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): October 29, 2020

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 7.01 Regulation FD Disclosure

On October 29, 2020, Emmaus Life Sciences, Inc. ("we," "us," "our," "Emmaus" or the "company") posted to its website the company presentation attached as Exhibit 99.1 hereto and incorporated herein by reference which management discussed at the virtual stockholders informational meeting held on September 17, 2020.

The information in this Item 7.01, including Exhibit 99.1, is being furnished pursuant to this Item 7.01 and shall not be deemed to be "filed" for any purpose of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of such Section, and shall not be deemed to be incorporated by reference into any of the company's filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof and regardless of any general incorporation language in such filings, except to the extent expressly set forth by specific reference 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.

Date: October 29, 2020

EMMAUS LIFE SCIENCES, INC.

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

INDEX TO EXHIBITS

Exhibit Number	Description
99.1	Company presentation at September 17, 2020 virtual stockholders informational meeting

Exhibit 99.1

Hope Delivered: Changing Lives Today

The first treatment approved by the FDA for Sickle Cell Disease in nearly 20 years

Informational Meeting of Stockholders

September 17, 2020

Safe Harbor Statement

This presentation by Emmaus Life Sciences, Inc. ("Emmaus" or the "Company") 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 the research, development and commercialization of pharmaceutical products. Such forward-looking statements are based on current expectations and are subject to numerous assumptions, risks and uncertainties which change over time, including factors that could delay, divert or change any of them, and could cause actual outcomes and results to differ materially from current expectations. Some of these important risks and uncertainties, including uncertainties related to the Company's working capital and ability to carry on its existing operations and obtain needed financing and other factors are previously described in the Company's reports filed with the Securities and Exchange Commission. Emmaus is providing this information as of the date of this publication or the dates stated within this publication and does not undertake any obligation to update any forward-looking statements as a result of new information, future events or otherwise.

Stockholders Informational Meeting

AGENDA:

- **Sales Updates**
- **Operational Updates**
- **Product Expansion & Pipeline**
- **Ube Plant**
- **COVID-19 Impact on Business**
- **Financial Position**
- **Audit Status (10-K and 10-Q filings) and Common Stock Trading Update**
- **Q & A Session**

Emmaus Life Sciences

Commercial-stage biopharmaceutical company focused on growing sales of Endari® and developing innovative treatments and therapies, including those in the rare and orphan disease categories

- **Endari® - prescription grade L-glutamine powder (PGLG) for sickle cell disease (SCD)**
  - ✓ FDA approval in 2017
  - ✓ Sales began in 2018
  - ✓ Strong growth in 2019
- **Platform provides for expanded applications of PGLG (diverticulosis and diabetes) and a series of potential additional product candidates to facilitate long term growth**

Emmaus LIFE SCIENCES, INC.

Emmaus and its FDA-Approved Product, Endari®:

Addressing an Unmet Medical Need; Positioned for Sustainable Growth

Sales Overview:

- Effective January 1, 2020, switched from using a contract sales organization (CSO) to our own direct sales force
- Emmaus currently has 20 employees in its sales and marketing departments
- Nationwide network of pharmacies in 44 states, Puerto Rico and Washington D.C.
- Expanding network of GPOs and PBMs
- Supporting sickle cell advocacy locally and nationally
- WAC price per patient averages $32,000 per year – net approximately $24,000
- Payers cover majority of patients: Medicaid, Medicare, Commercial
- Initiated Patient Adherence Programs

Endari® vs Competition:

- Endari® approved in July 2017 to treat SCD in adult and pediatric patients 5 years and older is well positioned with two successful years on the market
  - ✓ Broad Indication
  - ✓ No Black Box Warning
  - ✓ No Warnings and Precautions on Label
  - ✓ Lower Incidence of Acute Chest Syndrome
- Oxbryta (voxelotor) approved in November 2019 for the treatment of SCD in adults and pediatric patients 12 years and older
- Adakveo (crizanlizumab) approved in November 2019 for adults and pediatric patients 16 years and older with SCD
- Endari WAC price increased from $1,110 to $1,154 per box as of 1/1/2020 and is still priced considerably lower than Oxbryta and Adakveo

