Ardelyx Reports Second Quarter 2024 Financial Results and Provides Business Update

August 1, 2024

IBSRELA generates $35.4 million in net product sales revenue

XPHOZAH generates $37.1 million in net product sales revenue

Company ends Q2 with approximately $186 million in cash and investments

Conference call scheduled for 4:30 PM Eastern Time

WALTHAM, Mass., Aug. 01, 2024 (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, 2024 and provided a business update.

“In the second quarter, Ardelyx demonstrated our commitment to our mission and to ensuring that patients remain at the forefront of all of our efforts. We continued to drive expanded awareness and use of our two first-in-class medicines that represent new therapeutic options for patients who continue to have significant unmet medical needs. In addition, importantly, we are standing with the entire kidney community and fighting for patients whose health is at risk,” said Mike Raab, president and chief executive officer of Ardelyx.

Raab continued, “IBSRELA’s strong performance continued with consistent quarter-over-quarter gains. This performance further strengthens our conviction that IBSRELA is on track to achieve at least ten percent market share and $1 billion in annual sales before patent expiry. IBSRELA is providing meaningful clinical benefits to patients at a time when the need among IBS-C patients to address their symptoms remains significant. We believe IBSRELA is well placed to address this unmet need and we continue to invest, including the ongoing expansion of our sales team to further our growth trajectory. XPHOZAH’s remarkable performance continued, a clear indicator of the need for a novel therapy, like XPHOZAH, to help patients achieve target phosphorus levels. This is why it is so important that we take steps to protect patients against the dire consequences of the access restrictions that will occur if CMS moves oral-only phosphate lowering therapies into the End-Stage Renal Disease Prospective Payment System.”

IBSRELA® (tenapanor) records $35.4 million in net product sales revenue in Q2 2024
U.S. net product sales revenue for IBSRELA during the second quarter of 2024 was $35.4 million, showing approximately 25% quarter-over-quarter growth compared to the first quarter of 2024, and significant growth compared to the second quarter of 2023. The strong performance reflects the meaningful demand for IBSRELA, demonstrated by continued increases in new and refill prescriptions as well as growth in new and repeat writing healthcare providers.

Ardelyx continues to expect full-year 2024 U.S. net product sales revenue for IBSRELA to be between $140.0 and $150.0 million.

XPHOZAH® (tenapanor) launch progresses, records $37.1 million net product sales revenue during Q2 2024
Ardelyx continued to see a strong response to XPHOZAH from the nephrology community. U.S. net product sales revenue during Q2 2024 was $37.1 million, demonstrating significant quarter-over-quarter growth compared to the $15.2 million in net product sales revenue reported during the first quarter of 2024.

During the quarter, the company announced that an analysis of the Centers for Medicaid and Medicare Services (CMS) End-Stage Renal Disease Prospective Payment System (ESRD PPS) proposed rule to include oral-only medicines in the ESRD PPS revealed that the policy and the manner in which CMS intends to implement it are likely to cause significant restrictions on the use of XPHOZAH for all patients, irrespective of insurance coverage, because it interferes with the essential and appropriate shared decision-making between healthcare professionals and their patients. As part of an effort to protect patient access to XPHOZAH, the company announced on July 2 that it has chosen not to apply for the ESRD PPS Transitional Drug Add-on Payment Adjustment; and on July 18, the company announced that it has filed a lawsuit against CMS in partnership with the American Association of Kidney Patients and the National Minority Quality Forum claiming that CMS has violated its statutory and regulatory authority in its determination to include oral-only phosphate lowering therapies in the ESRD PPS.

