

# ARDELYX, INC.

## **FORM 8-K** (Current report filing)

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Address	34175 ARDENWOOD BLVD. FREMONT, CA 94555
Telephone	510-745-7047
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Symbol	ARDX
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**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 9, 2017**

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**ARDELYX, INC.**  
(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-36485**  
(Commission  
File Number)

**26-1303944**  
(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**

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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.

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**Item 2.02 Results of Operations and Financial Condition.**

On August 9, 2017, Ardelyx, Inc. (the “Company”) announced its financial results for the quarter ended June 30, 2017. 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.**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of Ardelyx, Inc.

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**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 9, 2017

ARDELYX, INC.

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

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**EXHIBIT INDEX**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release of Ardelyx, Inc.



## **Ardelyx Focuses Resources on Late-Stage Programs and Reports Second Quarter 2017 Operational Results**

*Restructuring Aligns Resources on Execution of Late-Stage Program Milestones*

*T3MPO-2 Phase 3 Trial Results of Tenapanor for IBS-C on Track for Early Fourth Quarter;  
RDX7675 Onset-of-Action Data Planned for Fourth Quarter*

*Conference Call to be Held at 8:00 a.m. ET Today*

**FREMONT, Calif., Aug. 9, 2017** — Ardelyx, Inc. (NASDAQ: ARDX), a late-stage clinical company focused on enhancing the treatment of patients with cardiorenal and gastrointestinal (GI) diseases, today announced an update of its business operations and clinical programs, as well as reported financial results for the second quarter ended June 30, 2017.

“At Ardelyx, we have advanced a unique, late-stage pipeline of programs, led by our first-in-class drug candidate, tenapanor, in Phase 3 development for both IBS-C and hyperphosphatemia, and RDX7675, our proprietary binder for the treatment of hyperkalemia, which is also in Phase 3 development,” said Mike Raab, president and chief executive officer of Ardelyx. “Based on the clinical data we’ve generated to date, we are highly confident in both the registration and commercial potential for tenapanor and RDX7675. In order to fully focus on the execution of our late-stage pipeline, we have implemented a plan designed to align our resources to deliver on these programs, while also creating strategic optionality and reinforcing our financial strength.”

Mr. Raab continued, “As a result of a comprehensive strategic review, we have chosen to reduce our workforce, an inherently difficult endeavor. I am proud of everything the Ardelyx team has accomplished over the years, and am incredibly grateful for the hard work, dedication and innovations contributed by each person impacted by this decision. As we look ahead, we are confident that the changes we are making now, and the extraordinary team that remains at Ardelyx, will best position us to efficiently execute on our near-term milestones and to create value in the future.”

### **Strategic Restructuring and Updated Financial Guidance**

Ardelyx completed a comprehensive strategic review of its operations, assessing several core areas, to optimally position the company to advance towards delivering on multiple significant opportunities with its late-stage portfolio and execute on its strategic objectives. This review resulted in the prioritization of resources to focus on the upcoming milestones for the late-stage programs, a delay in the development of a number of earlier-stage programs and a reduction in workforce of 28 percent, resulting in a remaining team of 76 employees.

Ardelyx believes that with this, and other cost-saving activities, the company is positioned to extend its operating runway to the end of 2018, excluding any revenues generated through potential partnerships. The company expects to incur approximately \$0.8 million in one-time, cash-related restructuring expenses, which will be recorded predominantly in the third quarter of 2017. Ardelyx will continue to evaluate all pathways, both internal and external, to maintain a strong balance sheet and ensure it has the necessary resources to fund its operations.

