

**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): December 10, 2024**

**TOURMALINE BIO, INC.**  
(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**001-40384**  
(Commission  
File Number)

**83-2377352**  
(I.R.S. Employer  
Identification No.)

**27 West 24th Street, Suite 702**  
**New York, NY**  
(Address of principal executive offices)

**10010**  
(Zip Code)

**Registrant's telephone number, including area code: (646) 481-9832**

**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 Instruction 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	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	TRML	The Nasdaq Global Select 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 7.01 Regulation FD Disclosure.**

On December 10, 2024, Tourmaline Bio, Inc. (the “Company”) issued a press release titled “Tourmaline Bio Highlights Cardiovascular Inflammation Focus and Announces Key Clinical and Strategic Updates at Investor Day.” The Company will host its Investor Day via webcast today, Tuesday, December 10, 2024, at 10:00 am, Eastern Time.

The Company will be posting to its website the presentation to be used in the Company’s Investor Day. The presentation and replays of the webcast will be available on the Company’s website at <https://ir.tourmalinebio.com>.

A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein. The information furnished under this Item 7.01, including Exhibit 99.1, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference into any of the Company’s filings with the Securities and Exchange Commission under the Exchange Act or the Securities Act of 1933, as amended, whether made before or after the date hereof, regardless of any general incorporation language in such a filing, except as otherwise expressly stated in such filing.

## **Item 8.01 Other Events.**

On December 10, 2024, the Company will host its Investor Day, during which it will outline progress across its pipeline and provide updates on its strategic priorities. The updates to be provided include:

### **Phase 2 TRANQUILITY Trial Progress**

The Company announced the over-enrollment of its Phase 2 TRANQUILITY trial, with a total of 143 patients enrolled as compared to 120 patients originally anticipated. The Company expects to report topline data from this trial in the second quarter of 2025.

### **Indication Expansion in Cardiovascular Inflammation**

The Company announced the nomination of abdominal aortic aneurysm (“AAA”) as an additional indication within its cardiovascular inflammation disease focus for pacibekitug. The Company expects to provide additional details on a planned Phase 2 proof-of-concept trial in AAA after topline results from the Phase 2 TRANQUILITY trial are reported in the second quarter of 2025.

### **Update on Thyroid Eye Disease (TED) Development Program**

The Company announced it expects to report topline data from the Phase 2b spiriTED trial in the second half of 2025 and that the initiation of a Phase 3 trial in TED is expected to be contingent on positive results from the spiriTED trial. Tourmaline plans to provide additional information on its future development plans in TED at that time.

This Current Report on Form 8-K contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including statements regarding the Company’s expectations regarding the development and potential therapeutic benefits of pacibekitug; the timing of initiation, progress and results of the Company’s current and future clinical trials for pacibekitug, including reporting of data therefrom and additional details regarding the planning thereof; the timing of future announcements regarding the Company’s development plans and the content of such announcements; the timing of a planned Phase 2 proof-of-concept clinical trial and of Phase 3 clinical trial readiness; and the timing and potential to expand pacibekitug into additional indications. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Many factors could cause the actual results, performance or achievements that may be expressed or implied by such forward-looking statements to vary from those described herein should one or more of these risks or uncertainties materialize, including those risk factors discussed or referred to in the Company’s filings with the SEC, including the “Risk Factors” section of the Company’s Quarterly Report on Form 10-Q, filed with the SEC on November 7, 2024, and its other documents subsequently filed with or furnished to the SEC. All forward-looking statements contained in this Current Report on Form 8-K speak only as of the date on which they were made. Except to the extent required by law, the Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

## **Item 9.01 Financial Statements and Exhibits.**

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(d) Exhibits.

Exhibit No.	Description
99.1	<a href="#">Press Release dated December 10, 2024</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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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.

**TOURMALINE BIO, INC.**

Date: December 10, 2024

By: /s/ Ryan Robinson

Name: Ryan Robinson

Title: Chief Financial Officer and Treasurer

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## Tourmaline Bio Highlights Cardiovascular Inflammation Focus and Announces Key Clinical and Strategic Updates at Investor Day

- Phase 2 TRANQUILITY trial surpasses enrollment target, with 143 total patients enrolled; topline data expected in second quarter of 2025 –
- Deepak L. Bhatt, MD, MPH, MBA and Dipender Gill, MD, PhD join Cardiovascular Scientific Advisory Board –
- Company nominates abdominal aortic aneurysm as second cardiovascular indication for pacibekitug, expanding development for inflammation-driven cardiovascular disease –

NEW YORK – Dec. 10, 2024 – Tourmaline Bio, Inc. (Tourmaline) (NASDAQ: TRML), a late-stage clinical biotechnology company developing transformative medicines to dramatically improve the lives of patients with life-altering immune and inflammatory diseases, today is hosting its Investor Day, beginning at 10 a.m. ET, during which it will outline progress across its pipeline and provide updates on its strategic priorities.

“We continue to be laser-focused on our development efforts for pacibekitug in order to maximize the potential of this program,” said Sandeep Kulkarni, MD, Co-Founder and Chief Executive Officer of Tourmaline Bio. “Today’s updates, including the over-enrollment of our TRANQUILITY trial, the expansion of our Cardiovascular Scientific Advisory Board, and the addition of a new indication, reflect the strength of our science, the caliber of our team, and our commitment to redefining standards of care for patients worldwide.”

### Phase 2 TRANQUILITY Trial Progress

Tourmaline today is announcing the over-enrollment of its Phase 2 TRANQUILITY trial, which evaluates quarterly and monthly subcutaneous dosing of pacibekitug in patients with elevated high-sensitivity C-reactive protein and chronic kidney disease. A total of 143 patients have been enrolled in the Phase 2 TRANQUILITY trial, as compared to 120 patients originally anticipated. Tourmaline expects to report topline data from this trial in the second quarter of 2025.

