Moleculin Reports First Quarter 2026 Financial Results and Provides Clinical Update on Pivotal MIRACLE Trial

Early blinded results show 40% composite complete remission rate across difficult-to-treat AML patient population in MIRACLE Trial

First interim unblinding expected in June 2026 following 45 subject enrollment milestone achieved in MIRACLE trial

Enrollment in MIRACLE trial continues to advance on pace with 90th subject expected in Q3 2026

HOUSTON, May 15, 2026 (GLOBE NEWSWIRE) -- Moleculin Biotech, Inc., (Nasdaq: MBRX) ("Moleculin" or the "Company"), today reported financial results for the first quarter ended March 31, 2026 and provided a corporate update.

"With enrollment now surpassing the first interim analysis threshold in the MIRACLE trial, we are just weeks away from beginning what we believe will be the most transformative period in the Company's history. The impressive preliminary blinded remission data trend we reported earlier this year continues with the 45 subject blinded data. This trend supports our belief in Annamycin's potential to meaningfully improve outcomes for patients with relapsed or refractory AML," said Walter Klemp, Chairman and Chief Executive Officer of Moleculin.

"We also believe Annamycin has the potential to redefine the anthracycline class by addressing one of the most significant limitations of these foundational therapies, cardiotoxicity, while potentially expanding access to treatment options for patients who otherwise may not be eligible for standard anthracycline-based therapy due to current life-time dose limits," Mr. Klemp added.

Recent Highlights

- Achieved enrollment of the first 45 subjects in the pivotal MIRACLE Phase 2B/3 trial evaluating Annamycin in combination with cytarabine ("AnnAraC") for the treatment of relapsed/refractory acute myeloid leukemia (AML)
- Continued to observe encouraging blinded efficacy trends in the MIRACLE trial, including a previously reported preliminary blinded composite complete remission (CRc) rate of 40% at the first 30 subjects treated mark and also at the 45th subject mark
- Completed financing transactions during the first quarter of 2026 resulting in approximately $8.3 million in gross proceeds, strengthening the Company's near-term operating runway
- Continued expansion of clinical trial operations across the United States and Europe to support accelerated enrollment and future development activities
- Bolstered global intellectual property strategy for Annamycin, now covering four continents

Clinical Development Update

Annamycin - MIRACLE Trial

Moleculin continues to advance the MIRACLE (Moleculin R/R AML AnnAraC Clinical Evaluation) trial, a pivotal adaptive-design Phase 3 study evaluating AnnAraC in adult patients with relapsed or refractory AML.

Expected Milestones for Annamycin Development Program

- Q2 2026: MIRACLE - Unblinding of data for 45 subjects

- Q3 2026: MIRACLE - Part A 90 subjects recruited and unblinding thereafter
- 2H 2026: MIRACLE - Start of Part B
- 2H 2026: Atlantic Health pancreatic cancer clinical trial begins
- 2027: Begin recruitment of 3rd line AML subjects
- 2027: Begin pediatric AML clinical study
- 2028: End recruitment of Part B
- 2028: Primary efficacy data for MIRACLE 2nd line subjects
- 2028: Begin submission of a Rolling New Drug Application (NDA) for the treatment of R/R AML for accelerated approval on primary endpoint of CR from MIRACLE

Additional Pipeline Programs

Moleculin continues to support externally funded and investigator-sponsored studies involving WP1066 and other pipeline candidates targeting difficult-to-treat cancers and viral diseases.

First Quarter 2026 Financial Results

Research and development expenses for the three months ended March 31, 2026 and 2025 were $5.4 million and $3.4 million, respectively. The increase of $2.0 million is mainly related to the MIRACLE clinical trials in Europe of $1.4 million, additional nonclinical studies of $0.3 million and other research costs during the current quarter as compared to the prior year quarter.

General and administrative expenses for the quarter ended March 31, 2026 were approximately $2.5 million, compared with $2.5 million for the same period in 2025.

As of March 31, 2026, the Company had cash and cash equivalents of approximately $10.3 million. Management believes current cash resources, together with recent financing proceeds, will support planned operations into the third quarter of 2026.

About Moleculin Biotech, Inc.

Moleculin Biotech, Inc. is a Phase 3 clinical stage pharmaceutical company advancing a pipeline of therapeutic candidates addressing hard-to-treat tumors and viruses. The Company's lead program, Annamycin (also known as naxtarubicin), is a highly efficacious and well tolerated anthracycline designed to avoid multidrug resistance mechanisms and to lack the cardiotoxicity common with currently prescribed anthracyclines. Annamycin is currently in development for the treatment of relapsed or refractory acute myeloid leukemia (AML) and soft tissue sarcoma (STS) lung metastases.

