UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of
The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 15, 2023

MATINAS BIOPHARMA HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-38022**	**46-3011414**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer ID Number)**

1545 Route 206 South, Suite 302 **Bedminster, New Jersey**	**07921**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (908) 484-8805

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock	MTNB	NYSE American

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On March 15, 2023, Matinas BioPharma Holdings, Inc. (the "Company") issued a press release announcing its financial results for the year ended December 31, 2022. The full text of the press release is furnished as Exhibit 99.1 hereto and is incorporated by reference herein.

The information in Item 2.02 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release, dated March 15, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MATINAS BIOPHARMA HOLDINGS, INC.

Dated: March 15, 2023

By: */s/ Jerome D. Jabbour*
Name: Jerome D. Jabbour
Title: Chief Executive Officer

Matinas BioPharma Reports 2022 Financial Results and Provides a Business Update

Near-term data readouts from internal and collaborative programs expected to support advancement of the LNC platform for delivery of nucleic acids

FDA feedback from MAT2203 Type B meeting expected to impact partnership discussions and facilitate potential non-dilutive BARDA and/or NIH funding

Conference call and webcast begin at 4:30 p.m. Eastern time today

BEDMINSTER, N.J. (March 15, 2023) – Matinas BioPharma (NYSE American: MTNB), a clinical-stage biopharmaceutical company focused on delivering groundbreaking therapies using its lipid nanocrystal (LNC) platform delivery technology, reports 2022 financial results and provides a business update.

"We are developing our LNC delivery platform with the goal of providing safe, extrahepatic delivery of nucleic acids and small molecules," said Jerome D. Jabbour, Chief Executive Officer of Matinas. "Phase 2 MAT2203 clinical trial results demonstrated the ability of our platform to efficaciously deliver a safe, well-tolerated oral form of amphotericin B with dramatic survival results. Success to-date with MAT2203 bolsters our confidence in moving forward into the delivery of nucleic acids, and we are encouraged by our progress in this area.

"Among upcoming milestones, we expect data readouts from our internal programs with smaller oligonucleotides, as well as data relating to the delivery of larger oligonucleotides like mRNA through collaborations with BioNTech and National Resilience, two of the world's leading mRNA companies," he added. "Importantly, these programs will provide critical information in maximizing the potential applications for our technology, thereby advancing our strategy of developing robust internal and external product pipelines.

"We are also preparing to meet with the U.S. Food and Drug Administration (FDA) to seek guidance on a Phase 3 study with MAT2203 for the treatment of invasive fungal infections (IFIs). Feedback from this meeting will be instrumental in guiding our efforts to secure non-dilutive funding from the Biomedical Advanced Research and Development Authority (BARDA) and/or the National Institutes of Health (NIH), as well as in advancing ongoing discussions with potential partners for further development of this promising oral therapy for treating life-threatening fungal infections," Mr. Jabbour concluded.

Anticipated Second Quarter 2023 Milestones

BioNTech Collaboration

- Generation of *in vivo* data arising from the combination of Matinas' LNC platform technology and BioNTech's mRNA formats resulting from our ongoing exclusive research collaboration. This collaboration has provided financial support, generated compelling *in vitro* results and provided a potential pathway for the ultimate oral delivery of mRNA, which, if successful, would represent a major breakthrough. Testing will continue with collaborative formulation work on multiple nucleic acids with *in vivo* data expected during the second quarter of 2023.

National Resilience Collaboration

- Results from *in vitro* testing under a Material Transfer and Evaluation Agreement with National Resilience, which was announced in January 2023. The parties are collaborating on a comprehensive research program including design, formulation, and optimization to explore the potential for oral delivery of certain nucleic acids with the LNC platform. The collaboration will continue with potential *in vivo* results expected in the second half of 2023.

Internal ASO/siRNA Program

- Generation of *in vitro* data from an internal program for the delivery of antisense oligonucleotides (ASO) and silencing RNA (siRNA) therapies. This program will continue with multiple *in vivo* biodistribution and animal efficacy studies in the second half of 2023. If successful, the Company anticipates being able to identify the next internal product candidate in late 2023. Study success could position Matinas to develop a pipeline of ASO and siRNA therapies.

MAT2203 (Oral Amphotericin B) Program

- Planned meeting with the FDA to discuss a Phase 3 trial to assess the safety, efficacy, and tolerability of oral MAT2203 in patients with serious, life-threatening IFIs and limited treatment options. The discussion is expected to cover the proposed trial design and strategy for potentially obtaining MAT2203 marketing approval under a streamlined 505(b)(2) regulatory pathway.

Anticipated Second Half 2023 Milestones

In addition to the milestones mentioned above, the Company anticipates the following milestones in the second half of 2023:

BARDA Grant for MAT2203 Development

- Potential award of BARDA funds for the continued development of MAT2203 in multiple IFIs. The Company believes MAT2203 is well positioned to receive funding due to its oral, well-tolerated and broad-spectrum profile, and its clinical success already demonstrated in the Phase 2 EnACT trial in cryptococcal meningitis, each of which aligns well with the criteria set forth by BARDA in awarding grants for promising antifungal treatments. A potential BARDA and/or NIH award could be sufficient to complete development of MAT2203 through market approval for the targeted IFI indications, as well as support supply chain and commercial readiness.

