# Akebia Therapeutics Reports Fourth Quarter and Full-Year 2021 Financial Results and Recent Business Highlights

March 1, 2022

**- Akebia is launch-ready pending FDA decision for vadadustat on PDUFA date, March 29, 2022**
**- Amended agreement with Vifor Pharma Group strengthens collaboration for a successful commercial launch of vadadustat, if approved**
**- Net Auryxia product revenue of $142.2 million for 2021, an increase of approximately 10% over 2020**

CAMBRIDGE, Mass., March 1, 2022 /PRNewswire/ -- Akebia Therapeutics®, Inc. (Nasdaq: AKBA), a biopharmaceutical company with the purpose to better the lives of people impacted by kidney disease, today reported financial results for the fourth quarter and full-year ended December 31, 2021 and recent business updates related to pre-commercialization activities ahead of a potential first-in-class U.S. launch for vadadustat, Akebia's investigational oral therapeutic for the treatment of anemia due to chronic kidney disease (CKD). Vadadustat is currently under review by the U.S. Food and Drug Administration (FDA) with a scheduled Prescription Drug User Fee Act (PDUFA) date of March 29, 2022.

"The PDUFA date for vadadustat is fast approaching. We recognize how transformational the potential approval would be for Akebia and, true to our purpose as a company, our team continues to work tirelessly to deliver a new oral therapeutic option for the patients we serve," said John P. Butler, Chief Executive Officer of Akebia. "We are prepared for what we believe will be a significant catalyst for the company marked by launching a potential first-in-class oral therapeutic for people living with anemia due to CKD, subject to regulatory approval."

Last month Akebia and Vifor Pharma Group (Vifor Pharma) amended and restated the terms of their license agreement, which provides important access to up to 60% of U.S. dialysis patients through existing Vifor Pharma relationships, supporting a successful commercial launch of vadadustat, if approved. Vifor Pharma completed a $20 million equity investment in Akebia, and will pay Akebia a $25 million upfront payment and contribute an initial $40 million in refundable working capital to partially fund launch supply. The companies also defined profit share economics of potential vadadustat revenue.

"Many of our on-going pre-commercialization activities, including amending the terms of our relationship with Vifor Pharma, are aimed at ensuring patient access for vadadustat," said Dell Faulkingham, Chief Commercial Officer of Akebia. "If approved, we will immediately initiate the process to secure reimbursement for vadadustat under the Transitional Drug Add-on Payment Adjustment (TDAPA) period for dialysis organizations, which we expect will take approximately six months. We believe TDAPA designation for vadadustat will be an important driver for adoption within U.S. dialysis organizations, if approved."

Akebia continues to optimize its sales, marketing, and payor strategies to support Auryxia® (ferric citrate). Akebia ended 2021 with notable Auryxia net product revenue growth and the strongest quarter of net product revenue to date while the phosphate binder market declined by 8.1% year-over-year in the U.S., due in part to the impact of COVID-19 on kidney disease patients. Akebia achieved $142.2 million in net product revenue in 2021 due to improved commercial contracts and payor mix.

"Both the 2021 and our expected 2022 Auryxia revenue growth is due to our team's commitment to patients and healthcare providers, even against the backdrop of the COVID-19 pandemic," added Dell Faulkingham. "Our renal focused field team has proven its ability to successfully engage with the kidney community and thoughtfully outline our value proposition. This expertise establishes a strong foundation from which to launch vadadustat, if approved."

**Fourth Quarter and Full-Year 2021 Financial Results**

**Revenues:** Total revenue was $59.6 million for the fourth quarter of 2021 compared to $56.7 million for the fourth quarter of 2020, and $213.6 million for the full-year 2021 compared to $295.3 million for the full-year 2020.

- Collaboration revenue was $17.5 million for the fourth quarter of 2021 compared to $22.1 million for the fourth quarter of 2020, and $71.4 million for the full-year 2021 compared with $166.4 million for the full-year 2020. The decrease in both periods compared to the same periods in 2020 was primarily due to lower collaboration revenue from Otsuka Pharmaceuticals Co. Ltd (Otsuka) driven by lower development costs incurred subject to cost share provisions under both the Otsuka collaboration agreement for the U.S. and the Otsuka collaboration agreement for certain territories outside the U.S. as Akebia successfully completed the INNO$_2$VATE and PRO$_2$TECT global Phase 3 clinical programs in 2020 and is currently engaged in close-out activities with respect to the programs.
- Net product revenue was $42.1 million for the fourth quarter of 2021 compared with $34.6 million for the fourth quarter of 2020, an increase of approximately 22 percent. Net product revenue was $142.2 million for the full-year 2021 compared to $128.9 million for the full-year 2020, an increase of approximately 10 percent.

