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): September 16, 2025

Pasithea Therapeutics Corp.
(Exact name of registrant as specified in its charter)

Delaware	**001-40804**	**85-1591963**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

1111 Lincoln Road, Suite 500 Miami Beach, Florida	**33139**
(Address of principal executive offices)	(Zip Code)

(786) 977-3380
(Registrant's telephone number, including area code)

N/A
(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:

☐ 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**
Common Stock, par value $0.0001 per share	KTTA	The Nasdaq Capital Market
Warrants to purchase shares of Common Stock, par value $0.0001 per share	KTTAW	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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 7.01 Regulation FD

On September 16, 2025, Pasithea Therapeutics Corp. (the "Company") issued the Press Release (as defined below). A copy of the Press Release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is hereby incorporated by reference herein.

The information in this Current Report on Form 8-K under Item 7.01, including the information contained in Exhibit 99.1, is being furnished to the Securities and Exchange Commission, and shall not be deemed to be "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, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by a specific reference in such filing.

Item 8.01 Other Events.

On September 16, 2025, the Company issued a press release (the "Press Release") relating to its Phase 1/1b open-label study to assess the safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of PAS-004 in adult participants with neurofibromatosis type 1 (NF1) (the "NF1 Trial"), announcing the activation of two clinical trial sites in South Korea—Asan Medical Centre and Severance Hospital Yonsei University Health System. These sites are now actively recruiting trial participants, and the first patient in South Korea has been dosed.

Beyond South Korea, the NF1 Trial is currently enrolling patients in Cohort 2, 8mg tablet, following the recent recommendation by the external Safety Review Committee to proceed past Cohort 1, 4mg tablet, without modification. Initial interim clinical data from the first two cohorts of the NF1 Trial is expected in the first quarter of 2026.

Forward Looking Statements

This Current Report on Form 8-K contains statements that constitute "forward-looking statements" made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include statements regarding the Company's ongoing Phase 1 clinical trial of PAS-004 in advanced cancer patients, the Company's ongoing Phase 1/1b clinical trial of PAS-004 in adult NF1 patients with NF1-associated plexiform neurofibromas, and the safety, tolerability, pharmacokinetic (PK), pharmacodynamics (PD) and preliminary efficacy of PAS-004, as well as all other statements, other than statements of historical fact, regarding the Company's current views and assumptions with respect to future events regarding its business, as well as other statements with respect to the Company's plans, assumptions, expectations, beliefs and objectives, the success of the Company's current and future business strategies, product development, pre-clinical studies, clinical studies, clinical and regulatory timelines, market opportunity, competitive position, business strategies, potential growth and financing opportunities and other statements that are predictive in nature. Forward-looking statements are subject to numerous conditions, many of which are beyond the control of the Company. While the Company believes these forward-looking statements are reasonable, undue reliance should not be placed on any such forward-looking statements, which are based on information available to the Company on the date of this Current Report. These forward-looking statements are based upon current estimates and assumptions and are subject to various risks and uncertainties, including risks that future clinical trial results may not match results observed to date, may be negative or ambiguous, or may not reach the level of statistical significance required for regulatory approval, as well as other factors set forth in the Company's most recent Annual Report on Form 10-K, Quarterly Report on Form 10-Q and other filings made with the U.S. Securities and Exchange Commission (SEC). Thus, actual results could be materially different. The Company undertakes no obligation to update these statements whether as a result of new information, future events or otherwise, after the date of this Current Report, except as required by law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated September 16, 2025.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURE

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.

PASITHEA THERAPEUTICS CORP.

Date: September 16, 2025

By: */s/ Tiago Reis Marques*
Name: Tiago Reis Marques
Title: Chief Executive Officer

Exhibit 99.1

Pasithea Therapeutics Announces Activation of Clinical Trial Sites in South Korea for Phase 1/1b Trial of PAS-004 in Adult NF1 Patients

-- First patient in South Korea dosed --

MIAMI, FL., September 16, 2025 (GLOBE NEWSWIRE) - Pasithea Therapeutics Corp. (NASDAQ: KTTA) ("Pasithea" or the "Company"), a clinical-stage biotechnology company developing PAS-004, a next-generation macrocyclic MEK inhibitor today announced activation of two South Korean clinical trial sites participating in its Phase 1/1b open label study to assess the safety, tolerability, pharmacokinetics (PK) and pharmacodynamics (PD) of PAS-004, in adult participants with neurofibromatosis type 1 (NF1) with symptomatic and inoperable, incompletely resected, or recurrent plexiform neurofibromas.

The South Korea clinical trial sites, ASAN Medical Centre and Severance Hospital Yonsei University Health System, are now actively recruiting NF1 trial participants.

Professor Lee Beom-Hee of the Department of Pediatrics at Asan Medical Center said, "I am very pleased to partner with the Pasithea team to initiate testing of PAS-004 in adult patients with plexiform neurofibromas associated with NF1 at Asan Medical Center. Our institution has the largest NF1 caseload in South Korea and a long history of research leadership in this field. Our team was among the first to report the therapeutic benefits of MEK inhibition on neurocognitive decline, café-au-lait spots, and growth retardation caused by neurofibromatosis. We are eager to evaluate PAS-004, a next-generation MEK inhibitor that to date has demonstrated a distinct pharmacokinetic profile and a more convenient dosing regimen, which we believe may provide important benefits for our NF1 patients."

