Ardelyx Reports Second Quarter 2023 Financial Results and Provides 2023 IBSRELA Net Sales Revenue Guidance

August 2, 2023

Continued successful launch of IBSRELA, with Q2 net sales revenue of $18.3 million; Company currently expects 2023 full year IBSRELA net sales revenue to be $72 to $77 million

XPHOZAH expected to launch in Q4, pending FDA approval

Company ends Q2 with $127.6 million in cash and investments

Conference call scheduled for 8:00 AM Eastern Time

WALTHAM, Mass., Aug. 02, 2023 (GLOBE NEWSWIRE) -- Ardelyx, Inc. (Nasdaq: ARDX), a biopharmaceutical company founded with a mission to discover, develop and commercialize innovative, first-in-class medicines that meet significant unmet medical needs, today reported financial results for the second quarter ended June 30, 2023 and provided a business update.

“Ardelyx continued the momentum we established during a historic 2022 through the first half of 2023 and we are poised to deliver on our corporate priorities to drive IBSRELA growth and prepare for the potential approval and launch of XPHOZAH in the fourth quarter,” said Mike Raab, president and chief executive officer. “IBSRELA is carving out an important role in treating IBS-C, offering a meaningful new option for patients looking for a different approach to manage their IBS-C. With 61% quarter-over-quarter net sales revenue growth from Q1 to Q2 and usage and awareness continuing to increase, we are establishing IBSRELA as a meaningful therapeutic choice for patients and building market acceptance among the prescribing community, both of which are critical to our success. Now, with more than a year of launch metrics to work with, we are pleased, for the first time, to share that we expect IBSRELA net sales revenue to be between $72 and $77 million for the full year 2023. This guidance reflects continued, meaningful growth and we believe demonstrates the potential for this drug to generate $500 million or more of annual peak net sales revenue.”

Raab continued, “We also have commercial launch preparations underway ahead of the goal review date for XPHOZAH of October 17. Pending FDA approval, we are looking forward to bringing this novel therapy to patients in the fourth quarter of this year, delivering on a promise to patients and the vision of Ardelyx for the second time in two years.”

IBSRELA® (tenapanor) Update: Growth continues with $18.3 million in net sales revenue in Q2 2023
Revenue for Ardelyx’s first commercialized product, IBSRELA, continued a persistent growth pattern, with the company reporting IBSRELA net sales revenue of $18.3 million, a 61% quarter-over-quarter growth compared to $11.4 million of net sales revenue reported in the first quarter of 2023. Launched in the U.S. in 2022 for the treatment of irritable bowel syndrome with constipation (IBS-C) in adults, IBSRELA has shown consistent growth across new and refill prescriptions as well as new and repeat writing healthcare providers. Spherix Global Insights, a premier market research firm that publishes independent, syndicated monthly tracking research, has included IBSRELA as one of the key gastrointestinal launches it tracks. The May 2023 LaunchDynamix report published in Q2 by Spherix reports significant increases in awareness and experience with IBSRELA, while continuing to rate the product highly, 12-months post-launch. Among the 76 gastroenterologists (GIs) surveyed in its market research in May 2023, 91% rate IBSRELA as either a substantial or moderate advance over currently available IBS-C therapies and among the surveyed GIs who reported using IBSRELA, 98% report high or moderate satisfaction.

XPHOZAH® (tenapanor) Update: New Drug Application (NDA) accepted; User fee goal date of Oct. 17, 2023
In May, Ardelyx announced that the U.S. Food and Drug Administration (FDA) had accepted the resubmitted New Drug Application (NDA) for XPHOZAH for the control of serum phosphorus in adult patients with chronic kidney disease on dialysis who have had an inadequate response or intolerance to a phosphate binder therapy. The FDA granted XPHOZAH a class 2, six-month review with a user fee goal date of October 17, 2023. The company is now preparing to launch XPHOZAH in the fourth quarter of 2023, pending FDA approval.

Other Corporate Developments

- In July, the company announced that an NDA for tenapanor had been accepted for review by China’s Center for Drug Evaluation of the National Medical Products Administration for the control of serum phosphorus in adult patients with chronic kidney disease on hemodialysis. This acceptance triggers a $2 million milestone payment to Ardelyx under the terms of the license agreement between Ardelyx and its collaboration partner in China, Shanghai Fosun Pharmaceutical Industrial Development Co. Ltd. (Fosun Pharma). A potential approval of the NDA submission in China is expected by the end of 2024.
- The company had a significant presence at the 2023 Digestive Disease Week Conference (DDW 2023) in Chicago, Ill from May 6-9. The company presented a poster which included a post-hoc data analysis from the Phase 3 T3MPO-2 study and sponsored a Product Theater titled: *Discover a Different Mechanism of Action to Treat Adults with IBS-C: A Case Based Discussion* where Darren Brenner, M.D., Professor of Medicine and Surgery, Northwestern University Feinberg School of Medicine, reviewed the multifactorial pathophysiology of IBS-C, the novel mechanism of action of IBSRELA, and efficacy and safety data of IBSRELA from the Phase 3 clinical trial program.