**COGS:** Cost of goods sold was $50.4 million for the fourth quarter of 2021 compared to $63.2 million for the fourth quarter of 2020. Cost of goods sold was $153.4 million for the full-year 2021, compared with $295.9 million for the full-year 2020. Cost of goods sold includes a non-cash charge related to excess purchase commitments of $18.0 million and $33.4 million, for the fourth quarter and full year 2021, respectively.

**R&D Expenses:** Research and development expenses were $29.6 million for the fourth quarter of 2021 compared to $37.6 million for the fourth quarter of 2020, and $147.9 million for the full-year 2021 compared to $218.5 million for the full-year 2020. Fourth quarter 2021 expenses included a one-time credit of $8.6 million representing a reimbursement from Vifor Pharma following the sale of the Priority Review Voucher (PRV), which proceeds were subsequently paid to Otsuka as reimbursement for their contribution to purchase the PRV.

**SG&A Expenses:** Selling, general and administrative expenses were $44.8 million for the fourth quarter of 2021 compared to $40.3 million for the fourth quarter of 2020, and $174.2 million for the full-year 2021 compared to $153.9 million for the full-year 2020. The increase for the full year 2021 was primarily due to higher marketing expenses, increased headcount-related costs, and one-time legal costs.

**Net Loss:** Net loss was $70.7 million for the fourth quarter of 2021 compared to $87.0 million for the fourth quarter of 2020, and $282.8 million for the full-year 2021 compared to $383.5 million for the full-year 2020. The decrease in net loss for the full-year 2021 compared to the prior year was due primarily to higher product revenues, lower cost of goods sold and lower operating expenses, partially offset by lower collaboration revenue.

**Cash Position:** Cash and cash equivalents as of December 31, 2021 were $149.8 million. Akebia believes that its cash resources will be sufficient to fund its current operating plan through at least the next twelve months. Akebia's base operating plan assumes a timely regulatory approval of vadadustat for the treatment of anemia due to CKD in dialysis dependent patients, as well as milestones and product revenues as an important source of funding of our cash runway.

**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 a potential first-in-class 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. The New Drug Application (NDA) and Marketing Authorization Application (MAA) for vadadustat for the treatment of anemia due to chronic kidney disease (CKD) are under review by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), respectively. Vadadustat is an investigational new drug and is not approved by the FDA or any regulatory authority with the exception of Japan's Ministry of Health, Labour and Welfare. In Japan, vadadustat is approved as a treatment for anemia due to CKD in both dialysis-dependent and non-dialysis dependent adult patients.

**About Anemia due to Chronic Kidney Disease (CKD)**
Anemia is a condition in which a person lacks enough healthy red blood cells to carry adequate oxygen to the body's tissues. It commonly occurs in people with CKD because their kidneys do not produce enough erythropoietin (EPO), a hormone that helps regulate production of red blood cells. Anemia due to CKD can have a profound impact on a person's quality of life as it can cause fatigue, dizziness, shortness of breath and cognitive dysfunction. Left untreated, anemia leads to deterioration in health and is associated with increased morbidity and mortality in people with CKD.

**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'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, including, but not limited to, statements regarding: the anticipated scheduled PDUFA date for vadadustat and the potential for vadadustat to be a significant catalyst and transformational for Akebia; Akebia's expectations regarding net product revenue growth for Auryxia in 2022; the potential for vadadustat's approval by the FDA; vadadustat's potential as a first-in-class oral therapeutic for the treatment of anemia due to CKD; vadadustat's potential first-in-class commercial launch in the U.S., the timing thereof, and Akebia's preparation and readiness related thereto; the ability of Akebia's pre-commercialization activities to ensure patient access for vadadustat; the market opportunity for vadadustat; Akebia's plans to secure reimbursement for vadadustat under TDAPA, the timing related thereto and the importance of such reimbursement with respect to adoption of vadadustat in U.S. dialysis organizations, if approved; COVID-19's impact on the overall phosphate binder market and the impact that may have on Akebia's revenues; and Akebia's expectations with respect to its base operating plan, cash resources and sources of funding for Akebia's cash runway.

