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): May 17, 2023

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)**

400 FIFTH AVE., SUITE 210, WALTHAM, MASSACHUSETTS 02451
(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001	ARDX	The Nasdaq Global 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. o

Item 7.01 Regulation FD Disclosure.

On May 17, 2023, Ardelyx, Inc. (the "Company") issued a press release (the "Press Release") announcing that the U.S. Food and Drug Administration (the "FDA") has accepted its resubmission of a New Drug Application ("NDA") for XPHOZAH® (tenapanor) for the control of serum phosphate in adult patients with chronic kidney disease on dialysis who have had an inadequate response or intolerance to a phosphate binder therapy. The FDA has determined that the NDA is a class 2 review, which results in a six-month review period from the date of resubmission. The FDA has set a user fee goal date of October 17, 2023. The Press Release is attached hereto as Exhibit 99.1 and incorporated by reference herein.

The information included in this Item 7.01 and Exhibit 99.1 of this Current Report on Form 8-K is not deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), nor shall this Item 7.01 and Exhibit 99.1 be incorporated by reference into the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such future filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of Ardelyx, Inc. dated May 17, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: May 17, 2023

ARDELYX, INC.

By: /s/ Justin Renz

Justin Renz
Chief Financial & Operations Officer

Ardelyx Announces FDA Acceptance and Six-Month Review for Resubmission of its New Drug Application of XPHOZAH® (tenapanor)

User Fee Goal Date: October 17, 2023

WALTHAM, Mass., May. 17, 2023 – Ardelyx, Inc. (Nasdaq: ARDX), a biopharmaceutical company founded with a mission to discover, develop and commercialize innovative, first-in-class medicines that meet significant unmet medical needs, today announced that the U.S. Food and Drug Administration (FDA) has accepted its resubmission of a New Drug Application (NDA) for XPHOZAH (tenapanor) for the control of serum phosphate in adult patients with chronic kidney disease on dialysis who have had an inadequate response or intolerance to a phosphate binder therapy. The FDA has determined that the NDA is a class 2 review, which results in a six-month review period from the date of resubmission. The FDA has set a user fee goal date of October 17, 2023. The company expects XPHOZAH to be commercially available in the fourth quarter of 2023, as soon as possible following an approval from the FDA.

“The acceptance of our NDA is a significant milestone in our journey to bring XPHOZAH to patients. We are excited about the prospect of working collaboratively with the FDA to finalize this review over the next few months,” said Mike Raab, president and chief executive officer of Ardelyx. “We are now in full preparation mode and intend to launch XPHOZAH to the physician and patient communities who have patiently waited for access to this novel therapy as soon as possible after we receive an approval notification from the FDA, finally bringing this much-needed treatment to patients.”

The NDA is supported by a comprehensive development program that included more than 1,200 patients in three Phase 3 clinical trials evaluating the safety and efficacy of XPHOZAH, all of which met their primary and key secondary endpoints (PHREEDOM, BLOCK and AMPLIFY), as well as two additional Phase 4 open-label clinical trials (OPTIMIZE and NORMALIZE).

About XPHOZAH® (tenapanor)
XPHOZAH, discovered and developed by Ardelyx, is a first-in-class, phosphate absorption inhibitor that has a novel mechanism of action and acts locally in the gut to inhibit the sodium hydrogen exchanger 3 (NHE3), reducing phosphate absorption through the paracellular pathway, the primary pathway of phosphate absorption. This novel blocking mechanism enables a one 30mg tablet twice daily dosing regimen. The most common side effect with XPHOZAH in clinical trials was diarrhea.

About Hyperphosphatemia
Hyperphosphatemia is a serious condition resulting in an abnormally elevated level of phosphate in the blood that is estimated to affect the vast majority of the 550,000 patients in the United States with chronic kidney disease (CKD) on maintenance dialysis. The kidney is the organ responsible for regulating phosphate, but when kidney function is significantly impaired, phosphate is not adequately eliminated from the body. As a result, hyperphosphatemia is a nearly universal condition among people with CKD on maintenance dialysis with internationally recognized KDIGO treatment guidelines that recommend lowering elevated phosphate levels toward the normal range (2.5-4.5mg/dL).

About Ardelyx, Inc.
Ardelyx was founded with a mission to discover, develop and commercialize innovative, first-in-class medicines that meet significant unmet medical needs. Ardelyx’s first approved product, IBSRELA® (tenapanor) is available in the United States and Canada. Ardelyx is developing XPHOZAH® (tenapanor), a novel product candidate for the control of serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis, which has completed three successful Phase 3 trials. Ardelyx has a Phase 2 potassium lowering compound, RDX013, for the potential treatment of elevated serum potassium, or hyperkalemia, a problem among certain patients with kidney and/or heart

disease and an early-stage program in metabolic acidosis, a serious electrolyte disorder in patients with CKD. Ardelyx has established agreements with Kyowa Kirin in Japan, Fosun Pharma in China and Knight Therapeutics in Canada for the development and commercialization of tenapanor in their respective territories. For more information, please visit https://ardelyx.com/ and connect with us on Twitter, LinkedIn and Facebook.

Forward Looking Statements

To the extent that statements contained in this press release are not descriptions of historical facts regarding Ardelyx, 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 Ardelyx's current expectation of the review goal date for the NDA and any subsequent commercial launch; and the potential role that tenapanor can play in offering a new treatment option for patients with hyperphosphatemia. Such forward-looking statements involve substantial risks and uncertainties that could cause Ardelyx'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, uncertainties associated with the process for regulatory approval. Ardelyx 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 Ardelyx's business in general, please refer to Ardelyx's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 3, 2023, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

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