NEWS RELEASE

# Marinus Pharmaceuticals Provides Business Update and Reports Fourth Quarter and Full Year 2023 Financial Results

3/5/2024

- Phase 3 RAISE trial interim analysis enrollment target achieved with Data Monitoring Committee (DMC) review scheduled and topline results expected in first half of Q2 2024
- Phase 3 TrustTSC trial approximately 85% enrolled with topline data now expected in first half of Q4 2024
- ZTALMY® (ganaxolone) net product revenue of $6.6 million for Q4 2023 and $19.6 million for the full year ended December 31, 2023
- Full year 2024 U.S. ZTALMY net product revenue guidance of between $32 and $34 million
- Cash runway projected into Q4 2024 with cash, cash equivalents and short-term investments of $150.3 million as of December 31, 2023
- Marinus to host conference call today at 4:30 p.m. ET

RADNOR, Pa.--(BUSINESS WIRE)-- **Marinus Pharmaceuticals**, Inc. (Nasdaq: MRNS), a pharmaceutical company dedicated to the development of innovative therapeutics to treat seizure disorders, today reported business highlights and financial results for the fourth quarter and year ended December 31, 2023.

“We are thrilled to announce we have exceeded the enrollment threshold required to conduct an interim analysis in the Phase 3 RAISE trial in refractory status epilepticus, a life-threatening condition,” said Scott Braunstein, M.D., Chairman and Chief Executive Officer of Marinus. “With over 90 patients now randomized following several months of increasingly strong enrollment trends, we are on track to announce topline data in the second quarter, assuming efficacy criteria for the interim analysis are met. We also remain focused on advancing the Phase 3 TrustTSC trial in tuberous sclerosis complex and are confident that the new titration schedule is having the desired effect with the current discontinuation rate below 7%. We continue to see steady adoption of ZTALMY in CDKL5 deficiency disorder

and are eager to build on this momentum throughout 2024 as we grow the ZTALMY franchise and prepare for RSE and TSC data this year."

## ZTALMY ®

- ZTALMY® (ganaxolone) oral suspension CV net product revenue of $6.6 million for the fourth quarter of 2023 and $19.6 million for the full year ended December 31, 2023
    - Continued growth in commercial patients with more than 165 patients active on therapy at the end of 2023
- Full year 2024 projected U.S. ZTALMY net product revenues of between $32 and $34 million
- Orion Corporation continues to prepare for commercial launches of ZTALMY in select European countries in 2024

## Clinical Pipeline

### Status Epilepticus

- Achieved enrollment target required for an interim analysis in the Phase 3 RAISE trial of intravenous (IV) ganaxolone in refractory status epilepticus (RSE)
    - If pre-defined stopping criteria for the interim analysis are met, the Company expects to report topline data in the first half of the second quarter of 2024
    - Strong enrollment trends have continued and now expect approximately 100 patients to be randomized by the conclusion of the interim analysis; this larger database will support health economic outcomes
    - Targeting submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) in early 2025 with priority review expected
- Phase 3 RAISE II trial in RSE (for European registration) underway with enrollment expected to complete in the fourth quarter of 2025
- Trial design underway with plans to submit a new protocol for IV ganaxolone in super refractory status epilepticus (SRSE) to the FDA in the second quarter of 2024
    - To date, the Company has received over 25 physician requests for the use of IV ganaxolone to treat SRSE patients

Ganaxolone development in the RAISE trial is being supported or in part by the Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA) under contract number 75A50120C00159.

### Tuberous Sclerosis Complex and Other Rare Genetic Epilepsies

- Enrollment in the global Phase 3 TrustTSC trial of oral ganaxolone in tuberous sclerosis complex now at 85% and expected to be completed in the second quarter of 2024
    - Topline data now anticipated in the first half of the fourth quarter of 2024
    - Targeting submission of a supplemental NDA to the FDA in the first half of 2025 with priority review expected
- Company now anticipates initiating a proof-of-concept study with oral ganaxolone to treat a range of epileptic encephalopathies, including Lennox-Gastaut syndrome in late 2024
- IND-enabling studies for a ganaxolone prodrug are expected to be completed by year-end 2024

## General Business and Financial Update

- Company expects that cash, cash equivalents and short-term investments of $150.3 million as of December 31, 2023, will be sufficient to fund the Company's operating expenses, capital expenditure requirements and maintain the minimum cash balance of $15 million required under the Company's debt facility into the fourth quarter of 2024.
- For the fiscal year 2024, the Company expects ZTALMY U.S. net product revenues of between $32 and $34 million.