The terms "believe," "expect," "anticipate," "potential," "continue," "will," and similar references are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement, including, but not limited to: the timing of any regulatory approvals; interactions with the FDA, including reviews and inspections, the timing related thereto and the outcome thereof; the potential therapeutic benefits, safety profile and effectiveness of Akebia's product and product candidates, including vadadustat; the direct or indirect impact of the COVID-19 pandemic on Akebia's business, operations, and the markets and communities in which Akebia and its partners, collaborators, vendors and customers operate; the timing and content of advice given and decisions made by health authorities, including approval and labeling decisions; the potential indications, demand and market potential and acceptance of, as well as coverage and reimbursement related to, Auryxia and vadadustat, if approved, including estimates regarding the potential market opportunity for Auryxia, vadadustat or any other product candidates, and the size of eligible patient populations; enrollment in clinical studies; manufacturing, supply and quality risks, and any recalls, write-downs, impairments or other related consequences or potential consequences; risks associated with hiring, training, management and retention and key personnel changes and transitional periods; the actual funding required to continue to commercialize Auryxia, to develop and commercialize vadadustat or any other product candidates, and to operate Akebia; the risks associated with potential generic entrants for Auryxia, vadadustat, if approved, or any other product candidate; early termination of or changes to the terms of agreements that Akebia has with any of its collaborators; Akebia's and its collaborators' ability to satisfy their obligations under Akebia's collaboration agreements, including the license agreement with Vifor Pharma; the competitive landscape for Auryxia, vadadustat, if approved, and any other product candidates; the scope, timing, and outcome of any legal, regulatory and administrative proceedings; changes in the economic and financial conditions of the businesses of Akebia and its collaboration partners and vendors; expected reliance on third parties, including with respect to the development, manufacturing, supply or commercialization of Akebia's product and product candidates; Akebia's expectations, projections and estimates regarding its capital requirements, going concern and material weaknesses; and Akebia's intellectual property position, including its ability to obtain, maintain and enforce patent and other intellectual property protection for its product and product candidates. 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 September 30, 2021 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 IR Contact**
ir@akebia.com

**Akebia Therapeutics Media Contact**
Mercedes Carrasco
mcarrasco@akebia.com

**AKEBIA THERAPEUTICS, INC.**
**Consolidated Statements of Operations**
**(in thousands, except share and per share data)**
**(unaudited)**

| | Three Months Ended | | Twelve Months Ended | |
|---|---|---|---|---|
| | December 31, 2021 | December 31, 2020 | December 31, 2021 | December 31, 2020 |
| Revenues: | | | | |
| Product revenue, net | $ 42,096 | $ 34,604 | $ 142,216 | $ 128,901 |
| License, collaboration and other revenue | 17,509 | 22,095 | 71,362 | 166,406 |
| Total revenues | 59,605 | 56,699 | 213,578 | 295,307 |
| Cost of goods sold: | | | | |
| Product | 41,340 | 56,026 | 117,352 | 148,866 |
| Amortization of intangibles | 9,010 | 7,208 | 36,042 | 31,515 |
| Impairment of intangible asset | — | — | — | 115,527 |
| Total cost of goods sold | 50,350 | 63,234 | 153,394 | 295,908 |
| Operating expenses: | | | | |
| Research and development | 29,556 | 37,578 | 147,852 | 218,485 |
| Selling, general and administrative | 44,825 | 40,311 | 174,161 | 153,947 |
| License expense | 1,029 | 979 | 3,489 | 3,409 |

| | | | | |
|---|---|---|---|---|
| Total operating expenses | 75,410 | 78,868 | 325,502 | 375,841 |
| Operating loss | (66,155) | (85,403) | (265,318) | (376,442) |
| Other income (expense), net | (4,523) | (1,597) | (17,522) | (7,015) |
| Net loss before income taxes | (70,678) | (87,000) | (282,840) | (383,457) |
| Benefit from income taxes | — | — | — | — |
| Net loss | $ (70,678) | $ (87,000) | $ (282,840) | $ (383,457) |
| Net loss per share - basic and diluted | $ (0.40) | $ (0.60) | $ (1.70) | $ (2.77) |
| Weighted-average number of common shares - basic and diluted | 175,605,992 | 145,111,415 | 165,949,695 | 138,463,152 |

**AKEBIA THERAPEUTICS, INC.**
**Selected Balance Sheet Data**
**(in thousands)**
**(unaudited)**

| | December 31, 2021 | December 31, 2020 |
|---|---|---|
| Cash, cash equivalents and available for sale securities | $149,800 | $268,690 |
| Working capital | 15,517 | 184,291 |
| Total assets | 525,550 | 644,139 |
| Total stockholders' equity | 76,456 | 247,618 |

View original content to download multimedia:https://www.prnewswire.com/news-releases/akebia-therapeutics-reports-fourth-quarter-and-full-year-2021-financial-results-and-recent-business-highlights-301493282.html

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