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): November 13, 2024

Mural Oncology plc

(Exact name of Registrant as Specified in Its Charter)

Ireland	**001-41837**	**98-1748617**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
10 Earlsfort Terrace **Dublin 2, D02 T380, Ireland** **(Address of Principal Executive Offices)**		**Not Applicable** **(Zip Code)**

Registrant's Telephone Number, Including Area Code: +353-1-905-8020

Not Applicable
(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 (see General Instructions A.2. below):

☐ 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
Ordinary Shares, nominal value $0.01	MURA	The Nasdaq Global 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 November 13, 2024, Mural Oncology plc (the "Company") issued a press release announcing the Company's financial results for the three months ended September 30, 2024. A copy of the press release is furnished herewith as Exhibit 99.1 and is incorporated herein by reference.

The information in this Form 8-K, including Exhibit 99.1, attached hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by Mural Oncology plc on November 13, 2024.
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.

Mural Oncology plc

Dated: November 13, 2024

By: /s/ Adam Cutler

Name: Adam Cutler

Title: Chief Financial Officer

Mural Oncology Announces Third Quarter 2024 Financial Results and Provides Update on Pipeline Progress

Company remains on track in late-stage, potentially registrational trials of nemvaleukin alfa, with data readouts expected in late Q1/early Q2 2025 for platinum-resistant ovarian cancer and Q2 2025 for mucosal melanoma

Candidate nominations for IL-18 and IL-12 programs expected in Q4 2024, and IND submission for Mural's IL-18 program planned for Q4 2025

Mural reiterates guidance on projected cash runway into Q4 2025

WALTHAM, Mass and DUBLIN – November 13, 2024 – Mural Oncology plc (Nasdaq: MURA), a clinical-stage immuno-oncology company developing novel, investigational engineered cytokine therapies designed to address areas of unmet need for patients with a variety of cancers, today announced financial results for the third quarter of 2024 and provided an update on pipeline progress.

"Mural launched as a stand-alone company one year ago with a mission to shepherd in the second wave of immuno-oncology for patients—IO 2.0—and we believe we are well on the path to realize that vision. With our deep expertise of protein engineering and cancer biology, we are working to address key limitations with cytokine therapies and unleash their full potential. We are now focused on clinical execution, with major readouts of our two potentially registrational studies of nemvaleukin in the first half of next year, and commercial readiness. We are also deepening our pipeline with candidate nominations for our IL-18 and IL-12 programs expected by the end of this year," said Caroline Loew, Ph.D., CEO of Mural Oncology.

Clinical Progress & Upcoming Catalysts:

Mural's late-stage trials of nemvaleukin alfa (nemvaleukin), an engineered fusion protein designed to leverage Interleukin-2's (IL-2) antitumor effects while mitigating its hallmark toxicities, remain on track. The company shared new information related to study design, statistical assumptions, and study execution at a virtual Investor Day in September 2024, including:

- Completion of enrollment in **ARTISTRY-7**, the company's potentially registrational phase 3 trial in platinum-resistant ovarian cancer (PROC), with a total of 456 patients enrolled. The study is comparing the combination of nemvaleukin and pembrolizumab versus investigator's choice single agent chemotherapy. Mural expects to report interim overall survival (OS) results in late Q1 or early Q2 based on an analysis performed at approximately 75% of OS events. If the hazard ratio meets the bar for success (0.727, or a 27.3% reduction in the risk of death assuming exactly 215 OS events), the company plans to file a Biologics License Application (BLA) in 2025 subject to discussions with the U.S. Food and Drug Administration (FDA). The company expects to report final results in the second quarter of 2026.
- Completion of enrollment in **ARTISTRY-6, Cohort 2,** the company's potentially registrational phase 2 study of single agent nemvaleukin in patients with unresectable or metastatic mucosal melanoma, with 92 patients enrolled. Mural anticipates reporting top-line results from cohort 2 of ARTISTRY-6 in Q2 of 2025. The target response rate is 25%. Mural believes that in this rare and highly aggressive tumor with poor outcomes even in the first line setting, demonstrating durable responses with a response rate of

20-25% would be meaningful for patients, and would support a discussion with the FDA regarding a BLA submission and potential accelerated approval.

For the full updates from Mural's Investor Day, please visit the webcast on our Events & Presentations page.

Mural is also evaluating a less-frequent intravenous (LFIV) dose of nemvaleukin in patients with cutaneous melanoma in **ARTISTRY-6, Cohort 3** (monotherapy) **and Cohort 4** (combination with pembrolizumab). The company continues to expect preliminary data readouts in the monotherapy cohort in the first half of 2025, and in the combination cohort in the second half of 2025.

