# Purple Biotech Reports Fourth Quarter and Full-Year 2024 Financial Results

*Completed successful clinical trials for CM24 and NT219 oncology assets, demonstrating clinical benefits and identifying potential biomarkers*

*CM24 is well positioned for personalized treatment, with planned biomarker-driven Phase 2b study based on serum biomarkers CEACAM1 and myeloperoxidase*

*NT219 headed into Phase 2 head and neck cancer study in combination with pembrolizumab (anti-PD1) and in combination with cetuximab (anti-EGFR)*

*CAPTN-3 tri-specific platform yields promising preclinical data, supporting its differentiated benefit and well positioning it in the multi-specific/engagers antibody space*

REHOVOT, Israel, March 10, 2025 (GLOBE NEWSWIRE) -- Purple Biotech Ltd. ("Purple Biotech" or "the Company") (NASDAQ/TASE: PPBT), a clinical-stage company developing first-in-class therapies that seek to overcome tumor immune evasion and drug resistance, today announced financial results for the three and twelve months ended December 31, 2024.

“Our major value-driving milestones in 2024 included completing successful trials for both of our clinical-stage programs, CM24 and NT219, as well as expanding the body of exciting preclinical data for our CAPTN-3 tri-specific platform, supporting its differentiated benefit,” stated Gil Efron, Purple Biotech CEO.

“CM24 met all of its efficacy endpoints in the randomized Phase 2 second-line pancreatic cancer trial, which also generated significant biomarker data that is now informing the design of our Phase 2b study for CM24, which we plan to initiate in the second half of 2025. As a biomarker-driven study, the Phase 2b study may evaluate CM24 across multiple oncology indications.

“Earlier in 2024, we concluded the dose escalation study for NT219, demonstrating activity in combination with cetuximab, good safety profile, and determining the recommended Phase 2 dose. This enabled us to move forward with a Phase 2 study in head and neck cancer in collaboration with the University of Colorado, which we expect will commence patient enrollment in the first half of 2025.

“We believe that our CAPTN-3 platform is well-positioned and differentiated in the T cell engagers (TCE) and multi-specific space, uniquely unleashes both innate and adaptive immune cells against the tumor, demonstrating synergistic effect of the T cell and NK cell activating arms. The unique NKG2A arm in the lead compound acts as a checkpoint inhibitor, enabling simultaneous NK and T cell activation, including effector subsets with high antitumor activity. We are excited about our CAPTN-3 collaboration with the Icahn School of Medicine at Mount Sinai. Our cash runway is expected to extend into mid-2026, providing us with the time to potentially deliver on more catalysts this year, in order to achieve our ambitious programs across all three assets,” Mr. Efron concluded.

Q4 2024 and Recent Clinical & Corporate Highlights:

- **CM24 Planned to Advance into Phase 2b Study Supported by Biomarker Data**
    - **Positive final results from randomized Phase 2 study of CM24 in second line pancreatic cancer**
    - **Serum CEACAM1 biomarker associated with 79% reduction in risk of death**

Purple Biotech reported positive final results from the randomized Phase 2 study of CM24, a humanized monoclonal antibody that blocks CEACAM1, in patients with second-line pancreatic ductal adenocarcinoma (PDAC). CM24, in combination with nivolumab and Nal-IRI/5FU/LV chemotherapy, demonstrated consistent improvements across all efficacy endpoints. The enhanced results in patients with elevated CEACAM1 and other serum markers suggest that selecting a biomarker-enriched patient population could further enhance CM24's efficacy, potentially positioning it as a treatment for multiple CEACAM1-expressing malignancies in line with its mechanism of action. A biomarker-enriched patient population analysis based on pretreatment serum CEACAM1 levels demonstrated a significant improvement in the treatment arm over the control arm, with a 79% reduction in risk of death (HR 0.21, p = 0.04), a median overall survival (OS) improvement of 5.1 months, and over 90% reduction in the risk of progression or death (HR < 0.1, p = 0.003), with a median progression-free survival (PFS) improvement of 2.9 months and improvement in the objective response rate (ORR) of 50% in the treatment arm compared to 0% in the control arm.

