NEWS RELEASE

Marinus Pharmaceuticals Provides Business Update and Reports Third Quarter 2023 Financial Results

11/7/2023

- ZTALMY® (ganaxolone) Q3 net product revenue of $5.4 million; 2023 net product revenue guidance increased to between $18.5 and $19 million
- Over 75% of patients required for the interim analysis are now enrolled in the Phase 3 RAISE trial in refractory status epilepticus; if the trial meets pre-defined stopping criteria at the interim analysis, topline data now anticipated Q2 2024
- Initiated the Marinus Access Program to expand global availability of ZTALMY
- Cash runway projected into Q4 2024 with cash, cash equivalents and short-term investments of $176.4 million as of September 30, 2023
- Marinus to host conference call on November 7, 2023, at 8:30 a.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 third quarter ended September 30, 2023.

“With strong quarter over quarter growth and robust payer coverage one year into the launch of ZTALMY, we continue to demonstrate our unique commercial capabilities in the orphan epilepsy space and are enthused by the opportunity ZTALMY and the ganaxolone franchise represent as an important long-term value driver for Marinus,” said Scott Braunstein, M.D., Chairman and Chief Executive Officer of Marinus.

Dr. Braunstein continued, “We remain acutely focused on advancing our Phase 3 clinical trials in refractory status epilepticus and tuberous sclerosis complex. While we’re disappointed that we now project RAISE enrollment to conclude by the end of the first quarter, we remain confident in the benefit that IV ganaxolone could bring to critically ill RSE patients and the significant commercial opportunity. We are committed to successfully completing

both the RAISE and TrustTSC trials in 2024 and continue to make the investments to prepare for these commercial launches."

ZTALMY ®

- ZTALMY® (ganaxolone) oral suspension CV net product revenue of $5.4 million for the third quarter of 2023
    - Continued growth in commercial patients with approximately 140 patients active on therapy at the end of the third quarter
- Increased full year 2023 expected ZTALMY net product revenues to between $18.5 and $19 million from a range of $17 to $18.5 million

CDKL5 Deficiency Disorder

- Initiated the Marinus Access Program expanding global availability of ZTALMY for eligible patients with seizures associated with CDKL5 deficiency disorder (CDD) in geographies where the product is not commercially available and as supported by local regulatory requirements
- The Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) has accepted and granted priority review of a New Drug Application (NDA) for ZTALMY in CDD; the NDA was submitted in China by Tenacia Biotechnology under the terms of a collaboration agreement with Marinus
- Orion Corporation continues to prepare for commercial launches of ZTALMY in select European countries in 2024

Clinical Pipeline

Status Epilepticus

- Over 75% of patients required for an interim analysis are now enrolled in the Phase 3 RAISE trial of intravenous (IV) ganaxolone in refractory status epilepticus (RSE)
    - Enrollment for the interim analysis expected to conclude in the first quarter of 2024 with topline data now anticipated in the second quarter of 2024, assuming pre-defined stopping criteria for an interim analysis are met
- 21 patients have now been treated for super refractory status epilepticus (SRSE) under emergency investigational new drug (EIND) applications
- Phase 3 RAISE II trial in RSE (for European registration) enrollment anticipated to begin before year end 2023
- To focus additional resources on the expansion of RSE clinical programs, including further investigation of potential development opportunities in SRSE, Marinus voluntarily discontinued the Phase 2 RESET trial in established status epilepticus

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

Tuberous Sclerosis Complex

- Continue to enroll patients in the global Phase 3 TrustTSC trial of oral ganaxolone in tuberous sclerosis complex with topline data anticipated mid-2024

Second Generation Product Development

- Enrollment in the multiple ascending dose (MAD) trial is well underway with preliminary data expected by year end 2023
- Planning to finalize clinical program design for Lennox-Gastaut syndrome in the first half of 2024, pending results of the MAD trial

General Business and Financial Update

- For the fiscal year 2023, the Company is updating its revenue and operating expense guidance:
    - The Company now expects ZTALMY net product revenues of between $18.5 and $19 million; this represents an increase from the previous guidance of between $17 and $18.5 million
    - The Company now expects GAAP operating expenses, inclusive of G&A and R&D, to be in the range of $158 to $162 million, of which the Company expects stock-based compensation to be approximately $16 million; this represents a decrease from the prior guidance range of $160 to $165 million
- Expect that cash, cash equivalents, and short-term investments of $176.4 million as of September 30, 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
    - During the quarter, a total of 3.7 million shares were sold through the Company's at-the-market (ATM) facility contributing net proceeds of $25.9 million

Financial Results

- Recognized $5.4 million and $13.0 million in net product revenues for the three and nine months ended September 30, 2023, respectively, as compared to $0.6 million in each of the same periods in the prior year. Net product revenue consists of ZTALMY product sales, which was launched in the U.S. in the third quarter of 2022.

