



November 6, 2014

## **Ardelyx Reports Third Quarter 2014 Financial Results**

### **Phase 2 Programs for Lead Product Candidate Tenapanor Continue to Advance in Multiple Indications Ardelyx Updates Projected Timing of Results from Phase 2b Study in ESRD patients with Hyperphosphatemia Conference Call and Webcast Today at 4:30 p.m. ET**

FREMONT, Calif., Nov. 6, 2014 /PRNewswire/ -- Ardelyx, Inc. (NASDAQ: ARDX), a clinical-stage biopharmaceutical company focused on cardio-renal, gastrointestinal and metabolic diseases, today announced financial results for the third quarter ended September 30, 2014.



"Ardelyx has continued to accelerate clinical development of our lead product candidate, tenapanor, in collaboration with our partner AstraZeneca," said Mike Raab, President and Chief Executive Officer. "In addition to recently announcing positive Phase 2b data for tenapanor in IBS-C, we continue to advance a separate Phase 2b study evaluating tenapanor in end-stage renal disease patients with hyperphosphatemia and we now expect to report results from that study during the first quarter of 2015. In an ongoing Phase 2a trial we are also evaluating tenapanor for its effect on markers of kidney disease and fluid overload in patients with chronic kidney disease, and expect to report results from that study in the second half of next year, as previously reported. We are excited about the progress of tenapanor, as well as the potential of earlier-stage programs in our R&D pipeline."

#### **Recent Clinical Development and Key Anticipated Milestones**

In October 2014, Ardelyx reported positive results from its Phase 2b clinical trial evaluating tenapanor in IBS-C patients. 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, with 60.7 percent of patients receiving tenapanor versus 33.7 percent receiving placebo ( $p < 0.001$ ). One of the key secondary endpoints, the rate of overall responders, also demonstrated statistical significance at the 50mg twice daily dose. Additionally, most secondary endpoints, including abdominal pain and other abdominal and IBS-C symptoms, demonstrated clinically meaningful improvements at the 50mg twice daily dose. Tenapanor was well-tolerated, and the safety results were consistent with those observed in previous tenapanor trials. As of October 31, 2014, a total of more than 910 individuals have received tenapanor in 12 clinical trials.

Anticipated tenapanor milestones include:

- Data from the Phase 2b trial of tenapanor in ESRD patients with hyperphosphatemia are expected in the first quarter of 2015, which represents an update from previous guidance that such data was expected to be available in the first half of 2015.
- Data from the Phase 2a trial evaluating tenapanor in chronic kidney disease patients are expected in the second half of 2015.

#### **Third Quarter 2014 Financial Results**

For the three months ended September 30, 2014, the Company reported a net income of \$74,000 or \$0.00 per basic and diluted share, compared to a net loss of \$0.9 million or a loss of \$0.81 per basic and diluted share, for the same quarter last year. The increase in net income was primarily driven by the increase in recognized licensing revenue related to milestone payments in accordance with the Company's agreement with AstraZeneca partially offset by expenses related to being a public company following the Company's June 2014 IPO and increased R&D expenses.

Total revenue is comprised of licensing revenue and collaborative development revenue. Licensing revenue for the three months ended September 30, 2014 was \$4.8 million compared to licensing revenue of \$2.0 million for the three months ended September 30, 2013. The increase 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, which is comprised of development expenses that are reimbursable to Ardelyx by AstraZeneca, was \$2.8 million for the three months ended September 30, 2014, compared to \$4.6 million for the three months ended September 30, 2013. The decrease of \$1.8 million from the prior year comparable period is primarily attributable to a decrease in the development activities performed by Ardelyx under the AstraZeneca agreement.

Research and development expenses were \$5.7 million for the three months ended September 30, 2014 compared to \$6.6 million for the three month period ended September 30, 2013. The \$0.9 million decrease compared to the prior year comparable period was primarily driven by a \$1.7 million decrease in expenses primarily related to the completion of certain clinical trial activities that are a part of the AstraZeneca agreement. This decrease in expense was partially offset by higher R&D expense of \$0.8 million due to 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.

General and administrative expenses were \$1.8 million for the three months ended September 30, 2014 compared to \$0.9 million for the three months ended September 30, 2013. The increase was primarily due to higher personnel related costs, public company expenses and additional costs to support the Company's infrastructure.

