR-928 in COVID-19 patients is delayed or stopped because of changes to the standard of care, the availability of alternative therapies, required protocol changes or lack of available patients, the risk that clinical trials of DUR-928 do not demonstrate the safety or efficacy of DUR-928 in a statistically significant manner, the risk that the FDA will not approve POSIMIR or approve POSIMIR with a limited label, the risk that additional time and resources may be required for development, testing and regulatory approval of DUR-928 or the Company's other product candidates, potential adverse effects arising from the testing or use of our drug candidates, our potential failure to maintain our collaborative agreements with third parties 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 November 3, 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.

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Exhibit 99.2

DURECT Corporation Announces Closing of LACTEL® Absorbable Polymer Product Line Sale to Evonik and Receipt of $15 Million

CUPERTINO, Calif., January 4, 2021 /PRNewswire/ -- DURECT Corporation (Nasdaq: DRRX) today announced that the sale of the LACTEL product line to Evonik closed and the $15 million payment was received on December 31, 2020.

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, COVID-19 patients with acute liver or kidney injury, and non-alcoholic 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 sustained-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 and follow us on Twitter https://twitter.com/DURECTCorp.

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