
**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 6, 2021



ARDELYX, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36485
(Commission
File Number)

26-1303944
(IRS Employer
Identification Number)

34175 ARDENWOOD BLVD., FREMONT, CALIFORNIA 94555
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.

Item 2.02 Results of Operations and Financial Condition.

On May 6, 2021, Ardelyx, Inc. (the “Company”) announced its financial results for the fiscal quarter ended March 31, 2021. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information furnished under this Item 2.02 shall not be considered “filed” under the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference into any future filing under the Securities Act of 1933, as amended, or under the Securities Exchange Act of 1934, as amended, unless the Company expressly sets forth in such future filing that such information is to be considered “filed” or incorporated by reference therein.

Item 9.01 Financial Statements and Exhibits.**(d) Exhibits.**

Exhibit No.	Description
99.1	Press release of Ardelyx, Inc.
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 6, 2021

ARDELYX, INC.

By: /s/ Justin Renz

Justin Renz

Chief Financial Officer

Ardelyx Reports First Quarter 2021 Financial Results and Recent Business Highlights

FREMONT, Calif. & WALTHAM, Mass., May 6, 2021 -- Ardelyx, Inc. (Nasdaq: ARDX), a biopharmaceutical company focused on developing innovative first-in-class medicines to improve treatment for people with kidney and cardiorenal diseases, today reported business highlights and financial results for the first quarter ended March 31, 2021.

“We continue to prepare for the potential approval and launch of tenapanor following the recent extension of our PDUFA date to July,” said Mike Raab, president and chief executive officer of Ardelyx. “We remain confident in the comprehensive data included in our New Drug Application and believe tenapanor represents an attractive alternative to currently available therapies to control serum phosphorus in CKD patients on dialysis. To that end, we are committed to working with the FDA through the completion of its review of our NDA and look forward to the possibility of making a significant impact in the lives of patients.”

Recent Business and Pipeline Updates

- Prescription Drug User Fee Act (PDUFA) date for tenapanor for the control of serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis was extended by three months to July 29, 2021.
- Received a \$5 million milestone payment in April 2021 from the company’s collaboration partner, Kyowa Kirin Co., Ltd. (KKC) following KKC’s initiation of four Phase 3 clinical studies of tenapanor for hyperphosphatemia patients on dialysis in Japan.
- Appointed industry veteran, Muna Bhanji, R.Ph., to the company’s board of directors.
- Presented two posters: 1) the mechanistic understanding of phosphate absorption and 2) continuing education needs of clinicians managing hyperphosphatemia, at the National Kidney Foundation 2021 Spring Clinical Meeting.
- Presented poster titled: A Long-Term, Open Label Study to Evaluate the Ability of Tenapanor Alone or in Combination with Sevelamer to Achieve Normal Serum Phosphorus in Patients with CKD on Dialysis (NORMALIZE) at the ISN World Congress of Nephrology 2021.

First Quarter 2021 Financial Results

- **Cash Position:** As of March 31, 2021, Ardelyx had total cash, cash equivalents and short-term investments of \$178.2 million, as compared to total cash, cash equivalents and short-term investments of \$188.6 million as of December 31, 2021.
- **Revenue:** The company generated \$6.6 million in revenue, which primarily represents a \$5.0 million milestone from KKC following its initiation of four Phase 3 clinical studies of tenapanor for hyperphosphatemia patients on dialysis in Japan.

- **R&D Expenses:** Research and development expenses were \$20.5 million for the three months ended March 31, 2021, an increase of \$4.6 million, or 29 percent, compared to \$15.8 million for the three months ended March 31, 2020. The increase was due primarily to clinical study costs from the advancement of the company's OPTIMIZE study which were partially offset by lower costs for the PHREEDOM clinical study, as well as higher employee-related expenses for the research and development workforce.
- **G&A Expenses:** General and administrative expenses were \$17.1 million for the three months ended March 31, 2021, an increase of \$10.0 million, or 140 percent, compared to \$7.1 million for the three months ended March 31, 2020. The increase in general and administrative expenses was primarily due to an increase in costs associated with building and staffing the company's commercial infrastructure as it prepares for the anticipated U.S. launch of tenapanor for the control of serum phosphorus in CKD patients on dialysis.
- **Net Loss:** Net loss for the quarter ended March 31, 2021 was \$33.2 million, as compared to \$22.4 million for the quarter ended March 31, 2020.

About Ardelyx, Inc.

Ardelyx is focused on discovering, developing and commercializing innovative first-in-class medicines to enhance the lives of patients with kidney and cardiorenal diseases. Ardelyx is advancing tenapanor, a novel product candidate to control serum phosphorus in adult patients with CKD on dialysis, for which the company's NDA is currently under review by the FDA. Ardelyx is also advancing RDX013, a potassium secretagogue, for the potential treatment of elevated serum potassium, or hyperkalemia, a problem among certain patients with kidney and/or heart disease and has an early-stage program in metabolic acidosis, a serious electrolyte disorder in patients with CKD. In addition, Ardelyx received FDA approval of IBSRELA® (tenapanor) on September 12, 2020. 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.

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. 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, the uncertainties associated with the regulatory approval process. 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 8, 2021, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

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Ardelyx, Inc.
Condensed Balance Sheets
(In thousands)

	<u>March 31, 2021</u> (Unaudited)	<u>December 31, 2020</u> (1)
Assets		
Cash and cash equivalents	\$ 84,070	\$ 91,032
Investments	94,142	97,566
Accounts receivable	5,783	—
Property and equipment, net	2,292	1,936
Right-of-use assets	1,667	2,274
Prepaid and other assets	22,339	8,754
Total assets	<u>\$ 210,293</u>	<u>\$ 201,562</u>
Liabilities and stockholders' equity		
Accounts payable	\$ 5,378	\$ 5,626
Accrued compensation and benefits	4,348	5,672
Current portion of operating lease liability	1,412	2,117
Loan payable, current portion	16,667	4,167
Deferred revenue	5,670	4,177
Accrued expenses and other liabilities	11,262	6,657
Operating lease liability, net of current portion	397	413
Loan payable, net of current portion	34,348	46,621
Stockholders' equity	130,811	126,112
Total liabilities and stockholders' equity	<u>\$ 210,293</u>	<u>\$ 201,562</u>

(1) Derived from the audited financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020.

Ardelyx, Inc.
Condensed Statements of Operations
(Unaudited)

(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2021	2020
Revenues:		
Collaborative development revenue	\$ 1,454	\$ 1,175
Product supply revenue	126	38
Licensing revenue	5,002	—
Total revenues	6,582	1,213
Operating expenses:		
Cost of revenue	1,000	—
Research and development	20,456	15,844
General and administrative	17,131	7,138
Total operating expenses	38,587	22,982
Loss from operations	(32,005)	(21,769)
Interest expense	(1,100)	(1,357)
Other income (expense), net	(49)	753
Loss before provision for income taxes	(33,154)	(22,373)
Provision for income taxes	\$ 1	\$ —
Net loss	\$ (33,155)	\$ (22,373)
Net loss per common share, basic and diluted	\$ (0.34)	\$ (0.25)
Shares used in computing net loss per share - basic and diluted	97,179,241	88,880,658