Ardelyx Reports First Quarter 2023 Financial Results and Provides Business Update

May 3, 2023

Continued successful launch of IBSRELA, with Q1 net product sales of $11.4 million

XPHOZAH New Drug Application resubmitted on April 17, 2023

Company ends Q1 with over $130 million in cash and investments

Conference call scheduled for 4:30 PM Eastern Time

WALTHAM, Mass., May 03, 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 first quarter ended March 31, 2023 and provided a business update.

“During the first quarter of 2023, we demonstrated progress towards achieving our goals for 2023. At one-year post-launch, IBSRELA is being recognized as an important medicine for IBS-C and is delivering meaningful benefits to patients. We are consistently gaining market share with our innovative commercial strategy. At the same time, during the first quarter, we continued to advance XPHOZAH to approval and launch and pursued business development opportunities that would bring our novel mechanism technologies to patients and strengthen our cash position,” said Mike Raab, president and chief executive officer of Ardelyx. “As we look towards the remainder of the year, we will continue to focus on achieving our near-term milestones, including driving IBSRELA adoption, preparing to launch XPHOZAH in the second half of this year pending FDA approval, and building on our strategy for the next phase of the company’s growth.”

IBSRELA® (tenapanor) Update: Growth continues with $11.4 million in net product sales in Q1 2023
In March 2023, Ardelyx completed one full year of IBSRELA sales following the U.S. launch in 2022 for the treatment of irritable bowel syndrome with constipation (IBS-C) in adults. IBSRELA continues to gain market share as a result of the company executing on its innovative launch strategy focused on high-writing physicians and the patients who experience persistent symptoms, despite treatment with a prescription therapy for IBS-C. The company continues to see increased new and refill prescriptions as well as persistent growth in new and repeat writing healthcare providers.

XPHOZAH® (tenapanor) Update: New Drug Application (NDA) resubmitted
On April 17, 2023, Ardelyx resubmitted the NDA for XPHOZAH for the control of serum phosphorus in patients with chronic kidney disease (CKD) on dialysis who have had an inadequate response or intolerance to a phosphate binder therapy to the U.S. Food and Drug Administration (FDA). An Acknowledgement of Receipt letter from the FDA, confirming the resubmission is complete, is expected in mid-May. The letter will include the classification of the resubmission and the review goal date. Launch preparation activities are underway to support a second half of 2023 launch, pending FDA approval.

Other Corporate Developments

- In April, the company signed an agreement with METiS Therapeutics, Inc. to license Ardelyx’s portfolio of TGR5 agonist compounds. METiS Therapeutics is a Boston-area company integrating drug discovery and delivery with AI and machine learning. The agreement provides METiS with the exclusive, worldwide rights to develop and commercialize a portfolio of TGR5 agonist compounds that were discovered and developed by Ardelyx for all therapeutic areas. Under the terms of the agreement, Ardelyx received an upfront payment of $750,000 and is eligible to receive additional development and sales milestones of up to $243 million, as well as tiered royalty payments on net sales ranging from the low- to mid-single digits. TGR5, as a metabolic regulator, is involved in energy homeostasis, bile acid homeostasis, glucose metabolism and metabolic regulation.
- Ardelyx presented three posters covering additional positive clinical observations of XPHOZAH at the National Kidney Foundation (NKF) 2023 Spring Clinical Meetings, which took place in Austin, TX from April 11-15, 2023.

First Quarter 2023 Financial Results

- **Cash Position**: As of March 31, 2023, the company had total cash, cash equivalents and short-term investments of $130.4 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 March 31, 2023, the company received gross proceeds of $51.9 million for the sale of 15.5 million shares of the company’s common stock under the company’s sales agreement with Jefferies LLC, dated August 13, 2021, deemed to be “at-the-market offerings.”
- **Product Sales**: Net product sales for IBSRELA were $11.4 million during the quarter ended March 31, 2023, compared to $0.5 million for the quarter ended March 31, 2022, when the first product sales for IBSRELA were recognized.
- **R&D Expenses**: Research and development expenses were $9.1 million for the quarter ended March 31, 2023, compared to $8.9 million for the quarter ended March 31, 2022.
- **SG&A Expenses**: Selling, general and administrative expenses were $26.8 million for the quarter ended March 31, 2023, an increase of $7.5 million compared to $19.3 million for the quarter ended March 31, 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 March 31, 2023 was $26.8 million, or $(0.13) per share, compared to net loss of $28.1 million, or $(0.21) per share, for the quarter ended March 31, 2022. The net loss for the quarter ended March 31, 2023 included share-based compensation expense of $2.9 million, non-cash interest expense related to the sale of future royalties of $1.0 million and a non-cash impairment of a lease right of use asset of $0.4 million.

Conference Call Details
The company will host a conference call today, May 3, 2023, 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

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, which has completed three successful Phase 3 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 expectation for the timing of receipt from FDA of the classification of the NDA for XPHOZAH and the goal review date for the NDA, as well as the current expectation for the timing of the launch of XPHOZAH, if approved, and the potential for Ardelyx to receive regulatory and sales milestone and royalty revenue from it collaboration partner, METiS Therapeutics. 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 May 3, 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)

	March 31, 2023 (Unaudited)	December 31, 2022 (1)
Assets		
Cash and cash equivalents	$ 92,487	$ 96,140
Investments	37,886	27,769
Accounts receivable	12,120	7,733
Prepaid commercial manufacturing	13,835	13,567
Inventory, current	4,823	3,282
Inventory, non-current	40,124	25,064
Property and equipment, net	1,102	1,223
Right-of-use assets	7,972	9,295
Prepaid and other assets	6,670	5,993
Total assets	$ 217,019	$ 190,066
Liabilities and stockholders' equity		
Accounts payable	$ 10,513	$ 10,859
Accrued compensation and benefits	5,074	7,548
Current portion of operating lease liability	3,998	3,894
Current portion of long-term debt	26,880	26,711
Deferred revenue	17,043	13,236
Accrued expenses and other liabilities	11,053	12,380
Operating lease liability, net of current portion	4,814	5,855
Deferred royalty obligation related to the sale of future royalties	12,223	11,254
Stockholders' equity	125,421	98,329
Total liabilities and stockholders' equity	$ 217,019	$ 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.

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

	Three Months Ended March 31,	
	2023	2022
Revenues:		
Product sales, net	$ 11,355	$ 450
Product supply revenue	2	14
Licensing revenue	12	4
Total revenues	11,369	468
Operating expenses:		
Cost of revenue	1,537	85
Research and development	9,093	8,851
Selling, general and administrative	26,803	19,339
Total operating expenses	37,433	28,275
Loss from operations	(26,064)	(27,807)
Interest expense	(1,028)	(746)
Non-cash interest expense related to the sale of future royalties	(969)	—
Other income, net	1,302	484
Loss before provision for income taxes	(26,759)	(28,069)

Provision for income taxes	14	2
Net loss	$ (26,773)	$ (28,071)
Net loss per share of common stock - basic and diluted	$ (0.13)	$ (0.21)
Shares used in computing net loss per share - basic and diluted	207,023,127	130,934,795

Source: Ardelyx, Inc.