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 6, 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 August 6, 2020, Ardelyx, Inc. (the "Company") announced its financial results for the quarter ended June 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: August 6, 2020

ARDELYX, INC.

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

Exhibit 99.1

Ardelyx Reports Second Quarter 2020 Financial Results and Recent Business Highlights

Submitted a New Drug Application to the U.S. Food and Drug Administration for the review of tenapanor as a first-in-class therapy to control serum phosphorus in adult patients with chronic kidney disease on dialysis

Maintains strong balance sheet with $204.8 million in cash, cash equivalents and short-term investments

FREMONT, Calif., August 6, 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 second quarter ended June 30, 2020.

“Over the last quarter, we continued to make critical progress towards our goal of providing our first-in-class therapy tenapanor to adult CKD patients on dialysis with elevated serum phosphorus, a condition, despite traditional therapies, that has been associated with poor survival outcomes,” said Mike Raab, president and chief executive officer of Ardelyx. “This past June, we submitted a New Drug Application to the FDA for this indication, and we expect to receive notification of its acceptance for substantive review and our PDUFA date by early September. As part of our filing, we included additional, robust data reconfirming tenapanor’s ability to lower and control serum phosphorous levels at a rate better than those reported with phosphate binders alone. In addition, during the quarter, we augmented our senior leadership team with the hiring of an experienced chief commercial officer and chief financial officer as we prepare for launch and evolving into a revenue-generating company.”

Recent Business and Pipeline Updates

- Submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for the review of tenapanor as a first-in-class therapy to control serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis. The filing is 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.

- Released additional positive data from the ongoing NORMALIZE Phase 4 study, which showed that foundational use of tenapanor as monotherapy or with sevelamer enabled up to 47.4% of CKD patients on dialysis to achieve normal serum phosphorus levels (<4.6 mg/dL), a 58% improvement over current standard of care.

- Announced that Ardelyx's collaboration partner in Japan, Kyowa Kirin Co., Ltd. (KKC), presented data at the European Renal Association-European Dialysis and Transplant Association annual meeting (ERA-EDTA 2020) from a Phase 2 study designed to evaluate if, with tenapanor, patients with hyperphosphatemia undergoing hemodialysis could achieve at least a 30% decrease in mean pill burden while maintaining their serum phosphorus level. The results demonstrated that tenapanor enabled a significant reduction in overall pill burden (mean reduction in phosphate binder pill usage by 80%), while maintaining serum phosphorus control.

- Strengthened leadership team with the appointment of two senior executives:
    - Justin Renz, a veteran biopharma executive with over 20 years of experience, as chief financial officer; and
    - Susan Rodriguez, a highly experienced global biopharma marketing and sales executive with a proven track record of building commercial organizations and leading successful new product launches, as chief commercial officer

Expected 2020 Milestones

- Receive notification from the FDA regarding the acceptance for substantive review of the NDA submission and PDUFA date in September 2020
- Initiate the OPTIMIZE clinical trial, a study designed to inform physicians on the integration of tenapanor as a foundational therapy into clinical practice, this year
- Present AMPLIFY and PHREEDOM Phase 3 clinical trial results at upcoming medical congresses
- Report completed NORMALIZE Phase 4 clinical trial results at an upcoming medical conference

