ARDELYX, INC.
Form 8-K
June 03, 2015

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): June 2, 2015

ARDELYX, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-36485**	**26-1303944**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification Number)**

34175 Ardenwood Blvd., Suite 200

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 1.01 Entry into a Material Definitive Agreement.

Termination Agreement with AstraZeneca

On June 2, 2015, Ardelyx, Inc. (the Company) entered into a Termination Agreement with AstraZeneca AB (AstraZeneca) pursuant to which the Company and AstraZeneca agreed to terminate the License Agreement dated as of October 4, 2012, as amended December 23, 2013 (the Collaboration Agreement). The Collaboration Agreement was entered into for the worldwide development and commercialization of tenapanor, the Company s lead product candidate which in clinical studies has demonstrated the ability to improve the symptoms of constipation-predominant irritable bowel syndrome (IBS-C) and to reduce the absorption of dietary sodium as well as phosphorus, a key component in the management of hyperphosphatemia in dialysis patients, and certain other NHE3 inhibitor compounds. AstraZeneca was responsible for all of the development and commercialization costs for tenapanor and the Company had retained an option to co-promote in the United States.

Pursuant to the Termination Agreement, all licenses granted by the Company to AstraZeneca under the Collaboration Agreement were terminated, except for the limited purpose of allowing AstraZeneca to satisfy its obligations under the Termination Agreement. In addition, AstraZeneca will assign certain agreements and licenses to the Company and will provide the Company with licenses, data, records and other materials to facilitate the Company s continued development and commercialization of tenapanor and the portfolio of NHE3 inhibitors licensed to AstraZeneca under the Collaboration Agreement. AstraZeneca will also supply the Company with clinical trial material and certain other materials, drug substances and drug products using transfer pricing for the aggregate amount of up to $10 million.

The Company has agreed to pay certain amounts to AstraZeneca for the return of the licenses previously granted to it, including (a) an upfront fee of $15 million, (b) future royalties at a royalty rate of 10% of net sales of tenapanor or other licensed products by the Company and its licensees and (c) 20% of non-royalty revenue received from a new collaboration partner should the Company elect to license, or otherwise provide rights, to a third party to develop and commercialize tenapanor. These amounts payable by the Company are capped at the aggregate amount of $90 million.

The Company has also agreed to pay AstraZeneca $10 million as reimbursement for research and development expenses incurred by AstraZeneca under the Collaboration Agreement during 2015, and in consideration of the accelerated transfer of information, data and materials to Ardelyx.

Securities Purchase Agreement

On June 2, 2015, the Company entered into a Securities Purchase Agreement (the Purchase Agreement) with the purchasers named therein (the Purchasers). Pursuant to the Purchase Agreement, the Company agreed to sell an aggregate of 7,242,992 shares of common stock (the Shares) and warrants (the Warrants) to purchase 2,172,898 shares of common stock (Warrant Shares) for aggregate gross proceeds of approximately $77.8 million (the Offering). The purchase price for each Share is $10.70, which is equal to the consolidated closing bid price on the NASDAQ Global Market on the day of pricing, June 2, 2015. The purchase price for each Warrant is equal to $0.125 for each Warrant Share, consistent with NASDAQ Global Market requirements for an at the market offering, and the Warrants are exercisable at an exercise price of $13.91 per share. The Company expects the Offering to close by June 5, 2015 subject to satisfaction of specified customary closing conditions. The Purchasers have irrevocably committed to purchase the securities, subject to satisfaction of the closing conditions. Investors participating in the offering include entities associated with New Enterprise Associates, a venture capital firm that is a significant shareholder in the Company, and a combination of new and existing investors, including RA Capital Management, Broadfin Capital LLC, Cormorant Asset Management LLC, Foresite Capital Management, LLC, Rock Springs Capital Management LP, and a fund managed by Sabby Capital, LLC.

In connection with the Purchase Agreement, the Company will enter into a Registration Rights Agreement (the Registration Rights Agreement) with the Purchasers. Pursuant to the Registration Rights Agreement, the Company

will agree to prepare and file a registration statement with the Securities and Exchange Commission (the SEC) within 45 days after the closing of the Offering for purposes of registering the resale of the Shares, the shares of common stock issuable upon exercise of the Warrants, and any shares of common stock issued as a dividend or other distribution with respect to the Shares or shares underlying the Warrants. The Company will agree to use its commercially reasonable efforts to cause this registration statement to be declared effective by the SEC within 90 days after the closing of the Offering (120 days in the event the registration statement is reviewed by the SEC). The Company will also agree, among other things, to indemnify the selling holders under the registration statements from certain liabilities and to pay all fees and expenses (excluding underwriting discounts and selling commissions and all legal fees of any selling holder) incident to the Company s obligations under the Registration Rights Agreement.

