

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): July 31, 2020

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 8.01. Other Events

On July 31, 2020, Emmaus Life Sciences, Inc. (“we,” “us,” “our,” “Emmaus” or the “company”) issued a press release to provide additional operational and OTC Markets updates. A copy of the press release is included as [Exhibit 99.1](#) to this Current Report and incorporated herein by reference.

We provide the following updated risk factors relating to the OTC Markets update:

Trading on the OTC Markets is volatile and sporadic, which could depress the market price of our common stock and make it difficult for our security holders to resell their common stock.

Until July 31, 2020 our common stock was quoted on the OTCQB tier of the OTC Markets Group, Inc. On August 3, 2020, our common stock will temporarily be quoted on the OTC Pink tier of the OTC Markets Group, Inc. pending the filing of our Annual Report on Form 10-K for 2019 and Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, posting of our OTCQB Certification and verification of the company profile through OTCIQ.com. Trading in securities quoted on the OTC Markets is often thin and characterized by wide fluctuations in trading prices due to many factors, some of which may have little to do with our operations or business prospects. This volatility could depress the market price of our common stock for reasons unrelated to our business or operating performance. Moreover, the OTC Markets is not a stock exchange, and trading of securities on the OTC Markets is often more sporadic than the trading of securities listed on a quotation system such as The Nasdaq Capital Market or a stock exchange like the NYSE American. These factors may result in investors having difficulty reselling shares of our common stock.

As long as our common stock is quoted on the OTC Markets, our stockholders may face significant restrictions on the resale of our common stock due to state “blue sky” laws.

Each state has its own securities laws, often called “blue sky” laws, which limit sales of securities to a state’s residents, unless the securities are registered in that state or qualify for an exemption from registration, and govern the reporting requirements for broker-dealers doing business directly or indirectly in the state. Before a security is sold in a state, there must be a registration in place to cover the transaction, or the transaction must be exempt from registration. The applicable broker must also be registered in that state. As long as our common stock is quoted on the OTC Pink tier or the OTCQB tier, a determination regarding registration will be made by those broker-dealers, if any, who agree to serve as market-makers for our common stock. There may be significant state blue sky law restrictions on the ability of investors to sell, and on purchasers to buy, our common stock. You should therefore consider the resale market for our common stock warrants to be limited, as you may be unable to resell your common stock without the significant expense of state registration or qualification

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: July 31, 2020

Emmaus Life Sciences, Inc.

By: /s/ JOSEPH C. SHERWOOD III

Name: Joseph C. Sherwood III

Title: Chief Financial Officer

INDEX TO EXHIBITS

Exhibit Number	Description
99.1	Press release dated July 31, 2020



Emmaus Life Sciences Provides Additional Operational and OTC Markets Updates

Torrance CA, July 31, 2020 - Emmaus Life Sciences, Inc. (OTCQB: EMMA) a leader in sickle cell disease treatment, provided today additional operational updates for the year ended December 31, 2019 as well as operational updates for the quarters ended March 31 and June 30, 2020 in advance of the filing of its Annual Report on Form 10-K for 2019 and Quarterly Reports on Form 10-Q for the first and second quarters of 2020.

“We continue to work with our predecessor auditor and current auditor in resolving the proposed adjustments to our 2018 financials in order to file our 2019 10-K and our 2020 first and second quarter 10-Qs as soon as possible. Emmaus looks forward to sharing its financial results with our current and prospective stakeholders,” said Dr. Yutaka Niihara, M.D., M.P.H., Chairman and Chief Executive Officer. “In advance of those filings, Emmaus is providing these updates regarding our operations and the status of trading in our common stock.”

Sales Activity – U.S.

- As previously reported, in 2019 Emmaus shipped 24,072 boxes of Endari® to its U.S. customers (primarily distributors and specialty pharmacies) compared to 16,304 boxes in 2018, a 48% increase. Product shipments by Emmaus to its customers are referred to as “Emmaus Unit Sales.”

In accordance with U.S. GAAP, Emmaus’ reported net revenue is determined by adjusting gross sales for shipments in transit, fees, discounts, rebates, other variable consideration, and adjustments to prior period estimates of variable consideration. The wholesale acquisition cost (WAC) per box of Endari® was \$1,110 in 2019. Effective January 1, 2020, Emmaus increased the WAC per box to \$1,154. The cost to patients is reduced by any applicable co-pay assistance programs and eligibility for certain of Emmaus’ patient assistance programs.

Emmaus also tracks the sell-through of Endari® by its distributors to pharmacies and by its specialty pharmacy customers to sickle cell disease patients (“Distributor Unit Sales”) since they can be a leading indicator of future Emmaus Unit Sales. In 2019, Distributor Unit Sales amounted to 22,934 boxes in the U.S. compared to 14,506 boxes in 2018, a 58% increase.

