

**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): August 13, 2019

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

Delaware (State or other jurisdiction of incorporation)	001-38022 (Commission File Number)	46-3011414 (IRS Employer ID Number)
1545 Route 206 South, Suite 302 Bedminster, New Jersey (Address of principal executive offices)		07921 (Zip Code)

Registrant's telephone number, including area code: (908) 443-1860

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))

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.

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

Item 2.02. Results of Operations and Financial Condition.

On August 13, 2019, Matinas BioPharma Holdings, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended June 30, 2019. The full text of the press release is furnished as Exhibit 99.1 hereto and is incorporated by reference herein.

Item 7.01 Regulation FD Disclosure.

The Company intends to use the presentation included as Exhibit 99.2 to this report in connection with its investor conference call on August 13, 2019.

The information in Item 2.02 and Item 7.01 of this Current Report on Form 8-K and Exhibits 99.1 and 99.2 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.

(d) The following exhibits are being furnished with this report:

Exhibit No.	Description
99.1	Press Release, dated August 13, 2019.
99.2	Presentation, dated August 13, 2019.

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: August 13, 2019

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

Matinas BioPharma Reports Second Quarter 2019 Financial Results and Provides Corporate Update

- MAT9001 program progressing ahead of schedule –
- Additional head to head data vs. Vascepa® expected in 2020 –
- NIH-funded Phase 1/2 EnACT trial of MAT2203 in cryptococcal meningitis to commence in Q4 2019 –
- Management to host conference call today, Tuesday, August 13th, at 8:00 a.m. ET –

Bedminster, NJ (August 13, 2019) – Matinas BioPharma Holdings, Inc. (NYSE AMER: MTNB), a clinical-stage biopharmaceutical company, today announced financial results for the quarter ended June 30, 2019, and provided an update on its product pipeline.

“I am extremely pleased with the progress we have made to date this year in advancing MAT9001, our potential best-in-class cardiovascular prescription-only omega-3 drug candidate” commented Jerome D. Jabbour, Chief Executive Officer of Matinas. “We have designed a pathway to approval intended to yield clinical data we believe could differentiate MAT9001 from the leading approved prescription-only omega-3 products and take advantage of exciting new developments within this class of drugs to potentially treat millions of patients. We have completed a required bridging toxicology study ahead of schedule, and expect to commence additional studies in the coming months for MAT9001, including an additional Phase 2 head-to-head pharmacokinetic (PK) and pharmacodynamic (PD) study against Vascepa® early in 2020 with topline data expected in the back half of 2020.”

“Regarding our LNC platform technology, we recently had a positive meeting with FDA focused on our development program for MAT2203 where we received important feedback in moving forward with our NIH-funded Phase 1/2 EnACT study. We also just received our fourth Qualified Infectious Disease Product (QIDP) designation with Fast Track status from the FDA for MAT2203 for the treatment of cryptococcal meningitis (CM). In leveraging our unique LNC Platform to deliver amphotericin B orally to patients suffering from this deadly brain fungal infection, we are positioning this important product for both potential induction and maintenance indications,” added Mr. Jabbour.

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

- Completed 28-day comparative bridging toxicology study of MAT9001.
- On track to commence a comparative clinical bridging bioavailability study in Q4 2019, with expected completion in Q1 2020.
- On track to initiate an additional head-to-head comparative study of MAT9001 and Vascepa® in Q1 2020. This study will evaluate pharmacokinetic (PK) and pharmacodynamic (PD) markers for MAT9001 and Vascepa in a 28-day crossover study in patients with elevated triglycerides (150 – 499 mg/dL), building on an earlier study showing that, compared to Vascepa, MAT9001 provided significantly greater reductions in PD markers known to be associated with increased risk of cardiovascular disease, including triglycerides, Total cholesterol, VLDL-C, non-HDL-C, ApoC3, and PCSK9, without any meaningful increase in LDL cholesterol. The objective of this second study is to further validate the enhanced bioavailability and greater PD effect of MAT9001 relative to Vascepa. The Company expects to announce data from the study in Q4 of 2020.

