



November 7, 2016

## **Ardelyx Reports Third Quarter 2016 Financial Results and Recent Progress**

### **Enrollment Completed in Phase 3 Trial of Tenapanor for Hyperphosphatemia in Patients with ESRD on Dialysis**

**Conference call to be held today at 4:05 p.m. ET**

FREMONT, Calif., Nov. 7, 2016 /PRNewswire/ -- Ardelyx, Inc. (NASDAQ: ARDX), a clinical-stage biopharmaceutical company focused on gastrointestinal and cardio-renal diseases, today reported an update on recent progress and financial results for the third quarter ended September 30, 2016.



"We have made substantial progress throughout 2016, both as a company and through the advancement of our clinical programs," said Mike Raab, president and chief executive officer of Ardelyx. "We have advanced our three ongoing Phase 3 clinical trials for tenapanor, are on-track to initiate Phase 3 development for our second product candidate, RDX227675, in patients with hyperkalemia before the end of the year and have further progressed our earlier-stage pipeline of novel therapies. As we look ahead, 2017 is set to be a transformational year for Ardelyx, with results from our Phase 3 clinical trial of tenapanor in patients with hyperphosphatemia expected in the first quarter and results from our T3MPO-1 and T3MPO-2 Phase 3 clinical trials of tenapanor in patients with IBS-C expected mid-year and at the end of the year, respectively."

### **Recent Highlights**

- | Ardelyx reported today that its Phase 3 clinical trial evaluating tenapanor for the treatment of hyperphosphatemia in end-stage renal disease (ESRD) patients on dialysis is fully enrolled and results are expected in the first quarter of 2017.
- | In October, positive, global endpoint data from the completed Phase 2b trial of tenapanor in patients with irritable bowel syndrome with constipation (IBS-C) were presented at the American College of Gastroenterology Annual Meeting. These pre-specified analyses build off of positive efficacy findings on the study's primary and key secondary endpoints in the same patient population, as previously announced in October 2014, and further validate the 50 milligram, twice-daily dose chosen for the ongoing Phase 3 trials of tenapanor in patients with IBS-C.
- | Ardelyx strengthened its management team with the appointment of Reginald Seeto, MBBS, to the newly created position of chief operating officer.

### **Upcoming Milestones**

Ardelyx has multiple clinical and pipeline milestones expected in the fourth quarter of 2016 and throughout 2017, including:

- | Initiation of an onset-of-action clinical trial and a Phase 3 clinical trial with RDX227675 for the treatment of patients with hyperkalemia expected in the fourth quarter of 2016;
- | Investigational new drug application submission for RDX98940, Ardelyx's lead TGR5 agonist, expected in the fourth quarter of 2016;
- | Results from the ongoing Phase 3 clinical trial of tenapanor for the treatment of hyperphosphatemia in ESRD patients on dialysis expected in the first quarter 2017;
- | Results from the RDX227675 onset-of-action clinical trial expected in the first half of 2017;
- | Initiation of the second Phase 3 clinical trial of tenapanor for the treatment of hyperphosphatemia in ESRD patients on dialysis expected during the first half of 2017;
- | Results from T3MPO-1, the ongoing 12-week Phase 3 clinical trial of tenapanor in patients with IBS-C expected in mid-2017; and,
- | Results from T3MPO-2, the ongoing 6-month Phase 3 clinical trial of tenapanor in patients with IBS-C expected by the end of 2017.

### **Third Quarter 2016 Financial Results**

- | **Net Loss:** Net loss for the third quarter of 2016 was \$29.0 million, or \$0.65 per basic and diluted share, compared to a net loss of \$18.1 million, or \$0.70 per basic and diluted share for the third quarter of 2015.
- | **Cash Position:** As of September 30, 2016, Ardelyx had cash and cash equivalents of \$160.4 million and short-term investments of \$69.7 million, for total capital resources including cash, cash equivalents and short-term investments of \$230.1 million. Cash and cash equivalents were \$160.4 million as of September 30, 2016 compared with \$107.0 million as of December 31, 2015. The increase was primarily the result of the completion of an underwritten public offering and a private placement of common stock in January 2016, which yielded approximately \$80.8 million in net proceeds and the completion of a private placement transaction in July 2016, which yielded approximately \$109.7 million in net proceeds. This was offset by purchases of short-term investments of \$69.7 million and capital equipment of \$2.1 million, as well as \$65.3 million in cash required for operating and other activities for the nine months ended September 30, 2016.
- | **R&D Expenses:** Research and development expense for the third quarter of 2016 increased to \$24.9 million from \$14.7 million for the third quarter of 2015. The increase was primarily due to expenses incurred for clinical development activities associated with tenapanor, including clinical trial expenses for the two Phase 3 clinical trials in IBS-C and the Phase 3 clinical trial in hyperphosphatemia, as well as clinical manufacturing and process development activities associated with tenapanor, RDX227675 and RDX98940.
- | **G&A Expenses:** General and administrative expenses were \$4.3 million for the third quarter of 2016 as compared to \$3.4 million for the third quarter of 2015. The increase was primarily due to an increase in professional services fees, including fees for market research and pre-commercialization activities, systems implementation and intellectual property management, as well as an increase in personnel-related expenses and facility costs.

