# 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): September 5, 2024

# 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<br>Identification No.)                        |  |
| 21250 Hawthorne Boulevard, Suite 800, Torn   | rance, CA  | 90503  |  |
| (Address of principal executive office   | <del>2</del> 8)  | (Zip Code)   |  |
| Regis  | strant's telephone number, including area code (310) 214   | 4-0065   |  |
| (Fo  | ormer name or former address, if changed, since last rep   | ort.)  |  |
| Check the appropriate box below if the Form 8-K filing is in   | ntended to simultaneously satisfy the filing obligation of | f the registrant under any of the following provisions:        |  |
| □ Written communications pursuant to Rule 425 under the  | e Securities Act (17 CFR 230.425)                          |  |  |
| □ Soliciting material pursuant to Rule 14a-12 under the E  | xchange 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 the Securities Exchange Act of 1934 (§240.12b-2 of this characteristics). |  | rities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of |  |
| Emerging growth company □  |  |  |  |
| If an emerging growth company, indicate by check mark if accounting standards provided pursuant to Section 13(a) of                    |  | ition period for complying with any new or revised financial   |  |
|  |  |  |  |
|  |  |  |  |

#### Item 2.02 Results of Operation and Financial Condition.

On September 10, 2024, Emmaus Life Sciences, Inc. ("we," "us," "our," "Emmaus" or the "company") issued a press release announcing the results of operations and financial condition as of and for the six months ended June 30, 2024, a copy of which 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 4.01 Changes in Registrant's Certifying Accountant

On September 5, 2024, Baker Tilly US, LLP, or BT, notified the Audit Committee of our Board of Directors that they would not stand for reappointment as our independent registered public accountants for the year ending December 31, 2024. Accordingly, we will undertake to evaluate and retain a replacement independent registered public accounting firm in time to review our interim financial statements for the quarter ending September 30, 2024.

The audit reports of BT on our consolidated financial statements for the years ended December 31, 2023 and 2022 did not contain an adverse opinion or a disclaimer of opinion and was not qualified or modified as to uncertainty, audit scope, or accounting principles, except that such report contained an explanatory paragraph regarding the Company's ability to continue as a going concern.

During the years ended December 31, 2023 and 2022 and subsequent interim periods through the date of this Current Report, there have been no disagreements with BT on any matter of accounting principles or practices, financial statement disclosure, or audit scope or procedure, which disagreements, if not resolved to the satisfaction of BT, would have caused BT to refer to the subject matter of the disagreement in connection with its reports on our financial statements for such periods.

During the two most recent years ended December 31, 2023 and 2022, there were no "reportable events" within the meaning of Item 304(a)(1)(v) of Regulation S-K.

We have provided BT with a copy of this Current Report and requested that BT furnish a letter addressed to the Securities and Exchange Commission stating whether it agrees with the statements made herein and, if not, stating the respects with which it does not agree. A copy of BT's letter dated September 10, 2024 is filed as Exhibit 16.1 to this Current Report.

## **Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

See the accompanying Index to Exhibits, which 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: September 10, 2024 Emmaus Life Sciences, Inc.

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

# INDEX TO EXHIBITS

| Exhibit Number | <b>Description</b>   |
|----------------|--|
| 16.1           | September 10, 2024 Letter of Baker Tilly US, LLP to the Securities and Exchange Commission |
| 99.1           | September 10, 2024 Press Release   |
| 104            | Cover Page Interactive Date File (embedded within Inline XBRL document)                    |
|                |  |
|                |  |



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September 10, 2024

Securities and Exchange Commission 100 F Street, NE Washington, DC 20549

Baker Tilly US, LLP

subsidiary entities provide tax and consulting services to their clients and are not licensed CPA firms.

Dear Ladies and Gentlemen:

We are the former independent registered public accounting firm for Emmaus Life Sciences, Inc. (the "Company"). We have read the Company's disclosure set forth in Item 4.01 "Changes in Registrant's Certifying Accountant" of the Company's Current Report on Form 8-K dated September 10, 2024 (the "Current Report") and are in agreement with the disclosure in the Current Report, insofar as it pertains to our firm.

