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Biotech Execs Face Investor Suit Over Medicare Claims

By **Sydney Price**

Law360 (September 9, 2024, 7:58 PM EDT) -- Executives and directors of biopharmaceutical company Ardelyx have been hit with a shareholder derivative suit in Massachusetts federal court alleging the company misled investors over its intentions and ability to apply for a Medicare reimbursement program for its kidney disease treatment.

According to the complaint filed on Friday by shareholder Ian Mofrad, Ardelyx obtained approval to distribute Xphozah, an oral therapy used to treat adults with chronic kidney disease on dialysis, in October 2023. Mofrad alleges that Ardelyx misled investors about its plan to apply for a program under which the Medicare and Medicaid programs would pay for Xphozah, telling investors that the successful distribution of the drug would depend in part on its inclusion in the program.

Ardelyx announced in July that would not request that the drug be included in the program, causing shares to fall by nearly a third of their value, according to the suit.

In addition to nominal defendant Ardelyx, the suit's individual defendants include Ardelyx CEO Michael Raab, Chief Financial and Operations Officer Justin Renz and several directors.

In addition to its Exchange Act claims, the complaint also accuses Raab and Renz of making approximately $2.5 million in insider sales during the relevant period, which begins Oct. 31, 2023.

On the first day of the relevant period, Ardelyx filed its third-quarter financial results with the U.S. Securities and Exchange Commission. In the filing, Ardelyx stated that the success of Xphozah would rest partially on the Centers for Medicare & Medicaid Services' Transitional Drug Add-on Payment Adjustment. This program was introduced in 2016 to pay for new end-stage renal disease therapies not already accounted for under its other dialysis payment program.

In the filing, and several others throughout the relevant period, Ardelyx indicated that it would apply to include Xphozah in TDAPA, the complaint states. But in reality, the suit alleges, the company had not yet reached a decision on whether to apply, and could not decide until after it first reviewed a rule issued by CMS that was not announced until June 27, 2024.

On July 2, 2024, Ardelyx declared that it had chosen not to apply to include Xphozah in TDAPA due to restrictions set forth by the rule issued by CMS the previous month, according to the complaint. Ardelyx said the rule would effectively eliminate all patient access to the drug, the suit states.

"Our decision not to apply for TDAPA reflects our steadfast commitment to preserving patients' access to our medicines and provides the best optionality for us to continue to explore alternatives to protect all patients," Ardelyx said in its statement that day, according to the complaint.

Following the announcement, shares of Ardelyx fell $2.29 each, or about 30%, to close at $5.28 on July 2, according to the suit.

The complaint also notes that Ardelyx is facing a securities class action over its decision to abstain from applying to include Xphozah in TDAPA.

Counsel for Mofrad and a representative of Ardelyx did not immediately respond to requests for comment on Monday.

Mofrad is represented by Timothy J. MacFall of Rigrodsky Law PA, Joshua H. Grabar of Grabar Law Office and Mitchell J. Matorin of Matorin Law Office LLC.

Counsel information for Ardelyx and the individual defendants was not immediately available on Monday.

The case is Mofrad v. Raab et al., case number 1:24-cv-12302, in the U.S. District Court for the District of Massachusetts.

--Editing by Jay Jackson Jr.
