UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K/A

(Amendment No. 1)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2020

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number: 001-35527

Emmaus Life Sciences, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**2834**	**87-0419387**
(State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

21250 Hawthorne Boulevard, Suite 800, Torrance, California 90503
(Address of principal executive offices, including zip code)

(310) 214-0065
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
None		

Securities Registered Pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☐ No ☒

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☐ No ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of shares of common stock held by non-affiliates of the registrant as of June 30, 2020, the last business day of the registrant's most recently completed second fiscal quarter, was $58,283,977 based upon the closing price of the common stock as reported on the OTCQB.

There were 49,311,864 shares of common stock outstanding as of July 31, 2021.

TABLE OF CONTENTS

EXPLANATORY NOTE

Emmaus Life Sciences, Inc. ("we," "our," "us," "Emmaus" or the "company") is filing this Form 10-K/A to amend the company's Annual Report on Form 10-K for the fiscal year ended December 31, 2020, filed with the Securities and Exchange Commission (the "SEC") on May 4, 2021 (the "Original Report").

The Original Report contained a qualified audit report of Baker Tilly US, LLP ("Baker Tilly"), our independent registered public accounting firm, on our financial statements as of and for the fiscal year ended December 31, 2020 (the "2020 Financial Statements"). As indicated in its report, Baker Tilly was unable to obtain audited financial statements supporting the company's equity in losses of EJ Holdings, Inc., or EJ Holdings, a privately held foreign affiliate, included in the company's reported net income of $1,100,000 and comprehensive income of $2,316,000 for the year ended December 31, 2020; nor were they able to satisfy themselves as to the equity in losses of the foreign affiliate by other auditing procedures. In light of Baker Tilly's qualified report, we determined that the 2020 Financial Statements did not meet the requirements of Regulation S-X, Article 2, governing financial statements filed as part of annual reports under the Securities Exchange Act of 1934, as amended, and undertook to arrange for Baker Tilly to audit the financial statements of the foreign affiliate to the extent necessary to enable Baker Tilly to render an unqualified audit report on the 2020 Financial Statements.

This Form 10-K/A contains in Part IV, Item 15 restated 2020 Financial Statements and Notes thereto reflecting changes resulting from Baker Tilly's audit of our equity in losses of EJ Holdings; specifically, increases of $254,000 in our net income, $7,000 in other comprehensive income, $261,000 in equity method investment, and $0.01 earnings per share and a decrease in $61,000 in deferred tax asset offset by an increase of valuation allowance from that reported in the Original Report. Also included in Part IV, Item 15 of this Form 10-K/A is a currently dated, unqualified audit report of Baker Tilly on the restated 2020 Financial Statements.

This Form 10-K/A also amends the following Items in the Original Report listed below as they relate to the changes reflected in the restated 2020 Financial Statements and the qualified nature of the audit report contained in the Original Report and restates in its entirety the Original Report:

Part I, Item 1A. Risk Factors

Part II, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

This Form 10-K/A also includes an added Exhibit 4.20 and currently dated certifications of our Chief Executive Officer and Principal Financial Officer under the Sarbanes Oxley Act of 2002 as Exhibits 31.1, 31.2 and 32.1 and the currently dated Consent of Baker Tilly as Exhibit 23.1.

Except as described above, this Form 10-K/A does not amend, update, or change any Items or disclosures in the Original Report and, as such, speaks only as of the date the Original Report was filed. Except as described above, we have not undertaken herein to amend, supplement or update any information contained in the Original Report to reflect any subsequent events.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains some statements that are not purely historical and that are considered "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, which we refer to as the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, which we refer to as the Exchange Act. Such forward-looking statements express our management's expectations, beliefs, and intentions regarding the future. The words "anticipates," "believes," "continue," "could," "estimates," "expects," "intends," "may," "might," "plans," "possible," "potential," "predicts," "projects," "seeks," "should," "will," "would" and similar expressions and variations, or comparable terminology, or the negatives of any of the foregoing, may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking.

The forward-looking statements contained in this Annual Report are based on current expectations and beliefs concerning future developments that are difficult to predict. We cannot guarantee future performance, or that future developments affecting our company will be those currently anticipated. These forward-looking statements involve risks, uncertainties (some of which are beyond our control) or assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements, including the factors referenced in this Annual Report under the sections entitled "Business," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

All forward-looking statements attributable to us are expressly qualified in their entirety by these risks and uncertainties, and you should not place undue reliance on any forward-looking statement. We undertake no obligation to update or revise any forward-looking statement, except as may be required under applicable securities laws.

RISK FACTOR SUMMARY

Following is a summary of certain material risks and uncertainties facing our business. This summary is not a complete discussion of the risk and uncertainties affecting us. A more complete discussion of these and other risks and uncertainties is set forth under "Risk Factors" in Part I, Item 1A of this Annual Report. Additional risks not presently known to us or that we presently deem immaterial may also affect us. If any of these risks occur, our business, financial condition or results of operations could be materially and adversely affected.

Risks Related to Our Business

We have operated at a loss and may continue to operate at a loss for the foreseeable future.

We are dependent on the commercial success of our only approved product, Endari®.

There are uncertainties regarding our working capital, and we may need to raise additional financing.

We face intense competition from companies with greater resources than us, and if our competitors are successful in marketing or developing alternative treatments, our commercial opportunities may be reduced or eliminated.

The majority of Endari® sales are to a few customers and loss of a customer could adversely affect our results of operations.

The market exclusivity for Endari® for sickle cell disease ("SCD") is limited, which could adversely affect our ability to compete in the market and adversely affect the commercial success of Endari®.

A variety of other risks associated with marketing Endari® internationally could hurt our business.

We expect to rely on third parties to conduct future clinical trials of our product candidates and those third parties may not perform satisfactorily, including failing to meet deadlines for the conduct of such trials.

The use of any of our product candidates in clinical trials and in the market may expose us to liability claims.

We will need to increase the size and complexity of our organization in the future, and we may experience difficulties in managing our growth and executing our growth strategy.

We have identified material weaknesses in our internal controls over financial reporting.

Risks Related to Our Intellectual Property

We may not be able to obtain and enforce intellectual property rights that cover our commercial activities or are sufficient to prevent third parties from competing against us.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

We may not be able to protect our intellectual property rights throughout the world.

Risks Related to Regulatory Oversight of Our Business and Compliance with Law

Endari® is subject to ongoing and continued regulatory review, compliance with which may result in significant expense and limit our ability to commercialize Endari®.

We may not be able to receive regulatory approval for our prescription grade L-glutamine treatment for diverticulosis or other indications, which would adversely affect our prospects.

The development process to obtain FDA approval for new drug therapies is very costly and time consuming and if we cannot complete our clinical trials in a cost-effective manner, our operations may be adversely affected.

If we fail to comply with federal and state healthcare laws, including fraud and abuse and health information privacy and security laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.

Even though we have obtained Orphan Drug designation for Endari®, we may not be able to maintain Orphan Drug marketing exclusivity for Endari® or any of our product candidates.

Risks Related to Our Investment in EJ Holdings, Inc.

EJ Holdings has no revenues and is dependent on us to fund its business and operations, and there is no assurance that we can continue to provide needed funding or that EJ Holdings will be able to continue its activities.

EJ Holdings is subject to risks inherent in a new business and may not be successful.

If EJ Holdings fails to reactivate its plant and obtain customers, it may not be able to sell its plant and property and we may lose our investment.

Risks Related to Our Securities

We have been delinquent in our SEC reporting obligations, which has had an adverse effect on the liquidity and trading prices of our common stock and could lead to the disqualification of our common stock for quotation on the OTC Markets Group, Inc.

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.

Stockholders may experience future dilution from future equity offerings.

Our common stock is not traded on a national securities exchange, which may adversely affect our ability to raise needed financing.

PART I

ITEM 1. BUSINESS

In this Annual Report, the terms, "we," "us," "our" or the "Company" refer to Emmaus Life Sciences, Inc., and its subsidiaries.

Overview

We are a commercial-stage biopharmaceutical company engaged in the discovery, development, marketing and sale of innovative treatments and therapies, primarily for rare and orphan diseases. On July 7, 2017, our lead product, Endari® (prescription grade L-glutamine oral powder), was approved by the U.S. Food and Drug Administration, or FDA, to reduce the acute complications of sickle cell disease ("SCD") in adult and pediatric patients five years of age and older. Endari® has received Orphan Drug designation from the FDA and Orphan Medicinal designation from the European Commission, which designations afford marketing exclusivity for Endari® for a seven-year period in the U.S. and ten-year period in the European Union, respectively, following marketing approval.

Endari® is marketed and sold in the U.S. by our internal commercial sales team. Endari® is reimbursable by the Centers for Medicare and Medicaid Services, and every state provides coverage for Endari® for outpatient prescriptions to all eligible Medicaid enrollees within their state Medicaid programs. Endari® is also reimbursable by many commercial payors. We have agreements in place with the nation's leading distributors, as well as physician group purchasing organizations and pharmacy benefits managers, making Endari® available at selected retail and specialty pharmacies nationwide.

SCD is a rare, debilitating and lifelong hereditary blood disorder that affects approximately 100,000 patients in the U.S. and up to 25 million patients worldwide, the majority of which are of African descent. Approximately one in every 365 African-American children are born with SCD. The FDA's approval of Endari® was based upon the results of a 48-week randomized, double-blind, placebo-controlled, multi-center Phase 3 clinical trial evaluating the effects of Endari®, as compared to placebo in 230 adults and children with SCD. The results demonstrated that Endari® reduced the frequency of sickle cell crises by 25% and hospitalizations by 33%. Additional findings included a 41% decrease in cumulative hospital days and greater than 60% fewer incidents of acute chest syndrome in patients treated with Endari®. The FDA has acknowledged that the clinical benefit of Endari® was observed irrespective of hydroxyurea use, which supports the use of Endari® as a monotherapy or in combination with hydroxyurea as safe and effective treatment options for patients with SCD.

The safety of Endari® was based upon data from 298 patients, 187 treated with Endari® and 111 patients treated with placebo in Phase 2 and Phase 3 studies. Endari®'s safety profile was similar to the placebo and Endari® was well-tolerated in pediatric and adult patients alike. The most common adverse reactions, occurring in more than 10% of patients treated with Endari®, were constipation, nausea, headache, abdominal pain, cough, pain in extremity, back pain, and chest pain (non-cardiac).

On July 4, 2018, the FDA acknowledged receipt of our investigational new drug application, or IND, for the treatment of diverticulosis using the same prescription grade L-glutamine oral powder ("PGLG") used in Endari®. We subsequently received a "Study May Proceed" letter from the FDA. In April 2019, we commenced a Pilot/Phase 1 study of the safety and efficacy of PGLG oral powder in diverticulosis. The study will evaluate the change in the number and size of colonic diverticula and assess safety in a total of up to 10 to 15 patients at multiple study sites. The COVID-19 pandemic has interrupted the progress of clinical trials in the pharmaceutical industry, in general, and our Pilot/Phase I study was temporarily interrupted. However, patient enrollment has now been completed and we expect to report the study results by the end of this year**.**

On August 5, 2020, we announced preliminary top-line data for two patients who had most recently completed the first six months of the scheduled twelve months of treatment in a pilot study of diverticulosis.

In each of these patients, the investigator also noted the appearance of healthier mucosa with pinkish coloration compared to the baseline. There were no safety concerns reported by the patients. Our study observations are focused on diverticula in the sigmoid colon, the most frequent site for diverticulitis.

An Emmaus-led team at The Lundquist Institute, formerly known as the Los Angeles Biomedical Research Institute, or TLI, an independent non-profit biomedical research organization academically affiliated with the David Geffen School of Medicine at University of California, at Los Angeles that works in partnership with Harbor-UCLA Medical Center, is conducting pre-clinical studies of Cultured Autologous Oral Mucosal Epithelial Cell Sheet, or CAOMECS, technology

licensed by us from CellSeed Inc., a Japanese company, which we refer to as CellSeed. Our lead CAOMECS program is for the treatment of corneal diseases. The development of CAOMECS for treating corneal and other diseases is in the early stages.

2020 Highlights

Establishment of Direct Sales Force - Effective January 1, 2020, we switched from the use of a contract sales organization to our own direct sales force. We currently have 23 employees in sales and marketing and we continue to expand our sales and marketing capabilities.

Increase in Sales Volume – In 2020, we sold 25,947 boxes of Endari®, which we refer to as "Unit Sales," compared to 24,797 boxes in 2019, an increase of 5%. The following table summarizes quarterly Unit Sales for 2019 and 2020:

	Q1-19	Q2-19	Q3-19	Q4-19	Q1-20	Q2-20	Q3-20	Q4-20
Unit Sales (boxes)	5,617	5,823	6,444	6,913	7,531	5,064	6,327	7,025
Percentage change	—	4 %	11 %	7 %	9 %	(33 %)	25 %	11 %

Diverticulosis Study - Our Pilot/Phase 1 study of the same prescription grade L-glutamine ("PGLG") oral powder used in Endari® in treating diverticulosis commenced in April 2019 and 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 trial sites was suspended temporarily. Patient enrollment was completed, and Emmaus is confident the study will ultimately evaluate the change in the number and size of colonic diverticula and assess safety in patients with diverticulosis. Limited interim study results were encouraging, suggesting that Endari® may be effective in slowing and reversing the progression of diverticulosis. We expect to announce further results by the end of 2021. The following table summarizes the data:

Number of diverticula in the sigmoid colon following six months treatment of PGLG

Patient	Baseline	Six Months	Percentage Reduction
52 year-old female	8	4	50%
59 year-old female	7	0	100%

As the sigmoid colon is the most frequent site for diverticulitis, our observations are focused on sigmoid diverticula. In addition to the significant reduction in the number of diverticula, in each of these patients, the investigator noted the appearance of healthier mucosa with pinkish coloration compared to the baseline. These were no safety concerns reported by the patients.

COVID-19 Impact – While the COVID-19 pandemic created challenges in 2020, patient compliance and adherence as well as health monitoring overall held up well, which may bode well for improved patient adherence as the nation's vaccine rollout accelerates and the pandemic subsides. However, ongoing stay-at-home orders and business lockdowns may adversely affect the Company's near-term revenues, results of operations and financial condition, and management will continue to monitor COVID-19 developments and take necessary actions to minimize any impact on our business.

Manufacturing - The COVID-19 pandemic has not interrupted our supply chain and we have ample inventory of Endari® and PGLG to meet current and projected patient needs and support ongoing clinical trials. Progress continues at the manufacturing facility in Ube, Japan purchased by a 40%-owned investee of Emmaus in December of 2019. To meet the long-term potential demand for PGLG, we, our partner and contractors are in the process of obtaining regulatory approvals and recertifications of the facility. We currently anticipate that test production will commence later in2021 with regulatory approval expected in 2022.

Middle East and North Africa ("MENA") Region - We continue to make progress in developing markets for Endari® in the MENA region. On June 29, 2020, we announced receipt of Endari® marketing authorization from the Israeli Ministry of Health and on July 23, 2020 announced the opening of our Dubai office to support our activities in the region. In addition, on November 10, 2020, we announced the submission of a temporary license application in Bahrain for Endari®. These developments are in pursuit of our efforts to reach the estimated 100,000 potentially treatable sickle cell disease patients in the MENA region.

Endari® Label Change – On October 27, 2020, we announced that the FDA had approved an updated label for Endari® to better inform healthcare professionals and their sickle cell disease patients. The updated label states that the clinical benefits of Endari® were observed irrespective of hydroxyurea use, thereby supporting the use of Endari® as a monotherapy or in combination with hydroxyurea as important treatment options for sickle cell disease patients.

Endari® Support Program – On December 8, 2020, we announced the launch of the Endari® Support Program to provide eligible patients access to Endari® at minimal or no cost. This program is in addition to our commercial co-pay assistance program. For more information, please see www.EndariRx.com/ESP.

Michigan Relaxes Prior Authorization Criteria for Endari®- In December 2020, the Michigan Department of Health and Human Services ("MDHHS") notified us that, effective January 1, 2021, the following changes will be made regarding the initial authorization of Endari® thereby allowing it to be prescribed to more of Michigan's sickle cell disease patients, more quickly, than under the prior authorization criteria: (i) the former requirement of a history of hydroxyurea use and adherence or intolerance/contraindication to hydroxyurea will be eliminated from the Endari® initial authorization documentation requirements and (ii) "patient/family refusal" will be added to the existing justifications of intolerance or contraindication to the use of hydroxyurea. With this recent revision, MDHHS joins many other state health and human services agencies in eliminating the prior use of hydroxyurea as a requirement for the initial authorization of Endari® for the treatment of sickle cell disease.

Sickle Cell Disease—Market Overview

Sickle cell disease ("SCD") is a genetic blood disorder that affects 20 million - 25 million people worldwide and occurs with increasing frequency among those whose ancestors are from regions including sub-Saharan Africa, South America, the Caribbean, Central America, the Middle East, India and Mediterranean regions such as Turkey, Greece and Italy. The U.S. Centers for Disease Control and Prevention estimates that there are as many as 100,000 people with SCD in the United States, and we estimate there are approximately 80,000 SCD sufferers in the EU. We estimate that there are over 100,000 SCD patients that could potentially be treated in the Persian Gulf States, as well as patients in other countries that comprise the Middle East and North Africa ("MENA") region.

SCD is characterized by the production of an altered form of hemoglobin which polymerizes and becomes fibrous, causing the red blood cells of patients with SCD to become sickle-shaped, inflexible and adhesive rather than round, smooth and flexible. The complications associated with SCD occur when these inflexible and sticky cells block, or occlude, small blood vessels, which can then cause severe and chronic pain throughout the body due to insufficient oxygen being delivered to tissue, or ischemia, and inflammation. According to an article in Annals of Internal Medicine, "*In the Clinic: Sickle Cell Disease*" by M.H. Steinberg (September 2011), which we refer to as the Steinberg Article, this leads to long-term organ damage, diminished exercise tolerance, increased risk of stroke and infection and decreased lifespan.

Sickle cell crisis, a broad term covering a range of disorders, is one of the most devastating complications of SCD. Types of sickle cell crisis include:

- *Vaso-occlusive crisis*, characterized by obstructed blood flow to organs such as the bones, liver, kidneys, eyes or central nervous system;
- *Aplastic crisis*, characterized by acute anemia typically due to viral infection;
- *Hemolytic crisis*, characterized by accelerated red blood cell death and reduced hemoglobin;
- *Splenic sequestration crisis*, characterized by painful enlargement of the spleen due to trapped red blood cells; and
- *Acute chest syndrome*, a potentially life-threatening obstruction of blood supply to the lungs characterized by fever, chest pain, cough, and lung infiltrates.

According to the Steinberg Article, acute chest syndrome affects more than half of all patients with SCD and is a common reason for hospitalization. Other symptoms and complications of SCD include swelling of the hands and feet, infections, pneumonia, vision loss, leg ulcers, gall stones and stroke.

A crisis is characterized by excruciating musculoskeletal pain, visceral pain and pain in other locations. These crises occur periodically throughout the life of a person with SCD. In adults, the acute pain typically persists for five or ten days or longer, followed by a dull, aching pain generally ending only after several weeks and sometimes persisting between crises. According to the Steinberg Article, the frequency of sickle cell crises varies within patients with SCD from rare occurrences

to occurrences several times a month. The frequency of crises tends to increase late in the second decade of life and to decrease after the fourth decade.

Treatment of sickle cell crises is burdensome and expensive for patients and payors, as it encompasses costs for hospitalization, urgent care and emergency room visits and prescription pain medication. Endari® enhances nicotinamide adenine dinucleotide ("NAD") synthesis to reduce excessive oxidative stress in sickle red blood cells, which is the cause of much of the damage leading to characteristic symptoms of SCD. We believe that Endari®, when taken daily, will decrease the incidence of sickle cell crisis by restoring the flexibility and function of red blood cells in patients with SCD. We believe that regular use of Endari® also will reduce the number of costly hospitalizations of patients with SCD, as well as unexpected urgent care and emergency room visits.

Limitations of the Current Standard of Care

Prior to the approval of Endari®, the only other FDA approved pharmaceutical targeting sickle cell crisis was hydroxyurea, which is available in both generic and branded formulations. Hydroxyurea, a drug originally developed as an anticancer chemotherapeutic agent, has been approved as a once-daily oral treatment for reducing the frequency of sickle cell crisis and the need for blood transfusions in adult patients with recurrent moderate to severe sickle cell crisis. In December 2017, the FDA granted Addmedica a regular approval for hydroxyurea (Siklos) to reduce the frequency of painful crises and the need for blood transfusions in pediatric patients two years of age and older with sickle cell anemia with recurrent moderate to severe painful crises. While hydroxyurea has been shown to reduce the frequency of sickle cell crisis in some patient groups, it is not suitable for many patients due to significant toxicities and side effects. In particular, hydroxyurea can cause a severe decrease in the number of blood cells in a patient's bone marrow, which may increase the risk that the patient will develop a serious infection or bleeding, or that the patient will develop certain cancers. Another potential treatment option for SCD, bone marrow transplant, is limited in its use due to the lack of availability of matched donors and the risk of serious complications, including graft versus host disease, infection and potentially death, as well as by its high cost.

Two new treatments for sickle cell disease were approved by the FDA at the end of 2019. Crizanlizumab, marketed under the brand name of Adakveo®by Novartis AG, is a humanized monoclonal antibody that binds to P-selectin. It was approved by the FDA on November 15, 2019 to reduce the frequency of vaso-occlusive crises in adults and pediatric patients aged 16 years and older with SCD. It is administered intravenously in two loading doses two weeks apart and every four weeks thereafter. Voxelotor, marketed under the brand name of Oxbryta™ by Global Blood Therapeutics, Inc., is an HbS polymerization inhibitor that reversibly binds to hemoglobin to stabilize the oxygenated hemoglobin state, thus shifting the oxyhemoglobin dissociation curve. Voxelotor was approved by the FDA on November 25, 2019 for the treatment of SCD in adults and pediatric patients 12 years of age and older.

Upon onset of sickle cell crisis, the current standard of care is focused on pain management, often with prescription narcotics omon-prescription oral medications taken at home. If the pain is not relieved, or if it progresses, patients may seek medical attention in a clinic or emergency department. Pain that is not controlled in these settings may require hospitalization for more potent pain medications, typically opioids administered intravenously. The patient must stay in the hospital to receive these intravenous pain medications until the sickle cell crisis resolves and the pain subsides. Other supportive measures during hospitalization may include hydration, supplemental oxygen and treatment of any concurrent infections or other conditions.

According to *Hematology in Clinical Practice*, by Robert S. Hillman et. al. (5th ed. 2011), sickle cell crisis, once it has started, almost always results in tissue damage at the affected site in the body, increasing the importance of preventative measures. While pain medications can be effective in managing pain during sickle cell crisis, they do not affect or resolve the underlying vascular occlusion, tissue ischemia or potential tissue damage. Additionally, opioid narcotics that are generally prescribed to treat pain can also lead to tissue or organ damage and resulting complications and morbidities, prolonged hospital stays and associated continuation of pain and suffering. Given the duration and frequency of sickle cell crises, addiction to these opioid narcotics is also a significant concern.

Endari®, Our Solution for SCD

We believe Endari® may provide a safe and effective means for reducing the frequency of sickle cell crises in patients with SCD and the need for costly hospital stays or treatment with highly addictive pain medications such as opioid narcotics. Published academic research has identified L-glutamine as a precursor to NAD, one of the major molecules that regulate and prevent oxidative damage in red blood cells. Several published studies have demonstrated that sickle red blood cells have a significantly increased rate of transport of L-glutamine, which appears to be driven by the cells' synthesis of NAD to protect against oxidative damage and thereby leading to further improvement in their regulation of oxidative stress.

In turn this makes sickle red blood cells less adhesive to cells of the interior wall of blood vessels, which suggests that there is decreased chance of blockage of blood vessels, especially small ones. In summary, improved regulation of oxidative stress appears to lead to less obstruction or blockage of small blood vessels, thereby alleviating a major cause of the pain and other problems associated with SCD.

In December 2013, we completed a Phase 3 prospective, randomized, double blind, placebo controlled, parallel group multicenter clinical trial to measure, over a 48-week time frame, as its primary outcome, the reduction in the number of occurrences of sickle cell crises experienced by patients in the trial. All participants other than those who received placebo, including children, received up to 30 grams of Endari® daily, dissolved in liquid, split between morning and evening; the same dosage as our Phase 2 clinical trial completed in 2009. Patients were randomized to the study treatment using a 2:1 ratio of Endari® to placebo. The randomization was stratified by investigational site and hydroxyurea usage.

The clinical trial evaluated the efficacy and safety of Endari® in 230 patients (5 to 58 years of age) with sickle cell anemia or sickle β°-thalassemia who had 2 or more painful crises within 12 months prior to enrollment. Eligible patients stabilized on hydroxyurea for at least 3 months continued their therapy throughout the study. The trial excluded patients who had received blood products within 3 weeks, had renal insufficiency or uncontrolled liver disease, or were pregnant (or planning pregnancy) or lactating. Study patients received Endari® or placebo for a treatment duration of 48 weeks followed by 3 weeks of tapering.

Efficacy was demonstrated by a reduction in the number of sickle cell crises through Week 48 and prior to the start of tapering among patients that received Endari® compared to patients who received placebo. A sickle cell crisis was defined as a visit to an emergency room/medical facility for sickle cell disease-related pain which was treated with a parenterally administered narcotic or parenterally administered ketorolac. In addition, the occurrence of acute chest syndrome, priapism, and splenic sequestration were considered sickle cell crises. Treatment with Endari® also resulted in fewer hospitalizations due to sickle cell pain at Week 48, fewer cumulative days in hospital, longer time until first sickle cell crisis and a lower incidence of acute chest syndrome.

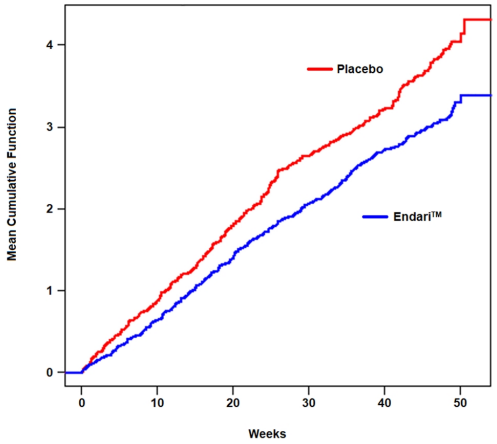
Table 1. Results from the Endari® Clinical Trial in Sickle Cell Disease

Event	**Endari (n = 152)**	**Placebo (n = 78)**
Median number of sickle cell crises (min, max)[1]	3 (0, 15)	4 (0, 15)
Median number of hospitalizations for sickle cell pain (min, max)[1]	2 (0, 14)	3 (0, 13)
Median cumulative days hospitalized (min, max)[1,]	6.5 (0, 94)	11 (0, 187)
Median time (days) to first sickle cell crisis (95% CI)[1,2]	84 (62, 109)	54 (31, 73)
Patients with occurrences of acute chest syndrome (%)[1]	13 (8.6%)	18 (23.1%)

1. Measured through 48 weeks of treatment.
2. Hazard Ratio=0.69 (95% CI=0.52, 0.93), estimated based on unstratified Cox's proportional model. Median time and 95% CI were estimated based on the Kaplan Meier method.

The recurrent crisis event time analysis (Figure 1) yielded an intensity rate ratio (IRR) value of 0.75 with 95% CI= (0.62, 0.90) and (0.55, 1.01) based on unstratified models using the Andersen-Gill and Lin, Wei, Yang and Ying methods, respectively in favor of Endari®, suggesting that over the entire 48- week period, the average cumulative crisis count was reduced by 25% from the Endari® group over the placebo group.

Figure 1. Recurrent Event Time for Sickle Cell Crises by Treatment Group



Endari® was studied in 2 placebo-controlled clinical trials (a phase 3 study, n=230 and a phase 2 study, n=70). In these trials, patients with sickle cell anemia or sickle β0-thalassemia were randomized to receive Endari® (n=187) or placebo (n=111) orally twice daily for 48 weeks followed by 3 weeks of tapering. Both studies included pediatric and adult patients (5-58 years of age) and 54% were female.

Treatment discontinuation due to adverse reactions was reported in 2.7% (n=5) of patients receiving Endari®. These adverse reactions included one case each of hypersplenism, abdominal pain, dyspepsia, burning sensation, and hot flash.

Serious adverse reactions were reported in both treatment groups, more frequently in the placebo group, and were consistent with the underlying disease.

Three deaths (3/187=1.6%) occurred during the study in the Endari® treatment group as compared to none in the placebo treatment group. None of the deaths were considered to be related to Endari® treatment. Adverse reactions occurring in greater than 10% of patients treated with Endari® are shown in Table 2 below.

Table 2. Adverse Reactions Occurring at an Incidence > 10% in Clinical

Adverse reaction	**Endari N = 187 (%)**	**Placebo N = 111 (%)**
Constipation	21	18
Nausea	19	14
Headache	18	15
Abdominal Pain[1]	17	16
Cough	16	14
Pain in extremity	13	7
Back pain	12	5
Chest pain	12	8

[1]Abdominal pain = abdominal pain and abdominal pain, upper

Commercialization and Distribution

United States

Our in-house commercial team encompasses marketing, market access, patient support, and distribution support

personnel. The sales team consists of sales representatives, sales management, and a National Sales Director. In February 2019 we established a Commercial Patient Assistance Program (C- PAP) to provide financial assistance to eligible patients who are unable to afford their monthly co-payments for Endari®. On December 8, 2020, we announced the launch of the Endari® Support Program to provide eligible patients access to Endari® at minimal or no cost.

Our sales and marketing efforts focus on the following groups: pediatric and adult hematologists who treat SCD patients with sickle cell disease, Community Based Organizations, or CBOs, government payors, insurance companies, and pharmacy benefit managers. SCD patients are primarily treated at specialized clinics located in children's hospitals, university hospitals and community-based out-patient locations. The current focus of our sales team is as follows:

- educating prescribers and CBOs on the approved use and benefits of Endari®; and

- establishing collaborative relationships with CBOs and patient support groups that focus on SCD education and patient advocacy in their respective communities.

We have contracted with AmerisourceBergen Specialty Group (ASD Healthcare LLC and US Bioservices Corporation), AmerisourceBergen Corporation companies, McKesson Plasma and Biologics LLC, a McKesson Corporation company, and Cardinal Health 108, LLC, a Cardinal Health Inc. company, to distribute Endari® to selected pharmacies and hospitals. AmerisourceBergen Corporation, McKesson Corporation and Cardinal Health, Inc. are the three largest specialty distributors of prescription drugs in the U.S.

Our two largest distributors, ASD Healthcare LLC and McKesson Plasma and Biologics LLC, each account for more than 20% of units sold for the year ended December 31, 2020. On a combined basis, the three distributors accounted for approximately 80% of our units sold in 2020.

Outside the United States

In July 2012, the European Commission, or EC, granted Orphan Drug Designation status in the European Union, or EU, for our prescription grade L-glutamine oral powder, to be known as Xyndari™ in the EU, for the treatment of SCD. In January 2018, the European Medicines Agency, or EMA, provided their agreement on the pediatric investigation plan, or PIP, for Xyndari™ and we filed with the EMA an application for marketing authorization, or MAA, in the EU. In May 2019, we announced that the EMA's Committee for Medicinal Products for Human Use, or CHMP, adopted a negative opinion regarding our MAA based upon the CHMP's position that our main clinical study did not conclusively support the efficacy of the treatment in SCD patients, although no safety concerns were raised. In light of the CHMP's opinion, we withdrew our MAA in September 2019 to consider pursuing alternative decentralized and centralized regulatory pathways for obtaining marketing authorization in an effort to ensure access to Xyndari™ for patients afflicted by SCD.

We are in the process of converting and updating our existing MAA or our FDA New Drug Application, or NDA, for both the UK national submission and for either a centralized procedure in the EU or separate national submissions in the EU. With Brexit in place, we will assess our overall data package and determine strategies for engagement with the U.K.'s Medicines and Healthcare Products Regulatory Agency, or MHRA, to determine the need for a pre-submission meeting for Xyndari™ in the U.K. We expect to provide an update in the second half of 2021 on the outcome of these efforts. On June 17, 2020 Endari® was approved for marketing in Israel by the Israeli Ministry of Health for the same indication approved under the FDA. On November 10, 2020, we announced the submission of a temporary license application for Endari® to the National Health Regulatory Authority in the Kingdom of Bahrain as a prerequisite for marketing authorization there. The temporary license will allow Endari® to be prescribed in the Kingdom pending marketing authorization. We are also currently engaged in marketing regulatory submissions in the Kingdom of Saudi Arabia and other Gulf Coast Cooperation Council countries.

We have entered into exclusive distribution agreements with strategic partners to register, commercialize and distribute Endari® in the Gulf Cooperation Council countries and other countries throughout the MENA region in collaboration with our branch office in Dubai.

We also are party to an exclusive early access agreement with a strategic partner in the EU pursuant to which our partner distributes Endari® on an early access basis only in France and certain other EU member states. We also are in talks with potential strategic partners in other countries to establish similar early access programs while we consider seeking marketing authorization in one of more of such countries.

We also may seek future collaborations with other pharmaceutical or biotechnology companies and identify potential licensees and other international opportunities to commercialize Endari®, if approved by foreign regulatory authorities.

Diverticulosis

Diverticulosis, or the presence of colonic diverticula (i.e., pouches in the colon wall), is very common in industrialized nations, with its prevalence increasing with age. An estimated 40% of 60 year-olds and 70% of 80 year-olds have diverticulosis. Of these individuals, 10% to 25% are expected to develop diverticulitis, or the advancement of peridiverticular inflammation and infection, resulting in abdominal pain, nausea, vomiting, constipation, diarrhea, fever, and leukocytosis.

The pathogenesis of diverticulosis is believed to result from structural abnormalities of the colonic wall, disordered motility and low fiber diets. The relationships between glutamine and intestinal physiology have been extensively studied in ulcerative colitis and Crohn's disease, short bowel syndrome and as a nutritional therapy for critical illnesses. Overall, glutamine elicits the following mechanisms of action within intestinal cells: promotion of enterocyte proliferation, regulation of tight junction proteins; suppression of pro-inflammatory signaling pathways; suppression of intestinal cell apoptosis and cellular stress; and microbiome regulation. Glutamine also helps to maintain intestinal tissue integrity through various signaling pathways.

See the discussion above of our Pilot/Phase 1 study of the safety and efficacy of prescription grade L-glutamine oral powder in diverticulosis.

We are party to a distributor agreement with Telcon pursuant to which we granted Telcon exclusive rights to our PGLG oral powder for the treatment of diverticulosis in South Korea, Japan and China. The agreement contemplates that Telcon will be responsible at its expense for obtaining marketing authorization assuming FDA approval is obtained and for all other commercial activities in the territories. In exchange for the exclusive rights, Telcon paid us a $10 million upfront fee, which is refundable in the event of termination of the distributor agreement for failure to obtain FDA approval, and agreed in the distributor agreement to purchase from us specified minimum quantities of the finished product.

CellSeed Collaboration

In June 2016, we entered into a non-exclusive agreement with the Japanese company, CellSeed, Inc. ("CellSeed"), and Dr. Kohji Nishida of the Graduate School of Medicine, Osaka University, Japan, for the development of Cultured Autologous Oral Mucosal Epithelial Cell Sheet ("CAOMECS") for the treatment of corneal impairments in the United States. Under the agreement, we will be required to pay a single-digit royalty based upon net sales of the technology.

A cell sheet is a composite of cells grown and harvested in an intact sheet, rather than as individual cells. These cell sheets can be used for tissue transplantation or to engineer complex multilayer cell sheets composed of different types of cells. CellSeed's technology involves culturing cells on a surface coated with the poly (N-isopropylacrylamide) temperature responsive polymer. The thinness of this polymer coating is measured at the nanometer scale. The cells cultured on this polymer can be harvested intact as a composite stratified cell sheet to transplant it precisely on the cornea. Using a patient's own oral mucosal epithelial cells, we are working toward being able to grow and harvest a cell sheet for directly transplanting onto the cornea of the patient's affected eye to repair the damaged cornea.

The development of CAOMECS for treating corneal and other diseases is in the early stages.

Research and Development

We incurred $2.4 million and $2.2 million of research and development expenses in 2020 and 2019, respectively, primarily relating to our Pilot/Phase 1 diverticulosis study.

