May 5, 2017

Ardelyx Reports First Quarter 2017 Operating Results and Highlights Recent Progress

Company on track to report data from T3MPO-1 Phase 3 trial of tenapanor in IBS-C in Q2 2017

FREMONT, Calif., May 5, 2017 /PRNewswire/ -- Ardelyx, Inc. (NASDAQ: ARDX), a late-stage clinical company focused on enhancing the treatment of patients with cardiorenal and gastrointestinal (GI) diseases, today reported an update on recent progress and financial results for the first quarter ended March 31, 2017.

"We've had a very active start to the year with the reporting of our first Phase 3 data evaluating tenapanor in patients with hyperphosphatemia from our cardiorenal portfolio, and have a lot more to look forward to in 2017," said Mike Raab, president and chief executive officer of Ardelyx. "We expect to complete our T3MPO program, which is evaluating tenapanor for the treatment of patients with IBS-C, by the end of this year. If successful, this program will be instrumental to our GI portfolio, and continue our progress towards becoming a commercial organization. These milestones bring us several steps closer to realizing our goal of becoming a fully integrated, revenue-generating biotech company that enhances the lives of people with cardiorenal and GI diseases."

Recent Highlights

- In February, Ardelyx reported positive results from its Phase 3 trial evaluating tenapanor for the treatment of hyperphosphatemia in patients with end-stage renal disease (ESRD) who are on dialysis. The trial met its primary endpoint, demonstrating a statistically significant difference in change in serum phosphorus between the pooled tenapanor-treated patients and placebo-treated patients from the end of the eight-week treatment period to the end of the four-week randomized withdrawal period, in the responder population. Notably, tenapanor demonstrated a positive safety profile, with GI tolerability in patients treated.
- In April, the company presented a poster titled "Effect of tenapanor on serum fibroblast growth factor 23 levels" at the National Kidney Foundation Spring Clinical Meetings in Orlando.
- On May 2, a poster titled "RDX7675 reduces intestinal potassium absorption to a greater extent than patiromer or sodium polystyrene sulfonate in mice" was presented at the European Society of Cardiology Heart Failure World Congress in Paris.

Upcoming Milestones

- Presentation of a poster titled "Minimally-systemic TGR5 agonist RDX8940 improves hepatic steatosis and insulin sensitivity in Western-diet-fed mice" at Digestive Disease Week in Chicago on May 9;
- Results from T3MPO-1, the ongoing 12-week Phase 3 clinical trial of tenapanor in patients with IBS-C, are expected in the second quarter of 2017. The company plans to hold a conference call in conjunction with the data announcement;
- Initiation of the second Phase 3 clinical trial of tenapanor for the treatment of hyperphosphatemia in ESRD patients on dialysis is expected in mid-2017;
- Results from the RDX7675 onset-of-action clinical trial are expected in the third quarter of 2017;
- Results from T3MPO-2, the ongoing six-month Phase 3 clinical trial of tenapanor in patients with IBS-C, are expected in the second half of 2017; and
- Completion of T3MPO-3, the long-term safety extension study of tenapanor in patients with IBS-C, is expected by late 2017.

First Quarter 2017 Financial Results

- **Cash Position:** As of March 31, 2017, Ardelyx had total capital resources including cash, cash equivalents and short-term investments of $173.4 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 $22.4 million for the three months ended March 31, 2017, an increase of $3.1 million, or 16 percent, compared to $19.3 million for the three months ended March 31,

2016. The increase consisted of a $3.4 million increase 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. This was offset by a net decrease of $0.3 million in our external program costs, primarily due to a reduction of clinical activities related to tenapanor offset by increased costs associated with product development activities related to RDX7675 and RDX8940.

- **G&A Expenses:** General and administrative expenses were $6.0 million for the three months ended March 31, 2017, an increase of $1.7 million, or 40 percent, compared to $4.3 million for the three months ended March 31, 2016. The increase was primarily due to increases of $1.2 million in personnel and other costs including share-based compensation, as a result of an increase in headcount and $0.5 million in professional fees.
- **Net Loss:** Net loss for the quarter ended March 31, 2017 was $28.0 million compared to a net loss of $23.5 million for the quarter ended March 31, 2016.

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, a TGR5 agonist approaching Phase 1 development. Leveraging the company's platform and unique gut-restriction chemistry, Ardelyx intends to build a fully integrated, revenue-generating biopharmaceutical company with leading cardiorenal and GI business portfolios. For more information, please visit 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; Ardelyx's future development plans for its 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; Ardelyx's corporate goals; and the potential of Ardelyx's drug discovery and design platform; Ardelyx's ability to commercialize its product candidates; and Ardelyx's ability to generate revenues in the future. 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, the uncertainties in the manufacture of clinical trial material, including process development, and 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 May 5, 2017, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

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

	March 31, 2017	December 31, 2016
	(Unaudited)	(1)
Assets		
Cash and cash equivalents	$ 71,213	$ 74,598
Short-term investments	102,210	126,225
Property and equipment, net	8,915	8,991
Prepaid and other assets	5,427	3,317
Total Assets	$ 187,765	$ 213,131
Liabilities and stockholders' equity		
Accounts payable and accrued liabilities	$ 19,314	$ 19,201
Other liabilities	767	779
Stockholders' equity	167,684	193,151

Total liabilities and stockholders' equity	$ 187,765	$ 213,131

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

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

	Three Months Ended March 31,	
	2017	**2016**
	(Unaudited)	**(Unaudited)**
Operating expenses:		
Research and development	$ 22,387	$ 19,250
General and administrative	6,047	4,279
Total operating expenses	28,434	23,529
Loss from operations	(28,434)	(23,539)
Other income (expense)	426	62
Provision for income taxes	-	-
Net loss	$ (28,008)	$ (23,467)
Net loss per common share, basic & diluted	$ (0.59)	$ (0.70)
Weighted-average shares used in computing net loss per share, basic and diluted	47,343,234	33,466,955

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/ardelyx-reports-first-quarter-2017-operating-results-and-highlights-recent-progress-300452088.html

SOURCE Ardelyx

News Provided by Acquire Media