The financing is exempt from registration pursuant to the exemption for transactions by an issuer not involving any public offering under Section 4(2) the Securities Act of 1933, as amended (the Securities Act), and Regulation D under the Securities Act.

The securities sold and issued in connection with the Purchase Agreement will not be registered under the Securities Act or any state securities laws and may not be offered or sold in the United States absent registration with the SEC or an applicable exemption from the registration requirements.

The foregoing description of the transaction is only a summary and is qualified in its entirety by reference to the Purchase Agreement, the Form of Warrant and the Registration Rights Agreement, copies of which will be filed as exhibits to our Quarterly Report on Form 10-Q for the quarter ended June 30, 2015.

Item 1.02 Termination of a Material Definitive Agreement.
The information called for by this item is contained in Item 1.01, which is incorporated herein by reference.

Item 3.02 Unregistered Sale of Equity Securities.
The information called for by this item is contained in Item 1.01, which is incorporated herein by reference.

Item 8.01 Other Events.
In connection with the Termination Agreement described in Item 1.01, the Company plans to accelerate the clinical development path for tenapanor in constipation-predominant IBS-C by initiating a Phase 3 clinical trial in IBS-C patients in the fourth quarter of 2015. Additionally in the fourth quarter of 2015, Ardelyx expects to begin a Phase 2b clinical trial to evaluate the optimal dosing regimen for tenapanor for the treatment of hyperphosphatemia in dialysis patients.

A copy of the Company s press release announcing its entry into the Termination Agreement and describing its development plans for tenapanor and its portfolio of NHE3 compounds is attached as Exhibit 99.1 to this Current Report on Form 8-K, and is incorporated herein by reference.

The Company also plans to develop a new product candidate, RDX022, for the treatment of hyperkalemia, or elevated potassium, a potentially dangerous problem common among patients with chronic kidney disease and heart failure. RDX022 is a novel form of polystyrene sulfonate that has been designed with improved chemical and physical properties as well as with formulation improvements with the goal of a more efficient binding of potassium and a more palatable dosage form than currently-marketed polystyrene sulfonate products. The Company will be pursuing a 505b(2) regulatory pathway in the United States for RDX022. It anticipates beginning clinical trials in mid-2015 and, assuming a successful completion of the early-stage clinical trials, expects to commence a Phase 3 clinical trial as early as the second half of 2016.

A copy of the Company s press release announcing its new product candidate for the treatment of hyperkalemia and its development timeline is attached as Exhibit 99.2 to this Current Report on Form 8-K, and is incorporated herein by reference.

The Company plans to use the proceeds from its private placement to develop both tenapanor and RDX022, two wholly-owned programs that have potential to be in Phase 3 clinical trials in the fourth quarter of 2015 and second

half of 2016, respectively. The Company currently anticipates that development costs to advance tenapanor through clinical trials based on its current development plan and a new drug application (NDA) submission will be approximately $65-80 million for the treatment of IBS-C and $40-50 million for the treatment of hyperphosphatemia and that the development costs to advance RDX022 through clinical trials based on its current development plan and NDA submission for the treatment of hyperkalemia will be approximately $40-50 million.

The Company will host a live conference call and webcast at 8:30 a.m. eastern time on Wednesday, June 3, 2015 to discuss the Termination Agreement, private placement and proposed development plans for tenapanor, RDX022 and its other research and development programs. The live webcast and a replay may be accessed by visiting the Company s website at http://ir.ardelyx.com/.

Conference call information is as follows: (855) 296-9612 (U.S.) or (920) 663-6277 (international). Conference ID number is 59352386.

Statements made in this current report on Form 8-K, other than statements of historical fact, are forward-looking statements, including, for example, statements relating to the Company s clinical development programs, its spending plans, including the intended use of the proceeds from the financing and for the timing of the closing of the financing. 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, cost, rate of spending, completion or success of clinical trials; there can be no assurance with respect to the consummation of financing activities; financial projections may not be accurate; and there can be no assurances that the Company will pursue further activities with respect to the clinical development of tenapanor or RDX022. These and other risk factors are set forth in the Company s annual report on Form 10-K for the fiscal year ended December 31, 2014 and subsequent SEC filings, including the Company s quarterly report on Form 10-Q for the quarter ended March 31, 2015. The Company disclaims any intention or duty to update any forward-looking statement made in this current report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit

No.	Description
99.1	Press Release dated June 3, 2015
99.2	Press Release dated June 3, 2015

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: June 3, 2015

ARDELYX, INC.

By: /s/ Mark Kaufmann

Mark Kaufmann
Chief Financial Officer

EXHIBIT INDEX

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