Raw Materials and Manufacturing

Our Endari® SCD treatment uses prescription grade L-glutamine ("PGLG"), which differs from non-prescription grade L-glutamine widely available as a nutritional supplement. PGLG is differentiated from ordinary L-glutamine by several factors, including the presence of a Drug Master File, constant oversight on purity and manufacturing process at FDA inspected facilities, pyrogen free product and stringent stability tested packaging. There are limited suppliers of PGLG, and we currently obtain all our PGLG, directly or indirectly, from a single supplier, Ajinomoto Health and Nutrition North America, Inc. ("Ajinomoto"), a subsidiary of Ajinomoto North American Holdings, Inc.

Ajinomoto provided PGLG to us free of charge for our clinical trials of Endari®, including our Phase 3 trial. In return, we have agreed to purchase from Ajinomoto substantially all our commercial needs for PGLG, subject to certain exceptions. We have no long-term supply agreement with Ajinomoto.

On June 12, 2017, we entered into an API supply agreement with Telcon RF Pharmaceutical, Inc. (formerly, Telcon, Inc.), a South Korea-based company, or Telcon, pursuant to which Telcon paid us approximately ₩36.0 billion KRW (approximately $31.8 million) in consideration of the right to supply 25% of our requirements for bulk containers of PGLG for a 15-year term. The amount was recorded as a deferred trade discount. On July 12, 2017, we entered into a raw material supply agreement with Telcon which revised certain terms of the API supply agreement, which we refer to as the "revised API agreement." The revised API agreement is effective for a term of five years and will renew automatically for 10 successive one-year renewal periods, except as either party may determine. In the revised API agreement, we have agreed to purchase a total of 940,000 kilograms of PGLG at a fixed price of $50 per kilogram, or a total of $47.0 million, over the term of the agreement. In September 2018, we entered into an agreement with Ajinomoto and Telcon to facilitate Telcon's purchase of PGLG from Ajinomoto for resale to us under the revised API agreement.

On June 27, 2019, we entered into an agreement with Telcon to adjust the price payable to Telcon under the revised API agreement from $50 per kilogram of PGLG to $100 kilogram from July 1, 2019 through June 30, 2020 with the price payable after June 30, 2020 to be subject to agreement between the parties. No new agreement has been reached and the price continues at $100 per kilogram. The PGLG raw material purchased from Telcon is recorded in inventory at net realizable value and the excess purchase price is recorded against deferred trade discount.

See Note 5 of the Notes to Consolidated Financial Statements in this Annual Report for a discussion of our pledge of marketable securities and other collateral to secure our obligations under the revised API Agreement.

In December 2019, EJ Holdings, Inc., or EJ Holdings a Japanese corporation which is 40% owned by us, purchased from Kyowa Hakko Bio Co. Ltd., or Kyowa, a subsidiary of Kyowa Hakko Kirin Co., Ltd., Kyowa's phased-out facility in Ube, Japan, for the manufacture of L-glutamine and other amino acids. EJ Holdings is engaged in phasing in the plant, including obtaining FDA and other regulatory approvals for the manufacture of PGLG in accordance with current Good Manufacturing Practices ("cGMP"). Once the plant is active, we expect to enter into a long-term agreement with EJ Holdings for the supply of PGLG. EJ Holdings has had no revenues since its inception, has depended on loans from us to acquire the Ube plant and fund its operations and will continue to be dependent on loans from us or other financing unless and until its plant is activated and it can secure customers, including us, for its products. As of December 31, 2020, we had loaned EJ Holdings a total of $18.6 million, including $4.0 million of loans made pursuant to our written commitment dated October 28, 2020 to loan EJ Holdings a total of up to $6.5 million through the period ending March 31, 2021. In addition to loans from us, EJ Holdings may require substantial financing in order bring the Ube plant online. EJ Holdings has no commitments or understandings regarding any additional financing. Under the asset purchase agreement pursuant to which EJ Holdings purchased the Ube plant, Kyowa has the right to repurchase the plant at the purchase price of $10.4 million plus certain taxes paid by EJ Holdings if the plant does not become operational within a reasonable period (not to exceed five years).

In May 2020 we entered into a memorandum of understanding and agreement, or MOU, with Japan Industrial Partners, Inc., or JIP, which owns 60% of the capital stock of EJ Holdings, to memorialize the parties' intentions with respect to the business and operations of the Ube plant and ownership of EJ Holdings. The MOU contemplates, among other things, that we will continue to be the principal source of funding for EJ Holdings' ownership and operation of the plant and that, subject to certain conditions, to the extent we provide additional funding our ownership interest in EJ Holdings is expected to increase accordingly and that the composition of EJ Holdings' board of directors and control of EJ Holdings would be modified consistent with the parties' relative ownership interests. The MOU also contemplates that the Ube plant will eventually supply us with the plant's output of amino acids and that the operation of the plant will be principally for our benefit and, accordingly, that major decisions affecting EJ Holdings and the Ube plant will be made by EJ Holdings' board of directors in consultation with us. At present, JIP owns 60% of EJ Holdings and is entitled to designate a majority of EJ Holdings' board of directors, its Chief Executive Officer, and outside auditors, and as such, controls the management, business and operations of EJ Holdings.

Endari® and any other commercial products we develop must be manufactured and packaged by facilities that meet FDA requirements for cGMP. We believe that Ajinomoto and Packaging Coordinators, Inc., or PCI, of Rockville, Illinois, which packages Endari®, meet FDA cGMP for manufacture and packaging of Endari®. Previous compliance with cGMP; however, does not guarantee future compliance. We have no long-term agreement with Ajinomoto or PCI. We may seek to enter into long-term supply agreements in the future and to establish one or more arrangements with alternative suppliers.

Competition

The biopharmaceutical industry is highly competitive and subject to rapid and significant technological change. We face potential competition from both large and small pharmaceutical and biotechnology companies, academic institutions, governmental agencies (such as the National Institutes of Health) and public and private research institutions. Many of our competitors and potential competitors have far greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. The key competitive factors affecting the success of each of our product candidates, if approved, are likely to be their safety, efficacy, convenience, price, the level of proprietary and generic competition, and the availability of coverage and reimbursement from government and other third-party payors. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer or more effective, have fewer or less severe side effects, or are more convenient or less expensive than any products that we may develop. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in their establishing a strong market position before we are able to enter the market.

Sickle Cell Disease

Endari® is approved as a therapy to reduce the acute complications of SCD in adult and pediatric patients 5 years of age and older. The other drugs which are indicated to treat sickle cell disease are hydroxyurea (marketed as DROXIA or Hydrea by Bristol-Myers Squibb Company and available in generic form), which is approved to reduce the frequency of painful crises and need for blood transfusions in patients with sickle cell anemia for the treatment of adults with SCD; Voxelotor (marketed as Oxbryta™ by Global Blood Therapeutics, Inc.) tablets for the treatment of SCD in adults and children 12 years of age and older;and crizanlizumab (marketed as Adakveo® by Novartis International AG) intravenous infusion approved to reduce the frequency of VOCs in adult and pediatric patients ages 16 years and older with SCD. Several companies are also developing product candidates for chronic treatment in SCD. GBT and several other companies are in clinical trials to investigate new treatments for SCD.

Endari® also faces potential competition from one-time therapies for treating patients with severe SCD, including LentiGlobin BB305, which is being developed by bluebird bio, Inc. to treat SCD by inserting a functional human beta-globin gene into a patient's hematopoietic stem cells, or HSCs, *ex vivo* and then transplanting the modified HSCs into the patient's bloodstream. Bluebird has indicated its plans to pursue an accelerated development and approval pathway for its gene therapy product in SCD. Others are seeking to develop one-time therapies such as hematopoietic stem cell transplantation, gene therapy and gene editing, including gene editing using CRISPR. Attempts to develop a cure for SCD through gene therapy are in the early stages, but if these attempts were to succeed and receive regulatory approval, it could adversely affect the market for Endari®.

We are also aware of efforts to develop cures for SCD through approaches such as bone marrow treatments. Although bone marrow transplant is currently available for SCD patients, its use is limited by the lack of availability of matched donors and by the risk of serious complications, including graft versus host disease and infection.

Endari® also may compete with non-prescription grade L-glutamine, which is widely available as a dietary supplement at substantially lower prices than Endari®. Dietary supplements may be marketed without FDA approval, are generally not reimbursed by payors and are not subject to the rigorous quality control standards required by regulatory authorities for prescription drug products. Also, unlike prescription drugs, manufacturers of dietary supplements may not make claims that the supplements will cure, mitigate, treat or prevent disease, and we are not aware of any reports in peer-reviewed literature regarding the effectiveness of non-prescription grade L-glutamine supplements in treating SCD in controlled clinical trials.

Oral Mucosa Epithelial Cell Sheet

Currently, the treatment of limbal stem cell deficiency ("LSCD") patients varies based on the severity of the LSCD. Treatment may include the use of non-invasive procedures such as autologous serum drops, therapeutic scleral lens and corneal scraping to more invasive surgical procedures such as limbal stem cells or oral mucosal stem cells graft. The source of the transplanted tissue can be from cells from the patient's healthy eye, matched living donors or cadavers. Transplantation with cells other than from the patient's own tissue can cause serious complications, including graft-versus-host disease. Using oral mucosal epithelial cells ("OMEC") of the LSCD patients lessens these risks. Specifically, the use of OMEC eliminates the risk of graft rejection, permits treatment of bilateral LSCD patients and allows engineered corneal epithelial cell sheets to be transplanted on LSCD patients' corneas.

The development of OMEC technology to treat LSCD is in the early stages. We are not aware of any FDA approved treatments using OMEC for LSCD.

Research institutions outside the United States (*e.g.,* The Centre Hospitalier National d'Ophtalmologie des Quinze Vingts lin Paris, France; Royan Institute Teheran in the Islamic Republic of Iran and Hospital San Raffaele in Milan, Italy) are researching the transplantation of corneal cells from patients' healthy eyes to reverse LSCD. However, results from these clinical trials were not published yet. This approach only allows unilateral LSCD patients to be treated and risks damage to the patients' one healthy corneas.

The use of OMEC is a promising alternative for treat LSCD. For example, the Chang Gung Memorial Hospital in South Korea, the He Eye Hospital in China and the Adisak Wongkajornsilp, Siriraj Hospital in Thailand are conducting phase 2 clinical trials using the OMEC. While many research institutions as are conducting such trials, we are not aware of published results of these studies.

Our OMEC-based regenerative medicine technology eliminates risks associated with donor-dependent transplantation and has shown some promising results in pilot studies (animal serum dependent) done by other groups in Japan and Europe. Our novel and innovative cell sheet therapy utilizes xeno-free media that allows harvested cell sheets to retain intact basal membranes and extracellular matrix (fibronectin, laminin, collagen type IV), reducing the inherent risks of suturing during transplantation. Our cell sheet therapy also makes possible to layer different types of cell sheets by harvesting the cell sheet without the use of harmful enzymes (trypsin or dispase) that may damage the cell-based therapy and potentially to construct *in vitro* stratified tissue equivalents by alternately layering different types of harvested cell sheets to provide regenerated tissue architectures, resembling human tissues. This technique holds promise for the study of cell-cell communications and angiogenesis in reconstructed, three-dimensional environments, as well as for tissues engineering with complex, multicellular architectures and drug-screening.

Government Regulation

The FDA has granted Endari Orphan Drug designation and the EC has granted our PGLG Orphan Medicinal designation for the treatment of SCD.

Orphan Drug Designation. The FDA has authority under the U.S. Orphan Drug Act to grant Orphan Drug designation to a drug or biological product intended to treat a rare disease or condition. This law defines a rare disease or condition generally as one that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of the development and distribution of the orphan product

in the United States will be recovered from sales of the product. Being granted Orphan Drug designation provides tax benefits to mitigate expenses of developing the orphan product. More importantly, Orphan Drug designation provides seven years of market exclusivity if the product receives the first FDA approval for the disease or condition for which it was granted such designation and the indication for which approval is granted matches the indication for which Orphan Drug designation was granted. During the seven-year exclusivity period, Orphan Drug exclusivity precludes FDA approval of a marketing application for the same active ingredient for the same indication. Orphan Drug exclusivity is limited and will not preclude the FDA from approving the same active ingredient for the same indication if the same product is shown to be clinically superior to the product previously granted exclusivity. In addition, a product that is the same as the orphan product may receive approval for a different indication (whether orphan or not) during the exclusivity period of the orphan product. Also, Orphan Drug market exclusivity will not bar a different product such as Global Blood Therapeutics, Inc.'s Oxbryta to treat the same orphan disease or condition from obtaining its own Orphan Drug designation and Orphan Drug exclusivity.

Orphan Medicinal status in the EU has similar benefits, including a ten-year marketing exclusivity period following marketing authorization in the EU.

505(b)(2) Applications. Under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act"), a person may submit an NDA for which one or more of the clinical studies relied upon by the applicant for approval were not conducted by or for the applicant and for which the applicant does not have a right of reference or use from the person by or for whom the clinical studies were conducted. Instead, a 505(b)(2) applicant may rely on published literature containing the specific information (e.g., clinical trials, animal studies) necessary to obtain approval of the application. The applicant may also rely on the FDA's finding of safety and/or effectiveness of a drug previously approved by the FDA when the applicant does not own or otherwise have the right to access the data in that previously approved application. The 505(b)(2) pathway to marketing authorization thus allows an applicant to submit a NDA without having to conduct its own studies to obtain data that are already documented in published reports or previously submitted NDAs. In addition to relying on safety data from the Phase 2 and 3 studies of Endari® and our previously approved product, NutreStore, we intend to take advantage of the 505(b)(2) pathway to the extent published literature will further support any NDA for PGLG.

Regulation by United States and foreign governmental authorities is a significant factor in the development, manufacture and expected marketing of our product candidates and in our ongoing research and development activities. The nature and extent to which such regulation will apply to us will vary depending on the nature of the product candidates we seek to develop.

Human therapeutic products, such as drugs, biologics and cell-based therapies, are subject to rigorous preclinical and clinical testing and other preapproval requirements of the FDA and similar regulatory authorities in other countries. Various federal and state statutes and regulations govern and influence pre- and post-approval requirements related to research, testing, manufacturing, labeling, packaging, storage, distribution and record keeping of such products to ensure the safety and effectiveness for their intended uses. The process of obtaining marketing approval and ensuring post approval compliance with the FD&C Act for drugs and biologics (and applicable provisions of the Public Health Service Act for biologics), and the regulations promulgated thereunder, and other applicable federal and state statutes and regulations, requires substantial time and financial resources. Any failure by us or our collaborators to obtain, or any delay in obtaining, marketing approval could adversely affect the marketing of any of our product candidates, our ability to receive product revenues, and our liquidity and capital resources.

The manufacture of these products is subject to cGMP regulations. The FDA inspects manufacturing facilities for compliance with cGMP regulations before deciding whether to approve a product candidate for marketing.

The steps required by the FDA before a new product, such as a drug, biologic or cell-based therapy, may be marketed in the United States include:

- completion of preclinical studies (during this stage, the treatment is called a development candidate);
- the submission to the FDA of a proposal for the design of a clinical trial program for studying in humans the safety and effectiveness of the product candidate. This submission is referred to as an IND. The FDA reviews the IND to ensure it adequately protects the safety and rights of trial participants and that the design of the studies is adequate to permit an evaluation of the product candidate's safety and effectiveness. The IND becomes effective within thirty days after the FDA receives the IND, unless the FDA notifies the sponsor that the investigations described in the IND are deficient and cannot begin;
- the conduct of adequate and well controlled clinical trials, usually completed in three phases, to demonstrate the safety and effectiveness of the product candidate for its intended use;

- the submission to the FDA of a marketing application, a NDA, if the product candidate is a drug, that provides data and other information to demonstrate the product is safe and effective for its intended use ("BLA"), if the product candidate is a biologic that provides data and other information to demonstrate that the product candidate is safe, pure, and potent; and

- the review and approval of the NDA by the FDA before the product candidate may be distributed commercially as a product.

In addition to obtaining FDA approval for each product candidate before we can market it as a product, the manufacturing establishment from which we obtain it must be registered and is subject to periodic FDA post approval inspections to ensure continued compliance with cGMP requirements. If, as a result of these inspections, the FDA determines that any equipment, facilities, laboratories, procedures or processes do not comply with applicable FDA regulations and the conditions of the product approval, the FDA may seek civil, criminal, or administrative sanctions and/or remedies against us, including the suspension of the manufacturing operations, recalls, the withdrawal of approval and debarment. Manufacturers must expend substantial time, money and effort in the area of production, quality assurance and quality control to ensure compliance with these standards.

Preclinical testing includes laboratory evaluation of the safety of a product candidate and characterization of its formulation. Preclinical testing is subject to Good Laboratory Practice ("GLP") regulations. Preclinical testing results are submitted to the FDA as a part of an IND which must become effective prior to commencement of clinical trials. Clinical trials are typically conducted in three sequential phases following submission of an IND. In Phase 1, the product candidate under investigation (and therefore often called an investigational product) is initially administered to a small group of humans, either patients or healthy volunteers, primarily to test for safety (e.g., to identify any adverse effects), dosage tolerance, absorption, distribution, metabolism, excretion and clinical pharmacology, and, if possible, to gain early evidence of effectiveness. In Phase 2, a slightly larger sample of patients who have the condition or disease for which the investigational product is being studied receive the investigational product to assess the effectiveness of the investigational product, to determine dose tolerance and the optimal dose range, and to gather additional information relating to safety and potential adverse effects. If the data show the investigational product may be effective and has an acceptable safety profile in the targeted patient population, Phase 3 studies, also referred to as pivotal studies or enabling studies, are initiated to further establish clinical safety and provide substantial evidence of the effectiveness of the investigational product in a broader sample of the general patient population, to determine the overall risk benefit ratio of the investigational product, and provide an adequate basis for physician and patient labeling. During all clinical studies, Good Clinical Practice ("GCP") standards and applicable human subject protection requirements must be followed. The results of the research and product development, manufacturing, preclinical studies, clinical studies, and related information are submitted in a NDA to the FDA.

The process of completing clinical testing and obtaining FDA approval for a new therapeutic product, such as a drug, biologic or cell-based product, is likely to take years and require the expenditure of substantial resources. If a NDA is submitted, there can be no assurance that the FDA will file, review, and approve it. Even after initial FDA approval has been obtained, post market studies could be required to provide additional data on safety or effectiveness. Additional pivotal studies would be required to support adding other indications to the labeling. Also, the FDA will require post market reporting and could require specific surveillance or risk mitigation programs to monitor for known and unknown side effects of the product. Results of post marketing programs could limit or expand the continued marketing of the product. Further, if there are any modifications to the product, including changes in indication, manufacturing process, labeling, or the location of the manufacturing facility, a NDA supplement would generally be required to be submitted to the FDA prior to or corresponding with that change, or for minor changes in the periodic safety update report that must be submitted annually to the FDA.

The rate of completion of any clinical trial depends upon, among other factors, sufficient patient enrollment and retention. Patient enrollment is a function of many factors, including the size of the patient population, the nature of the trial, the number of clinical sites, the availability of alternative therapies, the proximity of patients to clinical sites, and the eligibility and exclusion criteria for the trial. Delays in planned patient enrollment might result in increased costs and delays. Patient retention could be affected by patient noncompliance, adverse events, or any change in circumstances making the patient no longer eligible to remain in the trial.

Failure to adhere to regulatory requirements for the protection of human subjects, to ensure the integrity of data, other IND requirements, and GCP standards in conducting clinical trials could cause the FDA to place a "clinical hold" on one or more studies of a product candidate, which would stop the studies and delay or preclude further data collection necessary for product approval. Noncompliance with GCP standards would also have a negative impact on the FDA's evaluation of a NDA.

If at any time the FDA finds that a serious question regarding data integrity has been raised due to the appearance of a wrongful act, such as fraud, bribery or gross negligence, the FDA may invoke its Application Integrity Policy ("AIP") under which it could immediately suspend review of any pending NDA or refuse to accept the submission of a NDA as filed, require the sponsor to validate data, require additional clinical studies, disapprove a pending NDA or withdraw approval of marketed products, as well as require corrective and preventive action to ensure data integrity in future submissions. Significant noncompliance with IND regulations could result in the FDA not only refusing to accept a NDA as filed but could also result in enforcement actions, including civil and administrative actions, civil money penalties, criminal prosecution, criminal fines and debarment. Whether or not FDA approval has been obtained, approval of a product by regulatory authorities in foreign countries must be obtained prior to the commencement of marketing the product in those countries.

The requirements governing the conduct of clinical trials and product approvals vary widely from country to country, and the time required for approval might be longer or shorter than that required for FDA approval. Although there are some procedures for unified filings for some European countries, in general, each country at this time has its own procedures and requirements.

In most cases, if the FDA has not approved a product candidate for sale in the United States, the unapproved product may be exported to any country in the world for clinical trial or sale if it meets U.S. export requirements and has marketing authorization in any listed country without submitting an export request to the FDA or receiving FDA approval to export the product, as long as the product meets the regulatory requirements of the country to which the product is being exported. Listed countries include each member nation in the European Union or the European Economic Area, Canada, Australia, New Zealand, Japan, Israel, Switzerland and South Africa. If an unapproved product is not approved in one of the listed countries, the unapproved product may be exported directly to an unlisted country if the product meets the requirements of the regulatory authority of that country, and the FDA determines that the foreign country has statutory or regulatory requirements similar or equivalent to the United States.

In addition to the regulatory framework for product approvals, we and our collaborative partners must comply with federal, state and local laws and regulations regarding occupational safety, laboratory practices, the use, handling and disposition of radioactive materials, environmental protection and hazardous substance control, and other local, state, federal and foreign regulation. All facilities and manufacturing processes used by third parties to produce our product candidates for clinical use in the United States and our products for commercialization must be in compliance with cGMP requirements and are subject to periodic regulatory inspections. The failure of third-party manufacturers to comply with applicable regulations could extend, delay or cause the termination of clinical trials conducted for our product candidates or the withdrawal of our products from the market. The impact of government regulation upon us cannot be predicted and could be material and adverse. We cannot accurately predict the extent of government regulation that might result from future legislation or administrative action.

Patents, Proprietary Rights and Know-How

Our success will depend in part on our ability to obtain patents and otherwise preserve the intellectual property rights relating to the design, operation, sale and distribution of our products. We intend to seek patents on our products when we deem it commercially appropriate. The process of seeking patent protection can be lengthy and expensive, and there can be no assurance that patents will be issued for currently pending or future applications or that our existing patents or any new patents issued will be of sufficient scope or strength or provide meaningful protection or any commercial advantage to us. We may be subject to, or may initiate, litigation or patent office interference proceedings, which may require significant financial and management resources. The failure to obtain necessary licenses or other rights or the advent of litigation arising out of any such intellectual property claims could have a material adverse effect on our operations.

We have relied to date on a combination of patent licenses, trademark rights, trade secret protection, distribution agreements, manufacturing agreements, manufacturing capability and other unpatented proprietary information to protect our intellectual property rights. While we do not currently own any issued patents directed to the treatment of sickle cell anemia, we do own patent applications in that area, as well as issued patents and patent applications directed to the treatment of diverticulosis, diabetes and hypertriglyceridemia. We furthermore have Orphan Drug market exclusivity for the treatment of sickle cell anemia with Endari® in the United States (through July 7, 2024) and in the EU (ten years from the approval date, if approved).

We also rely on employee agreements to protect the proprietary nature of our products. We require that our officers and key employees enter into confidentiality agreements that require these officers and employees to assign to us the rights to any inventions developed by them during their employment with us. All the confidentiality agreements include non-solicitation provisions that remain effective during the course of employment and for periods following termination of employment.

Patents

We have issued patents related to compositions including PGLG and methods involving administration of PGLG for the treatment of diverticulosis in the United States, Europe, Japan, Australia, India, Mexico, China, Indonesia, Korea and Russia. Associated patent applications are currently pending in the United States, the EU, Brazil, Korea and Russia.

Patents directed to compositions for decreasing HbA1C levels in individuals who are shown to have average blood sugar levels in the diabetic range have issued in Japan, Indonesia and the Philippines. Associated applications are currently pending in the United States, Europe, Brazil, India, China, the Philippines, and Japan.

The company has issued patents directed to the treatment of hypertriglyceridemia in Japan and the Philippines. A corresponding European patent application has been granted and is currently the subject of an Opposition proceeding. Associated applications are pending in the United States, Brazil, India, China, and the Philippines.

A patent application directed to the treatment of sickle cell using a multi-component composition is pending in the United States and Europe. An international application directed to the same invention has been filed under the Patent Cooperation Treaty.

HbA1C levels are one of the best indicators of whether diabetics and prediabetics have blood sugar levels under control, through therapeutic application of L-glutamine. Diabetes is a chronic disease that occurs when the pancreas is no longer able to make insulin, or when the body cannot make good use of the insulin it produces. People with diabetes have an increased risk of developing serious health problems including cardiovascular disease, kidney failure and blindness. Japan has more than 7 million diagnosed cases of diabetes, which represents about 7.6% of Japanese between the ages of 20 and 79. According to the U.S. Centers for Disease Control and Prevention, there are an estimated 29 million Americans living with diabetes and an estimated 86 million Americans with prediabetes, a serious health condition that can increase a person's risk of developing type 2 diabetes.

Licenses and Promotional Rights Agreements

In June 2016, we entered into a non-exclusive agreement with CellSeed and Dr. Kohji Nishida for the development of CAOMECS technology under which we are required to pay royalties based upon net sales upon commercialization.

Trademarks

We hold U.S. trademark registrations for "Emmaus Medical" and "Endari" and a trademark registration for "Xyndari™" (as Endari® will be marketed if approved) in the EU. This Annual Report also contains trademarks, service marks, trade names and copyrights of other companies, which are the property of their respective owners. Solely for convenience, these trademarks, service marks, trade names and copyrights may appear without the® or TM symbols, but such references are not intended to indicate that we or the other owners do not assert, to the fullest extent under applicable law, our rights, or the rights of any licensor to the same.

Employees

As of March 31, 2021, we had 58 employees, 56 of whom were full time. We have not experienced any work stoppages and we consider our relations with our employees to be good.

Corporate Information

We were incorporated in Delaware on March 20, 1987 under the name Age Research, Inc. Prior to January 16, 2007, our company (then called Strativation, Inc.) existed as a "shell company" with nominal assets and whose sole business was to identify, evaluate and investigate various companies to acquire or with which to merge. On January 16, 2007, we entered into an Agreement and Plan of Merger with CNS Response, Inc., and CNS Merger Corporation, our wholly owned subsidiary, pursuant to which CNS Merger Corporation merged with and into CNS Response, Inc., which survived the merger. On March 7, 2007, we changed our corporate name to CNS Response, Inc. On November 2, 2015, we changed our corporate name to MYnd Analytics, Inc. On July 17, 2019, we completed our merger transaction with EMI Holding, Inc., formerly known as Emmaus Life Sciences, Inc. ("EMI"), with EMI surviving as our wholly owned subsidiary. On July 17, 2019, immediately following the merger, we changed our name to "Emmaus Life Sciences, Inc."

Our principal executive offices and corporate offices are located at 21250 Hawthorne Boulevard, Suite 800, Torrance, California and our telephone number at that address is (310) 214-0065. We maintain an Internet website at the following address: www.emmausmedical.com. The information on our website is not incorporated by reference in this Annual Report or in any other filings we make with the Securities and Exchange Commission ("SEC").

ITEM 1A. RISK FACTORS

Risks Related to Our Business

We have operated at a loss and may continue to operate at a loss for the foreseeable future.

Although we realized net income of $1.4 million for the year ended December 31, 2020, we have historically operated at a loss due to substantial expenditures related to commercialization of Endari®, pursuit of marketing authorization of Endari® outside the U.S., research and development of our other product candidates, interest on our outstanding indebtedness and general and administrative expenses. We incurred a net loss of $54.8 million for the year ended December 31, 2019 and had an accumulated deficit of $225.1 million as of December 31, 2020. There is no assurance that we will be able to increase our Endari® sales or remain profitable or that we will have sufficient capital resources to fund our operations until we are able to generate sufficient cash flow from operations.

We are dependent on the commercial success of our only approved product, Endari®.

Our ability to become profitable will depend upon the commercial success of Endari®. In addition to the risks discussed elsewhere in this section, our ability to generate future revenues from Endari® sales will depend on a number of factors, including, but not limited to:

- achievement of broad market acceptance and coverage by third-party payors for Endari®;
- the effectiveness of our in-house commercialization team and other efforts in marketing and selling Endari®;
- our ability to compete effectively against competing products, including hydroxyurea, Oxbryta™ (voxelotor) and Adakveo®(crizanlizumab);
- contract manufacturers' ability to successfully manufacture commercial quantities of Endari® at acceptable cost levels and in compliance with regulatory requirements;
- our ability to maintain a cost-efficient commercial organization and, to the extent we seek to do so, successfully partner with third parties;
- our ability to effectively work with physicians to ensure that their patients have access to Endari® and fill and refill prescriptions to adhere to their twice-daily regimen;
- the efficacy and safety of Endari®; and
- our ability to comply with ongoing regulatory requirements.

Because of the numerous risks and uncertainties associated with our commercialization efforts, we are unable to predict the extent of revenues we will generate from Endari® sales or the timing for when or the extent to which we will become and continue to be profitable, if ever. Even if we do achieve increased net revenues from Endari® sales and become profitable, we may not be able to sustain our revenues or maintain or increase our profitability on an ongoing basis.

There are uncertainties related to our working capital and we may need to raise additional financing.

As of December 31, 2020, we had cash and cash equivalents of $2.5 million. In February and March 2021, we sold and issued approximately $14.5 million of convertible promissory notes, the net proceeds of which will be used for working capital and general corporate purposes, including repayment of indebtedness. In March 2021, we used a portion of the net proceeds to prepay, in full, $6.2 million principal amount of outstanding Amended and Restated 10% Senior Secured Convertible Debentures, as amended, due August 31, 2021.

Based on our anticipated future revenues and operating expenses, our cash and cash equivalents of $2.5 million as of December 31, 2020, and the remaining net proceeds from the recent sale of convertible promissory notes, we believe our working capital is sufficient to meet our needs through at least the second quarter of 2022. If future revenues are less than anticipated or we incur more expenses than we anticipate, we may not have sufficient operating capital for our business without raising additional capital. Except as described under the caption "Liquidity and Capital Resources' in the

"Management's Discussion of Financial Condition and Results of Operations" section of this Annual Report, we have no understanding or arrangements with respect to future financings, and there can be no assurance of the availability of such capital on terms acceptable to us or at all. Because we were unable to timely file our Annual Report on Form 10-K for the year ended December 31, 2019 and Quarterly Reports for 2020 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), we are ineligible to utilize the short-form Registration Statement on Form S-3 for the public offer and sale of securities until we have timely filed all required reports under the Exchange Act for the 12 months prior to filing a Registration Statement on Form S-3. The inability to utilize Form S-3 may adversely impact our ability to raise capital in a timely manner and increase transaction costs.

The COVID-19 pandemic may adversely affect our revenues, results of operations and financial condition and impact our ability to obtain needed financing.

COVID-19 and the various precautionary measures taken by many governmental authorities around the world to limit its spread has had a severe effect on global markets and the global economy. The extent to which the coronavirus impacts our business and operations will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the nature and extent of governmental actions taken to contain it or treat its impact and the availability, cost, effectiveness and public acceptance of any FDA-approved vaccines, among others. COVID-19 and official actions in response to it have caused a major slowdown in overall economic activity in the U.S. and elsewhere, curtailed consumer spending and made it more challenging to adequately staff and manage our business and operations, including our accounting and financial operations. Although COVID-19 and official responses have not had a material adverse effect on our Endari® sales to date, COVID-19 or future official responses may deter or prevent sickle cell disease, or SCD, patients from traveling to see their doctors or filling or refilling their prescriptions for Endari®, our one approved product, which could cause a temporary or prolonged decline in our revenues and have a material adverse effect on our results of operations and financial condition. COVID-19 or the governmental response may adversely affect the timing and conduct of clinical studies or the ability of regulatory bodies to consider or grant approvals with respect to Endari® or our prescription grade L-glutamine drug candidates or oversee the development of our drug candidates, may further divert the attention and efforts of the medical community to coping with COVID-19 and disrupt the marketplace in which we operate. For example, we experienced a temporary disruption in 2020 in patient enrollment in our Pilot/Phase I study of our prescription grade L-glutamine oral powder in diverticulosis, but patient enrollment has now been completed. Any outbreak of COVID-19 among our executives or key employees or their families and loved ones could disrupt our management and operations and adversely affect our Endari® sales, results of operations and financial condition. The foregoing factors could also have an adverse effect on the market price of our common stock or the value of our other outstanding securities.

We regularly explore possible financing alternatives and intend to consider emergency federal or state funding that may be available to companies affected by COVID-19. There is no assurance that government funding will be available or that we will qualify for any such funding.

We may expend our limited resources to pursue a product candidate or indication and fail to capitalize on product candidates or indications for which there is a greater likelihood of commercial success.

Because we have limited financial and management resources, we focus on a limited number of research programs and product candidates. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable product candidates or profitable market opportunities. Our spending on current and future research and development programs and product candidates for the specific indications we selected may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

We face intense competition from companies with greater resources than us, and if our competitors are successful in marketing or develop alternative treatments our commercial opportunities may be reduced or eliminated.

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on developing proprietary therapeutics. We face competition from a number of sources, some of which may target the same indication as Endari®, such as pharmaceutical companies, including generic drug companies, biotechnology companies, drug delivery companies and academic and research institutions, many of which have greater financial resources, marketing capabilities, including well-established sales forces, manufacturing capabilities, research and development capabilities, experience in obtaining regulatory approvals for product candidates than do we. For example, in late 2019 the FDA approved a new drug application, or NDA, submitted by Novartis, permitting the marketing of ADAKVEO® (crizanlizumab-tmca) to

reduce the frequency of vaso-occlusive crises in adults and pediatric patients aged 16 years and older with SCD. ADAKVEO®, which is administered by intravenous infusion every four weeks, is a selectin blocker humanized IgG2 kappa monoclonal antibody that binds to P-selectin. Also, in late 2019, Global Blood Therapeutics, Inc. ("GBT") announced that the FDA approved its NDA for Oxbryta™ (voxelotor) tablets for the treatment of SCD in adults and children 12 years of age and older. Oxbryta™ is an oral, once-a-day therapy intended to treat SCD by targeting hemoglobin polymerization. Both Novartis and GBT have far greater financial, sales and marketing resources than our company and there is no assurance that we will be able to compete effectively with ADAKVEO® or Oxbryta™ as a stand-alone therapy or that Endari® will gain widespread use as an adjunct to the use of ADAKVEO® or Oxbryta™. If we are unable to compete effectively or successfully position Endari® as a complementary therapy, our Endari® sales and results of operation may suffer, which could have a material, adverse effect on our financial condition. We also face competition from hydroxyurea, and non-prescription grade L-glutamine supplements. L-glutamine is manufactured in large quantities, primarily by a few large chemical companies, and processed and sold as a nutritional supplement. The sale of non-prescription grade L-glutamine nutritional supplements at prices lower than the price that we charge for Endari® could have a material adverse effect on our sales of Endari® and results of operations.

If we are unable to achieve and maintain adequate levels of coverage and reimbursement for Endari®, on reasonable pricing terms, its commercial success may be severely hindered.

Successful sales of Endari® depend on the availability of adequate coverage and reimbursement from third-party payors and governmental healthcare programs, such as Medicare and Medicaid. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or a significant portion of the costs associated with their prescription drugs. Coverage determination depends on financial, clinical and economic outcomes that often disfavors new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Although Endari® is reimbursable by the Centers for Medicare and Medicaid Services, and every state provides coverage for Endari® for outpatient prescriptions to all eligible Medicaid enrollees within their state Medicaid programs, the reimbursement amounts are subject to change and may not be adequate and may require higher co-payments that patients find unacceptable. Patients are unlikely to use Endari® unless reimbursement is adequate to cover a significant portion of the cost of Endari®. Future coverage and reimbursement will likely be subject to increased pressure in the U.S. Third-party coverage and reimbursement for Endari® may cease to be available or adequate in the U.S., which could have a material adverse effect on our business, results of operations, financial condition and prospects.

In addition, the market for Endari® will depend significantly on access to third-party payors' drug formularies, which are lists of medications for which third-party payors provide coverage and reimbursement. The competition in the industry to be included in such formularies may lead to downward pricing pressures on us. Also, third-party payors may refuse to include Endari® in their formularies or otherwise restrict patient access to Endari® if a less costly generic equivalent or other alternative treatment is available.

The majority of Endari® sales are to a few customers and loss of a customer could adversely affect our results of operations.

The majority of Endari® sales are to specialty distributors and specialty pharmacies who, in turn, resell Endari® to pharmacies, hospitals and other customers. The loss of any of these specialty distributors and specialty pharmacies' accounts or a material reduction in their Endari® purchases could have a material adverse effect on our business, results of operations, financial condition and prospects.

