



Ardelyx Reports Third Quarter 2015 Financial Results

November 12, 2015

FREMONT, Calif., Nov. 12, 2015 /PRNewswire/ -- Ardelyx, Inc. (NASDAQ: ARDX), a clinical-stage biopharmaceutical company focused on gastrointestinal and cardio-renal diseases, today announced financial results for the third quarter ended September 30, 2015. The Company also today announced that two clinical trials were initiated in October 2015: a Phase 3 clinical trial evaluating tenapanor for the treatment of constipation-predominant irritable bowel syndrome (IBS-C) and a clinical study evaluating the pharmacodynamic activity of RDX022, a potassium binder for the treatment of hyperkalemia. Additionally, the Company indicated that it plans to initiate a Phase 2b study to evaluate tenapanor in CKD patients with hyperphosphatemia on dialysis in December 2015. Results from this study are currently expected in the second half of 2016.



"We have made a tremendous amount of progress in our key clinical programs over the last few months and are on pace to surpass our previously announced timelines for tenapanor and RDX022," Mike Raab, President and CEO of Ardelyx remarked. "We are pleased to announce that we commenced the first Phase 3 clinical study of tenapanor in IBS-C in October and we now expect to commence the second Phase 3 clinical study in December, rather than in the first quarter of 2016. A pharmacodynamic study is also now underway to evaluate our novel potassium binder, RDX022. While we previously anticipated that we would obtain results in the first half of 2016, due to the rapid progress of the study we can now confirm that we expect results in January 2016. We are pleased with the team's productivity and look forward to ending the year with several mid to late-stage programs advancing in the clinic."

Highlights from the Third Quarter 2015 and Recent Clinical and Corporate Developments

- At the 2015 American College of Gastroenterology Conference, Phase 2 clinical data showing measures of sustained response in tenapanor-treated IBS-C patients was presented in a poster entitled, "Tenapanor's Sustained Response in Patients With Constipation Predominant Irritable Bowel Syndrome: Post-hoc Analysis from a 12-Week, Double-Blind, Placebo-Controlled, Randomized Phase 2b Trial."
- At the American Society of Nephrology Kidney Week 2015, clinical data for tenapanor were highlighted in several posters and in an oral presentation entitled, "Tenapanor, an NHE3 Inhibitor, Reduces Serum Phosphate in Patients with CKD Stage 5D and Hyperphosphatemia."
- The Company initiated the first Phase 3 clinical trial for tenapanor in IBS-C patients and expects to initiate a second Phase 3 clinical trial in December.
- A pharmacodynamic (PD) study for RDX022, a novel potassium binder for the treatment of hyperkalemia, was initiated in October with results expected in January 2016. RDX022 is being developed through an accelerated 505(b)(2) pathway.
- Ardelyx strengthened its Board of Directors with the appointment of William Bertrand, Jr. Mr. Bertrand recently assumed the position of Executive Vice President and General Counsel for Infinity Pharmaceuticals, Inc., and prior to that he served as Senior Vice President, Acting Chief Executive Officer and General Counsel for Salix Pharmaceuticals, where he remained as General Manager through the integration of Salix's acquisition by Valeant Pharmaceuticals.

Third Quarter 2015 Financial Results

The net loss in the third quarter of 2015 was \$18.1 million, or \$0.70 per basic and diluted share, compared to a net income of zero or \$0.00 per basic and diluted share in the third quarter of 2014.

Total revenue is comprised of licensing revenue and collaborative development revenue, which were both related to the Company's license agreement with AstraZeneca. Total revenues decreased to zero in the third quarter of 2015 from \$7.6 million in the third quarter of 2014 because of the termination of the AstraZeneca agreement in June 2015.

Research and development expense in the third quarter of 2015 increased to \$14.7 million from \$5.7 million in the third quarter of 2014. The change was primarily due to the \$7.3 million in expenses incurred for the clinical trial material from AstraZeneca as well as an increase of \$1.7 million for clinical development activities associated with tenapanor and RDX022, and process development for RDX022.

General and administrative expense was \$3.4 million in the third quarter of 2015 as compared to \$1.8 million in the third quarter of 2014. The increase was primarily due to an increase in personnel expense and professional service fees.

