



February 25, 2015

Ardelyx Reports Fourth Quarter and Full Year 2014 Financial Results

Completed Two Tenapanor Phase 2b Clinical Trials in Patients with Constipation-Predominant Irritable Bowel Syndrome (IBS-C) and in Chronic Kidney Disease Patients with Hyperphosphatemia (CKD-5D) Phase 2a Data for Tenapanor in CKD Patients Expected in 2Q 2015 Conference Call and Webcast Today at 4:30 p.m. ET

FREMONT, Calif., Feb. 25, 2015 /PRNewswire/ -- Ardelyx, Inc. (NASDAQ: ARDX), a clinical-stage biopharmaceutical company focused on cardio-renal, gastrointestinal and metabolic diseases, today announced financial results for the fourth quarter and twelve months ended December 31, 2014.



"2014 has been a highly productive year at Ardelyx, with advancements in the clinical program for tenapanor, including the completion of two Phase 2b clinical trials in patients with constipation-predominant irritable bowel syndrome and in chronic kidney disease patients on dialysis with hyperphosphatemia," said Mike Raab, President and Chief Executive Officer. "We continue to work diligently with AstraZeneca to support the clinical development for tenapanor, and plan to report the results of the Phase 2a clinical trial in CKD patients in the second quarter of 2015. We are also accelerating the development of our own proprietary pipeline and expect to provide updates about our pipeline development activities mid-year."

Recent Clinical & Corporate Developments

- Ardelyx announced results from AstraZeneca's 161-patient Phase 2b clinical study evaluating tenapanor in hyperphosphatemic chronic kidney disease patients on dialysis (CKD-5D, also known as end-stage renal disease, or ESRD). The study met its primary endpoint by demonstrating a statistically significant dose-related decrease in serum phosphate levels for tenapanor-treated patients compared to patients receiving placebo ($p=0.012$). The most frequently observed adverse event was diarrhea, with the rate of diarrhea and the discontinuation rate due to diarrhea higher than observed in previous tenapanor trials. Higher discontinuations rates due to diarrhea were observed primarily in the 30mg once daily and 30mg twice daily dose groups.
- Ardelyx announced results from AstraZeneca's 371-patient Phase 2b clinical trial evaluating tenapanor in patients with constipation-predominant irritable bowel syndrome (IBS-C). At the 50 mg twice daily dose, the study met its primary efficacy endpoint of an increase in the complete spontaneous bowel movement (CSBM) responder rate, and produced a statistically significant effect in abdominal pain responder and overall responder rates. Most secondary endpoints, including abdominal pain and other abdominal and IBS-C symptoms, demonstrated statistically significant and clinically meaningful improvements also at 50mg twice daily.
- Ardelyx announced the appointment of Jeremy S. Caldwell, Ph.D. as Executive Vice President and Chief Scientific Officer.
- A \$25 million milestone payment was received from AstraZeneca under its collaboration agreement for the initiation of a Phase 2b clinical trial evaluating tenapanor for the treatment of hyperphosphatemia, or elevated serum phosphorus, in patients with CKD-5D.
- Ardelyx raised net proceeds of approximately \$61.2 million in an initial public offering of its common stock.
- Ardelyx licensed its novel NaP2b phosphate transport inhibitor program for the treatment of hyperphosphatemia in CKD-5D patients to Sanofi in exchange for an upfront payment and potential milestones that could total \$198 million.
- For additional information regarding the clinical trial results of tenapanor in the Phase 2b trials in CKD-5D and IBS-C, please refer to our Form 8-K filed with the Securities and Exchange Commission on February 9, 2015.

Upcoming Clinical Milestones

- AstraZeneca and Ardelyx are also evaluating tenapanor in a Phase 2a trial in 154 patients with chronic kidney disease, type 2 diabetes mellitus and albuminuria (NCT01847092). The study consists of a 4-week run-in period, 12 weeks of blinded treatment with tenapanor, and a 2-week follow-up period. Data from this clinical trial are expected in the second quarter 2015. Ardelyx currently expects AstraZeneca to determine its future clinical development plans for tenapanor after it has received all of the Phase 2 data.

