

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): May 13, 2022

Emmaus Life Sciences, Inc.
(Exact name of registrant as specified in its charter)

| | | |
|----------------------------------------------------|--------------------------|--------------------------------------|
| Delaware | 001-35527 | 87-0419387 |
| (State or other jurisdiction of incorporation) | (Commission File Number) | (I.R.S. Employer Identification No.) |
| 21250 Hawthorne Boulevard, Suite 800, Torrance, CA | | 90503 |
| (Address of principal executive offices) | | (Zip Code) |

Registrant's telephone number, including area code (310) 214-0065

(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:

- 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 240.13a-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 |
|---------------------|----------------|-------------------------------------------|
| None | | |

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

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 Operation and Financial Condition.

On May 13, 2022, Emmaus Life Sciences, Inc. issued a press release announcing earnings for the three months ended March 31, 2022. A copy of the press release is included as Exhibit 99.1 to this Current Report and incorporated herein by reference.

The information included in this Item 2.02 and in Exhibit 99.1 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 ("Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as otherwise expressly provided in such a filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

See the accompanying Index to Exhibits, which information is incorporated herein by reference.

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.

Date: May 13, 2022

Emmaus Life Sciences, Inc.

By: /s/ YASUSHI NAGASAKI

INDEX TO EXHIBITS

| Exhibit Number | Description |
|----------------|-------------------------------------------------------------------------|
| 99.1 | May 13, 2022 press release |
| 104 | Cover Page Interactive Data File (embedded within Inline XBRL document) |



Emmaus Life Sciences Reports Q1 2022 Financial Results and Provides Business Update

Torrance CA, May 13, 2022 - Emmaus Life Sciences, Inc. (OTCQX: EMMA) a commercial-stage biopharmaceutical company and leader in the treatment of sickle cell disease, today reported financial results for the three months ended March 31, 2022 and provided a business update.

Recent Highlights

- April 2022: Announced the launch of an innovative, full-service telehealth solution (<https://www.endarix.com/ask-physician>) with strategic partners including Asembia LLC, US Bioservices Corporation and UpScript IP Holdings, LLC. The telehealth program capitalizes on the expansion of telemedicine in the U.S. to afford sickle cell disease patients and providers on-line access to Endari® an important benefit, given that such on-line access is not available for competing branded products.
- April 2022: Announced positive real-world data on Endari® in preventing acute complications from sickle cell disease and hemolysis in pediatric and adult patients in French Guiana and Qatar. The data was introduced by Dr. Mohamed Yassin and his co-authors at the 62nd Annual Meeting of the British Society for Haematology (BSH), which was held April 3-5, 2022, at the Manchester Central in Manchester, England and virtually.
- March 2022: Announced that the Florida Medicaid Pharmaceutical & Therapeutics Committee has added Endari® to the Florida Medicaid Preferred Drug List, effective April 1, 2022, eliminating the need for prior authorization for Medicaid patients.
- March 2022: Received full marketing authorization for Endari® from the United Arab Emirates (U.A.E.) Ministry of Health.

“During the first quarter, our team continued to focus on the expansion of market and patient access to Endari®,” stated Yutaka Niihara, M.D., M.P.H., Chairman and Chief Executive Officer of Emmaus. “As a measure of the demand for this important therapeutic, immediately after the U.A.E. granted full marketing authorization in March, we received a significant order from one of our distributors in the country and expect to see a continuing flow of orders going forward. Additionally, the launch of our unique, full-service telehealth solution in April is expected to make a meaningful impact, as it gives both patients and providers on-line access to Endari®, allowing for same-day physician authorization and at-home delivery, if needed. Early indications from the uptake of the telehealth program are promising and should afford us a competitive advantage over other sickle cell treatments due to the fact that Endari®, which has proven to be safe and effective, is the only treatment able to be prescribed via telehealth because it does not require a blood test prior to or after treatment and is administered orally. Additionally, since a majority of sickle cell disease patients do not regularly see a doctor, we believe that our telehealth service will allow us to reach and capture a greater percentage of this unserved patient population.”