In addition, the distribution network for pharmaceutical products in the U.S. has undergone, and may continue to undergo, significant consolidation marked by mergers and acquisitions. As a result, a smaller number of large distributors control a significant share of the market, which has increased, and may continue to increase, competitive and pricing pressures on pharmaceutical products. There is no assurance that we can manage these pricing pressures or that specialty distributor and specialty pharmacy purchases will not fluctuate unexpectedly from period to period.

The market exclusivity for Endari® for SCD is limited, which could adversely affect our ability to compete in the market and adversely affect the commercial success of Endari®.

The exclusivity protections that protect Endari® for use for SCD are limited in ways that may affect our ability to effectively exclude third parties from competing against us. In particular:

- Orphan Drug market exclusivity protection for Endari® for SCD will expire in the U.S. July 7, 2024;
- Orphan Drug designation does not preclude the FDA from granting Orphan Drug designation to another sponsor developing the same drug for the same indication, granting Orphan Drug designation and approving such other drug after we receive approval if such drug is considered clinically superior to our product, approving a product that is the same as our product for a different indication, or approving a different product

intended to treat SCD; in this regard, Global Blood Therapeutics, Inc.'s Oxbryta for treating SCD also has been granted Orphan Drug status in the U.S. and in the EU;

- Orphan Medicinal status in the EU is subject to exclusions similar to those in the U.S.; and
- there are many countries, including some key markets for Endari®, in which we do not have intellectual property coverage and where neither orphan drug nor data exclusivity is available.

These limitations and any reductions in our expected protection, including other products that could be approved by FDA under the Orphan Drug Act, may subject Endari® to greater competition than we expect and could adversely affect our ability to generate revenue from Endari®, perhaps materially. These circumstances may also impair our ability to obtain license partners or other international commercialization opportunities on terms acceptable to us, if at all.

Many of our potential customers are in markets with underdeveloped health care systems.

Our only approved product, Endari®, is a prescription-grade L-glutamine oral powder treatment for sickle cell anemia and sickle ß0-thalassemia, two of the most common forms of SCD. SCD is a genetic blood disorder that affects 20 million to 25 million people worldwide and occurs primarily among those whose ancestors are from regions including sub-Saharan Africa, South America, the Caribbean, Central America, the Middle East, India and Mediterranean regions such as Turkey, Greece and Italy. Thus, while SCD affects people throughout the world, the prevalence of SCD is higher in certain geographies, such as central and sub-Saharan Africa and the Caribbean, that currently have underdeveloped health care systems or significantly lower rates of health insurance coverage and incidence of these conditions in the United States is relatively low. Furthermore, many potential patients in many of these geographies are low-income and may be unable to afford Endari®. These factors may ultimately limit our addressable market. Our ability to achieve and sustain profitability may be adversely impacted if we are unable to access markets with greater prevalence of SCD or reach enough SCD patients in geographies with more well-developed health care systems.

A variety of other risks associated with marketing any of our products internationally could hurt our business.

We are seeking regulatory approval for Endari® for SCD outside of the U.S. but may not be successful. For example, in January 2018, the European Medicines Agency, or EMA, provided their agreement on the pediatric investigation plan, or PIP, for our prescription grade L-glutamine oral powder in SCD and we filed with the EMA an application for marketing authorization, or MAA, in the EU. In May 2019, we announced that the EMA's Committee for Medicinal Products for Human Use, or CHMP, had adopted a negative opinion regarding our MAA based upon the CHMP's position that our main clinical study did not conclusively support the efficacy of the treatment in SCD patients. In light of the CHMP's opinion, we withdrew our MAA in September 2019 to consider pursuing alternative decentralized and centralized regulatory pathways for obtaining marketing authorization in the EU or one or more EU countries. There is no assurance that we will be successful in obtaining marketing authorization in the EU or other jurisdictions outside the U.S. If we obtain marketing authorization, we expect that we will be subject to additional risks related to operating in foreign countries including:

- business interruptions resulting from geopolitical actions, including war and terrorism or actual or potential public health emergencies, including the COVID-19 pandemic;
- differing regulatory requirements in foreign countries;
- the potential for parallel importing (i.e., when a local seller, faced with high or higher local prices, opts to import goods from a foreign market with low or lower prices rather than buying them locally);
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation or political instability in particular foreign markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations related to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the U.S.;
- potential liability under the U.S. Foreign Corrupt Practices Act or comparable foreign regulations;

- challenges enforcing our contractual and intellectual property rights, especially in foreign countries that do not respect and protect intellectual property rights to the same extent as the U.S.; and
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad.

These and other risks associated with international operations may compromise our ability to achieve or maintain profitability.

We may not be able to anticipate the demand for and appropriate supply of Endari®.

We monitor our distributors' inventories of Endari® using a combination of methods. However, our estimates of distributor inventories may differ significantly from actual inventory levels. Significant differences between actual and our estimated inventory levels may result in excessive production (requiring us to hold substantial quantities of unsold inventory which may result in the establishment of inventory reserves or actual write offs of expired inventory), inadequate supplies of products in distribution channels, insufficient product available at the retail level, and unexpected increases or decreases in orders from our specialty distributors. For example, as of December 31, 2020, we established a $1.2 million reserve against possible future inventory write offs. These changes may cause our revenues to fluctuate significantly from quarter to quarter, and in some cases may cause our operating results for a quarter to be below our expectations or the expectations of securities analysts or investors. In addition, we sometimes offer price discounts to our customers in advance of Endari® price increases, including a price increase as of March 1, 2021, or as an incentive for bulk orders of Endari®, which discounts may result in specialty distributor purchases in excess of customer demand, resulting in reduced specialty distributor purchases in later periods and substantial fluctuations in our results of operations from period to period. Sales attributable to one-time discounts offered by us increased in 2020 over 2019 and may adversely affect sales in subsequent periods. If our financial results are below analysts' or investors' expectations, the market price of our common stock may be adversely affected.

If the L-glutamine manufacturers upon which we rely fail to produce in the volumes and quality that we require on a timely basis, or fail to comply with stringent regulations applicable to pharmaceutical manufacturers, we may face interruptions in the commercialization of, or be unable to meet demand for, our L- glutamine based products, and may lose any marketing exclusivity and potential revenues.

We do not currently have our own manufacturing capabilities and depend entirely upon third-party manufacturers for commercial supplies of Endari® and clinical supplies of prescription grade L-glutamine used in our product candidates under development. Our third-party manufacturers and other key suppliers may experience manufacturing or production difficulties and may not be able to expand their capacity or to produce additional supplies for us in the event that demand for Endari® or our requirements for prescription grade L-glutamine were to increase substantially. If these manufacturers or key suppliers were to encounter any of these difficulties, or otherwise fail to comply with their regulatory and contractual obligations, our ability to expand our Endari® sales or timely launch any potential product candidate, if approved, would be jeopardized. If we are unable to ensure adequate supply of an orphan drug for which we have obtained marketing exclusivity, the FDA may approve another drug for marketing, which could have a material adverse effect on our business and financial condition.

We currently obtain substantially all our prescription grade L-glutamine from a single Japanese supplier, Ajinomoto Aminoscience LLC, or Ajinomoto. We intend to continue to rely on Ajinomoto to produce our pharmaceutical grade L-glutamine, but we have not entered into, and may not be able to establish, long-term supply agreements with this key supplier on acceptable terms. Furthermore, pursuant to a letter of intent with Ajinomoto, we have agreed to purchase from Ajinomoto substantially all of the L-glutamine that we will need for our commercial products. If Ajinomoto were to experience any manufacturing or production difficulties producing prescription grade L-glutamine, or we were unable to purchase sufficient quantities of prescription grade L-glutamine on acceptable terms, it could interrupt sales of Endari® and have a material, adverse effect on our financial condition and results of operations.

In addition, all manufacturers, packers, distributors and suppliers of pharmaceutical products must comply with applicable cGMP regulations for the manufacture of pharmaceutical products, which are enforced by the FDA through its facilities inspection program. If our manufacturers and key suppliers are not in compliance with cGMP requirements, it may result in a delay of approval for products undergoing regulatory review or the inability to meet market demands for any approved products, particularly if these sites are supplying single source ingredients required for the manufacture of any potential product. Furthermore, each manufacturing facility used to manufacture drug or biological products is subject to FDA inspection and must meet cGMP requirements. As a result, if one of the manufacturers that we rely on shifts production from one facility to another, the new facility must undergo a preapproval inspection and, for biological products, must be licensed by regulatory authorities prior to being used for commercial supply. A failure to comply with any applicable manufacturing requirements, including cGMP requirements, could delay or prevent the promotion, marketing or sale of our products. If the

FDA or any other applicable regulatory authorities do not approve the facilities for the manufacture of Endari® or if they withdraw any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to commercially supply Endari®.

If the safety of any quantities supplied is compromised due to a third-party manufacturer's failure to comply with or adhere to applicable laws or for other reasons, we may be liable for injuries suffered by patients who have taken such products and we may not be able to obtain regulatory approval for or successfully commercialize our products.

We expect to rely on third parties to conduct future clinical trials of our product candidates and those third parties may not perform satisfactorily, including failing to meet deadlines for the conduct of such trials.

We engaged a third-party contract research organization ("CRO") to conduct our clinical trials for Endari® and expect to engage a CRO to conduct any further required clinical trials of Endari® and any clinical trials with respect to any of our product candidates that may progress to clinical development. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct those clinical trials. Agreements with such third parties might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, it could delay our product development activities.

Our reliance on these third parties for research and development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as GCPs for conducting, recording and reporting the results of clinical trials to ensure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, www.ClinicalTrials.gov, within specified timeframes. Failure to do so can result in the FDA refusing to accept a NDA for the product candidate under study, fines, adverse publicity and civil and criminal sanctions.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements and our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize them as products. We also expect to rely on other third parties to store and distribute supplies of our product candidates for clinical trials of them. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of them as products, producing additional losses and depriving us of potential revenue.

Delays in the commencement, enrollment and completion of clinical trials could result in increased costs to us and delay in our ability to develop and obtain regulatory approval for product candidates. The commencement, enrollment and completion of clinical trials can be delayed for a variety of reasons, including delays or difficulties in enrolling patients due to unforeseen natural disasters, public health crises, political crises and other catastrophic events or other events outside of our control, such as the recent emergence and spread of COVID-19, which may cause participants to not want to participate in these trials or otherwise have any unnecessary contact with the medical community.

Endari® may cause undesirable side effects or have other unexpected properties that could result in post-approval regulatory action.

The most common side effects seen with Endari® included constipation, nausea, headache, pain in the stomach area, cough, pain in the hands or feet, back pain, and chest pain. If we or others identify previously unknown undesirable side effects, or other previously unknown problems, caused by Endari® or other products with the same or related active ingredients, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of Endari®;
- we may need to recall Endari®;
- we may need to add warnings or narrow the indication in the product label or to create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way Endari® is administered or modify Endari® in some other way;
- the FDA may require us to conduct additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product;

- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of the above events resulting from undesirable side effects or other previously unknown problems could prevent us from achieving or maintaining market acceptance of Endari® and could substantially increase the costs of commercializing Endari®.

We face potential product liability exposure relating to Endari® and, if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate.

The commercial use of Endari® will expose us to the risk of product liability claims despite the fact it is approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA. Any side effects, manufacturing defects, misuse or abuse associated with Endari® could result in injury to a patient or even death and product liability claims against us. In addition, a liability claim may be brought against us even if Endari® merely appears to have caused an injury. Product liability claims may be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with Endari® and we could incur substantial liabilities.

In addition, regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for Endari®;
- impairment of our business reputation;
- recall or withdrawal of Endari® from the market;
- costs related to litigation;
- distraction of management's attention from our business;
- substantial monetary awards to patients or other claimants; or
- loss of revenues.

We maintain product liability insurance coverage and carry commercial excess and umbrella coverage, but our insurance coverage may not be sufficient to cover product liability related expenses or losses and may not cover us for any consequential expenses or losses we may suffer. We may not be able to continue to maintain insurance coverage at a reasonable cost, in sufficient amounts or upon adequate terms to protect us against losses due to product liability. Large judgments have been awarded in class action or individual lawsuits based on drugs that had unanticipated side effects, including side effects that are less severe than those of Endari®. Successful product liability claims against us could cause the value of our common stock to decline and, if judgments exceed our insurance coverage, reduce our cash and have a material adverse effect on our business, results of operations, financial condition and prospects.

The use of any of our product candidates in clinical trials and in the market may expose us to liability claims.

We are exposed to potential liability risks inherent in the testing and manufacturing of our product candidates and marketing of any products. While in clinical stage testing, our product candidates could potentially harm people or allegedly harm people and we may be subject to costly and damaging product liability claims. Informed consent and contractual limitations on payments for subject injury or waivers we obtain may not be enforceable and may not protect us from liability or the costs of product liability litigation. Although we carry clinical product liability insurance, it may not be sufficient to cover future claims.

In addition, in some cases the contractors on which we rely for manufacturing our product candidates may indemnify us for third-party claims brought against us arising from matters for which these contractors are responsible. We could be materially and adversely affected if we were required to pay damages or incur defense costs in connection with a claim outside the scope of indemnity or insurance coverage, if the indemnity is not performed or enforced in accordance with its terms, or if our liability exceeds the amount of applicable insurance or indemnity. In addition, there can be no assurance that insurance will continue to be available in amounts and on terms acceptable to us, if at all, to cover any potential claims or liabilities.

We will need to increase the size and complexity of our organization in the future, and we may experience difficulties in managing our growth and executing our growth strategy.

We will need to expand our scientific, sales and marketing, managerial, operational, financial and other resources to support our planned commercialization activities. Continued operations and growth require that we manage our

commercialization activities for Endari® and product development efforts successfully and in a cost-effective manner. We will also need to continue to improve our operational, financial, management and regulatory compliance controls and reporting systems and procedures.

We will need to attract and retain sufficient talented employees and scientific collaborators.

Historically we have utilized, and continue to utilize, part-time outside consultants to perform certain tasks, including tasks related to accounting and finance, compliance programs, clinical trial management, regulatory affairs, formulation development and other drug development functions. Our growth strategy related to Endari® may entail expanding our use of consultants to implement these and other tasks going forward. There can be no assurance that we will be able to manage our existing consultants or engage other competent consultants, as needed, on economically reasonable terms.

In addition, we have scientific and clinical advisors who assist us in our commercialization strategies for Endari® and our other product development efforts, including development of new medical indications for L-glutamine-based products. Although we have established research collaborations, we cannot assure you that our relationships with our research collaborators and scientific and clinical advisors will continue or that we will be able to attract additional research partners and advisors. Without such scientific relationships to assist in our research and development, we may not be able to successfully develop our product candidates or expand our product offerings.

We rely heavily on Yutaka Niihara, M.D., M.P.H., our Chairman and Chief Executive Officer, and the loss of his services would have a material adverse effect upon our business and prospects.

Our success depends, to a significant extent, upon the continued services of Yutaka Niihara, M.D., M.P.H., our founder and Chairman and Chief Executive Officer. The loss of Dr. Niihara's services could materially and adversely affect our business and prospects. We do not maintain key man life insurance policies on Dr. Niihara or any of our other executive officers.

Our business and operations may be adversely affected by information technology ("IT") system failures or cybersecurity or data breaches.

We rely on IT networks and systems, including those of third-party service providers, to collect, process, store and transmit confidential information including, but not limited to, personal information and intellectual property for a variety of functions including, but not limited to, conducting clinical trials, financial reporting, data and inventory management. We also outsource certain services, including recruiting services, call center services, contract sales organization services and other ancillary services relating to the commercial marketing and sale of Endari® in the U.S., as well as significant elements of our IT security systems, as a result, our service providers have access to our confidential information.

Despite the implementation of security measures and recovery plans, our network and information systems and those of third party service providers may be vulnerable to damage from computer viruses, cyberattacks, physical or electronic break-ins, service disruptions, and security breaches from inadvertent or intentional actions by our employees or vendors, or from attacks by malicious third parties. While we have not experienced any such system failure or security breach to date, if such an event were to occur, our operations may be disrupted, and we may suffer from economic loss, reputational harm, regulatory actions or other legal proceedings. Further, such breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased risks of the actions described above. We expect that risks and exposures related to cybersecurity breaches will remain high for the foreseeable future due to the rapidly evolving nature and sophistication of these threats.

We have identified material weaknesses in our internal controls over financial reporting.

In connection with the preparation and filing of this Annual Report, our management concluded that the material weaknesses in our internal controls over financial reporting originally identified in our Annual Report on Form 10-K for the year ended December 31, 2018 had not been fully remediated and our disclosure controls and procedures were not effective as described in more detail in Part II – Item 9A "Controls and Procedures" in this Annual Report. Among other things, the weakness led our independent public accounting firm to qualify their audit report included in this Annual Report regarding the net loss attributable to our interest in EJ Holdings. We cannot guarantee when our disclosure controls and procedures will be fully effective or that we will not identify other material weaknesses in the future. Any material weaknesses in our internal control over financial reporting could result in errors in our consolidated financial statements, which could erode market confidence in our company, adversely affect the market price of our common stock and, in egregious circumstances, result in possible claims based upon such financial information.

Risks Related to Our Intellectual Property

We may not be able to obtain and enforce intellectual property rights that cover our commercial activities or are sufficient to prevent third parties from competing against us.

Our success with respect to Endari® will depend, in part, on our ability to preserve our trade secrets and to prevent third parties from infringing upon our proprietary rights because we do not have (and will do not expect to be able to obtain) composition of matter patents or methods of use patents that cover Endari®. In particular, the patent for the use of L-glutamine to treat SCD expired in May 2016 and our license to the patent terminated. This means that our competitors are free to utilize processes, technologies and methods that were previously protected by the SCD patent to potentially develop competing products. While we have an Orphan Drug designation for the use of L-glutamine for the treatment of SCD, Orphan Drug exclusivity may be lost if another L-glutamine product for the same indication demonstrates clinical superiority. If our competitors develop alternative L-glutamine products, it may have a material and adverse effect on our business and results of operations.

In addition to seeking patents for our intellectual property, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, in our business. We seek to protect our trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and remedies thereunder may not be adequate. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time consuming, and the outcome is unpredictable. Some courts inside and outside the U.S. are less willing or unwilling to protect trade secrets. In addition, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us.

Although we expect all our employees to assign their inventions to us, and all our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidential information and invention agreements, we cannot provide any assurances that all such agreements have been duly executed or will be enforceable.

We depend on licenses and sublicenses of certain patents. If any of these licenses, sublicenses, or the licenses under which we have been sublicensed terminates, or if any of the patents that have been licensed or sublicensed to us is challenged and we are limited in our ability to utilize any of those patents, we may be unable to develop, out-license, market and sell our products, which would cause a material adverse effect on our business, prospects, financial condition, and operating results.

Our ability to develop products depends on licenses and sublicenses we have obtained to patents that claim the use of L-glutamine to treat SCD, diverticulosis and diabetes and the use of CAOMECS for the treatment of corneal impairments.

These licenses and sublicenses could be terminated if we fail to satisfy our obligations under them. In addition, if the license under which we have been sublicensed terminates, our sublicense could also terminate. In the event any claims in the patents that we have been licensed or sublicensed are challenged, the court or patent authority could determine that such patent claims are invalid or unenforceable or not sufficiently broad in scope to protect our proprietary rights. As the licensee or sublicensee of such patents, our ability to participate in the defense or enforcement of such patents could be limited.

If we are unable to protect proprietary technology that we invent and develop, we may not be able to compete effectively, and our business and financial prospects may be harmed.

Where appropriate, we seek patent protection for inventions we conceive and reduce to practice, however, patent protection may be limited or not available for all these inventions. In addition, we may need to design around patents held by others. If we must spend significant time and money protecting our patents, designing around patents held by others or in-licensing patent or other proprietary rights held by others, potentially for large fees, our business and financial prospects may be harmed.

The patent prosecution process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We also may have to relinquish to strategic partners or other third parties to whom we license our technology the right to control the preparation, filing and prosecution of patent applications claiming our inventions and to maintain any resulting patents.

Therefore, patent applications and patents claiming our inventions may not be prosecuted and enforced in a manner consistent with the best interests of our business.

Our pending and future patent applications may not result in patents being issued that protect our product candidates, in whole or in part, or which effectively prevent others from commercializing competitive product candidates. Changes in either the patent laws or interpretation of the patent laws in the U.S. and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Even if our patent applications issue as patents, they may not issue in a form that will prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative treatments in a non-infringing manner.

In addition, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the U.S. and abroad. Such challenges may result in loss of exclusivity, freedom to operate and/or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to prevent others from commercializing products similar or identical to our product candidates or products, or limit the duration of the patent protection of our product candidates or products. Given the amount of time required for the development, testing and regulatory review of new therapeutics, patents protecting our product candidates might expire before or shortly after such candidates are commercialized as products. For example, our patent protection for Endari® expired in May 2016. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Risks Related to Regulatory Oversight of Our Business and Compliance with Law

Endari® is subject to ongoing and continued regulatory review, compliance with which may result in significant expense and limit our ability to commercialize Endari®.

We are subject to ongoing FDA obligations and continued regulatory review with respect to the manufacturing, processing, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for Endari®. These requirements include submission of safety and other post-marketing information and reports, as well as continued compliance with good clinical practices and good laboratory practices or cGMPs. In addition, our product advertising and promotion are subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription drug products. In particular, a drug product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling, although the FDA does not regulate the prescribing practices of physicians.

Manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where, or processes by which, the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturer or us, including requiring product recall, notice to physicians, withdrawal of the product from the market or suspension of manufacturing.

The FDA's regulations, policies or guidance may change, and new or additional statutes or government regulations may be enacted that could further restrict or regulate post-approval activities relating to our commercialization of Endari®. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market Endari®, which would adversely affect our ability to generate revenue and achieve or maintain profitability.

We may not be able to receive regulatory approval for our prescription grade L-glutamine treatment for diverticulosis or other indications, which would adversely affect our financial and operating condition.

All our other product candidates are still in preclinical or early-stage clinical development. Regulatory approval is required to market our prescription grade L-glutamine treatment for diverticulosis or other indications and for any other product candidates we may develop. Even if the FDA and other regulatory authorities approve our prescription grade L-glutamine treatment for diverticulosis, or any of our other product candidates, the manufacture, packaging, labeling, distribution, marketing and sale of such products will be subject to strict and ongoing post-approval regulations. Compliance with such regulations will be expensive and consume substantial financial and management resources.

The FDA has the authority to regulate the claims we make in marketing our prescription products to ensure that such claims are true, not misleading, supported by scientific evidence, and consistent with the approved labeling of those products. Failure to comply with FDA requirements in this regard could result in, among other things, warning letters, withdrawal of approvals, seizures, recalls, injunctions prohibiting a product's manufacture and distribution, restricting promotional activities, requiring corrective actions regarding sales and marketing activities, other operating restrictions, civil money penalties, disgorgement, and criminal prosecution. In addition, if we make any marketing claims that are related to a health care provider's unlawful submission for reimbursement from government programs, we could be subject to potential liability for violations of the False Claims Act, which may lead to disqualification from government programs or criminal prosecution, or both. Any of these government enforcement actions, if taken against us, could negatively impact our product sales and profitability.

Additionally, regulatory approval of any of our prescription products may be conditioned on our agreement to conduct costly post-marketing follow-up studies to monitor the safety or effectiveness of such products or to implement specific risk mitigation strategies. In addition, as clinical experience with any of our products following such approval, if any, expands after approval because the product is used by a greater number and more diverse group of patients than during clinical trials, unknown side effects or other problems may be observed that were not observed or anticipated during pre-approval clinical trials. In any such case, one or more regulatory authorities could require additional risk information be added to the labeling of the product, restrict the indications for which the product may be sold, restrict the distribution channels, or revoke the product's regulatory approval, which could hinder our ability to generate revenues from that product. If we fail to develop and commercialize our product candidates as planned, our financial results and financial condition will be adversely affected, we will have to delay or terminate some or all of our research product development programs, and we may be forced to cease operations.

The development process to obtain FDA approval for new drugs therapies is very costly and time consuming and if we cannot complete our clinical trials in a cost-effective manner, our operations may be adversely affected.

Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we or a collaborator must complete preclinical development and then complete one or more extensive clinical trials to demonstrate the safety and effectiveness of the product candidate in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. Costs of clinical trials may vary significantly over the life of a development project owing, but not limited to, the following:

- the number of patients that participate in the trials;
- the per patient trial costs;
- the number of sites and clinical investigators involved in the trials;
- the number and types of trials and studies that may need to be performed;
- the length of time required to recruit, screen, and enroll eligible patients;
- the duration of the clinical trials;
- the countries in which the trials are conducted;
- the number of doses that patients receive;
- adverse events experienced by trial participants;
- the drop out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the extent and duration of patient follow up;
- difficulties that could arise in analyzing and reporting to regulators the results of clinical trials; and
- the efficacy and safety profile of the product candidate.

If we are unable to control the timing and costs of our clinical trials and conduct our trials and apply for regulatory approvals in a timely and cost-effective manner, our operations may be adversely affected.

Our product development costs will also increase if any regulatory agencies impose a clinical hold on any of our clinical studies or we experience delays in obtaining marketing approvals, particularly if we are required to conduct additional

clinical studies beyond those that we submit in any NDA. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our approved product candidates or allow our competitors to bring products to market before we do, and thereby impair our ability to successfully commercialize our product candidates.

We may not be able to complete clinical trial programs for any of our product candidates successfully within any specific time period or at all, and if such clinical trials take longer to complete than we project, our ability to execute our current business strategy will be adversely affected.

Clinical testing is expensive, difficult to design and implement, can take many years to complete, and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of development. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of them.

Generally speaking, whether we complete our clinical trials in a timely manner, or at all, for any product candidate is dependent in part upon: (i) the date the applicable investigational new drug, or IND, becomes effective enabling us to commence the applicable clinical studies (which, under U.S. law, occurs no more than 30 days after the FDA receives the IND, unless the FDA places the IND on clinical hold, in which case the FDA may request us to provide additional data from completed preclinical studies or undertake additional preclinical studies, the latter of which could materially delay the clinical and regulatory development of the applicable product candidate); (ii) the engagement of clinical trial sites and clinical investigators; (iii) reaching an agreement with clinical investigators on acceptable clinical trial agreement terms, clinical trial protocols or informed consent forms; (iv) obtaining approval from the institutional review boards used by the clinical trial sites we seek to engage; (v) the rate of patient enrollment and retention; and (vi) the rate to collect, clean, lock and analyze the clinical trial database.

Clinical trials required for demonstration of substantial evidence of effectiveness and safety often require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit. Our ability to enroll sufficient numbers of patients in our clinical trials, especially when the disease or condition being studied is rare, depends on many factors, including the size of the relevant patient population, the nature and design of the protocol, the proximity of patients to clinical sites, the eligibility and exclusion criteria applicable for the trial, existence of competing clinical trials and the availability of already approved therapeutics for the indications being studied (whether or not such therapeutics are less safe or less effective than our product candidate under trial). If we fail to enroll and maintain the number of patients for which the clinical trial was designed, the statistical significance and/or statistical power of that clinical trial may be reduced which would make it harder to demonstrate that the product candidate being tested in such clinical trial is safe and effective for its intended use.

We may be required to suspend, repeat or terminate our clinical trials if they do not meet regulatory requirements, the results are negative or inconclusive, human subject protections are inadequate, the trials are not well designed, or clinical investigators fail to comply with all requirements for the conduct of trials under the applicable IND, any of which may result in significant negative repercussions on our business and financial condition.

We cannot market a pharmaceutical product in any jurisdiction until we have completed rigorous preclinical testing and clinical trials for that product, demonstrated the product's safety and substantial evidence of effectiveness for its intended use, obtained the approval of the applicable regulatory authority for our proposed labeling of the product, and met the other requirements of such jurisdiction's extensive regulatory approval process. Preclinical testing and the conduct of clinical trials are long and expensive. Data obtained from preclinical and clinical tests can be interpreted in different ways and could ultimately be deemed by regulatory authorities to be insufficient with respect to providing substantial evidence of effectiveness and safety required for regulatory approval, which could delay, limit or prevent regulatory approval. It may take us many years to complete the required testing of our product candidates to support an application for marketing approval and failure can occur at any stage during this process.

We cannot provide assurance that our preclinical testing and clinical trials will be completed successfully within any time period specified by us, or without significant additional resources or expertise provided by third parties to conduct such testing. We cannot provide assurance that any such testing will demonstrate that our product candidates meet regulatory approval requirements for safety and effectiveness or that any such product will be approved for a specific indication. Results from early clinical trials may not be indicative of the results that will be obtained in later-stage clinical trials or in the population of patients for whom the applicable product is prescribed following any approval. In addition, negative or inconclusive results

from the clinical trials we conduct, or adverse events experienced by the patients in such clinical trials, could cause us to have to suspend, repeat or terminate the clinical trials. Clinical trials are subject to continuing oversight by governmental regulatory authorities and institutional review boards and must meet the requirements of these authorities including but not limited to requirements for informed consent, human subject protection and good clinical practices; and we cannot guarantee that we will be able to comply, or that a regulatory authority will agree that we have complied, with such requirements.

We rely on third parties, such as CROs, contract laboratories, regulatory consultants and data management companies to assist us in overseeing and monitoring clinical trials as well as to process the clinical data and manage test requests, which may result in delays or failure to complete trials, if the third parties fail to perform or meet applicable regulatory requirements and standards. A failure by us or any such third parties to comply with the terms and conditions of the protocol for any clinical study or the regulatory requirements for a product candidate or to complete the clinical trials for a product candidate in the projected time frame could significantly delay or increase the cost of our studies and have a material adverse effect on our business and financial condition.

There are significant requirements imposed on us and on clinical investigators who conduct clinical trials under an IND. Although we are responsible for selecting qualified clinical investigators, providing them with the information they need to properly conduct an investigation, ensuring proper monitoring of the investigations and that the investigations are conducted in accordance with the general investigational plan and protocols contained in the IND, we cannot ensure the clinical investigators will maintain compliance with all regulatory requirements at all times. The pharmaceutical industry has experienced cases where clinical investigators have been found to incorrectly record data, omit data, or even falsify data. We cannot ensure that the clinical investigators in our trial will not make mistakes or otherwise compromise the integrity or validity of data, any of which would have a significant negative effect on our ability to obtain marketing approval.

Changes in regulatory requirements and guidance or unanticipated events during our clinical trials may occur, which may result in necessary changes to clinical trial protocols, informed consents and clinical trial budgets, any of which changes could result in increased costs to us, delay our development timeline or reduce the likelihood of successful completion of the clinical trial.

Changes in regulatory requirements or the FDA's interpretation of those requirements, which may be provided through guidance documents, or the occurrence of unanticipated events during our clinical trials could require us to amend clinical trial protocols, informed consent forms and trial budgets. If we experience delays in initiation, conduct or completion of any of our clinical trials, or if we terminate any of our clinical trials due to changes in regulatory requirements or guidance documents, unexpected and serious adverse events, or other unanticipated events, we may incur additional costs and have difficulty enrolling subjects or achieving clinical investigator or institutional review board acceptance of the changes and successfully completing the trial. Any such additional costs and difficulties could potentially materially harm the commercial prospects for our product candidates and delay our ability to generate product revenue.

There are various uncertainties related to the research, development and commercialization of the cell sheet engineering regenerative medicine products we are developing in collaboration with a strategic partner which could negatively affect our ability to commercialize such products.

We have historically focused on the research and development of our prescription grade L-glutamine treatment for SCD and have limited experience in the research, development or commercialization of cell sheet regenerative medicine products or any other biological product. No clinical trials of cell sheet regenerative products have been conducted in the U.S. and no biological products based on cell sheet engineering have been approved by regulatory authorities in any jurisdiction. Such products must be manufactured in conformance with current cGMP requirements as well as Good Tissue Practice ("GTP") requirements and demonstrate that they are safe, pure and potent to be effective for their intended uses to obtain FDA approval. The GTP requirements, which are specifically applicable to all cellular-based products, are intended to prevent communicable disease transmission. It is uncertain what type and quantity of scientific data would be required to support initiation of clinical studies or to sufficiently demonstrate the safety, purity and potency of cell sheet regenerative medicine products for their intended uses. Such uncertainties could delay our ability to obtain FDA approval for and to commercialize such products. In addition, the research and commercialization of cell sheet regenerative medicine products could be hindered if third-party manufacturers of such products are not compliant with cGMP, GTP, and any other applicable regulations. Any delay in the development of, obtaining FDA approval for, or the occurrence of any problems with third-party manufacturers of cell sheet regenerative medicine products would negatively affect our ability to commercialize such products.

We are subject to numerous complex regulations and failure to comply with these regulations, or the cost of compliance with these regulations, may harm our business.

The research, testing, development, manufacturing, quality control, approval, labeling, packaging, storage, recordkeeping, promotion, advertising, marketing, distribution, possession and use of Endari® are subject to regulation by numerous governmental authorities in the U.S. The FDA regulates drugs under the Federal Food, Drug and Cosmetic Act (the "FDC&A") and implementing regulations. Noncompliance with any applicable regulatory requirements can result in refusal to approve products for marketing, warning letters, product recalls or seizure of products, total or partial suspension of production, prohibitions or limitations on the commercial sale of products or refusal to allow the entering into of federal and state supply contracts, fines, civil penalties and/or criminal prosecution. Additionally, the FDA and comparable governmental authorities have the authority to withdraw product approvals that have been previously granted. Moreover, the regulatory requirements relating to Endari® may change from time to time, and it is impossible to predict what the impact of any such changes may be.

Health care reform measures and changes in policies, funding, staffing and leadership at the FDA and other agencies could hinder or prevent the commercial success of Endari®.

In the U.S., legislative and regulatory changes to the healthcare system could affect our future results of operations and the future results of operations of our potential customers. For example, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established a Part D prescription drug benefit, under which Medicare beneficiaries can obtain prescription drug coverage from private sector plans that are permitted to limit the number of prescription drugs that are covered in each therapeutic category and class on their formularies. If Endari® is not widely included on the formularies of these plans, our ability to market Endari® may be adversely affected.

Furthermore, there have been and continue to be initiatives at the federal and state levels that seek to reduce healthcare costs. In March 2010, President Obama signed into law the Patient Protection and Affordable Health Care Act of 2010, as amended by the Health Care and Education Affordability Reconciliation Act of 2010 (jointly, the "PPACA"), which includes measures to significantly change the way health care is financed by both governmental and private insurers. Among the provisions of the PPACA of importance to the pharmaceutical industry are the following:

- an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23% and 13% of the average manufacturer price for most branded and generic drugs, respectively;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D (the required discount was increased to 70% on January 1, 2019 pursuant to subsequent legislation);
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level, thereby potentially increasing both the volume of sales and manufacturers' Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- new requirements to report certain financial arrangements with physicians and teaching hospitals, as defined in the PPACA and its implementing regulations, including reporting any "transfer of value" made or distributed to teaching hospitals, prescribers, and other healthcare providers and reporting any ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations during the preceding calendar year, with data collection required and reporting to the CMS required by the 90th day of each calendar year;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians;

- expansion of health care fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- a licensure framework for follow-on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- creation of the Independent Payment Advisory Board which, beginning in 2014, will have authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law even if Congress does not act on the recommendations; and
- establishment of a Center for Medicare Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Additionally, individual states have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm out business, results of operations, financial condition and prospects.

In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This may reduce demand for Endari® or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

The commercial success of Endari® will depend, in part, upon the availability of coverage and reimbursement from third-party payors at the federal, state and private levels. Third-party payors include governmental programs such as Medicare or Medicaid, private insurance plans and managed care plans. These third-party payors may deny coverage or reimbursement for a product or therapy in whole or in part if they determine that the product or therapy was not medically appropriate or necessary. Also, third-party payors have attempted to control costs by limiting coverage through the use of formularies and other cost-containment mechanisms and the amount of reimbursement for particular procedures or drug treatments.

Additionally, given recent federal and state government initiatives directed at lowering the total cost of healthcare, Congress and state legislatures will likely continue to focus on healthcare reform, the cost of prescription drugs and the reform of the Medicare and Medicaid programs. While we cannot predict the full outcome of any such legislation, it may result in decreased reimbursement for prescription drugs, which may further exacerbate industry-wide pressure to reduce prescription drug prices. This could harm our ability to market Endari® and generate revenues. In addition, legislation has been introduced in Congress (the Affordable and Safe Prescription Drug Importation Act) that, if enacted, would permit more widespread importation or re-importation of pharmaceutical products from foreign countries into the U.S., including from countries where the products are sold at lower prices than in the U.S. Such legislation, or similar regulatory changes, could lead to a decision to decrease our prices to better compete, which, in turn, could adversely affect our business, results of operations, financial condition and prospects. It is also possible that other legislative proposals having similar effects will be adopted.