Additional biomarker analysis revealed statistically significant results for 80% of the patients (24 out of 30) with serum CEACAM1 (5-16K pg/mL) or serum NET marker myeloperoxidase (MPO) (200-600 ng/mL) demonstrating 61% reduction in the risk of death (HR 0.39, *p*= 0.039) and 72% reduction in the risk of progression or death (PFS HR 0.28, *P* 0.006) following treatment with CM24 and nivolumab in combination with Nal-IRI/5FU/LV chemotherapy

compared to same chemotherapy alone. In addition, median PFS increased by 2.2 months, and median OS increased by 2.4 months, from 5.5 months with chemotherapy alone to 7.9 months with the combination therapy.

- **NT219 Advances into Phase 2 Head and Neck Cancer Trial**
    - **Includes treatment arm of NT219 which we combine for the first time with pembrolizumab (Keytruda) immunotherapy, as well as expansion arm of NT219 combined with cetuximab**
    - **Collaboration with University of Colorado**
    - **Latest patent in U.S. enhances global IP protection**

The Phase 2 study will evaluate the efficacy and safety of NT219 which we combine for the first time with standard-of-care checkpoint inhibitors, such as pembrolizumab (Keytruda), for the treatment of recurrent/metastatic squamous cell carcinoma of the head and neck (R/M SCCHN) and in combination with epidermal growth factor receptor (EGFR) blockers, such as cetuximab (Erbitux), which demonstrated activity in Purple Biotech's Phase 1 dose escalation study. The Phase 2 study, expected to begin in the first half of 2025, is designed with two single-arm cohorts: one will evaluate NT219 in combination with pembrolizumab, and the other will evaluate NT219 in combination with cetuximab for the treatment of R/M SCCHN. Additionally, the study will explore potential biomarkers identified in a previous clinical study of NT219. The investigator-initiated Phase 2 trial is led by Dr. Antonio Jimeno, Professor and Director of the Head and Neck Cancer Program at the University of Colorado Anschutz Medical Campus.

The U.S. Patent and Trademark Office issued a patent for NT219 used in combination with EGFR antibodies for treating cancer patients who have acquired resistance to EGFR therapies. This latest U.S. patent completes the geographic patent protection for NT219 used in combination with cetuximab in major markets, such as the United States, Europe, China and Japan. We believe this additional patent positions the Company well for the potential future commercialization of NT219.

- **CAPTN-3 Tri-Specific Antibody Platform Preclinical Studies Advance Toward First-in-Human Clinical Trials**
    - **New data presented at EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics**
    - **Research collaboration with Icahn School of Medicine at Mount Sinai**

New data on CAPTN-3 were presented at the 36th European Organization for Research and Treatment of Cancer, National Cancer Institute, American Association for Cancer Research (EORTC-NCI-AACR) Symposium on Molecular Targets and Cancer Therapeutics. CAPTN-3 demonstrated sustained tumor regression in a triple-negative breast cancer in-vivo model, as well as dose-dependent activity and a synergistic effect of the engager arms in non-small cell lung cancer patient-derived explants. IM1240, Purple's lead tribody candidate, demonstrated that cytokine release is 5T4-dependent and suppressed by the conditionally activated capping technology, suggesting a potentially beneficial safety profile.

Purple Biotech entered into a Research Collaboration Agreement with the Icahn School of Medicine at Mount Sinai in New York to explore the immunoregulation of NK and T cells within the tumor microenvironment by CAPTN-3 multi-specific engagers, designed with the purpose of enhancing tumor-specific immunity against various cancer types. This collaboration offers an opportunity to deepen the understanding of tumor immune evasion mechanisms that CAPTN-3 uniquely addresses, with the goal of paving the way for effective treatments for many challenging tumor indications. Purple Biotech is working with Principal Investigator Amir Horowitz, PhD, and his team at Mount Sinai to validate the unique aspects of the CAPTN-3 design in a wide screen of patient-derived tumors, potentially providing new insights for overcoming resistance to standard frontline immunotherapies.

**Financial Results for the Three Months Ended December 31, 2024**

**Research and Development Expenses** were $0.5 million, a decrease of $4.7 million, or 90.4%, compared to $5.2 million in the same period of 2023, primarily due to reduced clinical trials expenses.