- Secured clinical intermediates of MAT9001 to support all planned studies through 2020; currently manufacturing proprietary capsules for the entirety of the next 12-months' clinical trials supply.

MAT2203 and Lipid Nano-Crystal (LNC) Technology Platform Update(*intracellular delivery of potentially life-saving medicines*)

- July 2019 – received Qualified Infectious Disease Product (QIDP) designation with Fast Track status for MAT2203 for the treatment of cryptococcal meningitis from the U.S. Food and Drug Administration (FDA).
- Plans underway to initiate Phase 1/2 EnACT (Encocleated Oral Amphotericin for Cryptococcal Meningitis Trial) of MAT2203 for the treatment of HIV-infected patients with cryptococcal meningitis in Q4 2019. This open-label, sequential cohort study, fully funded by the National Institutes of Health (NIH), will utilize the Company's Lipid- Nano-Crystal (LNC) drug delivery technology to orally deliver the traditionally IV-only fungicidal drug, Amphotericin B. While cumulative data from this study is expected to be available in the first half of 2021, management believes that progression of the study from cohort to cohort during 2020 may be interpreted positively.
- May 2019 – Publication of efficacy results from NIH studies using preclinical animal models evaluating MAT2203 for the treatment of cryptococcal meningitis in the American Society for Microbiology Journal, *mBio*.
- May 2019 – Matinas entered into a research collaboration with ViiV Healthcare to evaluate the use of Matinas' LNC platform delivery technology in the delivery of antivirals targeting HIV infection.

Second Quarter 2019 Financial Results

For the second quarter of 2019, the Company reported a net loss attributable to common shareholders of \$3.6 million, or a net loss per share of \$0.03 (basic and diluted), compared to a net loss attributable to common shareholders of \$3.6 million, or a net loss per share of \$0.04 (basic and diluted) for the same period in 2018.

Research and development (R&D) activities for the second quarter of 2019 were \$2.8 million, compared to \$1.5 million for the same period in 2018. The increase in R&D is due primarily to higher clinical development and overhead costs, specifically around the development of MAT9001.

General and administrative (G&A) expenses for the second quarter of 2019 were \$1.8 million, compared to \$2.0 million in the same period in 2018.

Cash and cash equivalents at June 30, 2019 were approximately \$36.8 million, compared to \$12.4 million at December 31, 2018. This increase includes net proceeds of \$30.1 million from the Company's public offering of its common stock completed in March 2019. Based on Management's current projections the Company believes that cash on hand is sufficient to fund operations into the first quarter of 2021.

*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 Tuesday, August 13, 2019 at 8:00 a.m. ET.

To participate in the call, please dial (877) 407-5976 (domestic) or (412) 902-0031 (international). The livewebcast will be available on the Events page of the Investors section of the Company's website (www.matinasbiopharma.com) and archived for 60 days.

About Matinas BioPharma

Matinas BioPharma is a clinical-stage biopharmaceutical company focused on the development of its lead product candidate, MAT9001, for the treatment of cardiovascular and metabolic conditions, and the advancement of its proprietary lipid nano-crystal ("LNC") platform technology for the safe delivery of therapies previously limited by toxicity or bioavailability issues.

MAT9001 is a prescription-only omega-3 fatty acid-based formulation, comprised primarily of EPA and DPA, under development for the treatment of hypertriglyceridemia. With the support of a world-class team of clinical key opinion leaders and regulatory consultants MAT9001 is moving rapidly forward along a streamlined registration pathway.

