



August 12, 2015

Ardelyx Reports Second Quarter 2015 Financial Results

Conference Call and Webcast Today at 8:00 a.m. ET

FREMONT, Calif., Aug. 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 second quarter ended June 30, 2015.



"We have made significant progress towards our goal of becoming a fully-integrated bio-pharmaceutical company," said Mike Raab, President and Chief Executive Officer. "Under our leadership, tenapanor's clinical development is accelerating, with a Phase 3 clinical program in IBS-C and a Phase 2b dosing trial in hyperphosphatemia patients on dialysis planned to begin in the fourth quarter of 2015. Our recent financing gives us the financial strength to initiate these late stage clinical programs and continue to pursue our goal to bring several compounds from the clinic to commercialization."

Recent Highlights and Anticipated Near-Term Milestones for Key Development Programs

- **IBS-C Phase 2b data at Digestive Disease Week:** In May 2015, the Company presented clinical data from its Phase 2b program evaluating tenapanor in IBS-C at the annual Digestive Disease Week conference in an oral presentation entitled, "Efficacy and Safety of Tenapanor Patients with Constipation Predominant Irritable Bowel Syndrome: A 12-Week, Double-Blind, Placebo-Controlled, Randomized Phase 2b Trial." Subsequently, the Company presented additional results from the Phase 2b trial, all of which achieved statistical significance with a clinically meaningful response versus placebo, including sustained overall responder rates, sustained overall complete spontaneous bowel movement (CSBM) responder rates, and sustained overall abdominal pain responder rates.
- **Re-acquisition of rights to tenapanor:** In June 2015, the Company entered into a termination agreement with AstraZeneca, under which all the rights to Ardelyx's portfolio of NHE3 inhibitors, including Ardelyx's lead product candidate, tenapanor, were returned to Ardelyx. Under the terms of the agreement, the Company agreed to pay AstraZeneca certain amounts for the return of the program, including (a) an upfront fee of \$15.0 million, (b) future royalties at a royalty rate of 10% of net sales of tenapanor or other NHE3 products by the Company or its licensees, and (c) 20% of non-royalty revenue received from a new collaboration partner, should it elect to license, or otherwise provide rights to develop and commercialize tenapanor or any other NHE3 product. The amounts payable to AstraZeneca in upfront payments, royalties and non-royalty revenue sharing are capped at the aggregate amount of \$90.0 million. In addition, the Company also paid AstraZeneca \$10.0 million as reimbursement for certain research and development expenses incurred by AstraZeneca under the collaboration agreement during 2015. Under the agreement, for an additional payment of up to \$10.0 million, AstraZeneca is obligated to supply the Company with clinical trial materials and all drug substance and drug product produced under the original agreement.
- **Announced clinical development plans for RDX022:** The Company recently announced its plans for the development of RDX022, Ardelyx's next generation potassium binder for the treatment of hyperkalemia. RDX022 is currently undergoing early-stage human trials, and Ardelyx expects to initiate a pharmacodynamic (PD) study of RDX022 in the fourth quarter of 2015. This new study will evaluate safety and PD effects of RDX022 with results expected in the first half of 2016. The Company has met with the FDA and, based on those discussions, intends to pursue an accelerated 505(b)2 development pathway for RDX022. Additionally, the Company expects to initiate a Phase 3 clinical trial to evaluate RDX022 for the treatment of hyperkalemia in the second half of 2016.
- **Hosted Inaugural R&D Day:** The Company provided a comprehensive update of its research and development programs at its first inaugural R&D Day in New York City on July 14, 2015. The Company emphasized its goal of creating a new standard in gastrointestinal and cardio-renal care and provided additional details regarding its robust clinical program. Specific highlights included:
 - Additional Phase 2b data for tenapanor in IBS-C demonstrating a sustained or durable responder rate of 14.6 percent greater than the placebo group
 - Proof of concept study in an animal model of chemotherapy-induced diarrhea for RDX009, a TGR5 agonist that stimulates local secretion of GLP-1 and GLP-2 in the gut
 - Proof of concept data demonstrating that RDX013, an oral potassium secretagogue, causes the secretion of potassium into the intestines in a preclinical model

Summary of Upcoming Clinical Milestones

- Initiation of a 12-week Phase 3 study of tenapanor in IBS-C patients in 4Q2015
- Initiation of a Phase 2b study of tenapanor in hyperphosphatemia patients on dialysis in 4Q2015 with results expected in 2H2016
- Initiation of pharmacodynamic study of RDX022 in 4Q2015 with results expected in 1H2016
- Initiation of a six-month Phase 3 study of tenapanor in IBS-C patients in 1H2016
- Initiation of a Phase 3 clinical trial to evaluate RDX022 for the treatment of hyperkalemia in 2H2016
- Planned submission of an IND for RDX009 in 2H2016

Second Quarter 2015 Financial Results

Net income in the second quarter of 2015 was \$9.0 million, or \$0.43 per basic and \$0.42 per diluted share, compared to a net income of \$3.8 million, or \$0.20 per basic and \$0.18 per diluted share in the second quarter of 2014.