Dr. Niihara added, “While the company’s financial results for the first quarter were adversely affected by overstocking of Endari® by our distributors in prior periods -- impacted, in part by the effects of the COVID-19 pandemic -- sell through of Endari® by distributors in the first three months of 2022 was substantially higher than in the same period in 2021 and we anticipate a possible uptick in sales in the U.S. and U.A.E, as well as additional marketing approvals in the Gulf Cooperation Council countries later this year. Domestically, our new telehealth solution should positively impact U.S. sales for the full year.”

Financial and Operating Results

Net Revenues. Net revenues for the three months ended March 31, 2022 were \$3.2 million, compared to \$5.3 million for same period in 2021. Although sell through by our distributors increased compared to 2021, net revenues were adversely affected by overstocking by distributors in response to discounts afforded by the company on bulk pre-orders in the first three months of 2022 as compared to the same period in 2020.

Operating Expenses. Total operating expenses for the three months ended March 31, 2022 were \$5.3 million, compared with \$6.5 million for the same period in 2021. Of the decreased expenses, \$1.3 million was attributable to decreased research and development expenses primarily related to one time license fees paid to Kainos Medicine, Inc. in 2021 relating to Kainos’ novel IRAK4 inhibitor in research. The company incurred a \$0.2 million increase in selling expenses resulting from more frequent travel associated with the lifting of COVID-19 related travel restrictions in the U.S. and foreign countries.

Loss From Operations. Loss from operations for the three months ended March 31, 2022 was \$3.1 million, compared with a loss of \$1.6 million in the same period in 2021.

Other Income (Expense). Other income increased by \$8.2 million, or 121%, to \$1.4 million for the three months ended March 31, 2022, compared to other expense of \$6.8 million in the same period in 2021. The increase in other expense in 2022 included a \$5.4 million decrease in change in fair value of conversion feature derivatives, a \$1.3 million decrease in change in fair value of warrant derivative liabilities and a lack of \$1.2 million loss on debt extinguishment in 2022.

Net Loss. For the quarter, the company realized a net loss attributable to common stockholders of \$1.5 million, or \$0.03 per share, based on approximately 49.3 million weighted average basic and diluted common shares. This compares to net loss of \$8.4 million, or \$0.17 per share, based on approximately 49.1 million weighted average basic and diluted common shares, for the first quarter of 2021. The decreased net loss was primarily attributable to the increase in other income for the three months ended March 31, 2022, partially offset by an increased loss from operations discussed above.

Liquidity and Capital Resources. At March 31, 2022, the company had cash and cash equivalents of \$0.8 million, compared with \$2.3 million at December 31, 2021. In light of the lower than anticipated net revenues in the quarter and based on the company’s cash and cash equivalents and anticipated future revenues and operating expenses, management believes the company’s working capital is insufficient to meet its needs for 2022 without obtaining additional loans from related parties or debt or equity financing from third parties or curtailing certain operations or activities at its Japanese joint venture in Ube, Japan.

About Emmaus Life Sciences

Emmaus Life Sciences, Inc. is a commercial-stage biopharmaceutical company and leader in the treatment of sickle cell disease. The company currently markets and sells Endari® (L-glutamine oral powder), indicated to reduce the acute complications of sickle cell disease in adults and children 5 years and older, in the U.S. and in the United Arab Emirates, or U.A.E., and is pursuing marketing authorization for Endari® in the Kingdom of Saudi Arabia, Bahrain and other Gulf Cooperation Council countries. The company is also engaged in the discovery and development of innovative treatments and therapies for certain rare and orphan diseases as well as those affecting larger populations, such as diverticulosis and certain cancers. For more information, please visit www.emmausmedical.com.

About Endari® (prescription grade L-glutamine oral powder)

Endari®, Emmaus’ prescription grade L-glutamine oral powder, is approved for marketing by the U.S. Food and Drug Administration the U.A.E. Ministry of Health for treating

sickle cell disease. Endari® is also available on a named-patient or early-access basis in France, the Netherlands, the United Kingdom, Saudi Arabia, Bahrain, Qatar, Oman, and Kuwait.

Indication

Endari® is indicated to reduce the acute complications of sickle cell disease in adult and pediatric patients five years of age and older.

Important Safety Information

The most common adverse reactions (incidence >10 percent) in clinical studies were constipation, nausea, headache, abdominal pain, cough, pain in extremities, back pain, and chest pain.