The TRANQUILITY trial is the starting point of Tourmaline’s clinical development program for pacibekitug for the potential treatment of atherosclerotic cardiovascular disease (ASCVD) and other cardiovascular diseases. If successful, results from the TRANQUILITY trial are expected to position Tourmaline to be Phase 3-ready for ASCVD.

### Expansion of Cardiovascular Scientific Advisory Board (CV SAB)

Tourmaline has expanded its CV SAB with two new appointments:

- **Deepak L. Bhatt, MD, MPH, MBA, FACC, FAHA, FESC, MSCAI** joins as Chair of the Tourmaline CV SAB. Dr. Bhatt is the Director of the Mount Sinai Fuster Heart Hospital and the Dr. Valentin Fuster Professor of Cardiovascular Medicine at the Icahn School of Medicine at Mount Sinai in New York City. Dr. Bhatt has served as principal investigator for a number of groundbreaking cardiovascular clinical trials, bringing to the CV SAB decades of clinical trial expertise.
- **Dipender Gill, MD, PhD** is the CEO of Sequoia Genetics and a specialist in leveraging human genetic evidence for drug development. Dr. Gill adds deep translational insight to Tourmaline’s strategic focus.

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## **Indication Expansion in Cardiovascular Inflammation**

Tourmaline has nominated abdominal aortic aneurysm (AAA) as an additional indication within its cardiovascular inflammation disease focus for pacibekitug. Tourmaline expects to provide additional details on a planned Phase 2 proof-of-concept trial in AAA after topline results from the Phase 2 TRANQUILITY trial are reported in Q2 2025.

## **Update on Thyroid Eye Disease (TED) Development Program**

In light of Tourmaline's focus on cardiovascular inflammation, initiation of a Phase 3 trial in TED will be dependent upon results from the ongoing Phase 2b spiriTED trial. Topline data from the Phase 2b spiriTED trial are expected in the second half of 2025; Tourmaline expects to provide additional information on its future development plans in TED at that time.

## **Investor Day Event Information**

Tourmaline's Investor Day will take place on December 10, 2024, beginning at 10 a.m. ET. To register for Tourmaline's Investor Day, please click [here](#) or visit the [Events and Presentations](#) section of Tourmaline's website. A replay of the webcast will be available on Tourmaline's website following the event. It is recommended that participants register at least 15 minutes in advance of the event.

## **About Tourmaline Bio**

Tourmaline is a late-stage clinical biotechnology company driven by its mission to develop transformative medicines that dramatically improve the lives of patients with life-altering immune and inflammatory diseases. Tourmaline's lead asset is pacibekitug (also referred to as TOUR006). For more information about Tourmaline Bio and pacibekitug, please visit <https://www.tourmalinebio.com> or follow us on [LinkedIn](#) or [X](#).

## **About Pacibekitug**

Pacibekitug (also referred to as TOUR006) is a long-acting, fully-human, anti-IL-6 monoclonal antibody with best-in-class potential and differentiated properties including a naturally long half-life, low immunogenicity, and high binding affinity to IL-6. Pacibekitug has been previously studied in approximately 450 participants, including patients with autoimmune disorders, across six completed clinical trials. Tourmaline is currently developing pacibekitug in atherosclerotic cardiovascular disease (ASCVD) and thyroid eye disease (TED) as its first two indications, with plans to expand into abdominal aortic aneurysm (AAA) and additional diseases in the future.

## **Cautionary Note Regarding Forward-Looking Statements**

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words and phrases such as "believe," "designed to," "expect," "may," "plan," "potential," "will" and similar expressions, and are based on Tourmaline's current beliefs and expectations. These forward-looking statements include expectations regarding the development and potential therapeutic benefits of pacibekitug; the timing of initiation, progress and results of Tourmaline's current and future clinical trials for pacibekitug, including reporting of data therefrom and additional details regarding the planning thereof; the timing of future announcements regarding Tourmaline's development plans and the content of such announcements; the timing of a planned Phase 2 proof-of-concept clinical trial and of Phase 3 clinical trial readiness; and the timing and potential to expand pacibekitug into additional indications. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Risks and uncertainties that may cause actual results to differ materially include uncertainties inherent in the development of therapeutic product candidates, such as the risk that any one or more of Tourmaline's current or future product candidates will not be successfully developed or commercialized; the risk of delay or cessation of any planned clinical trials of Tourmaline's current or future product

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candidates; the risk that prior results, such as signals of safety, activity or durability of effect, observed from preclinical trials and clinical trials, will not be replicated or will not continue in ongoing or future studies or clinical trials involving Tourmaline's current or future product candidates and/or current or future target indications; the risk that Tourmaline's current or future product candidates or procedures in connection with the administration thereof will not have the safety or efficacy profile that Tourmaline anticipates; risks regarding the accuracy of Tourmaline's estimates of expenses, capital requirements and needs for additional financing; changes in expected or existing competition; changes in the regulatory environment; the uncertainties and timing of the regulatory approval process; unexpected litigation or other disputes; the impacts of macroeconomic conditions on Tourmaline's business, clinical trials and financial position; and other risks and uncertainties that are described in Tourmaline's Quarterly Report on Form 10-Q filed with the U.S. Securities and Exchange Commission ("SEC") on November 7, 2024 and other filings that Tourmaline makes with the SEC from time to time. Any forward-looking statements speak only as of the date of this press release and are based on information available to Tourmaline as of the date hereof, and Tourmaline assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

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