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 31, 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 March 31, 2022, Emmaus Life Sciences, Inc. issued a press release announcing earnings for the year ended December 31, 2021. 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 expressly set forth by specific reference 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: March 31, 2022

Emmaus Life Sciences, Inc.

By: /s/ YASUSHI NAGASAKI
Name: Yasushi Nagasaki
Title: Chief Financial Officer

INDEX TO EXHIBITS

Exhibit Number	Description
99.1	March 31, 2022 press release.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Emmaus Life Sciences Reports 2021 Financial Results and Provides Business Update

Torrance CA, March 31, 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 year ended December 31, 2021 and an update on recent activities.

Recent Highlights

- 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 after a five-month review of the company's marketing authorization application.
- December 2021: Presented positive transfusion data from a post-hoc analysis of the phase 3 clinical study of Endari, the company's prescription L-glutamine oral powder, in patients with sickle cell disease, at the 63rd American Society of Hematology (ASH) Annual Meeting. Data confirmed that Endari meaningfully reduces both pain crises and hospitalizations.
- November 2021: Announced collaboration with UpScript to offer telehealth solutions to sickle cell disease patients, expanding access to Endari®. The partnership allows patients to see a doctor remotely and receive same-day physician authorization and prescriptions for Endari, which will be delivered directly to their home within just a few days.
- November 2021: Entered into an agreement with Asembia to provide expanded patient and provider support services to simplify access to Endari. Asembia provides a single point of contact for benefits investigation and financial and co-pay assistance, as well as patient and provider education.
- October 2021: Signed an agreement with Kainos Medicine, Inc., granting Emmaus an exclusive license to patent rights, know-how and other intellectual property relating to Kainos' novel IRAK4 inhibitor (KM10544) for the treatment of cancers, including leukemia, lymphoma and solid tumors.

"Recently, we have made substantial progress in expanding access to Endari for sickle cell disease patients in need," stated Yutaka Niihara, M.D., M.P.H., Chairman and Chief Executive Officer of Emmaus. "Although our financial results for 2021 were below our expectations, we anticipate that the full roll-out of our new telehealth solution in the coming weeks will improve patient access and efficiency in the delivery of Endari to sickle cell patients throughout the United States. Internationally, we are pleased to have recently received marketing approval of Endari in the U.A.E. and our first major order from our exclusive distributor there. We are actively pursuing additional marketing approvals of Endari to treat the approximately 225,000 sickle cell disease patients throughout the Middle East North Africa (MENA) region and we expect this expanded distribution, along with our telehealth solution, to help generate increased sales of Endari during 2022."

Dr. Niihara continued, "In addition to our focus on increasing patient access to Endari, we have expanded our clinical pipeline. In particular, we have seen promising results from our ongoing preclinical studies of the IRAK4 inhibitor licensed from Kainos Medicine, Inc. in October 2021, which may prove to be a novel, potential treatment option for hard-to-treat lymphomas such as Waldenström's Macroglobulinemia with MYD88 mutation. We also eagerly anticipate results from an additional proof-of-concept study of Endari as a treatment for diverticulosis, expected in mid-2022. If positive, we should be able to move directly into a registration trial. The current year is shaping up to be an exciting one for Emmaus and we look forward to providing updates throughout the year."

Financial and Operating Results

Net Revenues. Net revenues for the year ended December 31, 2021 were $20.6 million, compared to $23.2 million for 2020. Although sales volume as measured by number of boxes of Endari sold held steady compared to 2020, net revenues were adversely affected by somewhat higher and more frequent discounts afforded distributors on bulk pre-orders in 2021 compared to 2020.

Operating Expenses. Total operating expenses for the year were $23.4 million, compared with $21.0 million for 2020. Of the increased expenses, $1.7 million was attributable to increased research and development expenses primarily related to license fees paid to Kainos Medicine, Inc. relating to Kainos' novel IRAK4 inhibitor in research and development expenses associated with the company's pilot/phase 1 diverticulosis sub-study in which enrollment was completed in December 2021. The company also incurred a $1.0 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.