In parallel, the Company's LNC Platform is a unique potential solution for complex challenges arising in the delivery of both small molecules and biologics. This novel technology allows for the delivery of life-saving compounds in ways that can make them more tolerable, less toxic, potentially more effective, and even orally bioavailable. The most advanced compound using the LNC platform is MAT2203 – an orally-delivered formulation of Amphotericin-B that has the potential to substantially improve an otherwise challenging safety profile in critically ill patients.

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 MAT9001 and 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

	June 30, 2019 (Unaudited)	December 31, 2018 (Audited)
ASSETS:		
Current assets:		
Cash and cash equivalents	\$ 36,830,924	\$ 12,446,838
Restricted cash	100,000	100,000
Prepaid expenses	494,647	538,646
Total current assets	<u>37,425,571</u>	<u>13,085,484</u>
Non-current assets:		
Leasehold improvements and equipment - net	1,791,273	2,042,893
Operating lease right-of-use assets - net	3,990,941	-
Finance lease right-of-use assets - net	166,977	-
In-process research and development	3,017,377	3,017,377
Goodwill	1,336,488	1,336,488
Restricted cash - security deposit	486,000	461,000
Total non-current assets	<u>10,789,056</u>	<u>6,857,758</u>
Total assets	<u>\$ 48,214,627</u>	<u>\$ 19,943,242</u>
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	\$ 548,128	\$ 295,652
Note payable	-	199,842
Accrued expenses	1,274,963	1,086,868
Stock dividends payable	1,174,286	1,174,286
Operating lease liabilities - current	390,750	-
Financing lease liabilities - current	75,655	83,245
Total current liabilities	<u>3,463,782</u>	<u>2,839,893</u>
Non-current liabilities:		
Deferred tax liability	341,265	341,265
Operating lease liabilities - net of current portion	3,918,540	-
Financing lease liabilities - net of current portion	72,950	107,656
Deferred rent liability	-	512,704
Total non-current liabilities	<u>4,332,755</u>	<u>961,625</u>
Total liabilities	<u>7,796,537</u>	<u>3,801,518</u>
Stockholders' equity:		
Series A Convertible preferred stock, stated value \$5.00 per share, 1,600,000 shares authorized as of June 30, 2019 and December 31, 2018; 1,467,858 shares issued and outstanding as of June 30, 2019 and December 31, 2018 (liquidation preference - \$8,513,576 at June 30, 2019)	5,583,686	5,583,686
Series B Convertible preferred stock, stated value \$1,000 per share, 8,000 shares authorized as of June 30, 2019 and December 31, 2018; 4,630 and 4,819 shares issued and outstanding as of June 30, 2019 and December 31, 2018; (liquidation preference - \$4,630,000 at June 30, 2019)	4,031,959	4,196,547
Common stock par value \$0.0001 per share, 250,000,000 shares authorized at June 30, 2019 and December 31, 2018; 144,205,850 and 113,287,670 issued and outstanding as of June 30, 2019 and December 31, 2018, respectively	14,420	11,329
Additional paid in capital	104,601,220	72,294,921
Accumulated deficit	(73,813,195)	(65,944,759)
Total stockholders' equity	<u>40,418,090</u>	<u>16,141,724</u>
Total liabilities and stockholders' equity	<u>\$ 48,214,627</u>	<u>\$ 19,943,242</u>

