

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO SECTION 13A-16 OR 15D-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of February 2025

Commission File Number: 001-41316

Alpha Tau Medical Ltd.
(Exact Name of Registrant as Specified in Its Charter)

Kiryat HaMada St. 5
Jerusalem, Israel 9777605
+972 (3) 577-4115
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F Form 40-F

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On February 24, 2025, Alpha Tau Medical Ltd. (the "Company") issued a press release titled "Alpha Tau Receives Medical Device Single Audit Program (MDSAP) Certification." A copy of this press release is attached to this Form 6-K as Exhibit 99.1.

The information in this Report on Form 6-K, including in Exhibit 99.1 attached hereto is being furnished and shall not be deemed "filed" for the 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 made by the Company under the Securities Act of 1933, as amended, or the Exchange Act, except as otherwise set forth herein or as shall be expressly set forth by specific reference in such a filing.

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EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated February 24, 2025.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Alpha Tau Medical Ltd.

By: /s/ Uzi Sofer
Uzi Sofer
Chief Executive Officer

Date: February 24, 2025

Alpha Tau Receives Medical Device Single Audit Program (MDSAP) Certification

JERUSALEM, February 24, 2025 -- Alpha Tau Medical Ltd. ("Alpha Tau", or the "Company") (NASDAQ: DRTS, DRTSW), the developer of the innovative alpha-radiation cancer therapy Alpha DaRT®, today announced the achievement of Medical Device Single Audit Program (MDSAP) certification for the company's manufacturing facility in Jerusalem, as part of the Company's commitment to quality, safety, and regulatory compliance while accelerating the global expansion of alpha-radiation cancer therapy through the manufacturing of the Alpha DaRT.

MDSAP was established by a coalition of international medical device regulatory authorities from Australia, Brazil, Canada, Japan and the U.S., to enable medical device manufacturers to be audited once for compliance with ISO 13485 and the standards of these five different markets. MDSAP certification may also speed the timetable to commercialization within these participating geographies, as it allows for a streamlined auditing process, providing manufacturers with a comprehensive approach to meet international regulatory standards efficiently.

"This milestone underscores our ability to expand our manufacturing capabilities expediently and efficiently as we continue to pursue marketing approvals across multiple geographies," said Uzi Sofer, CEO of Alpha Tau. "We are hopeful that this will also expedite our progress in bringing to market a game-changing product for the treatment of solid tumors."

"This huge achievement was made possible by the diligent work of our teams across regulatory, QA, R&D, production and engineering, who remain ever committed to delivering high-end innovative quality products while continually increasing production capacity to meet the growing demand for our products in clinical trials," said Yaniv Sagie, VP of Quality & Regulatory Affairs at Alpha Tau.

About Alpha Tau Medical Ltd.

Founded in 2016, Alpha Tau is an Israeli oncology therapeutics company that focuses on research, development, and potential commercialization of the Alpha DaRT for the treatment of solid tumors. The technology was initially developed by Prof. Itzhak Kelson and Prof. Yona Keisari from Tel Aviv University.

About Alpha DaRT®

Alpha DaRT (Diffusing Alpha-emitters Radiation Therapy) is designed to enable highly potent and conformal alpha-irradiation of solid tumors by intratumoral delivery of radium-224 impregnated sources. When the radium decays, its short-lived daughters are released from the sources and disperse while emitting high-energy alpha particles with the goal of destroying the tumor. Since the alpha-emitting atoms diffuse only a short distance, Alpha DaRT aims to mainly affect the tumor, and to spare the healthy tissue around it.

Forward-Looking Statements

This press release includes "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. When used herein, words including "anticipate," "being," "will," "plan," "may," "continue," and similar expressions are intended to identify forward-looking statements. In addition, any statements or information that refer to expectations, beliefs, plans, projections, objectives, performance or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking. All forward-looking statements are based upon Alpha Tau's current expectations and various assumptions. Alpha Tau believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain. Alpha Tau may not realize its expectations, and its beliefs may not prove correct. Actual results could differ materially from those described or implied by such forward-looking statements as a result of various important factors, including, without limitation: (i) Alpha Tau's ability to receive regulatory approval for its Alpha DaRT technology or any future products or product candidates; (ii) Alpha Tau's limited operating history; (iii) Alpha Tau's incurrence of significant losses to date; (iv) Alpha Tau's need for additional funding and ability to raise capital when needed; (v) Alpha Tau's limited experience in medical device discovery and development; (vi) Alpha Tau's dependence on the success and commercialization of the Alpha DaRT technology; (vii) the failure of preliminary data from Alpha Tau's clinical studies to predict final study results; (viii) failure of Alpha Tau's early clinical studies or preclinical studies to predict future clinical studies; (ix) Alpha Tau's ability to enroll patients in its clinical trials; (x) undesirable side effects caused by Alpha Tau's Alpha DaRT technology or any future products or product candidates; (xi) Alpha Tau's exposure to patent infringement lawsuits; (xii) Alpha Tau's ability to comply with the extensive regulations applicable to it; (xiii) the ability to meet Nasdaq's listing standards; (xiv) costs related to being a public company; (xv) changes in applicable laws or regulations; and the other important factors discussed under the caption "Risk Factors" in Alpha Tau's annual report filed on form 20-F with the SEC on March 7, 2024, and other filings that Alpha Tau may make with the United States Securities and Exchange Commission. These and other important factors could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While Alpha Tau may elect to update such forward-looking statements at some point in the future, except as required by law, it disclaims any obligation to do so, even if subsequent events cause its views to change. These forward-looking statements should not be relied upon as representing Alpha Tau's views as of any date subsequent to the date of this press release.

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