

ARDELYX, INC.
Form 8-K
November 21, 2017

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): November 21, 2017

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))
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 8.01 Other Events.

On November 21, 2017, Ardelyx, Inc. (the Company) provided an update on the development of its cardiorenal pipeline with a focus on tenapanor and next-generation opportunities. The Company is preparing to initiate enrollment in the second Phase 3 registration study for tenapanor for the treatment of hyperphosphatemia following feedback from the United States Food and Drug Administration (the FDA). In addition, the Company reported clinically meaningful activity from its onset-of-action study for RDX7675 for the treatment of hyperkalemia; however, the Company also observed an unanticipated side effect of decreased serum bicarbonate. The Company believes this side effect will limit the commercial potential of RDX7675, and as a result has decided to discontinue development of RDX7675. The Company projects that this will result in a reduction in operating expenses of approximately \$40 million to the Company over the next 24 months, extending the Company's operating runway into 2019.

Tenapanor for Hyperphosphatemia Program Update

Following learnings from the Company's first completed Phase 3 study of tenapanor for the treatment of hyperphosphatemia in end-stage renal disease (ESRD) patients on dialysis, the Company sought feedback from the FDA on the design of its second Phase 3 registration study. Based on the feedback received from the FDA, the Company will add an active control arm to the study for safety assessment only, consistent with the design of registration studies for phosphate binders. The Company is updating the study protocol and preparing to begin enrollment.

RDX7675 for Hyperkalemia Program Update

On November 21, 2017, the Company also reported an update from its onset-of-action study for RDX7675, which was being developed for the treatment of hyperkalemia. The study showed that RDX7675 significantly reduced serum potassium in patients treated across all dose levels. However, an unexpected and drug-related reduction in serum bicarbonate was also observed. Given the needs of this patient population and the need for a treatment that can be used in a chronic setting, the Company made the decision to discontinue development of RDX7675, including both the onset-of-action and Phase 3 studies. The Company intends to shift its hyperkalemia efforts to RDX013, its earlier-stage, small molecule program.

Forward Looking Statements

To the extent that statements contained in this Current Report on Form 8-K are not descriptions of historical facts regarding the Company, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor of the Private Securities Reform Act of 1995, including the potential for the Company's product candidates in treating the diseases and conditions for which they are being developed; the Company's future development plans for tenapanor, RDX7675, RDX013 and other product candidates and the expected timing thereof; the Company's design of its second Phase 3 registration study of tenapanor for the treatment of hyperphosphatemia in ESRD patients on dialysis; and a reduction in the Company's projected expenses as a result of discontinuing the development of RDX7675. Such forward-looking statements involve substantial risks and uncertainties that could cause the development of the Company's product candidates or the Company's future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in research and the clinical development process, including the regulatory approval process. The Company undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the Company's business in general, please refer to the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the SEC) on November 7, 2017, and its future current and periodic reports to be filed with the SEC.

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: November 21, 2017

ARDELYX, INC.

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