**Sales, General and Administrative Expenses** were $0.6 million, compared to $1.0 million in the same period of 2023, a decrease of $0.4 million, or 40%, primarily due to a decrease in salary and salary related expenses and share based payment expenses.

**Operating Loss** was $1 million, a decrease of $5.3 million, or 84.1%, compared to $6.3 million in the same period of 2023, primarily due to the decrease in research and development expenses.

**Adjusted Operating Loss** (as reconciled below) was $1 million, a decrease of $5 million, compared to $6.0 million in the same period of 2023, primarily due to the decrease in research and development expenses.

**Net Loss** for the three months ended December 31, 2024, was $0.4 million, or $0.2 loss per basic ADS and $0.26 loss per diluted ADS, compared to a net loss of $4.9 million, or $3.8 per basic and diluted ADS, in the same period of 2023. The decrease in net loss was primarily due to the decrease in research and development expenses.

As of December 31, 2024, Purple Biotech had cash and cash equivalents and short-term deposits of $8.2 million, providing the Company a cash runway into mid-2026.

During the three months ended December 31, 2024, the Company raised $2.8 million through a registered direct offering. In addition, during the period the Company sold approximately 298 thousand ADSs, at an average price of $3.5 per ADS, under the Open Market Sale Agreement with Jefferies LLC, resulting in net proceeds to the Company of approximately $1.5 million, net of issuance expenses.

**Financial Results for the Twelve Months Ended December 31, 2024**

**Research and Development Expenses** were $7.6 million, a decrease of $9.4 million, or 55.3%, compared to $17 million in the same period of 2023. The decrease was primarily due to reduced clinical trials expenses.

**Sales, General and Administrative Expenses** were $3.2 million, a decrease of $2.0, or 38.5%, compared to $5.2 million in the same period of 2023, primarily due to a decrease in salary and salary related expenses and share based payment expenses.

**Operating Loss** was $11 million, a decrease of $11.3 million, or 50.7%, compared to $22.3 million in the same period of 2023, primarily due to the decrease in research and development expenses.

**Adjusted Operating Loss** (as reconciled below) was $10.4 million, a decrease of $10 million, compared to $20.4 million in the same period of 2023, primarily due to the decrease in research and development expenses.

**Net Loss** for the year ended December 31, 2024 was $7.3 million, or $4.44 loss per basic ADS and $4.99 loss per diluted ADS, compared to a net loss of $20 million, or $17.96 loss per basic and diluted ADS, in the same period of 2023. The decrease in net loss was primarily due to a $11.3 million decrease in operating expenses and a $1.4 million increase in financial income net.

**Non-IFRS Financial Measures.**

This press release includes information about certain financial measures that are not prepared in accordance with International Financial Reporting Standards ("IFRS"), including adjusted operating loss. This non-IFRS measure is not based on any standardized methodology prescribed by IFRS and is not necessarily comparable to similar measures presented by other companies. Adjusted operating loss adjusts for non-cash share-based compensation expenses. The Company's management and board of directors utilize this non-IFRS financial measure to evaluate the Company's performance. The Company provides this non-IFRS measure of the Company's performance to investors because management believes that this non-IFRS financial measure, when viewed with the Company's results under IFRS and the accompanying reconciliations, is useful in identifying underlying trends in ongoing operations. However, this non-IFRS measure is not a measure of financial performance under IFRS and, accordingly, should not be considered as an alternative to IFRS measures as indicators of operating performance. Further, this non-IFRS measure should not be considered a measure of the Company's liquidity. A reconciliation of certain IFRS to non-IFRS financial measures has been provided in the tables included in this press release.