Sincerely,

Baker Tilly Advisory Group, LP and Baker Tilly US, LLP, trading as Baker Tilly, are members of the global network of Baker Tilly International Ltd., the members of which are separate and independent legal entities. Baker Tilly US, LLP is a licensed CPA firm that provides assurance services to its clients. Baker Tilly Advisory Group, LP and its



# **Emmaus Life Sciences Reports Quarterly Financial Results**

Torrance CA, September 10, 2024 - Emmaus Life Sciences, Inc. (OTC Markets: EMMA), a commercial-stage biopharmaceutical company and leader in the treatment of sickle cell disease, today reported on its financial condition and results of operations as of and for the year quarters ended March 31 and June 30, 2024.

#### **Recent Highlights**

"As previously reported, after increasing annual net revenues in 2023 by nearly 61% as compared to 2022 we suffered a 55% decline in net revenues for the six months ended June 30 due to a prolonged shortage of inventory beginning in February and a further interruption in Supply beginning in mid-June that extended into August," noted Willis Lee, Chairman and Chief Executive Officer of Emmaus. "While our packager has resumed the production of new inventory and we have begun fulfilling back orders, we do not currently expect net revenues for the full year to reach the level achieved in 2023," he added.

"We are working with alternative manufacturers to avoid similar shortages in the future," remarked George Sekulich, Chief Commercial Officer. "We also are assessing the possible effect on Endari sales and net revenues of the recent launch of a generic L-Glutamine Oral Powder," he added.

## **Financial and Operating Results**

Net Revenues. Net revenues for the six months ended June 30 were \$7.9 million, compared to \$17.5 million in the same period in 2023. The decrease was primarily attributable to repeated delays in the production of finished goods inventory at our packager.

**Operating Expenses**. Total operating expenses for the six months were \$9.5 million compared with \$14.4 million in the comparable period in 2023. The decrease was due primarily to decrease of \$3.4 million in general and administrative expenses, \$1.3 million in selling expenses, and \$0.2 million in research and development expenses.

**Income (Loss) From Operations.** Loss from operations for the six months was \$2.2 million compared to income from operations of \$2.2 million in the same period in 2023. The decrease resulted from lower net revenues described above, partially offset by decreased operating expenses compared to 2023.

Other Expense. The company incurred other expense of \$4.4 million for the six months compared to \$7.2 million in the same period in 2023. The decrease was due primarily to an increase of \$1.0 million in gain on debt restructuring, a decrease of \$2.5 million in foreign exchange loss, and a \$1.0 million decrease in net loss on equity method investment, partially offset by a \$1.4 million decrease in change in fair value of embedded conversion option of convertible promissory notes.

Net Loss. For the six months, the company realized a net loss of \$6.5 million, or \$0.10 per share based on approximately 62.6 million weighted average basic common shares, compared to a net loss of \$5.0 million, or \$0.10 per share based on approximately 51.8 million weighted average basic and diluted common shares in the comparable period in 2023. The increase in net loss was primarily attributable to the decrease in income from operations, partially offset by the decrease in other expense.

Liquidity and Capital Resources. At June 30, 2024, the company had cash and cash equivalents of \$1.5 million, compared with \$2.5 million at December 31, 2023.

#### **About Emmaus Life Sciences**

Emmaus Life Sciences, Inc. is a commercial-stage biopharmaceutical company and leader in the treatment of sickle cell disease. Endari® (L-glutamine oral powder), indicated to reduce the acute complications of sickle cell disease in adults and children 5 years and older, is approved for marketing in the United States, Israel, Kuwait, Qatar, the United Arab Emirates, Bahrain and Oman and is available on a named patient or early access basis in France, the Netherlands, and the Kingdom of Saudi Arabia, where Emmaus' application for marketing authorization is awaiting final action by the Saudi Food & Drug Authority. 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 U.S. Food and Drug Administration (FDA) in July 2017 for treating sickle cell disease in adult and pediatric patients five years of age and older.

#### 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.

## **About Sickle Cell Disease**

There are approximately 100,000 people living with sickle cell disease (SCD) in the United States and millions more globally. The sickle gene is found in every ethnic group, not just among those of African descent; and in the United States an estimated 1-in-365 African Americans and 1-in-16,300 Hispanic Americans are born with SCD. The genetic mutation responsible for SCD causes an individual's red blood cells to distort into a "C" or a sickle shape, reducing their ability to transport oxygen throughout the body. These sickled red blood cells break down rapidly, become very sticky, and develop a propensity to clump together, which causes them to become stuck and cause damage within blood vessels. The result is reduced blood flow to distal organs, which leads to physical symptoms of incapacitating pain, tissue and organ damage, and early death.