Fourth Quarter and Year Ended December 31, 2014 Financial Results

Net loss for the year ended December 31, 2014 was \$3.2 million, or \$0.31 per basic and diluted share, compared to a net loss of \$6.6 million, or \$5.82 per basic and diluted share for the year ended December 31, 2013. Net loss for the fourth quarter of 2014 was \$4.0 million, or \$0.21 per basic and diluted share, compared to a net loss of \$4.3 million, or \$3.53 per basic and diluted share for the fourth quarter of 2013.

Total revenue is comprised of licensing revenue and collaborative development revenue. Licensing revenue for the year ended December 31, 2014 increased to \$18.4 million from \$8.1 million for the year ended December 31, 2013. Licensing revenue for the fourth quarter of 2014 increased to \$3.9 million from \$2.1 million for the fourth quarter of 2013. The increase in both the full year and the fourth quarter was primarily due to the amortization of deferred revenue from a \$15.0 million development milestone payment that the Company received in December 2013 and a milestone payment of \$25.0 million that the Company received in May 2014.

Collaborative development revenue is comprised of development expenses that are reimbursable to Ardelyx by AstraZeneca. Collaborative development revenue for the year ended December 31, 2014 decreased to \$13.2 million from \$20.9 million for the year ended December 31, 2013. Collaborative development revenue for the fourth quarter of 2014 decreased to \$2.5 million from \$6.4 million for the fourth quarter of 2013. The decrease in both the full year and fourth quarter was primarily attributable to a decrease in the development activities performed by Ardelyx under the collaboration agreement with AstraZeneca.

Total research and development expense is comprised of discovery research and AstraZeneca collaboration development expense. Discovery research expense for the year ended December 31, 2014 increased to \$12.7 million from \$7.7 million for the year ended December 31, 2013. Discovery research expense for the fourth quarter of 2014 increased to \$5.0 million from \$2.0 million for the fourth quarter of 2013. The increase in both the full year and fourth quarter was driven by an increase in personnel costs resulting from increased headcount, consultant service fees and lab supply expenses resulting from increased research activities for non-partnered programs.

AstraZeneca collaboration development expense for the year ended December 31, 2014 decreased to \$13.2 million from \$20.3 million for the year ended December 31, 2013. AstraZeneca collaboration development expense for the fourth quarter of 2014 decreased to \$2.4 million from \$6.4 million for the fourth quarter of 2013. The decrease in both the full year and fourth quarter was driven by a decrease in expenses primarily related to the completion of certain clinical trial activities that are a part of the AstraZeneca agreement.

General and administrative expense was \$7.3 million for the year ended December 31, 2014 as compared to \$3.7 million for the year ended December 31, 2013. General and administrative expense was \$2.9 million for the fourth quarter of 2014 as compared to \$0.9 million for fourth quarter of 2013. The increase in both the full year and the fourth quarter was primarily due to higher personnel related costs, public company expenses and additional costs to support the Company's infrastructure.

Cash and cash equivalents were \$107.3 million as of December 31, 2014 as compared to \$34.4 million as of December 31, 2013. The increase in cash and cash equivalents compared to December 31, 2013 was primarily due to receipt of milestone payments from AstraZeneca and completion of the Company's initial public offering in June 2014.

Conference Call & Webcast Information

Ardelyx management will host a live conference call and webcast today at 4:30 pm Eastern Time to discuss the financial results for the fourth quarter and year ended December 31, 2014. The live webcast and a replay may 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 920-663-6277 (International) to listen to the live conference call. The conference ID number for the live call is 89320171. Please dial in approximately 10 minutes prior to the call. An archived webcast replay will be available on the Company's website for two weeks.

