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 6, 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.
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 November 6, 2019, Ardelyx, Inc. (the "Company") announced its financial results for the quarter ended September 30, 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: November 6, 2019

ARDELYX, INC.

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

Exhibit 99.1

Ardelyx Reports Third Quarter 2019 Financial Results and Recent Highlights

PHREEDOM clinical trial to read out this quarter

FREMONT, Calif., November 6, 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 third quarter ended September 30, 2019.

"The third quarter was particularly exciting with two transformational milestones occurring in rapid succession and serving as major catalysts for growth and momentum at Ardelyx," said Mike Raab, president and chief executive officer of Ardelyx. "First, we were pleased to report successful results from our Phase 3 AMPLIFY study for tenapanor in hyperphosphatemia, positioning us one step closer to submitting our New Drug Application to the FDA and potentially providing our drug broadly to patients in need. On the heels of that milestone, we announced the approval of IBSRELA. This approval marked a momentous achievement for Ardelyx as our first ever product approved and represented the culmination of more than a decade of diligent execution and commitment by our talented team. Importantly, these milestones propel us toward fulfilling our mission to bring innovative first-in-class medicines to improve treatments for patients in need."

Business and Pipeline Updates

- In October 2019, Ardelyx hosted Analyst Day, the second of an anticipated annual event. The event featured Myles Wolf, M.D., chief of nephrology at Duke University, and the company's new team of sales and marketing leaders. The event focused on the significant need to improve hyperphosphatemia management in patients on dialysis, challenges with today's treatment options that are limited to phosphate binders, and the commercial strategy to bring tenapanor to market, if and when approved. A replay of the event is available on the Events and Presentations page under the investor relations section of Ardelyx's website at www.ardelyx.com.
- In September 2019, Ardelyx announced positive results from the pivotal Phase 3 AMPLIFY study evaluating tenapanor in dialysis patients who have uncontrolled hyperphosphatemia despite phosphate binder treatment. The AMPLIFY study met the primary and all key secondary endpoints, including demonstrating a statistically significant ($p=0.0004$) reduction in serum phosphorus levels for patients treated with tenapanor and phosphate binders compared to phosphate binders alone. Approximately two times more patients achieved the established serum phosphorus treatment goal of less than 5.5mg/dL in the tenapanor arm compared to binders alone (p -values$\leq$0.0097) for each week of treatment.
- In September 2019, Ardelyx received FDA approval for IBSRELA® (tenapanor), an NHE3 sodium transport inhibitor, for the treatment of irritable bowel syndrome with constipation. The approval was supported by two Phase 3 trials demonstrating a statistically significant reduction in constipation and abdominal pain in adult patients with IBS-C. The company continues discussions with potential strategic partners to market IBSRELA in the United States.

Upcoming Milestones

The company currently expects to announce results in the fourth quarter of 2019 from the PHREEDOM clinical trial, the company's second Phase 3 clinical trial evaluating tenapanor as a monotherapy treatment for hyperphosphatemia in patients with chronic kidney disease (CKD) who are on dialysis.

Third Quarter 2019 Financial Results

- Cash Position: As of September 30, 2019, Ardelyx had total capital resources including cash, cash equivalents and short-term investments of $103.5 million compared to total capital resources including cash, cash equivalents and short-term investments of $168.1 million as of December 31, 2018.

- R&D Expenses: Research and development expenses were $17.5 million for the three months ended September 30, 2019, a decrease of $0.4 million, or 2 percent, compared to $17.9 million for the three months ended September 30, 2018. The decrease in expense was primarily related to reduction in the company's manufacturing expense of tenapanor, a reduction in costs associated with the continued clinical development of tenapanor for the treatment of hyperphosphatemia in CKD patients on dialysis and a decrease in professional services, partially offset by an increase in expenses in the company's hyperkalemia program, RDX013, an increase in headcount and related personnel costs and an increase in stock-based compensation expenses.

