
**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**

Date of Report (Date of Earliest Event Reported): October 5, 2020 (September 30, 2020)

Allena Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38268
(Commission
File Number)

45-2729920
(I.R.S. Employer
Identification No.)

One Newton Executive Park, Suite 202
Newton, Massachusetts
(Address of principal executive offices)

02462
(Zip Code)

Registrant's telephone number, including area code (617) 467-4577

Not Applicable
(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))

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

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.

Resignation of Robert Tepper, M.D.

On September 30, 2020, Robert Tepper, M.D. notified the Allena Pharmaceuticals, Inc., a Delaware corporation (the “Company”) of his intent to resign from the Board of Directors (the “Board”) and from his position as member of the Nominating and Corporate Governance Committee of the Board, effective as of October 5, 2020. Dr. Tepper’s decision to not stand for reelection was not related to any disagreement with the Company on any matter relating to its operations, policies, practices or any issues regarding financial disclosures, accounting or legal matters.

Appointment of Ann C. Miller, M.D. to the Board of Directors

On October 5, 2020, the Board appointed Ann C. Miller, M.D. to the Board, effective October 5, 2020. Dr. Miller will serve as a Class III director with a term expiring at the Company’s next annual meeting of stockholders, which is expected to be held on November 17, 2020 (the “Annual Meeting”), and until such time as her successor is duly elected and qualified, or until her earlier death, resignation or removal. Further, effective immediately following the Annual Meeting, the Board appointed Dr. Miller to serve on the audit and compensation committees of the Board, subject to her election as a director by the Company’s stockholders at the Annual Meeting.

Ann Miller has served as a member of the board of directors of Inovio Pharmaceuticals, Inc., a publicly held biotechnology company focused on the discovery, development, and commercialization of its synthetic DNA technology targeted against cancers and infectious diseases since March 2019. She has also served as a member of the board of directors of Puma Biotechnology, Inc., a biopharmaceutical company with a focus on the development and commercialization of innovative products to enhance cancer care, since November 2019. Prior to that, Dr. Miller worked at Sanofi S.A. from 2012 until her retirement in September 2018, serving as Vice President of Marketing and Vice President of Global Marketing, Oncology Division. From 2009 to 2011, Dr. Miller served as Senior Vice President of Pharmaceutical Services at Eisai Co., Ltd., leading its Primary Care and Specialty Business unit. Dr. Miller previously served in management roles in global marketing at Amgen Inc. and in positions of increasing responsibility at Merck & Co., Inc. over a period of 16 years. Dr. Miller received an M.D. from the Duke University School of Medicine and a B.A. in chemistry with honors from Duke University. She is a member of the Duke University Medical Alumni Council. We believe Dr. Miller is qualified to serve on our Board of Directors based on her broad commercial background in the biopharmaceutical industry and her clinical training and experience.

As a non-employee director, Dr. Miller will receive cash and equity compensation paid by the Company pursuant to its non-employee director compensation policy. There are no arrangements or understandings between Dr. Miller and any other person pursuant to which Dr. Miller was selected as a director, and there are no transactions between Dr. Miller and the Company that would require disclosure under Item 404(a) of Regulation S-K. In addition, the Company has entered into an indemnification agreement with Dr. Miller in connection with her appointment to the Board which is in substantially the same form as that entered into with the other directors of the Company.

Following the appointment of Dr. Miller, the Company’s Class III directors consist of Robert Alexander, Ph.D., Ann C. Miller, M.D. and Gino Santini. The terms for the Company’s Class III directors will expire at the Annual Meeting.

A copy of the press release issued by the Company announcing the foregoing activities is furnished as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of the Company, dated October 5, 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.

Date: October 5, 2020

Allena Pharmaceuticals, Inc.

By: /s/Edward Wholihan
Edward Wholihan
Chief Financial Officer

Allena Pharmaceuticals Appoints Ann Miller, M.D. to its Board of Directors

Newton, Mass. – October 5, 2020 – Allena Pharmaceuticals, Inc. (NASDAQ:ALNA), a late-stage, biopharmaceutical company dedicated to developing and commercializing first-in-class, oral enzyme therapeutics to treat patients with rare and severe metabolic and kidney disorders, today announced the appointment of Ann Miller, M.D., to its board of directors.

