November 8, 2023

Matinas BioPharma Reports Third Quarter 2023 Financial Results and Provides a Business Update

FDA feedback on MAT2203 Phase 3 program supports a patient population in invasive aspergillosis with limited treatment options, acknowledges potential for LPAD pathway; composite superiority endpoint under evaluation to strengthen commercial opportunity without increasing study size

Patient with Candida krusei *infection achieved complete clinical resolution with MAT2203; additional patient enrolled in the Compassionate/Expanded Use Access Program*

Oral LNC formulation of docetaxel showed reduction in tumor size comparable to IV-docetaxel with no systemic toxicity in preclinical melanoma model

Conference call begins at 4:30 p.m. Eastern time today

BEDMINSTER, N.J., Nov. 08, 2023 (GLOBE NEWSWIRE) -- Matinas BioPharma (NYSE American: MTNB), a clinical-stage biopharmaceutical company focused on delivering groundbreaking therapies using its lipid nanocrystal (LNC) platform delivery technology, reports financial results for the three and nine months ended September 30, 2023 and provides a business update.

“We are very excited by the consistent, positive clinical data generated with MAT2203 in our Compassionate/Expanded Use Access Program. The patients treated under this program suffer from invasive fungal infections with few treatment options. We plan to treat a similar patient population in our Phase 3 study – those with invasive aspergillosis and limited treatment options,” said Jerome D. Jabbour, Chief Executive Officer of Matinas. “Our recent meeting with FDA supports our Phase 3 strategy, including the potential for LPAD registration. We’re highly encouraged by FDA’s openness to a superiority composite primary endpoint, which could be significant in positioning MAT2203 for commercial success. We look forward to finalizing the Phase 3 study design as soon as possible and advancing our ongoing partnership discussions for this important product.”

Key Program Updates

MAT2203 (Oral Amphotericin B) Program

FDA Meeting Feedback

- A meeting was held with the U.S. Food and Drug Administration (FDA) in mid-October with both the Director and Deputy Director of the Office of Infectious Diseases in

attendance. The FDA agreed with the Phase 3 study design for the treatment of invasive aspergillosis in patients with limited treatment options and confirmed that MAT2203 may be a candidate for the Limited Population Pathway for Antifungal and Antibacterial Drugs (LPAD).
- During discussions regarding the statistical assumptions for a noninferiority Phase 3 trial design, FDA expressed openness to a proposed alternative superiority composite endpoint, which we believe would best position MAT2203 for commercial success and differentiation upon approval. The revised superiority composite endpoint is being finalized and will be submitted to FDA for alignment in the next few weeks.
- The Company believes that a superiority study incorporating a composite endpoint would not change the projected study size (<200 patients) or enrollment timeline (22-24 mos.). The FDA has communicated its commitment to work with the Company on an off-cycle basis to finalize the Phase 3 protocol as soon as possible.

General MAT2203 Updates

- A total of 12 patients have been enrolled in the Company's Compassionate/Expanded Use Access Program. In October, the Company announced that a 61-year-old male with a challenging medical history achieved complete clinical resolution of a *Candida krusei* infection following only two weeks of treatment with MAT2203. Treatment with IV-amphotericin B was discontinued due to renal toxicity and the patient was transitioned to MAT2203, which was well-tolerated with no adverse effects. Treatment with MAT2203 led to complete resolution of his symptoms and improvement of his kidney function to baseline.
- Earlier this month, an additional patient was enrolled in this Program at Vanderbilt University Medical Center. This patient is suffering from a CNS-based fusarium infection and required transition from IV-amphotericin due to significant electrolyte abnormalities. The patient may also be able to be discharged from the hospital in order to receive treatment at home.
- University of Minnesota Medical School researchers published results from the Phase 2 EnACT trial evaluating MAT2203 for the treatment of cryptococcal meningitis as a Major Article and Editor's Choice in *Clinical Infectious Diseases*, an official publication of the Infectious Diseases Society of America (IDSA).
- The published results of the EnACT Phase 2 trial, the ongoing positive clinical outcomes in the Compassionate/Expanded Use Access Program, and the recent additional clarity and support from the FDA for the MAT2203 Phase 3 program have all resulted in significant new interest from potential partners for licensing, acquiring or otherwise collaborating on MAT2203.
- During a meeting held in the third quarter, the Biomedical Advanced Research and Development Authority (BARDA) invited the Company to submit a White Paper for Phase 3 funding consideration. The Company intends to submit the White Paper following finalization of the Phase 3 study design.

