# 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): August 13, 2026**

# KYNTRA BIO, INC.

**(Exact name of Registrant as Specified in Its Charter)**

| **Delaware** | **001-36740** | **77-0357827** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |
| **350 Bay Street Suite 100 #6009 San Francisco, California** | | **94133** |
| **(Address of Principal Executive Offices)** | | **(Zip Code)** |

**Registrant's Telephone Number, Including Area Code: 415 978-1200**

**(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, $0.01 par value | KYNB | The Nasdaq Global Select 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 2.02 Results of Operations and Financial Condition.**

On August 13, 2026, Kyntra Bio, Inc. ("Kyntra Bio") issued a press release announcing financial results for the quarter ended June 30, 2026. A copy of such press release is furnished as Exhibit 99.1 to this report and is incorporated herein by reference.

The information in this Item 2.02, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 2.02, in Exhibit 99.1 shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by Kyntra Bio, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release dated August 13, 2026 |
| 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.

KYNTRA BIO, INC.

Date: August 13, 2026

By: /s/ David DeLucia
David DeLucia
Senior Vice President and Chief Financial Officer

**Exhibit 99.1**

# Kyntra Bio Reports Second Quarter 2026 Financial Results and Provides Business Update

- *Phase 2 monotherapy trial of FG-3246, a potential first-in-class antibody drug conjugate (ADC) targeting CD46 in metastatic castration-resistant prostate cancer (mCRPC), continues enrolling with interim analysis on track for 4Q 2026*
- *Phase 3 protocol of roxadustat for the treatment of anemia in patients with lower-risk myelodysplastic syndromes (LR-MDS) and high transfusion burden (HTB) has been finalized with the goal to initiate the registrational study in 4Q 2026*
- *Additional data from the Phase 3 MATTERHORN study were presented at the European Hematology Association (EHA) Congress 2026, highlighting improvements in transfusion independence in patients with HTB and regardless of ring sideroblast status*
- *Cash, cash equivalents, investments, and accounts receivable of $95.7 million as of June 30, 2026*
- *Kyntra Bio to host conference call and webcast presentation today at 5:00 PM ET*

SAN FRANCISCO, August 13, 2026 (GLOBE NEWSWIRE) -- Kyntra Bio (Nasdaq: KYNB) today reported financial results for the second quarter 2026 and provided an update on the company's recent developments.

"We continue to make progress across our oncology and rare disease portfolio and remain laser-focused on advancing toward our goal of initiating a pivotal Phase 3 trial of roxadustat in LR-MDS in the fourth quarter of this year and conducting an interim analysis of the Phase 2 trial of FG-3246 in mCRPC, also in the fourth quarter of this year," said Thane Wettig, Chief Executive Officer of Kyntra Bio. "We believe we have the substrate that will enable us to create significant value for patients and stakeholders as we advance our pipeline and look forward to providing additional updates in the coming months."

**Key Highlights of Second Quarter, Recent Developments, and Upcoming Milestones**

**FG-3246 (CD46 Targeting ADC) and FG-3180 (CD46 Targeting PET Imaging Agent)**

- Enrollment in the Phase 2 monotherapy trial of FG-3246, a potential first-in-class ADC targeting CD46 in mCRPC continues; interim analysis is on track for the fourth quarter of 2026.

**Roxadustat**

- Pivotal Phase 3 trial protocol of roxadustat for the treatment of anemia in patients with LR-MDS and high transfusion burden (HTB) has been finalized.
- Additional data from the Phase 3 MATTERHORN study were presented at the European Hematology Association (EHA) Congress 2026.
  - In a post hoc analysis of the Phase 3 MATTERHORN study, patients treated with roxadustat showed a clinically meaningful improvement in transfusion independence (TI) in patients with LR-MDS and HTB compared to placebo.
  - Similar rates of TI for patients treated with roxadustat were observed in both ring sideroblast positive (RS+) and ring sideroblast negative (RS-) disease.
- Company continues to explore the opportunity to develop roxadustat internally or with a strategic partner, with the goal of initiating the Phase 3 trial in the fourth quarter of 2026.

**Financial**

- Total revenue from continuing operations for the second quarter of 2026 was $(1.5) million, as compared to $1.3 million for the second quarter of 2025.
- Net income from continuing operations for the second quarter of 2026 was $12.0 million, or $2.96 net income per basic and diluted share, compared to a net loss of $13.7 million, or $3.38 net loss per basic and diluted share, one year ago.
- As of June 30, 2026, Kyntra Bio reported $95.7 million in cash, cash equivalents, investments, and accounts receivable.
- The Company expects its cash, cash equivalents, investments, and accounts receivable to be sufficient to fund operating plans into 2028.

