



Press release – For immediate release
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Median Technologies Reports 2024 Q3 Operational and Financial Update and 2024 Half-Year Results

- eyonis™ LCS pivotal REALITY study met all primary and secondary endpoints
- A webcast including Key Opinion Leaders will be held on November 7, 2024, to discuss the REALITY study results
- On track to file U.S. & European marketing authorization for eyonis™ LCS in H1 2025
- €6.2 million Q3 2024 quarterly revenue, second highest ever, up 10.7% vs Q3 2023
- €17.1 million total year-to-date revenue as of September 30, 2024
- First 2 projects awarded in Q3 to Median iCRO as preferred provider to a Top 3 pharma in oncology
- €11.5 million cash and cash equivalents as of September 30, 2024

Sophia Antipolis, France - Median Technologies (*FROO11049824, ALMDT, PEA/SME eligible, “Median” or “The Company”*), a leading developer of eyonis™, a suite of artificial intelligence (AI) powered Software as a Medical Device (SaMD) for early cancer diagnostics, and a globally leading provider of AI analyses and imaging services for oncology drug developers, announces today that its Board of Directors approved the consolidated IFRS financial statements for the first half of 2024 on October 23, 2024, and provides operational and financial updates from the third quarter of 2024.

Fredrik Brag, CEO and Founder of Median Technologies, said: *“We are extremely encouraged that our wholly owned lead SaMD¹ eyonis™ Lung Cancer Screening (LCS) met all primary and secondary endpoints in REALITY during the third quarter. This was the first of two pivotal studies for this promising early lung cancer diagnostic candidate. We look forward to communicating data from RELIVE, the ongoing second pivotal trial of eyonis™ LCS in the coming months. In parallel, we are already getting ready to rapidly complete U.S. and European regulatory filings for marketing authorizations in the first half of 2025.*

“Lung cancer is the number one cancer killer because it is usually diagnosed too late. We believe eyonis™ LCS will enable physicians to diagnose lung cancer earlier – when it may still be cured. Curing early-stage lung cancer would also mean avoiding extremely costly advanced cancer care – offering tremendous savings for our healthcare systems globally. In the U.S, Lung Cancer Screening has been reimbursed since 2015. However, its broad adoption is hampered by the absence of approved software as medical devices proven to provide reliable and accurate early diagnosis, which is what the eyonis™ LCS aims to achieve.

“We also are delighted to report Q3 saw continuing revenue growth of our iCRO business unit. We have rapidly become the preferred partner for biopharma companies globally, including two of the top three global pharma companies in oncology. In addition, during Q3, we have established lucrative new deals in South Korea and Japan. Median iCRO’s central imaging services have offered trusted efficiency

¹ SaMD: Software as a Medical Device



for over a decade now, and our new and advanced AI analyses capabilities offer valuable knowledge, so our clients can conduct more efficient, and data driven drug development.”

Q3 2024 Operational and Financial Update

eyonis™ LCS SaMD: further to major advances in pivotal studies, regulatory submissions to obtain marketing authorizations, FDA 510(k) clearance and CE marking, are planned in H1 2025

The Company released in August the definitive positive results from REALITY ([Clinicaltrials.gov identifier: NCT06576232](https://clinicaltrials.gov/ct2/show/study/NCT06576232)), the first of the two pivotal eyonis™ LCS clinical studies, evaluating the standalone performance of eyonis™ LCS for accurately diagnosing lung cancer. Despite the inclusion of many challenging Low Dose Computed Tomography (LDCT) images, the eyonis™ LCS SaMD achieved exceptional results and met all primary and secondary endpoints with statistical significance. eyonis™ LCS achieved an area under the curve (AUC) value of 0.904 at patient level versus an AUC of 0.80 – the minimum value set as the primary endpoint for REALITY.

The positive REALITY outcome is a particularly impressive demonstration of the Median SaMD’s AI powered capability given the unusually challenging patient data that participating sites provided for analysis during the study. REALITY was enriched, compared to an average patient population, with small non-spiculated cancers, and large spiculated benign nodules, both of which are challenging for radiologists to diagnose in a real-world setting, without any robust computer-aided diagnosis system. A full 80% of the staged LDCT images included in the study were considered by the sites providing them to be difficult-to-diagnose Stage 1 cancers. The REALITY analyses by eyonis™ LCS were conducted on data from 1,147 patients provided by five major cancer centers in the US and Europe and two clinical data providers.

A webcast will be held on November 7, 2024, including internationally renowned Key Opinion Leaders who participated in the REALITY study, to discuss what these data mean for pulmonologists like themselves who regularly treat lung cancer patients in their clinical practice. An invitation with the specifics will be published shortly.

The second pivotal trial, RELIVE, is a *Multi-Reader Multi-Case* (MRMC) study that will offer clinical validation of eyonis™ LCS to complement the analytical validation already achieved with REALITY. The RELIVE study objective is to compare the ability of radiologists to successfully diagnose lung cancer in patients with or without the help of eyonis™ LCS. RELIVE is ongoing and scheduled for completion in the coming months, with an anticipated data read-out in Q1 2025.