Total revenue is comprised of licensing revenue and collaborative development revenue. Licensing revenue in the second quarter of 2015 increased to \$17.7 million from \$6.5 million in the second quarter of 2014. The increase was primarily due to recognition of the remaining deferred revenue balance of \$43.1 million during the three months ended June 30, 2015 as a result of the Company's termination agreement with AstraZeneca. This was partially offset by a \$15.0 million upfront payment for the return of the license granted to AstraZeneca as well as the \$10.0 million reimbursement for research and development expenses and for the acceleration of the transfer of information and materials.

Collaborative development revenue in the second quarter of 2015 decreased to \$0.4 million from \$2.6 million in the second quarter of 2014. The decrease was due to the termination of the Company's agreement with AstraZeneca.

Research and development expense in the second quarter of 2015 increased to \$6.2 million from \$5.2 million in the second quarter of 2014. The change resulted from a \$3.2 million increase in discovery research expenses primarily due to an increase in personnel costs, consultant service fees, process development costs and lab supply expenses from increased research activities for unpartnered programs. The increase was partially offset by a \$2.2 million decrease in AstraZeneca collaboration development expense due to the decrease in development activities related to tenapanor conducted by Ardelyx under the license agreement with AstraZeneca.

General and administrative expense was \$2.9 million in the second quarter of 2015 as compared to \$1.2 million in the second quarter of 2014. The increase 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 \$141.5 million as of June 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 \$74.4 million in net proceeds, after all costs, from 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.

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, the Company has discovered and designed tenapanor, which it is evaluating for the treatment of IBS-C and hyperphosphatemia in chronic kidney disease 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, and has discovered small molecule NaP2b inhibitors for the treatment of hyperphosphatemia in CKD patients on dialysis, a program licensed to Sanofi. Ardelyx is also independently 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 patients, the potential for tenapanor in treating hyperphosphatemia in chronic kidney disease patients on dialysis, Ardelyx's future development plans for tenapanor and the timing thereof, the potential for RDX022 in treating hyperkalemia, Ardelyx's future development plans for

RDX022 and the timing thereof, the potential of RDX009 in treating chemotherapy induced diarrhea and the potential timing for filing an IND for RDX009, 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, 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, Ardelyx's reliance upon AstraZeneca for the timely delivery of clinical trial material required for the initiation of the Phase 3 clinical program in IBS-C and the Phase 2b clinical trial in hyperphosphatemia, and Ardelyx's reliance upon AstraZeneca to facilitate a complete and timely transition of the tenapanor program from AstraZeneca 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 current report filed on Form 8-K with the Securities and Exchange Commission on July 14, 2015, and its future periodic reports to be filed with the Securities and Exchange Commission.

ARDELYX, INC.
CONDENSED BALANCE SHEETS
(in thousands)

	June 30, 2015	December 31, 2014
	(Unaudited)	(1)
Assets		
Cash and cash equivalents	\$ 141,534	\$ 107,286
Accounts receivable	27	2,584
Property and equipment, net	4,061	2,131
Prepaid and other assets	2,566	1,413
Total Assets	<u>\$ 148,188</u>	<u>\$ 113,414</u>
Liabilities and stockholders' equity		
Accounts payable and accrued liabilities	\$ 5,546	\$ 5,557
Deferred license revenue	—	47,053
Other liabilities	382	122
Stockholders' equity	142,260	60,682
Total liabilities and stockholders' equity	<u>\$ 148,188</u>	<u>\$ 113,414</u>

(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 June 30,		Six Months Ended June 30,	
	2015	2014	2015	2014
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Revenues:				
Licensing revenue	\$ 17,727	\$ 6,507	\$ 21,611	\$ 9,743
Collaborative development revenue	416	2,630	2,415	7,944
Total revenues	<u>18,143</u>	<u>9,137</u>	<u>24,026</u>	<u>17,687</u>
Operating expenses:				
Research and development expense	6,198	5,183	12,396	12,820
General and administrative expense	2,889	1,203	6,064	2,580
Total operating expenses	<u>9,087</u>	<u>6,386</u>	<u>18,460</u>	<u>15,400</u>
Income from operations	9,056	2,751	5,566	2,287
Other expense	(49)	(8)	(61)	(12)
Change in fair value of preferred stock warrant liability	-	1,010	-	(1,593)
Provision for income taxes	-	-	-	-
Net income and comprehensive income	<u>\$ 9,007</u>	<u>\$ 3,753</u>	<u>\$ 5,505</u>	<u>\$ 682</u>
Basic net income per share	<u>\$ 0.43</u>	<u>\$ 0.20</u>	<u>\$ 0.28</u>	<u>\$ -</u>
Diluted net income per share	<u>\$ 0.42</u>	<u>\$ 0.18</u>	<u>\$ 0.27</u>	<u>\$ -</u>
Shares used in computing basic net income per share	<u>20,880,235</u>	<u>2,611,259</u>	<u>19,749,778</u>	<u>1,937,509</u>
Shares used in computing diluted net income per share	<u>21,636,487</u>	<u>3,904,136</u>	<u>20,506,916</u>	<u>1,937,509</u>

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