- Effective January 1, 2020, Emmaus switched from use of a contract sales organization to its own direct sales force and continues to build its internal sales and marketing capabilities. Emmaus currently has 20 employees in its sales and marketing department.
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The following table summarizes Emmaus Unit Sales and Distributor Unit Sales by quarter for 2019 and 2020 (through June 30, 2020):

Boxes Shipped in U.S. by Quarter 2019 - 2020	Q1-19	Q2-19	Q3-19	Q4-19	Q1-20	Q2-20
Emmaus Unit Sales	5,347	5,626	6,295	6,804	7,456	4,864
Percentage Change Over Prior Quarter	NA	5%	12%	8%	10%	(35%)
Distributor Unit Sales	5,361	5,667	6,083	5,823	5,673	6,085
Percentage Change Over Prior Quarter	NA	6%	7%	(4%)	(3%)	7%

- Quarterly Emmaus Unit Sales are impacted by distributor inventory levels as well as the timing of bulk orders (i.e., large-volume purchases) placed periodically by Emmaus' distributors, which reduce Emmaus Unit Sales in subsequent quarters in which no similar bulk orders occur. A historically high level of bulk orders near the end of the first quarter of 2020 adversely impacted Emmaus Unit Sales in the second quarter of 2020. However, Distributor Unit Sales remained strong in the second quarter of 2020 and increased 7% over the first quarter.

Sales Updates – Outside the U.S.

- Emmaus continues to make progress in developing markets for Endari® in the Middle East and North Africa (MENA) region. On June 29, 2020 Emmaus announced it received Endari® marketing authorization from the Israeli Ministry of Health and on July 23, 2020 announced the opening of its Dubai office. These developments will accelerate the company's efforts to reach the estimated 100,000 potentially treatable sickle cell disease patients in the MENA region.

Patient Compliance and COVID-19 Impact

- Prescriptions from Emmaus' main specialty pharmacy partners increased in the second quarter as compared to the first quarter of 2020. Emmaus is encouraged that patient compliance and adherence as well as health monitoring appear to have held up well in the wake of the COVID-19 pandemic which may bode well for improved patient adherence as the pandemic subsides. In addition, Emmaus has recently developed certain patient support programs in conjunction with its main specialty pharmacy partners designed to improve patient access to Endari® where appropriate.

Research and Development

- Emmaus' Pilot/Phase 1 study of the same prescription grade L-glutamine oral powder active pharmaceutical ingredient found in Endari® in treating diverticulosis commenced in April 2019 is ongoing. The COVID-19 pandemic has slowed the progress of clinical trials in the pharmaceutical industry, in general, and patient enrollment at one of the three Emmaus trial sites was suspended temporarily. However, patient enrollment has now resumed, and Emmaus is confident that the study will ultimately evaluate the change in the number and size of colonic diverticula and assess safety in a total of up to 15 patients.

Based upon limited clinical results to date suggesting that Endari® may be effective in slowing and reversing the progression of diverticulosis, Emmaus announced on July 16, 2020 that it engaged Partner International to lead the out-licensing activity of its prescription grade L-glutamine powder for use in the treatment of diverticulosis.

- Emmaus is also exploring the possible investigational use of its prescription grade L-glutamine oral powder to mitigate the impact of COVID-19 or assist patients in their recovery.

Manufacturing

- As previously reported, the COVID-19 pandemic has not interrupted Emmaus' supply chain and the company has sufficient finished goods inventory of Endari® to meet current and projected patient needs and support ongoing clinical trials. Progress continues on the manufacturing facility in Ube, Japan purchased by a 40% owned investee of Emmaus in December of 2019. To meet the longer term potential demand for prescription grade L-glutamine, Emmaus, its partners and contractors are beginning the process of establishing and obtaining regulatory approval and recertification for the production of prescription grade L-glutamine and the company currently anticipates that test production will commence in early 2021 with regulatory approval expected in 2022.

OTCQB Eligibility

- On July 30, 2020, Emmaus was notified by the OTC Markets Group, Inc. that its common stock will no longer be eligible for quotation on the OTCQB tier as of the open of the market on August 3, 2020 due to the delays in filing the company's Annual Report on Form 10-K for 2019 and Quarterly Report on Form 10-Q for the quarter ended March 31, 2020. Once the company has filed its 10-K for 2019 and 10-Q for March 31, 2020 via EDGAR, posted the [OTCQB Certification](#) and verified the company profile through OTCIQ.com, the OTC Markets Group, Inc. will review the company to ensure that it still meets all of the requirements outlined in the [OTCQB Standards](#) at that time. If no further items are needed, the company's common stock will be moved back to the OTCQB tier for the next trading day. In the meantime, quotes will be available on the OTC Pink tier.

About Emmaus Life Sciences

Emmaus Life Sciences, Inc. is a commercial-stage biopharmaceutical company engaged in the discovery, development, marketing and sale of innovative treatments and therapies, including those in the rare and orphan disease categories. For more information, please visit www.emmausmedical.com.

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

Indication (U.S.) - 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

Sickle cell disease is an inherited blood disorder characterized by the production of an altered form of hemoglobin which polymerizes and becomes fibrous, causing red blood cells to become rigid and change form so that they appear sickle shaped instead of soft and rounded. Patients with sickle cell disease suffer from debilitating episodes of sickle cell crises, which occur when the rigid, adhesive and inflexible red blood cells occlude blood vessels. Sickle cell crises cause excruciating pain as a result of insufficient oxygen being delivered to tissue, referred to as tissue ischemia, and inflammation. These events may lead to organ damage, stroke, pulmonary complications, skin ulceration, infection and a variety of other adverse outcomes. Sickle cell disease is a significant unmet medical need, affecting approximately one hundred thousand patients in the U.S. and millions worldwide, the majority of which are of African descent. An estimated 1-in-365 African American children are born with sickle cell disease.

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 operating trends and research and development activities and possible future manufacturing activities. These forward-looking statements are subject to numerous assumptions, risks and uncertainties which change over time, including uncertainties related to Emmaus' working capital and ability to carry on its existing operations and obtain needed financing and other factors previously disclosed in the company's reports 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.

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