Median Technologies expects to submit regulatory filings in the US for eyonis™ LCS FDA 510(k) clearance and for CE mark in Europe in H1 2025. In addition, the company is preparing health economic studies to demonstrate the compelling life- and cost-saving benefits of eyonis™ LCS SaMD, which it expects to strongly support reimbursement with payers in the U.S. and Europe. Median also is in active discussion with a variety of potential regional and global distribution partners to prepare commercialization of eyonis™ LCS primarily in the US.



iCRO business performance and major achievements in Q3, 2024

Median Technologies' iCRO business delivers trusted central imaging services paired with unparalleled AI image analyses. Oncology drug developers all around the world work with Median iCRO, including two of the top three pharmaceutical companies (based on oncology sales), both of which have designated Median iCRO as "preferred provider", and many more leading oncology companies. As of today, the iCRO business unit has supported over 270 cancer trials, including more than 100 Phase III studies. Launched in 2022, the iCRO Imaging Lab provides partners with AI and machine learning for a diverse array of complex oncology drug development challenges. The iCRO's AI image analysis capabilities offer a powerful catalyst to increase the attractiveness of Median's imaging services to biopharmaceutical companies and unique added value compared to competitors.

In August 2024, the Company announced the [signature of an initial agreement](#) with a Top 10 oncology pharmaceutical company². The agreement aims at conducting AI-based imaging biomarker³ discovery on the clinical data of a drug candidate and could lead to a broader collaboration between the pharmaceutical company and Median. The drug-specific imaging biomarkers could ultimately be utilized as companion diagnostics⁴ to select patients who are most likely to benefit from the drug. The agreement involves Imaging Lab, a dedicated entity of Median's iCRO Business Unit, providing biopharma companies with advanced AI-based decision-making capabilities.

In September 2024, earlier than expected, Median was awarded two initial studies as part of its [preferred provider status](#) with the recently signed top 3 pharmaceutical company. This client has the largest pipeline of studies in oncology and could provide significant growth for Median in the coming quarters.

In September 2024, Median's offices in Shanghai obtained the ISO 9001:2015 Certification for the provision of software development of image evaluation and data processing for clinical trials, and the provision of independent image evaluation service solution for clinical trials. The ISO 9001:2015 certification represents a key milestone for Median. In addition, earlier this year, Median was awarded its first deals in Japan and South Korea for a total amount of €3.1 million. The Company expects the combination of these new Asian deals outside China, together with the newly obtained ISO 9001:2015 certification, to be strong catalysts for future sales in the dynamic East Asia clinical trial market.

The Company's Q3 2024 revenue was €6.2 million, up 10.7% from Q2 2024 (€5.6 million) and 10.7% compared to Q3 2023 revenue (€5.6 million). Q3 2024 revenue is the second highest quarterly revenue ever recorded by the Company.

Year-to-Date revenue amounted to €17.1 million, as of September 30, 2024, a slight increase compared to 2023 revenue over the same period. Strong levels of revenue in the third quarter made it possible to make up for the delays accumulated, primarily in China, during the first half of the year. All revenue comes from Median Technologies' iCRO business unit.

² Arjun Murthy – Top 15 biopharma companies by Oncology Sales in 2023

³ An imaging biomarker is a "defined characteristic that is measured as an indicator of normal biological processes, pathogenic processes or responses to an exposure or intervention, including therapeutic interventions" - <https://www.ncbi.nlm.nih.gov/books/NBK326791/>

⁴ <https://www.fda.gov/medical-devices/in-vitro-diagnostics/companion-diagnostics>

The order backlog⁵ stood at €68.2 million on September 30, 2024, vs €71.7 million as of June 30, 2024, and vs €62.7 million on September 30, 2023. In Q3 2024, the order backlog was negatively impacted by the Euros to US Dollars exchange rate.

Cash and cash equivalents of €11.5 million on September 30, 2024

Median Technologies' cash and cash equivalents stand at €11.5 million, as of September 30, 2024, compared to €16 million as of June 30, 2024. The cash position doesn't include the France's 2023 research and innovation tax credit expected at €1.6 million this year, which had not yet been received as of September 30, 2024.

The Company's operations are fully financed until the second quarter of 2025.

Moreover, Median has received approval from the European Investment Bank (EIB) to extend the maturity of its 2020 loan by six months until October 2025, subject to completion of legal documentation, and there are several options, currently in negotiation, to increase the cash runway including (but not limited to) finalizing an agreement with the EIB to establish a new financing facility; significant operational improvements to enhance the profitability of the iCRO business unit; as well as additional funding from strategic partners.

Based on these elements, the going concern assumption was adopted by the Board of Directors when approving the 2024 half-year financial statements.

