

**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 21, 2024

**Korro Bio, Inc.**

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of  
incorporation)

60 First Street, 2<sup>nd</sup> floor, Suite 250

Cambridge, MA

(Address of principal executive offices)

001-39062

(Commission  
File Number)

47-2324450

(IRS Employer  
Identification No.)

02141

(Zip Code)

Registrant's telephone number, including area code: (617) 468-1999

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 \$0.001 per share	KRRO	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 8.01. Other Events.**

On November 21, 2024, Korro Bio, Inc. issued a press release announcing that it has received approval from the Australian Bellberry Human Research Ethics Committee and Clinical Trial Notification clearance from the Australian Therapeutic Goods Administration to initiate a first-in-human Phase 1/2a clinical study of KRRO-110 for Alpha-1 Antitrypsin Deficiency. A copy of the press release is filed as Exhibit 99.1 to this current report on Form 8-K and is incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

<b>Exhibit No.</b>	<b>Description</b>
99.1	<a href="#">Press release of Korro Bio, Inc., dated November 21, 2024</a>
104	Cover Page Interactive Data File (Embedded within the Inline XBRL Document)

**SIGNATURES**

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.

**KORRO BIO, INC.**

Date: November 21, 2024

By: /s/ Ram Aiyar

Name: Ram Aiyar

Title: President and Chief Executive Officer

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## **Korro Receives Australian HREC Approval and CTN Clearance to Initiate Phase 1/2a Clinical Study (REWRITE) of KRRO-110 for Alpha-1 Antitrypsin Deficiency**

- *REWRITE study will evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of single and multiple escalating doses of KRRO-110*
- *First participant dosing anticipated in the first quarter of 2025*
- *Interim readout expected in second half of 2025 and completion of Phase 1/2a study anticipated in 2026*

CAMBRIDGE, Mass., November 21, 2024 — Korro Bio, Inc. (Korro) (Nasdaq: KRRO), a biopharmaceutical company focused on developing a new class of genetic medicines based on editing RNA for both rare and highly prevalent diseases, today announced that it has received approval from the Australian Bellberry Human Research Ethics Committee (HREC) and clearance from the Australian Therapeutic Goods Administration (TGA) to initiate a Phase 1/2a clinical study of KRRO-110 for Alpha-1 Antitrypsin Deficiency (AATD).

“We are thrilled to receive approval to proceed with our clinical study in Australia,” said Kemi Olugemo, MD, Chief Medical Officer at Korro. “Multiple dose treatment with KRRO-110 in a human transgenic mouse model of PiZZ genotype achieved greater than 60% editing and resulted in secretion of functional M-AAT at therapeutically relevant levels. This approval allows us to demonstrate the potential of KRRO-110 in patients with the PiZZ genotype who remain at risk for serious lung and liver complications despite receiving standard-of-care treatment.”

### **About REWRITE**

REWRITE is a two-part single and multiple dose-escalating study that will evaluate the safety and tolerability of KRRO-110 in up to 64 participants, including healthy adults and clinically stable AATD patients with the PiZZ genotype. Secondary and exploratory endpoints include pharmacokinetic and pharmacodynamic parameters that will guide optimal dose selection for later stage studies.

Korro expects to dose the first participant in the first quarter of 2025, and completion of the study is expected in 2026. An interim readout in PiZZ participants is anticipated in the second half of 2025.

For additional information about the REWRITE study, visit [ClinicalTrials.gov \(NCT06677307\)](https://ClinicalTrials.gov/NCT06677307).

### **About Alpha-1 Antitrypsin Deficiency (AATD) and KRRO-110**

AATD is a genetic disorder most commonly caused by a single missense mutation (G-to-A) in the SERPINA1 gene. Affected adult individuals experience pulmonary emphysema and/or hepatic cirrhosis, as well as end organ manifestations. KRRO-110 is the first RNA editing oligonucleotide product candidate from Korro’s proprietary RNA editing platform, Oligonucleotide Promoted Editing of RNA (OPERA™). KRRO-110 is designed to co-opt an endogenous enzyme, Adenosine Deaminase Acting on RNA (ADAR), to edit the “A” variant on SERPINA1 RNA, repair an amino acid codon, and restore secretion of normal AAT protein. This repair of the endogenous protein has the potential to clear protein aggregates from within liver cells to create a potentially clinically differentiated benefit for liver function and to preserve lung function by providing an adequate amount of normal AAT protein.

## **About Korro**

Korro is a biopharmaceutical company focused on developing a new class of genetic medicines for both rare and highly prevalent diseases using its proprietary RNA editing platform. Korro is generating a portfolio of differentiated programs that are designed to harness the body's natural RNA editing process to affect a precise yet transient single base edit. By editing RNA instead of DNA, Korro is expanding the reach of genetic medicines by delivering additional precision and tunability, which has the potential for increased specificity and improved long-term tolerability. Using an oligonucleotide-based approach, Korro expects to bring its medicines to patients by leveraging its proprietary platform with precedented delivery modalities, manufacturing know-how, and established regulatory pathways of approved oligonucleotide drugs. Korro is based in Cambridge, Massachusetts. For more information, visit [korrobio.com](http://korrobio.com).

## **Forward-Looking Statements**

Certain statements in this press release may constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements include, but are not limited to, express or implied statements regarding expectations, hopes, beliefs, intentions or strategies of Korro regarding the future including, without limitation, express or implied statements regarding: REWRITE study's ability to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of single and multiple escalating doses of KRRO-110; the clinical advancement of KRRO-110; the timing of Korro dosing the first participant, interim data readout and completion of the Phase 1/2 clinical study of KRRO-110 for AATD, including Korro's ability to complete the REWRITE study; the potential of KRRO-110 to help patients with the PiZZ genotype who remain at risk for serious lung and liver complications despite receiving standard-of-care treatment; among others. In addition, any statements that refer to projections, forecasts, or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "possible," "potential," "predict," "project," "should," "strive," "would," "aim," "target," "commit," and similar expressions may identify forward-looking statements, but the absence of these words does not mean that statement is not forward looking. Forward-looking statements are based on current expectations and assumptions that, while considered reasonable are inherently uncertain. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. Factors that may cause actual results to differ materially from current expectations include, but are not limited to, various factors beyond management's control including risks of conducting a first-in-human clinical study; challenges with addressing any regulatory concerns necessary to proceed with enrollment and dosing; risks associated with enrolling sufficient participants and other risks inherent in biopharmaceutical development; risks associated with conducting pre-clinical studies and clinical studies and risks of replicating results from pre-clinical studies in clinical studies; and other risks associated with obtaining regulatory approvals and protecting intellectual property; as well as risks associated with general economic conditions; and other risks and uncertainties indicated from time to time in Korro's filings with the SEC, including Part II Item 1A. "Risk Factors" in Korro's most recent Quarterly Report on Form 10-Q filed with the SEC, as such may be amended or supplemented by its other filings with the SEC. Nothing in this press release should be regarded as a representation by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved. You should not place undue reliance on forward-looking statements in this press release, which speak only as of the date they are made and are qualified in their entirety by reference to the cautionary statements herein. Except as required by law, Korro does not undertake or accept any duty to release publicly any updates or revisions to any forward-looking statements to reflect any change in its expectations or in the events, conditions or circumstances on which

any such statement is based. This press release does not purport to summarize all of the conditions, risks and other attributes of an investment in Korro.

**Korro Bio Contact Information**

Investor & Media Contact

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