November 6, 2020

Matinas BioPharma Reports Third Quarter 2020 Financial Results and Operational Highlights

EnACT study of MAT2203 in cryptococcal meningitis received unanimous Data and Safety Monitoring Board (DSMB) recommendation to proceed into second patient cohort

– ENHANCE-IT study of MAT9001 against Vascepa® fully enrolled with topline data anticipated Q1 2021; Phase 3 program on track to initiate H1 2021–

– Management to host conference call today, Friday, November 6th, at 8:30 a.m. ET –

BEDMINSTER, N.J., Nov. 06, 2020 (GLOBE NEWSWIRE) -- Matinas BioPharma Holdings, Inc. (NYSE AMER: MTNB), a clinical-stage biopharmaceutical company focused on developing next generation therapeutics to advance standards of care in areas of significant unmet medical need, today reported financial results for the third quarter ended September 30, 2020, along with a corporate update.

“The third quarter was very productive for the Company, as we continued to execute on our strategic priorities. We achieved a significant milestone in the EnACT study of MAT2203 with cohort progression, completed enrollment in the ENHANCE-IT study of MAT9001, and aligned with the FDA on key elements of our Phase 3 program for MAT9001,” commented Jerome D. Jabbour, Chief Executive Officer of Matinas. “Cohort progression in the EnACT study is both an important milestone for the development of MAT2203 as well as another critical step forward in further clinically validating the potential of our LNC platform delivery technology. As we look toward the remainder of the year and into 2021, we will intently focus on progressing our drug candidates through clinical development, with topline data from ENHANCE-IT anticipated in the first quarter of 2021 and a DSMB evaluation on progression from cohort 2 to cohort 3 in EnACT expected to occur in the middle of 2021. Finally, we continue to make good progress in identifying and advancing opportunities to expand the utilization of our LNC platform delivery technology with additional internal product candidates and external collaborations.”

MAT2203 Program Update *(orally bioavailable amphotericin B, with targeted delivery, under development for the treatment and prevention of invasive fungal infections, including cryptococcal meningitis)*

- In October, the Company announced that the independent DSMB of the EnACT study (Encochleated Oral Amphotericin for Cryptococcal Meningitis Trial) completed a pre-specified review of the first cohort and unanimously recommended progression to the second cohort. Enrollment in this next randomized EnACT cohort, with 40 active-treatment patients, is expected to begin shortly, with the next DSMB evaluation of

safety and efficacy data anticipated to occur in the middle of 2021.

- Data from the Phase 1 portion of the EnACT study were published in the *Antimicrobial Agents and Chemotherapy*, (ACC), a journal of the American Society of Microbiology, in a manuscript entitled "*Safety and tolerability of a novel oral formulation of amphotericin B: Phase I EnACT trial*". In the published manuscript, trial investigators concluded that MAT2203 was well-tolerated when administered in 4-6 divided daily doses without the toxicities commonly seen with IV amphotericin B.

- As previously reported, the U.S. Food and Drug Administration (FDA) has designated MAT2203 as a Qualified Infectious Disease Product (QIDP) with Fast Track status for four indications, specifically, the prevention of invasive fungal infections due to immunosuppressive therapy, and the treatment of invasive candidiasis, invasive aspergillus and cryptococcal meningitis. In addition, the FDA has granted orphan drug designation to MAT2203 for the treatment of cryptococcosis.

EnACT is a Phase 2 prospective, randomized, open-label, sequential cohort study, financially supported by the National Institutes of Health (NIH), evaluating the safety, tolerability and efficacy of MAT2203 in approximately 100 HIV-infected patients with cryptococcal meningitis. MAT2203 utilizes the Company's LNC platform delivery technology to orally deliver the traditionally IV-only fungicidal drug, amphotericin B. In total, the trial includes four cohorts of patients, with each cohort increasing the treatment duration of MAT2203 vs. IV amphotericin B. The primary efficacy endpoint includes a measure of reduction in fungal count in the cerebral spinal fluid. A control arm, which includes standard of care IV amphotericin B, is included with each cohort.

MAT9001 Program Update *(next generation, prescription-only omega-3 fatty acid-based composition under development for treatment of cardiovascular and metabolic conditions, including hypertriglyceridemia)*

- The Company completed enrollment in ENHANCE-IT (*Pharmacodynamic Effects of a Free-fatty Acid Formulation of Omega-3 Pentaenoic Acids to ENHANCE Efficacy in Adults with Hypertriglyceridemia*), a second head-to-head comparative study of MAT9001 vs. Vascepa. The study is assessing MAT9001's effectiveness in reducing triglyceride levels and other important lipid markers, as well as characterizing bioavailability and blood levels of eicosapentaenoic acid (EPA) and other omega-3 fatty acids. The Company continues to expect to have topline data available in the first quarter of 2021.