Furthermore, regulatory authorities' assessment of the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership. We cannot be sure whether future changes to the regulatory environment will be unfavorable to our business prospects.

If we fail to comply with federal and state healthcare laws, including fraud and abuse and health information privacy and security laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.

As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which constrains out marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, among other things,

soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment from Medicare, Medicaid, or other third-party payors;
- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under the U.S. federal Anti-Kickback Statute, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If we or our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in U.S. federal or state health care programs, and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could materially adversely affect our ability to operate our business and our financial results.

The FDA provides guidelines with respect to appropriate promotion and continuing medical and health education activities. Although we endeavor to follow these guidelines, the FDA or the Office of the Inspector General: U.S. Department of Health and Human Services may disagree, and we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. In addition, management's attention could be diverted, and our reputation could be damaged.

Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be eliminated entirely. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security and fraud laws may prove costly.

Even though we have obtained Orphan Drug designation for Endari®, we may not be able to maintain Orphan Drug marketing exclusivity for this product candidate or any of our other product candidates.

Regulatory authorities in some jurisdictions, including the U.S. and the European Union, may designate therapeutic products under development for relatively small patient populations as "orphan drugs". Under the Orphan Drug Act, the FDA may designate a therapeutic product as an Orphan Drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the U.S. We have obtained Orphan Drug designation from the FDA and Orphan Medicinal designation from the EC for L-glutamine treatment for SCD, and we may seek Orphan Drug designation for our other product candidates. Generally, if a product candidate with an Orphan Drug designation subsequently receives the first marketing approval for the indication for which it has been granted such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA or EC, as applicable, from approving another marketing application for the same product candidate prior to the expiration of that time period. The applicable period is seven years in the U.S. and ten years in the EU. The exclusivity period in the EU can be reduced to six years if the product no longer meets the criteria for Orphan Medicinal designation or if its commercialization is sufficiently profitable so that market exclusivity is no longer justified. Orphan Drug and Orphan Medicinal exclusivity may be lost if the FDA or EC determines that the request for designation was materially defective or if the manufacturer is unable to ensure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. In the U.S., Orphan Drug exclusivity may be lost if another L-glutamine product for the same indication demonstrates clinical superiority, such as a better safety or efficacy profile, in which case the FDA would be permitted to approve the third-party product. Orphan Drug exclusivity does not bar the FDA from approving another L-glutamine product for any other indication. Nor does Orphan Drug designation bar the FDA from granting Orphan

Drug designation and approving another product such as Oxbryta, from Global Blood Therapeutics, Inc. for treating SCD, for the same orphan disease or condition.

Any product candidate for which we obtain marketing approval would be subject to post-marketing regulatory requirements and limitations and could be subject to recall or withdrawal from the market, and we may be subject to penalties if we fail to comply with such regulatory requirements or if we experience unanticipated problems in commercializing any of our product candidates, when and if any of them are approved by regulators.

Any product candidate for which we obtain marketing approval, along with the collection and reporting of post-approval clinical data, manufacturing processes, labeling, advertising and promotional activities for the resulting product, will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and product listing requirements, cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Even if the FDA or other regulators outside the U.S. grant marketing approval to any of our product candidates, the approval may be subject to limitations on the indicated uses for which it may be marketed as a product or to the conditions of approval, including the requirement to implement a risk evaluation and mitigation strategy ("REMS"). If any of our product candidates receives marketing approval, the labeling (including the package insert) that must accompany its distribution as a product may limit its approved use, which could limit the total number of prescriptions written for such products.

In consultation with the FDA, Emmaus is designing clinical studies to generate data in stages to fulfill the post-marketing commitment for the current SCD indication of Endari®. These studies will require additional funding and are designed to include dosing and safety, particularly in those populations not yet given Endari®. On any future products, the FDA may also require additional costly post-marketing studies or clinical trials or surveillance to monitor the safety or effectiveness of any other approved product. The FDA closely regulates the post-approval marketing and promotion of therapeutic products to ensure they are marketed for the approved indications and in accordance with the provisions of the approved labeling, and that any marketing claims or communications by a person or company responsible for the manufacture and distribution of the product regarding off-label use are truthful and not misleading. If we market any of our products for indications that have not been approved in a manner that is considered misleading or not truthful, we may be subject to enforcement action for misbranding the product. Violations of the FDC&A relating to the promotion of prescription products may lead to investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws. In recent years, several pharmaceutical companies have been or settled lawsuits for fined significant amounts for such violations.

In addition, later discovery of previously unknown adverse events or other problems with any of our product candidates that are approved for marketing as products, the contract manufacturers from which we obtain supplies of these products, the manufacturing processes they use to manufacture these products, or our or their failure to comply with regulatory requirements, may have negative consequences, including:

- restrictions on the manufacturers or manufacturing processes for such products;
- restrictions on the labeling or marketing of such products;
- restrictions on distribution or use of such products;
- requirements to conduct post marketing studies or clinical trials;
- warning letters;
- recall or withdrawal of such products from the market;
- refusal to approve pending applications or supplements to approved marketing applications that we submit;
- clinical holds on clinical studies of such products;
- fines, restitution or disgorgement of revenue or profit generated by sales of such products;
- suspension or withdrawal of the marketing approvals of such products;
- refusal to permit the import or export of such products;
- seizure of such products;
- injunctions prohibiting the manufacture, marketing, sale, distribution, or related action in respect of such products;

- the imposition of civil or criminal penalties; and/or
- debarment of our company and any of our officers or other employees responsible for such problems from future dealings with the FDA.

Noncompliance with applicable regulatory requirements regarding safety monitoring, also called pharmacovigilance, and with requirements related to the development of therapeutics for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with applicable regulatory requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of our product candidates and then commercialize them as products and affect the prices we may obtain.

In the U.S. and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payors in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the U.S., the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act ("PPACA"), which intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the PPACA of importance to us are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers and enhanced penalties for noncompliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point of sale discounts off negotiated prices of applicable brand medicines to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's medicines purchased outside a hospital setting to be covered under Medicare Part D;
- extension of a manufacturer's Medicaid rebate liability to covered medicines dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding a new eligibility category for certain individuals with income at or below 133% of the federal poverty level beginning in 2014, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of the entities eligible for discounts under the 340B Public Health Service pharmaceutical pricing program;
- the new requirements under the federal Open Payments program and its implementing regulations;
- a new requirement to annually report samples of medicines that manufacturers and distributors provide to physicians; and
- a new Patient Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. On March 1, 2013, the President signed an executive order implementing the 2% Medicare payment reductions, and on April 1, 2013, these

reductions went into effect. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for any of our products, and, accordingly, our financial operations. Further, there have been multiple attempts through legislative action and legal challenge to repeal or amend the PPACA, and we cannot predict the impact that such a repeal or amendment would have on our business and operations.

On November 20, 2020, the U.S. Department of Health and Human Services published a Final Rule entitled "Removal of Safe Harbor Protection for Rebates to Plans or PBMs Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection," referred to as the Rebate Rule, which amends the discount safe harbor by eliminating protection for price concessions, including rebates, that are offered by pharmaceutical manufacturers to plan sponsors, or pharmacy benefit managers under contract with them, under the Medicare Part D program and Medicare Advantage Plans, unless the price reduction is one required by law. Effective January 1, 2022, in advance of the calendar year 2022 Part D plan year, safe harbor protection will be eliminated for manufacturer rebates paid directly (or indirectly through a pharmacy benefit manager) to Part D prescription drug plans and Medicare Advantage prescription drug plans. Effective December 30, 2020, the Rebate Rule will establish two new safe harbors. The first new safe harbor will protect price reductions paid by manufacturers to prescription drug plans (including prescription drug plans offered by Medicare Advantage organizations) and Medicaid managed care organizations, which are fully reflected at the point-of-sale. The second new safe harbor will protect fair-market-value service fees paid to pharmacy benefit managers by manufacturers. This new rule could result in a change in incentives for health plans and PBMs in negotiating rebates and discounts with manufactures for preferred formulary placement. Because the rule is not yet in effect, at this time we cannot predict how these changes would impact our business and operations.

We expect that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any of our products. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize any of our products.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for prescription medicines. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Risks Related to Our Investment in EJ Holdings, Inc.

EJ Holdings has no revenues and is dependent on us to fund its business and operations, and there is no assurance that we can continue to provide needed funding or that EJ Holdings will be able to continue its activities.

EJ Holdings, Inc., or EJ Holdings, a Japanese corporation 40% owned by us, is engaged in phasing in its amino acid manufacturing plant in Ube, Japan and obtaining regulatory clearances from the FDA and other regulatory agencies for the manufacture of PGLG in accordance with cGMP. EJ Holdings has had no revenues since its inception, has depended on loans from us to acquire the Ube plant and fund its operations and will continue to be dependent on loans from us or other financing unless and until its plant is activated and it can secure customers, including us, for its products. There is no assurance that we can continue to provide needed funding to EJ Holdings, or that needed funding will be available from other sources. EJ Holdings has no commitments or understandings regarding any additional funding. If EJ Holdings fails to obtain needed funding, it may need to suspend activities at the Ube plant. Under the asset purchase agreement by which EJ Holdings purchased the Ube plant, the seller has the right to repurchase the plant at the purchase price, plus certain taxes, paid by EJ Holdings if the plant does not become operational within a reasonable period of time (not to exceed five years). In that event, it is likely that we would lose some or all of our investment in EJ Holdings.

EJ Holdings may not be able to obtain needed financing or repay our loans, and our ownership interest in EJ Holdings may be diluted by additional financing

As of December 31, 2020, we had loaned EJ Holdings a total of $18.6 million, including $4.0 million of loans made pursuant to our written commitment dated October 28, 2020 to loan EJ Holdings a total of up to $6.5 million through the period ending March 31, 2021. Management of EJ Holdings believes such loans will be sufficient to fund its planned activities at the

Ube plant through the first quarter of 2021. It is possible, however, that EJ Holdings will need to secure additional debt financing or issue capital stock to fund such activities. We also anticipate that EJ Holdings will need to incur substantial debt or equity financing to fund the plant's operations once phase in is completed, including, but not limited to, maintaining the physical plant and maintaining regulatory approvals for the manufacture of its products. To the extent EJ Holdings raises additional debt or equity financing, its ability to repay our loans may be adversely affected or our ownership interest may be diluted.

If EJ Holdings fails to reactivate its plant and obtain customers, it may not be able to sell its plant and property and we may lose our investment.

If EJ Holdings fails to reactivate the Ube plant or to secure customers for its products, it may need to sell its plant and property. There is no assurance that it will be able to do so at an attractive price or at all. Our loans to EJ Holdings are general unsecured obligations of EJ Holdings and we have no mortgage or other security interest in the plant or other property of EJ Holdings. Depending on the price at which the plant and property can be sold if it becomes necessary, EJ Holdings may be unable to repay our loans and its other secured or unsecured obligations, and we may lose some or all of our investment in EJ Holdings.

EJ Holdings is subject to risks inherent in a new business and may not be successful.

EJ Holdings was formed in February 2017 for the purpose of acquiring, owning and operating Kyowa's phased-out amino acid manufacturing plant in Ube, Japan. EJ Holdings is engaged in phasing in the plant and obtaining regulatory clearances to reactivate the plant, including FDA and other regulatory approvals for the manufacture of PGLG in accordance with cGMP. EJ Holdings has no operating history, and there is no assurance that it will be successful in bringing the plant online on a timely basis, or at all, or if it does so that it will be able to secure customers for its products or successfully implement its business plan.

We do not control EJ Holdings, and EJ Holdings may engage in activities contrary to our best interests.

JIP owns 60% of EJ Holdings and is entitled to designate a majority of EJ Holdings' board of directors, its Chief Executive Officer and outside auditors, and, as such, controls the management, business and operations of EJ Holdings. It is possible that EJ Holdings will engage in actions or business activities that we believe are inconsistent with the MOU and not in our best interests and that may have an adverse effect on the economic or strategic value of our ownership interest in EJ Holdings.

EJ Holdings retains discretion over its use of any funds that we provide to it.

We do not control EJ Holdings' day-to-day operations. Accordingly, funds provided by us to EJ Holdings may be used by it in any manner its management deems appropriate, including making capital expenditures and paying of salaries and other compensation of its officers and other employees. There is no assurance that EJ Holdings will use our funds in a manner that will enhance the value of our ownership interest in EJ Holdings.

Risks Related to Our Securities

We have been delinquent in our SEC reporting obligations, which has adversely affected the ability of our security holders and prospective investors to have current information regarding our financial statements and status of our business and operations and could lead to the disqualification of our common stock for quotation on the OTC Markets Group, Inc.

We were unable to file with the SEC our Annual Report on Form 10-K for the year ended December 31, 2019 until January 2021 and this Annual Report is being filed after the SEC filing deadline. We also have yet to file our Quarterly Reports on Form 10-Q for 2020 or our Quarterly Report for the quarter ended March 31, 2021. Our failure to timely file our periodic SEC reports has adversely affected the ability of our security holders and prospective investors to have current information regarding our financial statements and status of our business and operations and is likely to have adversely affected the liquidity and trading prices of our common stock. Under applicable rules of the Financial Industry Regulatory Authority, or FINRA, our failure to timely our periodic reports with the SEC may result in the disqualification of our common stock for quotation on the OTC Markets Group, Inc. In such event, there may be no established trading market for our common stock unless and until we are in compliance with our SEC reporting obligations and our common stock once again becomes eligible for quotation on the OTC Markets Group, Inc. or is listed on a national securities exchange.

We have experienced, and may continue to experience, significant volatility in our stock price.

The trading price for our common stock has historically been volatile and traded at higher or lower prices that are seemingly uncorrelated with our results of operations, financial condition or prospects. Between January 1, 2020 and March 31, 2021, the closing sale price of our common stock as reported on the OTC Markets Group, Inc. ranged from a low of $0.72 to a high of $2.16 and may continue to exhibit volatility. Factors such as the following may affect the volatility in our stock price:

- Our ability or inability to timely file periodic reports with the SEC;
- our quarterly operating results;
- marketing approvals or other developments regarding Endari® or competing products;
- announcements of regulatory developments or technological innovations by us or our competitors;
- changes in our relationship with our vendors, distributors or other strategic partners;
- government regulation of drug pricing; and
- developments in patent or other technology ownership rights;

Other factors which may affect our stock price include general economic conditions or changes in the economy, the financial markets or the pharmaceutical or biotechnology industries driven by extraordinary events such as the COVID-19 pandemic. We may be particularly vulnerable to volatility caused by these conditions or events, as we have only a single approved product and have relatively thin trading volume in our stock.

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 was relegated to the OTC Pink tier of the OTC Markets Group, Inc. pending the filing of this Annual Report on Form 10-K and our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2020, June 30, 2020, and September 30, 2020 and 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 purchasing and reselling shares of our common stock.

Our outstanding warrants may result in further dilution to our stockholders.

Certain of our outstanding warrants to purchase a total of up to approximately 3,607,200 shares of our common stock provided for so-called full-ratchet anti-dilution adjustments in the event we sell or issue shares of common stock or common stock equivalents at an effective price less than the then exercise price of such warrants, subject to certain exceptions. These anti-dilution adjustments resulted in a reduction in the conversion price of the debentures and the exercise price of such warrants to $1.54 per share based upon our issuance in February 2021 of $500,000 of shares of our common stock valued at $1.54 per share. We also have outstanding approximately $14.5 million principal amount of convertible promissory notes which are convertible into shares of our common stock at a conversion price of $1.48 per share that is subject to possible future reductions on a quarterly basis in the event the prevailing trading prices of our common stock is less than the then-conversion price. The anti-dilution adjustments our outstanding warrants would be triggered by future issuances by us of shares of our common stock upon conversion of the convertible promissory notes, or otherwise, at a price per share below the then-exercise price of such warrants, which adjustments would have a further dilutive effect on our stockholders.

Stockholders may experience future dilution from future equity offerings.

To raise additional capital in the future we may sell and issue additional shares of our common stock or securities convertible into or exchangeable for our common stock, which sales would have a dilutive effect on the percentage ownership of our existing stockholders.

A substantial number of shares of common stock may be sold in the market, which may depress the market price for our common stock.

Sales of a substantial number of shares of our common stock in the public market, or the possibility such sales upon the exercise or conversion of our outstanding warrants or convertible promissory notes, could cause the market price of our common stock to decline or serve to depress the market price of our common stock. A substantial majority of the outstanding shares of our common stock are, and the shares of common stock issuable upon the exercise of our outstanding warrants and other convertible securities or shares which may be sold in future offerings by us will be, freely tradable without restriction or further registration under the Securities Act.

Out common stock is not traded on a national securities exchange, which may adversely affect our ability to raise needed financing.

The OTC Markets Group, Inc. is not a national securities exchange within the meaning of federal and state securities laws, so our common stock is not eligible for the exemption from state securities, or "blue sky," laws for "covered securities" within the meaning of the National Securities Markets Improvement Act of 1996, which may adversely affect our ability to sell our securities to raise needed financing and increase transactions costs of such financing.

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.

We may issue preferred stock in the future, and the terms of the preferred stock may reduce the value of our common stock.

We are authorized to issue up to 15,000,000 shares of preferred stock in one or more series. Our board of directors may determine the terms of future preferred stock offerings without further action by our stockholders. If we issue preferred stock, it could affect your rights or reduce the value of our outstanding common stock. In particular, specific rights granted to future holders of preferred stock may include voting rights, preferences as to dividends and liquidation, conversion and redemption rights, sinking fund provisions, and restrictions on our ability to merge with or sell our assets to a third party.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

We lease office space under operating leases from unrelated entities. The rent expense during the years ended December 31, 2020 and 2019 was approximately $1,201,000 and $926,000, respectively.

We lease 21,293 square feet of office space for our headquarters in Torrance, California, at a base rental of $79,375 per month, which the lease will expire on September 30, 2026. We also leased an additional 1,850 square feet office space in New York, New York, at a base rent of $8,691 per month, which the lease will expire on January 31, 2023.

In addition, we lease 1,322 square feet of office space in Tokyo, Japan, 465 square feet of office space in Seoul, Korea, and 1,163 square feet of office space in Dubai, UAE, which leases will expire on September 30, 2022, November 29, 2021, and June 19, 2023, respectively.

We believe our existing facilities are adequate for our current and planned future operations, and we expect to be able to renew the leases on commercially reasonable terms.

ITEM 3. LEGAL PROCEEDINGS

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON STOCK, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is quoted on the OTC Pink tier of the OTC Markets Group, Inc. The information reported on the OTC Pink tierefl ect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

	High	Low
Year Ended December 31, 2020		
First Quarter	$ 2.14	$ 0.85
Second Quarter	$ 1.99	$ 1.08
Third Quarter	$ 2.16	$ 0.85
Fourth Quarter	$ 1.36	$ 0.72
Year Ended December 31, 2021		
First Quarter (through March 31, 2021)	$ 1.83	$ 1.19

Holders

As of April 7, 2021, we had approximately 396 stockholders of record.

Dividends

We have never paid cash dividends on our common stock and do not expect to do so in the foreseeable future. The decision whether to pay cash dividends on our common stock will be made by our board of directors in its discretion and will depend on our financial condition, operating results, capital requirements and other factors that the board of directors considers relevant.

Recent Sales of Unregistered Securities

In February and March 2021, we sold and issued approximately $14.5 million in principal amount of convertible promissory notesto a limited number of accredited investors in a private placement pursuant to Rule 4(a)(2) of the Securities Act of 1933, as amended, and Regulation D thereunder.

Commencing one year from the original issue date, the convertible promissory notes will be convertible at the option of the holder into shares of our common stock at an initial conversion price of $1.48 per share, which equaled the "Average VWAP" (as defined) of our common stock on the effective date. The initial conversion price is subject to adjustment as of the end of each three-month period following the original issue date, commencing May 31, 2021, to equal the Average VWAP as of the end of such three-month period if such Average VWAP is less than the then-conversion price. The conversion price is subject to further adjustment in the event of a stock split, reverse stock split or certain other events specified in the convertible promissory notes.

The convertible promissory notes bear interest at the rate of 2% per annum payable semi-annually on the last business day of August and January of each year and will mature on the 3rd anniversary of the original issue date. The convertible promissory notes will become prepayable in whole or in part at the election of the holders on and after February 28, 2022 if our common shall not have been approved for listing on the NYSE American, the Nasdaq Capital Market or other "Trading Market" (as defined). We will be entitled to prepay up to 50% of the principal amount of the convertible promissory notes at any time after the 1st anniversary and on or before the 2nd anniversary of the original issue date for a prepayment amount equal to the principal amount being prepaid, accrued and unpaid interest thereon and a prepayment premium equal to 50% of such principal amount. The convertible promissory notes are general, unsecured obligations of the company.

The net proceeds of the sale of the convertible promissory notes will be used for working capital and general corporate purposes, which may include repayment of indebtedness.

Additional Information

Copies of our annual reports, quarterly reports, current reports, and any amendments to those reports are available free of charge on the Internet at www.sec.gov and on our website at www.emmausmedical.com. Such reports are not part of this Annual Report or incorporated by reference herein. All statements made in any of our reports, including all forward-looking statements, are made as of the date of such reports and we do not assume or undertake any obligation to update any of those statements or documents, except as required by law.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

Not required for a smaller reporting company

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Forward-Looking Statements

The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and the related notes, and the other financial information included in this Annual Report. This discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth under "Risk Factors" or in other parts of this Annual Report.

Company Overview

We are a commercial-stage biopharmaceutical company engaged in the discovery, development, marketing and sale of innovative treatments and therapies, primarily for rare and orphan diseases. On July 7, 2017, the U.S. Food and Drug Administration, or FDA, approved our lead product, Endari® (prescription-grade L-glutamine oral powder), to reduce the severe complications of sickle cell disease ("SCD") in adult and pediatric patients five years of age and older. Endari® has received Orphan Drug designation from the FDA and Orphan Medical designation from the European Commission, which designations afford marketing exclusivity for Endari® for a seven-year period in the U.S. and ten-year period in the European Union, respectively, following marketing approval.

We commenced commercialization of Endari® in the U.S. in January 2018 in collaboration with a contract sales organization. Effective January 2020, we have relied upon our in-house commercial sales team. Endari® is reimbursable by the Centers for Medicare and Medicaid Services, and every state provides coverage for Endari® for outpatient prescriptions to all eligible Medicaid enrollees within their state Medicaid programs. Endari® is also reimbursable by many commercial payors. We have distribution agreements in place with the nation's leading distributors as well as physician group purchasing organizations and pharmacy benefits managers, making Endari® available at selected pharmacies nationwide.

Until we began marketing and selling Endari® in the U.S. in early 2018, we had minimal revenues and relied upon funding from sales of equity securities and debt financings and loans, including loans from related parties to fund our business and operations. As of December 31, 2020, our accumulated deficit was $225.3 million, and we had cash and cash equivalents of $2.5 million. We expect net revenues to increase as we expand our commercialization of Endari® in the U.S. and expand or commence early access programs and eventual marketing and commercialization abroad.

Until we can generate sufficient net revenues, our future cash requirements are expected to be financed through public or private equity or debt financings, loans or corporate collaboration and licensing arrangements. While our operating loss declined significantly to $32,000 in 2020 compared to $4.5 million in 2019, we are unable to predict if or when we will become profitable.

As reported in more detail in our Current Report on Form 8-K filed with the SEC on July 22, 2019, as amended by our Form 8-K/A filed on August 14, 2019, on July 17, 2019, we completed our merger transaction with EMI Holding, Inc., formerly known as Emmaus Life Sciences, Inc. ("EMI"), in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of January 4, 2019, among us, Athena Merger Subsidiary, Inc., and EMI, as amended by Amendment No. 1 thereto, dated as of May 10, 2019, which we refer to as the merger agreement. Pursuant to the merger agreement, Athena Merger Subsidiary, Inc. merged into EMI, with EMI surviving as our wholly owned subsidiary. On July 17, 2019, immediately after completion of the merger, we changed our name to "Emmaus Life Sciences, Inc."

The merger was treated as a reverse recapitalization transaction under the acquisition method of accounting in accordance with accounting principles generally accepted in the U.S. For accounting purposes, EMI is considered to have acquired us. The merger is intended to qualify as a tax-free reorganization for U.S. federal income tax purposes.

Critical Accounting Policies

Management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States ("GAAP"). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses. On an ongoing basis, we evaluate these estimates and judgments, including those described below. We base our estimates on our historical experience and on various other assumptions that we believe to be

reasonable under the present circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates.

While our significant accounting policies are more fully described in Note 2 of the Notes to Financial Statements included in this Annual Report, we believe that the following accounting policies are the most critical to assist you in fully understanding and evaluating our reported financial results and affect the more significant judgments and estimates that we use in the preparation of our financial statements.

Financial Overview

Revenues, net

Since January 2018, we have generated net revenues primarily through the sale of Endari® as a treatment for SCD.

Net revenues from Endari® sales are recognized upon transfer to our distributors and specialty pharmacy providers. Distributors resell our products to other pharmacy and specialty pharmacy providers, health care providers, hospitals, and clinics. In addition to agreements with these distributors, we have entered into contractual arrangements with specialty pharmacy providers, in-office dispensing providers, physician group purchasing organizations, pharmacy benefits managers and government entities that provide for government-mandated or privately negotiated rebates, chargebacks and discounts with respect to the purchase of our products. These various discounts, rebates, and chargebacks are referred to as "variable consideration." Revenue from product sales is recorded net of variable consideration.

Under the Accounting Standards Codification ("ASC") 606, the Company recognizes revenue when its customers obtain control of the Company's product, which typically occurs on delivery. Revenue is recognized in an amount that reflects the consideration that the Company expects to receive in exchange for the product, or transaction price. To determine revenue recognition for contracts with customers within the scope of ASC 606, the Company performs the following: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the Company's performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies the relevant performance obligations.

Revenue from product sales is recorded at the transaction price, net of estimates for variable consideration consisting of sales discounts, returns, government rebates, chargebacks and commercial discounts. Variable consideration is estimated using the expected-value amount method, which is the sum of probability-weighted amounts in a range of possible transaction prices. Actual variable consideration may differ from the Company's estimates. If actual results vary from the Company's estimates, the Company adjusts the variable consideration in the period such variances become known, which would affect net revenues in that period. The following are our significant categories of variable consideration:

Sales Discounts: We provide our customers prompt payment discounts and from time to time offer additional discounts to encourage bulk orders to generate needed working capital. Sales attributable to one-time discounts offered by us increased in 2020 over 2019 and may adversely affect sales in subsequent periods.

Product Returns: We offer our distributors a right to return product principally based upon (i) overstocks, (ii) inactive product or non-moving product due to market conditions, and (iii) expired product. Product return allowances are estimated and recorded at the time of sale.

Government Rebates: We are subject to discount obligations under state Medicaid programs and the Medicare Part D prescription drug coverage gap program. We estimate Medicaid and Medicare Part D prescription drug coverage gap rebates based upon a range of possible outcomes that are probability-weighted for the estimated payor mix. These reserves are recorded in the same period the related revenues are recognized, resulting in a reduction of product revenues and the establishment of a current liability that is included as accounts payable and accrued expenses on our balance sheet. Our liability for these rebates consists primarily of estimates of claims expected to be received in future periods related to recognized revenues.

Chargebacks and Discounts: Chargebacks for fees and discounts represent the estimated obligations resulting from contractual commitments to sell products to certain specialty pharmacy providers, in-office dispensing providers, group purchasing organizations, and government entities at prices lower than the list prices charged to distributors. The distributors charge us for the difference between what they pay for the products and our contracted selling price to these specialty pharmacy providers, in-office dispensing providers, group purchasing organizations, and government entities. In addition, we have contractual agreements with pharmacy benefit managers who charge us for rebates and administrative fee in connection with

the utilization of product. These reserves are established in the same period that the related revenues are recognized, resulting in a reduction of revenues. Chargeback amounts are generally determined at the time of resale of product by our distributors.

Cost of Goods Sold

Cost of goods sold consists primarily of expenses for raw materials, packaging, shipping and distribution of Endari®.

Research and Development Expenses

Research and development expenses consist of expenditures for new products and technologies consisting primarily of fees paid to contract research organizations ("CRO") that conduct clinical trials of our product candidates, payroll-related expenses, study site payments, consultant fees and activities related to regulatory filings, manufacturing development costs and other related costs. The costs of later stage clinical studies such as Phase 2 and 3 trials are generally higher than those of earlier studies. This is primarily due to the larger size, expanded scope, patient related healthcare and regulatory compliance costs, and generally longer duration of later stage clinical studies.

Our contracts with CROs are generally based on time and materials expended, whereas study site agreements are generally based on costs per patient as well as other pass-through costs, including start-up costs and institutional review board fees. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones.

Future research and development expenses will depend on any new product candidates or technologies that we may introduce into our research and development pipeline. In addition, we cannot predict which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree, if any, such arrangements would affect our development plans and capital requirements.

Due to the inherently unpredictable nature of the drug approval process and the interpretation of the regulatory requirements, we are unable to estimate the amount of costs of obtaining regulatory approval of Endari® outside of the U.S. or the development of our other preclinical and clinical programs. Clinical development timelines, the probability of success and development costs can differ materially from expectations and can vary widely. These and other risks and uncertainties relating to product development are described in this Annual Report under the headings "Risk Factors—Risks Related to Our Business" and "Risk Factors—Risks Related to Regulatory Oversight of our Business and Compliance with Law."

General and Administrative Expense

General and administrative expense consists principally of salaries and related employee costs, including share-based compensation for our directors, executive officers and employees. Other general and administrative expense includes facility costs, patent filing costs, and professional fees and expenses for legal, consulting, auditing and tax services. Inflation has not had a material impact on our general and administrative expense over the past two years.

Selling Expenses

Selling expenses consist principally of salaries and related costs for personnel involved in the launch, promotion, sales and marketing of our products. Other selling cost include advertising, third party consulting costs, the cost of contracted and in-house sales personnel and travel-related costs. We expect selling expenses to increase as we acquire additional sales personnel to support the commercialization of Endari® in the U.S. and abroad.

Environmental Expenses

The cost of compliance with environmental laws has not been material over the past two years and any such costs are included in general and administrative costs.

Inventories

Inventories consist of raw materials, finished goods and work-in-process and are valued on a first-in, first-out basis and at the lower of cost or net realizable value. Substantially all raw materials purchased during the years ended December 31, 2020 and 2019 were supplied by one vendor.

Notes Payable, Convertible Notes Payable and Warrants

From time to time, we obtain financing in the form of notes payable or promissory notes with detachable warrants, some of which are convertible into shares of our common stock and some of which are issued to related parties. We analyze all of the terms of our notes payable and promissory notes issued with warrants to determine the appropriate accounting treatment, including determining whether conversion features are required to be bifurcated and treated as a discount, allocation of fair value of the issuance to the debt instrument, detachable stock purchase warrant, and any beneficial conversion features, and the applicable classification of the notes payable and warrants as debt, derivative liabilities, equity or temporary equity (i.e., mezzanine capital).

We allocate the proceeds from the issuance of debt instruments with detachable stock purchase warrants to the two elements based on the relative fair values of the debt instruments without the warrants and of the warrants themselves at the time of issuance. We account for the portion of the proceeds allocated to warrants in additional paid-in capital and the remaining proceeds are allocated to the debt instruments. The allocation to warrants results in a discount to notes payable which is amortized using the effective interest method to interest expense over the expected term of the note. We also include the intrinsic value of the embedded conversion feature of convertible debentures and promissory notes in the discount to notes payable, which is amortized and charged to interest expense over the expected term of the debentures and promissory notes.

We also estimate the total value of any beneficial conversion feature and accompanying warrants in allocating debt proceeds. The proceeds allocated to the beneficial conversion feature are determined by taking the estimated fair value of shares issuable under the convertible debentures and promissory notes less the fair value of the number of shares that would be issued if the conversion rate equaled the fair value of our common stock as of the date of issuance. In situations where the debt includes both a beneficial conversion feature and a warrant, the proceeds are allocated to the warrants and beneficial conversion feature based on the pro-rata fair value. We used the Binomial Monte-Carlo Cliquet (aka Ratchet) Option Pricing Model option pricing model to determine the fair value of our warrants prior to the Merger and Black-Scholes after the Merger.

Notes payable to related parties, interest expense and accrued interest to related parties are separately identified in our consolidated financial statements. We also disclose significant terms of all transactions with related parties.

Share-based Compensation

We recognize compensation expense for share-based compensation awards during the service term of the recipients of the awards. The fair value of share-based awards is calculated using the Black-Scholes-Merton pricing model. The Black-Scholes-Merton model requires subjective assumptions regarding future stock price volatility and expected time to exercise, which greatly affect the calculated values. The expected term of awards granted is calculated using the simplified method allowed under the Securities and Exchange Commission (“SEC”) Staff Accounting Bulletin Nos. 107 and 110. The risk-free rate used to value an award is based on the U.S. Treasury rate as of the date of the award that corresponds to the vesting period of the award. Until July 2019, as the accounting acquirer in the Merger, our common stock was not publicly traded and we lacked company specific historical and implied volatility information for our common stock. Therefore, the expected volatility was based on the historical volatility of the common stock of comparable publicly traded companies.

Fair Value Measurements

We define fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date in accordance with ASC 820. We measure fair value under a framework that provides a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are described as follows:

Level 1: Inputs to the valuation methodology are unadjusted quoted prices for identical assets or liabilities in active markets.

Level 2: Inputs to the valuation methodology include:

- Quoted prices for similar assets or liabilities in active markets;

- Quoted prices for identical or similar assets or liabilities in inactive markets;
- Inputs other than quoted prices that are observable for the asset or liability; and
- Inputs that are derived principally from or corroborated by observable market data by correlation or other means.

If the asset or liability has a specified (contractual) term, the Level 2 input must be observable for substantially the full term of the asset or liability.

Level 3: Inputs to the valuation methodology that are unobservable and significant to the fair value measurement.

An asset's or liability's fair value measurement level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. Valuation techniques used need to maximize the use of observable inputs and minimize the use of unobservable inputs. The fair value of marketable securities is determined based upon quoted prices on nationally recognized securities exchanges and are classified as Level 1 investments at December 31, 2019. The fair value of our debt instruments is not materially different from their carrying values as presented. The fair value of our convertible debt instruments was determined based on Level 2 inputs. The carrying value of the debt was discounted based on allocating proceeds to other financial instruments within the arrangement as discussed in Note 7 to our consolidated financial statements.

Certain of our outstanding warrants contain net cash settlement provision and, consequently, are accounted for as liabilities that are remeasured at fair value on a recurring basis using Level 3 inputs. The Level 3 inputs in the valuation of warrants include expected term and expected volatility.

Marketable Securities

Marketable securities are recorded at fair value using the quoted market prices and changes in fair value are recorded as net realized gains or losses in comprehensive income. We monitor these investments for impairment and make appropriate reductions in carrying values as necessary.

Financial Highlights

	Twelve Months Ended December 31,	
	2020	2019
CONSOLIDATED STATEMENTS OF OPERATIONS (in thousands)		
REVENUES, NET	$ 23,167	$ 22,752
COST OF GOODS SOLD	2,248	1,094
GROSS PROFIT	20,919	21,658
OPERATING EXPENSES		
Research and development	2,408	2,183
Selling	4,865	6,975
General and administrative	13,678	17,012
Total operating expenses	20,951	26,170
LOSS FROM OPERATIONS	(32)	(4,512)
OTHER INCOME (EXPENSE)		
Loss on debt extinguishment	(1,425)	(438)
Change in fair value of warrant derivative liabilities	392	3,545
Change in fair value of embedded conversion option	112	131
Net gain (loss) on investment in marketable securities	7,672	(21,947)
Net loss on equity method investment	(2,060)	(414)
Miscellaneous reverse merger costs	—	(309)
Notes conversion costs	—	(3,341)
Interest and other income	2,303	232
Interest expense	(5,989)	(27,625)
Total other income (expenses)	1,005	(50,166)
INCOME (LOSS) BEFORE INCOME TAXES	973	(54,678)
INCOME TAXES (BENEFIT)	(381)	164
NET INCOME (LOSS)	$ 1,354	$ (54,842)
EARNINGS (LOSS) PER COMMON SHARE	$ 0.03	$ (1.30)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING	48,897,004	42,259,460

Years ended December 31, 2020 and 2019

Net Income (Loss). Net income was $1.4 million for the year ended December 31, 2020 compared to a net loss of $54.8 million for the year ended December 31, 2019, representing an increase of $56.2 million, or 102%. The increase in net income was due primarily to a $51.2 million increase in other income and a $5.2 million decrease in operating expenses, as discussed below. As of December 31, 2020, we had an accumulated deficit of approximately $225.1 million. Our net income for the year ended December 31, 2020 included approximately $2.1 million of net loss on equity method investment attributable to our equity interest in EJ Holdings, a variable interest entity, or VIE. The loss attributable to our equity interest in EJ Holdings for the year ended December 31, 2019 was insignificant.

