

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
FORM 10-K

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

For the fiscal year ended December 31, 2019

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
(State or Other Jurisdiction of
Incorporation or Organization)

2834
(Primary Standard Industrial
Classification Code Number)

87-0419387
(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.		

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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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 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 48,987,189 shares of common stock outstanding as of January 5, 2021.

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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 a number of risks, uncertainties (some of which are beyond our control) or other 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.

EXPLANATORY NOTE

Overview of Restatement

This Annual Report on Form 10-K:

- (a) Restates the Consolidated Balance Sheet of EMI Holding, Inc., or EMI, the accounting acquirer in the reverse recapitalization transaction effected on July 17, 2019, and the related Consolidated Statements of Operations and Comprehensive Loss, Consolidated Statements of Cash Flows and Consolidated Statements of Changes in Stockholders' Equity (Deficit) for the year ended December 31, 2018 and the nine months ended September 30, 2019.
- (b) Amends "Management's Discussion and Analysis of Financial Condition and Results of Operations" as it relates to the year ended December 31, 2018.
- (c) Restates the "Unaudited Quarterly Financial Information" for the quarter ended September 30, 2019.

Background on the Restatement

As previously disclosed in the Company's Current Report on Form 8-K filed with the SEC on July 8, 2020, the board of directors of the Emmaus Life Sciences, Inc. ("we," "us," "our," "Emmaus" or the "Company"), based on the recommendation of the audit committee, concluded that, because of errors identified in the previously issued financial statements for the year ended December 31, 2018 as well as EMI Holding's unaudited consolidated financial statements for the three months ended March 31, 2019, the three and six months ended June 30, 2019 and our previously filed unaudited consolidated financial statements for three and nine months ended September 30, 2019, the Company would restate the previously issued financial statements.

These errors were discovered during the preparation of this Annual Report and the audit of the Company's financial statements for the year ended December 31, 2019. We have determined that these errors were the result of material weaknesses in internal control over financial reporting as described in management's report on internal control over financial reporting as of December 31, 2019 in Part II—Item 9A – Controls and Procedures of this Annual Report.

The restated financial statements correct the following errors:

- 1. The misclassification as equity of warrants issued by EMI in October of 2018, which warrants should have been accounted for as liabilities based upon fair value.
- 2. The erroneous consolidation as a Variable Interest Entity, or VIE, of EMI's interest in EJ Holdings, Inc., which should have been accounted for based upon the equity method.
- 3. The mistreatment of the fair value of cashless exercise warrants originally recorded in the Consolidated Statements of Operations and Comprehensive Loss, which fair value should have been recorded in additional paid-in capital in the Consolidated Balance Sheets.
- 4. In addition to the errors described above, the restated financial statements also include adjustments to correct certain immaterial errors identified during the audit of the Company's financial statements for the year ended December 31, 2019. Cumulatively through September 30, 2019, the restatement had the following effects on net loss (in thousands):

	Warrant Derivative Liability Adjustments	Consolidation of VIE Adjustments	Fair Value of Warrants Adjustments	Other Adjustments	Tax Effect of Adjustments	Total (Increase) Decrease in Net Loss
Year Ended December 31, 2018	\$ 2,425	\$ —	\$ (18,345)	\$ 1,264	\$ (33)	\$ (14,689)
Nine Months Ended September 30, 2019	7,222	—	—	(1,757)	—	5,465
	<u>\$ 9,647</u>	<u>\$ —</u>	<u>\$ (18,345)</u>	<u>\$ (493)</u>	<u>\$ (33)</u>	<u>\$ (9,224)</u>

Effects of Restatement

The following table sets forth the effects of the restatement on affected items within the previously reported Consolidated Statements of Operations and Comprehensive Loss (in thousands, except per share data):

		Nine Months Ended September 30, 2019	Year Ended December 31, 2018
Gross profit	As Originally Reported	\$ 16,687	\$ 14,313
	Adjustments	(1,498)	1,153
	As Restated	\$ 15,189	\$ 15,466
Loss from operations	As Originally Reported	\$ (4,791)	\$ (10,100)
	Adjustments	(421)	1,646
	As Restated	\$ (5,212)	\$ (8,454)
Net loss	As Originally Reported	\$ (58,943)	\$ (57,898)
	Adjustments	5,465	(14,689)
	As Restated	\$ (53,478)	\$ (72,587)
Net loss per common share - basic and diluted	As Originally Reported	\$ (1.46)	\$ (1.57)
	Adjustments	0.14	(0.40)
	As Restated	\$ (1.32)	\$ (1.97)

The adjustments resulting from the restatement are more fully discussed in Note 3, *Restatement of Previously Issued Financial Statements*, of the Notes to Consolidated Financial Statements included in this Annual Report. For further information regarding the effects of the accounting errors identified and the restatement adjustments, see Part II—Item 7—Management’s Discussion and Analysis of Financial Condition and Results of Operations included in this Annual Report. For a description of the control deficiencies identified by management and management’s plan to remediate those deficiencies, see Part II—Item 9A—Controls and Procedures.