H1 2024 Financial Highlights (IFRS consolidated financial statements)

Consolidated Statement of Cash-Flow

Cash flow (€ thousands)	06/30/2024 (6 months)	06/30/2023 (6 months)
Operating cash flow	(11,348)	(9,045)
Change in operating working capital requirement	1,058	(2,668)
Net cash flow from operating activities	(10,909)	(12,083)
Net cash flow from investing activities	(662)	(514)
Net cash flow from financing activities	8,020	(324)
Impact of changes in exchange rates	47	(207)
Net change in cash and cash equivalents	(3,503)	(13,128)
Cash at beginning of period	19,495	21,467
Cash at end of period	15,992	8,338

The €2.3 million increase in operating cash flow burn was offset by a working capital improvement of €3.7 million. Additionally, Median drew down a €8.5 million tranche of the 2019 EIB financing agreement early January, which resulted in an improved cash position at June end versus previous year.

⁵ The order backlog is the sum of orders received but not yet fulfilled. An increase or decrease in the order backlog corresponds to the order intake of the reporting period, net of invoiced services, completed or cancelled contracts, and currency impact for projects in foreign currency (re-evaluated at the exchange rate on closing date). Orders are booked once the customer confirms, in writing, its retention of the Company's services for a given project. The contract is usually signed a few months after written confirmation.

Net consolidated income statement under IFRS accounting rules

€ thousands	H1 2024	H1 2023
Revenue from ordinary activities	10,936	11,394
Personnel costs	(13,391)	(13,360)
External costs	(10,260)	(8,910)
Operating profit (loss)	(13,295)	(11,189)
Net financial income	853	1,221
Net profit (loss)	(12,457)	(10,088)

H1 2024 revenues were €10.9 million, versus €11.4 million in H1 2023, due to delays experienced on some sizeable projects that have been recovered since then, in Q3 2024. All revenue comes from the iCRO business.

Personnel costs remained stable in H1 2024 compared to H1 2023, as an increase of €1.0 million in payroll expenses, was offset by lesser share-based payments in an equivalent amount.

External costs amounted to €10.3 million as of June 30, 2024, compared with €8.9 million a year before. The €1.4 million difference in expenses essentially reflects an increase in Median's IT infrastructure costs to support the eyonis™ LCS development, and an increase in image reading costs (iCRO business).

Net financial income, which is a non-cash item mainly driven by stock price fluctuations, decreased by €0.4 million.

Median Technologies informs its shareholders and the financial community that its half year financial report on the accounts for the half year ending June 30, 2024, has been made available and filed with the French financial market authority (Autorité des Marchés Financiers).

The half year financial report is available on the Company's website:

<http://www.mediantechologies.com/investors/>

About eyonis™ LCS: eyonis™ Lung Cancer Screening (LCS) is an artificial intelligence (AI) powered diagnostic device that uses machine learning to help analyze imaging data generated with low dose computed tomography (LDCT) to diagnose lung cancer at the earliest stages, when it can still be cured in many patients. eyonis™ LCS has been classified by regulators as "Software as Medical Device", or SaMD, and is the subject of two pivotal studies required for marketing approvals in the U.S. and Europe: REALITY (successfully completed) and RELIVE (ongoing). Filing applications including these pivotal data are scheduled to be submitted for FDA 510(k) premarket clearance and CEmarking in 2025. Separately, Median's AI technology is being sold and deployed across cancer indications, via Median's iCRO business unit, to companies performing clinical trials of experimental therapeutics, including the world's leading pharmaceutical companies in cancer.

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About Median Technologies: Pioneering innovative imaging solutions and services, Median Technologies harnesses cutting-edge AI to enhance the accuracy of early cancer diagnoses and treatments. Median's offerings include iCRO, which provides medical image analysis and management in oncology trials, and eyonis™, an AI/ML tech-based suite of software as medical devices (SaMD). Median empowers biopharmaceutical entities and clinicians to advance patient care and expedite the development of novel therapies. The French-based company, with a presence in the U.S. and China, trades on the Euronext Growth market (ISIN: FR0011049824, ticker: ALMDT). Median is also eligible for the French SME equity savings plan scheme (PEA-PME). For more information, visit www.mediantechnologies.com.

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Forward-Looking Statements

This press release contains forward-looking statements. These statements are not historical facts. They include projections and estimates as well as the assumptions on which these are based, statements concerning projects, objectives, intentions, and expectations with respect to future financial results, events, operations, services, product development and potential, or future performance.

These forward-looking statements can often be identified by the words "expects," "anticipates," "believes," "intends," "estimates" or "plans" and any other similar expressions. Although Median's management believes that these forward-looking statements are reasonable, investors are cautioned that forward-looking statements are subject to numerous risks and uncertainties, many of which are difficult to predict and generally beyond the control of Median Technologies, that could cause actual results and events to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements.

All forward-looking statements in this press release are based on information available to Median Technologies as of the date of the press release. Median Technologies does not undertake to update any forward-looking information or statements, subject to applicable regulations, in particular Articles 223-1 et seq. of the General Regulation of the French Autorité des Marchés Financiers.