- A positive End of Phase 2 Meeting with the FDA during the third quarter of 2020, along with a review of the official minutes of the meeting, confirm that the FDA and Matinas are aligned on key next steps for MAT9001's Phase 3 development program and registration pathway for an initial indication to treat severe hypertriglyceridemia (SHTG). The Company and the FDA agreed on key elements of the Phase 3 program to support a New Drug Application (NDA) filing, including the requirement for a single 12-week study to support efficacy in SHTG. Moreover, FDA provided flexibility to Matinas in the totality of patient safety data needed to meet regulatory requirements for NDA submission. The Company continues to evaluate several ways to both meet these requirements and to potentially provide additional data differentiating MAT9001 from other prescription omega-3 drugs. The Company remains on track to initiate its

Phase 3 program in the first half of 2021.

ENHANCE-IT is an open-label, randomized, 28-day crossover study assessing the pharmacodynamic effects of MAT9001 vs. Vascepa. The study is now fully enrolled and includes adult men and women with elevated triglycerides (150-499 mg/dL), with at least 50% of study subjects with TGs ≥ 200 mg/dL. The study protocol involves two 28-day treatment periods, with a washout period of at least 28 days in between treatments and is being conducted at eight sites in the United States. MAT9001 and Vascepa are each administered as 2g twice daily with food in accordance with currently approved Vascepa labeling. Lipid parameters (triglycerides, Total-, LDL-, VLDL-, HDL-, and non-HDL cholesterol, apolipoproteins A1, B and C3, and PCSK9) and omega-3 blood levels are being measured at each baseline and at the end of each treatment period. The primary endpoint is the percent change from baseline to end-of-treatment in plasma triglycerides.

Third Quarter 2020 Financial Results

Cash, cash equivalents and marketable securities at September 30, 2020 were approximately $62.8 million, compared to $27.8 million at December 31, 2019. In January 2020, the Company sold an aggregate of 32,260,000 shares of its common stock at a price of $1.55 per share for net proceeds of approximately $46.7 million, after deducting underwriting discounts and commissions and other offering expenses. Based on current projections, the Company continues to believe that cash on hand is sufficient to fund operations into the first half of 2023.

For the third quarter of 2020, net loss attributable to common shareholders was $5.7 million, or a net loss of $0.03 per share (basic and diluted), compared to a net loss attributable to common shareholders of $4.6 million, or a net loss of $0.03 per share (basic and diluted) for the same period in 2019. The increase in net loss attributable to common shareholders was due primarily to an increase in operating expenses.

Research and development (R&D) expenses for the third quarter of 2020 were $3.3 million, compared to $2.7 million for the same period in 2019. The increase was due primarily to higher clinical development expenses and employee compensation related to the development of MAT9001 and MAT2203.

General and administrative (G&A) expenses for the third quarter of 2020 were $2.4 million, compared to $1.9 million in the same period in 2019. The increase was due primarily to higher employee compensation expense associated with increased headcount.

*VASCEPA® is a registered trademark of the Amarin group of companies.

Conference Call and Webcast Details

The Company will host a live conference call and webcast to discuss these results on Friday, November 6, 2020, at 8:30 a.m. ET.

To participate in the call, please dial (877) 407-5976 (domestic) or (412) 902-0031 (international). The live webcast will be accessible on the Investors section of Matinas' website, www.matinasbiopharma.com, and archived for 90 days.

About Matinas BioPharma

Matinas BioPharma is a clinical-stage biopharmaceutical company focused on developing next generation therapeutics to advance standards of care for patients in areas of significant unmet medical need. Company leadership has a deep history and knowledge of drug development and is supported by a world-class team of scientific advisors.

MAT9001, the Company's lead product candidate for the treatment of cardiovascular and metabolic conditions, is a prescription-only omega-3 fatty acid-based composition, comprised primarily of EPA and DPA, under development for hypertriglyceridemia. MAT9001 is currently in a second head-to-head comparative study against Vascepa® (ENHANCE-IT), with topline data expected in the first quarter of 2021.