Revenues, Net. Net revenues increased by $0.4 million, or 2% to $23.2 million for the year ended December 31, 2020 compared to 2019. Substantially all net revenues were attributable to Endari® sales. The increase was due to higher volume sales of Endari® in 2020 partially offset by a higher level of price discounts related to large volume orders in 2020 than in 2019. We expect net revenues to increase as we expand commercialization of Endari® in the U.S. and abroad.

Cost of Goods Sold. Cost of goods sold increased by $1.2 million, or 105% to $2.2 million for the year ended December 31, 2020 compared to 2019 as net revenues increased and we established a reserve relating to Endari® inventory with a shelf-life less than two years.

Research and Development Expenses. Research and development expenses increased by $0.2 million, or10%, to $2.4 million for the year ended December 31, 2020 compared to 2019. This increase was primarily due to an increase in expenses related to our Pilot/Phase 1 diverticulosis study. We expect our research and development costs to increase as the study progresses and as we undertake additional studies.

Selling Expenses. Selling expenses decreased by $2.1 million, or 30%, to $4.9 million for the year ended December 31, 2020 compared to 2019. The decrease was primarily due to a decrease of $4.2 million in contract sales organization fees and $0.5 million in other marketing activities including consulting expenses, public relations, and sponsorships for Endari® partially offset by an increase of $2.7 million in in-house sales team compensation as we have relied on our in-house commercial team for marketing and sales of Endari® in the US since January 2020.

General and Administrative Expenses. General and administrative expense decreased $3.3 million, or 20%, to $13.7 million for the year ended December 31, 2020 compared to 2019. The decrease was primarily due to a decrease of $3.0 million in stock compensation expense, including $2.4 million of one-time expenses attributable to stock option modifications relating to the merger transaction in 2019. We expect on-going general and administrative expenses to remain substantially the same for the foreseeable future.

Other Income and Expense. Total other income increased by $51.2 million, or 102%, to $1.0 million for the year ended December 31, 2020 compared to total other expenses of $50.2 million in 2019. The increase was primarily due to a $21.6 million decrease in interest expense in 2020, a net gain on investment in marketable securities of $7.6 million in 2020 compared to net loss of $21.9 million in 2019 and a $2.1 million increase in interest and other income.

Seasonality

There may be seasonal variations in our Endari® sales due to factors such as year-end holidays, severe winter weather conditions in certain regions of the U.S., seasonal conditions that may affect medical practices and provider activity, including influenza or the Covid-19 outbreaks that may inhibit patients from seeking treatment for their SCD or filling or refilling prescriptions for Endari® and possibly other factors relating to the timing of patient deductibles and co-insurance limits.

Inflation

We do not believe that inflation and changing prices have had a significant impact on our results of operations.

COVID-19

We do not believe that the COVID-19 pandemic and related governmental response have had a significant impact on our financial condition or results of operations.

Liquidity and Capital Resources

Although we realized net income of $1.1 million for the year ended December 31, 2020, the majority of net income was driven by non-operating activities. We anticipate that we will incur net losses for the foreseeable future until we can generate increased net revenues from Endari® sales. Based on anticipated future revenues and operating expenses, cash and cash equivalents of $2.5 million as of December 31, 2020, and the remaining net proceeds from the recent sale of convertible promissory notes, we believe our working capital is sufficient to meet our needs through at least the second quarter of 2022. If future revenues are less than anticipated or we incur more expenses than we anticipate, we may not have sufficient operating capital for our business without curtailing certain operations or raising additional capital. Except as described below, we have no understanding or arrangements with respect to future financings, and there can be no assurance of the availability of such capital on terms acceptable to us or at all.

On February 28, 2020, we entered into a Purchase Agreement with Lincoln Park Capital Fund, LLC ("LPC"), pursuant to which we may elect to sell to LPC up to $25,000,000 in shares of our common stock, subject to certain limitations and conditions set forth in the Purchase Agreement from time to time over the 36-month term of the Purchase Agreement. As of the date of filing of this Amended Annual Report, we are out of compliance with certain terms and conditions of the Purchase Agreement and unable to utilize the Purchase Agreement. We intend to seek to bring the Company into compliance or seek an appropriate waiver from LPC to regain our ability to utilize the Purchase Agreement, but there can be no assurance when or whether we may be able to do so.

Effective February 22, 2021, our subsidiary, Emmaus Medical, Inc., or Emmaus Medical, entered into a purchase and sale agreement with Prestige Capital Finance, LLC, or Prestige Capital, pursuant to which Emmaus Medical may offer and sell to Prestige Capital from time to time eligible accounts receivable in exchange for Prestige Capital's down payment, or advance, to Emmaus Medical of 70% (subject to increase to 75%) of the face amount of the accounts receivable, subject to a $7,500,000 cap on advances at any time. The balance of the face amount of the accounts receivable will be reserved by Prestige Capital and paid to Emmaus Medical, less discount fees of Prestige Capital ranging from 2.25% to 7.25% of the face amount, as and when

Prestige Capital collects the entire face amount of the accounts receivable. In March 2021, we completed our first transaction under the purchase and sale agreement.

Cash Flows

Net cash used in operating activities

Net cash used in operating activities decreased by $2.1 million, or 45.8% to $ 2.5 million for the year ended December 31, 2020 from $4.5 million for the year ended December 31, 2019. The decrease was primarily due to decrease in loss from operations from $4.5 million to $32,000 which was partially offset by increases in non-cash expenses included in the loss from operations.

Net cash provided by (used in) investing activities

Net cash provided by investing activities increased by $7.0 million, or 469%, to a positive $5.5 million for the year ended December 31, 2020 from a negative $1.5 million for the year ended December 31, 2019. The increase was primarily due to $35.6 million of proceeds from the sale of Telcon shares partially offset by a decrease of $26.1 million of purchase of a Telcon convertible bond and $4.0 million of additional loans made to EJ Holding, our equity method investee.

Net cash from financing activities

Net cash from financing activities decreased by $6.2 million, or 160%, to a negative $2.3 million for the year ended December 31, 2020 from a positive $3.9 million for the year ended December 31, 2019 primarily as a result of a $8.4 million decrease in cash proceeds from the issuance of common stock and a $1.8 million decrease in cash used for repayment of convertible notes.

Off-Balance-Sheet Arrangements

We had no off-balance sheet arrangements in the periods presented.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not required for a smaller reporting company.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this Item 8 is incorporated by reference to the information that begins on Page F-1 of this Annual Report.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We are responsible for establishing and maintaining disclosure controls and procedures ("DCP") that are designed to ensure that information required to be disclosed by us in the reports filed by us under the Exchange Act is: (a) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms; and (b) accumulated and communicated to our management, including our principal executive and principal financial officers, to allow timely decisions regarding required disclosures. In designing and evaluating our DCP, we recognize that any controls and procedures, no matter how well designed and implemented, can provide only reasonable assurance of achieving the desired control objectives.

We conducted an evaluation pursuant to Rule 13a-15 of the Exchange Act of the effectiveness of the design and operation of our DCP as of December 31, 2020. This evaluation was conducted under the supervision (and with the participation) of our management, including our Chief Executive Officer and Interim Chief Financial Officer. Based on that evaluation, our Chief Executive Officer and Interim Chief Financial Officer concluded that our DCP were not effective as of December 31, 2020, because of the continuance of a material weakness (the "Material Weakness") in our internal control over financial reporting due to inadequate application of generally accepted accounting principles (GAAP) in the United States of America on certain complex transactions, inadequate financial closing process, timely filing of periodic and annual financial statements, segregation of duties including access control of information technology especially financial information, inadequate documentation of policies and procedures over risk assessments, internal control and significant account process and insufficient entity risk assessment process. Notwithstanding the Material Weakness, our management concluded that our consolidated financial statements for the periods covered by and included in this Annual Report are fairly stated in all material respects in accordance with GAAP for each of the periods presented in this Annual Report.

We committed to remediating the control deficiencies that constituted the Material Weakness by implementing changes to our internal control over financial reporting. In 2018, we began to implement measures designed to remediate the underlying causes of the control deficiencies that gave rise to the Material Weakness, including, without limitation:

- engaging third-party accounting consulting firms to assist us in the review of our application of GAAP on complex debt financing transactions and revenue recognition under ASC 606;
- using GAAP Disclosure and SEC Reporting Checklists;
- increasing the continuing professional training and academic education on accounting subjects for accounting staff;
- enhancing the level of the precision of review controls related to our financial close and reporting; and
- engaging other supplemental internal and external resources.

Our management concluded that, as of December 31, 2020, we had not completed all the corrective measures that are necessary to remediate entirely the Material Weakness.

Management's Plan for Remediation

Our management and board of directors are committed to the remediation of the Material Weakness, as well as the continued improvement of our overall system of internal control over financial reporting. We are in the process of implementing measures to remediate the underlying causes of the control deficiency that gave rise to the Material Weakness, which primarily include engaging additional and supplemental internal and external resources with the technical expertise in GAAP to ensure the appropriate accounting treatment for complex and unusual transactions involving options, convertible securities and other financial instruments and intend to seek to hire a permanent Chief Financial Officer with expertise and experience in GAAP to support our financial department, as well as to implement new policies and procedures to provide more effective controls to track, process, analyze, and consolidate the financial data and reports. We also intend to consider upgrading our financial accounting systems and software as our finances permit. Further, we are in the process of reviewing plans to establish a Disclosure Committee to ensure more effective internal communication of significant transactions.

We believe these measures will remediate the control deficiencies that gave rise to a Material Weakness. As we continue to evaluate and work to remediate these control deficiencies, we may determine that additional measures may be required.

We are committed to maintaining a strong internal control environment and believe that these remediation actions will represent improvements in our internal control over financial reporting when they are fully implemented. The Material Weakness will not be considered fully remediated until controls have been designed and implemented for a sufficient period of time for our management to conclude that the control environment is operating effectively. Additional remediation measures may be required, which may require additional implementation time. We will continue to assess the effectiveness of our remediation efforts in connection with our evaluation of our internal control over financial reporting and DCP.

As we continue to evaluate and work to remediate the Material Weakness and enhance our internal control over financial reporting and DCP, we may determine that we need to modify or otherwise adjust the remediation measures described above. As a result, we cannot assure you that our remediation efforts will be successful or that our internal control over financial reporting or DCP will be effective.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles in the United States of America. Our internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and our dispositions of the assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Under the supervision and with the participation of our management, including our Chief Executive Officer and Interim Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the criteria set forth in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management concluded that our internal control over financial reporting was not effective as of December 31, 2020.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected on a timely basis. In conducting our review of our internal control over financial reporting, we identified the continuing Material Weakness described above.

Attestation Report

This Annual Report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. We are not subject to the attestation requirement because we are a non-accelerated filer.

Changes in Internal Control Over Financial Reporting

Except as described above, based on the evaluation of our management as required by paragraph (d) of Rule 13a-15 of the Exchange Act, we believe that there were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Compensatory Arrangement with CEO

On April 21, 2021, at the recommendation of the Compensation Committee of our board of directors, our board approved a one-year extension of a warrant to purchase 1,365,189 shares of our common stock at an exercise price of $4.76 a share held by Yutaka Niihara, M.D., M.P.H, our Chairman and Chief Executive Officer. No other changes were made to the warrant, which was granted to Dr. Niihara in 2016 and would have expired on May 9, 2021 absent the amendment.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors and Executive Officers

The following individuals constitute our board of directors and executive officers:

Name	Age	Position
Yutaka Niihara, M.D., M.P.H.	61	Chairman and Chief Executive Officer
Willis C. Lee	60	Director, Chief Operating Officer
Yasushi Nagasaki, C.P.A.	53	Interim Chief Financial Officer
Ian Zwicker	73	Director
Masaharu Osato, M.D.	66	Director
Wei Peu Zen	68	Director
Robert Dickey IV	65	Director
Jane Pine Wood	58	Director

Background of Officers and Directors

The following is a summary of the background of each of our directors and executive officers. Except as noted in their respective biographies below, each of our directors and officers became a director or officer as of the completion of our merger transaction with EMI Holding, Inc., or EMI Holding, on July 17, 2019. All directors serve until the next annual meeting of stockholders at which their successor is elected or their earlier resignation or removal as a director. One or more of our directors or officers also serve as directors or officers of one or more of our wholly owned subsidiaries.

Yutaka Niihara, M.D., M.P.H. served as Chairman and Chief Executive Officer since January 2016, as Chief Scientific Officer from April 2015 until December 2015, as President and Chief Executive Officer from April 2011 to April 2015 and as a director since April 2011 of EMI Holding, and as a director of EMI Holding's predecessor, Emmaus Medical, from 2003 to April 2011. Since May 2005, Dr. Niihara has also served as the President, Chief Executive Officer and Medical Director of Hope International Hospice, Inc., or Hope Hospice, a Medicare-certified hospice program. From June 1992 to October 2009, Dr. Niihara served as a physician specialist for Los Angeles County. Dr. Niihara is the principal inventor of the patented L-glutamine treatment for SCD. Dr. Niihara has been involved in patient care and research for sickle cell disease during most of his career and is a widely published author in the area of sickle cell disease. Dr. Niihara is board-certified by the American Board of Internal Medicine/Medical Oncology and by the American Board of Internal Medicine/Hematology. He is licensed to practice medicine in both the United States and Japan. Dr. Niihara is a Professor of Medicine at the David Geffen School of Medicine at UCLA. Dr. Niihara a holds B.A. degree in Religion from Loma Linda University, a M.D. degree from the Loma Linda University School of Medicine and a M.P.H. degree from Harvard School of Public Health. We believe Dr. Niihara is qualified to serve as a director due to his critical involvement in the research and development of Endari® and extensive knowledge and experience in treating sickle cell disease in the primary care setting.

Willis C. Lee, M.S. served as Chief Operating Officer since May 2011, as a director since December 2015, as Vice-Chairman of the board of directors since January 2016 and as Chief Financial Officer from October 2016 to July 2018 of EMI Holding. Mr. Lee also previously served as a director of EMI Holding from May 2011 to May 2014 and again from to December 2015 to January 2016. Mr. Lee served as the Co-Chief Operating Officer and Chief Financial Officer and as a director of Emmaus Medical from March 2010 to May 2011. Prior to that time, he was the Controller at Emmaus Medical from February 2009 to February 2010. From 2004 to 2010, Mr. Lee led worldwide sales and business development of Yield Dynamics product group at MKS Instruments, Inc., a provider of instruments, subsystems, and process control solutions for the semiconductor, flat panel display, solar cell, data storage media, medical equipment, pharmaceutical manufacturing, and energy generation and environmental monitoring industries. Prior to that time, Mr. Lee held various managerial and senior positions at various public and private companies in the semiconductor and other industries. Mr. Lee received his B.S. degree and a M.S. degree in Physics from University of Hawaii and University of South Carolina, respectively. We believe Mr. Lee is qualified to serve as a director due to his extensive knowledge and experience, as well as his intimate knowledge of the company through his service as an executive officer of the company and Emmaus Medical.

Yasushi Nagasaki, C.P.A. has served as our Interim Chief Financial Officer since September 1, 2020 and as Senior Vice President Finance from July 2019 to August 2020. Mr. Nagasaki also served as Senior Vice President Finance from April 2012 to July 2019 and as Chief Financial Officer from May 2011 to April 2012 of EMI Holding. From September 2005 until joining EMI Holding, Mr. Nagasaki was the Chief Financial Officer of Hexadyne Corporation, an aerospace and

defense supplier. Mr. Nagasaki also served on the board of directors at Hexadyne Corporation from September 2005 to April 2011. From May 2003 to August 2005, Mr. Nagasaki was the Controller at Upsilon Intertech Corporation, an international distributor of defense and aerospace parts and sub systems. Mr. Nagasaki is a Certified Public Accountant and received a B.A. in Commerce from Waseda University and a M.A. in International Policy Studies from the Monterey Institute of International Studies, a graduate school of Middlebury College.

Ian Zwicker is the founder of Zwicker Advisory Group and has been its Chief Executive Officer since 2014. From 1981 to 1990, Mr. Zwicker served as Managing Director and held a variety of management positions at the investment banking firms of SG Cowen and Hambrecht & Quist. From 1990 to 1999, Mr. Zwicker served as Managing Director and head of worldwide technology investment banking for Donaldson, Lufkin & Jenrette Securities Corporation, and from 2000 to 2001 as the President of WR Hambrecht + Co (WRH). He was a member of the board of directors of Stirling Energy Systems, Inc. from 2006 to 2012. Mr. Zwicker was a Partner at WRH and was also Head of Capital Markets from 2013 to 2014. We believe Mr. Zwicker is qualified to serve as a director due to his executive experience and business expertise in the investment banking industry and as a former director of a public company.

Masaharu Osato, M.D. has been practicing gastroenterology and internal medicine ("GI") at his private practice, the Osato Medical Clinic, Inc. in Torrance, CA, since 2001. Between 1998 and 2001 he completed a GI Fellowship at the Harbor-UCLA Medical Center. Between 1993 and 1997 and 1988 and 1993, respectively, Dr. Osato served as General Internist and Director of Health Screening Center at the Tokyo Adventist Hospital in Tokyo, Japan, and at the Kobe Adventist Hospital in Kobe, Japan. He attended the Loma Linda University School of Medicine in California between 1979 and 1983 and completed an internal medicine residency at the Kettering Memorial Medical Center at Wright State University between 1983 and 1986. Between 1986 and 1988 he completed a pediatric residency at the Loma Linda University Medical Center. We believe Dr. Osato is qualified to serve as a director due to his extensive knowledge of and experience in the GI sector.

Wei Peu Zen is Vice Chairman and Chief Executive Officer of Wai Kee Holdings Limited, a Hong Kong-based construction and infrastructure company whose shares are listed on the Main Board of Hong Kong Stock Exchange. He is also the Chairman, Chief Executive Officer and Managing Director of Build King Holdings Limited, a subsidiary of Wai Kee Holdings Limited. In addition, he is the Co-Chairman of Road King Infrastructure Limited, an associated corporation of Wai Kee Holdings Limited. The shares of both Build King Holdings Limited and Road King Infrastructure Limited are listed on the Main Board of Hong Kong Stock Exchange. Mr. Zen has over 40 years of experience in civil engineering and is responsible for the overall management of Wai Kee Group and oversees the operations of Wai Kee Group. Mr. Zen holds a B.Sc. degree in Engineering from The University of Hong Kong and a M.B.A. degree from The Chinese University of Hong Kong and is a member of both the Institution of Civil Engineers and the Hong Kong Institution of Engineers and a fellow member of the Institute of Quarrying, UK. He is a past Honorary Treasurer of Hong Kong Construction Association and a member of HKTDC Infrastructure Development Advisory Committee. He is also the President of Hong Kong Contract Bridge Association. We believe Mr. Zen is qualified to serve as a director due to his executive experience and business expertise. Mr. Zen also brings to the board of directors his diverse experience as a foreign national and board member and executive officer of Hong Kong-based publicly traded companies.

Robert Dickey IV has served as Managing Director at Foresite Advisors since March 2020 and was previously a Managing Director at Danforth Advisors from August 2018 to March 2020. Foresite Advisors provides finance support and strategy for life science companies, including CFO advisory, financial analysis, capital raising, and transactional support/execution for public offerings and M&A. Mr. Dickey served as a member on the board of directors at Sanuthera, Inc., a privately held medical device company, from 2013 to 2017, and was employed as Chief Financial Officer of Motif Bio Plc., a NASDAQ and London AIM exchange-listed antibiotics company, from January 2017 to February 2018. He also previously was employed with several other biotechnology companies, including as the Chief Financial Officer of Tyme Technologies, Inc. from May 2015 to January 2017, the Chief Financial Officer of NeoStem, Inc. from August 2013 to January 2015 and the Senior Vice President of Hemispherx Biopharma, Inc. from November 2008 to August 2013. Prior to that time, among other things, Mr. Dickey served as a Managing Director at Legg Mason Wood Walker, Inc. and as a Senior Vice President at Lehman Brothers. He received his undergraduate degree from Princeton University and an M.B.A. from The Wharton School of the University of Pennsylvania. We believe Mr. Dickey is qualified to serve as a director due to his experience as Chief Financial Officer of stock exchange listed life sciences company and other experiences in the life sciences industry, including as a former investment banker.

Jane Pine Wood was appointed as a director on March 25, 2020. She has served since October 3, 2016 as Chief Legal Counsel of BioReference Laboratories, Inc., Elmwood Park, New Jersey, a wholly owned subsidiary of OPKO Health, Inc. (NASDAQ: OPK), a diversified healthcare company. BioReference Laboratories, Inc. is the nation's third-largest clinical laboratory with a core genetic testing business and 400-person sales and marketing team. Ms. Wood has over 30 years of experience representing clinical and anatomic laboratories, physicians, imaging centers, home health agencies, mental health

providers, hospitals, other healthcare providers, and professional societies in corporate, regulatory, reimbursement, contractual, and other matters. She holds a B.A. degree, summa cum laude, from Texas A&M University and a J.D. degree from Vanderbilt University School of Law and is a member of the State Bars of New Jersey, Massachusetts, Ohio, and Tennessee. Ms. Wood is well suited to serve as a director in light of her extensive education and experiences in legal and regulatory affairs in the life science industry, including in advising a broad range of physicians and other healthcare providers and commercial healthcare companies. She adds her unique perspective as an expert in federal and state regulatory affairs and the only female director of the company.

Family and Other Relationships

There are no family relationships among any of our officers or directors.

Mr. Zen was originally appointed to the board of directors of EMI Holding on June 18, 2018 pursuant to the terms of outstanding convertible promissory notes dated November 6, 2017 and January 15, 2018 held by Mr. Zen and Wealth Threshold Limited, respectively, which entitled the note holders to designate one director if the aggregate investment in EMI Holding by the note holders and related note holders exceeded $20 million.

Board of Directors and Committees and Director Independence

Our board of directors currently consists of seven members. Our board of directors has determined that each of Ian Zwicker, Masaharu Osato, Wei Peu Zen, Robert Dickey IV and Jane Pine Wood is an "independent" director as defined by The NASDAQ Marketplace Rules currently in effect and all applicable rules and regulations of the SEC. All members of the Audit, Compensation, and Governance and Nominations Committees satisfy the "independence" standards of The NASDAQ Marketplace Rules applicable to members of such committees. The board of directors made this affirmative determination regarding these directors' independence based on discussions with the directors and its review of the directors' responses to a standard questionnaire regarding employment and compensation history, affiliations, family and other relationships and transactions between each director or any member of his or her immediate family and the Company or its subsidiaries or affiliates.

Audit Committee

Our Audit Committee consists of Mr. Dickey, Mr. Zwicker, Dr. Osato and Ms. Wood, each of whom is an independent director as defined by The NASDAQ Marketplace Rules. Mr. Dickey serves as Chairman of the Audit Committee and qualifies as an "audit committee financial expert" as defined under Item 407(d) of Regulation S-K. The purpose of the Audit Committee is to represent and assist our board of directors in its general oversight of our accounting and financial reporting processes, audits of the financial statements and internal control and audit functions. The Audit Committee's primary responsibilities and duties are to:

- Serve as an independent and objective party to monitor the Company's financial reporting process, internal control system and disclosure control system.
- Review and appraise the audit efforts of the company's independent accountants.
- Assume direct responsibility for the appointment, compensation, retention and oversight of the work of the outside auditors and for the resolution of disputes between the outside auditors and the company's management regarding financial reporting issues,
- Provide an open avenue of communication among the independent accountants, financial and senior management and the board of directors.

The board of directors has adopted a written charter for the Audit Committee. A copy of the Audit Committee Charter is available on our website at www.emmausmedical.com.

Governance and Nominations Committee

The purpose of the Governance and Nominations Committee is to:

- Assist the board of directors by identifying qualified candidates for director, and to recommend to the board the director nominees for the next annual meeting of stock holders
- To lead the board in its annual review of the board's performance.
- To recommend to the board nominees for each board Committee.
- To develop and recommend to the board corporate governance guidelines applicable to the company.

The Governance and Nominations Committee also currently consists of Mr. Dickey, Mr. Zwicker, Dr. Osato and Ms. Wood. Mr. Zwicker serves as Chairman of the Governance and Nominations Committee. A copy of the Governance and Nominations Committee Charter is available on our website at www.emmausmedical.com.

Compensation Committee

The purpose of the Compensation Committee is to review and approve of the company's compensation and benefit programs.The Compensation Committee also currently consists of Mr. Dickey, Mr. Zwicker, Dr. Osato and Ms. Wood. Mr. Zwicker serves as Chairman of the Compensation Committee. A copy of the Compensation Committee Charter is available on our website at www.emmausmedical.com.

Section 16(a) Beneficial Ownership Reporting Compliance

Our common stock is currently registered under Section 12 of the Securities Exchange Act of 1934, as amended. As a result, and pursuant to Rule 16a-2, our directors and officers and beneficial owners of 10% or more of our common stock are currently required to file statements of beneficial ownership with respect to their ownership of our equity securities under Sections 13 or 16 of the Exchange Act. Based on a review of written representations from our executive officers and directors and a review of Forms 3, 4 and 5 furnished to us, we believe that during the fiscal year ended December 31, 2020 our directors and, officers and owners of more than 10% of our common stock filed, on a timely basis, all reports required by Section 16(a) of the Exchange Act, except that Jane Pine Wood's initial statement of beneficial ownership of securities was filed late due to delays on our part in obtaining SEC filer codes on her behalf related to stay at home orders affecting our employees and her.

Code of Conduct and Ethics

Our board of directors has approved a Code of Conduct and Ethics, which we refer to as the Code of Ethics, which applies to our directors, officers and employees. The Code of Ethics addresses, among other things, honesty and ethical conduct, conflicts of interest, compliance with laws, regulations, and policies, including disclosure requirements under the federal securities laws, confidentiality, trading on inside information, and reporting of violations of the Code of Ethics. A copy of the Code of Ethics is available on our website at www.emmausmedical.com. Requests for copies of the Code of Ethics should be sent to Emmaus License Sciences, Inc., Attention: Secretary, 21250 Hawthorne Boulevard, Suite 800, Torrance, California 90503.

ITEM 11. EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth information concerning the compensation earned by our Chief Executive Officer, and our two other most highly compensated executive officers, whom we refer to as our "named executive officers," for the fiscal years ended December 31, 2020 and 2019:

Name and Position	Year ended December 31	Salary	Bonus	Stock Awards	Option Awards	All Other Compensation	Total
Yutaka Niihara, M.D., MPH	2020	385,000	—	—	—	—	385,000
Chairman and Chief Executive Officer	2019	385,000	—	—	—	—	385,000
Willis C. Lee	2020	240,000	—	—	—	—	240,000
Chief Operating Officer	2019	240,000	—	—	—	—	240,000
Yasushi Nagasaki	2020	240,000	—	—	—	—	240,000
Interim Chief Financial Officer (1)	2019	235,000	—	—	—	—	235,000

(1) Mr. Sherwood stepped down as Chief Financial Officer effective September 1, 2020.

The compensation of Dr. Niihara and Mr. Lee does not reflect annual performance bonuses provided for in their respective employment agreements. We did not grant such performance bonuses in 2020 or 2019, in part, to preserve available capital to fund operating expenses. Additionally, no specific performance criteria were established for our executive officers for 2020 or 2019. As of the filing of this Annual Report, the Compensation Committee has made no determination regarding any discretionary cash bonuses for 2020.

Outstanding Equity Awards at 2020 Fiscal Year End

The following table sets forth information regarding outstanding equity awards held by our named executive officers as of December 31, 2020:

Name	Number of Securities Underlying Unexercised Awards Exercisable	Number of Securities Underlying Unexercised Awards Unexercisable	Exercise Price	Expiration Date
Yutaka Niihara, M.D., MPH	262,536	—	$ 3.42	4/1/2022
	525,072	—	$ 3.42	2/28/2023
	315,043	—	$ 4.76	5/10/2026
	1,365,189	—	$ 4.76	5/9/2021
Willis C. Lee	262,536	—	$ 3.42	4/1/2022
	525,072	—	$ 3.42	2/28/2023
	315,043	—	$ 4.76	5/10/2026
Yasushi Nagasaki	262,536	—	$ 3.42	4/1/2022
	525,072	—	$ 3.42	2/28/2023
	315,043	—	$ 4.76	5/10/2026

Employment Agreements

On April 5, 2011, we entered into employment agreements with Dr. Niihara and Mr. Lee. Each of the Employment Agreements had an initial two-year term, which renews automatically for consecutive one-year periods unless we or the officer provides notice of non-renewal at least 60 days prior to the expiration of the then current term.

Base Salary, Bonus and Other Compensation. Dr. Niihara's, and Mr. Lee's current base salaries are $385,000 and $240,000 per year, respectively, which will be reviewed at least annually. In addition to the base salary, each officer may be entitled to receive an annual performance bonus based on the officer's performance. The Employment Agreements provide that the respective officer's performance will be measured against a set of targets and goals as mutually established by us and the officer. Historically, our board of directors and the Compensation Committee of the board have evaluated each officer's performance on an overall basis related to our progress on major milestones, without reliance on specific position by position pre-established targets and goals. The officers are also eligible to receive paid vacation and to participate in health and other benefit plans and to be reimbursed for reasonable and necessary business expenses on the same basis as our other employees.

Equity Compensation. The Employment Agreements provide that on December 31of each calendar year, or as soon as reasonably practicable after such date (each a "Grant Date"), we will grant non-qualified 10-year stock options with a Black-Scholes-Merton value of $100,000 to Dr. Niihara, and $50,000 to Mr. Lee in each case with an exercise price per share equal to the "Fair Market Value" (as such term is defined in our 2011 Stock Incentive Plan) on the applicable Grant Date. The options are to vest as to one-third of the option shares on each of the first three anniversaries of the Grant Date. Any unvested options are to vest immediately upon a change in control (as defined below), termination of the officer's employment other than a voluntary termination by the officer or our termination of the officer for cause. In the event the officer is terminated for any reason other than cause, death or disability or retirement, each option, to the extent that it is exercisable at the time of such termination, shall remain exercisable for the 90-day period following such termination, but in no event following the expiration of its term. In the event the officer's employment terminates on account of death, disability or, with respect to any non-qualified stock option, retirement, each option granted that is outstanding and vested as of the date of such termination shall remain exercisable by such officer (or the officer's legal representatives, heirs or legatees) for the one-year period following such termination, but in no event following the expiration of its term. No such stock option grants were made for either of the years ended December 31,2020 or 2019.

Severance Compensation. If Dr. Niihara's or Mr. Lee's employment is terminated for any reason during the term of his Employment Agreement, other than for cause or without good reason, he will be entitled to receive his or her base salary prorated through the termination date, any expense reimbursement due and owing for reasonable and necessary business expenses, and unpaid vacation benefits (the "Voluntary Termination Benefits"). If Dr. Niihara's or Mr. Lee's employment is terminated due to his death or disability during the term of his employment agreement, he will also receive an amount equal to his target annual performance bonus, if any, and in the case of a termination due to disability, six additional months of his base salary to be paid out over a six-month period and payment of COBRA benefits for six months following the termination. If Dr. Niihara's employment is terminated without cause or he resigns with good reason (but not within two years following a change in control), he will receive the Voluntary Termination Benefits and, subject to his signing a Release of all claims relating to his employment, a severance package equal to one year's base salary to be paid out over a 12-month period, a pro rata amount of the annual performance bonus for the calendar year in which the termination date occurs based on the achievement of any applicable performance terms or goals for the year, and payment of COBRA benefits for 12 months following the termination. If Mr. Lee's employment is terminated without cause or he resigns with good reason (but not within two years following a change in control) during the term of his employment agreement, he will receive the Voluntary Termination Benefits and, subject to his signing a Release if all claims relating to his employment, a severance package equal to six months' base salary to be paid out over a six-month period, an amount equal to half of the targeted annual performance bonus, if any, and payment of COBRA benefits for six months following the termination.

Termination with cause includes a proven act of dishonesty, fraud, embezzlement or misappropriation of company proprietary information; a conviction of, or plea of nolo contendere to, a felony or a crime involving moral turpitude; willful misconduct which cannot be cured on reasonable notice to the officer; or the officer's habitual failure or refusal to perform his duties if such failure or refusal is not cured within 20 days after receiving written notice thereof from the board of directors. Good reason includes a reduction of more than 10% to the officer's base salary or other compensation (except as part of a general reduction for all executive employees); a material diminution of the officer's authority, responsibilities, reporting or job duties (except for any reduction for cause); the company's material breach of the Employment Agreement; or a relocation of the business requiring the officer to move or drive to work more than 40 miles from the location of our former offices. The officer may terminate the Employment Agreement for good reason if he provides written notice to the Company within 90 days of the event constituting good reason and the Company fails to cure the good reason within 30 days after receiving such notice.

Change of Control. The Employment Agreements will not be terminated upon a "change of control," which means any merger or reorganization where the holders of the company's capital stock prior the transaction own fewer than 50% of the shares of capital stock after the transaction, an acquisition of 50% of the voting power of the company's outstanding securities by another entity, or a transfer of at least 50% of the fair market value of the company's assets. Upon Dr. Niihara's termination without cause or good reason that occurs within two years after a change of control, he will be entitled to receive the Voluntary Termination Benefits and, subject to his signing a Release of all claims relating to his employment, a severance package equal to two years' base salary to be paid out over a 12-month period, an amount equal to double his targeted annual performance bonus, if any, payment of COBRA benefits for 18 months following the termination, and a one-time cash payment of $3.0 million. Upon Mr. Lee's termination without cause or good reason that occurs within two years after a change of control, he will be entitle to receive the Voluntary Termination Benefits and, subject to his signing a Release of all claims relating to his employment, a severance package equal to one year's base salary to be paid out over a 12-month period, an amount equal to the full-year targeted annual performance bonus, payment of COBRA benefits for 12 months following the termination, and a one-time cash payment of $200,000. In addition, each officer's unvested equity awards shall vest upon such termination and the officer will have 36 months in which to sell or exercise such awards (subject to expiration of the term of such options). The

officer will also be free from all lock-up or other contractual restrictions upon the free sale of shares that are subject to waiver by the company upon such termination.

Director Compensation

The following is a summary of the current compensation of our non-employee directors:

- $100,000 per year cash compensation, payable in quarterly instalments;
- $1,000 per ad hoc board meeting attended in person or telephonically; and
- possible awards of stock options to be determined by the Compensation Committee.

The following table sets forth information regarding the compensation earned by our non-employee directors for the fiscal year ended December 31, 2020. Ms. Wood became a director on March 25, 2020. Our employee directors, Dr. Niihara, and Mr. Lee, are not compensated for their services as directors.

Name	Fees Earned or Paid in Cash	Option Awards	Total
Ian Zwicker	$ 100,000	$ —	$ 100,000
Masaharu Osato, M.D.	100,000	—	100,000
Wei Peu Zen	100,000	—	100,000
Robert Dickey IV	100,000	—	100,000
Jane Pine Wood (1)	75,000	—	75,000
Total	$ 475,000	$ —	$ 475,000

(1) Ms. Wood became a director on March 25, 2020.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth certain information as of March 31, 2021 with respect to beneficial ownership of our common stock based on issued and outstanding shares of common stock owned by:

- Each person known to be the beneficial owner of 5% or more of our outstanding common stock;
- Each named executive officer;
- Each director; and
- All our executive officers and directors as a group.

Beneficial ownership is determined in accordance with the rules of the SEC. In computing the number of shares beneficially owned by a person and the percentage of ownership of that person, shares of common stock subject to options, warrants and convertible notes held by that person that are currently exercisable or become exercisable within 60 days of March 31, 2021 are deemed outstanding even if they have not actually been exercised. Those shares, however, are not deemed outstanding for the purpose of computing the percentage ownership of any other person.

Unless otherwise indicated, the persons and entities named in the table have sole voting and sole investment power with respect to the shares set forth opposite the stockholder's name, subject to community property laws, where applicable.

Unless otherwise indicated in the table or footnotes, the address of each 5% or more owner is c/o Emmaus Life Sciences, Inc., 21250 Hawthorne Boulevard, Suite 800, Torrance, California 90503.