The Company has begun the MIRACLE (**M**olecul**i**n **R**/R AML **A**nnAraC **Cl**inical **E**valuation) Trial (MB-108), a pivotal, adaptive design Phase 3 trial evaluating Annamycin in combination with cytarabine, together referred to as AnnAraC (the combination of Annamycin and cytarabine, also referred to as "Ara-C"), for the treatment of relapsed or refractory acute myeloid leukemia. Following a successful Phase 1B/2 study (MB-106), with input from the FDA, the Company believes it has substantially de-risked the development pathway towards a potential approval for Annamycin for the treatment of AML. This study remains subject to appropriate future filings with potential additional feedback from the FDA and their foreign equivalents.

Additionally, the Company is developing WP1066, an Immune/Transcription Modulator capable of inhibiting p-STAT3 and other oncogenic transcription factors while also stimulating a natural immune response, targeting brain tumors, pancreatic and other cancers. Moleculin also has in its pipeline a portfolio of antimetabolites, including WP1122 for the potential treatment of pathogenic viruses, as well as certain cancer indications.

For more information about the Company, please visit www.moleculin.com and connect on X, LinkedIn and Facebook.

Forward-Looking Statements

Some of the statements in this release are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995, which involve risks and uncertainties. Forward-looking statements in this press release include, without limitation, the expected timing and results of the 45-subject interim data unblinding in the MIRACLE trial, the anticipated clinical milestones set forth above, the potential efficacy and safety of Annamycin and AnnAraC in R/R AML and other indications, the expected commencement and results of the pancreatic cancer and other investigator-initiated studies, the Company's ability to secure sufficient financing to fund planned operations, and the Company's expectations regarding the sufficiency of its cash resources into the third quarter of 2026. Moleculin will require significant additional financing, for which the Company has no commitments, in order to conduct its clinical trials as described in this press release, and the milestones described in this press release assume the Company's ability to secure such financing on a timely basis. Although Moleculin believes that the expectations reflected in such forward-looking statements are reasonable as of the date made, expectations may prove to have been materially different from the results expressed or implied by such forward-looking statements. The Company relies on the reports of its expert with regard to the absence of cardiotoxicity. The dataset referenced in this press release is subject to the review of the data from future subjects in its current and future clinical trials and long-term follow-up with subjects in its current trials. Moleculin has attempted to identify forward-looking statements by terminology including 'believes,' 'estimates,' 'anticipates,' 'expects,' 'plans,' 'projects,' 'intends,' 'potential,' 'may,' 'could,' 'might,' 'will,' 'should,' 'approximately' or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors, including those discussed under Item 1A. "Risk Factors" in our most recently filed Form 10-K filed with the Securities and Exchange Commission (SEC) and updated from time to time in our Form 10-Q filings and in our other public filings with the SEC. Any forward-looking statements contained in this release speak only as of its date. We undertake no obligation to update any forward-looking statements contained in this release to reflect events or circumstances occurring after its date or to reflect the occurrence of unanticipated events.

Investor Contact:
JTC Team, LLC
Jenene Thomas
(908) 824-0775
MBRX@jtcir.com

Moleculin Biotech, Inc.
Unaudited Condensed Consolidated Balance Sheets

(in thousands)	March 31, 2026	December 31, 2025
Current assets:		
Cash and cash equivalents	$ 10,317	$ 8,878
Prepaid expenses and other current assets	644	808
Total current assets	10,961	9,686
Intangible assets	11,148	11,148
Other non-current assets	900	900
Operating lease right-of-use asset	284	314
Furniture and equipment, net	70	78
Total assets	$ 23,363	$ 22,126
Current liabilities:		
Accounts payable and accrued expenses and other current liabilities	$ 7,962	$ 6,854
Total current liabilities	7,962	6,854
Operating lease liability - long-term, net of current portion	185	222
Warrant liability - long term	33	44
Total liabilities	8,180	7,120
Total stockholders' equity	15,183	15,006
Total liabilities and stockholders' equity	$ 23,363	$ 22,126

Unaudited Condensed Consolidated Statements of Operations

	Three Months Ended March 31,	
(in thousands, except share and per share amounts)	2026	2025
Revenues	$ -	$ -
Operating expenses:		
Research and development	5,378	3,435
General and administrative and depreciation and amortization	2,496	2,508
Total operating expenses	7,874	5,943
Loss from operations	(7,874)	(5,943)
Other income:		
Gain from change in fair value of warrant liability	10,770	-
Transaction costs allocated to warrant liabilities	(693)	-
Loss on issuance of warrant liabilities	(15,158)	-
Other income, net	76	9
Interest income, net	34	30
Net loss	$ (12,845)	$ (5,904)
Warrant deemed dividend	(1,765)	-
Net loss available to common stockholders	$ (14,610)	$ (5,904)
Net loss per common share - basic and diluted	$ (3.54)	$ (15.80)
Weighted average common shares outstanding - basic and diluted	4,124,482	373,751