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 7, 2019

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., Suite 200
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))

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. ☒

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

Item 2.02 Results of Operations and Financial Condition.

On May 7, 2019, Ardelyx, Inc. (the "Company") announced its financial results for the quarter ended March 31, 2019. 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.

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 7, 2019

ARDELYX, INC.

By: /s/ Mark Kaufmann
Mark Kaufmann
Chief Financial Officer

Exhibit 99.1

Ardelyx Reports First Quarter 2019 Financial Results and Recent Business Highlights

Two Pivotal Phase 3 readouts in 2H 2019

FREMONT, Calif., May 7, 2019 -- Ardelyx, Inc. (NASDAQ: ARDX), a specialized biopharmaceutical company focused on developing first-in-class medicines to improve treatment choices for people with cardiorenal diseases, today reported business highlights and financial results for the first quarter ended March 31, 2019.

"With our two ongoing Phase 3 clinical trials for tenapanor for the treatment of hyperphosphatemia in patients with ESRD on dialysis, one as a single agent therapy and the other as adjunctive therapy with phosphate binders, we are positioned for significant catalysts this year," said Mike Raab, president and chief executive officer of Ardelyx. "Current treatment options for hyperphosphatemia have many limitations, leading to poor adherence and inadequate phosphorus control. If the results from our PHREEDOM and AMPLIFY clinical trials are positive and tenapanor is approved, we believe tenapanor would be an enormous step forward in the management of hyperphosphatemia in ESRD patients on dialysis. Tenapanor provides a completely novel and differentiated mechanism that could lower pill burden and improve adherence thus improving efficacy of the patient's phosphate lowering therapy."

Recent Business and Pipeline Updates

- Published positive Phase 3 results of tenapanor for the treatment of hyperphosphatemia in the *Journal of the American Society of Nephrology*.
- Appointed renowned nephrologist Geoff A. Block, M.D., to its board of directors.

Expected 2019 Milestones

- The PHREEDOM clinical trial, the company's second Phase 3 clinical trial of tenapanor for hyperphosphatemia in patients with end-stage renal disease (ESRD) who are on dialysis, is currently expected to read out in the fourth quarter of 2019.
- The AMPLIFY clinical trial, the company's additional Phase 3 clinical trial of tenapanor as adjunctive therapy with phosphate binders for hyperphosphatemia in patients with ESRD who are on dialysis, is currently expected to read out in the second half of 2019.
- The company's New Drug Application for U.S. marketing authorization of tenapanor for patients with IBS-C has a target action date under the Prescription Drug User Fee Act (PDUFA) of September 12, 2019.

First Quarter 2019 Financial Results

- **Cash Position**: As of March 31, 2019, Ardelyx had total capital resources including cash, cash equivalents and short-term investments of $151.6 million compared to total capital resources including cash, cash equivalents and short-term investments of $168.1 million as of December 31, 2018.
- **Revenue**: Licensing revenue for the quarter ended March 31, 2019 was zero. The company generated $2.3 million related to license revenue for the quarter ended March 31, 2018.
- **Cost of Revenue**: Cost of revenue for the quarter ended March 31, 2019 was zero. The cost of revenue for the quarter ended March 31, 2018 was $0.5 million.

- **R&D Expenses**: Research and development expenses were $20.4 million for the three months ended March 31, 2019, an increase of $7.0 million, or 53 percent, compared to $13.4 million for the three months ended March 31, 2018. The increase was primarily related to the Company's PHREEDOM and AMPLIFY clinical trials as well as the RDX013 program.

- **G&A Expenses**: General and administrative expenses were $5.1 million for the three months ended March 31, 2019, a decrease of $1.1 million, or 17 percent, compared to $6.2 million for the three months ended March 31, 2018. The decrease was primarily related to a decrease in professional services and a reduction in stock-based compensation costs.

- **Net Loss**: Net loss for the quarter ended March 31, 2019, was $26.1 million compared to a net loss of $17.0 million for the quarter ended March 31, 2018.

About Ardelyx, Inc.
Ardelyx is focused on enhancing the way people with cardiorenal diseases are treated by developing first-in-class medicines. Ardelyx's cardiorenal pipeline includes the Phase 3 development of tenapanor for the treatment of hyperphosphatemia in people with end-stage renal disease (ESRD) who are on dialysis, and 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 has completed Phase 3 development of tenapanor for the treatment of irritable bowel syndrome with constipation (IBS-C) and submitted a new drug application, or NDA, to the U.S. Food and Drug Administration, or FDA, for the treatment of patients with IBS-C which has been granted a target action date under the Prescription Drug User Fee Act (PDUFA) of September 12, 2019. To efficiently bring its treatments to market, Ardelyx is pursuing strategic collaborations for tenapanor for IBS-C and hyperphosphatemia in certain territories. Ardelyx has established agreements with Kyowa Hakko Kirin in Japan, Fosun Pharma in China and Knight Therapeutics in Canada. For more information, please visit http://www.ardelyx.com and connect with us on Twitter @Ardelyx.

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 the potential for Ardelyx's product candidates in treating the diseases and conditions for which they are being developed, the potential for the use of tenapanor as monotherapy and in combination with phosphate binders as adjunctive therapy for the treatment of hyperphosphatemia, and Ardelyx's expected timing for receipt of data from its ongoing Phase 3 clinical trials of tenapanor for the treatment of hyperphosphatemia in ESRD patients. Such forward-looking statements involve substantial risks and uncertainties that could cause the development of Ardelyx's product candidates or 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 inherent in the clinical development process, including 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 7, 2019, 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)

	March 31, 2019 (Unaudited)	December 31, 2018 (1)
Assets		
Cash and cash equivalents	$ 92,036	$ 78,768
Short-term investments	59,524	89,321
Accounts receivable	7	85
Unbilled license revenue	—	5,000
Property and equipment, net	5,102	5,611
Right-of-use assets	5,371	—
Prepaid and other assets	4,095	4,547
Total assets	$ 166,135	$ 183,332
Liabilities and stockholders' equity		
Accounts payable and other current liabilities	$ 18,724	$ 16,728
Uncharged license fees	—	1,000
Current portion of operating lease liability	2,102	—
Operating lease liability, net of current portion	4,069	—
Loan payable, long term	49,399	49,209
Other long-term liabilities	—	582
Stockholders' equity	91,841	115,813
Total liabilities and stockholders' equity	$ 166,135	$ 183,332

(1) Derived from the audited consolidated financial statements included on Form 10-K for the year ended December 31, 2018.

Ardelyx, Inc.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2019	**2018**
	(Unaudited)	**(Unaudited)**
Revenue:		
Licensing revenue	$ —	$ 2,320
Cost of revenue	—	464
Gross profit	—	1,856
Operating expenses:		
Research and development	$ 20,381	$ 13,350
General and administrative	5,117	6,191
Total operating expenses	25,498	19,541
Loss from operations	(25,498)	(17,685)
Interest expense	(1,434)	—
Other income	790	670
Provision for income taxes	(2)	(4)
Net loss	$ (26,144)	$ (17,019)
Net loss per common share, basic & diluted	$ (0.42)	$ (0.36)
Shares used in computing net loss per share, basic and diluted	62,546,295	47,559,366