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 5, 2021

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 Identification No.)

21250 Hawthorne Boulevard, Suite 800, Torrance, CA	90503
(Address of principal executive offices)	(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 4.02. Non-Reliance on Previously Issued Financial Statements or a Related Audit Report or Completed Interim Review

On August 5, 2021, the Board of Directors of Emmaus Life Sciences, Inc. ("we," "us," "our," "Emmaus" or the "company"), in consultation with management and upon the recommendation of the Audit Committee of the Board of Directors, determined that our consolidated financial statements for the year ended December 31, 2020 (the "Original 2020 Financials") included in our Annual Report on Form 10-K (the "Original 2020 10-K") filed with the Securities and Exchange Commission ("SEC") on May 4, 2021 require restatement to correct the equity in losses on equity method investment in EJ Holdings, Inc., a Japanese affiliate ("EJ Holdings"), reflected in our net income and comprehensive income. As a result, the Original Financials can no longer be relied upon. Similarly, related press releases, earnings releases, and investor communications describing the Original 2020 Financials should no longer be relied upon.

The Original 2020 10-K contained a qualified audit report on the Original 2020 Financial Statements, because Baker Tilly US, LLP ("Baker Tilly"), our independent registered public accounting firm, was unable to obtain audited financial statements of EJ Holdings supporting our equity in losses of EJ Holdings included in our reported net income and comprehensive income, nor were they able to satisfy themselves as to the equity in losses of the foreign affiliate by other auditing procedures. In light of the qualification, we arranged for Baker Tilly to audit EJ Holdings' financial statements to the extent necessary to enable them to render an unqualified audit report.

Concurrently with the filing of this Current Report, we are filing with the SEC an amended and restated Annual Report on Form 10-K/A (the "Amended 2020 10-K") containing our restated consolidated financial statements for the year ended December 31, 2020 (the "Restated 2020 Financial Statements") reflecting changes resulting from the recently completed audit; specifically, increases of $254,000 in net income, $7,000 in other comprehensive income, $261,000 in equity method investment and $0.01 of earnings per share, and a decrease of $61,000 in deferred tax asset offset by an increase of valuation allowance from what was reported in the Original 2020 Financials. Net income as restated increased to $1.4 million from $1.1 million as originally reported compared, to a net loss of $54.8 million in 2019. The Amended 2020 10-K also contains a currently dated, unqualified audit report of Baker Tilly on the Restated 2020 Financial Statements.

These matters have been discussed with Baker Tilly.

We issued a press release regarding non-reliance on the Original 2020 Financials and the filing of our Amended 2020 10-K, a copy of which is included as Exhibit 99.1 to this Current Report and incorporated herein by reference.

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: August 9, 2021

Emmaus Life Sciences, Inc.

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

INDEX TO EXHIBITS

Exhibit Number	Description
99.1	Press release dated August 10, 2021

Emmaus Life Sciences Provides SEC Reporting Update

2020 Financial Statements Restated to Reflect Increase in Net Income Attributable to Change in Equity Method Investment in Japanese Affiliate

Amended and Restated Form 10-K Includes Complete Restated Financial Statements and Currently Dated, Unqualified Audit Report

Torrance CA, August 10, 2021 - Emmaus Life Sciences, Inc. (OTC: EMMA), a leader in sickle cell disease treatment, announced today that it has restated its financial statements for the fiscal year ended December 31, 2020, and that investors should no longer rely upon the financial statements included in its Annual Report on Form 10-K filed with the Securities and Exchange Commission (SEC) on May 4, 2021. Similarly, any earnings releases and other press releases and investor communications containing information derived from such financial statements should no longer be relied upon. Emmaus also provided an update on the filing of its delinquent quarterly reports.