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Revenue:				
Contract research revenue	\$ 89,812	\$ 89,813	\$ 89,812	\$ 119,750
Costs and expenses:				
Research and development	2,828,776	1,522,695	5,143,477	3,715,584
General and administrative	<u>1,781,717</u>	<u>1,972,048</u>	<u>3,570,131</u>	<u>3,929,847</u>
Total costs and expenses	<u>4,610,493</u>	<u>3,494,743</u>	<u>8,713,608</u>	<u>7,645,431</u>
Loss from operations	(4,520,681)	(3,404,930)	(8,623,796)	(7,525,681)
Sale of New Jersey net operating loss	1,007,082	-	1,007,082	-
Other income/(expense), net	<u>168,872</u>	<u>(6,101)</u>	<u>221,279</u>	<u>4,644</u>
Net loss	<u><u>\$ (3,344,727)</u></u>	<u><u>\$ (3,411,031)</u></u>	<u><u>\$ (7,395,435)</u></u>	<u><u>\$ (7,521,037)</u></u>
Preferred stock series A accumulated dividends	(146,786)	(146,786)	(293,572)	(294,072)
Preferred stock series B accumulated dividends	<u>(115,750)</u>	<u>(21,849)</u>	<u>(234,000)</u>	<u>(21,849)</u>
Net loss attributable to common shareholders	<u><u>\$ (3,607,263)</u></u>	<u><u>\$ (3,579,666)</u></u>	<u><u>\$ (7,923,007)</u></u>	<u><u>\$ (7,836,958)</u></u>
Net loss available for common shareholders per share - basic and diluted	<u><u>\$ (0.03)</u></u>	<u><u>\$ (0.04)</u></u>	<u><u>\$ (0.06)</u></u>	<u><u>\$ (0.08)</u></u>
Weighted average common shares outstanding - basic and diluted	<u><u>143,104,941</u></u>	<u><u>94,034,837</u></u>	<u><u>130,306,907</u></u>	<u><u>93,787,752</u></u>

Investor and Media Contacts

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Q2 2019 Investor Update
Conference Call
August 13, 2019

Forward-Looking Statement

This presentation contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including those relating to the Company's product development, clinical and regulatory timelines, market opportunity, cash flow 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.



MAT9001

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MAT9001 Key Highlights

Comparative toxicology study (28 Days) completed ahead of schedule

Secured supply for all planned studies through 2020

IND Reactivation Completed
– FDA “May Proceed”
Letter Received

Near-Term Next Steps

Bridging Comparative PK

Set to commence in Q4 2019

Open-label, randomized, 4 period crossover, single-dose study under high-fat and fasted conditions

36 healthy volunteers

Phase 2 Head to Head vs. Vascepa®

Crossover 28-day treatment study in patients with elevated triglycerides (n=70)

Patient pre-screening set to commence September 2019

FPI anticipated Q1 2020; Topline data expected Q4 2020



Head to Head Study vs. Vascepa

Phase 2 Comparative Pharmacokinetic and Pharmacodynamic Study to Vascepa

- **Design**

- Open-label, randomized, crossover to compare the PK and PD effects of MAT9001 with Vascepa in 70 men and women with elevated triglycerides (Fasting TG ≥ 150 mg/dL to ≤ 499 mg/dL)
- Dose: 4g/day either MAT9001 or Vascepa for 28 days followed by 28-day washout and crossover to alternate treatment for 28 days

- **Outcome Variables**

- Primary PK = Relative Bioavailability of EPA from MAT9001 and Vascepa
- Secondary PD = % change from baseline for key lipid markers

- **Status**

- Study protocol finalized
- Patient pre-screening to commence in September 2019
- Anticipated dosing Q1 2020
- Topline data readout Q4 2020



