

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): November 14, 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 November 14, 2022, Emmaus Life Sciences, Inc. issued a press release announcing its results of operations and financial condition as of and for the three months and nine months ended September 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	November 14, 2022 Press Release
104	Cover Page Interactive Data File (embedded within Inline XBRL document)



Emmaus Life Sciences Reports Q3 2022 Financial Results and Provides Business Update

Torrance CA, November 14, 2022 - Emmaus Life Sciences, Inc. (OTCQX: EMMA) a commercial-stage biopharmaceutical company and leader in the treatment of sickle cell disease, today reported on its results of operations and financial condition as of and for the three and nine months ended September 30, 2022 and provided a business update.

Recent Highlights

“We enjoyed a third straight substantial increase in quarterly net revenue due to increased sales in the Middle East North Africa region. The increase was less than anticipated because of a delay in production of product packaging specific to the region. The product is being processed and we are optimistic that the sales will be realized in Q4,” stated Yutaka Niihara, M.D., M.P.H., Chairman and Chief Executive Officer of Emmaus.

Dr. Niihara added, “We also are pleased to see significant decrease in the loss from operations compared to the previous quarters. We continue to discuss with stakeholder the possible restructuring or refinancing of our outstanding indebtedness and other current liabilities and will report on any transactions in this regard as they may occur.”

Financial and Operating Results

Net Revenues. Net revenues for the three months and nine months ended September 30, 2022 were \$4.9 million and \$12.5 million, respectively, compared to \$5.8 million and \$17.6 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 Q3 2022 increased by \$0.7 million, or nearly 15%, from Q2 2022 net revenues of \$4.3 million. Net revenues were positively affected by Q3 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 other Gulf Cooperation Council (GCC) countries. The company had no similar sales in Q1 2022 or in 2021.

Operating Expenses. Total operating expenses for the three months ended September 30, 2022 were \$5.1 million, compared with \$5.4 million for the same period in 2021. Of the decreased expenses in Q3, \$0.2 million was attributable to a decrease in professional fees. Total operating expenses for the nine months ended September 30, 2022 were \$15.7 million, compared with \$17.4 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’s patented IRAK4 inhibitor. Total operating expenses in Q3 2022 decreased slightly from Q2 2022 due to \$0.3 million decrease in selling expenses.

Loss From Operations. Loss from operations for the three months ended September 30, 2022 was \$0.7 million, compared to \$31,000 in the same period in 2021. Operating loss for nine months ended September 30, 2022 increased to \$5.2 million, compared to \$1.2 million for the same period last year. The increased operating loss resulted from lower net revenues in 2022 compared to 2021. Loss from operations in Q3 2022 decreased by \$0.8 million, or 54.2%, from \$1.4 million in Q2 2022 as a result of the increase in net revenues in Q3.

Other Income (Expense). Other income increased by \$3.1 million to \$0.2 million for the three months ended September 30, 2022, compared to other expense of \$2.9 million in the same period in 2021. Other income in Q3 included a \$5.2 million decrease in change in fair value of conversion feature derivatives and a \$1.2 million increase in foreign exchange loss as compared to Q3 2021.

Net Loss. For the quarter, the company realized a net loss of \$0.4 million, or \$0.01 per share based on approximately 49.6 million weighted average basic and diluted common shares. This compares to net loss of \$3.2 million, or \$0.06 per share based on approximately 49.3 million weighted average basic and diluted common shares for the third quarter of 2021. The decrease in net loss was primarily attributable to the increase of \$3.1 million in other income, partially offset by a decrease of \$0.7 million in loss from operations discussed above. For the nine months ended September 30, 2022, the company incurred a net loss of \$10.8 million, or \$0.22 per share, based on approximately 49.4 million weighted average basic and diluted common shares. This compares to a net loss of \$9.1 million, or \$0.18 per share, based on approximately 49.2 million weighted average basic and diluted common shares for the nine months ended September 30, 2021. Net loss for Q3 2022 decreased by \$8.5 million, or 96%, from \$8.9 million in Q2 2022 because of the increase of \$7.5 million in other income and a decrease of \$0.8 million in loss from operations, as discussed above.

Liquidity and Capital Resources. At September 30, 2022, the company had cash and cash equivalents of \$1.2 million, compared with \$2.3 million at December 31, 2021. Cash and cash equivalents at September 30 included the net proceeds of \$5.5 from related party loans. Based on the company’s cash and cash equivalents, anticipated future revenues, current liabilities and expected operating expenses, the company’s working capital is insufficient to meet its current liabilities and anticipated future working capital requirement 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 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 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 GCC countries, 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 September 30		Nine Months Ended September 30	
	2022	2021	2022	2021
Revenues, Net	\$ 4,939	\$ 5,766	\$ 12,460	\$ 17,590
Cost of Goods Sold	540	445	1,943	1,311
Gross Profit	4,399	5,321	10,517	16,279
Operating Expenses	5,059	5,352	15,685	17,442
Loss from Operations	(660)	(31)	(5,168)	(1,163)
Total Other Income (Expense)	234	(2,888)	(5,613)	(7,863)
Net Loss	(391)	(3,151)	(10,825)	(9,084)
Comprehensive Loss	(2,957)	(5,819)	(16,475)	(10,991)
Net Loss Per Share	\$ (0.01)	\$ (0.06)	\$ (0.22)	\$ (0.18)
Weighted Average Common Shares Outstanding	49,558,501	49,311,864	49,397,690	49,233,371

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

	As of	
	September 30, 2022	December 31, 2021
Assets		
Current Assets:		
Cash and cash equivalents	\$ 1,179	\$ 2,279
Accounts receivable, net	1,491	1,040
Inventories, net	2,739	4,392
Prepaid expenses and other current assets	973	1,380
Total Current Assets	6,382	9,091
Property and equipment, net	79	147
Equity method investment	16,594	17,616
Right of use assets	2,944	3,485
Investment in convertible bond	15,943	26,100
Other assets	259	295
Total Assets	\$ 42,201	\$ 56,734
Liabilities and Stockholders' Deficit		
Current Liabilities:		

Accounts payable and accrued expenses	\$ 11,134	\$ 9,189
Conversion feature derivative, notes payable	4,272	7,507
Notes payable, current portion	8,415	3,199
Convertible notes payable, net of discount	14,346	10,158
Other current liabilities	3,356	7,047
Total Current Liabilities	<u>41,523</u>	<u>37,100</u>
Notes payable, less current portion	-	1,500
Convertible notes payable, net of discount	-	3,150
Notes payable to related parties, net	3,381	-
Other long-term liabilities	34,886	36,434
Total Liabilities	<u>79,790</u>	<u>78,184</u>
Stockholders' Deficit	(37,589)	(21,450)
Total Liabilities & Stockholders' Deficit	<u>\$ 42,201</u>	<u>\$ 56,734</u>