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## Clinical Progress and Prioritized Pipeline Activities

- **T3MPO-1 Phase 3 Trial in IBS-C Achieves Primary Endpoint** – In May, Ardelyx reported positive, topline results from T3MPO-1, the first of two Phase 3 trials evaluating tenapanor for the treatment of irritable bowel syndrome with constipation (IBS-C). T3MPO-1 achieved statistical significance for the primary endpoint, the combined responder rate for six of 12 weeks, showing that a greater proportion of tenapanor-treated patients compared to patients receiving placebo had at least a 30 percent reduction in abdominal pain and an increase of one or more complete spontaneous bowel movements (CSBM) in the same week for at least six of the 12 weeks of the treatment period. Notably, tenapanor had a significant impact on both constipation and abdominal pain in nine of 12 weeks and demonstrated durable responses by maintaining the effect in three of the last four weeks in those patients. Tenapanor continues to demonstrate a favorable safety profile.
- **T3MPO-2 Data On-Track and IBS-C Registration Program to be Completed in 2017** – Enrollment has been completed in both T3MPO-2, the ongoing six-month Phase 3 trial of tenapanor in patients with IBS-C, and T3MPO-3, the long-term safety extension study of tenapanor in patients with IBS-C. Results from T3MPO-2 are expected early in the fourth quarter of 2017, with completion of T3MPO-3 expected by late 2017. Based on the success of T3MPO-1 and pending T3MPO-2 results, Ardelyx is preparing for its first New Drug Application for tenapanor for the treatment of IBS-C, which the company currently expects to submit in 2018.
- **Second Phase 3 Trial of Tenapanor for Hyperphosphatemia Preparing to Enroll** – Ardelyx successfully completed and achieved the primary endpoint in the first Phase 3 trial of tenapanor as a treatment for hyperphosphatemia in patients with end-stage renal disease (ESRD) on dialysis. Based on learnings from the first Phase 3 trial and in an effort to optimize the potential for clinical and regulatory success in its second Phase 3 trial, Ardelyx has sought feedback on the study protocol from the U.S. Food and Drug Administration. The company expects to begin patient enrollment by October of 2017. The study is expected to be comprised of a 26-week randomized treatment period followed by an up to 12-week, double-blind, placebo-controlled, randomized withdrawal (RW) period with an open-label extension.
- **Onset-of-Action Data for RDX7675 for Hyperkalemia to Follow T3MPO-2 Results** – Earlier this year, Ardelyx announced the initiation of an onset-of-action study, as well as a single Phase 3 trial designed to support the registration of RDX7675 for the treatment of hyperkalemia. Consistent with its efforts to ensure the on-time delivery of T3MPO-2 results, completion of T3MPO-3 and enrollment in the second hyperphosphatemia Phase 3 study, Ardelyx has adjusted the timing for the RDX7675 onset-of-action study results and currently expects to report data following the T3MPO-2 results in the fourth quarter of 2017.

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## Second Quarter 2017 Financial Results

- **Cash Position:** As of June 30, 2017, Ardelyx had total capital resources including cash, cash equivalents and short-term investments of \$148.7 million compared to total capital resources including cash, cash equivalents and short-term investments of \$200.8 million as of December 31, 2016.
- **R&D Expenses:** Research and development expenses were \$20.6 million for the three months ended June 30, 2017, a decrease of \$3.3 million, or 14 percent, compared to \$23.8 million for the three months ended June 30, 2016. The decrease consisted of a net \$5.8 million decrease in our external program costs, primarily due to a reduction of clinical activities related to tenapanor as well as product development activities related to RDX8940, offset by increased costs associated with product development activities related to RDX7675. This was offset by an increase of \$2.5 million in our internal program costs, primarily related to costs associated with research and development headcount to support the growth of our research and development activities.
- **G&A Expenses:** General and administrative expenses were \$5.8 million for the three months ended June 30, 2017, an increase of \$1.0 million, or 20 percent, compared to \$4.9 million for the three months ended June 30, 2016. The increase was primarily due to an increase of \$1.0 million in personnel and other costs including share-based compensation, as a result of an increase in headcount.
- **Net Loss:** Net loss for the quarter ended June 30, 2017 was \$25.7 million compared to a net loss of \$28.6 million for the quarter ended June 30, 2016.

