UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(D)
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): **November 28, 2025**

AKEBIA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-36352**	**20-8756903**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

245 First Street Cambridge, Massachusetts	**02142**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 871-2098

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.00001 per share	**AKBA**	**The Nasdaq Capital Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 1.01. Entry into a Material Definitive Agreement.

On November 28, 2025 (the "Closing Date"), Akebia Therapeutics, Inc. (the "Company") entered into an Asset Purchase Agreement (the "Agreement") with Q32 Bio Inc. and Q32 Bio Operations Inc. (together, "Q32"), pursuant to which Q32 sold and assigned to the Company, and the Company purchased and assumed from Q32, substantially all assets and liabilities of Q32 and its affiliates related to the research, development, manufacture, and commercialization of Q32's clinical-stage development candidate known as ADX-097 worldwide for the treatment, prevention or diagnosis of any disease or condition in humans. ADX-097, which has been evaluated in a Phase 1 clinical trial in healthy volunteers, is a tissue-targeted C3d-Factor H fusion protein complement inhibitor with the potential to treat rare kidney diseases.

Under the terms of the Agreement, the Company (i) made an upfront payment in an amount equal to $7.0 million on the Closing Date, (ii) will make an additional upfront payment in an amount equal to $3.0 million on the sixth-month anniversary of the Closing Date, (iii) will make certain milestone payments upon the achievement of specified development and regulatory milestone events related to the ADX-097 up to an aggregate amount equal to $94.5 million, including a $2.0 million development milestone payment upon the earlier of initiation of a Phase 2 clinical trial and December 31, 2026, (iv) will make certain milestone payments upon the achievement of specified commercial milestone events with respect to the net sales of ADX-097 up to an aggregate amount equal to $487.5 million, and (v) will make certain royalty payments based on the net sales of ADX-097 with royalty percentage tiers ranging from the low single digits to mid-teen percentages. The royalties will expire on a country-by-country basis on the later to occur of (a) the date of expiration of the last-to-expire valid claim of any transferred patent right that covers such product in such country, and (b) the tenth anniversary of the first commercial sale of such product.

The Agreement includes customary representations, warranties, conditions, covenants, and indemnification rights and obligations of the Company and Q32.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by reference to the Agreement, a copy of which the Company expects to file as an exhibit to its Annual Report on Form 10-K for the year ended December 31, 2025.

Item 7.01. Regulation FD Disclosure.

On December 1, 2025, the Company issued a press release announcing the acquisition of a clinical-stage development candidate and the establishment of its rare kidney disease pipeline comprised of two core product candidates: ADX-097 (now referred to as AKB-097), a complement inhibitor, and praliciguat, a soluble guanylate cyclase stimulator. A copy of the Company's press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

In addition, pursuant to the terms of Amendment #1 to the License Agreement, dated June 3, 2021, by and between the Company and Cyclerion Therapeutics, Inc., a Massachusetts corporation ("Cyclerion"), upon initiation (defined as first patient dosed) of a Phase 2 clinical trial in the U.S. for a product, a $1.0 million regulatory milestone payment will be due to Cyclerion.

The information in Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

The Company currently expects that its existing cash resources and cash from operations will be sufficient to fund its current operating plan for at least 2 years. There can be no assurance that the current operating plan will be achieved in the time frame anticipated by the Company, or that the Company's cash resources will fund its operating plan for the period of time anticipated by it, or that additional funding will be available on terms acceptable to the Company, or at all. The Company's forecast of the period of time through which its financial resources will be adequate to support its operations is a forward-looking statement and involves numerous risks and uncertainties, and actual results could vary as a result of a number of factors, many of which are outside its control. The Company has based this estimate on assumptions that may be substantially different than actual results, and the Company could utilize its available capital resources sooner than it currently expects. The Company does not plan to comment on profitability expectations at this time.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated December 1, 2025, issued by Akebia Therapeutics, Inc.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Cautionary Note Regarding Forward-Looking Statements

This Current Report on Form 8-K (the "Report") contains forward-looking statements of the Company that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Report are forward-looking statements. The words "anticipate," "believe," "build," "can," "contemplate," "continue," "could," "should," "designed," "estimate," "project," "expect," "forecast," "future," "goal," "intend," "likely," "may," "plan," "possible," "potential," "predict," "strategy," "seek," "target," "will," "would," derivatives of these words, and similar references are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among others, statements relating to the Company's expectations that its existing cash resources and cash from operations will be sufficient to fund its current operating plan for at least two years. Actual results may differ materially from those projected or implied in these forward-looking statements. You should not place undue reliance on these forward-looking statements. Certain risks and uncertainties relating to the Company and its business can be found under the caption "Risk Factors" included in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2025, and other filings that the Company may make with the U.S. Securities and Exchange Commission in the future. Any forward-looking statements contained in this Report (except as otherwise noted) speak only as of the date hereof, and, except as required by law, the Company does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this Report.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AKEBIA THERAPEUTICS, INC.