The restated 2020 financial statements are set forth in Emmaus' amended and restated Annual Report on Form 10-K/A for the fiscal year ended December 31, 2020, filed with the SEC today. The restated financial statements reflect a decrease in Emmaus' equity method investment in its Japanese affiliate and corresponding increases in net income, comprehensive income, and earnings per share. Net income as restated increased to $1.4 million from $1.1 million as originally reported, compared to a net loss of $54.8 million in 2019. The Form 10-K/A also contains a currently dated, unqualified audit report of Emmaus' independent public accounting firm on the restated financial statements.

"The original audit report of our independent registered public accountants on our 2020 annual financial statements contained a qualification regarding the accounting for our equity method investment in our Japanese affiliate, which caused us to undertake an audit of the affiliate's financial statements to address the qualification. The qualification also has prevented us from reporting our financial results for the first and second quarters of this year," said Yutaka Niihara, M.D., M.P.H., Chairman and Chief Executive Officer of Emmaus. "The former qualification has now been eliminated, and we look forward to reporting our complete interim financial results on our Forms 10-Q for the first and second quarters of this year as soon as possible. As we have previously reported, public quotations for our common stock on the OTC Pink tier or trading in the common stock by certain brokerage firms may be suspended unless we get current in our SEC reporting in accordance with SEC rule changes scheduled to go into effect on September 28, and we are striving to file our delinquent Forms 10-Q and Form 10-Q for Q2 of this year to avoid even a temporary interruption in trading," added Dr. Niihara.

Increase in Reported Net Income

The audit of the financial statements of Emmaus' Japanese affiliate resulted in a $254,000 decrease in Emmaus' net loss on equity method investment for 2020 and corresponding increases in net income, comprehensive income, and earnings per share as reflected in the condensed consolidated statements of operations set forth following the text of this press release. The complete restated financial statements for 2020 are included in the amended and restated Annual Report on Form 10-K/A available on the SEC's website at https://www.sec.gov/edgar/searchedgar/companysearch.html and on Emmaus' website at www.emmausmedical.com.

Interim Sales Volume

On July 22, 2021, Emmaus reported interim volume sales of Endari® for the three months and six months ended March 31, 2021 and June 30, 2021, respectively. Emmaus expects to report its full interim financial results in its Quarterly Reports on Form 10-Q for Q1 and Q2 2021 to be filed with the SEC in the coming weeks. In accordance with U.S. GAAP, reported net revenue will be determined by adjusting gross sales for shipments in transit, fees, discounts, rebates, and other variable consideration and any adjustments to prior period estimates.

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 - 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. [1] 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.[2]

[1]Source: Data & Statistics on Sickle Cell Disease – National Center on Birth Defects and Developmental Disabilities, Centers for Disease Control and Prevention, December

2020.

[2]Source: Committee on Addressing Sickle Cell Disease – A Strategic Plan and Blueprint for Action -- National Academy of Sciences Press, 2020.

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 trend in interim sales volume and financial results that have yet to be reported and risks relating to the possible suspension of public quotations for Emmaus common stock and the resumption of public quotations. These forward-looking statements are subject to numerous assumptions, risks and uncertainties which change over time, including factors disclosed in the Emmaus' amended and restated Annual Report on Form 10-K/A filed with the SEC on August 10, 2021, 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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Emmaus Life Sciences, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Income (Loss)
(in thousands, except share and per share amounts)

	Year Ended December 31,			
	2020			2019
	As Originally Reported	Increase/ Decrease	As Adjusted	
Revenues, Net	$ 23,167		$ 23,167	$ 22,752
Cost of Goods Sold	2,248		2,248	1,094
Gross Profit	20,919		20,919	21,658
Operating Expenses	20,951		20,951	26,170
Loss from Operations	(32)		(32)	(4,512)
Net (Loss) on Equity Method Investment	(2,314)	254	(2,060)	(414)
Total Other Income (Expense)	751	254	1,005	(50,166)
Net Income (Loss)	1,100	254	1,354	(54,842)
Comprehensive Income (Loss)	2,316	261	2,577	(54,852)
Earnings (Loss) Per Share	$ 0.02	$ 0.01	$ 0.03	$ (1.30)
Weighted Average Common Shares Outstanding	48,897,004			42,259,460