

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 15, 2022

Emmaus Life Sciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

001-35527

(Commission File Number)

87-0419387

(I.R.S. Employer
Identification No.)

21250 Hawthorne Boulevard, Suite 800, Torrance, CA

(Address of principal executive offices)

90503

(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 August 15, 2022, Emmaus Life Sciences, Inc. issued a press release announcing earnings for the three months and six months ended June 30, 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.

By: /s/ YASUSHI NAGASAKI

Name: Yasushi Nagasaki

Title: Chief Financial Officer

INDEX TO EXHIBITS

Exhibit Number	Description
99.1	August 15, 2022 Press Release
104	Cover Page Interactive Data File (embedded within Inline XBRL document)



Emmaus Life Sciences Reports Q2 2022 Financial Results and Provides Business Update

Torrance CA, August 15, 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 and six months ended June 30, 2022 and provided a business update.

Recent Highlights

“We are pleased to have realized significant increases in net revenues for two consecutive quarters after our sales were negatively impacted by COVID-19 related travel issues and lockdowns throughout much of 2021, and are looking forward to continued increases in sales in the Middle East North Africa region, where we are anticipating a decision on our marketing approval application for Endari in the Kingdom of Saudi Arabia before year-end and perhaps as early as the end of the third quarter,” stated Yutaka Niihara, M.D., M.P.H., Chairman and Chief Executive Officer of Emmaus.

Dr. Niihara added, “We also are in discussions to possibly restructure or refinance our outstanding indebtedness and other current liabilities in conjunction with our efforts to improve sales.”

Financial and Operating Results

Net Revenues. Net revenues for the three months and six months ended June 30, 2022 were \$4.3 million and \$7.5 million, respectively, compared to \$6.5 million and \$11.8 million, respectively, for same periods in 2021. The decrease was primarily attributable to lower bulk order purchases in 2022 compared to the same periods in 2021 due to overstocking by U.S. distributors in 2021. Net revenues in Q2 2022 increased by \$1.1 million, or nearly 33%, from Q1 2022 net revenues of \$3.2 million. Net revenues were positively affected by Q2 sales of Endari in the United Arab Emirates, where Endari was approved for marketing in May 2022, and, to a lesser extent, sales on an early access basis in the Kingdom of Saudi Arabia.

Operating Expenses. Total operating expenses for the three months ended June 30, 2022 were \$5.3 million, compared with \$5.6 million for the same period in 2021. Of the decreased expenses in Q2, \$0.5 million was attributable to a decrease in professional fees, partially offset by a \$0.2 million increase in payroll and travel expenses. Total operating expenses for the six months ended June 30, 2022 were \$10.6 million, compared with \$12.1 million for the same period in 2021. The decrease was due to a \$1.8 million decrease in research and development expenses related to \$0.5 million in cash and \$0.5 million in shares of the Company common stock paid and issued in 2021 to Kainos Medicine, Inc. (“Kainos”) to lead the clinical development of Kainos’ patented IRAK4 inhibitor. Total operating expenses in Q2 2022 were substantially unchanged from Q1 2022.

Loss From Operations. Loss from operations for the three months ended June 30, 2022 was \$1.4 million, compared to \$0.5 million of income from operations in the same period in 2021. Operating loss for six months ended June 30, 2022 increased to \$4.5 million, compared to \$1.1 million for the same period last year. The increased operating losses resulted from lower net revenues in 2022 compared to 2021. Loss from operations in Q2 2022 decreased by \$1.6 million, or 53.1%, from \$3.1 million in Q1 2022 as a result of the increase in net revenues in Q2.

Other Income (Expense). Other expense increased by \$9.1 million to \$7.3 million for the three months ended June 30, 2022, compared to other income of \$1.8 million in the same period in 2021. Other expense in Q2 included a \$6.3 million decrease in change in fair value of conversion feature derivatives and a \$2.4 million increase in foreign exchange loss as compared to Q1 2021.

