Tourmaline Bio Reports Fourth Quarter and Full Year 2024 Financial Results and Recent Business Highlights

March 13, 2025

– Phase 2 TRANQUILITY trial in patients with elevated high-sensitivity C-reactive protein and chronic kidney disease over-enrolled to 143 total participants, on track to report topline data in the second quarter of 2025 –

– Cardiovascular Scientific Advisory Board strengthened with recent appointments of Drs. Deepak L. Bhatt, Dipender Gill, Paul M. Ridker, and Tabassome Simon –

– Cash, cash equivalents, and investments of $294.9 million as of December 31, 2024, providing expected cash runway into the second half of 2027 –

NEW YORK, March 13, 2025 (GLOBE NEWSWIRE) -- 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 announced its financial results for the fourth quarter and year ended December 31, 2024 and outlined recent business highlights.

“2024 was an important year of execution as it relates to our clinical development programs in cardiovascular inflammation and thyroid eye disease,” said Sandeep Kulkarni, MD, Co-Founder and Chief Executive Officer of Tourmaline. “We are now transitioning into a potentially transformative year of data in 2025, leading off with topline data from our Phase 2 TRANQUILITY trial expected in the second quarter. Complemented by our strong balance sheet and with the support of our world-class team, we look forward to sharing our first data readouts this year and making further progress towards realizing the enormous standard-of-care changing potential of pacibekitug.”

Clinical Highlights and Upcoming Milestones:

Cardiovascular Inflammation

- In December 2024, Tourmaline announced 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 participants have been enrolled in the Phase 2 TRANQUILITY trial, as compared to 120 participants originally anticipated. Tourmaline remains on track to report topline data from the TRANQUILITY 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 pacibekitug to be Phase 3-ready for ASCVD.
- At its Investor Day in December 2024, Tourmaline announced the nomination of 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 TRANQUILITY trial are reported in the second quarter of 2025.

Thyroid Eye Disease (TED)

- The Phase 2b spiriTED trial remains ongoing, and Tourmaline continues to expect topline data from this trial in the second half of 2025.
- Tourmaline expects to provide additional information on its future development plans in TED after review of data from the Phase 2b spiriTED trial.

Other Corporate Highlights:

- Tourmaline has continued to bolster its world-class Cardiovascular Scientific Advisory Board (CV SAB), which is providing invaluable strategic guidance toward the expected future development of pacibekitug to reduce inflammation in cardiovascular diseases.

- In December 2024, Tourmaline announced that Deepak L. Bhatt, MD, MPH, MBA, FACC, FAHA, FESC, MSCAI and Dipender Gill, MD, PhD had joined the 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. Gill is the CEO and Founder of Sequoia Genetics.
- In January 2025, Tourmaline announced that Paul M. Ridker, MD, MPH had joined the CV SAB. Dr. Ridker is the Eugene Braunwald Professor of Medicine at the Harvard Medical School and Director of the Center for Cardiovascular Disease Prevention at Brigham and Women's Hospital.
- Additionally, Tourmaline is announcing today that Tabassome Simon, MD, PhD has joined the CV SAB. Dr. Simon is a Professor of Medicine and Clinical Pharmacology in the Department of Pharmacology at Assistance Publique-Hôpitaux de Paris (AP-HP, Saint-Antoine Hospital) and Sorbonne Université. Dr. Simon's primary research focuses on the impact of therapeutics on secondary prevention in cardiology and emergency care. She is currently the scientific coordinator of ongoing multi-center trials including studies in myocardial infarction, a member of several Executive Committees and Data Safety Monitoring Boards in national and international trials and has published more than 340 articles in international peer-reviewed journals, including *The New England Journal of Medicine*, *The Lancet*, *JAMA*, and *Annals of Internal Medicine*.

- In November 2024, Tourmaline hosted an expert webinar on the human genetic validation for IL-6 inhibition in cardiovascular disease with Dr. Gill. A replay of this webinar can be accessed here.
- In December 2024, Tourmaline hosted its first Investor Day, highlighting its focus on cardiovascular inflammation and featuring Dr. Marc Bonaca, Executive Director of CPC Clinical Research and Professor of Medicine and William R. Hiatt Endowed Chair in Cardiovascular Research at the University of Colorado Anschutz. Dr. Bonaca is also a member of Tourmaline's CV SAB. A replay of Investor Day can be accessed here.