Cash and cash equivalents were \$129.0 million as of September 30, 2015 as compared to \$107.3 million as of December 31, 2014. The increase in cash and cash equivalents compared to December 31, 2014 was primarily due to \$74.3 million in net proceeds, after all costs, from the issuance of common stock and warrants to purchase common stock offset by changes in working capital, cash paid for purchases of property and equipment, the \$15 million up-front payment to AstraZeneca in connection with the termination agreement, and the \$10 million payment to AstraZeneca for reimbursement of certain research and development expenses incurred by AstraZeneca under the collaboration agreement during 2015.

Conference Call & Webcast Information

Ardelyx management will host a live conference call and webcast today at 8:30 a.m. Eastern Time to discuss the third quarter financial results. The live webcast and a replay can be accessed by visiting Ardelyx's website on the investor page of the Company's website at <http://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 520-663-6277 (International) to listen to the live conference call. The conference ID number for the live call is 62864853. Please dial in approximately 10 minutes prior to the call. Following the webcast, an archived version of the call will be available until November 20, 2015.

About Ardelyx

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 (IBS-C) and for the control of hyperphosphatemia in CKD patients on dialysis. In addition to tenapanor, Ardelyx is developing RDX022, 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 CKD patients on dialysis. Ardelyx's future development plans for tenapanor and the timing thereof, the expected timing for the receipt of the results for the Phase 2b hyperphosphatemia clinical trial, the potential for RDX022 in treating hyperkalemia in kidney and heart disease patients, Ardelyx's future development plans for RDX022 and the timing thereof, the expected timing for the receipt of the results for the RDX022 pharmacodynamic clinical trial 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, RDX022, 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 August 12, 2015, the Form 10-Q expected to be filed on November 12, 2015 and its future current and periodic reports to be filed with the Securities and Exchange Commission.

ARDELYX, INC. CONDENSED BALANCE SHEETS (in thousands)

	September 30, December 31,	
	2015	2014
	(Unaudited)	(1)
Assets		
Cash and cash equivalents	\$ 129,047	107,286
Accounts receivable	--	2,584
Property and equipment, net	4,391	2,131
Prepaid and other assets	4,628	1,413
Total Assets	\$ 138,066	113,414
Liabilities and stockholders' equity		
Accounts payable and accrued liabilities	\$ 12,584	5,557
Deferred license revenue	--	47,053
Other liabilities	352	122
Stockholders' equity	125,130	60,682
Total liabilities and stockholders' equity	\$ 138,066	113,414

(1) Derived from the audited financial statements included on Form 10-K for the year ended December 31, 2014.

ARDELYX, INC. CONDENSED STATEMENTS OF OPERATIONS (in thousands, except share and per share amounts)

	Three Months Ended Sept. 30		Nine Months Ended Sept. 30,	
	2015	2014	2015	2014
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenues:				
Licensing revenue	\$ --	\$ 4,767	\$ 21,611	\$ 14,509
Collaborative development revenue	--	2,831	2,415	10,755
Total revenues	--	7,598	24,026	25,284
Operating expenses:				
Research and development expense	14,705	5,694	27,101	18,514
General and administrative expense	3,374	1,823	9,438	4,401
Total operating expenses	18,079	7,517	36,539	22,915
(Loss) income from operations	(18,079)	81	(12,513)	2,369
Other expense	(77)	(7)	(138)	(19)
Change in fair value of pref. stock warrant liability	--	--	--	(1,593)
Benefit from income taxes	30	--	30	--
Net (loss) income and comprehensive (loss) income	\$ (18,126)	\$ 74	(12,621)	\$ 757
Basic net (loss) income per share	\$ (0.70)	\$ --	\$ (0.58)	\$ --
Diluted net (loss) income per share	\$ (0.70)	\$ --	\$ (0.58)	\$ --
Shares used in computing basic net (loss) income per share	25,930,928	18,374,277	21,859,383	7,476,842

Shares used in computing diluted net (loss) income per share 25,930,928 19,133,217 21,859,383 7,476,642

Logo - <http://photos.pnnewswire.com/brrh/20140619/119451>

To view the original version on PR Newswire, visit <http://www.pnnewswire.com/news-releases/ardelyx-reports-third-quarter-2015-financial-results-300177323.html>

SOURCE Ardelyx

News Provided by Acquire Media