Other Corporate Developments

- In June, the company presented data detailing educational needs related to irritable bowel syndrome with constipation (IBS-C) across healthcare disciplines in a poster at the 2024 American Association of Nurse Practitioners National Conference.
- The company had a significant presence at the 2024 Digestive Disease Week Conference, held May 18-21, 2024. The company presented two posters providing additional data supporting IBSRELA. The company also sponsored a Product Theater titled: “Discover IBSRELA: a Different Mechanism of Action to Treat Adults With IBS-C: A Case-Based Discussion,” where Brooks Cash, MD, led an engaging discussion about important clinical considerations for managing IBS-C in adult patients.
- The company had a significant presence at the National Kidney Foundation 2024 Spring Clinical Meetings, held May 14-18, 2024. The company presented three posters providing additional data supporting XPHOZAH. The company also sponsored an Exhibitor Spotlight titled “A New Paradigm: Rethinking Hyperphosphatemia Management,” where David M. Spiegel, MD and Lisa Gutekunst MSEd, RD, CSR, CDN, FNKF, discussed the clinical application of XPHOZAH as add-on therapy for the many dialysis patients on a phosphate binder with serum phosphorus levels above guideline-established targets.

Second Quarter 2024 Financial Results

- Cash Position: As of June 30, 2024, the company had total cash, cash equivalents and short-term investments of

$186.0 million, as compared to total cash, cash equivalents and short-term investments of $184.3 million as of December 31, 2023.

- Revenues: Total revenue for the quarter ended June 30, 2024 was $73.2 million, compared to $22.3 million in total revenue during the quarter ended June 30, 2023, primarily reflecting increased net product sales.
  - IBSRELA U.S. net product sales revenue was $35.4 million, compared to $18.3 million during the same period of 2023.
  - XPHOZAH U.S. net product sales revenue was $37.1 million, with no comparable revenue during the same period of 2023.
  - There was no material product supply revenue during the quarter ended June 30, 2024, compared to $3.3 million during the same period of 2023.
  - Licensing revenue was $19 thousand, compared to $764 thousand during the same period of 2023.
  - Non-cash royalty revenue related to the sale of future royalties was $0.6 million, with no comparable revenue during the same period of 2023.

- R&D Expenses: Research and development expenses were $12.8 million for the quarter ended June 30, 2024, compared to $8.3 million for the quarter ended June 30, 2023.

- SG&A Expenses: Selling, general and administrative expenses were $64.7 million for the quarter ended June 30, 2024, an increase of $37.5 million compared to $27.2 million for the quarter ended June 30, 2023. The increase in selling, general and administrative expenses was primarily due to increased costs associated with the ongoing commercialization of IBSRELA and XPHOZAH.

- Net Loss: Net loss for the quarter ended June 30, 2024 was $16.5 million, or $(0.07) per share, compared to net loss of $17.1 million, or $(0.08) per share, for the quarter ended June 30, 2023. The $16.5 million net loss for the second quarter of 2024 included share-based compensation expense of $10.8 million and non-cash interest expense related to the sale of future royalties of $1.6 million.

Conference Call Details
The company will host a conference call today, August 1, 2024, at 4:30 PM ET to discuss today's announcement. 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 (IBSRELA)

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.

IMPORTANT SAFETY INFORMATION (XPHOZAH)

CONTRAINDICATIONS
XPHOZAH is contraindicated in:

- Pediatric patients under 6 years of age
- Patients with known or suspected mechanical gastrointestinal obstruction

WARNINGS AND PRECAUTIONS
Diarrhea
Patients may experience severe diarrhea. Treatment with XPHOZAH should be discontinued in patients who develop severe diarrhea.

MOST COMMON ADVERSE REACTIONS
Diarrhea, which occurred in 43-53% of patients, was the only adverse reaction reported in at least 5% of XPHOZAH-treated patients with CKD on dialysis across trials. The majority of diarrhea events in the XPHOZAH-treated patients were reported to be mild-to-moderate in severity and resolved over time, or with dose reduction. Diarrhea was typically reported soon after initiation but could occur at any time during treatment with XPHOZAH. Severe diarrhea was reported in 5% of XPHOZAH-treated patients in these trials.

INDICATION
XPHOZAH (tenapanor), 30 mg BID, is indicated to reduce serum phosphorus in adults with chronic kidney disease (CKD) on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy.

For additional safety information, please see full Prescribing Information.