**About Purple Biotech**

Purple Biotech Ltd. (NASDAQ/TASE: PPBT) is a clinical-stage company developing first-in-class therapies that seek to overcome tumor immune evasion and drug resistance. The Company's oncology pipeline includes CM24, NT219, and CAPTN-3. CM24 is a humanized monoclonal antibody that blocks CEACAM1, which supports tumor immune evasion and survival through multiple pathways. CEACAM1 on tumor cells, immune cells and neutrophils extracellular traps is a novel target for the treatment of multiple cancer indications. As proof of concept of these novel pathways, the Company completed a Phase 2 study for the treatment of pancreatic ductal adenocarcinoma (PDAC) with CM24 as a combination therapy with the anti-PD-1 checkpoint inhibitor nivolumab and chemotherapy, demonstrating clear and consistent improvement across all efficacy endpoints and the identification of two potential serum biomarkers. NT219 is a dual inhibitor, novel small molecule that simultaneously targets IRS1/2 and STAT3. A Phase 1 dose escalation study was concluded as a monotherapy and in combination with cetuximab, in which NT219 demonstrated anti-tumor activity in combination with cetuximab in second-line patients with recurrent and/or metastatic squamous cell carcinoma of the head and neck (R/M SCCHN). The Company is advancing NT219 into a Phase 2 study in collaboration with the University of Colorado, to treat R/M SCCHN patients in combination with cetuximab or pembrolizumab. The Company is advancing CAPTN-3, a preclinical platform of conditionally activated tri-specific antibodies, which engage both T cells and NK cells to induce a strong, localized immune response within the tumor microenvironment. The cleavable capping technology confines the compound's therapeutic activity to the local tumor microenvironment, thereby potentially increasing the anticipated therapeutic window in patients. The third arm specifically targets the Tumor Associated Antigen (TAA). The

technology presents a novel mechanism of action by unleashing both innate and adaptive immune systems to mount an optimal anti-tumoral immune response. IM1240 is the first tri-specific antibody in development that targets the 5T4 antigen, which is expressed in a variety of solid tumors and is associated with advanced disease, increased invasiveness, and poor clinical outcomes. The Company's corporate headquarters are located in Rehovot, Israel. For more information, please visit https://purple-biotech.com/.

**Forward-Looking Statements and Safe Harbor Statement**

Certain statements in this press release that are forward-looking and not statements of historical fact are forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include, but are not limited to, statements that are not statements of historical fact, and may be identified by words such as "believe", "expect", "intend", "plan", "may", "should", "could", "might", "seek", "target", "will", "project", "forecast", "continue" or "anticipate" or their negatives or variations of these words or other comparable words or by the fact that these statements do not relate strictly to historical matters. You should not place undue reliance on these forward-looking statements, which are not guarantees of future performance. Forward-looking statements reflect our current views, expectations, beliefs or intentions with respect to future events, and are subject to a number of assumptions, involve known and unknown risks, many of which are beyond our control, as well as uncertainties and other factors that may cause our actual results, performance or achievements to be significantly different from any future results, performance or achievements expressed or implied by the forward-looking statements. Important factors that could cause or contribute to such differences include, among others, risks relating to: the plans, strategies and objectives of management for future operations; product development for NT219, CM24 and IM1240; the process by which such early stage therapeutic candidates could potentially lead to an approved drug product is long and subject to highly significant risks, particularly with respect to a joint development collaboration; the fact that drug development and commercialization involves a lengthy and expensive process with uncertain outcomes; our ability to successfully develop and commercialize our pharmaceutical products; the expense, length, progress and results of any clinical trials; the impact of any changes in regulation and legislation that could affect the pharmaceutical industry; the difficulty in receiving the regulatory approvals necessary in order to commercialize our products; the difficulty of predicting actions of the U.S. Food and Drug Administration or any other applicable regulator of pharmaceutical products; the regulatory environment and changes in the health policies and regimes in the countries in which we operate; the uncertainty surrounding the actual market reception to our pharmaceutical products once cleared for marketing in a particular market; the introduction of competing products; patents obtained by competitors; dependence on the effectiveness of our patents and other protections for innovative products; our ability to obtain, maintain and defend issued patents; the commencement of any patent interference or infringement action against our patents, and our ability to prevail, obtain a favorable decision or recover damages in any such action; and the exposure to litigation, including patent litigation, and/or regulatory actions, and other factors that are discussed in our Annual Report on Form 20-F for the year ended December 31, 2024 and in our other filings with the U.S. Securities and Exchange Commission ("SEC"), including our cautionary discussion of risks and uncertainties under "Risk Factors" in our Registration Statements and Annual Reports. These are factors that we believe could cause our actual results to differ materially from expected results. Other factors besides those we have listed could also adversely affect us. Any forward-looking statement in this press release speaks only as of the date which it is made. We disclaim any intention or obligation to publicly update or revise any forward-looking statement or other information contained herein, whether as a result of new information, future events or otherwise, except as required by applicable law. You are advised, however, to consult any additional disclosures we make in our reports to the SEC, which are available on the SEC's website, https://www.sec.gov.

