August 8, 2016

Ardelyx Reports Second Quarter 2016 Financial Results

-- Results from the First Phase 3 trial for Tenapanor for the Treatment of Hyperphosphatemia in Patients with ESRD Expected Q1 2017 --
-- Ardelyx's Proprietary Potassium Binder, RDX227675, Obtains Notification of Allowance for Composition of Matter Claims --
Conference Call and Webcast Today at 4:30 p.m. ET

FREMONT, Calif., Aug. 8, 2016 /PRNewswire/ -- Ardelyx, Inc. (NASDAQ: ARDX), a clinical-stage biopharmaceutical company focused on gastrointestinal and cardio-renal diseases, today announced financial results for the second quarter ended June 30, 2016.

"2016 continues to be a momentous year," said Mike Raab, President and Chief Executive Officer of Ardelyx. "With the completion of our recently announced $110 million private placement, we have raised net proceeds of over $190 million in 2016. Now that we have strengthened our balance sheet with sufficient capital to support the company through our receipt of critical clinical milestones in 2017, our primary focus is the execution of our late-stage clinical programs and advancement of the company towards commercialization. During 2017, all three of our late-stage programs will generate important clinical data. This includes currently expected results in the first quarter of next year from our first Phase 3 trial of tenapanor for the treatment of hyperphosphatemia in ESRD patients on dialysis. We believe that tenapanor has the potential to be a truly important development for the treatment of hyperphosphatemia in these patients. We also currently expect results in the first half of 2017 from our onset-of-action trial for RDX227675 in patients with hyperkalemia. Finally, we currently expect results from both Phase 3 clinical trials of tenapanor for IBS-C, with T3MPO-1 mid-year and T3MPO-2 by the end of 2017."

Recent Highlights

- Announced positive End-of-Phase 2 (EoP2) meeting with the U.S. Food and Drug Administration (FDA) for tenapanor for the treatment of hyperphosphatemia in end-stage renal disease (ESRD) patients on dialysis. As a result of the meeting, the currently ongoing clinical trial will now serve as the first of two Phase 3 registration trials to support the filing of a new drug application (NDA);
- Once-daily-dosing of RDX227675 demonstrated effects equal to two or three times daily dosing;
- Strengthened the Board with the addition of industry veteran, Robert Bazemore, to the Company's Board of Directors. Mr. Bazemore currently serves as President and Chief Executive Officer of Epizyme, Inc.;
- Announced the receipt of a Notice of Allowance by the U.S. Patent and Trademark Office for a composition of matter patent application for RDX227675, providing important intellectual property protection for RDX227675 through 2035; and,
- Subsequent to the second quarter, completed a private placement of common stock in July 2016, with gross proceeds totaling approximately $110 million, providing for a *pro forma* cash and cash equivalents of $257 million as of June 30, 2016, after accounting for the proceeds of the offering.

Upcoming Clinical Milestones

- The expected initiation of both an onset-of-action clinical trial and a Phase 3 clinical trial for RDX227675, for the treatment of hyperkalemia, in 4Q 2016;
- An IND filing expected in 4Q 2016 for RDX98940, Ardelyx's lead product candidate in its TGR5 agonist program;
- Receipt of results currently expected in the first half of 2017 from the RDX227675 onset-of-action trial;
- Receipt of results currently expected during 1Q 2017 from the ongoing Phase 3 trial of tenapanor for the treatment of hyperphosphatemia in ESRD patients on dialysis;
- Initiation of the second Phase 3 trial of tenapanor for the treatment of hyperphosphatemia in ESRD patients on dialysis currently expected during 1H 2017;
- Receipt of results from T3MPO-1, currently expected in mid-2017, for the ongoing 12-week tenapanor IBS-C Phase 3

trial;
- Receipt of results from T3MPO-2, currently expected by the end of 2017 for the ongoing 6-month tenapanor IBS-C Phase 3 trial.

Second Quarter Ended June 30, 2016 Financial Results

Net loss for the second quarter of 2016 was $28.6 million, or $0.83 per basic and diluted share, compared to a net income of $9.0 million, or $0.43 per basic and $0.42 diluted share for the second quarter of 2015.

Total revenue is comprised of licensing revenue and collaborative development revenue. Licensing revenue for the second quarter of 2016 decreased to zero from $17.7 million for the second quarter of 2015. Licensing revenue for the three months ended June 30, 2015 was related to the recognition of revenue from upfront and milestone payments received from AstraZeneca. As the Company's 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 second quarter of 2016 decreased to zero from $0.4 million for the second quarter of 2015. The decrease was due 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 second quarter of 2016 increased to $23.8 million from $6.2 million for the second 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, RDX227675 and RDX98940.