Sales Growth Driven by Strong Clinical Data

As published in *The New England Journal of Medicine*, July 2018

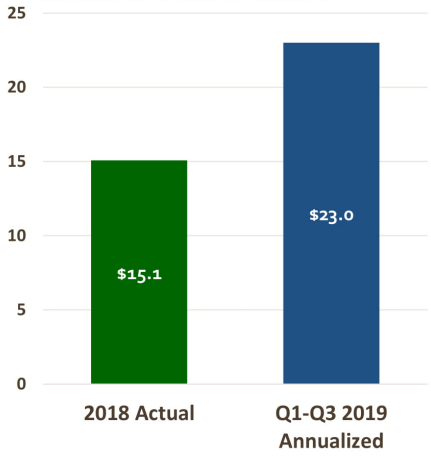
(48-week Phase 3 clinical trial of Endari® compared to placebo)

- ✓ **25% reduction in frequency of SCD crises**; p=0.005 (median 3 vs. median 4)
- ✓ **33% reduction in frequency of hospitalization**; p=0.005 (median 2 vs. median 3)
- ✓ **41% reduction in hospital days**; p=0.02 (median 6.5 days vs. median 11 days)
- ✓ **56% delay in the onset of first sickle cell crises;** p=0.02 (median 84 days vs. 54 days)
- ✓ **63% fewer cases of acute chest syndrome**; p=0.003 (13 of 152 patients [8.6%] had at least 1 case of ACS compared with 18 of 78 in the placebo group [23.1%])
- ✓ Safety profile similar to placebo with no serious adverse events. The most common adverse reactions (incidence >10%) in clinical studies were constipation, nausea, headache, abdominal pain, cough, pain in extremity, back pain and chest pain.

Annualized Statistics for Endari®

- ✓ **44% reduction in frequency of SCD crises; p=0.022 (median 2.4 vs. median 4.3)**
- ✓ **36% reduction in hospital days; p=0.042 (median 8.5 vs. median 13.2)**

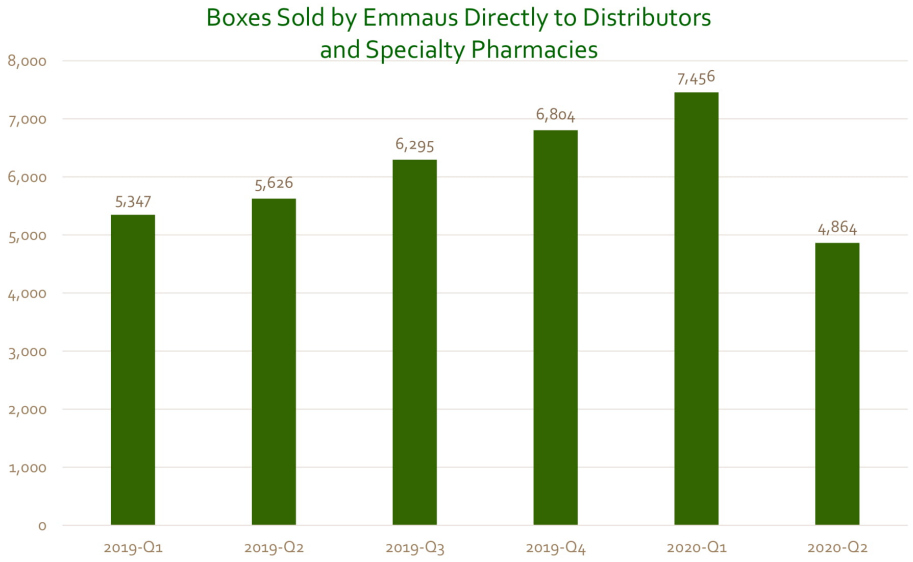
2018 Actual and Q1-Q3 2019 Annualized Net Revenue



Non-Endari sales of less than $500k in 2018 and 2019

Emmaus Unit Sales - Boxes Shipped in U.S.