Date: December 1, 2025

By: /s/ John P. Butler

Name: John P. Butler

Title: President and Chief Executive Officer

Exhibit 99.1

Akebia Announces Establishment of Rare Kidney Disease Pipeline

Acquires next generation tissue-targeted C3d-Factor H fusion protein complement inhibitor from Q32 Bio

Phase 2 basket trial planned to evaluate complement inhibitor in multiple rare kidney disease indications

Phase 2 trial of Praliciguat, an sGC stimulator, initiated in focal segmental glomerulosclerosis (FSGS)

Both trials planned to start treating subjects in 2026

CAMBRIDGE, Mass., December 1, 2025 — Akebia Therapeutics, Inc. (Nasdaq: AKBA), a biopharmaceutical company with the purpose to better the lives of people impacted by kidney disease, today announced the establishment of its rare kidney disease pipeline. The pipeline is comprised of two core product candidates: ADX-097, a potential next generation complement inhibitor (now referred to as AKB-097) and praliciguat, a soluble guanylate cyclase (sGC) stimulator. Akebia acquired all rights to AKB-097, a tissue-targeted C3d-Factor H fusion protein complement inhibitor, from Q32 Bio Inc. (Nasdaq: QTTB) and believes AKB-097 has applicability across a wide range of complement-mediated rare kidney diseases. AKB-097 is targeted to the sites of complement activation in tissues and is not expected to result in systemic complement inhibition seen with other inhibitors. Separately, Akebia is evaluating praliciguat initially in a clinical trial in the treatment of FSGS, a rare kidney disease, and also plans to assess its use in other rare podocytopathies.

“Our commitment to patients with kidney disease is supported by two pillars of our corporate strategy: first, to drive Vafseo to become standard of care in anemia due to CKD in dialysis, and second, to build and progress our kidney disease pipeline,” said John P. Butler, Chief Executive Officer of Akebia. “While our commercial and medical teams continue to build on the momentum of our Vafseo launch, we are excited to take an important step forward as a company with the establishment of our rare kidney disease development pipeline. We believe our differentiated complement inhibitor program can play a key role in addressing numerous rare kidney diseases, as can praliciguat, which we intend to initially study in FSGS. We look forward to enrolling patients in Phase 2 trials with each product candidate next year and expect to begin generating clinical data from an AKB-097 Phase 2 basket trial beginning in 2027.”

About Complement Inhibition and AKB-097

The body’s complement system, a series of proteins that work together as part of the immune system, can become dysregulated resulting in numerous inflammatory and autoimmune conditions, including multiple diseases of the kidney. Complement inhibitors work by binding to and preventing the activation of specific complement proteins, halting the cascade of inflammatory responses and reducing the destruction of cells.

AKB-097 is a humanized anti-C3d monoclonal antibody (mAb) fusion protein designed to act as a complement inhibitor through a tissue-targeted mechanism. AKB-097 has the potential to drive improved clinical activity by achieving therapeutic levels of inhibition and to address the limitations of the currently available systemic approaches to complement inhibition, including infection risk and the need for high drug doses and frequent administration.

In preclinical studies conducted by Q32 Bio, AKB-097 distributed to affected tissues/organs and demonstrated durable tissue pharmacokinetic (PK) and pharmacodynamic (PD) properties. AKB-097 was shown to be well-tolerated and demonstrated minimal anti-drug antibodies in a completed Phase 1 clinical trial in healthy volunteers. Akebia is planning to initiate an open label Phase 2 basket study in the second half of 2026 with initial data generation expected in 2027.

Financial Terms of Asset Purchase Agreement

On November 28, 2025, Akebia and Q32 Bio signed an Asset Purchase Agreement (APA) under which Akebia acquired global rights to Q32 Bio's ADX-097 (now referred to as AKB-097). In consideration, Akebia paid Q32 Bio an upfront payment of $7.0 million. Akebia will also make a $3.0 million payment upon the six-month anniversary of the closing, as well as additional development and regulatory milestones, commercial milestones and tiered royalties on annual net sales of AKB-097.