Second Quarter 2023 Financial Results

- **Cash Position:** As of June 30, 2023, the company had total cash, cash equivalents and short-term investments of

$127.6 million, as compared to total cash, cash equivalents and short-term investments of $123.9 million as of December 31, 2022. During the quarter ended June 30, 2023, the company received gross proceeds of $11.6 million for the sale of 3.0 million shares of the company's common stock under the company's sales agreement with Jefferies LLC deemed to be "at-the-market offerings."

- **Revenues:** Net product sales for IBSRELA were $18.3 million during the quarter ended June 30, 2023, compared to $1.6 million for the quarter ended June 30, 2022. Total revenues for the second quarter were $22.3 million, which included $4.0 million of product supply and licensing related revenue compared to $1.0 million in product supply and licensing related revenue in the same period in 2022.
- **R&D Expenses:** Research and development expenses were $8.3 million for the quarter ended June 30, 2023, compared to $9.7 million for the quarter ended June 30, 2022. R&D expenses in the prior year included higher tenapanor manufacturing expenses as well as regulatory consulting expenses related to the appeal of the FDA's July 2021 action on the NDA for XPHOZAH.
- **SG&A Expenses:** Selling, general and administrative expenses were $27.2 million for the quarter ended June 30, 2023, an increase of $8.3 million compared to $18.9 million for the quarter ended June 30, 2022. The increase in selling, general and administrative expenses was primarily due to increased costs associated with the ongoing commercial launch of IBSRELA.
- **Net Loss:** Net loss for the quarter ended June 30, 2023 was $17.1 million, or $(0.08) per share, compared to net loss of $26.9 million, or $(0.19) per share, for the quarter ended June 30, 2022.

Financial Guidance
Ardelyx currently expects full-year 2023 net product revenue for IBSRELA to be between $72.0 and $77.0 million.

Conference Call Details
The company will host a conference call today, August 2, 2023, at 8:00 AM ET to discuss these results. To participate in the conference call, please dial (844) 481-2838 (domestic) or (412) 317-1858 (international) and ask to be joined into the Ardelyx call. A webcast of the call can also be accessed by visiting the Investor page of the company's website, www.ardelyx.com, and will be available on the website for 30 days following the call.

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS DEHYDRATION IN PEDIATRIC PATIENTS

IBSRELA is contraindicated in patients less than 6 years of age; in nonclinical studies in young juvenile rats administration of tenapanor caused deaths presumed to be due to dehydration. Avoid use of IBSRELA in patients 6 years to less than 12 years of age. The safety and effectiveness of IBSRELA have not been established in patients less than 18 years of age.

CONTRAINDICATIONS

- IBSRELA is contraindicated in patients less than 6 years of age due to the risk of serious dehydration.
- IBSRELA is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

WARNINGS AND PRECAUTIONS
Risk of Serious Dehydration in Pediatric Patients

- IBSRELA is contraindicated in patients below 6 years of age. The safety and effectiveness of IBSRELA in patients less than 18 years of age have not been established. In young juvenile rats (less than 1 week old; approximate human age equivalent of less than 2 years of age), decreased body weight and deaths occurred, presumed to be due to dehydration, following oral administration of tenapanor. There are no data available in older juvenile rats (human age equivalent 2 years to less than 12 years).
- Avoid the use of IBSRELA in patients 6 years to less than 12 years of age. Although there are no data in older juvenile rats, given the deaths in younger rats and the lack of clinical safety and efficacy data in pediatric patients, avoid the use of IBSRELA in patients 6 years to less than 12 years of age.

Diarrhea
Diarrhea was the most common adverse reaction in two randomized, double-blind, placebo-controlled trials of IBS-C. Severe diarrhea was reported in 2.5% of IBSRELA-treated patients. If severe diarrhea occurs, suspend dosing and rehydrate patient.

MOST COMMON ADVERSE REACTIONS
The most common adverse reactions in IBSRELA-treated patients (incidence ≥2% and greater than placebo) were: diarrhea (16% vs 4% placebo), abdominal distension (3% vs <1%), flatulence (3% vs 1%) and dizziness (2% vs <1%).