Preclinical Program Updates:

Mural plans to nominate development candidates for its IL-18 and IL-12 programs by the end of 2024. The company expects to submit an Investigational New Drug (IND) Application for its IL-18 program to the FDA in Q4 2025.

Other Recent Corporate Highlights:

In September, Mural announced the appointment of Sachiyo Minegishi to its board of directors and chair of the Audit Committee. Ms. Minegishi brings over two decades of biopharma experience, with a focus on corporate strategy, finance, development, and commercialization. She is currently the Chief Operating Officer at Rectify Pharmaceuticals, driving corporate and financing strategy to advance its lead program from discovery to clinical stage. Prior to Rectify, she was Chief Financial Officer at Akouos, Inc., where she led corporate finance and business development strategy and played a key role in the acquisition of the company by Eli Lilly.

In October, Mural continued to prepare for potential launch readiness by creating a new commercial division in the company. Brandon Kotaniemi, SVP of Commercial, will drive Mural's commercial strategy as the company prepares for the potential BLA submission and launch of nemvaleukin. He will also partner closely with Mural's development team as the company looks to move its IL-18 program into the clinic.

In November, Mural presented clinical and preclinical data at the 39th Annual Meeting of the Society for Immunotherapy of Cancer (SITC). The three poster presentations included tumor microenvironment pharmacodynamic data from the phase 1/2 ARTISTRY-3 study of nemvaleukin as well as data from Mural's two preclinical research programs in IL-18 and IL-12.

Financial Results for the Quarter Ended September 30, 2024:

Cash Position: As of September 30, 2024, cash, cash equivalents, and marketable securities were $175.5 million.

R&D Expenses: Research and development expenses were $27.6 million for the third quarter of 2024 compared to $40.4 million for the third quarter of 2023. This decrease in R&D expenses was primarily due to different team composition compared to the personnel previously allocated to us by Alkermes plc (Alkermes), our former parent prior to the separation, as well as decreased spend on the ARTISTRY-1 and ARTISTRY-2 trials as activities related to these trials wound down in 2023, and decreased spend on the ARTISTRY-7 trial due to the timing of patient enrollment.

G&A Expenses: General and administrative expenses were $6.5 million for the third quarter of 2024 compared to $6.0 million for the third quarter of 2023. This increase in G&A expenses was primarily due to costs associated with operating as a standalone company after the separation. This includes professional fees as well as differences in costs of insurance and taxes compared to amounts previously allocated to us by Alkermes prior to the separation.

Net Loss: Net loss was $31.8 million for the third quarter of 2024 compared to $51.3 million for the third quarter of 2023.

Financial Guidance:
The company reaffirms guidance that its cash, cash equivalents, and marketable securities as of September 30, 2024 are expected to fund its operations into the fourth quarter of 2025.

As noted previously, management forecasts lower operating expenses in 2025 versus 2024 due to the timing of clinical trial expenses.

About Mural Oncology

Mural Oncology is leveraging its novel protein engineering platform to develop cytokine-based immunotherapies for the treatment of cancer. By combining our expertise in cytokine biology and immune cell modulation and our protein engineering platform, we are developing medicines to deliver meaningful and clinical benefits to people living with cancer. Our mission is to broaden the potential, and reach, of cytokine-based immunotherapies to improve the lives of patients. Our lead candidate, nemvaleukin, is currently in potentially registrational trials in platinum-resistant ovarian cancer and mucosal melanoma reading out in the first half of 2025. Mural Oncology has its registered office in Dublin, Ireland, and its primary facilities in Waltham, Mass. For more information, visit Mural Oncology's website at www.muraloncology.com and follow us on LinkedIn and X.

About Nemvaleukin

Nemvaleukin alfa (nemvaleukin) is an engineered fusion protein designed to leverage IL-2's antitumor effects while mitigating the hallmark toxicities that limit its use. Nemvaleukin selectively binds to the intermediate-affinity IL-2 receptor (IL-2R) and is sterically occluded from binding to the high-affinity IL-2R. Because of this molecular design, nemvaleukin treatment leads to preferential expansion of antitumor CD8+ T cells and natural killer cells, with minimal expansion of immunosuppressive regulatory T cells. Nemvaleukin is currently being evaluated in two potentially registrational late-stage trials.

