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Ardelyx Reports Second Quarter 2014 Financial Results

Successfully Completed Initial Public Offering; Raised Net Proceeds of \$61.2 Million Company Progressing Clinical Development of Lead Candidate, Tenapanor, In Three Ongoing Phase 2 Programs

FREMONT, Calif., Aug. 7, 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 second quarter ended June 30, 2014.

Summary of First Half 2014 Accomplishments

- Ardelyx raised net proceeds of approximately \$61.2 million in an initial public offering of its common stock, and on June 19, 2014, its shares began trading on the NASDAQ Global Market(SM) under the symbol "ARDX".
- The Company received a milestone payment under its collaboration agreement with AstraZeneca of \$25.0 million in May 2014 for the initiation of a Phase 2b clinical trial evaluating tenapanor for the treatment of hyperphosphatemia, or elevated serum phosphorus, in patients with end-stage renal disease on hemodialysis (ESRD-HD).
- Tenapanor, which has been shown in clinical trials to reduce the intestinal absorption of both dietary sodium and phosphorus, is currently being evaluated by Ardelyx and AstraZeneca in three separate Phase 2 clinical trials involving patients with constipation-predominant irritable bowel syndrome (IBS-C), end-stage renal disease (ESRD), and chronic kidney disease (CKD). The data from these trials are expected as follows:
 - Phase 2b results evaluating tenapanor to treat IBS-C in 4Q2014
 - Phase 2b results evaluating tenapanor to treat hyperphosphatemia in ESRD patients in 1H2015
 - Phase 2a results evaluating tenapanor to treat CKD patients with type 2 diabetes mellitus and albuminuria in 2H2015
- In Ardelyx's collaboration with AstraZeneca, a total of 12 clinical trials of tenapanor have been completed or are ongoing, enrolling over 1,200 subjects, including over 830 subjects who have been administered tenapanor to date.
- In February 2014, Ardelyx licensed its novel NaP2b phosphate transport inhibitor program for the treatment of hyperphosphatemia in ESRD patients to Sanofi in exchange for an upfront payment and potential milestones that could total \$198 million.

"Ardelyx achieved several significant milestones in the first half of 2014, including the completion of a successful IPO in June, as well as making significant progress with the clinical development program for tenapanor in collaboration with our partner AstraZeneca, accompanied by receipt of a \$25 million development milestone payment," said Mike Raab, President and Chief Executive Officer. "We look forward to presenting the data for tenapanor in patients with IBS-C in the fourth quarter of 2014 as the first of a series of data disclosures from our Phase 2 studies. We believe that we are well-capitalized to advance and expand our pipeline and further the development of our drug discovery and design platform."

Second Quarter 2014 Financial Results

For the three months ended June 30, 2014, the Company reported a net income of \$3.8 million, or \$0.20 per basic share and \$0.18 per diluted share, compared to a net loss of \$0.9 million or \$0.81 per basic and diluted share, for the same quarter last year. The increase in earnings per share was primarily driven by the increase in recognized licensing revenue related to one-time milestone payments in accordance with the Company's agreement with AstraZeneca.

Total revenue is comprised of licensing revenue and collaborative development revenue. Licensing revenue for the three months ended June 30, 2014 was \$6.5 million compared to licensing revenue of \$2.0 million for the three months ended June 30, 2013. The increase was primarily due to amounts recognized from a \$15.0 million milestone payment the Company received in December 2013 related to the amendment to the AstraZeneca agreement and a \$25.0 million milestone payment the Company received in May 2014 related to the dosing of the first patient in the Phase 2b ESRD clinical trial in hyperphosphatemia which commenced in April 2014. These payments are being recognized ratably over our expected period of performance under the agreement, which is estimated to conclude on December 31, 2016.

Collaborative development revenue, which is comprised of development expenses that are reimbursable to Ardelyx by AstraZeneca, was \$2.6 million for the three months ended June 30, 2014 compared to \$5.3 million for the three months ended June 30, 2013 primarily attributable to the completion of certain activities related to the clinical trials that are a part of the

AstraZeneca agreement.

Research and development expenses were \$5.2 million for the three months ended June 30, 2014 compared to \$7.2 million for the three months ended June 30, 2013. The decrease was primarily driven by a \$2.6 million decrease in development activities conducted by Ardelyx on behalf of AstraZeneca in accordance with the AstraZeneca agreement, from \$5.2 million for the three months ended June 30, 2013 to \$2.6 million in same period in 2014. This was offset by increased discovery research expenses of \$0.5 million due to increased research activities for non-partnered programs.