Fourth Quarter and Full Year 2024 Financial Results:

Cash Position

- Cash, cash equivalents and investments were $294.9 million as of December 31, 2024, as compared to $203.0 million as of December 31, 2023. Tourmaline anticipates that its current cash, cash equivalents, and investments will provide cash runway into the second half of 2027, funding its operations through key pacibekitug data readouts in cardiovascular inflammation and TED as well as other pacibekitug development activities.

Research and Development Expenses

- Research and development expenses were $20.5 million for the fourth quarter of 2024, as compared to $8.0 million for the fourth quarter of 2023.
- Research and development expenses were $67.0 million for the full year ended December 31, 2024, as compared to $32.4 million for the full year ended December 31, 2023.
- The increase in research and development expenses for both periods was primarily driven by increased employee compensation costs attributable to additional headcount, increased clinical trial expenses directly related to the TRANQUILITY and spiriTED trials, increased drug manufacturing expenses, and increased medical affairs costs.

General and Administrative Expenses

- General and administrative expenses were $5.3 million for the fourth quarter of 2024, as compared to $6.9 million for the fourth quarter of 2023.
- General and administrative expenses were $22.7 million for the full year ended December 31, 2024, as compared to $13.0 million for the full year ended December 31, 2023.
- The decrease in general and administrative expenses from the fourth quarter of 2023 to the fourth quarter of 2024 was primarily driven by decreased stock-based compensation expense. The increase in general and administrative expenses from the full year ended December 31, 2023 to the full year ended December 31, 2024 was primarily driven by employee compensation costs attributable to increased headcount, increased professional services fees, and increased insurance expenses associated with being a public company.

Net Loss

- Net loss was $22.2 million for the fourth quarter of 2024 and $12.9 million for the fourth quarter of 2023, resulting in basic and diluted net loss per share of $0.86 and $0.81, respectively.
- Net loss was $73.2 million for the full year ended December 31, 2024 and $42.1 million for the full year ended December 31, 2023, resulting in basic and diluted net loss per share of $2.89 and $8.87, respectively.
- The increase in net loss for both periods and the increase in net loss per share from the fourth quarter of 2023 to the fourth quarter of 2024 was attributable to increased operating expenses and Tourmaline's overall growth during 2024. The decrease in net loss per share from the full year ended December 31, 2023 to the full year ended December 31, 2024 was attributable to the issuance of additional shares of common stock in conjunction with Tourmaline's reverse merger and private placement completed in October 2023 and the underwritten follow-on public offering completed by Tourmaline in January 2024.

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, 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; the timing of Phase 3 clinical trial readiness; the standard-of-care changing potential of pacibekitug; 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 candidates; the risk that prior results, such as signals of safety, activity or durability of effect, observed from preclinical 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; 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 Tourmaline's business, clinical trials and financial position; and other risks and uncertainties that are described in Tourmaline's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission ("SEC") on March 13, 2025 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.

Tourmaline Bio, Inc.
Consolidated Statements of Operations (unaudited)
(amounts in thousands, except per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 20,545	$ 8,015	$ 66,985	$ 32,368
General and administrative	5,261	6,875	22,747	13,041
Total operating expenses	25,806	14,890	89,732	45,409
Loss from operations	(25,806)	(14,890)	(89,732)	(45,409)
Other income, net	3,571	1,988	16,522	3,285
Net loss	$ (22,235)	$ (12,902)	$ (73,210)	$ (42,124)
Net loss per share, basic and diluted	$ (0.86)	$ (0.81)	$ (2.89)	$ (8.87)
Weighted-average common shares outstanding, basic and diluted	25,796	16,003	25,348	4,747

Tourmaline Bio, Inc.
Selected Consolidated Balance Sheet Data (unaudited)
(amounts in thousands)

	December 31,	
	2024	**2023**
Cash, cash equivalents and investments	$ 294,936	$ 202,951
Working capital	$ 259,933	$ 203,872
Total assets	$ 309,001	$ 210,295
Total stockholders' equity	$ 300,052	$ 205,042

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