## Conference Call Information

The company will host a conference call today, August 9, 2017 at 8:00 a.m. ET to discuss the company's strategic review and second quarter financial results. To participate in the conference call, please dial (855) 296-9612 (toll-free) or (920) 663-6277 (toll) and reference call ID number 47784045. A webcast of the call, and reference slides, can also be accessed by visiting the Investor page of the company's website [www.ardelyx.com](http://www.ardelyx.com), and will be available on the website for 60 days following the call.

## About Ardelyx, Inc.

Ardelyx is focused on enhancing the way patients with cardiorenal and gastrointestinal (GI) diseases are treated by using the gut as the gateway to delivering medicines that matter. The company has established unique cardiorenal and GI business portfolios aimed at bringing new, effective medicines with distinct safety and dosing advantages to underserved patients. Ardelyx's cardiorenal portfolio includes the Phase 3 development of tenapanor for the treatment of hyperphosphatemia in people with end-stage renal disease who are on dialysis and the Phase 3 development of RDX7675 for the treatment of people with hyperkalemia. The company's GI portfolio includes the Phase 3 development of tenapanor for the treatment of people with irritable bowel syndrome with constipation (IBS-C), and RDX8940, the company's TGR5 agonist. For more information, please visit <http://www.ardelyx.com/> and connect with us on Twitter @Ardelyx.

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**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; Ardelyx's future development plans for tenapanor and its other product candidates and the expected timing thereof; Ardelyx's expectations regarding the timing of its initiation of, and receipt of results from its clinical trials evaluating its product candidates and for the completion of its T3MPO program; the potential of Ardelyx's drug discovery and design platform; Ardelyx's ability to generate revenues in the future; and Ardelyx's expectations regarding the exhaustion of its current capital resources. 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 research and the clinical development process, including the regulatory approval process, and the uncertainties in the manufacture of clinical trial material, including process development and the scale up of manufacturing processes, 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 9, 2017, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

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

	<u>June 30, 2017</u> (Unaudited)	<u>December 31, 2016</u> (1)
<b>Assets</b>		
Cash and cash equivalents	\$ 63,636	\$ 74,598
Short-term investments	85,088	126,225
Property and equipment, net	9,335	8,991
Prepaid and other assets	6,063	3,317
Total Assets	<u>\$ 164,122</u>	<u>\$ 213,131</u>
<b>Liabilities and stockholders' equity</b>		
Accounts payable and accrued liabilities	\$ 18,388	\$ 19,201
Other liabilities	756	779
Stockholders' equity	144,978	193,151
Total liabilities and stockholders' equity	<u>\$ 164,122</u>	<u>\$ 213,131</u>

(1) Derived from the audited financial statements included on Form 10-K for the year ended December 31, 2016.

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

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2017</u> (Unaudited)	<u>2016</u> (Unaudited)	<u>2017</u> (Unaudited)	<u>2016</u> (Unaudited)
<b>Operating expenses:</b>				
Research and development	\$ 20,572	\$ 23,838	\$ 42,960	\$ 43,091
General and administrative	5,846	4,852	11,892	9,130
Total operating expenses	<u>26,418</u>	<u>28,690</u>	<u>54,852</u>	<u>52,221</u>
<b>Loss from operations</b>	<u>(26,418)</u>	<u>(28,690)</u>	<u>(54,852)</u>	<u>(52,221)</u>
Other income	697	77	1,123	139
Provision for income taxes	—	—	—	—
<b>Net loss</b>	<u>\$ (25,721)</u>	<u>\$ (28,613)</u>	<u>\$ (53,729)</u>	<u>\$ (52,082)</u>
<b>Net loss per common share, basic &amp; diluted</b>	<u>\$ (0.54)</u>	<u>\$ (0.83)</u>	<u>\$ (1.13)</u>	<u>\$ (1.53)</u>
<b>Weighted-average shares used in computing net loss per share, basic and diluted</b>	<u>47,403,243</u>	<u>34,636,559</u>	<u>47,373,404</u>	<u>34,051,785</u>