

---

---

**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 12, 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)

**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 November 12, 2021, Ardelyx, Inc. (the “Company”) announced its financial results for the fiscal quarter ended September 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	<a href="#">Press release of Ardelyx, Inc.</a>
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: November 12, 2021

ARDELYX, INC.

By: /s/ Justin Renz

Justin Renz

Chief Financial Officer

## Ardelyx Reports Third Quarter 2021 Financial Results

**FREMONT, Calif. and WALTHAM, Mass., November 12, 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 third quarter ended September 30, 2021.

### Recent Business Events

- The company presented four posters at the American Society of Nephrology Kidney Week 2021 (ASN Kidney Week), which took place virtually on November 4 – November 7, 2021, highlighting additional positive clinical observations with tenapanor, a first-in-class phosphate absorption inhibitor which has completed three successful Phase 3 clinical trials for the control of serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis. The company also shared important data focusing on the patient experience with tenapanor from the Phase 4 OPTIMIZE trial, which is designed to optimize the treatment of hyperphosphatemia in patients with CKD on dialysis.
- On November 4, 2021, the company announced that it expects to submit a Formal Dispute Resolution Request (FDRR) by the end of the fourth quarter 2021 to appeal the issuance of a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) for the company's New Drug Application (NDA) for tenapanor for the control of serum phosphorus in adult patients with CKD on dialysis.
- On October 13, 2021, the company announced the results of an End of Review Type A meeting with FDA's Division of Cardiology and Nephrology, noting that the meeting did not provide clarity regarding a reasonable path forward for the resubmission of the company's NDA for tenapanor for the control of serum phosphorus in adult patients with CKD on dialysis.
- On October 12, 2021, the company announced that it began implementing a restructuring plan to reduce operating costs and better align the company's workforce with the needs of its business following the receipt of the CRL from the FDA on July 28, 2021, and the outcome of the End of Review Type A meeting. The restructuring plan is expected to be completed in December 2021.
- On September 3, 2021, the company announced the publication of the company's long term 52-week Phase 3 PHREEDOM trial in the American Society of Nephrology Journal, Kidney 360. The publication highlights a clinically meaningful reduction in mean serum phosphorus from 7.7 mg/dL to 5.1 mg/dL at the end of the 26-week treatment period in the efficacy analysis set.

### Third Quarter 2021 Financial Results

- **Cash Position:** As of September 30, 2021, Ardelyx had total cash, cash equivalents and short-term investments of \$141.7 million, as compared to total cash, cash equivalents and investments of \$188.6 million as of December 31, 2020.
- **Revenue:** The company generated \$1.2 million in revenue for the three months ended September 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 \$23.7 million for the three months ended September 30, 2021, an increase of \$11.5 million, or 94 percent, compared to \$12.2 million for the three months ended September 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. Research and development employee-related expenses included \$1.2 million severance payments and other employee-related costs associated with a restructuring implemented in August 2021.
- **G&A Expenses:** General and administrative expenses were \$19.7 million for the three months ended September 30, 2021, an increase of \$12.1 million, or 158 percent, compared to \$7.6 million for the three months ended September 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. General and administrative employee-related expenses included \$2.4 million in severance payments and other employee-related costs associated with a restructuring implemented in August 2021.
- **Net Loss:** Net loss for the quarter ended September 30, 2021 was \$43.6 million, compared to \$18.1 million for the quarter ended September 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<sup>®</sup> (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 to submit a Formal Dispute Resolution Request to appeal the FDA's issuance of a CRL for its NDA for tenapanor for the control of serum phosphorus in CKD patients on dialysis, and the expected timing thereof, and Ardelyx's expectations regarding the timing of the completion of the restructuring that it began implementing in October 2021. 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 NDA process, and the Formal Dispute Resolution process, as well as uncertainties associated with restructuring efforts. 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. 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 November 12, 2021, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

### **Investor and Media Contacts:**

Kimia Keshtbod  
[kkeshtbod@ardelyx.com](mailto:kkeshtbod@ardelyx.com)

Sylvia Wheeler  
Wheelhouse Life Science Advisors  
[swheeler@wheelhousesa.com](mailto:swheeler@wheelhousesa.com)

Alex Santos  
Wheelhouse Life Science Advisors  
[asantos@wheelhousesa.com](mailto:asantos@wheelhousesa.com)

**Ardelyx, Inc.**  
**Condensed Balance Sheets**  
(In thousands)

	<u>September 30, 2021</u>	<u>December 31, 2020</u>
	(Unaudited)	(1)
<b>Assets</b>		
Cash and cash equivalents	\$ 75,288	\$ 91,032
Investments	66,363	97,566
Accounts receivable	287	—
Property and equipment, net	2,651	1,936
Right-of-use assets	13,580	2,274
Prepaid and other assets	12,679	8,754
Total assets	<u>\$ 170,848</u>	<u>\$ 201,562</u>
<b>Liabilities and stockholders' equity</b>		
Accounts payable	\$ 4,263	\$ 5,626
Accrued compensation and benefits	4,770	5,672
Current portion of operating lease liability	3,391	2,117
Loan payable, current portion	44,444	4,167
Deferred revenue	3,474	4,177
Accrued expenses and other liabilities	11,373	6,657
Operating lease liability, net of current portion	10,669	413
Loan payable, net of current portion	7,032	46,621
Stockholders' equity	81,432	126,112
Total liabilities and stockholders' equity	<u>\$ 170,848</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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
<b>Revenues:</b>				
Collaborative development revenue	\$ 886	\$ 1,356	\$ 3,650	\$ 3,656
Product supply revenue	285	1,357	411	1,400
Licensing revenue	2	—	5,007	706
Total revenues	1,173	2,713	9,068	5,762
<b>Operating expenses:</b>				
Cost of revenue	—	—	1,000	141
Research and development	23,695	12,240	70,172	46,948
General and administrative	19,714	7,634	56,969	21,810
Total operating expenses	43,409	19,874	128,141	68,899
Loss from operations	(42,236)	(17,161)	(119,073)	(63,137)
Interest expense	(1,216)	(1,202)	(3,518)	(3,785)
Other (expense) income, net	(134)	255	664	1,485
<b>Loss before provision for income taxes</b>	(43,586)	(18,108)	\$ (121,927)	\$ (65,437)
<b>Provision for income taxes</b>	1	—	4	—
<b>Net loss</b>	\$ (43,587)	\$ (18,108)	\$ (121,931)	\$ (65,437)
<b>Net loss per common share, basic and diluted</b>	\$ (0.42)	\$ (0.20)	\$ (1.21)	\$ (0.73)
<b>Shares used in computing net loss per share - basic and diluted</b>	104,144,606	89,365,798	100,480,156	89,109,772