Name of Beneficial Owner	Title	Amount and Nature of Beneficial Ownership of Shares of Common Stock		Percent of Class (1)
Directors and Executive Officers				
Yutaka Niihara, M.D., M.P.H.	Chairman and Chief Executive Officer	13,332,380	(2)	25.7%
Willis C. Lee	Director, Chief Operating Officer	1,434,636	(3)	2.8%
Yasushi Nagasaki	Interim Chief Financial Officer	1,169,753	(4)	2.3%
Robert Dickey IV	Director	—		*
Masaharu Osato, M.D.	Director	735,396	(5)	1.5%
Jane Pine Wood	Director	—		*
Wei Peu Zen	Director	2,278,048	(6)	4.6%
Ian Zwicker.	Director	217,029		*
Officers and Directors as a Group (8 persons)		19,167,242	(7)	35.2%
5% or More Owners				
Telcon RF Pharmaceutical, Inc.		4,147,491	(8)	8.4%

* Represents beneficial ownership of less than one percent (1%).

(1) Based on 49,311,864 shares of common stock issued and outstanding as of March 31, 2021.

(2) Includes 10,864,540 shares of common that are held jointly by Dr. Niihara and Soomi Niihara, his wife. Also includes 63,000 shares held by Soomi Niihara and 92,794 shares owned by Hope International Hospice, Inc., or Hope Hospice. Dr. Niihara is the chief executive officer and a co-director of Hope Hospice and shares voting and investment power over such shares. Also includes 1,102,651 shares underlying stock options and 1,365,189 shares underlying warrants."

(3) Includes 1,102,651 shares underlying stock options.

(4) Includes 1,102,651 shares underlying stock options.

(5) Includes 516,152 shares held by Osato Medical Clinic and its pension plan. Also includes 217,029 shares underlying stock options.

(6) Includes 1,270,214 shares owned by Profit Preview International Group Limited, a Hong Kong limited company wholly owned by Mr. Zen. Excludes 521,827 shares owned by Smart Start investments Limited, a Hong Kong corporation and wholly owned subsidiary of Build King Holdings Limited, a Hong Kong stock exchange listed company, of which the Mr. Zen is a director and 9.96% shareholder, and 350,048 shares owned by Wealth Threshold Limited, a British Virgin Islands limited company and wholly owned subsidiary of Wai Kee Holdings Limited, a Hong Kong stock exchange listed company of which Mr. Zen is a director and 31.45% shareholder, as to which shares Mr. Zen disclaims beneficial ownership.

(7) Includes 4,844,662 shares underlying stock options and 1,365,189 shares underlying warrants.

(8) The information regarding Telcon RF Pharmaceutical, Inc. is based solely on its Schedule 13/G filed with the SEC on August 26, 2019. The address for the stockholder is S-Tower 14th Floor 439 Bongunsa-ro, Gangnam-gu, Seoul, South Korea.

Securities Authorized for Issuance under Equity Compensation Plans

The following table provides information as of December 31, 2020 regarding compensation plans, including any individual compensation arrangements, under which our equity securities are authorized for issuance:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans
Equity compensation plans approved by security holders	7,110,025	$ 4.63	2,302,475

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Except as described below in this section, since the beginning of our last fiscal year, there has not been, nor is there currently proposed, there has not been any transaction or series of similar transactions to which we were a party:

- in which the amount involved exceeds the lesser of $120,000 or 1% of the average of our total assets at year-end for the last two completed fiscal years; and
- in which any director, executive officer, or other stockholder of more than 5% of our common stock or any member of their immediate family had or will have a direct or indirect material interest.

Loans by Related Persons

In January 2020, we entered into revolving line of credit agreement with Dr. Yutaka Niihara. Under the agreement, at our request from time to time, Dr. Niihara may, but is not obligated to, loan or re-loan to us up to $1,000,000, including $600,000 loaned to us in December 2019. Outstanding amounts under the agreement are due and payable upon demand and bear interest, payable monthly, at a variable annual rate equal to the Prime Rate in effect from time to time plus 3%. In addition to the payment of interest, we agreed to pay Dr. Niihara an amount, which we refer to as a "tax gross-up," intended to make him whole for federal and state income taxes payable by him with respect to interest paid to him the previous year. As of December 31, 2020, the outstanding balance under the revolving line of credit agreement of $800,000 was reflected on our consolidated balance sheet. With the tax-gross up, the effective interest rate on the outstanding balance as of December 31, 2020 was 10.4%. The revolving line of credit agreement will expire on November 22, 2022.

The following table sets forth information relating to loans from related parties evidenced by promissory notes payable and convertible promissory notes payable to related persons outstanding at any time during the fiscal year ended December 31, 2020 (amounts in thousands).

Class	Lender	Interest Rate	Date of Loan	Term of Loan	Principal Amount Outstanding at December 31, 2020	Highest Principal Outstanding	Amount of Principal Repaid	Amount of Interest Paid
Current, Promissory note payable to related parties:								
	Lan T. Tran (2)	10%	4/29/2016	Due on Demand	20	20	—	—
	Lan T. Tran (2)	11%	2/10/2018	Due on Demand	—	159	159	35
	Lan T. Tran (2)	10%	2/9/2019	Due on Demand	14	14	—	—
	Hope Int'l Hospice (1)	12%	9/1/2020	Due on Demand	—	194	194	2
	Hope Int'l Homecare (1)	12%	9/1/2020	Due on Demand	—	189	189	1
	Soomi Niihara	12%	9/1/2020	Due on Demand	—	98	98	4
	Soomi Niihara	12%	10/28/2020	Due on Demand	—	395	395	12
	Willis Lee (2)	12%	9/1/2020	Due on Demand	—	685	685	1
	Willis Lee (2)	12%	10/29/2020	Due on Demand	100	100	100	—
				Subtotal	**$ 134**	**$ 1,854**	**$ 1,820**	**$ 55**
Revolving line of credit								
	Yutaka Niihara (2)	5%	12/27/2019	Due on Demand	800	800	200	37
				Subtotal	**$ 800**	**$ 800**	**$ 200**	**$ 37**
				Total	**$ 934**	**$ 2,654**	**$ 2,020**	**$ 92**

(1) Dr. Niihara, our Chairman and Chief Executive Officer, is the Chief Executive Officer, and he and his wife, Soomi Niihara, are co-owners and directors, of Hope International Hospice, Inc.
(2) Officer or former officer.
(3) Director

The proceeds of the above loans were used working capital purposes.

Prior to the reverse capitalization transaction completed in July 2019, there were outstanding approximately $34.5 million principal amount of promissory notes convertible into shares of common stock of EMI Holding at conversion prices ranging from $3.05 to $10.00 per share. None of the convertible promissory notes originally provided for their conversion into Emmaus common stock or assumption by Emmaus connection with the reverse capitalization transaction. In order to facilitate the transaction and to satisfy its covenants in the merger agreement, EMI entered into negotiations with the holders of the convertible promissory notes to amend the terms thereof to provide that they would be converted automatically into shares of EMI common stock at their respective conversion prices immediately prior to the effective time of the reverse capitalization transaction, which shares would be outstanding immediately prior to the reverse capitalization transaction and would be converted into shares of Emmaus common stock in the same manner as other outstanding shares of EMI common stock based the exchange ratio. In connection with such amendments, the conversion price of approximately $15.1 million principal amount of EMI convertible promissory notes, including $14.4 million principal amount of EMI convertible promissory notes held by Wei Peu Zen, an Emmaus director and a note holder affiliated with Mr. Zen, were reduced from $10 a share to $8.25 a share. Also, in conjunction with the reverse capitalization transaction, approximately $357,000 principal amount and accrued interest under a promissory note held by Dr. Niihara was converted into shares of Emmaus commons stock at a conversion price of $10 per share.

Policy for Approval of Related Party Transactions

The Audit Committee of our Board of Directors is responsible for reviewing and approving all related party transactions.

Board Independence

Our board of directors has determined that each of Ian Zwicker, Masaharu Osato, M.D., Wei Peu Zen, Robert Dickey IV and Jane Pine Wood is an “independent” director as defined by The NASDAQ Marketplace Rules currently in effect and all applicable rules and regulations of the SEC.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The following table presents all fees, including reimbursements for expenses, billed for professional services rendered by Baker Tilly US, LLP (“Baker Tilly”), our independent registered public accounting firm for the years ended December 31, 2020 and 2019 (in thousands):

	2020	2019
Audit Fees	$ 141	$ 156
Audit–Related Fees	—	—
Tax Fees	—	—
All Other Fees	—	—
Total	$ 141	$ 156

The engagement of Baker Tilly was approved by the Audit Committee of our Board of Directors on September 10, 2020.

The Audit Committee has adopted a formal policy on auditor independence requiring the advance approval by the Audit Committee of all audit and non-audit services provided by our independent registered public accounting firm. In determining whether to approve any services by our independent registered public accounting firm, the Audit Committee reviews the scope of and estimated fees for the services and considers whether the proposed services may adversely affect the

firm's independence. On an annual basis, our management reports to the Audit Committee all audit services performed during the previous 12 months and all fees billed by our independent registered public accounting firm for such services.

In fiscal 2020 and 2019, all audit services and the corresponding fees were approved by the Audit Committee.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

1. Financial Statements: See “Index to Consolidated Financial Statements” on page F-1 of this Annual Report.

2. Financial Statement Schedule: See Notes to Consolidated Financial Statements starting on page F-8 of this Annual Report.

3. Exhibits: The exhibits listed in the following “Exhibit Index” are filed or incorporated by reference as part of this Annual Report.

Exhibit Index

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished
		Form	File No.	Exhibit	Filing Date	
1.1	Purchase Agreement dated as of February 28, 2020 between Emmaus Life Sciences, Inc. and Lincoln Park Capital Fund, LLC.	8-K	001-35527	1.1	March 3, 2020	
2.1	Agreement and Plan of Merger and Reorganization dated as of January 4, 2019 by and among MYnd Analytics, Inc., Athena Merger Subsidiary, Inc. and Emmaus Life Sciences, Inc., as amended by Amendment No. 1 dated as of May 27, 2019.	424B3	333-229660	Annex A	June 14, 2019	
3.1	Restated Certificate of Incorporation.	10-K	001-35527	3.1	January 25, 2021	
3.2	Amended and Restated By-Laws.	8-K	001-35527	3.4	July 22, 2019	
4.1	Specimen Common Stock Certificate.	10-K	001-35527	4.1	January 25, 2021	
4.2+	MYnd Analytics, Inc. Amended and Restated 2012 Omnibus Incentive Compensation Plan	DEF14A	001-35527	Appendix A	November 2, 2018	
4.3+	Form of Restricted Share Agreement under Amended and Restated 2012 Omnibus Incentive Compensation Plan.	10-K	001-35527	4.4	December 22, 2016	
4.4+	Form of ISO Stock Option Award Certificate under Amended and Restated 2012 Omnibus Incentive Compensation Plan.	10-K	001-35527	4.5	December 22, 2016	
4.5+	Form of NQSO Stock Option Award Certificate under Amended and Restated 2012 Omnibus Incentive Compensation Plan.	10-K	001-35527	4.6	December 22, 2016	
4.6	Form of Warrant to Purchase Shares of Common Stock issued to the persons indicated in Schedule A thereto.	10-Q	000-142031	4.5	May 20, 2015	
4.7	Warrant to Purchase Stock.	10-Q	000-142031	4.3	August 19, 2016	
4.8	Warrant to Purchase Shares of Common Stock.	10-Q	000-142031	4.4	August 19, 2016	
4.9	Warrant to Purchase Shares of Common Stock.	10-Q	000-142031	4.3	November 14, 2016	
4.10	Common Stock Purchase Warrant dated December 29, 2017.	10-K	000-142031	4.32	April 16, 2018	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished
		Form	File No.	Exhibit	Filing Date	
4.11	Convertible Promissory Note dated January 15, 2018	10-Q	000-142031	4.1	May 15, 2018	
4.12+	Emmaus Life Sciences, Inc. Amended and Restated 2011 Equity Incentive Plan.	DEF14A	000-53072	Annex A	September 19, 2014	
4.13+	Form of Incentive Stock Option Agreement (Time-Based and Performance-Based Vesting) under 2011 Stock Incentive Plan.	8-K	000-142031	10.3a	May 4, 2011	
4.14+	Form of Incentive Stock Option Agreement (Time-Based Vesting) under 2011 Equity Incentive Plan.	8-K	000-142031	10.3b	May 4, 2011	
4.15+	Form of Non-Qualified Stock Option Agreement (Time-Based and Performance-Based Vesting) under 2011 Equity Incentive Plan.	8-K	000-142031	10.3c	May 4, 2011	
4.16+	Form of Non-Qualified Stock Option Agreement (Time-Based Vesting) under 2011 Equity Incentive Plan.	8-K	000-142031	10.3d	May 4, 2011	
4.17+	Form of the Restricted Stock Agreement (Time-Based and Performance-Based Vesting) under 2011 Equity Incentive Plan.	8-K	000-142031	10.3e	May 4, 2011	
4.18+	Form of Restricted Stock Agreement (Time-Based Vesting) under 2011 Equity Incentive Plan.	8-K	000-142031	10.3f	May 4, 2011	
4.19	Form of Warrant to Purchase Shares of Common Stock dated as of September 24, 2018 by and between MYnd Analytics, Inc. and the holder party thereto.	10-K	001-35527	10.14	December 11, 2018	
4.20	Warrant Agreement dated as of July 25, 2017 by and between MYnd Analytics, Inc. and American Stock Transfer & Trust Company, LLC, including form of Warrant Certificate attached thereto.	10-Q	001-35527	4.9	August 14, 2017	
4.21	Amendment dated June 28, 2019 to Warrant Agreements, dated July 19, 2017 and July 25, 2017, respectively, between MYnd Analytics, Inc. and American Stock Transfer & Trust Company, LLC.	8-K	001-35527	4.1	June 28, 2019	
4.22	Form of Warrant dated as of March 29, 2018 by and between MYnd Analytics, Inc. and the holder signatory thereto.	8-K	001-35527	10.2	April 3, 2018	
4.23	Form of Second Amended and Restated 10% Senior Secured Convertible Debenture Due April 21, 2021 of EMI Holding, Inc. (formerly, Emmaus Life Sciences, Inc.)	8-K	001-35527	4.1	February 27, 2020	
4.24	Form of Second Amended and Restated Common Stock Purchase Warrant.	8-K	001-35527	4.2	February 27, 2020	
4.25	Contingent Common Stock Purchase Warrant	10-K	001-35527	4.24	May 4, 2021	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished
		Form	File No.	Exhibit	Filing Date	
4.26	Form of July 31, 2020 Common Stock Purchase Warrants	10-K	001-35527	4.25	May 4, 2021	
4.27	Form of September 22, 2020 Common Stock Purchase Warrants	8-K	001-35527	10.1	September 24, 2020	
4.28	Form of October 8, 2020 Common Stock Purchase Warrants	10-K	001-35527	4.27	May 4, 2021	
10.1	Form of Registration Rights Agreement dated as of March 28, 2018 by and between MYnd Analytics, Inc. and the holder(s) signatory thereto.	8-K	001-35527	10.1	April 3, 2018	
10.2	Amended and Restated Separation Agreement dated as of March 27, 2019 by and among MYnd Analytics, Inc., a Delaware corporation, and MYnd Analytics, Inc., a California corporation.	424B3	333-229660	Annex B	June 14, 2019	
10.3	Loan Agreement dated as October 3, 2018 between EMI Holding, Inc. (formerly, Emmaus Life Sciences, Inc.) and EJ Holdings, Inc.	10-Q	001-35527	10.7	November 13, 2019	
10.4+	Executive Employment Agreement dated as of April 5, 2011 by and between Emmaus Medical, Inc. and Yutaka Niihara, M.D., M.P.H.	8-K	000-142031	10.12	May 4, 2011	
10.5+	Executive Employment Agreement dated as of April 5, 2011 by and between Emmaus Medical, Inc. and Willis Lee.	8-K	000-142031	10.13	May 4, 2011	
10.6+	Executive Employment Agreement dated as of April 5, 2011 by and between Emmaus Medical, Inc. and Lan T. Tran, M.P.H.	8-K	000-142031	10.14	May 4, 2011	
10.7+	Form of Indemnification Agreement between Emmaus Life Sciences, Inc. (formerly EMI Holding, Inc.) and its former and current directors and officers.	8-K	000-142031	10.20	May 4, 2011	
10.8	Letter of Intent by and between Ajinomoto Aminoscience LLC and Emmaus Medical, Inc.	8-K/A	000-142031	10.24	July 5, 2011	
10.9	Form of Promissory Note issued to the persons indicated on Schedule A thereto.	10-Q	000-142031	10.1	August 19, 2016	
10.10	Promissory Note dated February 10, 2018	10-Q	000-142031	10.1	May 15, 2018	
10.11	Promissory Note dated April 24, 2019.	10-K	001-35527	10.11	January 25, 2021	
10.12	Promissory Note dated May 26, 2019.	10-K	001-35527	10.12	January 25, 2021	
10.13	Securities Purchase Agreement entered into October 1, 2018 among EMI Holding, Inc. (formerly, Emmaus Life Sciences, Inc.) and the Purchasers thereunder.	8-K	000-142031	10.1	September 17, 2018	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished
		Form	File No.	Exhibit	Filing Date	
10.14	Second Amendment to Securities Purchase Agreement entered into October 1, 2018 among EMI Holding, Inc. (formerly, Emmaus Life Sciences, Inc.) and the Purchasers thereunder.	8-K/A	000-142031	10.6	October 5, 2018	
10.15	Form of Security Agreement among EMI Holding, Inc. (formerly, Emmaus Life Sciences, Inc.), Emmaus Medical, Inc., Newfield Nutrition Corporation and the holders of 10% Senior Secured Debentures.	8-K	000-142031	10.2	September 17, 2018	
10.16	Form of Subsidiary Guarantee among Emmaus Medical, Inc., Newfield Nutrition Corporation and the holders of 10% Senior Secured Debentures.	8-K	000-142031	10.3	September 17, 2018	
10.17	Security Amendment Agreement dated as of March 5, 2019 among EMI Holding, Inc. (formerly, Emmaus Life Sciences, Inc.) and the Holders thereunder.	8-K	000-142031	10.1	March 11, 2019	
10.18	Securities Amendment Agreement dated as of February 21, 2020 among EMI Holding, Inc. (formerly, Emmaus Life Sciences, Inc.) and the Holders thereunder, including Exhibits.	8-K	000-142031	10.1	February 27, 2020	
10.19	Securities Amendment Agreement dated as of September 22, 2020 among EMI Holding, Inc. (formerly, Emmaus Life Sciences, Inc.) and the Holders thereunder, including Exhibits.	8-K	001-35527	10.1	September 24, 2020	
10.20	Office Lease dated October 20, 2014 by and between EMI Holding, Inc. (formerly, Emmaus Life Sciences, Inc.) and Bixby Torrance LLC.	10-K	001-35527	10.23(F)	March 31, 2015	
10.21	First Amendment to Office Lease Agreement dated February 1, 2018 between EMI Holding, Inc. (formerly, Emmaus Life Sciences, Inc.) and RREF Pacific Center LLC.	10-K	000-142031	10.24a	March 21. 2019	
10.22	Second Amendment to Office Lease Agreement dated December , 2018 between EMI Holding, Inc. (formerly, Emmaus Life Sciences, Inc.) and RREF Pacific Center LLC.	10-K	000-142031	10.24b	March 21. 2019	
10.23	Third Amendment to Office Lease Agreement dated September 10, 2019 between EMI Holding, Inc. (formerly, Emmaus Life Sciences, Inc.) and RREF Pacific Center LLC.	10-K	001-35527	10.23	January 25, 2021	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished
		Form	File No.	Exhibit	Filing Date	
10.24	Revised Management Control Acquisition Agreement dated September 29, 2017 by and among the registrant, Telcon Holdings, Inc. and Telcon, Inc. (now known as Telcon RF Pharmaceutical Inc.)	10-Q	000-142031	10.3	November 14, 2017	
10.25	Distributor agreement entered into as of June 15, 2017 between Telcon Inc. (now known as Telcon RF Pharmaceutical Inc.)and Emmaus Life Sciences, Inc. (now known as EMI Holding, Inc.)	10-K	001-35527	10.25	January 25, 2021	
10.26	Amendment for Distributor Agreement entered into as of January 11, 2018 between Telcon Inc. (now known as Telcon RF Pharmaceutical Inc.) and Emmaus Life Sciences, Inc. (now known as EMI Holding, Inc.)	10-K	001-35527	10.26	January 25, 2021	
10.27	Raw Material Supply Agreement dated July 12, 2017 between Telcon Inc. (now known as Telcon RF Pharmaceutical Inc.) and Emmaus Life Sciences, Inc. (now known as EMI Holding, Inc.)	10-K	001-35527	10.27	January 25, 2021	
10.28	API Supply Agreement made as of June 16, 2017 between Telcon Inc. (now known as Telcon RF Pharmaceutical Inc.) and Emmaus Life Sciences, Inc. (now known as EMI Holding, Inc.)	10-K	001-35527	10.28	January 25, 2021	
10.29	Additional Agreement made as of July 2, 2018 between Telcon Inc. (now known as Telcon RF Pharmaceutical Inc.) and Emmaus Life Sciences, Inc. (now known as EMI Holding, Inc.) and add asterixis in Filed/Furnished column.	10-K	001-35527	10.29	January 25, 2021	
10.30	Agreement dated December 23, 2019 between Telcon RF Pharmaceutical Inc. and Emmaus Life Sciences, Inc.	10-K	001-35527	10.30	January 25, 2021	
10.31	Registration Rights Agreement dated as of February 28, 2020 between Emmaus Life Sciences, Inc. and Lincoln Park Capital Fund, LLC.	8-K	001-35527	10.1	March 3, 2020	
10.32	Letter of Commitment dated December 23, 2019 between EMI Holding, Inc. (formerly, Emmaus Life Sciences, Inc) and Telcon RF Pharmaceutical, Inc.	10-K	001-35527	10.33	January 25, 2021	
10.33	Convertible Bond Purchase Agreement between Emmaus Life Sciences, Inc. and Telcon RF Pharmaceutical, Inc.	10-K	001-35527	10.34	January 25, 2021	
10.34	Right to Sell (Call Option) Agreement between Emmaus Life Sciences, Inc. and Telcon RF Pharmaceutical, Inc.	10-K	001-35527	10.35	January 25, 2021	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished
		Form	File No.	Exhibit	Filing Date	
10.35	Loan Agreement Dated October 28, 2020 Between Emmaus Life Sciences, Inc. and EJ Holdings, Inc.	8-K	001-35527	10.1	November 13, 2020	
10.36+	Credit Access and Loan Agreement dated as of January 10, 2020 by and between Emmaus Life Sciences, Inc. and Yutaka Niihara, M.D., M.P.H.	10-K	001-35527	10.37	January 25, 2021	
10.37	Amendment No. 2 to Convertible Promissory Note of EMI Holding, Inc. (formerly, Emmaus Life Sciences, Inc.) dated as of January 15, 2020	10-K	001-35527	10.37	May 4, 2021	
10.38	Amendment No. 3 to Convertible Promissory Note as of June 15, 2020 of EMI Holding, Inc. (formerly, Emmaus Life Sciences, Inc.)	10-K	001-35527	10.38	May 4, 2021	
21.1	List of Subsidiaries.	10-K	001-35527	21.1	January 25, 2021	
23.1	Consent of Independent Registered Public Accounting Firm Baker Tilly US, LLP					*
31.1	Certification of Chief Executive Officer pursuant to Item 601(b) (31) of Regulation S-K, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					*
31.2	Certification of Chief Financial Officer pursuant of Item 601(b) (31) of Regulation S-K, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.					*
32.1	Certification of Chief Executive Office and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.					*
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document					
101.SCH	Inline XBRL Taxonomy Extension Schema Document					
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)					

+ Management contract or compensatory plan, contract or arrangement

* Filed herewith.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Torrance, California, on August 9, 2021.

Emmaus Life Sciences, Inc.

By: /s/ Yutaka Niihara
Name: Yutaka Niihara, M.D., M.P.H.
Title: *Chairman and Chief Executive Officer*

INDEX TO FINANCIAL STATEMENTS

EMMAUS LIFE SCIENCES, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and the Board of Directors of Emmaus Life Sciences, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Emmaus Life Sciences, Inc. and its subsidiaries (the "Company") as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, changes in stockholders' deficit, and cash flows, for the years then ended, and the related notes to the consolidated financial statements (collectively, the "financial statements"). In our opinion the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2020 and 2019, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current-period audit of the financial statements that were communicated or required to be communicated to the Company's Audit Committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

REVENUE RECOGNITION - VARIABLE CONSIDERATION

Critical Audit Matter Description

As described in Note 2 to the financial statements, the Company's records revenue at the transaction price, net of estimates for variable consideration consisting primarily of chargebacks, discounts, and returns. Variable considerations are estimated using the expected-value amount method, which is the sum of probability-weighted amounts in a range of possible consideration amounts. Actual amounts of consideration ultimately received may differ from estimates. If actual results vary materially from estimates, the Company will adjust these estimates, which will affect net sales of the products and results from operations in the period such estimates are adjusted.

We identified the determination of variable consideration as a critical audit matter. Significant judgment is exercised by the Company in estimating variable consideration when determining the amount of revenue to recognize.

Given these factors, the related audit effort in evaluating management's judgments in determining the amount of variable consideration used to determine the transaction price was extensive and required a high degree of auditor judgment.

How We Addressed the Matter in Our Audit

The primary procedures we performed to address this critical audit matter included:

- Evaluated management's accounting policies related to the determination of variable consideration in the calculation of the transaction price.
- Evaluated the reasonableness of management's estimate of variable consideration in accordance with their accounting policies based on contractual terms and historical data and variable consideration estimates.
- Tested variable consideration amounts on a sample basis by recalculating recorded amounts based on contractual terms.
- Tested the mathematical accuracy of management's calculations of net revenue and the associated timing of net revenue recognized in the financial statements.

INVESTMENT IN CONVERTIBLE BOND – DETERMINATION OF FAIR VALUE

Critical Audit Matter Description

As described in note 5 to the financial statements, the Company purchased a convertible bond and elected the fair value option. The fair value was determined using the Lattice pricing model and the change in value was recorded as part of other comprehensive income (loss).

We identified the determination of the fair value of the convertible bond as a critical audit matter. Significant judgment is exercised by the Company in determining the fair value of the convertible bond. Given these factors, the related audit effort in evaluating management's judgments in determining the fair value of the convertible bond was complex and required a high degree of auditor judgment.

How We Addressed the Matter in Our Audit

The primary procedures we performed to address this critical audit matter included:

- Obtained an understanding of the Company's process of accounting for convertible bonds.
- Evaluated the methods and significant assumptions used by the Company's valuation professional.
- Tested the accuracy and the completeness of the underlying data and the mathematical accuracy of the valuation report.
- Engaged auditor's valuation professional to assist in the evaluation of the methodology used by the Company and assumptions included in determining the fair value of the convertible bond.
- Evaluated the related disclosures in the financial statements.

/s/ BAKER TILLY US, LLP

We have served as the Company's auditor since 2020.

San Diego, California
August 9, 2021

Emmaus Life Sciences, Inc.
Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	As of	
	December 31, 2020	December 31, 2019
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 2,487	$ 1,769
Accounts receivable, net	198	2,150
Inventories, net	7,087	7,971
Investment in marketable securities	—	27,929
Prepaid expenses and other current assets	1,485	1,402
Total current assets	11,257	41,221
Property and equipment, net	120	151
Equity method investment	15,925	13,325
Right of use assets	4,072	4,474
Investment in convertible bond	27,866	—
Other assets	296	285
Total assets	$ 59,536	$ 59,456
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$ 7,460	$ 11,498
Operating lease liabilities, current portion	1,143	991
Other current liabilities	2,706	5,748
Revolving line of credit from related party	800	600
Warrant derivative liabilities	1,071	38
Notes payable	4,588	3,749
Notes payable to related parties	134	193
Convertible debentures, net of discount	5,480	7,015
Convertible notes payable, net of discount	—	2,995
Total current liabilities	23,382	32,827
Operating lease liabilities, less current portion	3,470	3,932
Other long-term liabilities	34,470	33,750
Notes payable, less current portion	222	—
Convertible notes payable	3,150	—
Total liabilities	64,694	70,509
STOCKHOLDERS' DEFICIT		
Preferred stock — par value $ 0.001 per share, 15,000,000 shares authorized, none issued and outstanding	—	—
Common stock — par value $ 0.001 per share, 250,000,000 shares authorized, shares 48,987,189 and 48,471,446 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	49	48
Additional paid-in capital	218,728	215,207
Accumulated other comprehensive Income (loss)	1,144	(79)
Accumulated deficit	(225,079)	(226,229)
Total stockholders' deficit	(5,158)	(11,053)
Total liabilities & stockholders' deficit	$ 59,536	$ 59,456

The accompanying notes are an integral part of these consolidated financial statements.

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

	Twelve Months Ended December 31,	
	2020	**2019**
REVENUES, NET	$ 23,167	$ 22,752
COST OF GOODS SOLD	2,248	1,094
GROSS PROFIT	20,919	21,658
OPERATING EXPENSES		
Research and development	2,408	2,183
Selling	4,865	6,975
General and administrative	13,678	17,012
Total operating expenses	20,951	26,170
LOSS FROM OPERATIONS	(32)	(4,512)
OTHER INCOME (EXPENSE)		
Loss on debt extinguishment	(1,425)	(438)
Change in fair value of warrant derivative liabilities	392	3,545
Change in fair value of embedded conversion option	112	131
Net gain (loss) on investment in marketable securities	7,672	(21,947)
Net loss on equity method investment	(2,060)	(414)
Miscellaneous reverse merger costs	—	(309)
Notes conversion costs	—	(3,341)
Interest and other income	2,303	232
Interest expense	(5,989)	(27,625)
Total other income (expense)	1,005	(50,166)
INCOME (LOSS) BEFORE INCOME TAXES	973	(54,678)
INCOME TAXES (BENEFIT)	(381)	164
NET INCOME (LOSS)	1,354	(54,842)
COMPONENTS OF OTHER COMPREHENSIVE INCOME (LOSS)		
Unrealized gain on debt securities available for sale (net of tax)	1,280	—
Foreign currency translation adjustments	(57)	(10)
Other comprehensive income (loss)	1,223	(10)
COMPREHENSIVE INCOME (LOSS)	$ 2,577	$ (54,852)
EARNINGS (LOSS) PER COMMON SHARE - BASIC and DILUTED	$ 0.03	$ (1.30)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING	48,897,004	42,259,460

The accompanying notes are an integral part of these consolidated financial statements.

Emmaus Life Sciences, Inc.
Consolidated Statements of changes IN stockholders' deficit
(In thousands, except share and per share amounts)

	Common Stock					
	Shares	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity / (Deficit)
Balance, December 31, 2018, as restated	37,341,393	$ 37	$ 149,682	$ (69)	$ (171,358)	$ (21,708)
Cumulative effect adjustment on adoption of ASC 842	—	—	—	—	(29)	(29)
Beneficial conversion feature relating to convertible notes payable	—	—	8,765	—	—	8,765
Common stock issued for cash (net of issuance cost)	1,677,013	2	8,587	—	—	8,589
Common stock issued in merger	2,330,548	2	(1,647)	—	—	(1,645)
Conversion of convertible notes payable and notes payable to common stock	7,068,760	7	39,492	—	—	39,499
Exercise of stock options	175	—	1	—	—	1
Exercise of warrants	53,557	—	186	—	—	186
Warrant and conversion feature reclassified to equity	—	—	6,336	—	—	6,336
Fair value of replacement equity awards	—	—	2,438	—	—	2,438
Foreign currency translation effect	—	—	—	(10)	—	(10)
Share-based compensation	—	—	1,367	—	—	1,367
Net loss	—	—	—	—	(54,842)	(54,842)
Balance, December 31, 2019	48,471,446	$ 48	$ 215,207	$ (79)	$ (226,229)	(11,053)
Common stock issued for cash (net of issuance cost)	515,743	1	141	—	—	142
Fair value of warrants including down-round protection adjustments	—	—	2,641	—	(204)	2,437
Unrealized gain on debt securities available for sale (net of tax)	—	—	—	1,280	—	1,280
Foreign currency translation effect	—	—	—	(57)	—	(57)
Share-based compensation	—	—	739	—	—	739
Net income	—	—	—	—	1,354	1,354
Balance, December 31, 2020	48,987,189	$ 49	$ 218,728	$ 1,144	$ (225,079)	$ (5,158)

The accompanying notes are an integral part of these consolidated financial statements.

Emmaus Life Sciences, Inc.
Consolidated Statements of Cash Flows
(In thousands)

	Twelve Months Ended December 31,	
	2020	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Income (loss)	$ 1,354	$ (54,842)
Adjustments to reconcile net loss to net cash flows from operating activities		
Depreciation and amortization	60	73
Impairment loss on long-term investment	—	515
Inventory reserve	1,134	—
Amortization of discount of notes payable and convertible notes payable	4,027	23,781
Foreign exchange adjustments	(678)	(115)
Tax benefit recognized on unrealized gain on debt securities	(427)	—
Net (gain) losses on investment in marketable securities	(7,672)	21,432
Loss on equity method investment	2,060	414
Loss on debt extinguishment	1,425	438
Share-based compensation and fair value of replacement equity award	739	3,805
Notes conversion costs	—	3,341
Change in fair value of warrant derivative liabilities	(392)	(3,545)
Change in fair value of embedded conversion option	(112)	(131)
Net changes in operating assets and liabilities		
Accounts receivable	1,953	(361)
Inventories	(245)	(3,267)
Prepaid expenses and other current assets	33	(720)
Other non-current assets	380	(4,364)
Income tax receivable and payable	(100)	(64)
Accounts payable and accrued expenses	(3,345)	6,527
Deferred rent	—	(317)
Other current liabilities	(3,053)	426
Other long-term liabilities	408	2,451
Net cash flows used in operating activities	(2,451)	(4,523)
CASH FLOWS FROM INVESTING ACTIVITIES		
Cash paid in connection with the Merger	—	(1,645)
Sale of marketable securities	35,601	221
Purchases of property and equipment	(15)	(60)
Purchase of convertible bonds	(26,160)	—
Loan to equity method investee	(3,956)	—
Net cash flows provided by (used in) investing activities	5,470	(1,484)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from notes payable issued, net of issuance cost and discount	2,765	600
Payments of notes payable	(1,717)	(143)
Payments of convertible notes	(3,500)	(5,348)
Proceeds from exercise of warrants	—	186
Proceeds from issuance of common stock, net of issuance cost	142	8,589
Net cash flows provided by (used in) financing activities	(2,310)	3,884
Effect of exchange rate changes on cash	9	(13)
Net increase (decrease) in cash, cash equivalents and restricted cash	718	(2,136)
Cash, cash equivalents and restricted cash, beginning of period	1,769	3,905
Cash, cash equivalents and restricted cash, end of period	$ 2,487	$ 1,769
SUPPLEMENTAL DISCLOSURES OF CASH FLOW ACTIVITIES		
Interest paid	$ 1,481	$ 1,543
Income taxes paid	$ 144	$ 227
NON-CASH INVESTMENT AND FINANCING ACTIVITIES		
Warrant liabilities reclassified to equity	$ —	$ 6,337
Conversion of convertible notes and notes payable to common stock	$ —	$ 33,777
Conversion of accrued interest payable to common stock	$ —	$ 5,722
Initial recognition of right-of-use lease asset	$ —	$ 2,922

The accompanying notes are an integral part of these consolidated financial statements.

NOTE 1—DESCRIPTION OF BUSINESS

Organization—On July 17, 2019 Emmaus Life Sciences, Inc. (formerly, "MYnd Analytics, Inc." and herein the "Company" or "Emmaus") completed its merger transaction (the "Merger") with EMI Holding, Inc., formerly known as Emmaus Life Sciences, Inc. ("EMI") a wholly owned subsidiary of the Company merged into EMI Holding, with EMI Holding surviving the Merger as a wholly owned subsidiary. Immediately after completion of the Merger, the Company changed its name to "Emmaus Life Sciences, Inc."

The Merger was treated as a reverse recapitalization under the acquisition method of accounting in accordance with accounting principles generally accepted in the U.S. ("GAAP") For accounting purposed, EMI Holding was considered to have acquired the Company.

In connection with and prior to the Merger, the Company contributed and transferred to Telemynd, Inc. ("Telemynd"), a newly formed, subsidiary of the Company, all or substantially all of the Company's historical business, assets and liabilities and the Company's board of directors declared a stock dividend of one share of the Telemynd common stock held by the Company for each outstanding share of Company common stock after giving effect to a 1-for-6 reverse stock of the Company's outstanding shares of common stock. The dividend, together with the contribution and transfer of the Company's historical business, assets, and liabilities described above, is referred to as the spin-off.

As a result of the spin-off and the Merger, the Company's ongoing business became EMI Holding's business, which is that of a commercial-stage biopharmaceutical company focused on the development, marketing and sale of innovative treatments and therapies, including those in the rare and orphan disease categories.

References herein to the "Company" or "Emmaus" means Emmaus Life Sciences, Inc. and its direct and direct subsidiaries.