About Praliciguat and Planned Phase 2 Trial in FSGS

Praliciguat, is an oral soluble guanylate cyclase (sGC) licensed by Akebia from Cyclerion Therapeutics, Inc. in June 2021. No significant safety issues were observed with praliciguat in Phase 1 studies in healthy volunteers and Phase 2 studies in heart failure and diabetic kidney disease. Praliciguat adverse events were infrequent and consistent with its known blood pressure lowering effect.

Akebia filed its Investigational New Drug Application with the U.S. Food and Drug Administration (FDA) and recently initiated a Phase 2 clinical trial in FSGS. The Phase 2 clinical trial is expected to enroll up to 60 patients at U.S. sites. The primary efficacy endpoint is change in urine protein-to-creatinine ratio between baseline and Week 24.

FSGS is a chronic disease characterized by scarring in some parts of the kidney's filtering units known as glomeruli. Left untreated, FSGS can cause various symptoms including high cholesterol, high blood pressure and kidney failure. FSGS is heterogenous with a wide range of causes and symptoms among those impacted and has been diagnosed in approximately 40,000 people in the U.S. No treatments specifically indicated for FSGS are currently on the market and most patients are treated with antihypertensives and non-specific immunosuppressive therapies.

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 Vafseo® (vadadustat) tablets
Vafseo® (vadadustat) tablets is a once-daily oral hypoxia-inducible factor prolyl hydroxylase inhibitor that activates the physiologic response to hypoxia to stimulate endogenous production of erythropoietin, increasing hemoglobin and red blood cell production to manage anemia. Vafseo is approved for use in 37 countries.

INDICATION

VAFSEO is indicated for the treatment of anemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least three months.

Limitations of Use
- VAFSEO has not been shown to improve quality of life, fatigue, or patient well-being.
- VAFSEO is not indicated for use:
  - As a substitute for red blood cell transfusions in patients who require immediate correction of anemia.
  - In patients with anemia due to CKD not on dialysis.

IMPORTANT SAFETY INFORMATION about VAFSEO (vadadustat) tablets

WARNING: INCREASED RISK OF DEATH, MYOCARDIAL INFARCTION, STROKE, VENOUS THROMBOEMBOLISM, and THROMBOSIS OF VASCULAR ACCESS.

VAFSEO increases the risk of thrombotic vascular events, including major adverse cardiovascular events (MACE).

Targeting a hemoglobin level greater than 11 g/dL is expected to further increase the risk of death and arterial and venous thrombotic events, as occurs with erythropoietin stimulating agents (ESAs), which also increase erythropoietin levels.

No trial has identified a hemoglobin target level, dose of VAFSEO, or dosing strategy that does not increase these risks.

Use the lowest dose of VAFSEO sufficient to reduce the need for red blood cell transfusions.

CONTRAINDICATIONS
- Known hypersensitivity to VAFSEO or any of its components
- Uncontrolled hypertension

WARNINGS AND PRECAUTIONS

- **Increased Risk of Death, Myocardial Infarction (MI), Stroke, Venous Thromboembolism, and Thrombosis of Vascular Access**
  A rise in hemoglobin (Hb) levels greater than 1 g/dL over 2 weeks can increase these risks. Avoid in patients with a history of MI, cerebrovascular event, or acute coronary syndrome within the 3 months prior to starting VAFSEO. Targeting a Hb level of greater than 11 g/dL is expected to further increase the risk of death and arterial and venous thrombotic events. Use the lowest effective dose to reduce the need for red blood cell (RBC) transfusions. Adhere to dosing and Hb monitoring recommendations to avoid excessive erythropoiesis.

- **Hepatotoxicity**
  Hepatocellular injury attributed to VAFSEO was reported in less than 1% of patients, including one severe case with jaundice. Elevated serum ALT, AST, and bilirubin levels were observed in 1.8%, 1.8%, and 0.3% of CKD patients treated with VAFSEO, respectively. Measure ALT, AST, and bilirubin before treatment and monthly for the first 6 months, then as clinically indicated. Discontinue VAFSEO if ALT or AST is persistently elevated or accompanied by elevated bilirubin. Not recommended in patients with cirrhosis or active, acute liver disease.

- **Hypertension**
  Worsening of hypertension was reported in 14% of VAFSEO and 17% of darbepoetin alfa patients. Serious worsening of hypertension was reported in 2.7% of VAFSEO and 3% of darbepoetin alfa patients. Cases of hypertensive crisis, including hypertensive encephalopathy and seizures, have also been reported in patients receiving VAFSEO. Monitor blood pressure. Adjust anti-hypertensive therapy as needed.

- **Seizures**
  Seizures occurred in 1.6% of VAFSEO and 1.6% of darbepoetin alfa patients. Monitor for new-onset seizures, premonitory symptoms, or change in seizure frequency.