INDICATION
IBSRELA (tenapanor) is indicated for the treatment of Irritable Bowel Syndrome with Constipation (IBS-C) in adults.

Please see full Prescribing Information, including Boxed Warning, for additional risk information.

About Ardelyx, Inc.
Ardelyx was founded with a mission to discover, develop and commercialize innovative, first-in-class medicines that meet significant unmet medical

needs. Ardelyx's first approved product, IBSRELA® (tenapanor) is available in the United States and Canada. Ardelyx is developing XPHOZAH® (tenapanor), a novel product candidate for the control of serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis who have had an inadequate response or intolerance to phosphate binder therapy, which has completed three successful Phase 3 trials and an additional two Phase 4 open label trials. Ardelyx has a Phase 2 potassium lowering compound, RDX013, for the potential treatment of elevated serum potassium, or hyperkalemia, a problem among certain patients with kidney and/or heart disease and an early-stage program in metabolic acidosis, a serious electrolyte disorder in patients with CKD. Ardelyx has established agreements with Kyowa Kirin in Japan, Fosun Pharma in China and Knight Therapeutics in Canada for the development and commercialization of tenapanor in their respective territories. For more information, please visit https://ardelyx.com/ and connect with us on Twitter, LinkedIn and Facebook.

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 Ardelyx's expectation regarding opportunities for continued IBSRELA adoption, Ardelyx's current expectation of the user fee goal date for the NDA for XPHOZAH and any subsequent commercial launch of XPHOZAH; the projected net revenue for IBSRELA for full year 2023; the timing of the review for the NDA for tenapanor for hyperphosphatemia in China; and the potential role that tenapanor can play in offering a new treatment option for patients with hyperphosphatemia. Such forward-looking statements involve substantial risks and uncertainties that could cause 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, uncertainties associated with the development of, regulatory process for, and commercialization of drugs in the U.S. and internationally. 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 2, 2023, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

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Ardelyx, Inc.
Condensed Balance Sheets
(In thousands)

	June 30, 2023 (Unaudited)	December 31, 2022 (1)
Assets		
Cash and cash equivalents	$ 30,058	$ 96,140
Investments	97,521	27,769
Accounts receivable	9,109	7,733
Prepaid commercial manufacturing	13,166	13,567
Inventory, current	7,617	3,282
Inventory, non-current	40,295	25,064
Property and equipment, net	1,064	1,223
Right-of-use assets	7,053	9,295
Prepaid and other assets	5,320	5,993
Total assets	$ 211,203	$ 190,066
Liabilities and stockholders' equity		
Accounts payable	$ 5,294	$ 10,859
Accrued compensation and benefits	6,880	7,548
Current portion of operating lease liability	4,105	3,894
Current portion of long-term debt	27,052	26,711
Deferred revenue	15,197	13,236
Accrued expenses and other liabilities	12,571	12,380
Operating lease liability, net of current portion	3,752	5,855
Deferred royalty obligation related to the sale of future royalties	13,191	11,254
Stockholders' equity	123,161	98,329
Total liabilities and stockholders' equity	$ 211,203	$ 190,066

(1) Derived from the audited financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

Condensed Statements of Operations
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Revenues:				
Product sales, net	$ 18,309	$ 1,564	$ 29,664	$ 2,014
Product supply revenue	3,260	952	3,262	966
Licensing revenue	764	10	776	14
Total revenues	22,333	2,526	33,702	2,994
Cost of goods sold:				
Cost of sales	492	44	864	57
Other cost of revenue	2,997	94	4,162	166
Total cost of goods sold	3,489	138	5,026	223
Operating expenses:				
Research and development	8,282	9,741	17,375	18,592
Selling, general and administrative	27,186	18,862	53,989	38,201
Total operating expenses	35,468	28,603	71,364	56,793
Loss from operations	(16,624)	(26,215)	(42,688)	(54,022)
Interest expense	(1,075)	(777)	(2,103)	(1,523)
Non-cash interest expense related to the sale of future royalties	(968)	(10)	(1,937)	(10)
Other income, net	1,546	70	2,848	554
Loss before provision for income taxes	(17,121)	(26,932)	(43,880)	(55,001)
Provision for income taxes	—	6	14	8
Net loss	$ (17,121)	$ (26,938)	$ (43,894)	$ (55,009)
Net loss per share of common stock - basic and diluted	$ (0.08)	$ (0.19)	$ (0.21)	$ (0.40)
Shares used in computing net loss per share - basic and diluted	214,951,127	145,544,372	211,009,029	138,279,945

Source: Ardelyx, Inc.