
**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): August 13, 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 August 13, 2021, Ardelyx, Inc. (the “Company”) announced its financial results for the fiscal quarter ended June 30, 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: August 13, 2021

ARDELYX, INC.

By: /s/ Justin Renz

Justin Renz

Chief Financial Officer

Ardelyx Reports Second Quarter 2021 Financial Results

FREMONT, Calif. & WALTHAM, Mass., August 13, 2021 -- Ardelyx, Inc. (Nasdaq: ARDX), a biopharmaceutical company focused on the discovery, development, and commercialization of innovative first-in-class medicines to improve treatment for people with kidney and cardiorenal diseases, today reported business events and financial results for the second quarter ended June 30, 2021.

Recent Business Events

- The company previously announced that the U.S. Food & Drug Administration (FDA) issued a Complete Response Letter (CRL) for the New Drug Application (NDA) for tenapanor for the control of serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis. The company plans to request a Type A meeting with the FDA to discuss the CRL and potential next steps to support approval of the company's NDA.
- On August 2, 2021, the company began implementing a restructuring plan to better align the company's workforce and anticipated commercial and development spend with the company's capital resources and the needs of its business following the receipt of the CRL. In connection with the restructuring, the company estimates that it will incur aggregate restructuring charges of approximately \$3.4 million, which will be recorded primarily in the third quarter 2021, related to one-time termination notice and severance payments and other employee-related costs. The company expects that the workforce reduction will decrease its annual cash compensation costs by approximately \$17 million.
- Separately, two presentations further highlighting promising tenapanor data were given at the European Renal Association – European Dialysis and Transplant Association (ERA-EDTA) Virtual Congress 2021.

Second Quarter 2021 Financial Results

- **Cash Position:** As of June 30, 2021, Ardelyx had total cash, cash equivalents and short-term investments of \$171.8 million, as compared to total cash, cash equivalents and investments of \$188.6 million as of December 31, 2020.

- **Revenue:** The company generated \$1.3 million in revenue for the three months ended June 30, 2021, which primarily represents collaborative development revenue from the 2019 Research Collaboration and Option Agreement between the company and Kyowa Kirin Co., Ltd.
- **R&D Expenses:** Research and development expenses were \$26.0 million for the three months ended June 30, 2021, an increase of \$7.2 million, or 38 percent, compared to \$18.9 million for the three months ended June 30, 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 \$20.1 million for the three months ended June 30, 2021, an increase of \$13.1 million, or 186 percent, compared to \$7.0 million for the three months ended June 30, 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 prepared for the potential regulatory approval and U.S. launch of tenapanor for the control of serum phosphorus in adult patients with CKD on dialysis.
- **Net Loss:** Net loss for the quarter ended June 30, 2021 was \$45.2 million, as compared to \$25.0 million for the quarter ended June 30, 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 developing tenapanor, a novel product candidate to control serum phosphorus in adult patients with CKD on dialysis, which has completed three successful Phase 3 trials. 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, 2019. 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, including Ardelyx's expectation with regard to its interactions and communications with the FDA and its plans and expectations as to the possibility of a pathway to approval of tenapanor for the control of serum phosphorus in adult patients with chronic kidney disease on dialysis, and Ardelyx's expectations regarding the costs associated with its restructuring plan and the reduction in annual cash compensation costs resulting from the workforce reduction.. 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, whether the company will be able to address the deficiencies identified by the FDA, whether additional trials will be necessary and if so, the scope of those trials, and whether and to what extent the restructuring costs may be in excess of what Ardelyx expects. 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 August 13, 2021, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

Investor and Media Contacts:

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Ardelyx, Inc.
Condensed Balance Sheets
(In thousands)

	June 30, 2021	December 31, 2020
	(Unaudited)	(1)
Assets		
Cash and cash equivalents	\$ 86,745	\$ 91,032
Investments	85,064	97,566
Property and equipment, net	2,666	1,936
Right-of-use assets	14,519	2,274
Prepaid and other assets	15,988	8,754
Total assets	\$ 204,982	\$ 201,562
Liabilities and stockholders' equity		
Accounts payable	\$ 2,587	\$ 5,626
Accrued compensation and benefits	5,939	5,672
Current portion of operating lease liability	3,184	2,117
Loan payable, current portion	36,111	4,167
Deferred revenue	4,359	4,177
Accrued expenses and other liabilities	8,552	6,657
Operating lease liability, net of current portion	11,548	413
Loan payable, net of current portion	15,133	46,621
Stockholders' equity	117,569	126,112
Total liabilities and stockholders' equity	\$ 204,982	\$ 201,562

(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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Revenues:				
Collaborative development revenue	1,310	1,125	2,764	2,300
Product supply revenue	—	5	126	43
Licensing revenue	3	706	5,005	706
Total revenues	1,313	1,836	7,895	3,049
Operating expenses:				
Cost of revenue	—	141	1,000	141
Research and development	26,021	18,864	46,477	34,708
General and administrative	20,124	7,038	37,255	14,176
Total operating expenses	46,145	26,043	84,732	49,025
Loss from operations	(44,832)	(24,207)	(76,837)	(45,976)
Interest expense	(1,202)	(1,226)	(2,302)	(2,583)
Other income (expense), net	847	477	798	1,230
Loss before provision for income taxes	(45,187)	(24,956)	\$ (78,341)	\$ (47,329)
Provision for income taxes	\$ 2	\$ —	\$ 3	\$ —
Net loss	\$ (45,189)	\$ (24,956)	\$ (78,344)	\$ (47,329)
Net loss per common share, basic and diluted	\$ (0.45)	\$ (0.28)	\$ (0.79)	\$ (0.53)
Shares used in computing net loss per share - basic and diluted	100,040,083	89,080,046	98,617,564	88,890,353