#### 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 the expected net revenues for the full year 2024 and the possible effect on Endari sales and net revenues of the introduction of competing generic drugs. These forward-looking statements are subject to numerous assumptions, risks and uncertainties which change over time, including the company's need to restructure or refinance its existing indebtedness and raise additional funds from related-party loans, third-party loans or other financing to meet its current liabilities and fund its business and operations and doubt about the company's ability to continue as a going concern and other factors disclosed in the company's Annual Report on Form 10-K for the year ended December 31, 2023 and Quarterly Reports on Form 10-Q for the quarters ended March 31, 2024 and June 30, 2024, 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. Investor Relations (310) 214-0065 IR@emmauslifesciences.com

(Financial Tables Follow)

Source: Data & Statistics on Sickle Cell Disease - National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention, December 2020.

<sup>&</sup>lt;sup>2</sup> Source: Committee on Addressing Sickle Cell Disease – A Strategic Plan and Blueprint for Action -- National Academy of Sciences Press, 2020.

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

|  | Three Months Ended June 30 |            |    | Six Months Ended June 30 |    |            |    |            |
|--|----------------------------|------------|----|--------------------------|----|------------|----|------------|
|  |                            | 2024       |    | 2023                     |    | 2024       |    | 2023       |
| Revenues, Net                              | \$                         | 5,377      | \$ | 10,759                   | \$ | 7,883      | \$ | 17,512     |
| Cost of Goods Sold                         |                            | 241        |    | 508                      |    | 498        |    | 937        |
| Gross Profit                               |                            | 5,136      | _  | 10,251                   |    | 7,385      |    | 16,575     |
| Operating Expenses                         |                            | 4,554      |    | 6,925                    |    | 9,543      |    | 14,414     |
| Income (Loss) from Operations              |                            | 582        | _  | 3,326                    |    | (2,158)    |    | 2,161      |
| Total Other Expenses                       |                            | (2,735)    |    | (4,918)                  |    | (4,350)    |    | (7,155)    |
| Net Loss                                   |                            | (2,184)    |    | (1,558)                  |    | (6,532)    |    | (5,009)    |
| Comprehensive Income (Loss)                |                            | (3,708)    |    | 1,305                    |    | (9,766)    |    | (2,504)    |
| Net Loss Per Share                         | \$                         | (0.03)     | \$ | (0.03)                   | \$ | (0.10)     | \$ | (0.10)     |
| Weighted Average Common Shares Outstanding |                            | 63,355,121 |    | 52,865,353               |    | 62,600,542 |    | 51,793,445 |

# Emmaus Life Sciences, Inc. Condensed Consolidated Balance Sheets

(In thousands)

|  | As of                        |           |  |
|--|------------------------------|-----------|--|
|  | June 30, 2024<br>(Unaudited) |           |  |
| Assets                                       | <br>                         |           |  |
| Current Assets:                              |                              |           |  |
| Cash and cash equivalents                    | \$<br>1,525                  | \$ 2,547  |  |
| Accounts receivable, net                     | 4,598                        | 5,524     |  |
| Inventories, net                             | 1,628                        | 1,711     |  |
| Prepaid expenses and other current assets    | <br>1,261                    | 1,727     |  |
| Total Current Assets                         | 9,012                        | 11,509    |  |
| Property and equipment, net                  | <br>54                       | 59        |  |
| Right of use assets                          | 1,903                        | 2,337     |  |
| Investment in convertible bond               | 14,662                       | 20,978    |  |
| Other assets                                 | <br>308                      | 296       |  |
| Total Assets                                 | \$<br>25,939                 | \$ 35,179 |  |
| Liabilities and Stockholders' Deficit        |                              |           |  |
| Current Liabilities:                         |                              |           |  |
| Accounts payable and accrued expenses        | \$<br>18,920                 | \$ 17,725 |  |
| Conversion feature derivative, notes payable | 2,800                        | 451       |  |
| Notes payable, current portion               | 7,879                        | 8,215     |  |
| Convertible notes payable, net of discount   | 16,329                       | 16,383    |  |
| Other current liabilities                    | <br>18,097                   | 18,733    |  |
| Total Current Liabilities                    | 64,025                       | 61,507    |  |
| Other long-term liabilities                  | 18,928                       | 21,428    |  |
| Total Liabilities                            | 82,953                       | 82,935    |  |
| Stockholders' Deficit                        | <br>(57,014)                 | (47,756   |  |
| Total Liabilities & Stockholders' Deficit    | \$<br>                       | \$ 35,179 |  |