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 5, 2020

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.
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))

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 5, 2020, Ardelyx, Inc. (the "Company") announced its financial results for the quarter ended September 30, 2020. 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: November 5, 2020

ARDELYX, INC.

By: /s/ Justin Renz
Justin Renz
Chief Financial Officer

Exhibit 99.1

Ardelyx Reports Third Quarter 2020 Financial Results and Business Highlights

Tenapanor NDA Accepted for Review by FDA; PDUFA Goal Date set for April 29, 2021

Maintains strong balance sheet with $185.5 million in cash, cash equivalents and short-term investments

FREMONT, Calif., November 5, 2020 -- Ardelyx, Inc. (Nasdaq: ARDX), a specialized biopharmaceutical company focused on developing innovative first-in-class medicines to improve treatment for people with kidney and cardiovascular diseases, today reported business highlights and financial results for the third quarter ended September 30, 2020.

“The FDA’s acceptance of our New Drug Application for tenapanor is a major milestone that continues our progress toward the potential launch of this novel therapeutic for the many dialysis patients who struggle with controlling hyperphosphatemia.” said Mike Raab, president and chief executive officer of Ardelyx. “Our commitment to this field was further highlighted in clinical data presented at ASN Kidney Week 2020 generated by Ardelyx and our Japanese partner KKC, supporting the clinical safety and efficacy of tenapanor and reinforcing its potential to transform the treatment landscape for patients.”

Recent Business and Pipeline Updates

- The United States Food and Drug Administration (FDA) accepted the New Drug Application (NDA) for tenapanor to control serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis with a Prescription Drug User Fee Act (“PDUFA”) goal date of April 29, 2021. The filing was supported by three successful Phase 3 studies demonstrating tenapanor’s ability to reduce phosphate levels, with two trials evaluating tenapanor as a monotherapy and the third evaluating tenapanor as part of a dual mechanism approach with phosphate binders.

- Presented new clinical data supporting the clinical safety and efficacy of tenapanor at ASN Kidney Week 2020. Three poster presentations highlighted data from Phase 3 trials conducted by Ardelyx, including the BLOCK, AMPLIFY and PHREEDOM studies. Additionally, the company's partner for tenapanor in Japan, Kyowa Kirin Co., Ltd., presented the results from two Phase 2 studies evaluating the efficacy and safety of tenapanor in Japanese patients on hemodialysis.

Third Quarter 2020 Financial Results

- **Cash Position**: As of September 30, 2020, Ardelyx had total cash, cash equivalents and short-term investments of $185.5 million, as compared to total cash, cash equivalents and short-term investments of $247.5 million as of December 31, 2019.

- **Revenue**: The company generated $2.7 million in revenue during the three months ended September 30, 2020, which primarily represents collaborative development revenue and sales of tenapanor for clinical supply to KKC.

- **R&D Expenses**: Research and development expenses were $12.2 million for the three months ended September 30, 2020, a decrease of approximately $5.4 million, or 30 percent, compared to $17.6 million for the three months ended September 30, 2019. The decrease was primarily due to the

completion of the Phase 3 PHREEDOM and AMPLIFY clinical trials evaluating tenapanor for the control of hyperphosphatemia.

- **G&A Expenses**: General and administrative expenses were $7.6 million for the three months ended September 30, 2020, an increase of $0.7 million, or approximately 10 percent, compared to $6.9 million for the three months September 30, 2019. The increase was primarily due to an increase in costs associated with building and staffing our commercial infrastructure and teams as we prepare 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 September 30, 2020 was $18.1 million, or ($0.20) per common share, as compared to $23.5 million, or ($0.37) per common share, for the quarter ended September 30, 2019.

About Ardelyx, Inc.
Ardelyx is focused on developing innovative first-in-class medicines to enhance the lives of patients with kidney and cardiovascular 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, with a PDUFA goal date of April 29, 2021. Ardelyx is also advancing RDX013, a potassium secretagogue program, for the potential treatment of high potassium, or hyperkalemia, a problem among certain patients with kidney and/or heart disease. 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 the 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 statements regarding the potential for the use of tenapanor as monotherapy and as part of a dual mechanism approach with tenapanor and phosphate binders for the treatment of 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, the uncertainties associated with the regulatory approval process and uncertainties in the drug commercialization 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 Quarterly Report on Form 10-Q to be filed with the Securities and Exchange Commission on November 5, 2020, 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)

	September 30, 2020 (Unaudited)	December 31, 2019 (1)
Assets		
Cash and cash equivalents	$ 91,009	$ 181,133
Short-term investments	94,488	66,379
Unbilled revenue	750	750
Property and equipment, net	2,111	3,436
Right-of-use assets	2,402	3,970
Prepaid and other assets	7,795	4,114
Total assets	$ 198,555	$ 259,782
Liabilities and stockholders' equity		
Accounts payable	$ 2,490	$ 2,187
Accrued compensation and benefits	3,722	4,453
Current portion of operating lease liability	2,770	2,608
Loan payable, current portion	—	1,183
Deferred revenue	885	4,541
Accrued expenses and other liabilities	6,667	7,248
Operating lease liability, net of current portion	—	2,076
Loan payable, net of current portion	50,681	48,831
Stockholders' equity	131,340	186,655
Total liabilities and stockholders' equity	$ 198,555	$ 259,782

(1) Derived from the audited financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2019.

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,	
	2020	2019	2020	2019
Revenues:				
Licensing revenue	$ —	$ 3,000	$ 706	$ 3,000
Collaborative development revenue	1,356	—	3,656	—
Other revenue	1,357	13	1,400	31
Total revenues	2,713	3,013	5,762	3,031
Operating expenses:				
Cost of revenue	—	600	141	600
Research and development	12,240	17,580	46,948	57,436
General and administrative	7,634	6,922	21,810	17,410
Total operating expenses	19,874	25,102	68,899	75,446
Loss from operations	(17,161)	(22,089)	(63,137)	(72,415)
Interest expense	(1,202)	(1,443)	(3,785)	(4,328)
Other income, net	255	294	1,485	1,896
Loss before provision for income taxes	(18,108)	(23,238)	(65,437)	(74,847)
Provision for income taxes	—	301	—	303
Net loss	$ (18,108)	$ (23,539)	$ (65,437)	$ (75,150)
Net loss per common share, basic and diluted	$ (0.20)	$ (0.37)	$ (0.73)	$ (1.20)
Shares used in computing net loss per share - basic and diluted	89,365,798	62,828,513	89,109,772	62,676,591