About Ardelyx
Ardelyx was founded with a mission to discover, develop and commercialize innovative, first-in-class medicines that meet significant unmet medical needs. Ardelyx has two commercial products approved in the United States, IBSRELA® (tenapanor) and XPHOZAH® (tenapanor). Ardelyx has agreements for the development and commercialization of tenapanor outside of the U.S. Kyowa Kirin commercializes PHOZEVEL® (tenapanor) for hyperphosphatemia in Japan. A New Drug Application for tenapanor for hyperphosphatemia has been submitted in China with Fosun Pharma. Knight Therapeutics commercializes IBSRELA in Canada. For more information, please visit https://ardelyx.com/ and connect with us on X (formerly known as 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 current expectation regarding opportunities for continued IBSRELA and XPHOZAH adoption; the potential market share for IBSRELA and annual U.S. net product sales revenue prior to patent expiry; projected U.S. net product sales revenue for IBSRELA for full year 2024; the impact of the Transitional Drug Add-on Payment Adjustment (TDAPA) period and the ESRD PPS policy on access to XPHOZAH; and Ardelyx's current belief that not applying for TDAPA may help to protect patient access to XPHOZAH. 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 1, 2024, 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, 2024 (Unaudited)	December 31, 2023 (1)
Assets		
Cash and cash equivalents	$ 41,890	$ 21,470
Investments	144,071	162,829
Accounts receivable	37,241	22,031
Prepaid commercial manufacturing	14,797	18,925
Prepaid commercial manufacturing, non-current	—	4,235
Inventory, current	13,756	12,448
Inventory, non-current	69,676	37,039
Property and equipment, net	1,016	1,009
Right-of-use assets	4,324	5,589
Prepaid and other assets	16,717	12,004
Total assets	$ 343,488	$ 297,579
Liabilities and stockholders' equity		
Accounts payable	$ 10,881	$ 11,138
Accrued compensation and benefits	10,458	12,597
Current portion of operating lease liability	3,550	4,435
Deferred revenue	20,442	15,826
Accrued expenses and other liabilities	26,718	15,041
Operating lease liability, net of current portion	1,096	1,725

Long-term debt	100,249	49,822
Deferred royalty obligation related to the sale of future royalties	23,104	20,179
Stockholders' equity	146,990	166,816
Total liabilities and stockholders' equity	$ 343,488	$ 297,579

(1) Derived from the audited financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2023.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Revenues:				
Product sales, net:				
IBSRELA	$ 35,445	$ 18,309	$ 63,806	$ 29,664
XPHOZAH	37,146	—	52,297	—
Total product sales, net	72,591	18,309	116,103	29,664
Product supply revenue	13	3,260	2,139	3,262
Licensing revenue	19	764	36	776
Non-cash royalty revenue related to the sale of future royalties	599	—	967	—
Total revenues	73,222	22,333	119,245	33,702
Cost of goods sold:				
Cost of product sales	1,405	492	2,418	864
Other cost of revenue	8,031	2,997	14,146	4,162
Total cost of goods sold	9,436	3,489	16,564	5,026
Operating expenses:				
Research and development	12,762	8,282	23,341	17,375
Selling, general and administrative	64,654	27,186	117,648	53,989
Total operating expenses	77,416	35,468	140,989	71,364
Loss from operations	(13,630)	(16,624)	(38,308)	(42,688)
Interest expense	(3,326)	(1,075)	(5,682)	(2,103)
Non-cash interest expense related to the sale of future royalties	(1,576)	(968)	(3,278)	(1,937)
Other income, net	2,145	1,546	4,484	2,848
Loss before provision for income taxes	(16,387)	(17,121)	(42,784)	(43,880)
Provision for income taxes	67	—	188	14
Net loss	$ (16,454)	$ (17,121)	$ (42,972)	$ (43,894)
Net loss per share of common stock - basic and diluted	$ (0.07)	$ (0.08)	$ (0.18)	$ (0.21)
Shares used in computing net loss per share - basic and diluted	234,571,192	214,951,127	233,818,576	211,009,029

Source: Ardelyx, Inc.