Previously filed annual reports on Form 10-K of EMI and quarterly reports on Form 10-Q of EMI and the Company for the periods affected by the restatement have not been amended and the financial information included therein is superseded in its entirety by the restatements included in this Form 10-K. Accordingly, investors should no longer rely upon the previously released financial statements for these periods and any earnings releases or other communications relating to these periods, and, for these periods, investors should rely solely on the financial statements and other financial data for the relevant periods included in this Annual Report. See Note 15, Unaudited Quarterly Financial Statements, of the Notes to the Consolidated Financial Statements in this Annual Report for the impact of these adjustments for the three and nine months ended September 30, 2019. Our quarterly reports for 2020 will also include restated results for the corresponding interim periods of fiscal 2019. All amounts in this Annual Report on Form 10-K give effect to the restatement adjustments.

ITEM 1. BUSINESS

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

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.

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), which is indicated 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 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. Since January 2020, we have relied upon 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. 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. We expect net revenue to increase as we expand our commercialization of Endari® in the United States and grow or commence early access programs and eventual marketing and commercialization of Endari® outside the United States.

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. FDA 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®. In addition, 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 that of 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 slowed

the progress of clinical trials in the pharmaceutical industry, in general. However, patient enrollment has now been completed.

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. The following table summarizes the data:

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

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

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.

Sickle Cell Disease—Market Overview

Sickle cell disease 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 patients with SCD in the United States, and we estimate there are approximately 80,000 patients 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 or non-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^0 -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 and a lower incidence of acute chest syndrome.

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

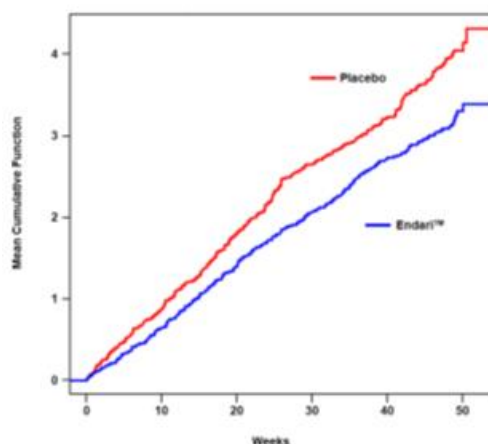
Event	Endari (n = 152)	Placebo (n = 78)
Median number of sickle cell crises (min, max) ¹	3 (0, 15)	4 (0, 15)
Median number of hospitalizations for sickle cell pain (min, max) ¹	2 (0, 14)	3 (0, 13)
Median cumulative days hospitalized (min, max) ¹	6.5 (0, 94)	11 (0, 187)
Median time (days) to first sickle 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 β^0 -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

In January 2018 we commenced commercialization of Endari® in the U.S utilizing a contract sales organization or CSO to support our internal sales activities. We terminated our relationship with the CSO in December 2019 and in January 2020 we internalized the sales function in order to have greater control over sales activities. 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®.

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 and McKesson Plasma and Biologics LLC, each account for more than 20% of units sold for the year ended December 31, 2019. On a combined basis, the three distributors accounted for approximately 87% of our units sold in 2019.

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 meeting with the regulatory authorities at the EMA and perhaps in other EU member nations to determine whether there is a viable regulatory path forward for Xyndari™, including whether or what additional data might be necessary to support future MAAs. With Brexit in place, we will also work directly with the U.K.'s Medicines and Healthcare Products Regulatory Agency, or MHRA, to determine the regulatory pathway for Xyndari™ in the U.K. We expect to provide an update in the first 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 office in Dubai. Under the terms of the agreements the distributors generally are responsible for registration and will bear all or substantially all costs for commercialization in their respective countries in return for a share in net revenues from Endari® sales in the countries.

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 patients, 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 inflammatory bowel diseases (i.e., 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.

See the discussion above of preclinical studies on our lead CAOMECS program for treatment of corneal diseases.

Research and Development

We spent \$2.2 million and \$1.7 million, respectively, in 2019 and 2018 on research and development, primarily relating to our Pilot/Phase 1 diverticulosis study. None of these costs are borne or sponsored by our customers.

Raw Materials and Manufacturing

Our SCD treatment uses prescription grade L-glutamine (“PGLG”), which differs from non-prescription grade L-glutamine available as a nutritional supplement. 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 USD) 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. 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 12 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 October 31, 2020, we had loaned EJ Holdings a total of \$16.0 million, including \$2.8 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, 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 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 according 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, as such, 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. Ajinomoto and Packaging Coordinators, Inc., or PCI, of Rockville, Illinois, which packages Endari®, currently meet FDA cGMP for manufacture and packaging of our commercial supplies 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 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 reduce the frequency of sickle cell crisis 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. Several other companies are in clinical trials to investigate new mechanisms of action for the chronic treatment of 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. 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 in 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 uni-lateral 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 L-glutamine 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 product for the same indication. Orphan Drug exclusivity is limited and will not preclude the FDA from approving the same product for the same indication if the same product is shown to be clinically superior to the product previously granted exclusivity. For example, if the same product for the same indication is shown to have significantly fewer side effects, the FDA may approve the second product despite the Orphan Drug exclusivity granted to the first product. 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 intended 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 a 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 505(b)(2) 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. A patent application related to the same subject matter has been allowed in the United States, and associated patent applications are currently pending in the United States, the EU, Brazil, India, Korea and Russia.