Second Quarter 2020 Financial Results

- **Cash Position**: As of June 30, 2020, Ardelyx had total cash, cash equivalents and short-term investments of $204.8 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 $1.8 million in revenue, which primarily represents collaborative development revenue, for the three months ended June 30, 2020.
- **R&D Expenses**: Research and development expenses were $18.9 million for the three months ended June 30, 2020, a decrease of $0.6 million, or approximately 3 percent, compared to $19.5 million for the three months ended June 30, 2019. The decrease was due primarily to a decrease in external R&D expenses, with a $1.1 million decrease in tenapanor-related expenses, as well as a $0.6 million decrease in RDX013 program-related expenses, partially offset by $0.7 million of higher expenses attributable to the research programs being conducted under the Research Collaboration and Option Agreement entered into between Ardelyx and KKC in 2019 and general R&D expenses. Of the overall tenapanor-related decrease, approximately $7.9 million was related to lower clinical study costs due to the winding down of expenses associated with the Phase 3 clinical program for tenapanor for the control of hyperphosphatemia, offset by an out-of-period adjustment that reduced clinical trial expenses by $4.1 million; and an approximately $2.1 million decrease in validation-related manufacturing expenses; offset by increase of $4.6 million related to regulatory expenses that included $2.9 million paid to the FDA for the filing of the NDA for tenapanor for control of serum phosphorus.
- **G&A Expenses**: General and administrative expenses were $7.0 million for the three months ended June 30, 2020, an increase of $1.6 million, or approximately 31 percent, compared to $5.4 million for the three months ended June 30, 2019. The increase was primarily due to an increase in headcount and related personnel costs, including stock-based compensation costs, and an increase in professional services.

- **Net Loss**: Net loss for the quarter ended June 30, 2020 was $25.0 million, as compared to $25.5 million for the quarter ended June 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 submitted an NDA to the FDA on June 30, 2020. 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 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 as part of a dual mechanism approach with tenapanor and phosphate binders for the treatment of hyperphosphatemia, the potential for tenapanor alone or with adjunctive use of phosphate binders to achieve normal serum phosphorus levels, Ardelyx's expectations regarding the potential receipt, and the timing thereof, of notification from the FDA of the acceptance for substantive review of its NDA for tenapanor, and Ardelyx's expectations regarding the presentation of its clinical data at medical congresses in 2020. 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 filed with the Securities and Exchange Commission on August 6, 2020, 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)

	June 30, 2020 (Unaudited)	December 31, 2019 (1)
Assets		
Cash and cash equivalents	$ 100,494	$ 181,133
Short-term investments	104,347	66,379
Unbilled revenue	750	750
Property and equipment, net	2,501	3,436
Right-of-use assets	2,945	3,970
Prepaid and other assets	6,306	4,114
Total assets	$ 217,343	$ 259,782
Liabilities and stockholders' equity		
Accounts payable	$ 4,212	$ 2,187
Accrued compensation and benefits	3,081	4,453
Current portion of operating lease liability	2,826	2,608
Loan payable, current portion	13,716	1,183
Deferred revenue	2,241	4,541
Accrued expenses and other liabilities	7,574	7,248
Operating lease liability, net of current portion	608	2,076
Loan payable, net of current portion	36,735	48,831
Stockholders' equity	146,350	186,655
Total liabilities and stockholders' equity	$ 217,343	$ 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 and Comprehensive Loss
(In thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020 (Unaudited)	2019 (Unaudited)	2020 (Unaudited)	2019 (Unaudited)
Revenues:				
Licensing revenue	$ 706	$ —	$ 706	$ —
Collaborative development revenue	1,125	—	2,300	—
Other revenue	5	18	43	18
Total revenues	1,836	18	3,049	18
Operating expenses:				
Cost of revenue	141	—	141	—
Research and development	18,864	19,475	34,708	39,856
General and administrative	7,038	5,371	14,176	10,488
Total operating expenses	26,043	24,846	49,025	50,344
Loss from operations	(24,207)	(24,828)	(45,976)	(50,326)
Interest expense	(1,226)	(1,451)	(2,583)	(2,885)
Other income, net	477	812	1,230	1,602
Loss before provision for income taxes	(24,956)	(25,467)	(47,329)	(51,609)
Provision for income taxes	—	—	—	2
Net loss	$ (24,956)	$ (25,467)	$ (47,329)	$ (51,611)
Net loss per common share, basic and diluted	$ (0.28)	$ (0.41)	$ (0.53)	$ (0.82)
Shares used in computing net loss per share - basic and diluted	89,080,046	62,651,863	88,980,353	62,599,371
Comprehensive loss:				
Net loss	$ (24,956)	$ (25,467)	$ (47,329)	$ (51,611)
Unrealized gains on available-for-sale securities	361	4	297	54
Comprehensive loss	$ (24,595)	$ (25,463)	$ (47,032)	$ (51,557)