**CONTACTS:**

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**Purple Biotech Ltd.**

**Consolidated Statements of Financial Position as of December 31,**

| | 2024<br>USD thousands | 2023<br>USD thousands |
|---|---|---|
| **Assets** | | |
| Cash and cash equivalents | **7,401** | 14,489 |
| Short term deposits | **848** | 850 |
| Other investments | **275** | 73 |
| Other current assets | **384** | 376 |

| | | |
|---|---|---|
| **Total current assets** | **8,908** | 15,788 |
| | | |
| **Non-current assets** | | |
| Right to use assets | **164** | 316 |
| Fixed assets, net | **124** | 154 |
| Intangible assets | **27,842** | 28,044 |
| | | |
| **Total non - current assets** | **28,130** | 28,514 |
| | | |
| **Total assets** | **37,038** | 44,302 |
| | | |
| **Liabilities** | | |
| Current maturity of lease liabilities | **183** | 188 |
| Trade payable | **1,455** | 3,532 |
| Warrants | **1,149** | (*)2,518 |
| Other payables | **1,200** | 3,463 |
| | | |
| **Total current liabilities** | **3,987** | 9,701 |
| | | |
| **Non-current liabilities** | | |
| | | |
| Lease liability | **-** | 163 |
| Post-employment benefit liabilities | **140** | 141 |
| | | |
| **Total non - current liabilities** | **140** | 304 |
| | | |
| **Equity** | | |
| | | |
| Share capital, no par value | - | - |
| Share premium | **147,631** | 133,184 |
| Receipts on account of warrants | **21,145** | 28,467 |
| Capital reserve for share-based payments | **8,875** | 10,088 |
| Capital reserve from transactions with related parties | **761** | 761 |
| Capital reserve from hedging | **-** | 19 |
| Capital reserve from transactions with non- controlling interest | **(859)** | (859) |
| Accumulated loss | **(144,693)** | (137,453) |
| | | |
| Equity attributable to owners of the Company | **32,860** | 34,207 |
| Non-controlling interests | **51** | 90 |
| **Total equity** | **32,911** | 34,297 |
| | | |
| **Total liabilities and equity** | **37,038** | 44,302 |

* Restated following amendments to IAS 1

**Consolidated Unaudited Statements of Operations and Other Comprehensive Loss**

| | For the year ended December 31, | | For the three months ended December 31, | |
|---|---|---|---|---|
| | **2024** | **2023** | **2024** | **2023** |
| | **USD thousands** | **USD thousands** | **USD thousands** | **USD thousands** |
| Research and development expenses | **7,620** | 17,034 | **458** | 5,242 |
| Sales, general and administrative expenses | **3,183** | 5,237 | **558** | 1,025 |
| Impairment loss | **202** | - | **-** | - |
| | | | | |
| **Operating Loss** | **11,005** | 22,271 | **1,016** | 6,267 |
| | | | | |
| Change in fair value of warrants | **(3,341)** | (3,497) | **(76)** | (3,497) |
| Finance expenses | **483** | 2,195 | **(69)** | 2,089 |
| Finance income | **(868)** | (992) | **(456)** | - |

