Ardelyx Reports First Quarter 2024 Financial Results and Provides Business Update

May 2, 2024

Company reports $45.6 million in Q1 product-related revenue, including $28.4 million in net product sales revenue for IBSRELA and $15.2 million in net product sales revenue for XPHOZAH

Company ends Q1 with approximately $203 million in cash and investments

Conference call scheduled for 4:30 PM Eastern Time

WALTHAM, Mass., May 02, 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 first quarter ended March 31, 2024 and provided a business update.

"The first quarter of 2024 marked an important milestone for Ardelyx as a commercial company. We continued to execute our disruptive approach to commercializing IBSRELA and XPHOZAH by targeting patients in established therapeutic areas who continue to have unmet treatment needs that can be addressed with our first-in-class medicines," said Mike Raab, president and chief executive officer of Ardelyx. "We drove substantial topline growth as a result of the continued commercial performance of IBSRELA and the incredibly strong launch of XPHOZAH. At the same time, we thoughtfully managed our expenses, ending the quarter with a strong cash position, enabling us to invest in expanding our market position."

IBSRELA® (tenapanor) records $28.4 million in net product sales revenue in Q1 2024
U.S. net product sales revenue for IBSRELA during the first quarter of 2024 was $28.4 million, reflecting significant year-over-year growth as well as quarter-over-quarter growth. Demand for IBSRELA continued during the quarter, including new and refill prescription growth along with expansion of new and repeat writing healthcare providers.

Ardelyx currently expects 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 $15.2 million net product sales revenue during Q1 2024
Following approval by the U.S. Food and Drug Administration of XPHOZAH in October 2023, Ardelyx continued to see a strong response from the nephrology community. U.S. net product sales revenue during Q1 2024 was $15.2 million, the first full quarter of sales following the product's launch in November 2023. Spherix Global Insights, a premier market research firm that publishes independent, syndicated monthly tracking research, reports high levels of awareness, intent to adopt and satisfaction with XPHOZAH in the April 2024 LaunchDynamix report. Among the 77 nephrologists surveyed, 98% rate XPHOZAH as an advance over currently available hyperphosphatemia therapies. 56% of surveyed nephrologists report initiating a patient on XPHOZAH, and among those reported users, 98% report satisfaction with treatment.

Other Corporate Developments

- In March, the company announced the appointment of veteran biopharma executive Mike Kelliher as Executive Vice President, Corporate Development and Strategy.

First Quarter 2024 Financial Results

- **Cash Position:** As of March 31, 2024, the company had total cash, cash equivalents and short-term investments of $202.6 million, as compared to total cash, cash equivalents and short-term investments of $184.3 million as of December 31, 2023. During the quarter ended March 31, 2024, the company drew $49.8 million in net proceeds under its term loan with SLR Investment Corp.
- **Revenues:** Total revenue for the quarter ended March 31, 2024 was $46.0 million, compared to $11.4 million in total revenue during the quarter ended March 31, 2023, primarily reflecting increased net product sales and product supply revenue.
    - IBSRELA U.S. net product sales revenue was $28.4 million, compared to $11.4 million during the same period of 2023.
    - XPHOZAH U.S. net product sales revenue was $15.2 million, with no comparable revenue during the same period of 2023.
    - Product supply revenue was $2.1 million, compared to $2 thousand during the same period of 2023.
    - Licensing revenue was $17 thousand, compared to $12 thousand during the same period of 2023.
    - Non-cash royalty revenue related to the sale of future royalties was $0.4 million, with no comparable revenue during the same period of 2023.
- **R&D Expenses**: Research and development expenses were $10.6 million for the quarter ended March 31, 2024, compared to $9.1 million for the quarter ended March 31, 2023.
- **SG&A Expenses:** Selling, general and administrative expenses were $53.0 million for the quarter ended March 31, 2024, an increase of $26.2 million compared to $26.8 million for the quarter ended March 31, 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 March 31, 2024 was $26.5 million, or $(0.11) per share, compared to net loss of $26.8 million, or $(0.13) per share, for the quarter ended March 31, 2023. The net loss for the first quarter of 2024 included share-based compensation expense of $7.6 million and non-cash interest expense related to the sale of future royalties of $1.7 million.

Conference Call Details
The company will host a conference call today, May 2, 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) as well as early-stage pipeline candidates. 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 for U.S. net product sales revenue for IBSRELA for full year 2024. 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission on May 2, 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)

	March 31, 2024 (Unaudited)	December 31, 2023 (1)
Assets		
Cash and cash equivalents	$ 36,147	$ 21,470
Investments	166,431	162,829
Accounts receivable	28,162	22,031
Prepaid commercial manufacturing	5,519	18,925
Prepaid commercial manufacturing, non-current	4,235	4,235
Inventory, current	9,813	12,448
Inventory, non-current	69,045	37,039
Property and equipment, net	1,019	1,009
Right-of-use assets	4,641	5,589
Prepaid and other assets	17,370	12,004
Total assets	$ 342,382	$ 297,579
Liabilities and stockholders' equity		
Accounts payable	$ 17,277	$ 11,138
Accrued compensation and benefits	6,727	12,597
Current portion of operating lease liability	4,314	4,435
Deferred revenue	18,689	15,826
Accrued expenses and other liabilities	21,991	15,041
Operating lease liability, net of current portion	778	1,725
Long-term debt, net of current portion	99,834	49,822
Deferred royalty obligation related to the sale of future royalties	21,881	20,179
Stockholders' equity	150,891	166,816
Total liabilities and stockholders' equity	$ 342,382	$ 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 March 31,	
	2024	2023

Revenues:		
Product sales, net:		
IBSRELA	$ 28,361	$ 11,355
XPHOZAH	15,151	—
Total product sales, net	43,512	11,355
Product supply revenue	2,126	2
Licensing revenue	17	12
Non-cash royalty revenue related to the sale of future royalties	368	—
Total revenues	46,023	11,369
Cost of goods sold:		
Cost of product sales	1,013	372
Other cost of revenue	6,115	1,165
Total cost of goods sold	7,128	1,537
Operating expenses:		
Research and development	10,579	9,093
Selling, general and administrative	52,994	26,803
Total operating expenses	63,573	35,896
Loss from operations	(24,678)	(26,064)
Interest expense	(2,356)	(1,028)
Non-cash interest expense related to the sale of future royalties	(1,702)	(969)
Other income, net	2,339	1,302
Loss before provision for income taxes	(26,397)	(26,759)
Provision for income taxes	121	14
Net loss	$ (26,518)	$ (26,773)
Net loss per share of common stock - basic and diluted	$ (0.11)	$ (0.13)
Shares used in computing net loss per share - basic and diluted	233,065,960	207,023,127

Source: Ardelyx, Inc.