About Mural Oncology's IL-18 Program

IL-18 is a potent immune-stimulating cytokine, but its efficacy is blunted by IL-18 binding protein (IL-18BP), a high affinity decoy receptor that binds to, and neutralizes, IL-18, thereby rendering it ineffective. Native IL-18's potency is also limited by its short half-life. Mural Oncology's novel approach to protein engineering is designed to mitigate these issues. First, Mural introduced mutations to IL-18 that eliminate binding to IL-18BP while minimally impacting the native IL-18 structure. Second, it fused IL-18 to protein scaffolds which extend the half-life and increase IL-18's exposure. Together, these have demonstrated more durable immunological effect in preclinical studies. Mural intends to nominate a development candidate for its IL-18 program by the end of this year and file an IND submission in Q4 2025.

About Mural Oncology's IL-12 Program

Native IL-12 is a highly potent pro-inflammatory cytokine, but because of its very narrow therapeutic index, it can also be toxic with systemic exposure. To mitigate this hallmark toxicity, Mural, through its novel approach to protein engineering, split the IL-12p70 heterodimer into two inactive monomers: IL12p35 and IL-12p40. These individual subunits are then separately fused to antibody fragments and sequentially injected, which deliver and concentrate IL-12 specifically in the tumor microenvironment to limit systemic exposure. In preclinical studies, Mural's engineered IL-12 achieved the desired reduction in serum while maintaining tumor concentrations providing the potential to reduce systemic toxicities. Mural intends to nominate a development candidate for its IL-12 program by the end of this year.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding: the company's pipeline and development programs, including the expected timing of clinical updates from the ARTISTRY-6 and ARTISTRY-7 trials, the expected timing of preclinical updates, candidate nomination, and IND submission, including with respect to the Company's IL-18 and IL-12 programs, the potential of the company's product candidates and programs to address unmet medical needs, and the continued progress of its pipeline and programs. Any forward-looking statements in this press release are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. Risks that contribute to the uncertain nature of the forward-looking statements include, among others, the inherent risks and uncertainties associated with competitive developments, preclinical development, clinical trials, recruitment of patients, product development activities and regulatory approval requirements; that preclinical or interim results and data from ongoing clinical studies of the company's cytokine programs and product candidates may not be predictive of future or final results from such studies, results of future clinical studies or real-world results; future clinical trials or future stages of ongoing clinical trials may not be initiated or completed on time or at all; the company's product candidates, including nemvaleukin, could be shown to be unsafe or ineffective; changes in the cost, scope and duration of development activities; the U.S. Food and Drug Administration may make adverse decisions regarding the company's product candidates; and those other risks and uncertainties set forth in the company's filings with the Securities and Exchange Commission ("SEC"), including its Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2024 and in subsequent filings the company may make with the SEC. All forward-looking statements contained in this press release speak only as of the date of this press release. The company anticipates that subsequent events and developments will cause its views to change. However, the company undertakes no obligation to update such forward-looking statements to reflect events that occur or circumstances that exist after the date of this press release, except as required by law.

Mural Oncology plc and Subsidiaries
Consolidated Balance Sheet Data
(Unaudited)

(in thousands)	September 30, 2024	December 31, 2023
ASSETS		
Cash, cash equivalents, and marketable securities	$ 175,501	$ 270,852
Receivable from Former Parent	1,393	5,548
Prepaid expenses and other assets	6,927	937
Property and equipment, net	8,851	11,403
Right-of-use assets	8,633	12,747
Restricted cash	1,969	258
TOTAL ASSETS	$ 203,274	$ 301,745
LIABILITIES AND EQUITY		
Accounts payable and accrued expenses	$ 19,449	$ 22,919
Operating lease liabilities	9,546	15,009
Other liabilities	138	—
Total equity	174,141	263,817
TOTAL LIABILITIES AND EQUITY	$ 203,274	$ 301,745

Mural Oncology plc and Subsidiaries
Condensed Consolidated Statements of Operations
(Unaudited)

(in thousands except share and per share amounts)	Three Months Ended September 30, 2024	2023
Operating expenses		
Research and development	$ 27,585	$ 40,354
General and administrative	6,513	5,959
Total operating expenses	34,098	46,313
Operating loss	(34,098)	(46,313)
Other income	2,339	—
Income tax provision	—	(4,966)
Net loss	$ (31,759)	$ (51,279)
Net loss per ordinary share - basic and diluted	$ (1.87)	$ (3.07)
Weighted average ordinary shares outstanding - basic and diluted	17,028,552	16,689,740

Contact:

Katie Sullivan

katie.sullivan@muraloncology.com