

Matinas BioPharma Reports Second Quarter 2024 Financial Results and Provides a Business Update

Signs non-binding term sheet granting global rights to develop and commercialize oral MAT2203 for invasive aspergillosis and potentially other invasive fungal infections

31 patients have enrolled in the MAT2203 Compassionate/Expanded Use Access Program with 6 additional patients under evaluation

Additional LNC platform work in inflammation and oncology completed; Company evaluating next steps

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

BEDMINSTER, N.J., Aug. 14, 2024 (GLOBE NEWSWIRE) -- <u>Matinas BioPharma</u> Holdings, Inc. (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 six months ended June 30, 2024 and provides a business update.

"We continue to engage in constructive partnership dialogues for MAT2203 and are pleased to announce that we have signed a non-binding term sheet for global licensing rights to this oral formulation of the potent, yet toxic antifungal amphotericin B," said Jerome D. Jabbour. Chief Executive Officer of Matinas. "Since June, seven additional patients have gained access to oral MAT2203 in our Compassionate/Expanded Use Access Program with an additional six patients under evaluation. We are experiencing a dramatic increase in requests by physicians seeking access for their patients who have limited or no treatment options, which we attribute to the consistently positive clinical impact of MAT2203 in successfully treating a variety of deadly invasive fungal infections.

"Recent studies have increased our understanding of the potential for our LNC platform in delivering both small oligonucleotides and small molecule oncology drugs, including LNC cellular uptake and cargo delivery," he added. "We continue to expand our knowledge base and are evaluating the next best steps for this technology as we determine how to maximize return to shareholders. We expect to be in a better position to provide additional guidance following the consummation of a MAT2203 partnership."

Key Program Updates

MAT2203 (Oral Amphotericin B)

- Matinas signed a non-binding term sheet with a single partner for global licensing rights to develop, manufacture and commercialize MAT2203 for all future treatment indications, including the intended initial indication of treatment for patients with invasive aspergillosis with limited or no other treatment options. Preparations are ongoing to enable the initiation of the ORALTO Phase 3 registration trial of MAT2203 to commence as soon as possible following a successful partnership announcement.
- Under the Compassionate/Expanded Use Access Program, 31 patients with a variety
 of serious and even life-threatening invasive fungal infections with limited or no other
 treatment options have been provided access to oral MAT2203, and 6 additional
 requests are under evaluation. Importantly, 7 patients have been or are being treated
 for invasive aspergillosis, each with positive results.
- Of the 15 patients in the Compassionate/Expanded Use Access Program who have completed treatment with MAT2203 (median treatment of 16 weeks with a range of 2 to 49 weeks), 8 had a complete response and 7 were improved. Response to treatment was assessed by the treating physician. Nine additional patients are continuing to receive longer-term treatment with positive ongoing effects and 5 have just recently initiated treatment. To date, only 2 patients have discontinued MAT2203 in this program, both occurring during the first week of treatment, with one due to an intolerance and the other due to a terminal condition not otherwise related to the underlying fungal infection.

LNC Platform

- Following early success in melanoma, recent additional in vivo studies in animal breast, prostate and lung cancer models have demonstrated varying degrees of tumor growth inhibition with daily oral dosing of LNC-docetaxel. Additionally, daily oral LNCdocetaxel in combination with intravenous docetaxel demonstrated greater degrees of tumor inhibition, but also resulted in additional weight loss. Additional studies are evaluating several strategies to potentially improve the therapeutic index of docetaxel.
- An LNC formulation of an additional chemotherapeutic agent, miriplatin, a highly toxic
 agent only approved outside the U.S. for intra-arterial use, demonstrated strong
 cellular uptake and tumor cell-killing capabilities in vitro in testing conducted during the
 second quarter. More recent in vivo testing showed the oral LNC formulation of
 miriplatin as very effective in reducing tumor sizes with significant weight loss also
 observed.
- A series of *in vitro* studies was recently completed investigating potential relationships between the amount of surface phosphatidylserine (PS) and the extent of LNC uptake into certain tumor cells. Based upon these studies, surface PS expression appears to be one, but not the only, driving factor for cellular uptake. Additional work is ongoing to better understand and predict the efficacy of LNC-delivered chemotherapeutics.
- Following early encouraging in vivo data demonstrating the successful oral delivery, biological activity, and potential therapeutic efficacy of two different LNC-formulated small oligonucleotides targeting inflammatory cytokines IL-17A and TNFα, more recent follow-up in vivo studies of orally administered LNC-formulated small oligonucleotides have been less consistent in showing therapeutic efficacy in certain inflammatory

conditions. Additional optimization is required prior to identifying a potential product candidate.

Second Quarter Financial Results

The Company reported no revenue for the second guarters of 2024 and 2023.

Total costs and expenses for the second quarter of 2024 were \$5.8 million, compared with \$6.2 million for the second quarter of 2023. The decrease was primarily due to lower clinical development expenses, personnel costs and administrative expenses.

The net loss for the second quarter of 2024 was \$5.7 million, or \$0.02 per share, compared with a net loss for the second quarter of 2023 of \$6.1 million, or \$0.03 per share.

