November 9, 2023

Dermata Therapeutics Provides Corporate Update and Reports Third Quarter 2023 Financial Results

- Raised an aggregate of $6.8 million in gross proceeds from two financings completed in 1H 2023 -

- Received positive feedback from FDA on its End of Phase 2 meeting package in June 2023 -

- Completed start-up activities to support DMT310 Phase 3 STAR-1 clinical trial in acne -

SAN DIEGO, CA / ACCESSWIRE / November 9, 2023 /Dermata Therapeutics, Inc. (NASDAQ:DRMA)(NASDAQ:DRMAW) ("Dermata," or the "Company"), a clinical-stage biotechnology company focusing on the treatment of medical and aesthetic skin diseases and conditions, today highlighted recent corporate progress, and reported financial results for the third quarter ended September 30, 2023.

"We're excited to have received positive feedback from FDA on our End of Phase 2 meeting package and are eager to move into Phase 3. The FDA agreed that the Phase 3 clinical program appears acceptable for filing an NDA, while recommending we include traditional laboratory measurements, electrocardiograms (ECGs), and an extension study to the DMT310 Phase 3 program," said Gerry Proehl, Dermata's Chairman, President, and Chief Executive Officer. "We have submitted the updated protocols with FDA's recommended changes and are currently waiting for final approval before we may begin enrolling patients in the first Phase 3 trial. In the meantime, our team has completed all start-up activities in preparation for initiating the DMT310 Phase 3 STAR-1 clinical trial in moderate-to-severe acne," concluded Mr. Proehl.

Corporate Highlights

- **Dermata submitted amended DMT310 Phase 3 clinical trial protocols to FDA.** In response to FDA's recommended additions to the DMT310 Phase 3 clinical program, the Company submitted amended protocols, which included all of FDA's recommended additions, (laboratory measurements, ECGs, and an extension study) in the DMT310 Phase 3 clinical program. Upon approval from FDA to begin Phase 3, the Company plans to initiate enrollment.
- **Dermata has completed start-up activities to support the initiation of DMT310**

Phase 3 STAR-1 clinical trial. Since receiving FDA feedback on its End of Phase 2 meeting package, the Company has completed its manufacturing campaign to support the first Phase 3 clinical trial, including preparing all clinical trial supplies for shipment to clinical sites. The Company has also identified the clinical sites to enroll the over 500 patients with moderate-to-severe acne who will be participating in this first Phase 3 clinical trial. The Company believes completion of these start-up activities may shorten the time between FDA approval of the amended Phase 3 protocols and enrollment of the first patient.

Anticipated Upcoming Milestones

- **Initiate DMT310 Phase 3 Program in moderate-to-severe acne.** After receiving responses from FDA on the amended Phase 3 clinical trial protocols, the Company intends to initiate its DMT310 Phase 3 STAR-1 clinical trial before the end of 2023. STAR-1 will be the first of two Phase 3 clinical studies the Company will need to complete prior to filing a new drug application (NDA). If the Phase 3 program is successful, the Company intends to submit an NDA to FDA seeking regulatory approval of DMT310 for the treatment of moderate-to-severe acne.
- **DMT410 Partnership Discussions.** The Company continues partnership discussions for its DMT410 program for the topical delivery of botulinum toxin.

Third Quarter 2023 Financial Results

As of September 30, 2023, the Company had approximately $6.6 million in cash and cash equivalents, compared to $6.2 million as of December 31, 2022. The increase in cash and cash equivalents resulted from $5.7 million net proceeds from the financings that closed in March 2023 and May 2023, offset by $5.3 million of cash used in operations for the nine months ended September 30, 2023. The Company expects its current cash resources are sufficient to fund operations into the second quarter of 2024.

Research and development expenses were $0.9 million for the quarter ended September 30, 2023, compared to $1.6 million for the quarter ended September 30, 2022. The decrease in research and development expenses was due to decreased clinical and non-clinical expenses, offset by increased manufacturing expenses in anticipation of the DMT310 Phase 3 program and initiation of the STAR-1 clinical trial.

