

ARDELYX, INC.
Form 8-K
January 06, 2016

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): January 4, 2016

ARDELYX, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction

of incorporation)

001-36485
(Commission

File Number)
34175 Ardenwood Blvd., Suite 200

26-1303944
(IRS Employer

Identification Number)

Fremont, CA 94555

(Address of principal executive offices, including Zip Code)

Registrant's telephone number, including area code: (510) 745-1700

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))

Item 8.01 Other Events.

Appointment of Chief Medical Officer.

On January 4, 2016, Ardelyx, Inc. (Ardelyx) issued a press release announcing that Paul Korner, M.D., M.B.A., joined Ardelyx in a newly-created position as Executive Vice President and Chief Medical Officer.

Prior to joining Ardelyx, Dr. Korner served as President of Ferring International Pharmascience Center U.S. (FIPCUS) for seven years, where he built and led Ferring Pharmaceuticals U.S. clinical development subsidiary across the gastroenterology, urology, reproductive health and orthopedics therapeutic areas. Dr. Korner joined Ferring as Vice President, Medical Affairs where he built and led the organization responsible for the medical support of marketed products across all therapeutic areas, including Medical Information and Pharmacovigilance. Prior to joining Ferring, Dr. Korner held various leadership positions within R&D and Medical Affairs at Solvay, Wyeth and Bayer Healthcare. He received his M.D. from Loyola University Stritch School of Medicine and is a board-certified obstetrician and gynecologist, having practiced in Illinois and Georgia prior to entering the pharmaceutical industry. Dr. Korner also holds an M.B.A. degree from The Michael J. Coles College of Business, Kennesaw State University, Georgia with a healthcare administration concentration.

Clinical Results of RDX022 for the Treatment of Hyperkalemia.

On January 5, 2016, Ardelyx issued a press release announcing positive results of an open label clinical study evaluating the pharmacodynamic activity of RDX022 in healthy adult volunteers. RDX022 is Ardelyx's proprietary oral, non-absorbed, potassium-binding polymer based on polystyrene sulfonate, a well-known and well-characterized polymer, also known as Kayexalate®. The study demonstrated that RDX022 effectively binds potassium in the gastrointestinal tract supporting plans to proceed with a Phase 3 clinical program currently expected to begin in the second half of 2016. RDX022 was generally well-tolerated at all doses administered (up to 27.5 g/day) in the study. The results of the study will be presented in a future scientific format. Based on discussions with the FDA, the Company is pursuing a 505(b)(2) regulatory pathway for RDX022.

Proposed Public Offering of Common Stock.

On January 6, 2016, Ardelyx issued a press release announcing a proposed public offering of shares of its common stock (the Offering). In connection with the Offering, Ardelyx filed a prospectus supplement with the Securities and Exchange Commission on January 6, 2016 (the Prospectus Supplement), which prospectus supplement is part of a registration statement on Form S-3 initially filed with the Securities and Exchange Commission on July 13, 2015 (Registration No. 333-205631).

Clinical Trials Timeline for Tenapanor.

In connection with the Offering, Ardelyx disclosed updated guidance in the Prospectus Supplement on the projected timing of its clinical trials for its lead product candidate, tenapanor. Tenapanor is currently being evaluated in two pivotal Phase 3 clinical studies in patients with constipation-predominant irritable bowel syndrome (IBS-C). In a Phase 2b clinical study, tenapanor demonstrated the ability to improve the symptoms of IBS-C. In a separate Phase 2b clinical trial, tenapanor demonstrated the ability to lower elevated serum phosphorus levels in patients with end-stage renal disease (ESRD). Ardelyx has initiated an additional Phase 2b clinical trial to evaluate dosing regimens of tenapanor for the treatment of hyperphosphatemia in ESRD patients, and it expects to receive results from this trial in the second half of 2016.

Statements made in this Current Report on Form 8-K, other than statements of historical fact, are forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including, for example, statements relating to Ardelyx's projected timing of its clinical trials and receipt of results from

such trials for tenapanor and RDX022. Forward-looking statements are subject to a number of known and unknown risks and uncertainties that might cause actual results to differ materially from those expressed or implied by such statements. For example, there can be no assurances with respect to the commencement, pace of enrollment, completion or success of clinical trials; and there can be no assurances that Ardelyx will pursue further activities with respect to the clinical development of tenapanor or RDX022. These and other risk factors are set forth in Ardelyx's annual report on Form 10-K for the fiscal year ended December 31, 2014 and subsequent SEC filings, including Ardelyx's Quarterly Reports on Form 10-Q and Current Reports on Form 8-K filed with the Securities and Exchange Commission. Ardelyx disclaims any intention or duty to update any forward-looking statement made in this Current Report on Form 8-K.

SIGNATURES

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

Date: January 6, 2016

ARDELYX, INC.

By: /s/ Mark Kaufmann
Mark Kaufmann
Chief Financial Officer