Operating Income (Loss). Operating loss for the year ended December 31, 2021 was $6.1 million, compared with operating loss of $32,000 in 2020.

Other Income (Expense). Other expense increased by $10.8 million, or 1,074%, to $9.8 million for the year ended December 31, 2021, compared to other income of $1.0 million in 2020, which included a $7.7 million gain from sale of marketable securities. The company did not realize a similar gain in 2021. The increase in other expense in 2021 included a $3.5 million increase in foreign exchange loss and a $2.0 million increase in change in fair value of conversion feature derivatives, partially offset by a $2.9 million decrease in interest expense.

Net Income (Loss). For the year, the company reported a net loss attributable to common stockholders of $15.9 million, or $0.32 per share, based on approximately 49.3 million weighted average basic and diluted common shares. This compares to net income of $1.4 million, or $0.03 per share, based on approximately 49.0 million weighted average basic and diluted common shares, for 2020. The increased net loss was primarily attributable to the operating loss for the year and increase in other expense discussed above.

Liquidity and Capital Resources. At December 31, 2021, the company had cash and cash equivalents of $2.3 million, compared with $2.5 million at December 31, 2020.

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 U.S. Food and Drug Administration approved Endari® (L-glutamine oral powder), indicated to reduce the acute complications of sickle cell disease in adults and children 5 years and older. 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. For more information, please visit www.emmausmedical.com.

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

Endari®, Emmaus' prescription grade L-glutamine oral powder, was approved by the FDA in July 2017 for treating sickle cell disease in adult and pediatric patients five years of age and older. Sales of Endari® began in the United States in 2018.

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.com/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 region. These forward-looking statements are subject to numerous assumptions, risks and uncertainties which change over time, including uncertainties related to the company's working capital and ability to carry on its existing operations and obtain needed financing, risks inherent in the commercialization of Endari in the U.S. and abroad, and other factors 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)

	Year Ended December 31	
	2021	2020
Revenues, Net	$ 20,610	$ 23,167
Cost of Goods Sold	3,312	2,248
Gross Profit	17,298	20,919
Operating Expenses	23,426	20,951
Loss from Operations	(6,128)	(32)
Total Other Income (Expense)	(9,793)	1,005
Net Income (Loss)	(15,946)	1,354
Comprehensive Income (Loss)	(17,345)	2,577
Earnings (Net Loss) per Share	$ (0.32)	$ 0.03
Weighted Average Common Shares Outstanding	49,253,156	48,897,004

Emmaus Life Sciences, Inc.
Condensed Consolidated Balance Sheets

(In thousands)

	As of December 31,	
	2021	2020
Assets		
Current Assets:		
Cash and cash equivalents	$ 2,279	$ 2,487
Accounts receivable, net	1,040	198
Inventories, net	4,392	7,087
Prepaid expenses and other current assets	1,380	1,485
Total Current Assets	9,091	11,257
Property and Equipment, net	147	120
Equity method investment	17,616	15,925
Right of use assets	3,485	4,072
Investment in convertible bond	26,100	27,866
Other Assets	295	296
Total Assets	$ 56,734	$ 59,536
Liabilities and Stockholders' Deficit		
Current Liabilities:		
Accounts payable and accrued expenses	$ 9,189	$ 7,460
Conversion feature derivative, notes payable	7,507	--
Notes payable, current portion	2,399	4,588
Convertible debentures, net of discount	--	5,480
Convertible notes payable, net of discount	10,158	--
Other current liabilities	7,847	5,854
Total Current Liabilities	37,100	23,382
Notes payable, less current portion	1,500	222
Convertible notes payable, net of discount	3,150	3,150
Other long-term liabilities	36,434	37,940
Total Liabilities	78,184	64,694
Stockholders' Deficit	(21,450)	(5,158)
Total Liabilities & Stockholders' Deficit	$ 56,734	$ 59,536