NEWS RELEASE

Marinus Pharmaceuticals Provides Business Update and Reports Fourth Quarter and Full Year 2022 Financial Results

3/7/2023

- ZTALMY® U.S. net product revenue of $2.3 million for the fourth quarter of 2022 and $2.9 million for the fiscal year ended December 31, 2022
- Company expects ZTALMYU.S. net product revenues of between $15 million and $17 million for the fiscal year ending December 31, 2023
- Second generation oral formulation development continues to advance based on encouraging Phase 1 data
- Actively recruiting Phase 3 clinical trials in refractory status epilepticus and tuberous sclerosis complex; data continues to be expected 2H 2023 and Q1 2024, respectively
- Phase 2 clinical trial of oral ganaxolone in PCDH-19 published in **Epilepsy Research**
- Cash and cash equivalents of $240.6 million as of December 31, 2022
- Marinus to host conference call on March 7, 2023, 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, 2022.

“2022 was a year of significant growth and execution for Marinus, underscored by the successful U.S. launch of ZTALMY,” said Scott Braunstein, M.D., Chairman and Chief Executive Officer of Marinus. “With a strong balance sheet and continued progress advancing our second generation formulation and Phase 3 trials in status epilepticus and tuberous sclerosis complex, we entered 2023 with increased confidence in our ability to expand the value proposition of ganaxolone in rare epilepsies.”

ZTALMY ®

- Continued to execute U.S. commercial launch of ZTALMY® (ganaxolone) oral suspension CV, resulting in net product revenue of $2.3 million for the fourth quarter of 2022 and $2.9 million for the fiscal year ended December 31, 2022
    - Consistent growth in commercial patients with over 90 total completed CDKL5 deficiency disorder (CDD) prescription enrollment forms received from over 60 unique accounts for the fiscal year ended December 31, 2022
- Full year 2023 expected ZTALMY net product revenues of $15 million to $17 million
- As of February 28, 2023, total coverage for ZTALMY increased to approximately 220 million lives, including both commercial and government programs
    - ZTALMY received favorable coverage determinations representing approximately 125 million commercial lives, or 79% of commercial plans
    - Medicaid access in all U.S. states, Washington D.C. and Puerto Rico, representing approximately 95 million lives

Clinical Pipeline

Status Epilepticus

- Protocol amendment for the Phase 3 RAISE trial of intravenous (IV) ganaxolone in refractory status epilepticus (RSE) has been broadly adopted and topline results continue to be expected in the second half of 2023
- 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) site activations underway with first cohort data anticipated before year end 2023
- Successfully manufactured modified IV formulation of ganaxolone with new buffer, targeting a shelf life of at least 24 months, and expect to incorporate in RAISE trial in Q2 2023
    - Registration batches of modified formulation to be placed on stability by Q2 2023
- Received Notice of Allowance from the U.S. Patent and Trademark Office for a second patent with claims related to the Company's clinical therapeutic regimen for the treatment of status epilepticus using IV ganaxolone

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.

Second Generation Product Development

- A Phase 1 single ascending dose study of a second generation oral formulation was conducted
    - Preliminary Phase 1 data showed linear dose response up to 1200 mg and the potential for BID dosing with less peak / trough variability
    - Second generation ganaxolone was generally well tolerated with no new safety signals
- Multiple ascending dose (MAD) study expected to initiate in the second quarter of 2023
- Planning to finalize clinical program design for Lennox-Gastaut syndrome in second half of 2023
- Prodrug development continues to advance with lead oral candidate selected; Phase 1 data targeted for 2024

Tuberous Sclerosis Complex (TSC)

- Actively screening and enrolling patients in Phase 3 TrustTSC trial of oral ganaxolone at sites in the U.S. and Europe
- Targeting approximately 90 clinical sites, including additional activations in Canada, Israel, Italy, Belgium, Australia, and China
- Topline data continues to be anticipated in the first quarter of 2024

CDKL5 Deficiency Disorder (CDD) Marketing Authorization Application (MAA)

- Marinus received the Day 180 report from the European Medicines Agency (EMA) in January 2023 containing outstanding major objections, including the choice of regulatory starting material
- The Committee for Medicinal Products for Human Use (CHMP) is expected to present its opinion on the MAA in the second quarter of 2023

PCDH-19

- Results of Phase 2 placebo-controlled clinical trial of oral ganaxolone in PCDH19-clustering epilepsy recently published in **Epilepsy Research**

General Business and Financial Update

- Steven Pfanstiel promoted to Chief Operating Officer in addition to current role as Chief Financial Officer.
- Expect that cash and cash equivalents of $240.6 million as of December 31, 2022 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.
- In Q4 2022, Marinus completed a follow-on equity offering, a revenue interest financing agreement, and a development and commercialization agreement with Tenacia Biotechnology for the Chinese market.

Combined, these three deals brought in net funding of over $100 million within the quarter.