LNC Platform Updates

Oral LNC-Docetaxel

- The Company announced positive results from an *in vivo* animal study of an oral LNC formulation of docetaxel, a well-known chemotherapeutic agent used in the management of multiple metastatic and unresectable tumors. Anti-tumor effects of

daily oral LNC-docetaxel were comparable to IV-docetaxel with statistically significant reductions in tumor volume compared with untreated controls at Day 14 (high dose oral LNC -63%; low dose oral LNC -57%; IV docetaxel -68%), and similar reductions in tumor weight at Day 14. No systemic toxicities were noted. Body weight was stable over treatment duration and hematologic parameters were similar to untreated controls.
- Potential next steps include evaluating the efficacy of the current LNC-docetaxel formulation in other tumor models and evaluating longer-term treatment regimens to confirm lack of toxicity. Additionally, the Company plans to evaluate the potential anti-tumor activity of LNC formulations of small oligonucleotides.

Internal Oral LNC Small Oligonucleotide Program

- The Company is investigating a variety of LNC formulations of two small oligonucleotides designed to target inflammatory cytokines IL-17A and TNFa, and has conducted a series of *in vitro* and *in vivo* studies to evaluate the biological activity associated with oral delivery as well as the corresponding associated clinical benefit of IL-17A knockdown in an imiquimod (IMQ) induced murine psoriasis disease model.
- These preliminary studies have documented biological activity in the form of cytokine knockdown and have also provided some evidence of associated tangible clinical benefit with improvements in skin lesion appearance (redness, scaling) in this qualitative psoriasis model. These data remain under evaluation and the analyses are focused on (a) clarifying the strength and time course of cytokine inhibition, and (b) evaluating cytokine mRNA levels and specific tissue responses in these models to better understand and interpret these data.
- Additional *in vivo* studies of LNC-formulated small oligonucleotides in other disease models are ongoing with additional data expected in the fourth quarter of this year.

Third Quarter Financial Results

The Company reported no revenue for the third quarter of 2023 compared with $1.1 million of revenue for the third quarter of 2022, which was generated from the Company's research collaborations with BioNTech SE.

Total costs and expenses for the third quarter of 2023 were $6.1 million compared with $6.5 million for the third quarter of 2022. The decrease was primarily attributable to decreases in costs for the manufacturing of clinical trial materials, and lower clinical trial consulting and headcount costs.

The net loss for the third quarter of 2023 was $6.1 million, or $0.03 per share, compared with a net loss for the third quarter of 2022 of $5.5 million, or $0.03 per share.

Nine Month Financial Results

Revenue for the first nine months of 2023 was $1.1 million compared with $2.1 million for the first nine months of 2022. Total costs and expenses for the first nine months of 2023 were $19.0 million compared with $21.2 million for the first nine months of 2022.

The net loss for the first nine months of 2023 was $17.6 million, or $0.08 per share, compared with a net loss for the first nine months of 2022 of $17.4 million, or $0.08 per

share.

Cash, cash equivalents and marketable securities as of September 30, 2023, were $18.2 million compared with $28.8 million as of December 31, 2022. Based on current projections, the Company believes its cash position is sufficient to fund planned operations into the third quarter of 2024.

The Company is seeking to extend its cash runway by securing non-dilutive funding from potential third-party development partners and government grant programs through agencies such as BARDA, as well as from potential public or private equity offerings.

Conference Call and Webcast

Matinas will host a conference call and webcast today beginning at 4:30 p.m. Eastern time. To participate in the call, please dial 800-267-6316 or 203-518-9783. The live webcast will be accessible on the Investors section of the company's website and archived for 90 days.

About Matinas BioPharma
Matinas BioPharma is a biopharmaceutical company focused on delivering groundbreaking therapies using its lipid nanocrystal (LNC) platform delivery technology.

Matinas' lead LNC-based therapy is MAT2203, an oral formulation of the broad-spectrum antifungal drug amphotericin B, which although highly potent, can be associated with significant toxicity. Matinas' LNC platform provides oral delivery of amphotericin B without the significant nephrotoxicity otherwise associated with IV-delivered formulations. MAT2203 also allows for safe, longer-term use outside of a hospital setting, which could have substantial favorable pharmacoeconomic impact. MAT2203 was successfully evaluated in the completed Phase 2 EnACT study in cryptococcal meningitis, meeting its primary endpoint and achieving robust survival. MAT2203 will be further evaluated as an oral step-down monotherapy treatment following IV amphotericin B in a single pivotal Phase 3 study in the treatment of aspergillosis in persons with limited treatment options who are unable to be treated with azoles for reasons related to drug-drug interactions, resistance or for whom these antifungal agents are unable to be used for other clinical reasons.

In addition to MAT2203, preclinical and clinical data have demonstrated that this novel technology can potentially provide solutions to many of the challenges standing in the way of achieving safe and effective intracellular delivery of both small molecules and larger, more complex molecular cargos such as RNAi, antisense oligonucleotides, and vaccines. The combination of its unique mechanism of action and flexibility with routes of administration (including oral) positions Matinas' LNC technology to potentially become a preferred next-generation orally available intracellular drug delivery platform. For more information, please visit www.matinasbiopharma.com.

