

November 12, 2021



## Emmaus Life Sciences Reports Third Quarter Financial Results and Business Highlights

**-- Net Revenues Increased 4% for the Nine Months Ended September 30, 2021 --**

TORRANCE, Calif., Nov. 12, 2021 /PRNewswire/ --**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 quarter and nine months ended September 30, 2021.



### Recent Highlights

- November: Formed a partnership with UpScript to offer telehealth solutions to sickle cell disease patients, expanding access to Endari®. The partnership will allow 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: Entered into an agreement with Asembia to provide expanded patient and provider support services to simplify access to Endari. Asembia will provide a single point of contact for benefits investigation, financial and co-pay assistance, as well as patient and provider education.
- October: Submitted an application for marketing authorization of Endari to the United Arab Emirates (UAE) Ministry of Health. During the review period, which is expected to take 10 to 12 months, Endari may be prescribed on a named patient, or early access, basis.
- October: 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.
- August: Announced the approval by the National Health Regulatory Authority (NHRA)

of the Kingdom of Bahrain for a Temporary License for Importation of Pharmaceutical Product for Endari.

"The Emmaus team has made significant progress in our efforts to expand access to Endari, the company's prescription L-glutamine oral powder for the treatment of sickle cell disease," stated Yutaka Niihara, M.D., M.P.H., Chairman and Chief Executive Officer of Emmaus. "We expect our new partnership with UpScript to provide an important and convenient telehealth solution for sickle cell disease patients already taking or seeking to take Endari, while our newly signed agreement with Asembia will improve the patient and provider experience with Endari. Together, these new relationships will provide sickle cell patients more flexibility in managing this debilitating disease. Additionally, during the third quarter, we received approval of a Temporary License for Importation of Endari from the Kingdom of Bahrain and submitted a marketing authorization application in the UAE representing the first of several full marketing applications we expect to file in Gulf Cooperation Council states for Endari to treat the approximately 225,000 sickle cell disease patients throughout the Middle East North Africa region."

Dr. Niihara continued, "In October, we expanded our pipeline by obtaining an exclusive license to the intellectual property surrounding Kainos' IRAK4 inhibitor a novel potential treatment option for some of the hard-to-treat lymphomas such as Waldenström's Macroglobulinemia with MYD88 mutation, and others. This addition to the pipeline fits squarely with our mission to improve the lives of people in need through the discovery, development and commercialization of innovative treatments and therapies."

### **Financial and Operating Results for the Period Ending September 30, 2021**

**Net Revenues.** Net revenues for the three months ended September 30, 2021 increased 3% to \$5.8 million, up from \$5.6 million for the same period last year. The increase was driven primarily by the increasing market acceptance of Endari in the U.S., partially offset by discounts afforded customers on bulk orders. Net revenues declined 6% compared to the second quarter of 2021 primarily due to lower bulk orders in the third quarter than in the second quarter.

Net revenues for the nine months ended September 30, 2021 increased 4% to \$17.6 million, up from \$16.9 million for the same period in 2020. The increase was primarily attributable to higher bulk order purchases compared to the same period in 2020 and the ongoing recovery from the temporary disruptions in revenues related the COVID-19 pandemic and severe winter weather during 2020.

**Operating Expenses.** Total operating expenses for the three months ended September 30, 2021 were \$5.4 million, compared with \$5.1 million for the same period in 2020. Of the increased expenses, \$0.2 million was attributable to outside accounting fees relating to catch-up SEC filings made in the third quarter. The company also incurred a \$0.2 million increase in selling expenses primarily due to increased travel expenses, partially offset by a \$0.2 million decrease in research and development expenses associated with the company's pilot/phase 1 diverticulosis study, which is nearing completion.

Total operating expenses for the nine months ended September 30, 2021 were \$17.4 million, compared with \$15.9 million for the same period in the prior year. The increase was primarily due to upfront payments in cash and shares of the company's stock under the

agreement with Kainos to lead the clinical development of Kainos' patented IRAK4 inhibitor and an increase of \$0.6 million related to a pharmacokinetic characteristic and safety study for Endari<sup>®</sup> and clinical study in Europe. The company also incurred a \$0.2 million increase in selling expenses primarily due to increased travel expenses, partially offset by \$0.2 million decrease in research and development expenses associated with the winding up of the company's pilot/phase 1 diverticulosis study.

**Operating Income (Loss).** Operating loss for the quarter ended September 30, 2021 was \$31,000, compared with operating income of \$8,000 for the same period in the previous year and operating loss of \$483,000 in the second quarter of 2021.

Operating loss for the nine months ended September 30, 2021 increased to \$1.2 million, versus \$0.4 million for the comparable period last year.

**Other Income (Expense).** Total other expense increased by \$8.8 million, or 149%, to \$2.9 million for the three months ended September 30, 2021, compared to \$5.9 million of other income for the three months ended September 30, 2020. The increase was primarily due to decreases of \$6.5 million in net income on investment in marketable securities, \$1.4 million in change in fair value of embedded conversion option and \$0.9 million in change in fair value of warrant derivative liabilities, and an increase of \$0.9 million in foreign exchange loss, partially offset by a decrease of \$0.9 million in interest expense.

Total other expense increased by \$10.0 million, or 475%, to \$7.9 million for the nine months ended September 30, 2021, compared to \$2.1 million of other income for the nine months ended September 30, 2020. The increase in other expenses was primarily due to decreases of \$7.7 million in net gain on investment in marketable securities, \$1.2 million in change in fair value of conversion feature derivative and \$1.0 million in change in fair value of warrant derivative liabilities, and an increase of \$2.1 million in loss in foreign exchange loss, partially offset by a decrease of \$2.3 million interest expenses.