“Ann is an experienced and successful industry executive, who has built multiple high-performing commercial teams and successfully delivered blockbuster therapies to patients across a range of therapeutic areas,” said Louis Brenner, M.D., President and Chief Executive Officer of Allena Pharmaceuticals. “She will bring her extensive commercial experience to the Allena team, as we continue advancing our Phase 3 URIROX program and turn our attention to preparing for the potential launch of reloxaliase for enteric hyperoxaluria. We look forward to Ann’s insights as we work to build a fully-integrated, patient-focused commercial organization, and deliver on the promise of reloxaliase and our broader portfolio of oral enzyme therapeutics for people with rare and severe metabolic and kidney diseases.”

Dr. Miller has launched and grown multiple blockbuster products and built leading franchises over the course of her career. Most recently, she spent six years at Sanofi, ultimately serving as Vice President, Marketing, where she was selected to lead a corporate-wide initiative on Marketing Excellence. Prior to Sanofi, Dr. Miller spent two years as Senior Vice President at Eisai, where she led the Pharmaceutical Services and Primary Care and Specialty Business units, including the blockbuster franchises Aricept® and Aciphex®. Earlier in her career, Dr. Miller worked at Amgen, where she contributed to building the Global Marketing function, including serving as Executive Director, North American Commercial Operations and Executive Director, Global Marketing, and provided commercialization and life cycle management oversight for key products, including Neulasta® and Vectibix®. Before that, Dr. Miller spent 16 years at Merck & Co., where she held a series of roles of increasing responsibility, including brand leadership for Fosamax®, Mevacor®, and Zocor®. Dr. Miller currently serves on the board of Inovio Pharmaceuticals and Puma Biotechnology. She holds both B.A., with honors, and her M.D. from Duke University.

“I am pleased to join Allena’s board of directors,” said Ann Miller, M.D. “Based on the clinical data generated to date, I believe reloxaliase could usher in a new era in the treatment of enteric hyperoxaluria, offering patients a targeted, first-in-class therapeutic option. I look forward to working closely with the Allena team to develop an efficient and effective strategy for delivering reloxaliase to patients, and to fully maximize its potential to help patients.”

In conjunction with Dr. Miller’s appointment, Allena announced that founding board member Bob Tepper, M.D., a partner at Third Rock Ventures and founding member of the company’s board of directors since 2011, has resigned from the Allena Board.

“On behalf of the entire Allena team, I want to thank Bob for his many years of service,” Dr. Brenner continued. “His support and guidance was critical to launching Allena, and his insights have enabled us to translate the promise of our oral enzyme technology platform into a growing pipeline of novel, oral enzyme therapeutic candidates for people living with rare and severe metabolic diseases.”

About Allena Pharmaceuticals

Allena Pharmaceuticals, Inc. is a late-stage biopharmaceutical company dedicated to developing and commercializing first-in-class, oral enzyme therapeutics to treat patients with rare and severe metabolic and kidney disorders. Allena’s lead product candidate, reloxaliase, is currently being evaluated in a pivotal Phase 3 clinical program for the treatment of enteric hyperoxaluria, a metabolic disorder characterized by markedly elevated urinary oxalate levels and commonly associated with kidney stones, chronic kidney disease and other serious kidney disorders. Allena is also developing ALLN-346, currently being evaluated in a Phase 1 clinical trial, for the treatment of hyperuricemia in the setting of gout and advanced chronic kidney disease.

Forward-Looking Statements

This release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 including, without limitation, statements regarding the development and potential commercialization of reloxaliase, Allena’s pipeline of oral enzyme therapeutic candidates and Allena’s plans to build a commercial organization. Any forward-looking statements in this press release are based on management’s current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: market and other conditions, the timing for completion of Allena’s clinical trials of its product candidates, risks associated with obtaining, maintaining and protecting intellectual property; risks associated with Allena’s ability to enforce its patents against infringers and defend its patent portfolio against challenges from third parties; the risk of competition from other companies developing products for similar uses; risk associated with Allena’s financial condition and its need to obtain additional funding to support its business activities, including the future clinical development of reloxaliase and its ability to continue as a going concern; risks associated with Allena’s dependence on third parties; and risks related to the COVID-19 coronavirus. For a discussion of other risks and uncertainties, and other important factors, any of which could cause Allena’s actual results to differ from those contained in the forward-looking statements, see the section entitled “Risk Factors” in Item 1A of Part I of Allena’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, as well as discussions of potential risks, uncertainties and other important factors in Allena’s subsequent filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Allena undertakes no duty to update this information unless required by law.

Investor Contact

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