## Financial Results

- Recognized $6.6 million and $19.6 million in net product revenues for the three and twelve months ended December 31, 2023, respectively, as compared to $2.3 million and $2.9 million for the three and twelve months ended December 31, 2022, respectively.
- Recognized $0.6 million and $11.4 million in Biomedical Advanced Research and Development Authority (BARDA) federal contract revenue for the three and twelve months ended December 31, 2023, respectively, as compared to $1.8 million and $6.9 million for the three and twelve months ended December 31, 2022, respectively.
- Research and development (R&D) expenses were $26.4 million and $99.4 million for the three and twelve months ended December 31, 2023, respectively, as compared to $21.4 million and $79.9 million, respectively, for the same periods in the prior year; the increase was due primarily to increased costs associated with our API onshoring effort, increased TSC and RSE clinical trial activity, and increased headcount.
- Selling, general and administrative (SG&A) expenses were $15.4 million and $61.2 million for the three and twelve months ended December 31, 2023, respectively, as compared to $14.7 million and $56.8 million, respectively, for the same periods in the prior year; the primary drivers of the change were annualization of the U.S. ZTALMY launch costs and increased headcount.
- The Company had net losses of $41.8 million and $141.4 million for the three and twelve months ended

December 31, 2023, respectively; cash used in operating activities increased to $118.0 million for the twelve months ended December 31, 2023, compared to $112.9 million for the same period a year ago.

- At December 31, 2023, the Company had cash, cash equivalents and short-term investments of $150.3 million, compared to cash and cash equivalents of $240.6 million at December 31, 2022.
- Readers are referred to, and encouraged to read in its entirety, the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, to be filed with the Securities and Exchange Commission on March 5, 2024, which includes further details on the Company's business plans, operations, financial condition, and results of operations.

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Selected Financial Data (in thousands, except share and per share amounts)

| | December 31, 2023 (unaudited) | December 31, 2022 |
|---|---|---|
| ASSETS | | |
| Cash and cash equivalents | $ 120,572 | $ 240,551 |
| Short-term investments | 29,716 | - |
| Other assets | 20,620 | 18,967 |
| Total assets | $ 170,908 | $ 259,518 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities | $ 40,624 | $ 25,017 |
| Long term debt, net | 61,423 | 71,018 |
| Revenue interest financing payable, net | 33,766 | 29,857 |
| Other long-term liabilities | 18,330 | 17,626 |
| Total liabilities | 154,143 | 143,518 |
| Total stockholders' equity | 16,765 | 116,000 |
| Total liabilities and stockholders' equity | $ 170,908 | $ 259,518 |

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| | Three Months Ended December 31, | | Year Ended December 31 | |
|---|---|---|---|---|
| | 2023 (unaudited) | 2022 | 2023 (unaudited) | 2022 |
| Revenue: | | | | |
| Product revenue, net | $ 6,551 | $ 2,317 | $ 19,561 | $ 2,872 |
| Federal contract revenue | 621 | 1,847 | 11,374 | 6,935 |
| Collaboration revenue | 18 | 2,998 | 54 | 15,671 |
| Total revenue | 7,190 | 7,162 | 30,989 | 25,478 |
| Expenses: | | | | |
| Research and development | 26,382 | 21,424 | 99,388 | 79,912 |
| Selling, general and administrative | 15,383 | 14,658 | 61,152 | 56,845 |
| Cost of product revenue | 862 | 142 | 1,909 | 190 |
| Cost of collaboration revenue | - | 150 | 25 | 150 |
| Cost of IP license fee | - | - | - | 1,169 |
| Total expenses: | 42,627 | 36,374 | 162,474 | 138,266 |
| Loss from operations | (35,437) | (29,212) | (131,485) | (112,788) |
| Interest income | 1,747 | 1,744 | 8,113 | 2,354 |
| Interest expense | (4,298) | (3,690) | (16,895) | (10,672) |
| (Loss) gain from sale of priority review voucher, net | (4,000) | - | (4,000) | 107,375 |
| Other income (expense), net | 219 | (1,517) | 1,324 | (2,696) |
| | | | (142,943) | |

| | | | | |
|---|---|---|---|---|
| Loss before income taxes | (41,769) | (32,675) | [illegible] | (16,427) |
| (Provision) benefit for income taxes | - | (1,637) | 1,538 | (3,389) |
| Net loss applicable to common shareholders | $ (41,769) | $ (34,312) | $ (141,405) | $ (19,816) |
| Per share information: | | | | |
| Net loss per share of common stock—basic and diluted | $ (0.74) | $ (0.76) | $ (2.63) | $ (0.51) |
| Basic and diluted weighted average shares outstanding | 56,688,400 | 44,973,371 | 53,746,518 | 39,072,599 |
| Other comprehensive income (loss) | | | | |
| Unrealized gain (loss) on available-for-sale securities | 51 | - | (20) | - |
| Total comprehensive loss | $ (41,718) | (34,312) | (141,425) | (19,816) |