**Net Income (Loss).** For the quarter ended September 30, 2021, the company reported a net loss attributable to common stockholders of \$3.2 million, or \$0.06 per share, based on approximately 49.3 million weighted average basic and diluted common shares. This compares to net income of \$5.6 million, or \$0.11 per share, based on approximately 49.0 million weighted average basic and diluted common shares, for the quarter ended September 30, 2020.

For the nine months ended September 30, 2021, the company reported a comprehensive loss attributable to common stockholders of \$11.0 million, or \$0.18 per share, based on approximately 49.2 million weighted average basic and diluted common shares. This compares to comprehensive net income of \$1.6 million, or \$0.03 per share, based on approximately 48.9 million weighted average basic and diluted common shares for the nine months ended September 30, 2020.

**Liquidity and Capital Resources.** At September 30, 2021, the company had cash and cash equivalents totaling \$2.3 million, compared with \$2.5 million at December 31, 2020. Based on the company's losses, anticipated future revenues and operating expenses, and cash and cash equivalents as of September 30, 2021, management believes the company's working capital is sufficient to meet its needs at least through the fourth quarter of 2022.

## **Update on Swiss Regulatory Authorization**

Emmaus also reported that it has withdrawn the Application for Marketing Authorization for Endari in Switzerland, announced in June. The Application consisted of an abbreviated dossier under so-called Article 13. The company is considering whether to submit a full dossier instead, in light of the relatively small incidence of SCD in the country.

## **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<sup>®</sup> (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](http://www.emmausmedical.com).

## **About Endari<sup>®</sup>** (prescription grade L-glutamine oral powder)

Endari<sup>®</sup>, 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<sup>®</sup> began in the United States in 2018.

## **Indication**

Endari<sup>®</sup> 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: <http://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 available through telemedicine and potential marketing authorization for Endari. These forward-looking statements are subject to numerous assumptions, risks and uncertainties which change over time, including risks inherent in the regulatory approval process and other factors previously disclosed in the company's Annual Report on Form 10-K/A filed with the Securities and Exchange Commission on August 10, 2021 and our Quarterly Reports on Form 10-Q, 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.

(Financial Tables Follow)

**Emmaus Life Sciences, Inc.**  
**Condensed Consolidated Statements of Operations and Comprehensive Income**  
**(Loss)**

(In thousands, except share and per share amounts) (Unaudited)

|                                               | Three Months Ended<br>September 30 |            | Nine Months Ended<br>September 30 |            |
|-----------------------------------------------|------------------------------------|------------|-----------------------------------|------------|
|                                               | 2021                               | 2020       | 2021                              | 2020       |
| Revenues, Net                                 | \$5,766                            | \$5,601    | \$17,590                          | \$16,915   |
| Cost of Goods Sold                            | 445                                | 484        | 1,311                             | 1,408      |
| Gross Profit                                  | 5,321                              | 5,117      | 16,279                            | 15,507     |
| Operating Expenses                            | 5,352                              | 5,109      | 17,442                            | 15,900     |
| Loss from Operations                          | (31)                               | 8          | (1,163)                           | (393)      |
| Total Other Income (Expense)                  | (2,888)                            | 5,870      | (7,863)                           | 2,094      |
| Net Income (Loss)                             | (3,151)                            | 5,585      | (9,084)                           | 1,621      |
| Comprehensive Income (Loss)                   | (5,819)                            | 5,550      | (10,991)                          | 1,614      |
| Earnings (Net Loss) Per<br>Common Share       | (\$0.06)                           | \$0.11     | (\$0.18)                          | \$0.03     |
| Weighted Average Common<br>Shares Outstanding | 49,311,864                         | 48,987,189 | 49,233,371                        | 48,866,724 |

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

|                                              | As of                             |                   |
|----------------------------------------------|-----------------------------------|-------------------|
|                                              | September 30, 2021<br>(Unaudited) | December 31, 2020 |
| <b>Assets</b>                                |                                   |                   |
| Current Assets:                              |                                   |                   |
| Cash and cash equivalents                    | \$2,321                           | \$2,487           |
| Accounts receivable, net                     | 2,663                             | 198               |
| Inventories, net                             | 6,252                             | 7,087             |
| Prepaid expenses and other current assets    | 1,238                             | 1,485             |
| Total Current Assets                         | 12,474                            | 11,257            |
| Property and Equipment, net                  | 97                                | 120               |
| Equity Method Investment                     | 17,835                            | 15,925            |
| Right of Use Assets                          | 3,642                             | 4,072             |
|                                              | 25,716                            | 27,866            |
| Investment in Convertible Bond               |                                   |                   |
| Other Assets                                 | 293                               | 296               |
| Total Assets                                 | \$60,057                          | \$59,536          |
| <b>Liabilities and Stockholders' Deficit</b> |                                   |                   |
| Current Liabilities:                         |                                   |                   |
| Accounts payable and accrued expenses        | \$6,973                           | \$7,460           |
| Conversion feature derivative, notes payable | \$6,733                           | --                |
| Notes payable                                | 3,269                             | 4,588             |
| Convertible debentures, net of discount      | --                                | 5,480             |
| Other current liabilities                    | 8,051                             | 5,854             |
| Total Current Liabilities                    | 25,026                            | 23,382            |
| Notes Payable, less current portion          | 1500                              | 222               |
| Convertible Notes Payable                    | 12,908                            | 3,150             |
| Other Long-term Liabilities                  | 35,724                            | 37,940            |
| Total Liabilities                            | 75,158                            | 64,694            |
| Stockholders' Deficit                        | (15,101)                          | (5,158)           |
| Total Liabilities & Stockholders' Deficit    | \$60,057                          | \$59,536          |

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