



NEWS RELEASE

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

8/10/2023

- ZTALMY® (ganaxolone) second quarter net product revenue of \$4.2 million; 2023 net product revenue guidance increased to between \$17 and \$18.5 million
- European Commission approved ZTALMY in CDKL5 deficiency disorder
- Interim analysis for the Phase 3 refractory status epilepticus trial now expected Q1 2024
- First patient dosed in MAD trial with second generation ganaxolone formulation
- New emergency IND dosing paradigm for super refractory status epilepticus showing encouraging initial results
- Granted a new method of use patent by USPTO for ganaxolone in tuberous sclerosis complex
- Cash runway expected into second half of 2024 with cash, cash equivalents and short-term investments of \$175.3 million as of June 30, 2023
- Marinus to host conference call on August 10, 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 second quarter ended June 30, 2023.

“With continued demand growth and robust payer coverage for ZTALMY, we are pleased to increase our 2023 net product revenue guidance to a range of \$17 to \$18.5 million,” said Scott Braunstein, M.D., Chairman and Chief Executive Officer of Marinus. “Additionally, the European Commission’s recent approval of ZTALMY in CDKL5 deficiency disorder offers a novel therapeutic option for patients and families and creates new opportunities for ganaxolone in the international market.”

“Our clinical pipeline is progressing at an encouraging pace as we continue to overcome industry headwinds



affecting clinical trial recruitment. We are confident in our ability to execute against our updated RAISE timeline and previously stated TrustTSC timeline, which would result in two pivotal Phase 3 data readouts next year. We are excited to have initiated the MAD trial of our second generation ganaxolone formulation and are on track for preliminary data before the end of the year.”

ZTALMY®

- ZTALMY® (ganaxolone) oral suspension CV net product revenue of \$4.2 million for the second quarter of 2023
 - Continued growth in commercial patients with approximately 120 patients active on therapy at the end of the second quarter
- Increased full year 2023 expected ZTALMY net product revenues to between \$17 and \$18.5 million from a range of \$15 to \$17 million
- European Commission **granted marketing authorization** for ZTALMY in CDKL5 deficiency disorder in July 2023
 - Marinus is eligible to begin receiving royalties and commercialization and sales milestones under the Collaboration Agreement with Orion Corporation
- At two years in the open label extension phase of the Marigold study, patients (n=50) continuing treatment with ZTALMY experienced a median 48.2% reduction in major motor seizure frequency, suggesting that patients who remain on treatment long-term may demonstrate sustained reductions in seizure frequency

Clinical Pipeline

Status Epilepticus

- Topline data from an interim analysis of the Phase 3 RAISE trial of intravenous (IV) ganaxolone in refractory status epilepticus (RSE) now expected in the first quarter of 2024, if it meets the pre-defined stopping criteria
 - RAISE sites are being resupplied with the new citrate buffer formulation of IV ganaxolone
- 18 patients have now been treated for super refractory status epilepticus (SRSE) under emergency investigational new drug (EIND) applications
 - New EIND dosing paradigm for SRSE showing encouraging initial results
- Phase 3 RAISE II trial in RSE (for European registration) enrollment anticipated to begin in the second half of 2023
- Phase 2 RESET trial in established status epilepticus (ESE) completion of first cohort anticipated before year end 2023

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 (TSC)

- Continue to enroll patients in the global Phase 3 TrustTSC trial of oral ganaxolone with topline data anticipated mid-2024
- New method of use patent granted by USPTO for ganaxolone in TSC, expiring in 2040

Second Generation Product Development

- Enrollment in the multiple ascending dose (MAD) trial has initiated with preliminary data expected by year end 2023
- Planning to finalize clinical program design for Lennox-Gastaut syndrome in the first quarter of 2024, pending results of the MAD trial
- Prodrug development continues to advance with lead oral candidate selected; IND application submission targeted for the fourth quarter of 2024

General Business and Financial Update

- For the fiscal year 2023, the Company is updating its revenue and operating expense guidance:
 - ZTALMY Revenue: The Company now expects ZTALMY net product revenues of between \$17 and \$18.5 million; this represents an increase from the previous guidance of between \$15 and \$17 million
 - BARDA Revenue: The Company now expects BARDA revenues between \$11 and \$12 million; this represents an increase from the previous guidance of between \$8 and \$11 million
 - GAAP Operating Expense: The Company now expects GAAP operating expenses, inclusive of G&A and R&D, to be in the range of \$160 to \$165 million, of which the Company expects stock-based compensation to be approximately \$15 million; this represents a decrease from the prior guidance range of \$165 to \$175 million
- Expect that cash, cash equivalents, and short-term investments of \$175.3 million as of June 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 second half of 2024.