Nature of Business—The Company is a commercial-stage biopharmaceutical company engaged in the discovery, development, marketing and sales of innovative treatments and therapies, primarily for rare and orphan diseases. On July 7, 2017, the U.S. Food and Drug Administration, or FDA, approved our lead product Endari® (prescription grade L-glutamine oral powder), to reduce the severe complications of sickle cell disease ("SCD") in adult and pediatric patients five years of age and older. Endari® has received Orphan Drug designation from the FDA and Orphan Medicinal designation from the European Commission, or EC, which designations generally afford marketing exclusivity for Endari® for a seven-year period in the U.S. and for a ten-year period in the EU, respectively, following marketing approval. Endari® also will be entitled to an additional two years of marketing exclusivity in the EU based on Emmaus' accepted pediatric investigation plan.

The Company commenced commercialization of Endari® in the U.S. in January 2018 in collaboration with a contract sales organization.Since January 2020, the Company has relied upon our in-house commercial sales team. Endari® is reimbursable by the Centers for Medicare and Medicaid Services, and every state provides coverage for Endari® for outpatient prescriptions to all eligible Medicaid enrollees within their state Medicaid programs. Endari® is also reimbursable by many commercial payors. The Company has distribution agreements in place with the nation's leading distributors, as well as physician group purchasing organizations and pharmacy benefits managers, making Endari® available at selected pharmacies nationwide. Prior to 2018, the Company had minimal revenues and relied upon funding from sales of equity securities and debt financings and loans, including loans from related parties to fund our business and operations.

On July 4, 2018, the FDA acknowledged receipt of the Company's investigational new drug application, or IND, for the treatment of diverticulosis using the same prescription-grade L-glutamine oral powder used in Endari®. The Company subsequently received a "Study May Proceed" letter from the FDA, and in July 2019 the Company successfully enrolled 1st subject in a Pilot/Phase 1 study of the safety and efficacy of prescription-grade L-glutamine oral powder and expects to enroll 10 to 15 patients at multiple study sites. The study will evaluate the change in the number and size of colonic diverticula and assess safety.

NOTE 2—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of presentation—The accompanying consolidated financial statements have been prepared in accordance with GAAP codified in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

Going concern— In accordance with Accounting Standards Update ("ASU") No. 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40), the Company has evaluated whether there are certain conditions and event, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued.

The accompanying consolidated financial statements have been prepared on the basis that the Company will continue as a going concern. The Company had net income of $1.4 million and net loss of $54.8 million for the years ended December 31, 2020 and 2019, respectively. The Company had $7.2 million of convertible debentures due within the next twelve months. However, the Company raised approximately $14.5 million in the first quarter of 2021 and paid off the entire debenture balance. In addition, the Company entered into a purchase and sale agreement with Prestige Capital Finance, LLC, pursuant to which Emmaus Medical may offer and sell to Prestige Capital from time to time eligible accounts receivable in exchange for Prestige Capital's down payment, or advance, to Emmaus Medical of 70% (subject to increase to 75%) of the face amount of the accounts receivable, subject to a $7,500,000 cap on advances at any time. After the Company becomes current with its SEC filing requirements, it could activate the Equity Purchase Agreement with Lincoln Park Capital Fund, LLC. (See Note 13), which could provide additional equity funding as necessary. Therefore, management concluded due to the improvement of the Company's ability to meet its current operating and capital expenses, there is no substantial doubt about the Company's ability to continue as a going concern.

Principles of consolidation—The consolidated financial statements include the accounts of the Company and EMI and its wholly-owned subsidiary, Emmaus Medical Inc., and Emmaus Medical, Inc's wholly-owned subsidiaries. All significant intercompany transactions have been eliminated.

Estimates—Financial statements prepared in accordance with GAAP require management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant assumptions made by management include those relating to revenue recognition on product sales, the estimated useful lives of equipment, impairment of assets, the variables used to calculate the valuation of conversion features, stock options and warrants, and estimated accruals on an ongoing basis. The Company' base's its estimates on historical experience and on various other assumptions that management believes to be reasonable under the circumstances. Actual results could differ from those estimates under different assumptions or conditions. To the extent there are material differences between these estimates and actuals, the Company's financial statements will be affected.

Revenue recognition— Net revenues from Endari® sales are recognized upon transfer to our distributors and specialty pharmacy providers. Distributors resell our products to other pharmacy and specialty pharmacy providers, health care providers, hospitals, and clinics. In addition to agreements with these distributors, we have contractual arrangements with specialty pharmacy providers, in-office dispensing providers, physician group purchasing organizations, pharmacy benefits managers and government entities that provide for government-mandated or privately negotiated rebates, chargebacks and discounts with respect to the purchase of Endari®. These various discounts, rebates, and chargebacks are referred to as "variable consideration." Revenue from product sales is recorded net of variable consideration.

Under ASC 606, the Company recognizes revenue when its customers obtain control of the Company's product, which typically occurs on delivery. Revenue is recognized in an amount that reflects the consideration that the Company expects to receive in exchange for the product, or transaction price. To determine revenue recognition for contracts with customers within the scope of ASC 606, the Company performs the following 5 steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the Company's performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies the relevant performance obligations.

Revenue from product sales is recorded at the transaction price, net of estimates for variable consideration consisting of sales discounts, returns, government rebates, chargebacks and commercial discounts. Variable consideration is estimated using the expected-value amount method, which is the sum of probability-weighted amounts in a range of possible transaction prices. Actual variable consideration may differ from the Company's estimates. If actual results vary from the Company's estimates, the Company adjusts the variable consideration in the period such variances becomes known, which

would affect net revenues in that period. The following are our significant categories of variable consideration:

Sales Discounts: The Company provides its customers prompt payment discounts and from time to time offers additional one-time discounts for bulk orders that are recorded as a reduction of revenues in the period the revenues are recognized.

Product Returns: The Company offers its distributors a right to return product purchased directly from the Company, which is principally based upon (i) overstocks, (ii) inactive product or non-moving product due to market conditions, and (iii) expired products. Product return allowances are estimated and recorded at the time of sale.

Government Rebates: The Company is subject to discount obligations under state Medicaid programs and the Medicare Part D prescription drug coverage gap program. The Company's management estimates Medicaid and Medicare Part D prescription drug coverage gap rebates based upon a range of possible outcomes that are probability-weighted for the estimated payor mix. These reserves are recorded in the same period the related revenues are recognized, resulting in a reduction of product revenues and the establishment of a current liability that is included as an accounts payable and accrued expenses in the balance sheet. The liability for these rebates consists primarily of estimates of claims expected to be received in future periods related to recognized revenues.

Chargebacks and Discounts: Chargebacks for fees and discounts represent the estimated obligations resulting from contractual commitments to sell products to certain specialty pharmacy providers, in-office dispensing providers, group purchasing organizations, and government entities at prices lower than the list prices charged to distributors. The distributors charge the Company for the difference between what they pay for the products and the Company's contracted selling price to these specialty pharmacy providers, in-office dispensing providers, group purchasing organizations, and government entities. In addition, we have contractual agreements with pharmacy benefit managers who charge us for rebates and administrative fee in connection with the utilization of product. These reserves are established in the same period that the related revenues are recognized, resulting in a reduction of revenues. Chargeback amounts are generally determined at the time of resale of products by the distributors.

Leases — The Company adopted ASU 2016-02 – Leases (Topic 842) ("ASC 842") as of January 1, 2019. Pursuant to ASC 842, all of the Company's leases outstanding on January 1, 2019 continued to be classified as operating leases. With the adoption of ASC 842, the Company recorded a right-of-use asset and an operating lease liability on our balance sheet. Right-of-use assets represent our right to use the underlying asset during the lease term and the operating lease liabilities represent the Company commitment to make lease payments arising from the lease. Right-of-use assets and operating lease liabilities were recognized based on the present value of remaining lease payments over the lease term. As the Company's leases do not provide an implicit rate, the Company has used an estimated incremental borrowing rate based on the information available at our adoption date in determining the present value of lease payments. Operating lease expense is recognized on a straight-line basis over the lease term. Variable lease costs such as common area costs and other operating costs are expensed as incurred. For all lease agreements, we combine lease and non-lease components. No right-of-use asset and related lease liability are recorded for leases with an initial term of 12 months or less.

Cash and cash equivalents—Cash and cash equivalents include short-term securities with original maturities of less than ninety days. The Company maintains its cash and cash equivalents at insured financial institutions, the balances of which may, at times, exceed federally insured limits. Management believes that the risk of loss due to the concentrations is minimal.

Accounts Receivable— Accounts receivables are primarily due from product sales to customers. The Company makes judgements as to its ability to collect outstanding receivables and provides an allowance for receivables when collection becomes doubtful. Provisions are made based upon a specific review of all significant outstanding invoices and the quality and age of those invoices. The Company believes the credit risks associated with its customers are not significant.

Inventories—Inventories consist of raw materials, finished goods and work-in-process and are valued on a first-in, first-out basis at the lesser of cost or net realizable value. Work-in-process inventories consist of L-glutamine for the Company's products that has not yet been packaged and labeled for sale. Substantially all raw materials purchase during the years ended December 31, 2020 and 2019 were supplied by one vendor.

Prepaid expenses and other current assets— Prepaid expenses and other current assets consist primarily of cost paid for future services or refunds from vendors which will occur within a year. Prepaid expenses include prepayment in

insurance, subscription services, consulting and other services which are being amortized over the contract terms or recognized upon services are performed.

Property and equipment— Equipment, Furniture and fixtures are recorded at historical cost and amortized on a straight-line basis over their estimated useful lives of five to seven years. Leasehold improvements are recorded at historical cost and amortized on a straight-line basis over the shorter of their estimated useful lives or the lease terms. Maintenance and repairs are expensed as incurred, while major additions and improvements are capitalized. Gains and losses on disposition are included in other income (expenses), if any.

Impairment of long-lived assets—The Company evaluates the carrying value of its long-lived assets for impairment whenever events or changes in circumstances indicate that such carrying values may not be recoverable. The Management uses its best judgment based on the current facts and circumstances relating to the Company's business when determining whether any significant impairment factors exist.

If the Company determines that the carrying values of long-lived assets may not be recoverable based upon the existence of one or more indicators of impairment, the Company performs an undiscounted cash flow analysis to determine if impairment exists. If impairment exists, the Company measures the impairment based on the difference between the asset's carrying amount and its fair value, and the impairment is charged to the consolidated statement of operations in the period in which the long-lived asset impairment is determined to have occurred. No impairment existed as of December 31, 2020 and 2019.

Research and development—Research and development consists of expenditures for the research and development of new products and technologies, which primarily involve contract research, payroll-related expenses and other related supplies. Research and development costs are expensed as incurred.

Share-based compensation—The Company recognizes compensation cost for share-based compensation awards over the service term of the recipients of the share-based awards. The fair value of share-based compensation is calculated using the Black-Scholes-Merton pricing model. The Black-Scholes-Merton model requires subjective assumptions regarding future stock price volatility and expected time to exercise, which greatly affect the calculated values. The expected term of awards granted is calculated using the simplified method allowed under the Securities and Exchange Commission ("SEC") Staff Accounting Bulletin Nos. 107 and 110. The risk-free rate selected to value any grant is based on the U.S. Treasury rate on the grant date that corresponds to the expected term of the award. Prior to the Merger, the Company common stock was not publicly traded. Therefore, the expected volatility was based on the historical volatility of common stock of comparable publicly traded companies.

Income taxes—The Company accounts for income taxes under the asset and liability method, wherein deferred tax assets and liabilities are recognized for the future tax consequences attributable to the differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period the enactment occurs. A valuation allowance is provided for certain deferred tax assets if it is more likely than not that the Company will not realize tax assets through the generation of future taxable income for the related jurisdictions.

When tax returns are filed, it is highly probable that some positions taken would be sustained upon examination by the taxing authorities, while others are subject to uncertainty about the merits of the position taken or the amount of the position that would be ultimately sustained. The benefit of a tax position is recognized in the financial statements in the period during which, based on all available evidence, management believes it is more likely than not that the position will be sustained upon examination, including the resolution of appeals or litigation processes, if any. Tax positions taken are not offset or aggregated with other positions. Tax positions that meet the more-likely-than-not recognition threshold are recorded at the largest amount of tax benefit that is more than 50 percent likely of being realized upon examination by the applicable taxing authority. The portion of the benefits associated with tax positions taken that exceeds the amount measured as described above is reflected as a liability for unrecognized tax benefits along with any associated interest and penalties that would be payable to the taxing authorities upon examination.

As of December 31, 2020 and December 31, 2019, the Company hadno unrecognized tax benefits, and the Company had no positions which, in the opinion of management, would be reversed if challenged by a taxing authority. In

the event the Company is assessed interest and/or penalties, such amounts will be classified as income tax expense in the financial statements.

Comprehensive income (loss)—Comprehensive income (loss) includes net loss and other comprehensive income (loss) relating to foreign translation adjustments of the Company's subsidiaries.

Marketable securities— The Company measures equity investments that do not result in consolidation and are not accounted for under the equity method at fair value and recognize any changes in earnings. The Company uses quoted market prices to determine the fair value of equity securities with readily determinable fair values. For equity securities without readily determinable fair values, the Company has elected the measurement alternative under which the Company measures these investments at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer. Management assesses each of these investments on an individual basis. Additionally, on a quarterly basis, management is required to make a qualitative assessment of whether the investment is impaired; however, the Company is not required to determine the fair value of these investments unless impairment indicators existed. When impairment indicators exist, the Company generally uses discounted cash flow analyses to determine the fair value.

Equity method investment – The Company owns 40% of the capital shares of EJ Holdings. A variable interest entity ("VIE") such as EJ Holdings is to be consolidated by its primary beneficiary if the Company has both a) the power to direct the activities of the VIE that most significantly impact the VIE's economic performance and b) the obligation to absorb losses of, or the right to receive benefits from, the VIE that could potentially be significant to the VIE. The Company determined that it does not meet the power criterion for consolidating EJ Holdings and, accordingly, accounts for its variable interest in EJ Holdings under the equity method. See Note 5 for additional details.

Investment in convertible bond – The Company has elected the fair value option measuring investment in convertible bond. The convertible bond is classified as available for sales and the changes in fair value are reported in other comprehensive income for each reporting period.

Foreign currency translation—The Company's reporting currency is the U.S. dollar. The functional currencies of its foreign subsidiaries are the primary currencies within the counties in which they operate. Assets and liabilities of their operations are translated into U.S. dollars at period-end exchange rates, and revenues, if any, and expenses are translated into U.S. dollars at average exchange rates in effect during each reporting period. Adjustments resulting from the translation are reported in other comprehensive income or loss.

Financial instruments—Financial instruments included in the financial statements are comprised of cash and cash equivalents, restricted cash, investment in marketable securities, marketable securities pledged to creditor, long-term investment at cost, investment in convertible bond, accounts receivable, note receivable, warrant derivative liabilities, accounts payable, certain accrued liabilities, convertible notes payable, notes payable, conversion feature liabilities and other contingent liabilities.

Fair value measurements—The Company defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The Company measures fair value under a framework that provides a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). The three levels of the fair value hierarchy are described as follows:

Level 1: Inputs to the valuation methodology are unadjusted quoted prices for identical assets or liabilities in active markets.

Level 2: Inputs to the valuation methodology include:

Quoted prices for similar assets or liabilities in active markets;

Quoted prices for identical or similar assets or liabilities in inactive markets;

Inputs other than quoted prices that are observable for the asset or liability;

Inputs that are derived principally from or corroborated by observable market data by correlation or other means.

If the asset or liability has a specified (contractual) term, the Level 2 inputs must be observable for substantially the full term of the asset or liability.

Level 3: Inputs to the valuation methodology are unobservable and significant to the fair value measurement.

An asset's or liability's fair value measurement level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. Valuation techniques used need to maximize the use of observable inputs and minimize the use of unobservable inputs. The carrying values of cash and cash equivalents, accounts receivables, other current assets, account payable and accrued expenses and revolving line of credit approximate fair value due to the short-term maturity of those instruments. The fair value assigned to marketable securities is determined by obtaining quoted prices on nationally recognized securities exchanges and are classified as Level 1 investments as of December 31, 2019. The fair value of the Company's convertible debt instruments was determined based on Level 2 inputs. The carrying value of the debt was discounted based on allocating proceeds to other financial instruments within the arrangement as discussed in Note 7.

Beneficial conversion features of convertible notes payable - The convertible feature of certain notes payable provides for a conversion rate that is below market value. Such feature is normally characterized as a Beneficial Conversion Feature or BCF. The Company measures the estimated intrinsic value of the BCF when the conversion feature is not required to be separately accounted from the notes payable. The value of BCF is recorded as a discount from the face amount of the notes and amortized to interest expense over the term of the notes.

Earnings (loss) per share—In accordance with ASC 260, *"Earnings per Share,*" the basic loss per common share is computed by dividing net loss available to common stockholders by the weighted-average number of common shares outstanding. Dilutive loss per share is computed in a manner similar to the basic loss per common share except that the denominator is increased to include the number of additional common shares that would have been outstanding if the potential common shares had been issued and if the additional common shares were dilutive. As of December 31, 2020 and 2019, there were 18,449,925 shares and 12,933,664 shares, respectively of potentially dilutive securities outstanding. None of the potentially dilutive securities were included in the calculation of diluted loss per share since their effect would be anti-dilutive for all periods presented.

Segment reporting—The Company operates in one reportable segment.

Recent accounting pronouncements— In June 2016, the FASB issued ASU 2016-13—Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments, which represents a new credit loss standard that will change the impairment model for most financial assets and certain other financial instruments. Specifically, this guidance will require entities to utilize a new "expected loss" model as it relates to trade and other receivables. In addition, entities will be required to recognize an allowance for estimated credit losses on available-for-sale debt securities, regardless of the length of time that a security has been in an unrealized loss position. This guidance was effective for annual reporting periods beginning after December 15, 2023 for small reporting companies, including interim periods within those annual reporting periods. Early adoption is permitted. The Company is currently evaluating the potential impact that the adoption of ASU 2019-12 may have on the Company's financial position and results of operations.

In August 2018, the FASB issued ASU No. 2018-13, Fair Value Measurement (Topic 820):*Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"), which changes the fair value measurement disclosure requirements of ASC 820. The amendments in this Update removes some disclosures, modifies others, and add some new disclosure requirements. The amendments in this ASU are effective for all entities for fiscal years, and interim period within those fiscal years, beginning after December 15, 2019 with early adoption permitted. The adoption of ASU 2018-13 did not have a material impact on the Company's financial position and results of operations.

In October 2018, the FASB issued ASU No. 2018-17,*Consolidation (Topic 810): Targeted Improvements to Related Party Guidance for Variable Interest Entities* ("ASU 2018-17"). The update is intended to improve general purpose financial reporting by considering indirect interests held through related parties in common control arrangements on a proportional basis for determining whether fees paid to decision makers and service providers are variable interests. The amendments in ASU 2018-17 will be effective for fiscal years beginning after December 15, 2019, with early adoption permitted. The Company is currently evaluating the potential impact that the adoption of ASU 2019-12 may have on the Company's financial position and results of operations.

In December 2019, the FASB issued ASU No. 2019-12,*Income Taxes (Topic 740): Simplifying the Accounting for Income Taxe.* ("ASU 2019-12"), which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and clarifies and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. The Company is currently evaluating the potential impact that the adoption of ASU 2019-12 may have on the Company's financial position and results of operations.

In August 2020, the FASB issued ASU No. 2020-06,*Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging— Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* ("ASU 2020-06"). The amendments in ASU 2020-06 simplify the accounting for certain financial instruments with characteristics of liabilities and equity, including convertible instruments and contracts on an entity's own equity. Under ASU 2020-06, a convertible debt instrument will be accounted for as a single liability measured at its amortized cost as long as no other features require bifurcation and recognition as derivatives. These changes will reduce reported interest expense and increase reported net income for entities that have issued a convertible instrument that was bifurcated under previously existing guidance. The new guidance also requires the if-converted method to be applied for all convertible instruments. The standard is effective for public companies for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2021. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of ASU 2020-06 may have on the Company's financial position and results of operation.

NOTE 3—REVENUES

Revenues by category were as follows (in thousands):

	Year ended December 31,	
	2020	2019
Endari®	$ 22,564	22,311
Other	603	441
Revenues, net	$ 23,167	$ 22,752

The following table summarizes the revenue allowance and accrual activities for the years ended December 31, 2020 and 2019 (in thousands):

	Trade Discounts, Allowances and Chargebacks	Government Rebates and Other Incentives	Returns	Total
Balance as of December 31, 2018	$ 84	$ 798	$ 99	981
Provision related to sales in the current year	1,393	3,082	216	4,691
Credit and payments made	(1,249)	(2,526)	—	(3,775)
Balance as of December 31, 2019	228	1,354	315	1,897
Provision related to sales in the current year	2,686	3,752	245	6,683
Adjustments related to prior period sales	16	(44)	(87)	(115)
Credit and payments made	(2,796)	(2,943)	—	(5,739)
Balance as of December 31, 2020	$ 134	$ 2,119	$ 473	$ 2,726

The following table sets forth information regarding customers that accounted for 10% or more of net revenues:

	Revenue for year ended December 31,	
	2020	2019
Customer A	60 %	60 %
Customer B	20 %	24 %

The Company is party to a distributor agreement with Telcon pursuant to which it granted Telcon exclusive rights to the Company's pharmaceutical grade L-glutamine ("PGLG") oral powder for the treatment of diverticulosis in South Korea, Japan and China in exchange for Telcon's payment of a $10 million upfront fee and agreement to purchase from us specified minimum quantities of the finished product. In a related license agreement with Telcon, the Company agreed to use commercially reasonable best efforts to obtain product registration in these territories within three years of obtaining FDA marketing authorization for PGLG in this indication. Telcon has the right to terminate the distributor agreement in certain circumstances for failure to obtain such product registrations, in which event the Company would be obliged to return to Telcon the $10 million upfront fee. The upfront fee of $10 million is included in other long-term liabilities as unearned revenue as of December 31, 2020 and 2019. Refer Note 12 for related party transaction details.

The Company received a non refundable deposit of $500,000 in connection with entering into a distribution agreement with a strategic partner in 2018 to distribute Endari® in the Middle East and North Africa region. The payment was recorded as unearned revenue and included in other long-term liabilities to be recognized as revenue when the performance obligations are satisfied. During 2020, the agreement was terminated and the Company recognized the upfront payment of $500,000 in other income.

NOTE 4—SELECTED FINANCIAL STATEMENT CAPTIONS - ASSETS

Inventories consisted of the following (in thousand):

	As of December 31,	
	2020	2019
Raw materials and components	$ 1,486	$ 1,187
Work-in-process	721	1,629
Finished goods	6,064	5,204
Inventory reserve	(1,184)	(49)
Total	$ 7,087	$ 7,971

Prepaid expenses and other current assets consisted of the following (in thousands):

	As of December 31,	
	2020	2019
Other prepaid expenses and current assets	1,097	667
Prepaid insurance	$ 388	$ 735
Total	$ 1,485	$ 1,402

Property and equipment consisted of the following (in thousands):

	As of December 31,	
	2020	2019
Equipment	$ 347	$ 335
Leasehold improvements	39	77
Furniture and fixtures	99	95
Total property and equipment	485	507
Less: accumulated depreciation	(365)	(356)
Property and Equipment, net	$ 120	$ 151

For the years ended December 31, 2020 and 2019, depreciation expense was approximately $46,000 and $47,000, respectively.

NOTE 5 — INVESTMENTS

Equity securities— The Company held 6,643,559 shares of capital stock of Telcon RF Pharmaceutical, Inc., a Korean corporation (formerly, Telcon Inc. and herein "Telcon"), which were acquired in July 2017 for approximately $31.8 million. As of December 31, 2019, the closing prices per Telecon share on the Korean Securities Dealers Automated Quotations ("KOSDAQ") was approximately $4.20. The balance measured at fair value was $27.9 million recorded in investment in marketable securities and net unrealized losses on available-for sale marketable securities held as of December

31, 2019 was $43.2 million.

Prior to December 31, 2019, all shares of Telcon common stock were pledged to secure our obligation under the revised API agreement with Telcon. In December 2019, the API agreement was amended to permit the release the Telcon shares from the pledge and to permit the Company to sell the shares in exchange for a portion of the net sale proceeds to be used to purchase a 10-year convertible bond of Telcon in the principal amount of KRW30 billion, or approximately $26.1 million to be substituted for the Telcon shares and pledged to Telcon to secure the Company's obligations under the revised API Agreement between the Company and Telcon. During the year ended December 31, 2020, the Company sold all shares for $35.6 million. Refer Note 12 for more information regarding this agreement.

The Company measures equity investments that do not result in consolidation and are not accounted for under the equity method at fair value and recognize any changes in earnings. The Company uses quoted market prices to determine the fair value of equity securities with readily determinable fair values. For equity securities without readily determinable fair values, the Company has elected the measurement alternative under which the Company measures these investments at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer. Management assesses each of these investments on an individual basis. Additionally, on a quarterly basis, management is required to make a qualitative assessment of whether the investment is impaired; however, the Company is not required to determine the fair value of these investments unless impairment indicators existed. When impairment indicators exist, the Company generally uses discounted cash flow analyses to determine the fair value. For the year ended December 31, 2019, the Company recognized approximately $515,000 in impairment loss for equity securities without readily determinable fair value level 3 fair value hierarchy attributable to an investment in KPS Co., Ltd.

Investment in convertible bonds - On September 28, 2020, the Company entered into a convertible bond purchase agreement pursuant to which it purchased at face value a convertible bond of Telcon in the principal amount of approximately $26.1 million which matures on October 16, 2030 and bears interest at the rate of2.1% a year, payable quarterly. Beginning on October 16, 2021, the Company will be entitled on a quarterly basis to call for early redemption of all or any portion of the principal amount of the convertible bond. The convertible bond is convertible at the holder's option at any time and from time to time into common shares of Telcon at an initial conversion price of approximately $8.00, per share. The conversion price is subject to antidilution adjustments in the event of the issuance of Telcon shares or share equivalents at a price below the market price of Telcon shares, a merger or similar reorganization of Telcon or a stock split, reverse stock split, stock dividend or similar event. The convertible bond and any proceeds therefrom, including proceeds from any exercise of the early redemption right or the call option described below, are pledged as collateral to secure the Company's obligations under the revised API Supply Agreement with Telcon.

In connection with the purchase of the convertible bond, the Company entered into a call option agreement dated September 28, 2020 with Telcon pursuant to which Telcon or its designee is entitled to repurchase, at par, up to 50% in principal amount of the convertible bond commencing October 16, 2021 and prior to maturity. If the Company transfers the convertible bond, it will be obliged under the call option agreement to see to it that the transferee is bound by such call option.

The Company has elected fair value option to measure the investment in convertible bond.The investment in convertible bonds is classified available for sale securities and remeasured at fair value on a recurring basis using Level 3 inputs, with any changes in the fair value option recorded in other comprehensive income. The fair value and any changes in fair value in convertible bonds are determined using a binominal lattice model. The model produces an estimated fair value based on changes in the price of the underlying common stock over successive periods of time.

The following table sets forth the fair value of the investment in convertible bonds as of December 31, 2020 and 2019 (in thousands):

Investment in convertible bonds	December 31, 2020
Balance, beginning of period	$ —
Fair value at issuance date	22,059
Change in fair value included in the statement of other comprehensive income (loss)	5,827
Balance, end of period	$ 27,886

The fair values as of October 16, 2020 and December 31, 2020 were based upon following assumptions:

	December 31, 2020	At Issuance
Principal outstanding (South Korean won)	KRW 30 billion	KRW 30 billion
Stock price	KRW 6,060	KRW 7,210
Expected life (in years)	9.79	10.00
Selected yield	10.50 %	13.00 %
Expected volatility (Telcon common stock)	85.80 %	86.90 %
Risk-free interest rate (South Korea government bond)	1.72 %	1.50 %
Expected dividend yield	0.00 %	0.00 %
Conversion price	KRW 6,028	KRW 9,232

Equity method investment – During 2018, the Company and Japan Industrial Partners, Inc., or JIP, formed EJ Holdings to acquire, own and operate an amino acids manufacturing facility in Ube, Japan. As part of the formation, the Company invested approximately $32,000 in exchange for 40% of EJ Holdings voting shares. JIP owns 60% of EJ Holdings voting shares. In October 2018, the Company entered into a loan agreement with EJ Holdings under which the Company made an unsecured loan to EJ Holdings in the amount of $13.6 million. The loan matures on September 30, 2028 and bears interest at the rate of 1% payable annually. The loan proceeds were used by EJ Holdings to purchase the Ube facility in December 2019 and pay related taxes. In October 2020, the Company entered into a loan agreement with EJ Holdings pursuant to which it agrees to loan to EJ Holdings a total of approximately $6.5 million, in monthly instalments through March 2021. The loans will be unsecured general obligations of EJ Holdings, will bear interest at a nominal annual rate payable on September 30 of each year beginning in 2021 and will be due and payable in a lump sum at maturity on September 30, 2020. The proceeds of the loans will be used by EJ Holdings to fund its activities and operations at its Ube facility. The parties also contemplated that the Ube facility will eventually supply the Company with the facility's output of amino acids, that the operation of the facility will be principally for our benefit and, as such, that major decisions affecting EJ Holdings and the Ube facility will be made by EJ Holdings' board of directors, a majority of which are representatives of JIP. During the year ended December 31, 2020, the Company made additional $4.0 million loans to EJ Holdings. As of December 31, 2020, and 2019,the loan receivables were approximately $18.6 million and $13.8 million, respectively.

EJ Holdings is engaged in phasing in the Ube facility, including obtaining FDA and other regulatory approvals for the manufacture of PGLG in accordance with cGMP. EJ Holdings has had no revenues since its inception, has depended on loans from the Company to acquire the Ube facility and fund its operations and will continue to be dependent on loans from us or other financing unless and until the Ube facility is activated and EJ Holdings can secure customers for its products.

The Company has determined that EJ Holdings is a variable interest entity, or VIE, based upon the facts that the Company provided the loan financing to acquire the Ube facility and the EJ Holdings activities at the facility are principally for the Company's benefit. JIP, however, owns 60% of EJ Holdings and is entitled to designate a majority of EJ Holdings' board of directors and its Chief Executive Officer and outside auditors, and, as such, controls the management, business and operations of EJ Holdings. Accordingly, the Company accounts for its variable interest in EJ Holdings under the equity method.

The Company's share of the losses reported by EJ Holdings are classified as net losses from equity method investment. The investment is evaluated for impairment annually and if facts and circumstances indicate that the carrying value may not be recoverable, an impairment charge would be recorded.

The following table sets forth certain unaudited financial information of EJ Holdings for years ended December 31, 2020 and 2019 (in thousands):

	As of December 31,	
	2020	2019
ASSETS		
CURRENT ASSETS	$ 1,136	$ 2,310
OTHER ASSETS	11,824	10,654
Total assets	$ 12,960	$ 12,964
LIABILITIES		
CURRENT LIABILITIES	$ 987	$ 296
LONG-TERM LIABILITIES	18,560	13,870
Total liabilities	$ 19,547	$ 14,166
NONCONTROLLING INTEREST	$ (3,952)	$ (721)

	Year Ended December 31,	
	2020	2019
REVENUES, NET	$ 261	$ 229
NET LOSS	$ (5,150)	$ (1,035)

NOTE 6—SELECTED FINANCIAL STATEMENT CAPTIONS - LIABILITIES

Accounts payable and accrued expenses consisted of the following (in thousands):

	December 31, 2020	December 31, 2019
Accounts payable:		
Clinical and regulatory expenses	$ 262	$ 232
Professional fees	252	1,183
Selling expenses	395	1,303
Manufacturing cost	596	4,541
Other vendors	518	18
Total accounts payable	2,023	7,277
Accrued interest payable, related parties	41	42
Accrued interest payable	627	991
Accrued expenses:		
Payroll expenses	1,053	891
Government rebates and other rebates	2,659	1,355
Due to EJ Holdings	545	238
Other accrued expenses	512	704
Total accrued expenses	4,769	3,188
Total accounts payable and accrued expenses	$ 7,460	$ 11,498

Other long-term liabilities consisted of the following (in thousands):

	As of December 31,	
	2020	2019
Trade discount	$ 24,453	$ 23,242
Unearned revenue	10,000	10,500
Other long-term liabilities	17	8
Total other long-term liabilities	$ 34,470	$ 33,750

On June 12, 2017, the Company entered into an API Supply Agreement, as subsequently amended (as so amended, the "API Agreement"), with Telcon pursuant to which Telcon advanced to the Company approximately $31.8 million as an advance trade discount in consideration of the Company's agreement to purchase from Telcon the Company's requirements for bulk containers of PGLG. The Company purchased $2.2 million and $4.5 million of PGLG from Telcon during years ended December 31, 2020, and 2019, respectively, of which $208,000 and $3.7 million were reflected in accounts payable as of December 31, 2020 and 2019, respectively. See Note 11 for additional details.

NOTE 7—NOTES PAYABLE

Notes payable consisted of the following at December 31, 2020 and 2019 (in thousands except for conversion price and shares):

Year Issued	Interest Rate Range	Term of Notes	Conversion Price	Principal Outstanding December 31, 2020	Discount Amount December 31, 2020	Carrying Amount December 31, 2020	Shares Underlying Notes December 31, 2020	Principal Outstanding December 31, 2019	Discount Amount December 31, 2019	Carrying Amount December 31, 2019	Shares Underlying Notes December 31, 2019
Notes payable											
2013	10%	Due on demand	—	$ 969	$ —	$ 969	—	$ 920	$ —	$ 920	—
2019	11%	Due on demand	—	2,899	—	2,899	—	2,829	—	2,829	—
2020	11%	Due on demand	—	942	—	942	—	—	—	—	—
				$ 4,810	**$ —**	**$ 4,810**	**—**	**$ 3,749**	**$ —**	**$ 3,749**	**—**
		Current		$ 4,588	$ —	$ 4,588	—	$ 3,749	$ —	$ 3,749	—
		Non-current		$ 222	$ —	$ 222	—	$ —	$ —	$ —	—
Notes payable - related party											
2016	10% - 11%	Due on demand	—	$ 20	$ —	$ 20	—	$ 20	—	$ 20	—
2018	11%	Due on demand	—	—	—	—	—	159	—	159	—
2019	10%	Due on demand	—	14	—	14	—	14	—	14	—
2020	12%	Due on demand	—	100	—	100	—	—	—	—	—
				$ 134	**$ —**	**$ 134**	**—**	**$ 193**	**$ —**	**$ 193**	**—**
		Current		$ 134	$ —	$ 134	—	$ 193	$ —	$ 193	—
Convertible debentures											
2019	10%	18 months	$2.00-$9.52	$ 7,200	$ 1,720	$ 5,480	3,630 (a)	$ 10,200	$ 3,185	$ 7,015	1,080,415
				$ 7,200	**$ 1,720**	**$ 5,480**	**3,630**	**$ 10,200**	**$ 3,185**	**$ 7,015**	**1,080,415**
		Current		$ 7,200	$ 1,720	$ 5,480		$ 10,200	$ 3,185	$ 7,015	—
Convertible notes payable											
2018	6% - 10%	Due on demand - 2 years	$ 10.00	3,150	$ —	3,150	316,723 (b)	3,000	5	2,995	363,876
				$ 3,150	**$ —**	**$ 3,150**	**316,723**	**$ 3,000**	**$ 5**	**$ 2,995**	**363,876**
		Non-current		$ 3,150	$ —	$ 3,150	—	$ —	$ —	$ —	—
		Grand Total		**$ 15,294**	**$ 1,720**	**$ 13,574**	**$ 320,353**	**$ 17,142**	**$ 3,190**	**$ 13,952**	**$ 1,444,291**

(a) The notes are convertible into Emmaus Life Sciences, Inc. shares.

(b) This note is convertible into EMI Holdings Inc. shares.

The average stated interest rate of notes payable was10% for the years ended December 31, 2020 and 2019. The average effective interest rate of notes payable for the years ended December 31, 2020 and 2019 was 37% and 66%, respectively, after giving effect to discounts relating to warrants, beneficial conversion features and deferred financing cost in connection with these notes.

As of December 31, 2020, future contractual principal payments due on notes payable were as follows (in thousands):

Year Ending	December 31, 2020
2021	$ 11,922
2022	222
2023	3,150
Total	$ 15,294

Immediately prior to the completion of the Merger, all but one of the convertible notes payable were converted into shares of EMI common stock at their respective conversion prices. Upon completion of the Merger, the conversion shares were exchanged for shares of the Company common stock in the same manner as other outstanding shares of common stock of EMI based on the Merger "exchange ratio." The unconverted convertible note payable of EMI is convertible into shares of common stock of EMI at conversion price of $10.00 per share and included in convertible notes payable.