Net Income (Loss). For the quarter, the company realized a net loss of \$8.9 million, or \$0.18 per share based on approximately 49.3 million weighted average basic and diluted common shares. This compares to net income of \$2.5 million and earnings per share of \$0.05 based on approximately 49.3 million weighted average basic and diluted common shares for the second quarter of 2021. The net loss was primarily attributable to the increase of \$9.1 million in other expense and a \$1.9 million increase in loss from operations discussed above. For the six months ended June 30, 2022, the company reported a net loss of \$10.4 million, or \$0.21 per share, based on approximately 49.3 million weighted average basic and diluted common shares. This compares to a net loss of \$5.9 million, or \$0.12 per share, based on approximately 49.2 million weighted average basic and diluted common shares for the six months ended June 30, 2021. Net loss for Q2 2022 increased by \$7.4 million, or 477%, from \$1.5 million in Q1 2022 because of the increase of \$8.7 million in other expense, partially offset by a decrease of \$1.6 million in loss from operations, as discussed above.

Liquidity and Capital Resources. At June 30, 2022, the company had cash and cash equivalents of \$1.0 million, compared with \$2.3 million at December 31, 2021. Cash and cash equivalents at June 30 included the net proceeds of a \$1.8 million short-term loan from a third party finance lender. Based on the company’s cash and cash equivalents, anticipated future revenues, current liabilities and expected operating expenses, management believes the company’s working capital is insufficient to meet its needs for the next 12 months without restructuring or refinancing its existing indebtedness and other current liabilities and obtaining additional loans from related parties or debt or equity financing from third parties or curtailing certain operations or activities.

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 and 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 sales of Endari® in the U.A.E., possible marketing approval in the Kingdom of Saudi Arabia and perhaps other countries in the Middle East North Africa (MENA) region, possible restructuring or refinancing of outstanding indebtedness or possible equity or debt financings. 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 ability to raise needed financing, risks inherent in the regulatory approval process and commercialization of Endari® in the MENA region, and other factors disclosed in the company's Annual Report on Form 10-K for 2021 and Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission, 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:

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(Financial Tables Follow)

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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 June 30		Six Months Ended June 30	
	2022	2021	2022	2021
Revenues, Net	\$ 4,287	\$ 6,489	\$ 7,521	\$ 11,824
Cost of Goods Sold	396	430	1,403	866
Gross Profit	3,891	6,059	6,118	10,958
Operating Expenses	5,331	5,576	10,626	12,090
Loss from Operations	(1,440)	483	(4,508)	(1,132)
Total Other Income (Expense)	(7,270)	1,814	(5,847)	(4,975)
Net Income (Loss)	(8,892)	2,489	(10,434)	(5,933)
Comprehensive Income (Loss)	(12,664)	3,027	(13,518)	(5,172)
Earnings (Net Loss) Per Share	\$ (0.18)	\$ 0.05	\$ (0.21)	\$ (0.12)
Weighted Average Common Shares Outstanding	49,319,995	49,311,864	49,315,952	49,193,474

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

	As of	
	June 30, 2022 (Unaudited)	December 31, 2021
Assets		
Current Assets:		
Cash and cash equivalents	\$ 982	\$ 2,279
Accounts receivable, net	1,235	1,040
Inventories, net	3,134	4,392
Prepaid expenses and other current assets	1,235	1,380
Total Current Assets	6,586	9,091
Property and equipment, net	85	147
Equity method investment	16,982	17,616
Right of use assets	3,085	3,485
Investment in convertible bond	18,990	26,100
Other assets	261	295
Total Assets	\$ 45,989	\$ 56,734
Liabilities and Stockholders' Deficit		

Current Liabilities:

Accounts payable and accrued expenses	\$ 10,718	\$ 9,189
Conversion feature derivative, notes payable	8,122	7,507
Notes payable, current portion	9,265	3,199
Convertible notes payable, net of discount	14,062	10,158
Other current liabilities	3,909	7,047
Total Current Liabilities	<u>46,076</u>	<u>37,100</u>
Notes payable, less current portion	-	1,500
Convertible notes payable, net of discount	-	3,150
Other long-term liabilities	34,548	36,434
Total Liabilities	<u>80,624</u>	<u>78,184</u>
Stockholders' Deficit	<u>(34,635)</u>	<u>(21,450)</u>
Total Liabilities & Stockholders' Deficit	<u>\$ 45,989</u>	<u>\$ 56,734</u>