Financial Results

- Recognized \$4.2 million and \$7.6 million in net product revenues for the three and six months ended June 30, 2023, respectively. Net product revenue consists of ZTALMY product sales, which was launched in the U.S. in the third quarter of 2022.

- Recognized \$1.8 million and \$8.9 million in Biomedical Advanced Research and Development Authority (BARDA) federal contract revenue for the three and six months ended June 30, 2023, respectively, as compared to \$1.8 million and \$3.3 million for the same periods in the prior year, respectively. The increase on a year-to-date basis was primarily driven by activity associated with start-up of the API onshoring initiative.
- Research and development (R&D) expenses were \$21.4 million and \$49.3 million for the three and six months ended June 30, 2023, respectively, as compared to \$21.5 million and \$39.5 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 \$15.7 million and \$30.9 million for the three and six months ended June 30, 2023, respectively, as compared to \$17.1 million and \$28.8 million, respectively, for the same periods in the prior year; the increase on a year-to-date basis was due primarily to increased commercial headcount associated with the US launch of ZTALMY.
- The Company had net losses of \$31.9 million and \$66.7 million for the three and six months ended June 30, 2023, respectively; cash used in operating activities increased to \$65.8 million for the six months ended June 30, 2023, compared to \$61.3 million for the same period a year ago.
- At June 30, 2023, the Company had cash, cash equivalents, and short-term investments of \$175.3 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 six months ended June 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.

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

	June 30, 2023 (Unaudited)	December 31, 2022
ASSETS		
Cash and cash equivalents	\$ 127,787	\$ 240,551
Short-term investments	47,549	-
Other assets	25,864	18,967
Total assets	<u>\$ 201,200</u>	<u>\$ 259,518</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities	\$ 25,603	\$ 25,017
Long term debt, net	68,136	71,018
Revenue interest financing payable, net	31,950	29,857
Other long-term liabilities	18,172	17,626
Total liabilities	<u>143,861</u>	<u>143,518</u>
Total stockholders' equity	57,339	116,000
Total liabilities and stockholders' equity	<u>\$ 201,200</u>	<u>\$ 259,518</u>

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenue:				
Product revenue, net	\$ 4,249	\$ —	\$ 7,581	\$ —
Federal contract revenue	1,814	1,790	8,862	3,303
Collaboration revenue	18	—	18	12,673
Total revenue	6,081	1,790	16,461	15,976
Expenses:				
Research and development	21,412	21,495	49,345	39,486
Selling, general and administrative	15,722	17,061	30,926	28,798
Cost of product revenue	386	—	592	—
Cost of IP license fee	—	—	—	1,169
Total expenses:	37,520	38,556	80,863	69,453
Loss from operations	(31,439)	(36,766)	(64,402)	(53,477)
Interest income	2,128	84	4,471	96
Interest expense	(4,208)	(2,656)	(8,355)	(4,348)
Other income (expense), net	47	(95)	84	(1,065)
Loss before income taxes	(33,472)	(39,433)	(68,202)	(58,794)
Benefit for income taxes	1,538	—	1,538	—
Net loss applicable to common shareholders	\$ (31,934)	\$ (39,433)	\$ (66,664)	\$ (58,794)
Per share information:				
Net loss per share of common stock—basic and diluted	\$ (0.61)	\$ (1.06)	\$ (1.28)	\$ (1.59)
Basic and diluted weighted average shares outstanding	52,551,918	37,155,917	52,162,962	37,023,976
Other comprehensive loss				
Unrealized loss on available-for-sale securities	(188)	—	(114)	—
Total comprehensive loss	\$ (32,122)	\$ (39,433)	\$ (66,778)	\$ (58,794)

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 cash runway; our expectations regarding BARDA funding; 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 expectation regarding the impact of the COVID-19 pandemic on our business and clinical development plans; 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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