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 cardiovascular, gastrointestinal and metabolic diseases. The Company 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. Ardelyx formed a collaborative partnership with AstraZeneca in October 2012 to develop and commercialize tenapanor. In addition to tenapanor, the Company has discovered small molecule NaP2b inhibitors

for the treatment of hyperphosphatemia in CKD-5D, a program licensed to Sanofi, and independently is advancing several additional research programs focused in cardio-renal, gastrointestinal and metabolic 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 statements regarding our intentions to provide updates regarding progress on our proprietary pipeline and the timing thereof, the availability and timing of data from the ongoing Phase 2a clinical trial evaluating tenapanor in chronic kidney disease patients, the timing of AstraZeneca's decisions regarding future development plans for tenapanor, the potential for tenapanor in treating IBS-C patients, the potential for tenapanor in treating hyperphosphatemia in patients with end stage renal disease on dialysis, and the potential of our drug discovery and design platform. Such forward-looking statements involve substantial risks and uncertainties that could cause the development of tenapanor, 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 the clinical development process, Ardelyx's reliance upon AstraZeneca for the development of tenapanor, AstraZeneca's right under the license agreement to choose which indication or indications for which tenapanor will be developed, and AstraZeneca's right under the license agreement to terminate the agreement upon written notice to Ardelyx. 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 third quarter report filed on Form 10-Q with the Securities and Exchange Commission on November 7, 2014, and its future periodic reports to be filed with the Securities and Exchange Commission.

Ardelyx Inc.
Condensed Balance Sheets
(In thousands)

	December 31, 2014	December 31, 2013
	(Unaudited)	(1)
Assets		
Cash and cash equivalents	\$ 107,286	\$ 34,435
Accounts receivable	2,584	6,436
Property and equipment, net	2,131	530
Prepaid and other assets	1,413	1,503
Total assets	<u>\$ 113,414</u>	<u>\$ 42,904</u>
Liabilities, convertible preferred stock, and stockholders' equity (deficit)		
Accounts payable and accrued liabilities	\$ 5,557	\$ 3,311
Deferred license revenue	47,053	40,298
Convertible preferred stock warrant liability	—	6,456
Other liabilities	122	163
Convertible preferred stock	—	56,155
Shareholders' equity (deficit)	60,682	(63,479)
Total liabilities, convertible preferred stock, and stockholders' equity	<u>\$ 113,414</u>	<u>\$ 42,904</u>

(1) Information derived from audited financial statements included on form S1 for the year ended December 31, 2013.

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

Three Months Ended	Twelve Months Ended
December 31,	December 31,

	<u>2014</u>	<u>2013</u>	<u>2014</u>	<u>2013</u>
	(Unaudited)	(Unaudited)	(Unaudited)	(1)
Revenue:				
Licensing revenue	\$ 3,884	\$ 2,096	\$ 18,394	\$ 8,063
Collaborative development revenue	2,454	6,392	13,229	20,865
Total revenue	<u>6,338</u>	<u>8,488</u>	<u>31,623</u>	<u>28,928</u>
Operating expenses:				
Research and development				
Discovery research expense	4,964	1,958	12,734	7,746
AZ collaboration development expense	2,422	6,378	13,166	20,347
Total research and development expense	<u>7,386</u>	<u>8,336</u>	<u>25,900</u>	<u>28,093</u>
General and administrative	<u>2,884</u>	<u>870</u>	<u>7,287</u>	<u>3,700</u>
Total operating expenses	<u>10,270</u>	<u>9,206</u>	<u>33,187</u>	<u>31,793</u>
Income (loss) from operations	(3,932)	(718)	(1,564)	(2,865)
Other income (expense)	29	(3,516)	(1,583)	(3,558)
Benefit from (provision for) income taxes	(67)	(35)	(67)	(141)
Net income (loss) and comprehensive income (loss)	<u>\$ (3,970)</u>	<u>\$ (4,269)</u>	<u>\$ (3,214)</u>	<u>\$ (6,564)</u>
Basic and diluted net income (loss) per share	\$ (0.21)	\$ (3.53)	\$ (0.31)	\$ (5.82)
Shares used in computing basic and diluted net loss per share...	18,473,542	1,208,229	10,248,337	1,127,948

(1) Information derived from audited financial statements included on form S1 for the year ended December 31, 2013.

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