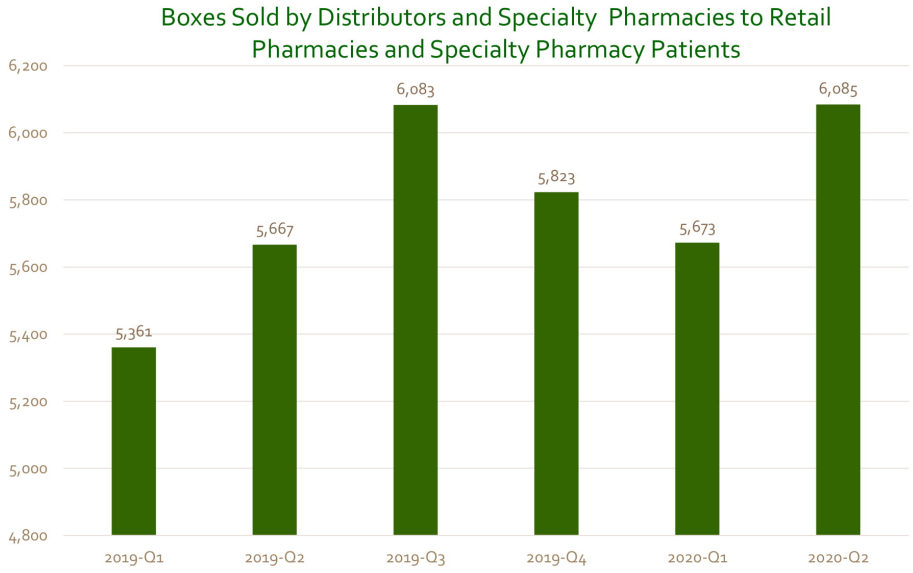
- Average quarterly growth of 8.4% in 2019 (Q1-Q4)
- Q1-2020 up 39% over Q1-2019
- COVID-19 pandemic begins March 2020 impacting Q2-2020 sales to Distributors and Specialty Pharmacies
- Q2-2020 down 14% compared to Q2-2019
- As of 9/14/2020 Emmaus has sold 5,785 boxes in Q3-2020 with two weeks left in Q3-2020



Emmaus LIFE SCIENCES, INC.

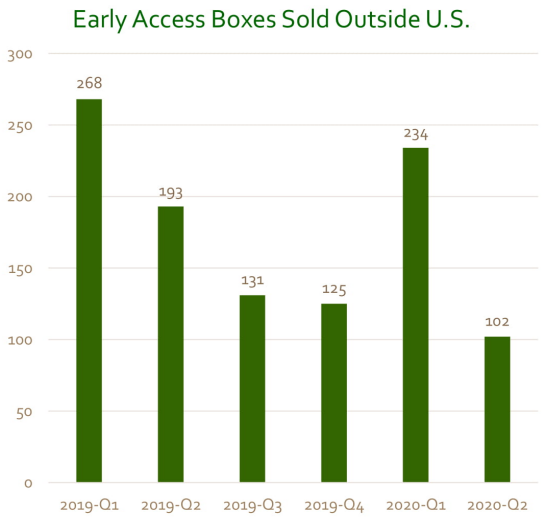
Distributor Unit Sales (Sell-Through) – U.S.

- Despite COVID-19 pandemic (begins March 2020), demand at the retail pharmacy and patient level remained strong in Q2-2020
- As of 9/14/2020 sell-through was 4,413 boxes in Q3-2020 with two weeks left in Q3-2020.
- Q3-2019 included some large retail pharmacy purchases from distributors



Emmaus Unit Sales - Outside U.S.

- Early Access Program (EAP) operational in France
- Scientific Advice Working Party (SAWP) and Committee for Medicinal Products for Human Use (CHMP) advice received regarding path to European Medicines Agency (EMA) approval
- Establishing direct business in the Middle East and North Africa (MENA) region - Dubai office opened in July 2020
- Over 225,000 SCD patients (100,000 potentially treatable) in the MENA region
- Submitted Marketing Authorization for Endari® to the Saudi Food and Drug Authority (SFDA) in August 2020 (previously granted priority review designation)
- Israeli Ministry of Health approval of Endari® in June 2020