## Conference Call Information

Tuesday, March 5, 4:30 p.m. ET

Participants may access the conference call via webcast on the Investor page of Marinus' website at **ir.marinuspharma.com/events-and-presentations**. An archived version of the call will be available approximately two hours after the completion of the event on the website.

Telephone Access:

Domestic: (888) 550-5280

International: (646) 960-0813

Webcast Registration: **https://events.q4inc.com/attendee/513453609**

Conference ID: 2696394

## About Marinus Pharmaceuticals

Marinus is a commercial-stage pharmaceutical company dedicated to the development of innovative therapeutics for seizure disorders. The Company first introduced FDA-approved prescription medication ZTALMY® (ganaxolone) oral suspension CV in the U.S. in 2022 and continues to invest in the potential of ganaxolone in IV and oral formulations to maximize therapeutic reach for adult and pediatric patients in acute and chronic care settings. For more information, visit **www.marinuspharma.com**.

## Forward-Looking Statements

To the extent that statements contained in this press release are not descriptions of historical facts regarding Marinus, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Words such as "may",

"will", "expect", "anticipate", "estimate", "intend", "believe", and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. Examples of forward-looking statements contained in this press release include, among others, statements regarding our commercialization and marketing plans for ZTALMY; our net product revenue guidance; the potential benefits ZTALMY will provide for physicians and patients; statements regarding our expected clinical development plans, enrollment in our clinical trials, regulatory communications and submissions for ganaxolone, and the timing thereof; our expected data readouts; our expected cash runway; our expectations and beliefs regarding the FDA and EMA with respect to our product candidates; our expectations regarding the development of new formulations and prodrug candidates; our expectations regarding our strategic partners; our financial projections; the potential safety and efficacy of ganaxolone, as well as its therapeutic potential in a number of indications; and other statements regarding the company's future operations, financial performance, financial position, prospects, objectives and other future event.

Forward-looking statements in this press release involve substantial risks and uncertainties that could cause our clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the company's ability to continue as a going concern; unexpected market acceptance, payor coverage or future prescriptions and revenue generated by ZTALMY; unexpected actions by the FDA or other regulatory agencies with respect to our products; competitive conditions and unexpected adverse events or patient outcomes from being treated with ZTALMY, uncertainties and delays relating to the design, enrollment, completion, and results of clinical trials; unanticipated costs and expenses; the company's cash and cash equivalents may not be sufficient to support our operating plan for as long as anticipated; our ability to comply with the FDA's requirement for additional post-marketing studies in the required time frames; the timing of regulatory filings for our other product candidates; clinical trial results may not support regulatory approval or further development in a specified indication or at all; actions or advice of the FDA or EMA may affect the design, initiation, timing, continuation and/or progress of clinical trials or result in the need for additional clinical trials; the size and growth potential of the markets for the company's product candidates, and the company's ability to service those markets; our ability to develop new formulations of ganaxolone or prodrugs; our ability to obtain, maintain, protect and defend intellectual property for our product candidates; the potential negative impact of third party patents on our or our collaborators' ability to commercialize ganaxolone; delays, interruptions or failures in the manufacture and supply of our product candidate; the company's expectations, projections and estimates regarding expenses, future revenue, capital requirements, and the availability of and the need for additional financing; the company's ability to obtain additional funding to support its clinical development and commercial programs; the potential for our ex-US partners to breach their obligations under their respective agreements with us or terminate such agreements in accordance with their respective terms; the risk that drug product quality requirements may not support continued clinical investigation of our product candidates and result in delays or termination of such clinical studies and

product approvals; and the availability or potential availability of alternative products or treatments for conditions targeted by us that could affect the availability or commercial potential of our product candidate. This list is not exhaustive and these and other risks are described in our periodic reports, including the annual report on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, filed with or furnished to the Securities and Exchange Commission and available at **www.sec.gov**. Any forward-looking statements that we make in this press release speak only as of the date of this press release. We assume no obligation to update forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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