**Conference Call and Webcast Presentation**
Kyntra Bio management team will host a conference call and webcast presentation to discuss the financial results and provide a business update. A live Q&A session will follow the brief presentation. Interested parties may access a live audio webcast of the conference call here. To access the call by phone, please register here, and you will be provided with dial in details. A replay of the webcast will also be available for a limited time on the Events & Presentations page on Kyntra Bio's website.

**About FG-3246 and FG-3180**
FG-3246 (FOR46) is a potential first-in-class fully human antibody-drug conjugate (ADC), exclusively in-licensed from Fortis Therapeutics, and is being developed by Kyntra Bio for metastatic castration-resistant prostate cancer and potentially other tumor types. FG-3246 binds to an epitope of CD46, a cell receptor target, that induces internalization upon antibody binding, is present at high levels in prostate cancer and other tumor types and demonstrates very limited expression in most normal tissues. FG-3246 is comprised of an anti-CD46 antibody, YS5, linked to the anti-mitotic agent, MMAE, which is a clinically and commercially validated ADC payload. FG-3246 has demonstrated anti-tumor activity in both preclinical and clinical studies. FG-3180 is a companion diagnostic PET imaging agent, using the same CD46-targeting antibody together with an 89Zr tracer. To date, FG-3180 demonstrated specific uptake in CD46 positive tumors and is currently being evaluated as a biomarker for its potential to inform patient selection.

**About Roxadustat**
Roxadustat, an oral medication, is the first in a new class of medicines comprising HIF-PH inhibitors that promote erythropoiesis, or red blood cell production, through increased endogenous production of erythropoietin, improved iron absorption and mobilization, and downregulation of hepcidin.

Roxadustat is approved in Europe, Japan, China, and numerous other countries for the treatment of anemia of CKD in adult patients on dialysis (DD) and not on dialysis (NDD). Kyntra Bio has the sole rights to roxadustat in the United States, Canada, Mexico, and in all markets not held by AstraZeneca or licensed to Astellas. Astellas and Kyntra Bio are collaborating on the commercialization of roxadustat for the treatment of anemia in territories including Japan, Europe, Turkey, Russia, and the Commonwealth of Independent States, the Middle East, and South Africa.

**About Kyntra Bio**
Kyntra Bio is a biopharmaceutical company focused on development of novel therapies in oncology and rare disease. Roxadustat (爱瑞卓®, EVRENZO™) is currently approved in Europe, Japan, China, and numerous other countries for the treatment of anemia in chronic kidney disease (CKD) patients on dialysis and not on dialysis. The Company continues to evaluate the development plan for the Phase 3 trial of roxadustat in anemia associated with lower-risk myelodysplastic syndromes (LR-MDS) in the U.S. FG-3246 (also known as FOR46), a first-in-class antibody-drug conjugate (ADC) targeting CD46, is in Phase 2 development for the treatment of metastatic castration-resistant prostate cancer. This program also includes the development of FG-3180, an associated CD46-targeted PET biomarker. For more information, please visit www.kyntrabio.com.

**Forward-Looking Statements**

This release contains forward-looking statements regarding Kyntra Bio's strategy, future plans and prospects, including statements regarding its commercial products and clinical programs and those of its partners Fortis and UCSF. These forward-looking statements include, but are not limited to, statements regarding the efficacy, safety, and potential clinical or commercial success of Kyntra Bio products and product candidates, statements under the caption "Recent Highlights and Upcoming Milestones", statements about regulatory interactions, statements regarding cash, such as the expectation that cash, cash equivalents and accounts receivable will be sufficient to fund Kyntra Bio's operating plans into 2028, and statements about Kyntra Bio's plans and objectives. These forward-looking statements are typically identified by use of terms such as "may," "will", "should," "on track," "could," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential," "continue" and similar words, although some forward-looking statements are expressed differently. Kyntra Bio's actual results may differ materially from those indicated in these forward-looking statements due to risks and uncertainties related to the continued progress and timing of its various programs, including the enrollment and results from ongoing and potential future clinical trials, and other matters that are described in Kyntra Bio's most recent Annual Report on Form 10-K and Quarterly Report on Form 10-Q, each as filed with the Securities and Exchange Commission (SEC), including the risk factors set forth therein. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release, and Kyntra Bio undertakes no obligation to update any forward-looking statement in this press release, except as required by law.

