



Akebia Therapeutics Provides Update on Form 10-Q Filing

August 10, 2023

- Akebia announces late filing of its second quarter earnings and Form 10-Q
- Akebia reaffirms 2023 net product revenue guidance of \$175 - \$180 million
- Akebia believes its cash resources as of June 30, 2023 will be sufficient to fund its current operating plan through at least the next twelve months
- Akebia expects to resubmit NDA for vadadustat as a treatment for anemia due to CKD in adult patients on dialysis in Q3 2023

CAMBRIDGE, Mass., Aug. 10, 2023 /PRNewswire/ -- [Akebia Therapeutics® Inc.](https://www.akebia.com) (Nasdaq: AKBA), a biopharmaceutical company with the purpose to better the lives of people impacted by kidney disease, today announced that it has filed with the U.S. Securities and Exchange Commission (SEC) a Form 12b-25 Notification of Late Filing with regard to its Quarterly Report on Form 10Q for the quarter ended June 30, 2023.

Through the course of preparing its financial statements for the second quarter, Akebia identified certain accounting errors relating to recording and reporting of return reserves for Auryxia® (ferric citrate). Akebia does not currently anticipate that the correction of the accounting errors will impact Akebia's previously issued 2023 Auryxia net product revenue guidance of \$175-180 million. In addition, based on its current operating plan, Akebia believes that its cash resources as of June 30, 2023 and revenues from Auryxia will be sufficient to allow Akebia to fund its current operating plan through at least the next twelve months from the date of this filing.

The delay in filing will not affect Akebia's ability to serve existing or new patients. Akebia continues to expect to resubmit its New Drug Application for vadadustat as a treatment for anemia due to chronic kidney disease in adult patients on dialysis by the end of this quarter.

About Akebia Therapeutics

Akebia Therapeutics, Inc. is a fully integrated biopharmaceutical company with the purpose to better the lives of people impacted by kidney disease. Akebia was founded in 2007 and is headquartered in Cambridge, Massachusetts. For more information, please visit our website at www.akebia.com, which does not form a part of this release.

About Vadadustat

Vadadustat is an oral hypoxia-inducible factor prolyl hydroxylase inhibitor designed to mimic the physiologic effect of altitude on oxygen availability. At higher altitudes, the body responds to lower oxygen availability with stabilization of hypoxia-inducible factor, which can lead to increased red blood cell production and improved oxygen delivery to tissues. Vadadustat is not approved by the U.S. Food and Drug Administration. Vadadustat is approved in Europe for the treatment of symptomatic anemia due to CKD in adult patients on chronic maintenance dialysis. In Japan, vadadustat is approved as a treatment for anemia due to CKD in both dialysis-dependent and non-dialysis dependent adult patients.

IMPORTANT U.S. SAFETY INFORMATION FOR AURYXIA (ferric citrate) CONTRAINDICATION

AURYXIA (ferric citrate) is contraindicated in patients with iron overload syndromes, e.g., hemochromatosis.

WARNINGS AND PRECAUTIONS

- **Iron Overload:** Increases in serum ferritin and transferrin saturation (TSAT) were observed in clinical trials with AURYXIA in patients with chronic kidney disease (CKD) on dialysis treated for hyperphosphatemia, which may lead to excessive elevations in iron stores. Assess iron parameters prior to initiating AURYXIA and monitor while on therapy. Patients receiving concomitant intravenous (IV) iron may require a reduction in dose or discontinuation of IV iron therapy.
- **Risk of Overdosage in Children Due to Accidental Ingestion:** Accidental ingestion and resulting overdose of iron-containing products is a leading cause of fatal poisoning in children under 6 years of age. Advise patients of the risks to children and to keep AURYXIA out of the reach of children.

ADVERSE REACTIONS

Most common adverse reactions with AURYXIA were:

- **Hyperphosphatemia in CKD on Dialysis:** Diarrhea (21%), discolored feces (19%), nausea (11%), constipation (8%), vomiting (7%) and cough (6%).
- **Iron Deficiency Anemia in CKD Not on Dialysis:** Discolored feces (22%), diarrhea (21%), constipation (18%), nausea (10%), abdominal pain (5%) and hyperkalemia (5%).

SPECIFIC POPULATIONS

- **Pregnancy and Lactation:** There are no available data on AURYXIA use in pregnant women to inform a drug-associated risk of major birth defects and miscarriage. However, an overdose of iron in pregnant women may carry a risk for spontaneous abortion, gestational diabetes and fetal malformation. Data from rat studies have shown the transfer of iron into milk, hence, there is a possibility of infant exposure when AURYXIA is administered to a nursing woman.

To report suspected adverse reactions, contact Akebia Therapeutics at 1-844-445-3799.

Please see full [Prescribing Information](#)

Forward-Looking Statements

Statements in this press release regarding Akebia Therapeutics, Inc.'s ("Akebia's") strategy, plans, prospects, expectations, beliefs, intentions and goals are forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, as amended, and include, but are not limited to, statements regarding: Akebia's expectations regarding the timing of filing of its Quarterly Report on Form 10-Q; Akebia's ongoing review of its financial statements; Akebia's expectations and plans with respect to the resubmission of its NDA for vadadustat, including the timing thereof; Akebia's revenue guidance for Auryxia in 2023 and assumptions related thereto; Akebia's expectations about the impacts of the accounting errors and the delay in filing; and Akebia's goals, objectives and expectations with respect to its operating plan, expenses, cash resources and sources of funding for its cash runway, including its belief that its existing cash resources and revenues from Auryxia will be sufficient to fund its current operating plan for at least the next twelve months. The terms "intend," "believe," "plan," "goal," "expect," "potential," "will," "continue," derivatives of these words, and similar references are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results, performance or experience may differ materially from those expressed or implied by any forward-looking statement as a result of various risks, uncertainties and other factors, including, but not limited to, risks associated with: the risk that additional information may arise in the process of completing the review or audit of any revised financial statements that would require Akebia to make additional or different adjustments; the time, effort and expense required to complete any corrections in Akebia's financial statements; the potential demand and market potential and acceptance of, as well as coverage and reimbursement related to, Auryxia, including estimates regarding the potential market opportunity; the competitive landscape for Auryxia, including potential generic entrants; the ability of Akebia to attract and retain qualified personnel; Akebia's ability to implement cost avoidance measures and reduce operating expenses; decisions made by health authorities, such as the FDA, with respect to regulatory filings, including the anticipated resubmission of the New Drug Application for vadadustat; the potential therapeutic benefits, safety profile, and effectiveness of vadadustat; the results of preclinical and clinical research; the direct or indirect impact of the COVID-19 pandemic on regulators and Akebia's business, operations, and the markets and communities in which Akebia and its partners, collaborators, vendors and customers operate; manufacturing, supply chain and quality matters and any recalls, write-downs, impairments or other related consequences or potential consequences; and early termination of any of Akebia's collaborations. Other risks and uncertainties include those identified under the heading "Risk Factors" in Akebia's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, and other filings that Akebia may make with the U.S. Securities and Exchange Commission in the future. These forward-looking statements (except as otherwise noted) speak only as of the date of this press release, and, except as required by law, Akebia does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this press release.

Akebia Therapeutics® and Auryxia® (ferric citrate) are registered trademarks of Akebia Therapeutics, Inc. and its affiliates.

Akebia Therapeutics Contact

Mercedes Carrasco

mcarrasco@akebia.com

 View original content to download multimedia: <https://www.prnewswire.com/news-releases/akebia-therapeutics-provides-update-on-form-10-q-filing-301898359.html>

SOURCE Akebia Therapeutics