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

November 16, 2026

- *Completed restructuring of royalty financing agreement, reducing the maximum aggregate payment obligation by $60 million, with only $15 million in future royalty-backed payments remaining*
- *Initiation of the pivotal Phase 3 trial of roxadustat for the treatment of anemia in LR-MDS patients with high transfusion burden (HTB) planned in 1Q 2027, subject to the execution of either a strategic partnership or an external capital raise*
- *Decision to discontinue development of FG-3246 and FG-3180 following insufficient efficacy at the pre-specified Phase 2 interim analysis in metastatic castration-resistant prostate cancer (mCRPC), resulting in a reduction of over $20 million in operating expenses in 2027 and 2028*
- *Cash, cash equivalents, investments, and accounts receivable of $44.1 million as of September 30, 2026, with a cash runway now into 2028*
- *Kyntra Bio to host conference call and webcast presentation today at 5:00 PM ET*

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

"Following a pre-planned interim analysis showing insufficient efficacy, we have made the decision to terminate the FG-3246 Phase 2 trial," said Thane Wettig, Chief Executive Officer of Kyntra Bio. "We continue to work towards the completion of our transformation to a pure-play, rare disease company laser-focused on the initiation and execution of the Phase 3 roxadustat trial. The unmet medical need and corresponding multi-billion-dollar commercial opportunity in LR-MDS is significant. Subject to the execution of either a strategic partnership or an external capital raise, we plan on initiating the pivotal Phase 3 trial in the first quarter of 2027."

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

Roxadustat

- Initiation of the pivotal Phase 3 trial of roxadustat for the treatment of anemia in patients with LR-MDS and HTB planned in the first quarter of 2027, subject to the execution of either a strategic partnership or an external capital raise.

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

- Following a pre-specified interim analysis of the ongoing Phase 2 study of FG-3246 in mCRPC, the Company decided to close enrollment in the study and discontinue development of the program.
  - Preliminary efficacy results at the interim analysis did not meet the threshold required to support continued development.
- The Company plans to complete the close-out of the study over the coming months and will cancel all planned future investment in the program.
- The Company expects to save over $20 million in operating expenses in 2027 and 2028 from the termination of the study.

Corporate

- In August 2026, the company signed an amendment and restatement of its existing royalty financing agreement with NQ Project Phoebus, L.P., materially reducing its payment obligations under the agreement in exchange for an accelerated upfront payment. The amendment included the following terms:
  - Reduction of the maximum aggregate payments under the agreement from $125 million to $65 million, including the $42.6 million accelerated payment to NQ Project Phoebus, L.P., bringing total payments made to date to $50 million, a full return of NQ Project Phoebus, L.P.'s invested capital.
  - Remaining payments, capped at $15 million, to be paid from 50% of the roxadustat drug product revenue Kyntra

Bio recognizes from Astellas in the Astellas territories excluding Japan.

- Once the $15 million cap is reached, the amended agreement will terminate, with Kyntra Bio retaining all subsequent EVRENZO™ royalties in the Astellas territories.

- Appointed Andrew E. Singer, MBA to the Board of Directors.

Financial

- Total revenue from continuing operations for the third quarter of 2026 was $1.8 million, as compared to $1.1 million for the third quarter of 2025.
- Net income from continuing operations for the third quarter of 2026 was $0.2 million, or $0.04 net income per basic and diluted share, compared to a net loss of $13.1 million, or $3.25 net loss per basic and diluted share, one year ago.
- As of September 30, 2026, Kyntra Bio reported $44.1 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 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.

Following promising results from the Phase 2/3 MATTERHORN study, the Company is planning to study roxadustat in a pivotal Phase 3 trial in patients with anemia associated with lower-risk myelodysplastic syndromes (LR-MDS) and high transfusion burden (HTB).

About Kyntra Bio
Kyntra Bio is a pure play, rare disease biopharmaceutical company focused on the development of roxadustat for anemia associated with lower-risk myelodysplastic syndromes (LR-MDS). 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 is planning to study roxadustat in a pivotal Phase 3 trial in patients with anemia associated with lower-risk myelodysplastic syndromes (LR-MDS). 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)

	September 30, 2026	December 31, 2025
	(Unaudited)	(1)
Assets		
Current assets:		
Cash and cash equivalents	$ 9,905	$ 47,872
Short-term investments	30,385	41,106
Accounts receivable, net	3,848	216
Inventory	3,255	3,743
Prepaid expenses and other current assets	1,227	6,136
Total current assets	48,620	99,073
Long-term investments	—	20,160
Other assets	231	361
Total assets	$ 48,851	$ 119,594
Liabilities, stockholders' equity and non-controlling interests		
Current liabilities:		
Accounts payable	$ 4,581	$ 3,745
Accrued and other liabilities	31,005	20,183
Deferred revenue	6,170	5,314
Total current liabilities	41,756	29,242
Product development obligations	—	19,560
Deferred revenue, net of current	2,957	255
Liability related to sale of future revenues, non-current	11,268	65,980
Other long-term liabilities	60	82
Total liabilities	56,041	115,119
Redeemable non-controlling interests	21,480	21,480
Total stockholders' deficit attributable to Kyntra Bio	(29,190)	(30,038)
Nonredeemable non-controlling interests	520	13,033
Total deficit	(28,670)	(17,005)
Total liabilities, redeemable non-controlling interests and deficit	$ 48,851	$ 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 September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	(Unaudited)			
Revenue:				
Development and other revenue	$ 99	$ 119	449	396
Drug product revenue, net	1,663	957	3,577	4,767
Total revenue	1,762	1,076	4,026	5,163
Operating costs and expenses:				
Cost of goods sold	619	(58)	4,727	278
Research and development	8,266	1,209	22,654	16,249
Selling, general and administrative	5,757	5,295	20,951	20,459
Restructuring charge	(15)	41	(48)	560
Total operating costs and expenses	14,627	6,487	48,284	37,546
Loss from operations	(12,865)	(5,411)	(44,258)	(32,383)
Interest and other, net:				

Interest expense	(1,632)	(2,083)	(6,426)	(6,346)
Gain on deconsolidation of subsidiary	—	—	30,940	—
Loss on debt extinguishments	—	(6,583)	—	(6,583)
Gain on debt restructuring	14,011	—	14,011	—
Interest income and other income (expenses), net	643	931	2,731	1,628
Total interest and other, net	13,022	(7,735)	41,256	(11,301)
Income (loss) from continuing operations before income taxes	157	(13,146)	(3,002)	(43,684)
Benefit from income taxes	—	—	(1)	(90)
Income (loss) from continuing operations	157	(13,146)	(3,001)	(43,594)
Income (loss) from discontinued operations, net of tax	—	213,782	(66)	241,266
Net income (loss)	$ 157	$ 200,636	$ (3,067)	$ 197,672
Income (loss) from continuing operations per share - basic and diluted	$ 0.04	$ (3.25)	$ (0.74)	$ (10.79)
Income (loss) from discontinued operations per share - basic and diluted	—	52.86	(0.02)	59.69
Net income (loss) per share - basic and diluted	$ 0.04	$ 49.61	$ (0.76)	$ 48.90
Weighted average number of common shares used to calculate net income (loss) per share:				
Basic	4,049	4,044	4,048	4,042
Diluted	4,050	4,044	4,048	4,042

For Investor Inquiries:
David DeLucia, CFA
Senior Vice President and Chief Financial Officer
ir@kyntrabio.com

Source: Kyntra Bio