General and administrative expenses were $0.9 million for the quarter ended September 30, 2023, compared to $0.9 million for the quarter ended September 30, 2022.

About Dermata Therapeutics

Dermata Therapeutics, Inc. is a clinical-stage biotechnology company focusing on the treatment of medical and aesthetic skin diseases and conditions. The Company's lead product candidate, DMT310, is the Company's first product candidate being developed from its *Spongilla* technology platform. DMT310 is a once-weekly topical product candidate derived from a naturally sourced freshwater sponge with multiple unique mechanisms of action. DMT310 has been studied for the treatment of acne, rosacea, and psoriasis. The Company's second product candidate, DMT410, uses its *Spongilla* technology as a new method for topical intradermal delivery of botulinum toxin for the treatment of hyperhidrosis and multiple aesthetic skin conditions. Dermata is headquartered in San Diego, California.

For more information, please visit http://www.dermatarx.com/.

Forward-Looking Statements

Statements in this press release that are not strictly historical in nature are forward-looking statements. These statements are based on the Company's current beliefs and expectations and new risks may emerge from time to time. Forward-looking statements are subject to known and unknown risks, uncertainties, assumptions, and other factors including, but are not limited to, statements related to: expectations with regard to the timing of meetings and/or responses from submissions with regulatory bodies; expectations with regard to the timing of submission of an NDA; the uncertainties inherent in clinical trials; expectations with regard to any potential partnership opportunities for any of the Company's product candidates; the Company's expectations with regard to current cash and cash equivalents and the amount of time it will fund operations; the success, cost, and timing of its product candidates DMT310 and DMT410 development activities and ongoing and planned clinical trials; and whether the results of any ongoing or planned clinical trials of DMT310 or DMT410 will lead to future product development. These statements are only predictions based on current information and expectations and involve a number of risks and uncertainties. Actual events or results may differ materially from those projected in any of such statements due to various factors, including the risks and uncertainties inherent in drug development, approval, and commercialization, and the fact that past results of clinical trials may not be indicative of future trial results. For a discussion of these and other factors, please refer to Dermata's filings with the Securities and Exchange Commission. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. All forward-looking statements are qualified in their entirety by this cautionary statement and Dermata undertakes no obligation to revise or update this press release to reflect events or circumstances after the date hereof, except as required by law.

DERMATA THERAPEUTICS, INC.
Balance Sheets

In 000's	**September 30, 2023** (unaudited)	**December 31, 2022**
Assets		
Cash and cash equivalents	$ 6,631	$ 6,241
Prepaid expenses and other current assets	692	703
Total assets	7,323	6,944
Liabilities		
Accounts payable	475	496
Accrued liabilities	442	426
Total liabilities	917	922
Equity	6,407	6,022
Total liabilities and equity	$ 7,323	$ 6,944

DERMATA THERAPEUTICS, INC.

Statements of Operations

In 000's, except share and per share data	Three Months Ended September 30, 2023 (unaudited)	Three Months Ended September 30, 2022 (unaudited)	Nine Months Ended September 30, 2023 (unaudited)	Nine Months Ended September 30, 2022 (unaudited)
Operating expenses				
Research and development [1]	$ 903	$ 1,553	$ 2,935	$ 4,762
General and administrative [1]	909	893	2,887	3,201
Total operating expenses	1,812	2,446	5,822	7,963
Loss from operations	(1,812)	(2,446)	(5,822)	(7,963)
Interest income, net	93	21	161	21
Net loss	$ (1,719)	$ (2,425)	$ (5,661)	$ (7,942)
Net loss per common share, basic and diluted	$ (0.54)	$ (3.16)	$ (2.46)	$ (11.96)
Weighted average common shares outstanding, basic and diluted	3,189,034	767,275	2,301,360	663,892
[1] Includes the following stock-based compensation expense:				
Research and development	$ 48	$ 55	$ 145	$ 163
General and administrative	$ 83	$ 180	$ 248	$ 546

Investors:

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SOURCE: Dermata Therapeutics

View source version on accesswire.com:
https://www.accesswire.com/801697/dermata-therapeutics-provides-corporate-update-and-reports-third-quarter-2023-financial-results