| | | | | |
|---|---|---|---|---|
| **Finance income, net** | **(3,726)** | (2,294) | **(601)** | (1,408) |
| **Loss for the period** | **7,279** | 19,977 | **415** | 4,859 |
| **Other comprehensive loss:** | | | | |
| **Items that will be transferred to profit or loss:** | | | | |
| Loss (profit) from cash flow hedges | **19** | (25) | **(2)** | (21) |
| **Total comprehensive loss for the period** | **7,298** | 19,952 | **413** | 4,838 |
| **Loss attributable to:** | | | | |
| Owners of the Company | **7,240** | 19,880 | **410** | 4,828 |
| Non-controlling interests | **39** | 97 | **5** | 31 |
| | **7,279** | 19,977 | **415** | 4,859 |
| **Total comprehensive loss attributable to:** | | | | |
| Owners of the Company | **7,259** | 19,855 | **408** | 4,807 |
| Non-controlling interests | **39** | 97 | **5** | 31 |
| | **7,298** | 19,952 | **413** | 4,838 |
| **Loss per share data** | | | | |
| Basic loss per ADS - USD | **4.44** | (*)17.96 | **(*)0.20** | 3.8 |
| Diluted loss per ADS - USD | **4.99** | (*)17.96 | **(*)0.26** | 3.8 |
| Number of ADSs used in calculating basic loss per ADS | **1,639,566** | (*)1,106,665 | **(*)2,048,319** | (*)1,289,488 |
| Number of ADSs used in calculating diluted loss per ADS | **1,639,787** | (*)1,106,665 | **2,048,764** | (*)1,289,488 |

* Restated to reflect a 1:20 reverse ratio of the ADS's, that took place September 2024.

**Consolidated Statements of Cash Flows for the year ended December 31,**

| | **2024** | **2023** |
|---|---|---|
| **Cash flows from operating activities:** | | |
| Loss for the year | **(7,279)** | (19,977) |
| Adjustments: | | |
| Depreciation | **186** | 197 |
| Impairment loss | **202** | - |
| Finance income, net | **(3,726)** | (2,294) |
| Share-based payments | **582** | 1,875 |
| | **(10,035)** | (20,199) |
| **Changes in assets and liabilities:** | | |
| Changes in other current assets | **96** | 178 |
| Changes in trade payables | **(2,076)** | 1,334 |
| Changes in other payables | **(2,352)** | (1,076) |
| Changes in post-employment benefit liabilities | **-** | (162) |
| | **(4,332)** | 274 |
| **Net cash used in operating activities** | **(14,367)** | (19,925) |
| **Cash flows from investing activities:** | | |
| Acquisition of subsidiary, net of cash acquired | **-** | (3,549) |
| Proceed from other investments | **187** | 875 |
| Acquisition of intangible asset | **-** | - |
| Decrease in short term deposits | **2** | 15,803 |
| Decrease in long term deposits | **-** | - |

| | | |
|---|---|---|
| Interest received | **320** | 755 |
| Acquisition of fixed assets | **-** | (3) |
| **Net cash provided by investing activities** | **509** | 13,881 |
| | | |
| **Cash flows from financing activities:** | | |
| Proceeds from issuance of ADSs | **5,809** | 1,563 |
| ADS issuance expenses paid | **(556)** | (229) |
| Proceeds from issuance of warrants and prefunded warrants | **-** | 5,000 |
| Proceeds from warrant inducement transaction | **2,028** | - |
| Warrants issuance expenses paid | **(280)** | (661) |
| Repayment of lease liability | **(183)** | (168) |
| Interest paid | **(44)** | (56) |
| **Net cash provided by financing activities** | **6,774** | 5,449 |
| | | |
| **Net increase (decrease) in cash and cash equivalents** | **(7,084)** | (595) |
| **Cash and cash equivalents at the beginning of the year** | **14,489** | 15,030 |
| **Effect of translation adjustments on cash and cash equivalents** | **(4)** | 54 |
| **Cash and cash equivalents at end of the year** | **7,401** | 14,489 |

**Reconciliation of Non-IFRS Financial Results**

**Reconciliation of Adjusted Operating Loss**

| | **For the year ended December 31,** | | **For the three months ended December 31,** | |
|---|---|---|---|---|
| | **2024** | **2023** | **2024** | **2023** |
| | **USD thousands** | **USD thousands** | **USD thousands** | **USD thousands** |
| Operating loss for the period | **11,005** | 22,271 | **1,016** | 6,267 |
| Less ESOP expenses | **(582)** | (1,875) | **34** | (181) |
| | **10,423** | 20,396 | **1,050** | 6,086 |