



May 9, 2016

Ardelyx Reports First Quarter 2016 Financial Results

Conference Call and Webcast Today at 4:30 p.m. ET

FREMONT, Calif., May 9, 2016 /PRNewswire/ -- Ardelyx, Inc. (NASDAQ: ARDX), a clinical-stage biopharmaceutical company focused on gastrointestinal and cardio-renal diseases, today announced financial results for the first quarter ended March 31, 2016.



"We are very pleased with the progress we have made thus far in 2016," said Mike Raab, President and Chief Executive Officer of Ardelyx. "The remainder of the year looks to be an exciting period for Ardelyx, as we expect to execute on multiple upcoming milestones. We expect results from the second Phase 2b clinical trial evaluating tenapanor for the treatment of hyperphosphatemia in ESRD patients in the second half of 2016. We look forward to building upon the positive results from our clinical trial evaluating the pharmacodynamic activity of the lead product candidate from our RDX022 program in healthy volunteers, which we announced in January, and we plan to initiate a Phase 3 clinical trial in patients with hyperkalemia during the fourth quarter 2016. In the fourth quarter, we also expect to submit an IND for RDX98940, the lead development candidate from our RDX009 program."

Highlights from the First Quarter 2016 and Upcoming Clinical Milestones

- 1 Completed an underwritten follow-on public offering of common stock in January 2016, with net proceeds totaling approximately \$80.8 million;
- 1 Reported positive results from the pharmacodynamic (PD) clinical trial evaluating the activity of RDX227675, the lead product candidate from our RDX022 program, in 60 healthy adult volunteers in January 2016. RDX227675 successfully demonstrated the ability to bind potassium in the gastrointestinal tract and was generally well-tolerated at all doses administered up to 27.5 g/day;
- 1 Ardelyx plans to proceed with a Phase 3 clinical trial for RDX227675, which it currently intends to initiate in the fourth quarter 2016. Ardelyx expects to pursue FDA approval for RDX227675 using the 505(b)(2) regulatory pathway;
- 1 Results from the second Phase 2b clinical trial evaluating tenapanor for the treatment of hyperphosphatemia in end-stage renal disease (ESRD) patients are expected in the second half of 2016;
- 1 Ardelyx currently expects to file an IND in the fourth quarter of 2016 for RDX98940, Ardelyx's lead development candidate in its RDX009 program; RDX98940 is a minimally-systemic TGR5 agonist that stimulates local secretion of GLP-1 and GLP-2 in the gastrointestinal tract; and
- 1 Results from T3MPO-1 and T3MPO-2, two ongoing Phase 3 clinical trials evaluating tenapanor for the treatment of IBS-C, are expected in 2017.

First Quarter Ended March 31, 2016 Financial Results

Net loss for the first quarter of 2016 was \$23.5 million, or \$0.70 per basic and diluted share, compared to a net loss of \$3.5 million, or \$0.19 per basic and diluted share for the first quarter of 2015.

Total revenue is comprised of licensing revenue and collaborative development revenue. Licensing revenue for the first quarter of 2016 decreased to zero from \$3.9 million for the first quarter of 2015. Licensing revenue for the three months ended March 31, 2015 related to the recognition of revenue from upfront and milestone payments received from AstraZeneca. As our collaboration agreement with AstraZeneca was terminated in June 2015, there was no further recognition of revenue related to the upfront and milestone payments after the six-month period ended June 30, 2015.

Collaborative development revenue is comprised of development expenses that were reimbursable to Ardelyx by AstraZeneca. Collaborative development revenue for the first quarter of 2016 decreased to zero from \$2.0 million for the first quarter of 2015. The decrease was attributable to the termination of the AstraZeneca agreement in June 2015 and related cessation of reimbursement of research and development expenses.

Research and development expense for the first quarter of 2016 increased to \$19.3 million from \$6.2 million for the first

quarter of 2015. The increase was due to expenses incurred primarily for clinical development activities as well as clinical manufacturing and process development activities associated with tenapanor and RDX227675.