- G&A Expenses: General and administrative expenses were $6.9 million for the three months ended September 30, 2019, an increase of $0.9 million, or 16 percent, compared to $6.0 million for the three months ended September 30, 2018. The increase was primarily related to an increase in stock-based compensation costs and an increase in professional services, partially offset by a decrease in personnel costs related to a one-time severance payment during the three months ended September 30, 2018.

- Net Loss: Net loss for the three months ended September 30, 2019 was $23.5 million, or $0.37 per share, compared to a net loss of $24.1 million, or $0.39 per share, for the three months ended September 30, 2018.

Financial Guidance

Ardelyx maintains its expectation that its cash, cash equivalents and short-term investments are sufficient to fund the company's operations until at least early 2021 based on its current operating plans.

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 received approval of IBSRELA (tenapanor). 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 Kirin (formerly known as 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 products and product candidates in treating the diseases and conditions for which they are approved and being developed, the potential for the use of tenapanor as monotherapy and in combination with phosphate binders for the treatment of hyperphosphatemia, Ardelyx's expected timing for receipt and announcement of data from its ongoing PHREEDOM Phase 3 clinical trial of tenapanor for the treatment of hyperphosphatemia in CKD patients on dialysis, the potential to submit a New Drug Application to the FDA for tenapanor for the treatment of hyperphosphatemia in CKD patients on dialysis and the potential for the FDA approval of tenapanor in such indication, and Ardelyx's expectation regarding the exhaustion of its current capital resources. Such forward-looking statements involve substantial risks and uncertainties that could cause the development and commercialization of Ardelyx's products and 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 research and the clinical development process; the uncertainties associated with the regulatory approval process; and the 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 filed with the Securities and Exchange Commission on November 6, 2019, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

Investor and Media Contact:
Kimia Keshtbod
510-745-1751

kkeshtbod@ardelyx.com

Sylvia Wheeler
Wheelhouse Life Science Advisors
swheeler@wheelhouselsa.com

Alex Santos
Wheelhouse Life Science Advisors
asantos@wheelhouselsa.com

Ardelyx, Inc.
Condensed Balance Sheets
(In thousands)

	September 30, 2019 (Unaudited)	December 31, 2018 (1)
Assets		
Cash and cash equivalents	$ 92,673	$ 78,768
Short-term investments	10,870	89,321
Accounts receivable	2,699	85
Unbilled license revenue	—	5,000
Property and equipment, net	3,943	5,611
Right-of-use assets	4,453	—
Prepaid and other assets	4,772	4,547
Total assets	$ 119,410	$ 183,332
Liabilities and stockholders' equity		
Accounts payable and other current liabilities	$ 15,175	$ 16,728
Uncharged license fees	—	1,000
Current portion of operating lease liability	2,504	—
Operating lease liability, net of current portion	2,770	—
Loan payable, long term	49,803	49,209
Other long-term liabilities	—	582
Stockholders' equity	49,158	115,813
Total liabilities and stockholders' equity	$ 119,410	$ 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 September 30,		Nine Months Ended September 30,	
	2019 (Unaudited)	2018 (Unaudited)	2019 (Unaudited)	2018 (Unaudited)
Revenue:				
Licensing revenue	$ 3,000	$ —	$ 3,000	$ 2,320
Other revenue	13	172	31	202
Total revenues	3,013	172	3,031	2,522
Cost of revenue	600	2	600	466
Gross Profit	2,413	170	2,431	2,056
Operating expenses:				
Research and development	$ 17,580	$ 17,941	$ 57,436	$ 47,337
General and administrative	6,922	5,961	17,410	18,290
Total operating expenses	24,502	23,902	74,846	65,627
Loss from operations	(22,089)	(23,732)	(72,415)	(63,571)
Interest Expense	(1,443)	(1,404)	(4,328)	(2,096)
Other income (expense), net	294	1,010	1,896	2,237
Provision for income taxes	(301)	—	(303)	(6)
Net loss	$ (23,539)	$ (24,126)	$ (75,150)	$ (63,436)
Net loss per common share, basic & diluted	$ (0.37)	$ (0.39)	$ (1.20)	$ (1.17)
Shares used in computing net loss per share, basic and diluted	62,828,513	62,071,397	62, 676,591	54,204,907

####