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**Condensed Consolidated Balance Sheets**
(In thousands)

| | June 30, 2026 (Unaudited) | December 31, 2025 (1) |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 50,644 | $ 47,872 |
| Short-term investments | 40,674 | 41,106 |
| Accounts receivable, net | 347 | 216 |
| Inventory | 3,384 | 3,743 |
| Prepaid expenses and other current assets | 1,776 | 6,136 |
| Total current assets | 96,825 | 99,073 |
| Long-term investments | 4,012 | 20,160 |
| Other assets | 241 | 361 |
| **Total assets** | $ 101,078 | $ 119,594 |
| | | |
| **Liabilities, stockholders' equity and non-controlling interests** | | |
| Current liabilities: | | |
| Accounts payable | $ 7,510 | $ 3,745 |
| Accrued and other liabilities | 23,112 | 20,183 |
| Deferred revenue | 5,418 | 5,314 |
| Total current liabilities | 36,040 | 29,242 |
| Product development obligations | — | 19,560 |
| Deferred revenue, net of current | 2,620 | 255 |
| Liability related to sale of future revenues, non-current | 70,495 | 65,980 |
| Other long-term liabilities | 67 | 82 |
| Total liabilities | 109,222 | 115,119 |
| | | |
| Redeemable non-controlling interests | 21,480 | 21,480 |
| Total stockholders' deficit attributable to Kyntra Bio | (30,144) | (30,038) |
| Nonredeemable non-controlling interests | 520 | 13,033 |
| Total deficit | (29,624) | (17,005) |
| **Total liabilities, redeemable non-controlling interests and deficit** | $ 101,078 | $ 119,594 |

(1) The condensed consolidated balance sheet amounts at December 31, 2025 are derived from audited financial statements.

**Condensed Consolidated Statements of Operations**
(In thousands, except per share data)

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2026 | 2025 | 2026 | 2025 |
| | (Unaudited) | | | |
| **Revenue:** | | | | |
| Development and other revenue | $ 103 | $ 133 | 349 | 277 |
| Drug product revenue, net | (1,577) | 1,215 | 1,915 | 3,811 |
| Total revenue | (1,474) | 1,348 | 2,264 | 4,088 |
| | | | | |
| **Operating costs and expenses:** | | | | |
| Cost of goods sold | 2 | 85 | 4,108 | 337 |
| Research and development | 6,821 | 5,865 | 14,387 | 15,040 |
| Selling, general and administrative | 9,266 | 7,057 | 15,128 | 15,164 |
| Restructuring charge | 11 | 393 | 33 | 519 |
| Total operating costs and expenses | 16,100 | 13,400 | 33,656 | 31,060 |
| **Loss from operations** | (17,574) | (12,052) | (31,392) | (26,972) |
| | | | | |
| **Interest and other, net:** | | | | |
| Interest expense | (2,368) | (2,009) | (4,795) | (4,265) |
| Gain on deconsolidation of subsidiary | 30,940 | — | 30,940 | — |
| Interest income and other income (expenses), net | 975 | 286 | 2,088 | 698 |
| Total interest and other, net | 29,547 | (1,723) | 28,233 | (3,567) |
| | | | | |
| **Income (loss) from continuing operations before income taxes** | 11,973 | (13,775) | (3,159) | (30,539) |
| Benefit from income taxes | (1) | (92) | (1) | (90) |
| **Income (loss) from continuing operations** | 11,974 | (13,683) | (3,158) | (30,449) |
| Income (loss) from discontinued operations, net of tax | — | 6,080 | (66) | 27,485 |
| **Net income (loss)** | $ 11,974 | $ (7,603) | $ (3,224) | $ (2,964) |
| | | | | |
| Income (loss) from continuing operations per share - basic and diluted | $ 2.96 | $ (3.38) | $ (0.78) | $ (7.54) |
| Income (loss) from discontinued operations per share - basic and diluted | — | 1.50 | (0.02) | 6.81 |
| **Net income (loss) per share - basic and diluted** | $ 2.96 | $ (1.88) | $ (0.80) | $ (0.73) |
| | | | | |
| Weighted average number of common shares used to calculate net income (loss) per share - basic and diluted | 4,048 | 4,042 | 4,048 | 4,040 |

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**For Investor Inquiries:**

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