Dr. Tiago Reis Marques, chief executive officer of Pasithea commented, "With access to world-class facilities and an estimated 10,000 NF1 patients in South Korea, we believe our clinical sites in the country will play a pivotal role in the success of this trial. We are excited to include South Korean patients in our NF1 study and look forward to advancing meaningful treatment options for this community."

Asan Medical Center is a reference hospital and the teaching hospital of the University of Ulsan College of Medicine, located in Seoul, South Korea. With 2,432 beds for patients and a total floor area of approximately 280,000 square meters, it is the largest hospital in South Korea.

Severance Hospital is a teaching hospital located in Sinchon-dong, Seodaemun District, South Korea. It is one of the oldest and biggest university hospitals in South Korea. It has 2,437 beds and treats approximately 2,500,000 outpatients and 840,000 inpatients annually.

About the Phase 1/1b Clinical Trial in Adult NF1 Patients

The primary objective of the Phase 1/1b study (NCT06961565) is to evaluate the safety and tolerability of PAS-004 when administered for one 28-day treatment cycle in adult NF1 participants with at least one and up to two additional target plexiform neurofibromas (PNs) that are symptomatic and inoperable, incompletely resected, or recurrent. Secondary objectives are (i) to identify the recommended Part B dose ("RPBD") or Maximum Tolerated Dose (MTD) of PAS-004, (ii) to characterize the PK and PD profile of PAS-004, (iii) to evaluate the preliminary efficacy of PAS-004 on target PN volume, (iv) to evaluate the preliminary efficacy of PAS-004 on the size, appearance, and associated symptoms of cutaneous neurofibromas (CNs), and (v) to evaluate the impact of PAS-004 on quality of life ("QOL") and any physical symptoms attributed to the target PN. Experimental objectives are (i) to evaluate the impact of PAS-004 on QOL and any physical symptoms attributed to CNs, (ii) to evaluate the impact of PAS-004 on pain and function attributed to PNs, and (iii) to investigate PAS-004 effects on CN tumor cellular and molecular biology.

The trial will be conducted in two parts. In Part A (dose escalation phase), following a screening period of up to 28 days, up to 24 eligible participants will be enrolled sequentially to receive one of four planned dose levels of PAS-004 tablets (4mg, 8mg, 12mg, 18mg) in a modified 3+3 design. Part A will identify the recommended RPBD. During Part B (expansion phase), approximately 24 eligible participants will be enrolled in parallel to receive one of two planned dose levels of PAS-004 tablets. Participants will be dosed at the RPBD level and at a dose level below the RPBD for up to six continuous 28-day treatment cycles. Part B will identify the recommended phase 2 dose (RP2D).

The study is planned to be conducted at five clinical trial sites in Australia, South Korea and the U.S.

About Pasithea Therapeutics Corp.

Pasithea is a clinical-stage biotechnology company primarily focused on the research and development of its lead drug candidate, PAS-004, a next-generation macrocyclic MEK inhibitor intended for the treatment of RASopathies, MAPK pathway-driven tumors, and other diseases. The Company is currently testing PAS-004 in a Phase 1 clinical trial in advanced cancer patients (NCT06299839), and a Phase 1/1b clinical trial in adult patients with neurofibromatosis type 1 (NF1)-associated plexiform neurofibromas (NCT06961565).

Forward Looking Statements

This press release contains statements that constitute “forward-looking statements” made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include statements regarding the Company’s ongoing Phase 1 clinical trial of PAS-004 in advanced cancer patients, the Company’s Phase 1/1b clinical trial of PAS-004 in adult patients with NF1-associated plexiform neurofibromas, and the safety, tolerability, pharmacokinetic (PK), pharmacodynamics (PD) and preliminary efficacy of PAS-004, as well as all other statements, other than statements of historical fact, regarding the Company’s current views and assumptions with respect to future events regarding its business, as well as other statements with respect to the Company’s plans, assumptions, expectations, beliefs and objectives, the success of the Company’s current and future business strategies, product development, pre-clinical studies, clinical studies, clinical and regulatory timelines, market opportunity, competitive position, business strategies, potential growth opportunities and other statements that are predictive in nature. Forward-looking statements are subject to numerous conditions, many of which are beyond the control of the Company. While the Company believes these forward-looking statements are reasonable, undue reliance should not be placed on any such forward-looking statements, which are based on information available to the Company on the date of this release. These forward-looking statements are based upon current estimates and assumptions and are subject to various risks and uncertainties, including risks that future clinical trial results may not match results observed to date, may be negative or ambiguous, or may not reach the level of statistical significance required for regulatory approval, as well as other factors set forth in the Company’s most recent Annual Report on Form 10-K, Quarterly Report on Form 10-Q and other filings made with the U.S. Securities and Exchange Commission (SEC). Thus, actual results could be materially different. The Company undertakes no obligation to update these statements whether as a result of new information, future events or otherwise, after the date of this release, except as required by law.

Pasithea Therapeutics Contact

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