MAT2203 Domestic/Global Partnership

- Potential for a pharmaceutical partnership for the continued development and commercialization of MAT2203 based on its success in the EnACT Phase 2 trial in cryptococcal meningitis and feedback from the FDA for the treatment of multiple serious IFIs.

2022 Financial Results

Revenue for the year ended December 31, 2022 was $3.2 million, which was generated from the research collaboration with BioNTech SE. This compares with revenue for the year ended December 31, 2021 of $33,000, which was generated from the feasibility study agreement with Genentech Inc.

Total costs and expenses for 2022 were $27.8 million compared with $24.8 million for 2021. The increase was due primarily to higher research and development expenses reflecting the later stage of the Company's clinical development programs. Income from selling unused New Jersey net operating losses (NOLs) and research and development tax credits was $3.5 million and $1.3 million for 2022 and 2021, respectively.

The net loss attributable to common shareholders for 2022 was $21.0 million, or $0.10 per share, compared with a net loss attributable to common shareholders for 2021 of $23.7 million, or $0.11 per share.

Cash, cash equivalents and marketable securities as of December 31, 2022 were $28.8 million compared with $49.6 million as of December 31, 2021. Based on current projections, the Company believes its cash position is sufficient to fund planned operations into the second quarter of 2024.

Conference Call and Webcast Details

Matinas will host a conference call and webcast today beginning at 4:30 p.m. Eastern time. To participate in the call, please dial 888-609-1607 (Toll-Free) or 862-298-0702 (Toll). 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 to maximize global clinical impact and patient access. The Company is developing its own internal portfolio of products as well as partnering with leading pharmaceutical companies to develop novel formulations that capitalize on the unique characteristics of the LNC platform.

Preclinical and clinical studies have demonstrated that this novel technology can provide solutions to many of the challenges in achieving safe and effective intracellular delivery for both small molecules and larger, more complex molecules such as mRNA, DNA plasmids, antisense oligonucleotides and vaccines. The combination of a unique mechanism of action and flexibility with formulation and route of administration (including oral) positions Matinas' LNC technology potentially to become the preferred next-generation intracellular drug delivery vehicle with distinct advantages over both lipid nanoparticles and viral vectors. 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 collaborations with National Resilience, Inc. and BioNTech SE, the potential of our LNC platform delivery technology, and the future development of its product candidates, the Company's ability to identify and pursue development, licensing and partnership opportunities for its products or platform delivery technology 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 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:

LHA Investor Relations
Jody Cain
Jcain@lhai.com
310-691-7100

Financial Tables to Follow

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

	December 31, 2022	December 31, 2021
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 6,830	$ 21,030
Marketable debt securities	21,933	28,592
Restricted cash – security deposit	50	50
Prepaid expenses and other current assets	5,719	1,321

Total current assets	34,532	50,993
Non-current assets:		
Leasehold improvements and equipment - net	2,091	1,538
Operating lease right-of-use assets - net	3,613	4,219
Finance lease right-of-use assets - net	30	23
In-process research and development	3,017	3,017
Goodwill	1,336	1,336
Restricted cash - security deposit	200	200
Total non-current assets	10,287	10,333
Total assets	$ 44,819	$ 61,326
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	$ 618	$ 937
Accrued expenses and other liabilities	3,099	2,851
Operating lease liabilities - current	562	539
Financing lease liabilities - current	7	21
Total current liabilities	4,286	4,348
Non-current liabilities:		
Deferred tax liability	341	341
Operating lease liabilities - net of current portion	3,533	4,140
Financing lease liabilities - net of current portion	22	3
Total non-current liabilities	3,896	4,484
Total liabilities	8,182	8,832
Stockholders' equity:		
Common stock par value $0.0001 per share, 500,000,000 shares authorized at December 31, 2022 and 2021, respectively; 217,264,526 and 216,269,450 issued and outstanding as of December 31, 2022 and 2021, respectively	22	22
Additional paid-in capital	190,070	184,251
Accumulated deficit	(152,631)	(131,634)
Accumulated other comprehensive loss	(824)	(145)
Total stockholders' equity	36,637	52,494
Total liabilities and stockholders' equity	$ 44,819	$ 61,326

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

	For the Year Ended December 31,	
	2022	**2021**
Revenue:		
Research and development	$ 3,188	$ 33
Costs and Expenses:		
Research and development	16,678	14,583
General and administrative	11,100	10,185
Total costs and expenses	27,778	24,768
Loss from operations	(24,590)	(24,735)
Sale of New Jersey net operating loss & tax credits	3,491	1,328
Other income, net	102	124
Net loss	$ (20,997)	$ (23,283)
Preferred stock series B accumulated dividends	-	(396)
Net loss attributable to common shareholders	$ (20,997)	$ (23,679)
Net loss attributable to common shareholders per share – basic and diluted	$ (0.10)	$ (0.11)
Weighted average common shares outstanding:		
Basic and diluted	216,811,439	210,178,332
Other comprehensive loss, net of tax		
Net unrealized loss on securities available-for-sale	(679)	(374)
Other comprehensive loss, net of tax	(679)	(374)
Comprehensive loss attributable to shareholders	$ (21,676)	$ (23,657)

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