General and administrative expenses were \$1.2 million for the three months ended June 30, 2014 compared to \$0.9 million for the three months ended June 30, 2013. The increase was primarily due to an increase in professional services fees and an increase of personnel-related expenses.

For the three months ended June 30, 2014, the Company recorded \$0.1 million of stock based compensation.

On June 30, 2014, the Company had \$117.8 million in cash and cash equivalents compared to \$34.4 million on December 31, 2013, an increase of \$83.4 million. The Company has no outstanding debt as of June 30, 2014. On June 30, 2014, the Company had 18,335,620 shares of common stock issued and outstanding.

About Ardelyx, Inc.

Ardelyx is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of innovative, non-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, a product currently in three separate Phase 2 clinical trials for the treatment of constipation-predominant irritable bowel syndrome (IBS-C), complications associated with end-stage renal disease (ESRD), and chronic kidney disease (CKD).

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.

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, potential milestone payments from our collaboration partners, and the potential sufficiency of capital resources available to further develop our pipeline and 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, Ardelyx's reliance upon Sanofi for the discovery and development under the licensed NaP2b inhibitor program, and the uncertainties inherent in the research and discovery 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 prospectus filed with the Securities and Exchange Commission on June 19, 2014, and its future periodic reports to be filed with the Securities and Exchange Commission.

Condensed Balance Sheets (In thousands)

	June 30, 2014	December 31, 2013 (1)
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 117,814	\$ 34,435
Accounts receivable	3,025	6,436
Prepaid expenses and other current assets	1,308	965

Total current assets	122,147	41,836
Property and equipment, net	1,138	530
Other assets	13	358
Restricted cash	180	180
Total assets	<u>\$ 123,478</u>	<u>\$ 42,904</u>
Liabilities, convertible preferred stock, and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 2,308	\$ 2,284
Accrued compensation and benefits	802	927
Other accrued liabilities	1,003	95
Deferred rent	—	5
Deferred revenue, current portion	23,221	13,828
Total current liabilities	27,334	17,139
Deferred revenue, non-current	33,170	26,470
Convertible preferred stock warrant liability	—	6,456
Liabilities related to early exercise of options	107	163
Total liabilities	60,611	50,228
Commitments and contingencies		
Convertible preferred stock	—	56,155
Stockholders' equity (deficit):		
Preferred stock	—	—
Common stock	2	—
Additional paid-in capital	130,836	5,174
Accumulated deficit	(67,971)	(68,653)
Total stockholders' equity (deficit)	62,867	(63,479)
Total liabilities, convertible preferred stock, and stockholders' equity (deficit)	<u>\$ 123,478</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)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2014	2013	2014	2013
Revenue:				
Licensing revenue	\$ 6,507	\$ 1,989	\$ 9,743	\$ 3,978
Collaborative development revenue	2,630	5,302	7,944	9,869
Total revenue	9,137	7,291	17,687	13,847
Operating expenses:				
Research and development	5,183	7,234	12,820	13,173
General and administrative	1,203	908	2,580	1,935
Total operating expenses	6,386	8,142	15,400	15,108
Income (loss) from operations	2,751	(851)	2,287	(1,261)
Other expense, net	(8)	(4)	(12)	(29)
Change in fair value of preferred stock warrant liability	1,010	—	(1,593)	—
Income (loss) before provision for income taxes	3,753	(855)	682	(1,290)
Provision for income taxes	—	36	—	71
Net income (loss) and comprehensive income (loss)	<u>\$ 3,753</u>	<u>\$ (891)</u>	<u>\$ 682</u>	<u>\$ (1,361)</u>
Net income (loss) attributable to common stockholders:				
Basic	<u>\$ 515</u>	<u>\$ (891)</u>	<u>\$ —</u>	<u>\$ (1,361)</u>
Diluted	<u>\$ 703</u>	<u>\$ (891)</u>	<u>\$ —</u>	<u>\$ (1,361)</u>
Shares used to compute net income (loss) per share attributable to common stockholders:				
Basic	<u>2,611,259</u>	<u>1,102,093</u>	<u>1,937,509</u>	<u>1,072,583</u>
Diluted	<u>3,904,136</u>	<u>1,102,093</u>	<u>1,937,509</u>	<u>1,072,583</u>
Net income (loss) per share attributable to common stockholders:				
Basic	<u>\$ 0.20</u>	<u>\$ (0.81)</u>	<u>\$ —</u>	<u>\$ (1.27)</u>
Diluted	<u>\$ 0.18</u>	<u>\$ (0.81)</u>	<u>\$ —</u>	<u>\$ (1.27)</u>