- **Gastrointestinal (GI) Erosion**
  Gastric or esophageal erosions occurred in 6.4% of VAFSEO and 5.3% of darbepoetin alfa patients. Serious GI erosions, including GI bleeding and the need for RBC transfusions, were reported in 3.4% of VAFSEO and 3.3% of darbepoetin alfa patients. Consider this risk in patients at increased risk of GI erosion. Advise patients about signs of erosions and GI bleeding and urge them to seek prompt medical care if present.

- **Serious Adverse Reactions in Patients with Anemia Due to CKD and Not on Dialysis**
  The safety of VAFSEO has not been established for the treatment of anemia due to CKD in adults not on dialysis and its use is not recommended in this setting. In large clinical trials in adults with anemia of CKD who were not on dialysis, an increased risk of mortality, stroke, MI, serious acute kidney injury, serious hepatic injury, and serious GI erosions was observed in patients treated with VAFSEO compared to darbepoetin alfa.

- **Malignancy**
  VAFSEO has not been studied and is not recommended in patients with active malignancies. Malignancies were observed in 2.2% of VAFSEO and 3.0% of darbepoetin alfa patients. No evidence of increased carcinogenicity was observed in animal studies.

ADVERSE REACTIONS

- The most common adverse reactions (occurring at ≥ 10%) were hypertension and diarrhea.

DRUG INTERACTIONS

- **Iron supplements and iron-containing phosphate binders:** Administer VAFSEO at least 1 hour before products containing iron.
- **Non-iron-containing phosphate binders**: Administer VAFSEO at least 1 hour before or 2 hours after non-iron-containing phosphate binders.
- **BCRP substrates**: Monitor for signs of substrate adverse reactions and consider dose reduction.
- **Statins**: Monitor for statin-related adverse reactions. Limit the daily dose of simvastatin to 20 mg and rosuvastatin to 5 mg.

USE IN SPECIFIC POPULATIONS

- Pregnancy: May cause fetal harm.
- Lactation: Breastfeeding not recommended until two days after the final dose.
- Hepatic Impairment**:** Not recommended in patients with cirrhosis or active, acute liver disease.

Please note that this information is not comprehensive. Please click here for the Full Prescribing Information, including BOXED WARNING and Medication Guide.

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 plans and expectations with respect to the establishment of its rare kidney disease development pipeline, including AKB-097 and praliciguat; Akebia’s beliefs that AKB-097 has applicability across a wide range of complement-mediated rare kidney diseases; Akebia’s beliefs and expectations that AKB-097 is targeted to the sites of complement activation in tissues and is not expected to result in systemic complement inhibition seen with other inhibitors; Akebia’s plans with respect to praliciguat, including its use in a clinical trial in the treatment of FSGS and the expected timing of enrollment and number of patients therein, its potential use in other rare podocytopathies and the potential market size for FSGS; Akebia’s plans and expectations about its corporate strategy, including to drive Vafseo to become the standard of care in anemia due to CKD in

dialysis, and to build and progress its kidney disease pipeline; Akebia's plans to continue to build on the momentum of its Vafseo launch; Akebia's beliefs that AKB-097's differentiated complement inhibitor program can play a key role in addressing numerous rare kidney diseases, as can praliciguat; and Akebia's plans and expectations with respect to the initiation of a Phase 2 basket trial to evaluate AKB-097 in multiple rare kidney disease indications, including the timing of patient enrollment and initial data generation.

The terms "intend," "believe," "plan," "goal," "potential," "anticipate, "estimate," "expect," "future," "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 potential therapeutic benefits, safety profile, and effectiveness of Vafseo and Akebia's development candidates; the results of preclinical and clinical research; Akebia's ability to enroll patients in its clinical trials; decisions made by health authorities, such as the FDA, with respect to regulatory filings and other interactions; the potential demand and market potential and acceptance of, as well as coverage and reimbursement related to, Vafseo, including estimates regarding the potential market opportunity; the competitive landscape for Vafseo, including generic entrants and the timing thereof; the ability of Akebia to attract and retain qualified personnel; Akebia's ability to achieve and maintain profitability and to maintain operating expenses consistent with its operating plan; manufacturing, supply chain and quality matters and any recalls, write-downs, impairments or other related consequences or potential consequences; early termination of any of Akebia's collaborations; and changes in the geopolitical environment and uncertainty surrounding U.S. trade policy on tariffs. 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, 2025, 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 Contact
Mercedes Carrasco
mcarrasco@akebia.com