Forward-looking Statements
This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including those relating to our business activities, our strategy and plans, our collaboration with National Resilience, Inc., the potential of our LNC platform technology, and the future development of its product candidates, including MAT2203, the Company's ability to identify and pursue development, licensing and partnership opportunities for its products, including MAT2203, or platform delivery

technologies on favorable terms, if at all, and the ability to obtain required regulatory approval and other statements that are predictive in nature, that depend upon or refer to future events or conditions. All statements other than statements of historical fact are statements that could be forward-looking statements. Forward-looking statements include words such as "expects," "anticipates," "intends," "plans," "could," "believes," "estimates" and similar expressions. These statements involve known and unknown risks, uncertainties and other factors which may cause actual results to be materially different from any future results expressed or implied by the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including, but not limited to, our ability to continue as a going concern, our ability to obtain additional capital to meet our liquidity needs on acceptable terms, or at all, including the additional capital which will be necessary to complete the clinical trials of our product candidates; our ability to successfully complete research and further development and commercialization of our product candidates; the uncertainties inherent in clinical testing; the timing, cost and uncertainty of obtaining regulatory approvals; our ability to protect the Company's intellectual property; the loss of any executive officers or key personnel or consultants; competition; changes in the regulatory landscape or the imposition of regulations that affect the Company's products; and the other factors listed under "Risk Factors" in our filings with the SEC, including Forms 10-K, 10-Q and 8-K. Investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this release. Except as may be required by law, the Company does not undertake any obligation to release publicly any revisions to such forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. Matinas BioPharma's product candidates are all in a development stage and are not available for sale or use.

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[*Financial Tables to Follow*]

Matinas BioPharma Holdings, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except for share data)

	September 30, 2023 (Unaudited)	December 31, 2022 (Audited)
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 6,407	$ 6,830
Marketable debt securities	11,809	21,933

Restricted cash – security deposit	50	50
Prepaid expenses and other current assets	1,723	5,719
Total current assets	19,989	34,532
Non-current assets:		
Leasehold improvements and equipment – net	2,021	2,091
Operating lease right-of-use assets – net	3,206	3,613
Finance lease right-of-use assets – net	22	30
In-process research and development	3,017	3,017
Goodwill	1,336	1,336
Restricted cash – security deposit	200	200
Total non-current assets	9,802	10,287
Total assets	$ 29,791	$ 44,819
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	$ 835	$ 618
Accrued expenses	1,757	3,099
Operating lease liabilities – current	632	562
Financing lease liabilities – current	5	7
Total current liabilities	3,229	4,286
Non-current liabilities:		
Deferred tax liability	341	341
Operating lease liabilities – net of current portion	3,052	3,533
Financing lease liabilities – net of current portion	19	22
Total non-current liabilities	3,412	3,896
Total liabilities	6,641	8,182
Stockholders' equity:		
Common stock par value $0.0001 per share, 500,000,000 shares authorized at September 30, 2023 and December 31, 2022; 217,264,526 issued and outstanding as of September 30, 2023 and December 31, 2022	22	22
Additional paid-in capital	193,746	190,070
Accumulated deficit	(170,259)	(152,631)
Accumulated other comprehensive loss	(359)	(824)
Total stockholders' equity	23,150	36,637
Total liabilities and stockholders' equity	$ 29,791	$ 44,819

Matinas BioPharma Holdings, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)
Unaudited

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Revenue:				
Contract Revenue	$ —	$ 1,063	$ 1,096	$ 2,125
Costs and expenses:				
Research and development	3,295	3,707	10,824	12,811
General and administrative	2,839	2,818	8,151	8,424
Total costs and expenses	6,134	6,525	18,975	21,235
Loss from operations	(6,134)	(5,462)	(17,879)	(19,110)
Sale of New Jersey net operating losses & tax credits	—	—	—	1,734
Other income, net	79	—	251	13
Net loss	$ (6,055)	$ (5,462)	$ (17,628)	$ (17,363)
Net loss per share – basic and diluted	$ (0.03)	$ (0.03)	$ (0.08)	$ (0.08)
Weighted average common shares outstanding:				
Basic and diluted	217,264,526	216,864,526	217,264,526	216,792,083
Other comprehensive gain/(loss), net of tax				
Unrealized gain/(loss) on securities available-for-sale	155	(181)	465	(790)
Other comprehensive gain/(loss), net of tax	155	(181)	465	(790)
Comprehensive loss	$ (5,900)	$ (5,643)	$ (17,163)	$ (18,153)

Source: Matinas BioPharma Holdings, Inc.