Financial Results (Preliminary)

- Recognized $2.3 million and $2.9 million in net product revenues for the three and twelve months ended December 31, 2022, respectively. Net product revenue consists of ZTALMY product sales in the U.S. market, and the 4th quarter of 2022 represents the first full quarter of sales based on the Company's July 2022 launch of ZTALMY.
- Recognized $1.8 million and $6.9 million in Biomedical Advanced Research and Development Authority (BARDA) federal contract revenue for the three and twelve months ended December 31, 2022, respectively, as compared to $1.5 million and $6.4 million for the three and twelve months ended December 31, 2021, respectively.
- Recognized collaboration revenue of $3.0 million in the fourth quarter of 2022 related to the upfront payment associated with the Company's development and commercialization agreement with Tenacia.
- Research and development (R&D) expenses were $21.4 million and $79.9 million for the three and twelve months ended December 31, 2022, respectively, as compared to $18.0 million and $73.5 million, respectively, for the same periods in the prior year; the increase was due primarily to increased R&D headcount and clinical trial activity including the ongoing RSE, TSC, and ESE trials.
- Selling, general and administrative (SG&A) expenses were $14.7 million and $56.8 million for the three and twelve months ended December 31, 2022, respectively, as compared to $10.6 million and $37.3 million, respectively, for the same periods in the prior year; the primary drivers of the change were increased headcount and commercial support for the U.S. launch of ZTALMY.
- The Company had net losses of $34.3 million and $19.8 million for the three and twelve months ended December 31, 2022, respectively; cash used in operating activities increased to $112.9 million for the twelve months ended December 31, 2022, compared to $55.5 million for the same period a year ago.
- At December 31, 2022, the Company had cash and cash equivalents of $240.6 million, compared to $122.9 million at December 31, 2021.
- 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, 2022, to be filed with the Securities and Exchange Commission, which includes further details on the Company's business plans, operations, financial condition, and results of operations.

Corporate Guidance

- For the fiscal year 2023, the Company expects ZTALMY U.S. net product revenues of between $15 million and $17 million, BARDA revenues in the range of $8 million to $11 million and total GAAP operating expenses, inclusive of SG&A and R&D, to be in the range of $165 to $175 million, of which the company expects stock-

based compensation to be approximately $16 million.

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

	December 31, 2022 (Unaudited)	December 31, 2021
ASSETS		
Cash and cash equivalents	$ 240,551	$ 122,927
Other assets	18,967	13,913
Total assets	$ 259,518	$ 136,840
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities	$ 25,017	$ 40,566
Long term debt, net	71,018	40,809
Revenue interest financing payable, net of deferred financing costs	29,857	-
Other long-term liabilities	17,626	1,979
Total liabilities	143,518	83,354
Total stockholders' equity	116,000	53,486
Total liabilities and stockholders' equity	$ 259,518	$ 136,840

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2022 (unaudited)	2021	2022 (unaudited)	2021
Revenue:				
Product revenue, net	$ 2,317	$ -	$ 2,872	$ -
Federal contract revenue	1,847	1,520	6,935	6,358
Collaboration revenue	2,998	-	15,671	8,987
Total revenue	7,162	1,520	25,478	15,345
Expenses:				
Research and development	21,424	18,014	79,912	73,520
Selling, general and administrative	14,658	10,622	56,845	37,278
Cost of product revenue	142	-	190	-
Cost of collaboration revenue	150	-	150	1,478
Cost of IP license fee	-	-	1,169	-
Total expenses:	36,374	28,636	138,266	112,276
Loss from operations	(29,212)	(27,116)	(112,788)	(96,931)
Interest income	1,744	23	2,354	80
Interest expense	(3,690)	(1,553)	(10,672)	(2,582)
Gain from sale of priority review voucher, net	-	-	107,375	-
Other (expense) income, net	(1,517)	341	(2,696)	657
Loss before income taxes	(32,675)	(28,305)	(16,427)	(98,776)
Provision for income taxes	(1,637)	-	(3,389)	-
Net loss and comprehensive loss	$ (34,312)	$ (28,305)	$ (19,816)	$ (98,776)
Per share information:				
Net loss per share of common stock – basic and diluted	$ (0.76)	$ (0.77)	$ (0.51)	$ (2.69)
Basic and diluted weighted average shares outstanding	44,973,371	36,746,112	39,072,599	36,697,171

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's commercial product, ZTALMY® (ganaxolone) oral suspension CV, has been

approved by the U.S. FDA for the treatment of seizures associated with CDKL5 deficiency disorder in patients two years of age and older. The potential of ganaxolone is also being studied in other seizure disorders, including in Phase 3 trials in tuberous sclerosis complex and refractory status epilepticus. Ganaxolone is a neuroactive steroid GABAA receptor modulator that acts on a well-characterized target in the brain known to have anti-seizure effects. It is being developed 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; the potential benefits ZTALMY will provide for physicians and patients; our expectations regarding the ZTALMY One program; 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 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 including with respect to the CDD MAA; 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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