For the three months ended September 30, 2014, the Company recorded total stock based compensation of \$0.3 million.

On September 30, 2014, the Company had \$112.0 million in cash and cash equivalents compared to \$34.4 million on 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. The Company had no outstanding debt as of September 30, 2014. On September 30, 2014, the Company had 18.5 million shares of common stock issued and outstanding which included 133,844 common shares subject to the Company's right of repurchase.

### **Conference Call & Webcast Information**

Ardelyx management will host a live conference call and webcast today at 4:30 pm Eastern Time to discuss the third quarter financial results. 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 20728157. 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, 2014.

### **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 cardio-renal, 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 ESRD, 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](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 statements regarding the availability and timing of data from ongoing tenapanor clinical trials, the potential for tenapanor in treating IBS-C patients, the potential for tenapanor in treating the renal indications for which it is currently being evaluated, and the potential of our drug discover 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, and AstraZeneca's right under the license agreement to choose which indication or indications for which tenapanor will be developed. 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 second quarter report filed on Form 10-Q with the Securities and Exchange Commission on August 8, 2014, and its future periodic reports to be filed with the Securities and Exchange Commission.

### Condensed Balance Sheets

(In thousands)

	<u>September 30, 2014</u>	<u>December 31, 2013 (1)</u>
	(Unaudited)	
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 112,044	\$ 34,435
Accounts receivable	2,660	6,436
Prepaid expenses and other current assets	1,669	965
Total current assets	116,373	41,836
Property and equipment, net	1,152	530
Other assets	—	358
Restricted cash	204	180
Total assets	<u>\$ 117,729</u>	<u>\$ 42,904</u>
<b>Liabilities, convertible preferred stock, and stockholders' equity (deficit)</b>		
Current liabilities:		
Accounts payable	\$ 1,022	\$ 2,284
Accrued compensation and benefits	1,106	927
Other accrued liabilities	789	95
Deferred rent	—	5
Deferred revenue, current portion	16,480	13,828
Total current liabilities	19,397	17,139
Deferred revenue, non-current	34,959	26,470
Convertible preferred stock warrant liability	—	6,456
Liabilities related to early exercise of options	72	163
Total liabilities	54,428	50,228
Commitments and contingencies		
Convertible preferred stock	—	56,155
Stockholders' equity (deficit):		
Preferred stock	—	—
Common stock	2	—
Additional paid-in capital	131,195	5,174
Accumulated deficit	(67,896)	(68,653)
Total stockholders' equity (deficit)	63,301	(63,479)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	<u>\$ 117,729</u>	<u>\$ 42,904</u>

(1) Information derived from audited financial statements.

### Condensed Statements of Operations and Comprehensive Income (Loss)

(Unaudited)

(In thousands, except share and per share amounts)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2014</u>	<u>2013</u>	<u>2014</u>	<u>2013</u>
Revenue:				
Licensing revenue	\$ 4,767	\$ 1,989	\$ 14,509	\$ 5,967
Collaborative development revenue	2,831	4,604	10,775	14,473
Total revenue	7,598	6,593	25,284	20,440
Operating expenses:				
Research and development	5,694	6,584	18,514	19,757
General and administrative	1,823	895	4,401	2,830
Total operating expenses	7,517	7,479	22,915	22,587
Income (loss) from operations	81	(886)	2,369	(2,147)
Other expense, net	(7)	(13)	(19)	(42)
Change in fair value of preferred stock warrant liability	—	—	(1,593)	—
Income (loss) before provision for income taxes	74	(899)	757	(2,189)
Provision for income taxes	—	35	—	106
Net income (loss) and comprehensive income (loss)	<u>\$ 74</u>	<u>\$ (934)</u>	<u>\$ 757</u>	<u>\$ (2,295)</u>

Net income (loss) attributable to common stockholders:				
Basic	\$ 74	\$ (934)	\$ —	\$ (2,295)
Diluted	\$ 74	\$ (934)	\$ —	\$ (2,295)
Shares used to compute net income (loss) per share attributable to common stockholders:				
Basic	18,374,277	1,156,446	7,476,642	1,100,885
Diluted	19,133,217	1,156,446	7,476,642	1,100,885
Net income (loss) per share attributable to common stockholders				(2.08)
Basic	\$ —	\$ (0.81)	\$ —	\$
Diluted	\$ —	\$ (0.81)	\$ —	\$ (2.08)

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