## Conference Call Information

Ardelyx will host a conference call and audio webcast today at 4:05 p.m. Eastern Time to provide a business update and discuss third quarter 2016 financial results. To participate in the conference call, please dial (855) 296-9612 (domestic) or (920) 663-6277 (international) and refer to conference ID 11901928. The webcast can be accessed under "Events and Presentations" in the Investor Center section of the company's website at [www.ardelyx.com](http://www.ardelyx.com).

## About Ardelyx, Inc.

Ardelyx is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of innovative, minimally-systemic, small molecule therapeutics that work exclusively in the gastrointestinal (GI) tract to treat GI and cardio-renal diseases. Ardelyx has developed a proprietary drug discovery and design platform enabling it, in a rapid and cost-efficient manner, to discover and design novel drug candidates. Utilizing this platform, Ardelyx has discovered and designed tenapanor, which it is evaluating for the treatment of irritable bowel syndrome with constipation (IBS-C) and for the treatment of hyperphosphatemia in patients with end-stage renal disease (ESRD) on dialysis. In addition to tenapanor, Ardelyx is developing RDX227675, a non-absorbed polymer for the treatment of hyperkalemia, or high potassium, a problem prevalent in patients with kidney and heart disease. Ardelyx is also advancing several research programs focused in GI and cardio-renal diseases. Ardelyx is located in Fremont, Calif. For more information, please visit Ardelyx's website at [www.ardelyx.com](http://www.ardelyx.com).

## 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 of tenapanor in the treatment of IBS-C, the expected timing for the receipt of the results from Ardelyx's two on-going Phase 3 clinical trials evaluating tenapanor for the treatment of IBS-C, the potential for tenapanor in treating hyperphosphatemia in ESRD patients on dialysis, the expected timing of the results of the ongoing Phase 3 clinical trial evaluating tenapanor for the treatment of hyperphosphatemia in ESRD patients on dialysis, the expected timing of the initiation of the second Phase 3 clinical trial evaluating tenapanor for the treatment of hyperphosphatemia, the potential for RDX227675 in treating hyperkalemia, the expected timing of the initiation of the onset-of-action and Phase 3 clinical trials evaluating RDX227675 in treating hyperkalemia and the expected timing of the results of the onset-of-action clinical trial, the expected timing for the filing of an investigational new drug (IND) application for RDX98940 and the potential of Ardelyx's drug discovery and design platform. Such forward-looking statements involve substantial risks and uncertainties that could cause the development of tenapanor, RDX227675, RDX98940 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 and the uncertainties in the manufacture of clinical trial material, including process development, and scale up. 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 7, 2016, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

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

	<b>September 30, 2016</b>	<b>December 31, 2015</b>
	<b>(Unaudited)</b>	<b>(1)</b>
<b>Assets</b>		
Cash and cash equivalents	\$ 160,360	\$ 107,004
Short-term investments	69,726	—
Property and equipment, net	6,969	4,711
Prepaid and other assets	4,262	5,231
Total Assets	<u>\$ 241,317</u>	<u>\$ 116,946</u>
<b>Liabilities and stockholders' equity</b>		
Accounts payable and accrued liabilities	\$ 17,635	\$ 7,723
Other liabilities	789	322
Stockholders' equity	222,893	108,901
Total liabilities and stockholders' equity	<u>\$ 241,317</u>	<u>\$ 116,946</u>

(1) Derived from the audited financial statements included on Form 10-K for the year ended December 31, 2015.

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

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2016</b>	<b>2015</b>	<b>2016</b>	<b>2015</b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>	<b>(Unaudited)</b>	<b>(Unaudited)</b>
<b>Revenue:</b>				
Licensing revenue	\$ —	\$ —	\$ —	\$ 21,611
Collaborative development revenue	—	—	—	2,415
	—	—	—	24,026
<b>Operating expenses:</b>				
Research and development	24,863	14,705	67,951	27,101
General and administrative	4,337	3,374	13,469	9,438
Total operating expenses	<u>29,200</u>	<u>18,079</u>	<u>81,420</u>	<u>36,539</u>
<b>Loss from operations</b>	<u>(29,200)</u>	<u>(18,079)</u>	<u>(81,420)</u>	<u>(12,513)</u>
Other income (expense)	169	(77)	307	(138)
Provision for income taxes	—	30	—	30
<b>Net loss</b>	<u>\$ (29,031)</u>	<u>\$ (18,126)</u>	<u>\$ (81,113)</u>	<u>\$ (12,621)</u>
<b>Net loss per common share, basic &amp; diluted</b>	<u>\$ (0.65)</u>	<u>\$ (0.70)</u>	<u>\$ (2.15)</u>	<u>\$ (0.58)</u>
<b>Shares used in computing basic net loss per share, basic and diluted</b>	<u>44,935,126</u>	<u>25,930,928</u>	<u>37,706,045</u>	<u>21,859,383</u>

Logo - <http://photos.prnewswire.com/prnh/20140619/119451>

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/ardelyx-reports-third-quarter-2016-financial-results-and-recent-progress-300358527.html>

SOURCE Ardelyx

News Provided by Acquire Media