Six Month Financial Results

The Company reported no revenue for the six months ended June 30, 2024, compared with \$1.1 million for the six months ended June 30, 2023, which was generated from research collaborations with BioNTech SE and Genentech Inc.

Total costs and expenses for the first six months of 2024 were \$11.7 million, compared with \$12.8 million for the first six months of 2023.

The net loss for the first six months of 2024 was \$11.5 million, or \$0.05 per share, compared with a net loss for the first six months of 2023 of \$11.6 million, or \$0.05 per share.

Cash, cash equivalents and marketable securities as of June 30, 2024, were \$14.3 million, compared with \$13.8 million as of December 31, 2023. In April 2024, the Company raised gross proceeds of \$10.0 million through a registered direct offering.

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 (866) 682-6100 or (862) 298-0702. 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. Combining comparable fungicidal activity with targeted delivery results in a lower risk of toxicity and potentially creates the ideal antifungal agent for the treatment of invasive fungal infections. MAT2203 was successfully evaluated in the completed Phase 2 EnACT study in HIV patients suffering from cryptococcal meningitis, meeting its primary endpoint and achieving robust survival. MAT2203 will be further evaluated in a single Phase 3 registration trial (the "ORALTO" trial) as an oral step-down monotherapy following treatment with AmBisome® (liposomal amphotericin B) compared with the standard of care in patients with invasive

aspergillosis who have limited treatment options.

In addition to MAT2203, preclinical and clinical data have demonstrated that this novel technology can potentially provide solutions to many challenges of achieving safe and effective intracellular delivery of both small molecules and larger, more complex molecular cargos including small oligonucleotides such as ASOs and siRNA. 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, the potential of our LNC platform technology, and the future development of our 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.

Investor Contact:

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[Financial Tables to Follow]

Matinas BioPharma Holdings, Inc. Condensed Consolidated Balance Sheets

(in thousands, except for share data)

	June 30, 2024	
ASSETS:	(Unaudited)	(Audited)
Current assets:		
Cash and cash equivalents	\$ 4,21	6 \$ 4,787
Marketable debt securities	10,09	•
Restricted cash – security deposit	•	0 50
Prepaid expenses and other current assets	92	
Total current assets	15,28	
Non-current assets:		
Leasehold improvements and equipment – net	1,73	9 1,923
Operating lease right-of-use assets – net	2,77	0 3,064
Finance lease right-of-use assets – net	1	8 21
In-process research and development	3,01	7 3,017
Goodwill	1,33	•
Restricted cash – security deposit	20	0 200
Total non-current assets	9,08	
Total assets	\$ 24,36	5 \$ 25,104
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	\$ 23	8 \$ 514
Accrued expenses	1,44	2 1,447
Operating lease liabilities – current	70	7 656
Financing lease liabilities – current		5 5
Total current liabilities	2,39	2,622
Non-current liabilities:		
Deferred tax liability	34	
Operating lease liabilities – net of current portion	2,51	•
Financing lease liabilities – net of current portion	•	5 18
Total non-current liabilities	2,87	
Total liabilities	5,26	2 5,858

Stockholders' equity:

Common stock par value \$0.0001 per share, 500,000,000 shares authorized at June 30, 2024 and December 31, 2023; 250,816,164 and 217,264,526 issued and outstanding as of June 30, 2024 and 25 22 December 31, 2023, respectively Additional paid-in capital 206,245 195,018 Accumulated deficit (187,116)(175,573)(221)Accumulated other comprehensive loss (51)Total stockholders' equity 19,103 19,246 24,365 \$ Total liabilities and stockholders' equity 25,104

Matinas BioPharma Holdings, Inc. Condensed Consolidated Statements of Operations and Comprehensive Loss

(in thousands, except for share and per share data)

Unaudited

	Three Months Ended June 30,				Six Months Ended June 30,			
		2024		2023		2024		2023
Revenue:								
Contract revenue	\$	_	\$	_	\$	_	\$	1,096
Costs and expenses:								
Research and								
development		3,371		3,559		6,817		7,530
General and		0.400		0.000		4.005		5.044
administrative		2,468		2,600	_	4,925	_	5,311
Total costs and expenses		5,839	_	6,159	_	11,742	_	12,841
Loss from operations		(5,839)		(6,159)		(11,742)		(11,745)
Other income, net		120		99		199	_	172
Net loss	\$	(5,719)	\$	(6,060)	\$	(11,543)	\$	(11,573)
Net loss per share – basic and diluted								
arra anatoa	\$	(0.02)	\$	(0.03)	\$	(0.05)	\$	(0.05)
Weighted average common shares outstanding:								
Basic and diluted	24	9,350,963		217,264,526		233,354,524		217,264,526

Other comprehensive gain, net of tax Unrealized gain on securities available-for-81 170 310 sale 83 Other comprehensive 81 (5,979) \$ gain, net of tax 83 310 Comprehensive loss (5,636) \$ (11,263)



Source: Matinas BioPharma Holdings, Inc.