Tourmaline Bio Reports Fourth Quarter and Full Year 2023 Financial Results and Recent Business Highlights

March 19, 2024

– Initiated pivotal spiriTED Phase 2b trial in Thyroid Eye Disease (TED) in 2023 and expanded TED clinical development plan, including accelerating the planned initiation of a pivotal Phase 3 trial into 2024 –

– Reached alignment with the U.S. FDA on the clinical development program in Atherosclerotic Cardiovascular Disease (ASCVD) in 2023 and received clearance for Investigational New Drug application (IND) in March 2024 –

– Completed reverse merger with Talaris Therapeutics in October 2023, including a concurrent private placement of $75.0 million –

– Completed underwritten follow-on public offering in January 2024, raising gross proceeds of $172.5 million –

– Expected cash runway into 2027, providing funding for key TOUR006 data readouts in TED and cardiovascular disease and the opportunity to expand into additional indications –

NEW YORK, March 19, 2024 (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, 2023 and outlined recent business highlights.

“2023 was a transformational year for Tourmaline. We became a public company and continued our efforts to lead an IL-6 renaissance with TOUR006, which we believe can achieve a best-in-class profile by providing a long-acting, patient-friendly treatment through low-volume subcutaneous injections,” said Sandeep Kulkarni, MD, Co-Founder and Chief Executive Officer of Tourmaline. “With the support of our expanding team, the clinical and patient communities, and our shareholders, we look forward to executing on our two strategic paths. We aim to harness the exciting and emerging insights in the IL-6 field towards addressing significant unmet medical needs in TED, ASCVD, and other autoantibody and inflammation-driven diseases.”

Clinical Highlights and Upcoming Milestones:

Tourmaline is pursuing development of TOUR006 in two areas of high unmet need: FcRn+ and cardiovascular inflammation.

FcRn+

- Tourmaline believes that TOUR006, a long-acting, fully-human, anti-IL-6 monoclonal antibody, can potentially deliver substantial therapeutic benefit to address a wide range of autoantibody-driven disorders, including a more durable response and patient-friendly administration than therapies currently on the market or in clinical development by others.
- The pivotal spiriTED Phase 2b trial in TED is currently enrolling, and Tourmaline continues to expect topline data in the first half of 2025.
- Tourmaline plans to accelerate the initiation of a pivotal Phase 3 trial evaluating subcutaneous TOUR006 every 8 weeks as first-line treatment for TED in 2024, with topline data expected in 2026.
- Tourmaline continues to explore additional indications with significant unmet medical need under its FcRn+ strategic path.

Cardiovascular Inflammation

- During 2023, Tourmaline reached alignment with the U.S. Food and Drug Administration (FDA) on the clinical development program of TOUR006 in ASCVD, and Tourmaline received clearance for the related IND in March 2024.
- Tourmaline plans to commence a Phase 2 trial evaluating quarterly subcutaneous dosing of TOUR006 in patients with elevated cardiovascular risk in the first half of 2024. Data from this Phase 2 trial are expected in the first half of 2025.

Other Corporate Highlights:

- In October 2023, Tourmaline become a publicly-traded company via reverse merger with Talaris Therapeutics, including a concurrent private placement of $75.0 million.

- In December 2023, Tourmaline expanded its Board of Directors with the appointment of Dr. Clay Siegall as Chairman.
- Tourmaline also continued to expand its executive leadership team during 2023, including the appointments of Gerhard Hagn as SVP, Head of Commercial and Business Development and Dr. Emil deGoma as SVP, Medical Research.
- In December 2023, Tourmaline was added to the NASDAQ Biotechnology Index (NASDAQ: NBI).
- In January 2024, Tourmaline completed an underwritten follow-on public offering of its common stock, which included the full exercise of the underwriters' option to purchase additional shares, resulting in gross proceeds of $172.5 million. Net proceeds were $161.3 million after deducting underwriting discounts and offering expenses.

Fourth Quarter and Full Year 2023 Financial Results:

Cash Position

- Cash, cash equivalents and investments were $203.0 million as of December 31, 2023, as compared to $8.3 million as of December 31, 2022. Tourmaline anticipates that its current cash, cash equivalents and investments as of the date hereof, which includes $161.3 million of net proceeds received from the January 2024 underwritten public offering, will provide cash runway into 2027, funding key TOUR006 data readouts in TED and cardiovascular disease and the opportunity to expand development efforts into additional indications.

Research and Development Expenses

- Research and development expenses were $8.0 million for the fourth quarter of 2023, as compared to $3.8 million for the fourth quarter of 2022.
- Research and development expenses were $32.4 million for the full year ended December 31, 2023, as compared to $17.5 million for the full year ended December 31, 2022.
- The increase in research and development expenses for both periods was primarily driven by employee compensation costs attributable to increased headcount, costs associated with the manufacture of drug substance and drug product for Tourmaline’s clinical trials, and clinical trial costs related to the spiriTED trial.

General and Administrative Expenses

- General and administrative expenses were $6.9 million for the fourth quarter of 2023, as compared to $1.1 million for the fourth quarter of 2022.
- General and administrative expenses were $13.0 million for the full year ended December 31, 2023, as compared to $2.2 million for the full year ended December 31, 2022.
- The increase in general and administrative expenses for both periods was primarily driven by employee compensation costs attributable to increased headcount, increased recruiting and commercial consulting expenses, and increased professional service fees.

Net Loss

- Net loss was $12.9 million for the fourth quarter of 2023 and $4.9 million for the fourth quarter of 2022, resulting in basic and diluted net loss per share of $0.81 and $5.51, respectively.
- Net loss was $42.1 million for the full year ended December 31, 2023 and $19.7 million for the full year ended December 31, 2022, resulting in basic and diluted net loss per share of $8.87 and $22.46, respectively.
- The increase in net loss for both periods was attributable to increased operating expenses and the overall growth of Tourmaline during 2023 as compared to 2022. The decrease in net loss

per share for both periods was attributable to the issuance of additional shares of common stock in conjunction with the reverse merger and private placement that were completed in October 2023.

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 TOUR006.

About TOUR006:

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. To date, TOUR006 has been studied in 448 participants, including patients with autoimmune disorders, across six clinical trials. Tourmaline is developing TOUR006 in TED and ASCVD as its first two indications, with additional diseases under consideration.

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 TOUR006; the timing of initiation, progress and results of Tourmaline's current and future clinical trials for TOUR006, including reporting of data therefrom; the timing and potential of preclinical research and development activities; market opportunities; and Tourmaline's anticipated cash runway. 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 or about March 19, 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.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 8,015	$ 3,794	$ 32,368	$ 17,526
General and administrative	6,875	1,126	13,041	2,175
Total operating expenses	14,890	4,920	45,409	19,701
Loss from operations	(14,890)	(4,920)	(45,409)	(19,701)
Other income, net	1,988	—	3,285	—
Net loss	$ (12,902)	$ (4,920)	$ (42,124)	$ (19,701)
Net loss per share, basic and diluted	$ (0.81)	$ (5.51)	$ (8.87)	$ (22.46)
Weighted-average common shares outstanding, basic and diluted	16,003	893	4,747	877

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

	December 31,	
	2023	2022
Cash, cash equivalents and investments	$ 202,951	$ 8,258
Working capital	$ 203,872	$ 6,949
Total assets	$ 210,295	$ 9,098
Total stockholders' equity (deficit)	$ 205,042	$ (19,732)

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Source: Tourmaline Bio, Inc.