In addition, Matinas is developing a portfolio of products based upon its proprietary lipid nano-crystal (LNC) drug delivery platform, which can solve complex challenges relating to the safe and effective delivery of potent medicines, making them more targeted, less toxic and orally bioavailable.

MAT2203, the Company's lead product candidate utilizing its LNC platform, is an oral, encochleated formulation of the well-known, but highly toxic, antifungal medicine amphotericin B, to treat serious invasive fungal infections. MAT2203 is currently in a Phase 2 open-label, sequential cohort study (EnACT) in HIV-infected patients with cryptococcal meningitis. EnACT will promptly begin enrolling patients in its second cohort, with the next DSMB evaluation of safety and efficacy data anticipated to occur in the middle of 2021.

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 the Company's anticipated capital and liquidity needs, strategic focus and the future development of its product candidates, including MAT2203, the anticipated timing of regulatory submissions, the anticipated timing of clinical studies, the anticipated timing of regulatory interactions, the Company's ability to identify and pursue development 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.

Matinas BioPharma Holdings Inc.
Condensed Consolidated Balance Sheets

	September 30, 2020 (Unaudited)	December 31, 2019 (Audited)
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 7,051,225	$ 22,170,438
Marketable securities	55,719,661	5,604,634
Restricted cash	186,000	250,000
Prepaid expenses and other current assets	2,246,128	1,897,784
Total current assets	65,203,014	29,922,856
Non-current assets:		
Leasehold improvements and equipment - net	1,581,762	1,749,259
Operating lease right-of-use assets - net	3,401,136	3,761,207
Finance lease right-of-use assets - net	66,649	116,968
In-process research and development	3,017,377	3,017,377
Goodwill	1,336,488	1,336,488
Restricted cash - security deposits	200,000	336,000
Total non-current assets	9,603,412	10,317,299
Total assets	$ 74,806,426	$ 40,240,155
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	$ 373,066	$ 679,310
Accrued expenses	2,015,102	1,939,510
Operating lease liabilities - current	417,874	423,741
Financing lease liabilities - current	32,278	54,673
Total current liabilities	2,838,320	3,097,234
Non-current liabilities:		

Deferred tax liability	341,265	341,265
Operating lease liabilities - net of current portion	3,391,568	3,695,561
Financing lease liabilities - net of current portion	30,054	54,513
Total non-current liabilities	3,762,887	4,091,339
Total liabilities	6,601,207	7,188,573
Stockholders' equity:		
Series B Convertible preferred stock	3,964,034	3,985,805
Common stock	19,896	16,315
Additional paid-in capital	165,024,057	113,427,897
Accumulated deficit	(101,166,313)	(84,377,555)
Accumulated other comprehensive income/(loss)	363,545	(880)
Total stockholders' equity	68,205,219	33,051,582
Total liabilities and stockholders' equity	$ 74,806,426	$ 40,240,155

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Revenue:				
Contract research revenue	$ 95,833	$ -	$ 95,833	$ 89,812
Costs and expenses:				
Research and development	3,336,225	2,671,365	10,833,345	7,814,842
General and administrative	2,364,214	1,889,892	6,980,155	5,460,023
Total costs and expenses	5,700,439	4,561,257	17,813,500	13,274,865
Loss from operations	(5,604,606)	(4,561,257)	(17,717,667)	(13,185,053)
Sale of New Jersey net operating loss	-	-	1,073,289	1,007,082
Other income, net	155,093	156,872	538,420	378,151
Net loss	$ (5,449,513)	$ (4,404,385)	$ (16,105,958)	$ (11,799,820)

Preferred stock series A accumulated dividends	-	(45,041)	-	(338,613)
Preferred stock series B accumulated dividends	(227,600)	(115,500)	(575,392)	(349,500)
Net loss attributable to common shareholders	$ (5,677,113)	$ (4,564,926)	$ (16,681,350)	$ (12,487,933)
Net loss available for common shareholders per share - basic and diluted	$ (0.03)	$ (0.03)	$ (0.09)	$ (0.09)
Weighted average common shares outstanding - basic and diluted	198,909,016	156,889,602	196,070,952	139,265,178
Other comprehensive (loss)/income, net of tax				
Net unrealized (loss)/gain on securities available-for-sale	(114,159)	-	367,144	-
Reclassifications to net loss	-	-	(2,719)	-
Other comprehensive (loss)/income, net of tax	(114,159)	-	364,425	-
Comprehensive loss attributable to shareholders	$ (5,563,672)	$ (4,404,385)	$ (15,741,533)	$ (11,799,820)

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