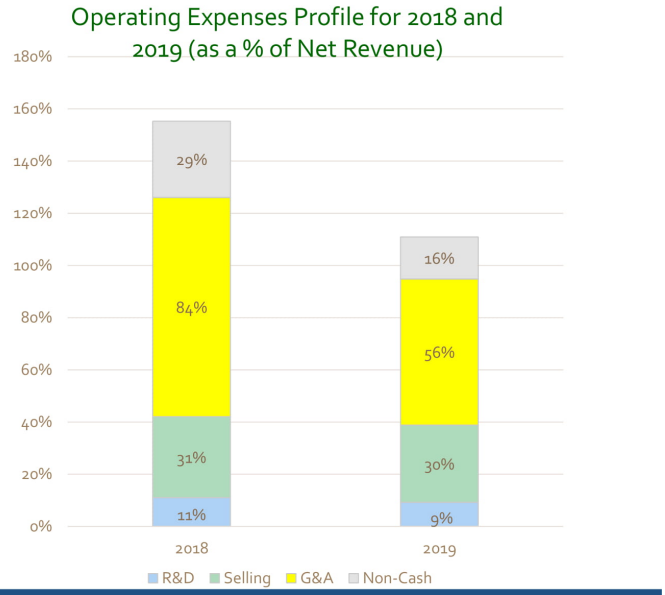


Operational Updates

Operational Updates	Transitioned from a contract sales organization (CSO) to internal sales department effective January 1, 2020
	Emmaus currently has 50 full-time employees as follows: Selling & Marketing: 20 General & Administrative: 20 Research & Development: 10
	COVID-19 impact: (i) temporarily slowed progress of our diverticulosis clinical trial at one of the sites but patient enrollment has now resumed (ii) business operations have run effectively and efficiently without any interruption

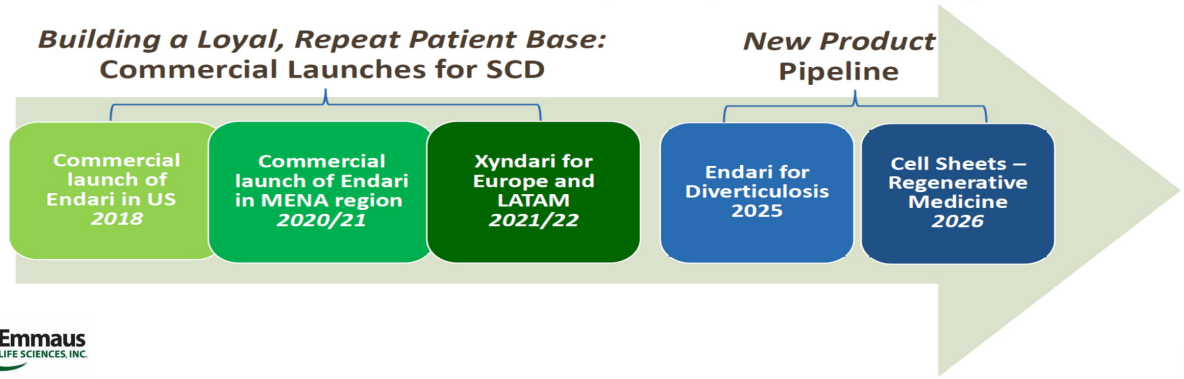
Operating Expenses - Profile for 2018 and 2019

- Achieved operating profit in Q4-2019 and Q1-2020 as net revenue exceed operating expenses
- Working towards continuous profit at the operating income line
- 2019 includes one-time, non-recurring merger related costs in Q3
- Non-cash relates to amortization of stock options previously granted
- Note: Net Revenue is determined and reported by adjusting gross sales for shipments in transit, fees, discounts, rebates, other variable consideration, and adjustments to prior period estimates of variable consideration in accordance with ASC 606



Product Expansion & Pipeline

- Commercial launch of Endari® in MENA region 2020/21
- Anticipated Xyndari (named filed with the EMA) for:
  - ✓ Europe 2021/22
  - ✓ LATAM 2021/22
- Diverticulosis – (i) preliminary pilot trial results are very promising, (ii) pilot study ongoing and preparing for Phase 3 trial, (iii) pursuing licensing deal through Partner International, and (iv) large potential patient population
- Other: Diabetes, Cell Sheets (CAOMECS), Sickle Cell Trait, COVID-19, Ointment for treating Skin Ulcerations in SCD (exclusive patent license from NIH)