General and administrative expense was $4.9 million for the second quarter of 2016 as compared to $2.9 million for second quarter of 2015. The increase was primarily due to an increase in professional services fees including fees for market research and pre-commercialization activities, systems implementation and intellectual property management, as well as an increase in personnel-related expenses and facility costs.

Accounting for the net proceeds from the Company's private placement in July 2016, the Company's *pro forma* cash and cash equivalents as of June 30, 2016 were approximately $257 million including $146.7 million in cash and cash equivalents as of June 30, 2016 plus gross proceeds from the private placement completed in July 2016 of approximately $110 million. Cash and cash equivalents were $146.7 million as of June 30, 2016 compared with $107.0 million as of December 31, 2015 primarily as a result of the completion of an underwritten public offering of common stock in January 2016 that yielded approximately $80.8 million in net proceeds, offset by $41.1 million in cash required for operating and other activities for the period of December 31, 2015 through June 30, 2016.

Conference Call & Webcast Information

Ardelyx management will host a live conference call and webcast today at 4:30 p.m. Eastern Time to discuss the second quarter financial results. 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 56269341. Please dial in approximately 10 minutes prior to the call. An archived webcast replay will be available on the Company's website until August 22, 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 (GI) tract to treat GI 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 irritable bowel syndrome with constipation (IBS-C) and for the treatment of hyperphosphatemia in patients with end-stage renal disease (ESRD) on dialysis. In addition to tenapanor, Ardelyx is developing RDX227675, a non-absorbed polymer for the treatment of hyperkalemia, or high potassium, a problem prevalent in patients with kidney and heart disease. Ardelyx is also advancing several research programs focused in GI 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 of tenapanor in the treatment of IBS-C, the expected timing for the receipt of the results from Ardelyx's two on-going Phase 3 clinical trials evaluating tenapanor for the treatment of IBS-C, the potential for tenapanor in treating hyperphosphatemia in ESRD patients on dialysis, the expected timing of the results of the ongoing Phase 3 clinical trial evaluating tenapanor for the treatment of hyperphosphatemia in ESRD patients on dialysis, the expected timing of the initiation of the second Phase 3 clinical trial evaluating tenapanor for the treatment of hyperphosphatemia, the potential for RDX227675 in treating hyperkalemia in CKD patients, the expected timing of the initiation of the onset-of-action and Phase 3 clinical trials evaluating RDX227675 in treating hyperkalemia in CKD patients and the expected timing of the results of the onset-of-action clinical trial, the expected timing for the filing of an investigational new drug (IND) application 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, and scale up. 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 8, 2016, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

Ardelyx, Inc.
Condensed Balance Sheets
(In thousands)

	June 30, 2016 (Unaudited)	December 31, 2015 (1)
Assets		
Cash and cash equivalents	$ 146,669	$ 107,004
Property and equipment, net	4,827	4,711
Prepaid and other assets	3,883	5,231
Total Assets	$ 155,379	$ 116,946
Liabilities and stockholders' equity		
Accounts payable and accrued liabilities	$ 14,061	$ 7,723
Other liabilities	713	322
Stockholders' equity	140,605	108,901
Total liabilities and stockholders' equity	$ 155,379	$ 116,946

(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) Income
(In thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016 (Unaudited)	2015 (Unaudited)	2016 (Unaudited)	2015 (Unaudited)
Revenues:				
Licensing revenue	$ —	$ 17,727	$ —	$ 21,611
Collaborative development revenue	—	416	—	2,415
Total revenues	—	18,143	—	24,026
Operating expenses:				
Research and development expense	23,838	6,198	43,091	12,396
General and administrative expense	4,852	2,889	9,130	6,064
Total operating expenses	28,690	9,087	52,221	18,460
(Loss) income from operations	(28,690)	9,056	(52,221)	5,566
Other income (expense)	77	(49)	139	(61)

Provision for income taxes	—	—	—	—
Net (loss) income and comprehensive (loss) income	$ (28,613)	$ 9,007	$ (52,082)	$ 5,505
Basic net income (loss) per common share	$ (0.83)	$ 0.43	$ (1.53)	$ 0.28
Diluted net income (loss) per common share	$ (0.83)	$ 0.42	$ (1.53)	$ 0.27
Shares used in computing basic net (loss) income per share	34,636,559	20,880,235	34,051,785	19,749,778
Shares used in computing diluted net (loss) income per share	34,636,559	21,636,487	34,051,785	20,506,916

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To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/ardelyx-reports-second-quarter-2016-financial-results-300310605.html

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