General and administrative expense was \$4.3 million for the first quarter of 2016 as compared to \$3.2 million for first quarter of 2015. The increase was primarily due to an increase in professional services fees, personnel and public company costs.

Cash and cash equivalents were \$171.7 million as of March 31, 2016 compared with \$107.0 million as of December 31, 2015 primarily because of an underwritten public offering completed in January 2016 that yielded approximately \$80.8 million in net proceeds, offset by \$16.1 million in cash required for operating and other activities.

Conference Call & Webcast Information

Ardelyx management will host a live conference call and webcast today at 4:30 p.m. ET to discuss the financial results for the first quarter ended March 31, 2016. The live webcast and a replay may be accessed by visiting the investor relations section of the Ardelyx website at ir.ardelyx.com.

Please connect to the Company's website at least 15 minutes prior to the live webcast to ensure adequate time for any software download that may be needed to access the webcast. Alternatively, please call 1-855-296-9612 (US) or 920-663-6277 (International) to listen to the live conference call. The conference ID number for the live call is 1292888. Please dial in approximately 10 minutes prior to the call. An archived webcast replay will be available on the Company's website until May 23, 2016.

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 tract to treat gastrointestinal 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 constipation-predominant irritable bowel syndrome, or IBS-C, and management of hyperphosphatemia in patients with end-stage renal disease. In addition to tenapanor, Ardelyx is developing RDX227675, a non-absorbed polymer for the treatment of hyperkalemia, or high potassium, in kidney and heart disease patients. Ardelyx is also advancing several research programs focused in gastrointestinal and cardio-renal diseases. Ardelyx is located in Fremont, California. For more information, please visit Ardelyx's website at 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 for tenapanor in treating IBS-C and hyperphosphatemia in end-stage renal disease patients, Ardelyx's future development plans for tenapanor and the timing thereof, the expected timing for the receipt of results from T3MPO-1 and T3MPO-2, the two ongoing Phase 3 clinical trials evaluating tenapanor for the treatment of IBS-C, the expected timing for the receipt of the results for the Phase 2b hyperphosphatemia clinical trial, the potential for RDX227675 in treating hyperkalemia in kidney and heart disease patients, Ardelyx's future development plans for RDX227675 and the timing thereof, the expected timing for the initiation of the Phase 3 clinical trial for RDX227675, the expected timing for the filing of an IND 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, 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, scale up and tech transfer of manufacturing processes. 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 9, 2016, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

Ardelyx, Inc.
Condensed Balance Sheets
(In thousands)

	March 31, 2016	December 31, 2015
Assets	(Unaudited)	(1)
Cash and cash equivalents	\$ 171,678	\$ 107,004
Property and equipment, net	4,597	4,711

Prepaid and other assets	4,223	5,231
Total Assets	<u>\$ 180,498</u>	<u>\$ 116,946</u>

Liabilities and stockholders' equity

Accounts payable and accrued liabilities	\$ 12,458	\$ 7,723
Other liabilities	292	322
Stockholders' equity	<u>167,748</u>	<u>108,901</u>
Total liabilities and stockholders' equity	<u>\$ 180,498</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 and Comprehensive Loss
(In thousands, except share and per share amounts)

	Three Months Ended	
	March 31,	
	2016	2015
	(Unaudited)	(Unaudited)
Revenues		
Licensing revenue	\$ --	\$ 3,884
Collaborative development revenue	--	1,999
Total revenue	<u>--</u>	<u>5,883</u>
Operating expenses		
Research and development	19,250	6,198
General and administrative	4,279	3,175
Total operating expenses	<u>23,529</u>	<u>9,373</u>
Loss from operations	<u>\$ (23,529)</u>	<u>\$ (3,490)</u>
Other income (expense), net	62	(12)
Provision for from income taxes	<u>—</u>	<u>—</u>
Net loss and comprehensive loss	<u>\$ (23,467)</u>	<u>\$ (3,502)</u>
Basic and diluted net loss per share	\$ (0.70)	\$ (0.19)
Shares used in computing basic and diluted net loss per share	33,466,955	18,606,760

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-first-quarter-2016-financial-results-300265219.html>

SOURCE Ardelyx

News Provided by Acquire Media