MAT2203

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MAT2203 Key Highlights

Advancing Clinical Development Program in Cryptococcal Meningitis

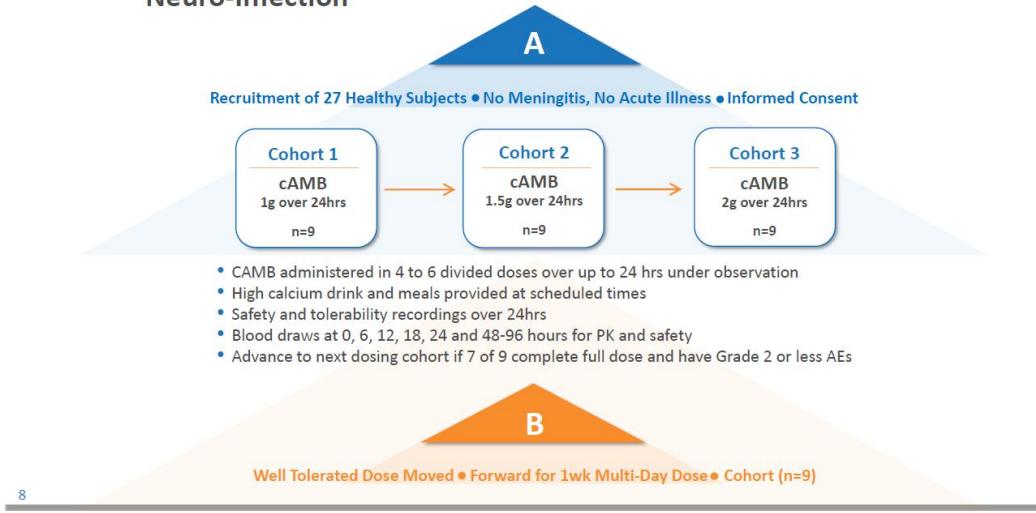
Amphotericin B → **Broad spectrum antifungal agent** → **Gold standard** of treatment for immunocompromised patients

NIH funding of Phase 1/2 study of
MAT2203 in Cryptococcal Meningitis

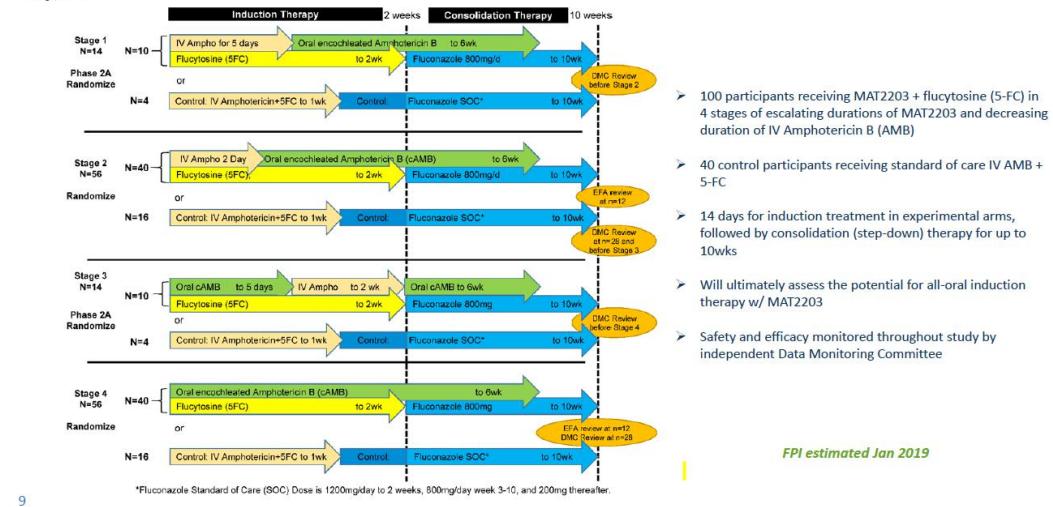


Positive FDA meeting
EnACT Study initiation in Q4 2019

EnACT: Phase 1 Safety and Tolerability in Subjects without Active Neuro-Infection



EnACT : Ph 2 safety, tolerability and efficacy of MAT2203 in combo w/ 5-FC in HIV-infected pts w/ crypto



Key Takeaways

MAT9001 - initiate comparative PK bridging study in Q4 2019

Patient pre-screening set to commence for head-to-head study vs. Vascepa

MAT9001 head-to-head dosing to commence Q1 2020 with topline data expected Q4 2020

QIDP and Fast Track Designation for MAT2203 in treatment of cryptococcal meningitis

Positive FDA interaction on MAT2203 EnACT trial with study initiation set for Q4 2019
- Fully funded by NIH -

MAT2203 EnACT updates periodically throughout 2020

Q&A

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