Ube Plant

Ube Plant (Ube, Japan)	Manufacturing facility in Ube, Japan purchased by a 40% owned investee of Emmaus in December of 2019 to meet the Company's future demand for prescription grade L-glutamine (PGLG) to support patient needs and ongoing clinical trials
	Beginning the process of establishing and obtaining regulatory approval and recertification for the production of PGLG and currently anticipate that test production will commence in early 2021 with regulatory approval expected in 2022
	($ in millions) Initial Purchase Price: $10.4 Expenditures to Date: 1.9 Total Investment to Date: $12.3 Appraisal by Marshall & Stevens (as of 12/25/19): $53.5 Emmaus Ownership Percentage: 40.0% Appraised Amount Allocated to Emmaus: $21.4

COVID-19 Impact on Business

COVID-19 Impact on Business	Sales – some challenges faced by salesforce in calling on their customers, distributors taking a cautious view in terms of inventory levels (i.e. lowering days sales ratios), other factors
	Distributor Unit Sales to retail pharmacy and Specialty Pharmacy Unit Sales to patients continued to trend upward during Q2-2020 despite the COVID-19 pandemic that began March 2020
	Operations – have been able to run the business effectively without any interruption
	Supply Chain - no interruption, PGLG/Endari® levels are sufficient to support sales as well as clinical trials
	Clinical trials – patient enrollment at one of the three Emmaus trial sites was temporarily suspended but patient enrollment has resumed
	Researching the benefit of PGLG/Endari® on countering adverse effects of COVID-19 and/or assisting patients in their recovery

Financial Position

How we are working to improve our financial position	Simple capital structure with common stock, options and warrants outstanding
	Debt reduced significantly in 2019, mainly due to reverse merger and related conversion of approximately of $33.8 million of debt and $2.4 million of related accrued interest into common stock
	Accounts receivable (A/R) from high credit rated customers (e.g. McKesson, AmerisourceBergen, Cardinal), A/R financing (factoring) facility pending to use when/if needed
	Payroll Protection Program (PPP) Loan will most likely be forgiven
	Debt Modifications – extensions and/or revised principal amortization

Audit Status & Common Stock Trading Update

Audit Status	Delay in 2019 audit primarily attributable to predecessor auditor and current auditor not being able to reach agreement on path forward to complete the 2019 audit and adjustments to the 2018 financials
	Based on the above, the Audit Committee has agreed with management's recommendation to engage a new auditor to audit both our 2019 and 2018 financials and review our 2020 10-Qs
	Goal for filing 2019 10-K and 2020 10-Qs (Q1, Q2 and Q3) is mid-to-late November 2020
Common Stock Trading Update	Recently relegated to the OTC Pink tier due to delay in filing of 10-K and 10-Qs
	We will be back on the OTCQB tier once we are current with our SEC reports for 2019 and 2020
	Plan is to up-list to NASDAQ or NYSE American as soon as possible after reinstatement to OTCQB
	Ticker (OTCPK): EMMA Shares Outstanding: 48,987,189 30-Day Average Volume: 20,571 shares Recent Price (9/14/2020): $1.17 52-Week High: $3.48 52-Week Low: $0.85 Market Capitalization: $57,315,011 Enterprise Valuation: $74,842,501

Thank you and we now welcome your questions

Appendix

Emmaus Unit Sales (boxes shipped) - Q1 and Q2 2020

Q1 and Q2 2020 **Summary Management Commentary**	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 could reduce Emmaus Unit Sales in subsequent quarters in which no similar bulk orders occur
	A historically high level of bulk orders during Q1-2020 adversely impacted Emmaus Unit Sales in Q2-2020
	Distributor inventories, at new highs in Q1-2020, as of July 31, 2020 are now 32% lower compared to March 31, 2020
	The factors above could continue and possibly impact Q3 and Q4-2020 as the COVID-19 pandemic continues (potentially impacting doctor and pharmacy availability) and distributors/wholesalers may decide to carry lower than normal inventory levels (days sales ratios)
	Boxes sold by Emmaus to its Distributor and Specialty Pharmacy customers (Emmaus Unit Sales) declined from 7,456 in Q1-2020 to 4,864 in Q2-2020
	However, Distributor Unit Sales growth remained strong in Q2-2020 and increased 7% over Q1-2020 in the U.S. market (6,085 boxes vs. 5,673 boxes)