Kyntra Bio Reports Fourth Quarter and Full Year 2025 Financial Results and Provides Business Update

March 16, 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 actively enrolling and remains on track for interim analysis in 2H 2026*
- *Positive results from the investigator-sponsored study of FG-3246 in combination with enzalutamide in patients with mCRPC, further validating key Phase 2 monotherapy design elements, were presented at the 2026 ASCO GU*
- *Submitted the pivotal Phase 3 clinical trial protocol for roxadustat for the treatment of anemia in patients with lower-risk myelodysplastic syndromes (LR-MDS) and high transfusion burden to the U.S. Food and Drug Administration*
- *Cash, cash equivalents, investments, and accounts receivable of $109.4 million, providing cash runway into 2028*
- *Kyntra Bio to host conference call and webcast presentation today at 5:00 PM ET*

SAN FRANCISCO, March 16, 2026 (GLOBE NEWSWIRE) -- Kyntra Bio (Nasdaq: KYNB) today reported financial results for the fourth quarter and full year 2025 and provided an update on the company's recent developments.

"The encouraging results from the investigator-sponsored combination trial of FG-3246 with enzalutamide provide us with valuable insights and reinforce key design elements in our Phase 2 monotherapy study," said Thane Wettig, Chief Executive Officer of Kyntra Bio. "Our Phase 2 monotherapy trial of FG-3246 is progressing as planned, with interim results expected in the second half of 2026. Additionally, we have submitted the Phase 3 trial protocol for roxadustat for the treatment of anemia in patients with LR-MDS and expect feedback from the FDA shortly, with the intention to start a Phase 3 trial in the second half of 2026. With our successful transformation in 2025, we are well-positioned to execute our strategic plan in 2026 and anticipate an exciting year ahead."

Key Highlights of Fourth Quarter 2025, 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 second half 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
    - FG-3246 and enzalutamide combination therapy, in biomarker unselected patients with androgen receptor pathway inhibitor (ARPI)-treated, taxane-naïve mCRPC, led to a median radiographic progression free survival (rPFS) of 7.0 months in the overall study cohort, with median rPFS of 10.1 months observed 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

- Granted Orphan Drug Designation from the FDA for the treatment of MDS.
- Submitted the pivotal Phase 3 clinical trial protocol for roxadustat for the treatment of anemia in patients with LR-MDS and high transfusion burden to the U.S. Food and Drug Administration.

- Company is currently exploring the opportunity to develop roxadustat internally or with a strategic partner, with the goal of starting the Phase 3 trial in the second half of 2026.

Financial

- Total revenue from continuing operations for the fourth quarter of 2025 was $1.3 million, as compared to $3.1 million for the fourth quarter of 2024.
- Total revenue from continuing operations for the full year 2025 was $6.4 million, as compared to $29.6 million for the full year 2024.
- Net loss from continuing operations for the fourth quarter of 2025 was $14.6 million, or $3.61 net loss per basic and diluted share, compared to a net loss of $8.7 million, or $2.15 net loss per basic and diluted share, one year ago.
- Net loss from continuing operations for the full year 2025 was $58.2 million, or $14.40 net loss per basic and diluted share, compared to a net loss of $153.1 million, or $38.26 net loss per basic and diluted share, for the full year 2024.
- As of December 31, 2025, Kyntra Bio reported $109.4 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 ^{89}Zr tracker. 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)

	December 31, 2025 (Unaudited)	December 31, 2024 (1)
Assets		
Current assets:		
Cash and cash equivalents	$ 47,872	$ 50,482
Short-term investments	41,106	—
Accounts receivable, net	216	481
Inventory	3,743	3,155
Prepaid expenses and other current assets	6,136	31,542
Current assets held for sale	—	110,849
Total current assets	99,073	196,509
Long-term investments	20,160	—
Other assets	361	1,405
Long-term assets held for sale	—	16,611
Total assets	$ 119,594	$ 214,525
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 3,745	$ 5,064
Accrued and other liabilities	20,183	62,035
Deferred revenue	5,314	27,290
Current liabilities held for sale	—	38,917
Total current liabilities	29,242	133,306
Product development obligations	19,560	17,012
Deferred revenue, net of current	255	114,708
Senior secured term loan facilities, non-current	—	73,092
Liability related to sale of future revenues, non-current	65,980	58,864
Other long-term liabilities	82	822
Long-term liabilities held for sale	—	356
Total liabilities	115,119	398,160
Redeemable non-controlling interests	21,480	21,480
Total stockholders' deficit attributable to FibroGen	(30,038)	(225,602)
Nonredeemable non-controlling interests	13,033	20,487
Total deficit	(17,005)	(205,115)
Total liabilities, redeemable non-controlling interests and deficit	$ 119,594	$ 214,525

(1) The condensed consolidated balance sheet amounts at December 31, 2024 are derived from audited financial statements.

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

	Three Months Ended December 31,		Years Ended December 31,	
	2025	2024	2025	2024
	(Unaudited)		(Unaudited)	(1)
Revenue:				
Development and other revenue	$ 197	$ 416	592	1,948
Drug product revenue, net	1,081	2,720	5,848	27,673
Total revenue	1,278	3,136	6,440	29,621
Operating costs and expenses:				
Cost of goods sold	278	(5,845)	556	15,561
Research and development	7,268	6,870	23,517	95,692
Selling, general and administrative	7,251	8,345	27,709	49,330
Restructuring charge	(7)	900	553	19,454
Total operating costs and expenses	14,790	10,270	52,335	180,037
Loss from operations	(13,512)	(7,134)	(45,895)	(150,416)
Interest and other, net:				
Interest expense	(2,413)	(2,217)	(8,759)	(8,247)
Loss on debt extinguishments	—	—	(6,583)	—
Interest income and other income (expenses), net	1,316	688	2,943	5,296
Total interest and other, net	(1,097)	(1,529)	(12,399)	(2,951)
Loss from continuing operations before income taxes	(14,609)	(8,663)	(58,294)	(153,367)
Provision for (benefit from) income taxes	—	2	(90)	(269)
Loss from continuing operations	(14,609)	(8,665)	(58,204)	(153,098)
Income from discontinued operations, net of tax	389	26,647	241,656	105,519
Net income (loss)	$ (14,220)	$ 17,982	$ 183,452	$ (47,579)
Loss from continuing operations per share - basic and diluted	$ (3.61)	$ (2.15)	$ (14.40)	$ (38.26)
Income from discontinued operations per share - basic and diluted	0.10	6.61	59.77	26.37
Net income (loss) per share - basic and diluted	$ (3.51)	$ 4.46	$ 45.37	$ (11.89)
Weighted average number of common shares used to calculate net income (loss) per share - basic and diluted	4,046	4,033	4,043	4,002

(1) The condensed consolidated statement of operations amounts for the year ended December 31, 2024 are derived from audited financial statements.

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Source: Kyntra Bio