



Kyntra Bio Reports First Quarter 2026 Financial Results and Provides Business Update

May 11, 2026

- *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) is progressing well with the interim analysis anticipated in 4Q 2026*
- *Positive results from the investigator-sponsored study of FG-3246 in combination with enzalutamide in patients with mCRPC were presented at ASCO GU in February 2026, further validating key Phase 2 monotherapy design elements*
- *Pivotal Phase 3 trial protocol of roxadustat for the treatment of anemia in patients with lower-risk myelodysplastic syndromes (LR-MDS) and high transfusion burden is being finalized following feedback from the U.S. Food and Drug Administration (FDA)*
- *Cash, cash equivalents, investments, and accounts receivable of \$100.3 million, providing cash runway into 2028*
- *Kyntra Bio to host conference call and webcast presentation today at 5:00 PM ET*

SAN FRANCISCO, May 11, 2026 (GLOBE NEWSWIRE) -- Kyntra Bio (Nasdaq: KYNB) today reported financial results for the first quarter 2026 and provided an update on the company's recent developments.

"In the first quarter, we continued to make steady progress across our pipeline. We are encouraged by the pace of enrollment in our Phase 2 trial of FG-3246 in patients with mCRPC and are on track for the interim analysis in the fourth quarter of 2026. We remain confident in the potential of FG-3246 to deliver competitive progression free survival results in the Phase 2 monotherapy trial," commented Thane Wettig, Chief Executive Officer of Kyntra Bio. "In addition, following FDA feedback, we are finalizing the protocol for the pivotal Phase 3 trial of roxadustat for the treatment of lower-risk MDS, and anticipate trial initiation in the second half of 2026."

Key Highlights of First Quarter, Recent Developments, and Upcoming Milestones

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

- Phase 2 monotherapy trial of FG-3246, a potential first-in-class ADC targeting CD46, in mCRPC is actively enrolling and remains on track for interim analysis in the fourth quarter of 2026
- Topline results from the investigator-sponsored Phase 1b/2 study, conducted by UCSF, of FG-3246 in combination with enzalutamide in patients with mCRPC were presented at ASCO GU 2026
 - In biomarker unselected patients with androgen receptor pathway inhibitor (ARPI)-treated, taxane-naïve mCRPC, the combination of FG-3246 and enzalutamide led to a median radiographic progression free survival (rPFS) of 7.0 months in the overall study cohort, and a median rPFS of 10.1 months in patients who progressed on only one prior ARPI.
 - Higher tumor uptake of FG-3180 was numerically associated with PSA50 response (nominal $p=0.053$), highlighting its potential as a biomarker for patient selection.
 - Combination therapy had a similar safety and exposure profile to the previous FG-3246 Phase 1 monotherapy trial.
 - Results further validate key FG-3246 Phase 2 monotherapy design elements, most importantly the inclusion of patients who have progressed on only one prior ARPI and integration of baseline FG-3180 PET for all enrolled patients.

Roxadustat

- Pivotal Phase 3 trial protocol of roxadustat for the treatment of anemia in patients with LR-MDS and high transfusion burden is being finalized based on feedback received from the FDA
- 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 second half of 2026

Financial

- o Total revenue from continuing operations for the first quarter of 2026 was \$3.7 million, as compared to \$2.7 million for the first quarter of 2025.
- o Net loss from continuing operations for the first quarter of 2026 was \$15.1 million, or \$3.74 net loss per basic and diluted share, compared to a net loss of \$16.8 million, or \$4.15 net loss per basic and diluted share, one year ago.
- o As of March 31, 2026, Kyntra Bio reported \$100.3 million in cash, cash equivalents, investments, and accounts receivable.
- o 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.

Condensed Consolidated Balance Sheets

(In thousands)

	March 31, 2026	December 31, 2025
	(Unaudited)	(1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 36,997	\$ 47,872
Short-term investments	50,240	41,106
Accounts receivable, net	5,040	216
Inventory	3,384	3,743
Prepaid expenses and other current assets	5,694	6,136
Total current assets	101,355	99,073
Long-term investments	8,026	20,160
Other assets	248	361
Total assets	\$ 109,629	\$ 119,594
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	\$ 5,094	\$ 3,745
Accrued and other liabilities	17,340	20,183
Deferred revenue	5,680	5,314
Total current liabilities	28,114	29,242
Product development obligations	19,249	19,560
Deferred revenue, net of current	4,075	255
Liability related to sale of future revenues, non-current	67,405	65,980
Other long-term liabilities	76	82
Total liabilities	118,919	115,119
Redeemable non-controlling interests	21,480	21,480
Total stockholders' deficit attributable to Kyntra Bio	(43,803)	(30,038)
Nonredeemable non-controlling interests	13,033	13,033
Total deficit	(30,770)	(17,005)
Total liabilities, redeemable non-controlling interests and deficit	\$ 109,629	\$ 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 March 31,	
	2026	2025
	(Unaudited)	
Revenue:		
Development and other revenue	\$ 246	\$ 144
Drug product revenue, net	3,492	2,595
Total revenue	3,738	2,739
Operating costs and expenses:		
Cost of goods sold	4,106	252
Research and development	7,566	9,175
Selling, general and administrative	5,862	8,106
Restructuring charge	22	126
Total operating costs and expenses	17,556	17,659
Loss from operations	(13,818)	(14,920)
Interest and other, net:		
Interest expense	(2,427)	(2,257)
Interest income and other income (expenses), net	1,113	413

Total interest and other, net	(1,314)	(1,844)
Loss from continuing operations before income taxes	(15,132)	(16,764)
Provision for income taxes	—	2
Loss from continuing operations	(15,132)	(16,766)
Income (loss) from discontinued operations, net of tax	(66)	21,405
Net income (loss)	<u><u>\$ (15,198)</u></u>	<u><u>\$ 4,639</u></u>
Loss from continuing operations per share – basic and diluted	\$ (3.74)	\$ (4.15)
Income (loss) from discontinued operations per share – basic and diluted	(0.02)	5.30
Net income (loss) per share – basic and diluted	<u><u>\$ (3.76)</u></u>	<u><u>\$ 1.15</u></u>
Weighted average number of common shares used to calculate net income (loss) per share – basic and diluted	4,047	4,038

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Source: Kyntra Bio