- Recognized $1.9 million and $10.8 million in Biomedical Advanced Research and Development Authority (BARDA) federal contract revenue for the three and nine months ended September 30, 2023, respectively, as compared to $1.8 million and $5.1 million for the same periods in the prior year, respectively. The increase on a year-to-date basis was primarily driven by activities associated with the startup of the API onshoring initiative.
- Research and development (R&D) expenses were $23.7 million and $73.0 million for the three and nine months ended September 30, 2023, respectively, as compared to $19.0 million and $58.5 million, respectively, for the same periods in the prior year; the increase on a year-to-date basis was due primarily to increased investment associated with our API onshoring effort, increased TSC and RSE clinical trial activity, and increased headcount.
- Selling, general and administrative (SG&A) expenses were $14.9 million and $45.8 million for the three and nine months ended September 30, 2023, respectively, as compared to $13.4 million and $42.2 million, respectively, for the same periods in the prior year; the increase on a year-to-date basis was due primarily to increased headcount associated with the U.S. launch of ZTALMY.
- The Company had net losses of $33.0 million and $99.6 million for the three and nine months ended September 30, 2023, respectively; cash used in operating activities was $91.0 million for each of the nine months ended September 30, 2023 and 2022
- At September 30, 2023, the Company had cash, cash equivalents, and short-term investments of $176.4 million, compared to $240.6 million at December 31, 2022.

Readers are referred to, and encouraged to read in its entirety, the Company's Quarterly Report on Form 10-Q for the nine months ended September 30, 2023, to be filed with the Securities and Exchange Commission, which includes further detail on the company's business plans, operations, financial condition, and results of operations.

Financial Results

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

	September 30, 2023 (unaudited)	December 31, 2022
ASSETS		
Cash and cash equivalents	$ 140,437	$ 240,551
Short-term investments	35,919	-
Other assets	24,450	18,967
Total assets	$ 200,806	$ 259,518
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities	$ 30,555	$ 25,017
Long term debt, net	64,783	71,018
Revenue interest financing payable, net	32,855	29,857
Other long-term liabilities	18,076	17,626

Total liabilities	146,269	143,518
Total stockholders' equity	54,537	116,000
Total liabilities and stockholders' equity	$ 200,806	$ 259,518

	Three Months Ended September 30, (unaudited)		Nine Months Ended September 30, (unaudited)	
	2023	2022	2023	2022
Revenue:				
Product revenue, net	$ 5,429	$ 555	$ 13,010	$ 555
Federal contract revenue	1,891	1,785	10,753	5,088
Collaboration revenue	18	—	36	12,673
Total revenue	7,338	2,340	23,799	18,316
Expenses:				
Research and development	23,661	19,002	73,006	58,488
Selling, general and administrative	14,868	13,389	45,794	42,187
Cost of product revenue	455	48	1,047	48
Cost of IP license fee	—	—	—	1,169
Total expenses:	38,984	32,439	119,847	101,892
Loss from operations	(31,646)	(30,099)	(96,048)	(83,576)
Interest income	1,895	514	6,366	610
Interest expense	(4,242)	(2,634)	(12,597)	(6,982)
Gain from sale of priority review voucher, net	—	107,375	—	107,375
Other income (expense), net	1,021	(114)	1,105	(1,179)
(Loss) income before income taxes	(32,972)	75,042	(101,174)	16,248
(Provision) benefit for income taxes	—	(1,752)	1,538	(1,752)
Net (loss) income	$ (32,972)	$ 73,290	$ (99,636)	$ 14,496
Net income allocated to preferred shareholders	—	1,656	—	336
Net (loss) income applicable to common shareholders	(32,972)	71,634	(99,636)	14,160
Per share information:				
Net (loss) income per share of common stock—basic	$ (0.61)	$ 1.93	$ (1.89)	$ 0.38
Net (loss) income per share of common stock—diluted	$ (0.61)	$ 1.89	$ (1.89)	$ 0.37
Basic weighted average shares outstanding	53,920,109	37,202,269	52,755,114	37,084,060
Diluted weighted average shares outstanding	53,920,109	37,910,511	52,755,114	38,393,754
Other comprehensive income (loss)				
Unrealized gain (loss) on available-for-sale securities	43	—	(71)	—
Total comprehensive (loss) income	$ (32,929)	73,290	(99,707)	14,496

Conference Call Information

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.

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; the potential benefits from the U.S. onshoring of the manufacturing capabilities for ganaxolone API; 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, unexpected results or delays in the commercialization of ZTALMY; 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 varying interpretation of clinical data; 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; the potential that regulatory authorities, including the FDA and EMA, may not grant or may delay approval for our product candidates; early clinical trials may not be indicative of the results in later clinical trials; 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; our ability to obtain and maintain regulatory approval for our product candidate; 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 size and growth

potential of the markets for the company's product candidates, and the company's ability to service those markets; the company's cash and cash equivalents may not be sufficient to support its operating plan for as long as anticipated; 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; the effect of the COVID-19 pandemic on our business, the medical community, regulators and the global economy; 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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