Adverse reactions leading to treatment discontinuation included one case each of hypersplenism, abdominal pain, dyspepsia, burning sensation, and hot flash.

The safety and efficacy of Endari® in pediatric patients with sickle cell disease younger than five years of age has not been established.

For more information, please see full Prescribing Information of Endari® at: www.ENDARIRx.co/PI.

Forward-looking Statements

This press release contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, as amended, including statements regarding possible increased access to Endari® in the U.S. through telemedicine and potential increased sales of Endari® following full marketing authorization for Endari® in the U.A.E. and, possibly, other countries in the Middle East North Africa (MENA) region. These forward-looking statements are subject to numerous assumptions, risks and uncertainties which change over time, including risks and uncertainties relating to the company's working capital and need for financing, risks inherent in the regulatory approval process and commercialization of Endari® in the MENA region, and other factors previously disclosed in the company's Annual Report on Form 10-K for 2021 filed with the Securities and Exchange Commission on March 31, 2022, and actual results may differ materially. Such forward-looking statements speak only as of the date they are made, and Emmaus assumes no duty to update them, except as may be required by law.

Company Contact:

Emmaus Life Sciences, Inc.
Willis Lee
Chief Operating Officer
(310) 214-0065, Ext. 1130
wlee@emmauslifesciences.com

Investor Relations Contact:

Rx Communications Group
Michael Miller
(917)-633-6086
mmiller@rxir.com

(Financial Tables Follow)

Emmaus Life Sciences, Inc.
Condensed Consolidated Statement of Operations and Comprehensive Income (Loss)
(in thousands, except share and per share amounts) (Unaudited)

| | Three Months Ended March 31 | |
|--------------------------------------------|-----------------------------|------------|
| | 2022 | 2021 |
| Revenues, Net | \$ 3,234 | \$ 5,335 |
| Cost of Goods Sold | 1,007 | 436 |
| Gross Profit | 2,227 | 4,899 |
| Operating Expenses | 5,295 | 6,514 |
| Loss from Operations | (3,068) | (1,615) |
| Total Other Income (Expense) | 1,423 | (6,789) |
| Net Loss | (1,542) | (8,422) |
| Comprehensive Loss | (854) | (8,199) |
| Net Loss per Share | (\$ 0.03) | (\$ 0.17) |
| Weighted Average Common Shares Outstanding | 49,311,864 | 49,073,769 |

Emmaus Life Sciences, Inc.
Condensed Consolidated Balance Sheets
(In thousands)

| | As of | |
|---------------------------|-------------------------------|----------------------|
| | March 31, 2022 (Unaudited) | December 31, 2021 |
| Assets | | |
| Current Assets: | | |
| Cash and cash equivalents | \$ 813 | \$ 2,279 |
| Accounts receivable, net | 938 | 1,040 |
| Inventories, net | 3,453 | 4,392 |

| | | |
|----------------------------------------------|-----------------|-----------------|
| Prepaid expenses and other current assets | 1,244 | 1,380 |
| Total Current Assets | 6,448 | 9,091 |
| Property and Equipment, net | 138 | 147 |
| Equity method investment | 17,771 | 17,616 |
| Right of use assets | 3,318 | 3,485 |
| Investment in convertible bond | 23,521 | 26,100 |
| Other Assets | 297 | 295 |
| Total Assets | \$ 51,493 | \$ 56,734 |
| Liabilities and Stockholders' Deficit | | |
| Current Liabilities: | | |
| Accounts payable and accrued expenses | \$ 9,718 | \$ 9,189 |
| Conversion feature derivative, notes payable | 4,427 | 7,507 |
| Notes payable, current portion | 2,286 | 2,399 |
| Convertible notes payable, net of discount | 10,569 | 10,158 |
| Other current liabilities | 7,551 | 7,847 |
| Total Current Liabilities | 34,551 | 37,100 |
| Notes payable, less current portion | 1,500 | 1,500 |
| Convertible notes payable, net of discount | 3,150 | 3,150 |
| Other long-term liabilities | 34,591 | 36,434 |
| Total Liabilities | <u>73,792</u> | <u>78,184</u> |
| Stockholders' Deficit | <u>(22,299)</u> | <u>(21,450)</u> |
| Total Liabilities & Stockholders' Deficit | \$ 51,493 | \$ 56,734 |