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 4, 2024

Korro Bio, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-39062**	**47-2324450**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
60 First Street, 2nd floor, Suite 250 Cambridge, MA		**02141**
(Address of principal executive offices)		**(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 4, 2024, Korro Bio, Inc. issued a press release announcing its first regulatory filing for KRRO-110. 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.

Exhibit No.	Description
99.1	Press release of Korro Bio, Inc., dated November 4, 2024
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 4, 2024

By: /s/ Ram Aiyar

Name: Ram Aiyar

Title: President and Chief Executive Officer

Exhibit 99.1

Korro Announces Regulatory Filing for Initiation of KRRO-110 First-In-Human Study and Formation of Clinical Advisory Board

- *Regulatory filing of Phase 1/2 clinical study for Alpha-1 Antitrypsin Deficiency (AATD) submitted to Australian Bellberry Human Research Ethics Committee (HREC)*
- *Clinical Advisory Board of lung and liver experts formed to support development of KRRO-110*
- *First participant dosing anticipated in first quarter of 2025*
- *Interim readout expected in second half of 2025 and completion of Phase 1/2 study anticipated in 2026*

CAMBRIDGE, Mass., Nov. 4, 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 a submission to the Bellberry HREC for a Phase 1/2 clinical study of KRRO-110 for AATD. A clinical advisory board (CAB) comprised of distinguished lung and liver researchers and experts in AATD has also been assembled to help guide the clinical development strategy for KRRO-110.

"This regulatory filing reflects Korro's transition to a clinical-stage company, and another important milestone in the development of KRRO-110," said Kemi Olugemo, MD, Chief Medical Officer at Korro. "There remains significant unmet medical need for people living with AATD, and based on our preclinical data, KRRO-110 has the potential to be a best-in-class therapy given our differentiated approach for RNA editing. The breadth of pulmonary and hepatic expertise in our CAB will be invaluable to our clinical and regulatory strategy, ensuring we consider the holistic needs of patients with AATD. We are honored to work alongside the world's leading experts in AATD who share our commitment to scientific excellence and improving patient outcomes."

Subject to approval by the HREC and acceptance of the clinical trial notification (CTN) by Australia's Therapeutic Goods Administration (TGA), Korro anticipates dosing the first participant in the Phase 1/2 study in the first quarter of 2025. An interim data readout for the Phase 1/2 study of KRRO-110 is anticipated in the second half of 2025, and completion of the study is expected in 2026.

"This is a major achievement for a company founded on RNA editing – to go from initial concepts and ideas to a first-in-human clinical study. I am immensely proud of the progress we have made since nomination of KRRO-110 for AATD in December 2023 and the contributions of the entire team at Korro," added Ram Aiyar, PhD, CEO and President of Korro. "Our robust pipeline of fully owned and partnered programs showcases the transformative potential of our OPERA™ platform. With a strong balance sheet to support completion of the Phase 1/2 study and to advance the next set of programs, I am excited to see the potential of our platform realized."

The newly appointed CAB members, listed below, include:

- **Daniel Chambers, MBBS (Hons 1, University Medal), MRCP, FRACP, MD, FQA,** Professor of Medicine, Thoracic & Transplant Physician, Interstitial Lung Disease Expert and Translational Clinician Researcher at The University of Queensland and The Prince Charles Hospital,

Australia. Prof. Chambers is an internationally recognized authority in the fields of lung fibrosis, cell therapy for lung disease and lung transplantation.

- **Monica Goldklang, MD**, Assistant Professor of Medicine in Anesthesiology and Director, Alpha-1 Foundation Clinical Resource Center, Columbia University New York, USA. Dr. Goldklang's main area of research interest is in translational studies, investigating the pathogenesis of smoking related lung disease and mechanisms of protease upregulation in lung injury.
- **Noel G. McElvaney, MBBCh, FRCPI, DSc,** Professor of Medicine at the Royal College of Surgeons in Ireland, Head of the Irish Centre for Genetic Lung Disease, Beaumont Hospital, Dublin, Ireland, and Founder of the Alpha-1 Foundation of Ireland. Prof. McElvaney's main research areas are in AATD, chronic obstructive lung disease and cystic fibrosis.
- **Pavel Strnad, MD**, Professor of Translational Gastroenterology and Senior Physician at the University Hospital Aachen, Department of Medicine III, Aachen, Germany. Dr. Strnad currently leads a European initiative for the study of AATD-associated liver disease.
- **Jeffrey Teckman, MD**, Professor of Pediatrics, Biochemistry and Molecular Biology at Saint Louis University, USA. Dr. Teckman's research with the Alpha-1 Foundation's Liver Initiative focuses on adult Alphas, and his work with the Childhood Liver Disease Research and Education Network (ChiLDREN) focuses on rare pediatric liver disease.
- **Alice M. Turner, MBChB (Hons), MRCP, PGCE (MedEd), PhD**, Professor of Respiratory Medicine and Department Director of Research Knowledge and Transfer at the University of Birmingham Institute of Applied Health Research, UK. Dr. Turner's research interests are predominantly in clinical aspects of AATD and chronic obstructive pulmonary disease, fields in which she has published widely.

For full CAB member bios, visit www.korrobio.com/our-team/

About alpha-1 antitrypsin deficiency (AATD) and KRRO-110

AATD is a genetic disorder 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's (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.

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: approval by the Australian Bellberry Human Research Ethics Committee of Korro's regulatory filing to commence a Phase 1/2 clinical trial of KRRO-110 for AATD; acceptance by Australia's Therapeutic Goods Administration of Korro's clinical trial notification for the Phase 1/2 clinical trial of KRRO-110 for AATD; the timing of Korro dosing the first participant, interim data readout and completion of the Phase 1/2 clinical trial, including its ability to complete such trial; KRRO-110's potential to be a best-in-class therapy; the transformative potential of Korro's OPERA™ platform; Korro's ability to advance its next set of pipeline programs and the strength of its balance sheet to support completion; 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 trial; 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 trials and risks of replicating results from pre-clinical studies in clinical trials; 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 Quarterly Report on Form 10-Q filed with the SEC on August 13, 2024, 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
Tim Palmer
IR@korrobio.com