The Company estimated the total fair value of any beneficial conversion feature and any accompanying warrants in allocating the proceeds from the sale of convertible notes payable. The proceeds allocated to the beneficial conversion feature were determined by taking the estimated fair value of shares underlying the convertible notes less the fair value of the number of shares that would be issued if the conversion rate equaled the fair value of common stock as of the date of issuance. In situations where the notes included both a beneficial conversion feature and a warrant, the proceeds were allocated to the beneficial conversion feature and the warrants based on the pro-rata fair value.

The 10% Senior Secured Debentures were amended and restated immediately prior to the Merger to, among other things, make them convertible into shares of common stock of EMI and to provide for adjustments in the conversion shares issuable upon conversion of the Debentures and the conversion price in the event of a merger, reorganization and similar events. Accordingly, upon completion of the Merger the Amended and Restated 10% Senior Secured Convertible Debentures became convertible into shares of common stock of the Company and included in convertible notes payable.

The conversion feature of the Amended and Restated 10% Senior Secured Convertible Debentures was separately accounted for at fair value as derivative liabilities under guidance in ASC 815 that is remeasured at fair value on a recurring basis using Level 3 inputs, with any changes in the fair value of the conversion feature liabilities recorded in earnings. The following table sets forth the fair value of the conversion feature liabilities, which is included in the other current liabilities as of December 31, 2020 and 2019 (in thousands):

Conversion feature liabilities—Amended and Restated 10% Senior Secured Convertible Debentures	December 31, 2020	December 31, 2019
Balance, beginning of period	$ 1	$ —
Fair value at issuance date	—	132
Fair value at modification date	118	—
Change in fair value	(112)	(131)
Balance, end of period	$ 7	$ 1

The fair value and any changes in fair value of conversion feature liabilities are determined using a binominal lattice model. The model produces an estimated fair value based on changes in the price of the underlying common stock over successive periods of time.

The fair values as of December 31,2020, the February 21, 2020 modification date and December 31,2019 and as of the Merger date were based upon following assumptions:

	December 31, 2020	February 21, 2020 (Modification date)	December 31, 2019
Stock price	$ 1.23	$ 1.89	$ 1.97
Conversion price	$ 2.00	$ 3.00	$ 9.52
Selected yield	10.48 %	19.12 %	16.77 %
Expected volatility (peer group)	95.00 %	65.00 %	50.00 %
Expected life (in years)	0.67	1.16	0.81
Expected dividend yield	—	—	—
Risk-free rate	Term structure	Term structure	Term structure

See Note 14 for information regarding the recent prepayment of the Amended and Restated 10% Senior Secured Convertible Debentures.

The Company is party to a revolving line of credit agreement with Dr. Niihara, the Company's Chairman and Chief Executive Officer. Under the agreement, at the Company's request from time to time, Dr. Niihara may, but is not obligated to, loan or re-loan to the Company up to $1,000,000. Outstanding amounts under the agreement are due and payable upon demand and bear interest, payable monthly, at a variable annual rate equal to the Prime Rate in effect from time to time plus 3%. In addition to the payment of interest, the Company is obligated to pay Dr. Niihara a "tax gross-up" intended to make him whole for federal and state income taxes payable by him with respect to interest paid to him in the previous year. As of December 31, 2020, and 2019, the outstanding balances of $800,000 and $600,000 were reflected in revolving line of credit, related party on the consolidated balance sheet. With the tax-gross up, the effective interest rate on the outstanding balance as of December 31, 2020 and 2019 was 10.4%. The revolving line of credit agreement will expire on November 22, 2022. Refer to Note 12 for more information regarding this arrangement.

On May 8, 2020, the Company received a loan in the amount of $797,840 under the Small Business Administration Paycheck Protection Program ("PPP"). The PPP, established as part of the Coronavirus Aid, Relief and Economic Security Act ("CARES Act"), provides for loans to qualifying businesses for amounts up to 2.5 times of the average monthly payroll expenses of the qualifying business. The loan, which is in the form of a Promissory Note dated April 29, 2020, matures on April 29, 2022 and bears interest at a rate of 1% per annum, payable monthly commencing on December 8, 2020 unless the PPP loan is forgiven prior to the date of the first monthly payment or the loan forgiveness process has commenced. The Note may be prepaid by the Company at any time prior to maturity with no prepayment penalties.The loan and accrued interest are forgivable after a specific period as long as the Company uses the loan proceeds for eligible purposes, including payroll, benefits, rent and utilities, and maintains its payroll levels. The Company has applied for PPP loan forgiveness. The amount of loan forgiveness would be reduced if the Company were to terminate employees or reduce salaries during such period. The PPP loan amount of $797,840 was included in note payable on the consolidated balance sheet.

NOTE 8—STOCKHOLDERS' DEFICIT

Purchase Agreement with GPB—On December 29, 2017, the Company entered into the Purchase Agreement with GPB Debt Holdings II, LLC ("GPB"), pursuant to which the Company issued to GPB a $13 million principal amount senior secured convertible promissory note (the "GPB Note") for an aggregate purchase price of $12.5 million, reflecting a 4.0% original issue discount.

In connection with the issuance of GPB Note, the Company also issued to GPB a warrant (the "GPB Warrant") to purchase up to 240,764 of common stock at an exercise price of $10.80 per share, with customary adjustments for stock splits, stock dividends and other recapitalization events and anti-dilution provisions set forth in the GPB Warrant. The GPB Warrant became exercisable six months after issuance and has a term of five years from the initial exercise date.

The Company determined that under ASC 815-40, GPB Warrant should be separately recognized at fair value as a liability upon issuance. The warrant liability is remeasured at fair value on a recurring basis using Level 3 inputs and any change in the fair value of the liability is recorded in earnings.

The following table sets forth the fair values of the warrants as of December 31, 2020 and 2019 (in thousands):

Warrant liability—GPB	December 31, 2020	December 31, 2019
Balance, beginning of period	$ 38	$ 1,399
Change in fair value included in the statement of operations	45	(1,361)
Balance, end of period	$ 83	$ 38

Prior to the Merger, the value of warrant derivative liabilities and any change in fair value were determined using a Binominal Monte-Carlo Cliquet Option Pricing Model. After the Merger, the fair value of the warrant derivative liabilities was determined using the Black-Scholes option pricing models.

The value as of the dates set forth the in the table below, were based on upon following assumptions:

	December 31, 2020	December 31, 2019
Stock price	$ 1.23	$ 1.97
Risk-free interest rate	0.15 %	1.64 %
Expected volatility (peer group)	120.00 %	60.00 %
Expected life (in years)	2.50	3.50
Expected dividend yield	—	—
Number outstanding	252,802	252,802

Purchase Agreement with Holders of 10% Senior Secured Debentures—In October 2018, EMI sold and issued $12.2 million principal amount of 10% Senior Secured Debentures and common stock purchase warrants to purchase an aggregate of up to 1,220,000 shares of EMI common stock to a limited number of accredited investors. EMI's obligations under the Debentures were secured by a security interest in substantially all EMI assets and guaranteed by EMI's U.S. subsidiaries. The net proceeds of the sale of the debentures and warrants were used to fund EMI's original $13.2 million loan to EJ Holdings, Inc. in October 2018 reflected on the Company's consolidated balance sheets.

As described in Note 7 above, the Debentures were amended and restated in their entirety in conjunction with the Merger. The common stock purchase warrants issued in conjunction with the original Debentures also were amended and restated in their entirety in conjunction with the Merger.

The Amended and Restated 10% Senior Secured Convertible Debentures issued in conjunction with the Merger were convertible at the option of each holder into shares of EMI common stock immediately prior to the Merger at a conversion price of $10.00 a share, subject to adjustment for stock splits, merger reorganizations and other customary events. The related amended and restated warrants were exercisable immediately prior to the Merger for an aggregate of 1,460,000 shares of EMI common stock at an initial exercise price of $10.00 per share. The exercise price of the warrants was subject to reduction in connection with a "going public event" such as the Merger based upon the "VWAP" (i.e., volume-weighted average trading price) of the Company common stock at the time of the Merger. Upon completion of the Merger, the amended and restated warrants became exercisable for shares of the Company common stock and the exercise price of the warrants and the number of underlying warrant shares were adjusted based upon exchange ratio in the Merger. The exercise price of the amended and restated warrants was subsequently adjusted in accordance with their terms to $5.87 per share based upon the VWAP of the Company common stock on the day following completion of the Merger.

Pursuant to the terms of a securities amendment agreement entered into in February 2020, the Amended and Restated10% Senior Secured Convertible Debentures were once again amended and restated in their entirety to extend their maturity date to April 21, 2021 and reduce the conversion price of thereof to $3.00 per share from $9.52 per share. The related amended and restate common stock purchase warrants also were amended and restated again to reduce the exercise price thereof to $3.00 per share from $5.87 per share. The newly Amended and Restated 10% Senior Secured Convertible Debentures and related newly amended and restated warrants provide for so-called full-ratchet anti-dilution adjustments in the event we sell or issue shares of common stock or common stock equivalents at an effective price per share less than the conversion price of the debentures or the exercise price of the warrants, subject to certain exceptions. The conversion price of the Amended and Restated 10% Senior Secured Convertible Debentures and the exercise price of the related amended and restated warrants were reduced to $2.00 a share as a result of the Company's sale of100,000 shares of common stock at a price of $2.00 a share under

the Purchase Agreement with Lincoln Park Capital LLC described below and were subsequently reduced again as described in Note 14. See Note 14 for information regarding our recent prepayment of the Debentures.

The Company evaluated the common stock purchase warrants issued in connection with the original issuance of the 10% Senior Secured Debentures in October 2018 under ASC 815-40 and concluded that the warrants should be separately recognized at fair value as a liability. The liability is remeasured at fair value on a recurring basis using Level 3 input and any changes in fair value is recorded in earnings. In 2019, the Debentures were amended and restated to be convertible into common stock of EMI immediately prior to completion of the Merger, which resulted in the related warrants being reclassified to equity.

Purchase agreement with Holder of a Convertible Promissory Note - On June 15, 2020, the holder of a convertible promissory note in the principal amount of $3,150,000 agreed to an extension of the maturity date to June 15, 2023 in exchange for an increase in the interest rate on the note from 1% to 12%. In conjunction with this amendment, the Company issued to the holder of note five-year common stock purchase warrants to purchase a total of up to 1,250,000 shares of the Company common stock at an exercise price of $2.05 a share. The modification of debt was considered as debt extinguishment and $1.4 million of loss on debt extinguishment was recognized in the consolidated statement of comprehensive income. Under ASC 815-40, the Company concluded that the warrants issued to the holder of the notes should be recognized at fair value as a liability. The warrant liability is remeasured at fair value on a recurring basis using Level 3 input and any changes in the fair value of liability is recorded in earnings.

The following table presents the change in fair value of the warrants as of December 31, 2020 (in thousands):

Warrant liability—Wealth Threshold	**December 31, 2020**
Balance, beginning of period	$ —
Fair value at issuance date	1,425
Change in fair value included in the statement of comprehensive income (loss)	(437)
Balance, end of period	$ 988

The fair value of the warrant derivative liabilities was determined using the Black-Scholes Merton model and was based upon following assumptions:

	December 31, 2020	**At Issuance**
Exercise price	$ 2.05	$ 2.05
Stock price	$ 1.68	$ 1.23
Risk-free interest rate	0.31 %	0.33 %
Expected volatility (peer group)	101.00 %	94.00 %
Expected life (in years)	4.46	5.00
Expected dividend yield	—	—
Number outstanding	1,250,000	1,250,000

A summary of the Company's warrants activity for the years ended December 31, 2020 and 2019 is presented below:

	December 31, 2020	**December 31, 2019**	
Warrants outstanding, beginning of period	4,931,099	3,436,431	
Assumed as part of Merger	—	1,044,939	
Deemed Granted	3,625,000	500,729	(a)
Exercised	—	(51,000)	
Cancelled, forfeited and expired	(116,619)	—	
Warrants outstanding, end of period	8,439,480	4,931,099	

(a) Represents warrant shares issuable upon the Merger by reason of antidilution adjustments under former EMI warrants.

A summary of outstanding warrants by year issued and exercise price as of December 31, 2020 is presented below.

		Outstanding			Exercisable	
Year issued	Exercise Price	Number of Warrants Issued	Weighted Average Remaining Contractual Life (Years)	Weighted Average Exercise Price	Total	Weighted Average Exercise Price
Prior to January 1, 2019						
	$4.29-$10.28	3,439,007	1.66	$ 4.38	3,439,007	$ 4.38
	Total	3,439,007			3,439,007	
At December 31, 2019						
	$ 6.12	32,391	4.41	$ 6.12	32,391	$ 6.12
	$ 12.00	76,575	3.73	$ 12.00	76,575	$ 12.00
	$ 14.04	174,999	3.24	$ 14.04	174,999	$ 14.04
	$ 31.50	737,975	2.57	$ 31.50	737,975	$ 31.50
	$ 36.24	22,333	2.57	$ 36.24	22,333	$ 36.24
	$ 5.87	256,200	3.83	$ 5.87	256,200	$ 5.87
	$ 7.68	75,000	4.55	$ 7.68	75,000	$ 7.68
	2019 Total	1,375,473			1,375,473	
At December 31, 2020						
	$ 2.10	75,000	4.73	$ 2.10	75,000	$ 4.70
	$ 2.05	1,250,000	4.46	$ 2.05	—	$ —
	$ 2.00	2,300,000	4.70	$ 2.00	2,300,000	$ 4.70
	2020 Total	3,625,000			2,375,000	
	Grand Total	8,439,480			7,189,480	

Stock Options – Upon completion of the Merger, the EMI Amended and Restated 2011 Stock Incentive Plan was assumed by the Company. The 2011 Stock Incentive Plan permits grants of incentive stock options to employees, including executive officers, and other share-based awards such as stock appreciation rights, restricted stock, stock units, stock bonus and unrestricted stock awards to employees, directors, and consultants for up to 9,000,000 shares of common stock. Options granted under the 2011 Stock Incentive Plan expire ten years after grant. Options granted to directors vest in quarterly installments and all other option grants vest over a minimum period ofthree years, in each case, subject to continuous service with the Company. Each stock option outstanding under the 2011 Stock Incentive Plan at the effective time of the Merger was automatically converted into a stock option exercisable for a number of shares of the Company's common stock and at an exercise price calculated based on the exchange ratios in the Merger.

The Company also had an Amended and Restated 2012 Omnibus Incentive Compensation Plan under which the Company may grant incentive stock options to selected employees including officers, non-employee consultants and non-employee directors. All outstanding stock award under the 2012 Omnibus Incentive Compensation Plan were fully vested prior to the Merger and the Company intends not to make any further award under thereunder.

Management has valued stock options at their date of grant utilizing the Black-Scholes-Merton Option pricing model. The fair value of the underlying shares was determined by the market value of stock of similar companies and recent arm's length transactions involving the sale of the Company's common stock. Prior the Merger, the Company lacked company-specific historical and implied volatility information for its common stock. Therefore, the expected volatility was calculated using the historical volatility of a comparative public traded companies. The following table presents the assumptions used on recent dates on which options were granted by the Company.

	June 29, 2020	June 19, 2019
Stock Price	$ 1.67	$ 10.30
Exercise Price	$ 2.05	$ 10.30
Term	5.5-6 years	6 years
Risk-Free Rate	0.28% - 0.38%	1.83%
Dividend Yield	—	—
Volatility	78.91%-80.49%	67.16%

The risk-free interest rate is based on the implied yield available on U.S. Treasury issues with a term approximating the expected life of the options depending on the date of the grant and expected life of the respective options.

During the year ended December 31, 2020, the Company granted options to purchase up to 90,000 shares of common stock. The options have an exercise prices of $2.05 per share. December 31, 2019, the Company granted options to purchase 50,000 shares of common stock. The options have an exercise price of $10.30 per share. All of the options are exercisable with respect to one-third (1/3) of the underlying shares on the first anniversary of the grant date and as to the remaining two-thirds (2/3) of shares in twenty-four (24) approximately equal monthly installments over a period of two years thereafter.

A summary of the Company's stock option activity for the years ended December 31, 2020 and 2019 is presented below:

	December 31, 2020		December 31, 2019		
	Number of Options	Weighted-Average Exercise Price	Number of Options		Weighted-Average Exercise Price
Options outstanding, beginning of period	7,245,350	$ 4.68	6,642,200		$ 4.40
Granted or deemed issued	90,000	$ 2.05	636,683	(a)	$ 10.10
Exercised	—	—	(167)		$ 5.00
Cancelled, forfeited and expired	(225,325)	$ 5.08	(33,366)		$ 11.29
Options outstanding, end of period	7,110,025	$ 4.63	7,245,350		$ 4.68
Options exercisable at end of year	6,986,268	$ 4.47	7,001,680		$ 4.47
Options available for future grant	2,302,475		2,167,150		

(a) Upon the Merger, the exercise prices of outstanding EMI options were adjusted and additional options were deemed issued based upon the exchange ratio in the Merger.

During the years ended December 31, 2020 and 2019, the Company recognized $0.7 million and $3.7 million, respectively, of share-based compensation cost arising from stock option grants. As of December 31, 2020, there was approximately $474,000 of total unrecognized compensation cost related to unvested share-based compensation arrangements granted under the 2011 Stock Incentive Plan. That cost is expected to be recognized over the weighted-average remaining period of 0.8 years.

Purchase Agreement with Lincoln Park Capital Fund, LLC—On February 28, 2020, the Company entered into a Purchase Agreement with Lincoln Park Capital Fund, LLC ("LPC"), pursuant to which the Company may elect to sell to LPC up to $25,000,000 in shares of its common stock, subject to certain limitations and conditions set forth in the Purchase Agreement, including 100,000 initial shares that the Company sold to LPC at a price of $2.00 per share.

Pursuant to the Purchase Agreement, on any business day over the 36-month term of the Purchase Agreement the Company has the right at its discretion and subject to certain conditions to direct LPC to purchase up to 20,000 shares of common stock, which amount is subject to increase under certain circumstances based upon increases in the market price of its common stock. The purchase price of the common stock will be based upon the prevailing market price of common stock at the time of the purchase without any fixed discount. In addition, the Company may direct LPC to purchase additional amounts as accelerated purchases and additional accelerated purchases under certain circumstances. Apart from the initial sale of shares described above, the Company is not obliged to sell any shares of common stock pursuant to the Purchase Agreement, and the Company will control the timing and amount of any such sales, but in no event will LPC be required to purchase more than $1,000,000 of common stock in any single regular purchase (excluding accelerated or additional accelerated purchases).

Concurrently with the execution of the Purchase Agreement on February 28, 2020, the Company entered into a Registration Rights Agreement pursuant to which the Company agreed to file a prospectus supplement pursuant to Rule 424(b) relating to the sale shares of common stock to be issued and sold to LPC under the Purchase Agreement under our effective shelf registration statement or a new registration statement and to use our reasonable best efforts to keep such registration statement effective during the term of the Purchase Agreement.

The Purchase Agreement contains customary representations, warranties, indemnification rights and other obligations and agreements of the company and LPC. There are no limitations and conditions to completing future transactions other than a prohibition against entering into a "Variable Rate Transaction" as defined in the Purchase Agreement. There is no upper limit

on the price per share that LPC could be obligated to pay for common stock, but shares will only be sold to LPC on a day the Company's closing price is less than the floor price as set forth in the Purchase Agreement and if the sale of the shares would not result in LPC and its affiliates having beneficial ownership of more than 4.99% of the Company's total outstanding shares of common stock. The Company has the right to terminate the Purchase Agreement at any time, at no cost or penalty. As consideration for LPC's commitments under the Purchase Agreement, the Company issued to LPC 415,743 shares of common stock, which valued at $750,000, recorded as an addition to equity for common stock and reduction for cost of capital raised.

As of the date of filing of this Annual Report, we are out of compliance with certain terms and conditions of the Purchase Agreement and unable to utilize the Purchase Agreement. We intend to seek to bring the Company into compliance or seek an appropriate waiver from LPC to regain our ability to utilize the Purchase Agreement, but there can be no assurance when or whether we may be able to do so. If we are able to utilize the Purchase Agreement, whether or to what extent the Company sells shares of common stock to LPC under the Purchase Agreement will depend on a variety of factors to be determined by the company from time to time, including, among others, its net revenue and other results of operations, its working capital and other funding needs, the prevailing market prices of the Company's common stock and the availability of other sources of funding.

NOTE 9—INCOME TAXES

The provision for income taxes consists of the following for the years ended December 31, 2020 and 2019 (in thousands):

	2020	2019
Current U.S.	$ 46	$ 164
International	—	—
Deferred U.S.	(427)	—
International	—	—
	$ (381)	$ 164

Deferred tax assets consist of the following as of December 31, 2020 and 2019 (in thousands):

	2020	2019
Net operating loss carryforward	$ 17,090	$ 16,773
General business tax credit	10,490	9,888
Stock options	5,924	5,723
Charitable contribution	82	81
Accrued expenses	276	166
Unearned revenue	2,425	2,373
Allowance for bad AR	1	175
Unrealized gain on long term investment	472	1,400
Other	1,903	1,629
Total gross deferred tax assets	38,663	38,208
Less valuation allowance	(37,430)	(38,019)
Net deferred tax assets	$ 1,233	$ 189

Deferred tax liabilities consist of the following as of December 31, 2020 and 2019 (in thousands):

	2020	2019
Unrealized loss on foreign exchange translation and others	$ (347)	$ (185)
Unrealized gain on available-for-sale securities	(427)	—
Other	(459)	(4)
Total deferred tax liabilities	$ (1,233)	$ (189)

A valuation allowance for the net deferred tax assets is recorded when it is more likely than not that the Company will not realize these assets through future operations. The valuation allowance decreased by approximately $0.6 million for the years ended December 31, 2020, while it increased $3.8 million for the years ended December 31, 2019.

As of December 31, 2020 and December 31, 2019, the Company had net operating loss carryforwards for federal income tax purposes of approximately $63.1 million and $62.9 million, respectively, available to offset future federal taxable income, if any. Net operating loss generated in 2017 and prior years expire in various years through 2037. Net operating losses for federal income tax purpose generated in 2018 and after will be available indefinitely. In addition, the Company had net operating loss carryforwards for state income tax purposes of approximately $57.6 million and $55.9 million respectively, which expire in various years through2040. As of December 31, 2020 and December 31, 2019, the Company has general business tax credits of $10.5 million and $9.9 million, respectively, for federal income tax purposes. The tax credits are available to offset future tax liabilities, if any, through 2040. The Company's utilization of net operating loss carryforwards could be subject to an annual limitation as a result of certain past or future events, such as stock sales or other equity events constituting a "change in ownership" under the provisions of the Internal Revenue Code of 1986, as amended, and similar state provisions. The annual limitations could result in the expiration of net operating loss carryforwards and tax credits before they can be utilized.

The income tax provision differs from that computed using the statutory federal tax rate of 21% due to the following factors (in thousands):

	2020	2019
Tax benefit at statutory federal rate	$ 187	$ (11,365)
State taxes, net of federal tax benefit	191	(666)
Increase (decreases) in valuation allowance	(517)	3,411
Permanent items	859	5,710
General business tax credit	(602)	(545)
Other	(499)	3,619
	$ (381)	$ 164

As of December 31, 2020 and December 31, 2019, the Company had no unrecognized tax benefits or position which, in the opinion of management, would be reversed if challenged by a taxing authority. In the event the Company is assessed interest or penalties, such amounts would be classified as income tax expense. As of December 31, 2020, all federal tax returns since 2017 are subject to audit. The expiration of the state returns varies by state, but the 2016 and subsequent years' returns generally are subject to audit. No tax returns are currently being examined by taxing authorities.

NOTE 10—LEASES

Operating leases — During the years ended December 31, 2020 and 2019, the Company leased its office space under operating leases with unrelated entities.

The Company leased 21,293 square feet of office space for its headquarters in Torrance, California, at a base rental of $79,375 per month, which the lease will expire on September 30, 2026, and leased an additional 1,850 square feet office space in New York, New York, at a base rent of $8,691, which leases expired on January 31, 2023.

The Company leased 1,322 square feet of office space in Tokyo, Japan, which the lease expired onSeptember 30, 2022 and 1,163 square feet of office space in Dubai, United Arab Emirates.

The rent expense for the years ended December 31, 2020 and 2019 amounted to approximately $1.2 million and $926,000, respectively.

Future minimum lease payments were as follows as of December 31, 2020 (in thousands):

	Amount
2021	$ 1,143
2022	1,166
2023	1,050
2024	1,059
2025 and thereafter	1,925
Total lease payments	6,343
Less: Interest	(1,730)
Operating lease liabilities	$ 4,613

The Company adopted ASU 2016-02 on January 1, 2019 using a modified retrospective approach and elected the transition method and the practical expedients permitted under the transition guidance, which allowed to carryforward the historical lease classification and our assessment on whether a contract is or contains a lease. The Company also elected to combine lease and non-lease components, such as common area maintenance charges, as single lease, and elected to use the short-term lease exception permitted by the standard as noted in Note 2.

As a result of the adoption of Topic 842 on January 1, 2019, the Company recorded a $3.0 million in operating right-of-use asset and $3.3 million in lease liability and derecognized $287,000 of deferred rent as of the adoption date. These were calculated using the present value of the Company's remaining lease payments using an estimated incremental borrowing rate. The Company also recorded a $29,000 cumulative effect increase on our accumulated deficit as of January 1, 2019. As of December 31, 2020, and 2019, the Company had an operating lease right-of-use asset of $4.1 million $4.5 million, respectively and lease liability of $4.6 million and $4.9 million, respectively in the balance sheet. The weighted average remaining term of the Company's leases as of December 31, 2020 was 5.5 years and the weighted-average discount rate was 11.4%.

NOTE 11—COMMITMENTS AND CONTINGENCIES

API Supply Agreement — On June 12, 2017, the Company entered into an API Supply Agreement (the "API Agreement") with Telcon pursuant to which Telcon paid the Company approximately $31.8 million in consideration of the right to supply 25% of the Company's requirements for bulk containers of PGLG for a fifteen-year term. The amount was recorded as deferred trade discount. On July 12, 2017, the Company entered into a raw material supply agreement with Telcon which revised certain terms of the API supply agreement (the "revised API agreement"). The revised API agreement is effective for a term of five years and will renew automatically for 10 successive one-year renewal periods, except as either party may determine. In the revised API agreement, the Company has agreed to purchase a total of 940,000 kilograms of PGLG at $50 USD per kilogram, or a total of $47.0 million, over the term of the agreement. In September 2018, the Company entered into an agreement with Ajinomoto and Telcon to facilitate Telcon's purchase of PGLG from Ajinomoto for resale to the Company under the revised API agreement.

On June 16, 2019, the Company entered into an agreement with Telcon to adjust the price payable to Telcon under the revised API agreement from $50 per kilogram of PGLG to $100 per kilogram from July 1, 2019 through June 30, 2020, with the price payable after June 30, 2020 to be subject to agreement between the parties. The PGLG raw material purchased from Telcon is recorded in inventory at net realizable value and the excess purchase price is recorded against deferred trade discount. Refer to Note 12 for related party transaction details.

NOTE 12—RELATED PARTY TRANSACTIONS

The following table sets forth information relating to our loans from related persons outstanding at any time during the year ended December 31, 2020 (in thousands except for conversion rate and share information).

Class	Lender	Interest Rate	Date of Loan	Term of Loan	Principal Amount Outstanding at December 31, 2020	Highest Principal Outstanding	Amount of Principal Repaid or Converted into Stock	Amount of Interest Paid
Current, Promissory note payable to related parties:								
	Lan T. Tran (2)	10%	4/29/2016	Due on Demand	$ 20	$ 20	$ —	$ —
	Lan T. Tran (2)	11%	2/10/2018	Due on Demand	—	159	159	35
	Lan T. Tran (2)	10%	2/9/2019	Due on Demand	14	14	—	—
	Hope Int'l Hospice (1)	12%	9/1/2020	Due on Demand	—	194	194	2
	Hope Int'l Homecare (1)	12%	9/1/2020	Due on Demand	—	189	189	1
	Soomi Niihara	12%	9/1/2020	Due on Demand	—	98	98	4
	Soomi Niihara	12%	10/28/2020	Due on Demand	—	395	395	12
	Willis Lee (2)	12%	9/1/2020	Due on Demand	—	685	685	1
	Willis Lee (2)	12%	10/29/2020	Due on Demand	100	100	100	—
				Subtotal	**$ 134**	**$ 1,854**	**$ 1,820**	**$ 55**
Revolving line of credit								
	Yutaka Niihara (2)	5.25%	12/27/2019	Due on Demand	$ 800	$ 800	$ 200	$ 37
				Subtotal	**$ 800**	**$ 800**	**$ 200**	**$ 37**
				Total	**$ 934**	**$ 2,654**	**$ 2,020**	**$ 92**

The following table sets forth information relating to our loans from related persons outstanding at any time during the year ended December 31, 2019 (in thousands except for conversion rate and share information).

Class	Lender	Interest Rate	Date of Loan	Term of Loan	Principal Amount Outstanding at December 31, 2019	Highest Principal Outstanding	Amount of Principal Repaid or Converted into Stock	Amount of Interest Paid	Conversion Rate
Current, Promissory note payable to related parties:									
	Lan T. Tran (2)	10%	4/29/2016	Due on Demand	$ 20	$ 20	$ —	$ —	—
	Hope Int'l Hospice (1)	10%	6/3/2016	Due on Demand	—	250	250	78	—
	Lan T. Tran (2)	10%	2/9/2017	Due on Demand	—	12	—	2	—
	Yutaka Niihara (2)(3)	10%	9/14/2017	Due on Demand	—	904	27	2	—
	Lan T. Tran (2)	11%	2/10/2018	Due on Demand	159	159	—	—	—
	Lan T. Tran (2)	10%	2/9/2019	Due on Demand	14	14	—	—	—
				Subtotal	**$ 193**	**$ 1,359**	**$ 277**	**$ 82**	
Current, Convertible notes payable to related parties:									
	Yasushi Nagasaki (2)	10%	6/29/2012	Due on Demand	$ —	$ 200	$ 200	$ 56	$ 3.30
	Yutaka & Soomi Niihara (2)(3)	10%	11/16/2015	2 years	—	200	200	73	$ 4.50
	Wei Peu Zen (3)	10%	11/6/2017	2 years	—	5,000	5,000	597	$ 10.00
	Profit Preview International Group, Ltd. (4)	10%	2/1/2018	2 years	—	4,037	4,037	385	$ 10.00
	Profit Preview International Group, Ltd. (4)	10%	3/21/2018	2 years	—	5,363	5,363	442	$ 10.00
				Subtotal	**$ —**	**$ 14,800**	**$ 14,800**	**$ 1,553**	
Revolving line of credit									
	Yutaka Niihara (2)	5%	12/27/2019	Due on Demand	$ 600	$ 600	$ —	$ —	
				Subtotal	**$ 600**	**$ 600**	**$ —**	**$ —**	
				Total	**$ 793**	**$ 16,759**	**$ 15,077**	**$ 1,635**	

(1) Dr. Niihara, the Chairman of the Board and Chief Executive Officer of the Company, is co-owner with his wife Soomi Niihara, a director and the Chief Executive Officer of Hope International Hospice, Inc.
(2) Officer
(3) Director
(4) Mr. Zen, a director of the Company, is the sole owner of Profit Preview International Group, Ltd.

See Note 7 for a discussion of the Company's revolving line of credit agreement with Dr. Niihara.

See Notes 6 and 11 for a discussion of the Company's distribution and supply agreements with Telcon, which holds4,147,491 shares of the Company common stock, or approximately 8.5% of the common stock outstanding as of December 31, 2020.The Company also purchased a convertible bond of Telcon in the principal amount of KRW 30 billion, or approximately $27.9 million which matures on October 16, 2030 and bears interest at2.1% a year, payable quarterly.

NOTE 13—DEFINED CONTRIBUTION PLAN

The Company has a defined contribution plan (the "401(k) Plan") covering substantially all of the Company's employees. The Emmaus 401(k) Plan is a tax-qualified retirement saving plan, pursuant to which all employees are able to contribute the lesser of 90% of their eligible annual compensation (as defined) or the limit prescribed by the Internal Revenue Service (the "IRS") to the 401(k) Plan on a before-tax basis. Since January 1, 2020, the Company matches 50% of employee contributions to the Company's 401(k) Plan based on each participant's contribution during the plan year, up to 4.0% of each participant's annual compensation.

For the years ended December 31, 2020, the Company made matching contributions to the Company's 401(k) Plans of $71,000.

NOTE 14—SUBSEQUENT EVENTS

Subsequent to the year ended December 31, 2020, the Company issued the following securities:

	Dollar Amount	Number of Shares Issued
Common stock	$ 500,000	324,675

On February 9, 2021, the Company entered into a securities purchase agreement with an effective date of February 8, 2021 pursuant to which the Company has agreed to sell and issue to the purchasers thereunder in a private placement a total of up to $17 million in principal amount of convertible promissory notes of the company for a purchase price equal to the principal amount thereof. On April 4, 2021, the Company had completed the transaction and sold approximately $14.5 million of the convertible promissory notes. the net proceeds from the sale of the convertible promissory notes, $6.2 million was used to prepay the outstanding 10% Senior Secured Convertible Debentures as described Note 7 and 8. Commencing one year from the original issue date, the convertible promissory notes will be convertible at the option of the holder into shares of the Company's common stock at an initial conversion price of $1.48 per share. The conversion price will be subject to further adjustment in the event of a stock split, reverse stock split or certain other events specified in the convertible promissory notes. The convertible promissory notes will bear interest at the rate of 2% per annum payable semi-annually on the last business day of August and January of each year and will mature on the 3rd anniversary of the original issue date.

Effective February 22, 2021, Emmaus Medical, Inc., or Emmaus Medical, entered into a purchase and sale agreement with Prestige Capital Finance, LLC, or Prestige Capital, pursuant to which Emmaus Medical may offer and sell to Prestige Capital from time to time eligible accounts receivable in exchange for Prestige Capital's down payment, or advance, to Emmaus Medical of 70% (subject to increase to 75%) of the face amount of the accounts receivable, subject to a $7,500,000 cap on advances at any time. The balance of the face amount of the accounts receivable will be reserved by Prestige Capital and paid to Emmaus Medical, less discount fees of Prestige Capital ranging from 2.25% to 7.25% of the face amount, as and when Prestige Capital collects the entire face amount of the accounts receivable. Emmaus Medical's obligations to Prestige Capital under the purchase and sale agreement are secured by a security interest in the accounts receivable and all or substantially all other assets of Emmaus Medical. In connection with the purchase and sale agreement, we agreed to guarantee Emmaus Medical's obligations under the purchase and sale agreement. Our obligations under the guarantee are unsecured.

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Emmaus Life Sciences, Inc.
Torrance, CA

We consent to the incorporation by reference in Registration Statements (No. 333-225100) on Form S-3 and (No. 333-150398), (No. 333-193016), (No. 333-225050), (No. 333-228835), and (No. 333-233718) on Form S-8 of Emmaus Life Sciences, Inc. of our report dated August 9, 2021 relating to the consolidated financial statements of Emmaus Life Sciences, Inc. appearing in this Annual Report on Form 10-K/A of Emmaus Life Sciences, Inc. as of December 31, 2020 and 2019 and for the years then ended.

/s/ BAKER TILLY US, LLP

San Diego, California
August 9, 2021

Exhibit 31.1

Certification of Chief Executive Officer pursuant to Item 601(b)(31) of Regulation S-K,
as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Yutaka Niihara, certify that:

1. I have reviewed this annual report of Emmaus Life Sciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Yutaka Niihara
Yutaka Niihara
Chief Executive Officer
(Principal Executive Officer)
Date: August 9, 2021

Exhibit 31.2

**Certification of Chief Financial Officer pursuant to Item 601(b)(31) of Regulation S-K,
as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Yasushi Nagasaki, certify that:

1. I have reviewed this annual report of Emmaus Life Sciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Yasushi Nagasaki
Yasushi Nagasaki
Interim Chief Financial Officer
(Principal Financial and Accounting Officer)
Date: August 9, 2021

Exhibit 32.1

Certification of Chief Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

In connection with the annual report of Emmaus Life Sciences, Inc. (the "Company") on Form 10-K/A for the year ending December 31, 2020, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned, in the capacities and on the date indicated below, hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Yutaka Niihara
Yutaka Niihara
Chief Executive Officer
(Principal Executive Officer)
August 9 2021

/s/ Yasushi Nagasaki
Yasushi Nagasaki
Interim Chief Financial Officer
(Principal Financial and Accounting Officer)
August 9, 2021