Patent directed to compositions for decreasing HbA1C levels in individuals who are shown to have average blood sugar levels in the diabetic range has issued in Japan and Indonesia; a related Philippines patent application has been allowed. Associated applications are currently pending in the United States, Europe, Brazil, India, China and Indonesia.

The company has issued patents directed to the treatment of hypertriglyceridemia in Japan and the Philippines. A corresponding European patent application has been allowed. Associated applications are pending in the United States, Europe, Brazil, India, China and Indonesia.

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 a number of 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 this agreement, upon commercialization we are required to pay royalties based upon net sales.

Trademarks

We currently own U.S. trademark registrations for “Emmaus Medical” and “Endari” and were recently granted 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 do not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to the same.

Employees

As of January 5, 2021, we had 55 employees, 53 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, after completion of our merger transaction with EMI described in the lead-in to this Item 1, 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

An investment in our common stock involves a high degree of risk. If any of these risks occur, our business, financial condition, results of operations, or cash flow could be materially and adversely affected. This could cause the market price of our common stock to decline, resulting in a loss of all or part of your investment.

Risks Related to Our Business

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

We have 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 net losses of \$54.8 million and \$72.6 million for the years ended December 31, 2019 and 2018, respectively, and had an accumulated deficit of \$226.2 million as of December 31, 2019. There is no assurance that we will be able to increase our Endari® sales or become profitable or that we will have sufficient capital resources to fund our operations until we are able to generate sufficient revenues to become profitable.

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 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 to which we will generate revenues from Endari® sales or the timing for when or the extent to which we will become profitable, if ever. Even if we do achieve increased 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.

We are dependent on financing to sustain our operations, and there is substantial doubt regarding our ability to continue as a going concern.

Unless and until we become profitable, we will continue to depend upon proceeds from sales of our debt or equity securities (including the exercise of options and warrants) or other financing arrangements, and to a lesser extent, upon payments from potential strategic partners and licensees, to generate funds needed to finance our business and operations. As of December 31, 2019, we had cash and cash equivalents of \$1.8 million, and investments in marketable securities of \$27.9 million, which consisted of common shares of Telecon RF Pharmaceutical, Inc., or Telcon, pledged by us to secure our obligations under our API Supply Agreement with Telcon. The API Supply Agreement was amended on December 23, 2019 to release the Telcon shares from the pledge and to permit us to sell the shares in exchange for our agreement to use a portion of the net sale proceeds to purchase a 10-year convertible bond of Telcon be pledged to Telcon pursuant to the API Supply Agreement in substitution of the pledge of the Telcon shares. On September 28, 2020, we entered into a convertible bond purchase agreement pursuant to which we purchased at face value a convertible bond of Telcon in the principal amount of KRW30 billion, or approximately \$26.1 million, on the terms described in the convertible bond purchase agreement. We purchased the convertible bond with a portion of the net proceeds from the sale of Telcon common shares owned by us as reported in our October 14, 2020 press release. As contemplated by our December 23, 2019 agreement with Telcon, the convertible bond and any proceeds therefrom replace our former Telcon shares and proceeds therefrom as collateral security under the API Supply Agreement with Telcon.

Depending upon our future results of operations and other factors, we will need additional financing to fund our business and operations, including our commitment to provide funding to EJ Holdings, Inc. described below under "Risks Relating to Our Investment in EJ Holdings, Inc.," and will continue to be dependent on future financing until such time, if ever, as we can generate sufficient revenues to become profitable. We have no current understandings or commitments to obtain any additional financing. Accordingly, we may not be able to obtain future financing on favorable terms, or at all. If we are unable to obtain needed future financing, we may have to curtail some of our business activities or modify our business plans and may be unable to meet our commitment to provide funding to EJ Holdings, Inc. Due to the uncertainty of our ability to meet our current and future operating and capital expenses, there is substantial doubt about our ability to continue as a going concern.

Because we were unable to timely file this Annual Report and other periodic reports under the Securities Exchange Act of 1934, as amended (the "Exchange Act") we are ineligible to register securities on the short-form Registration Statement on Form S-3 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.

In light of the foregoing, there is substantial doubt regarding our ability to continue as a going concern and the report of our independent public accounting firm on our financial statements as of and for the year ended December 31, 2019 contains a going concern qualification.

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 operation 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 earlier 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 resumed. 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 will continue to depend upon proceeds from loans, including loans from related parties, and sales of our debt or equity securities to generate funds needed to finance our business and operations. We have no commitment from third parties to provide us with any additional financing. Until the U.S. economy and capital markets stabilize, our ability to obtain future financing is likely to be challenging. 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 we will qualify for any government funding or otherwise be able to obtain any needed financing.

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, 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 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 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 part of the costs associated with their prescription drugs. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Assuming we obtain coverage for Endari®, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. 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 restrictions 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. We cannot assure you 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 July 7, 2024.
- Orphan Drug designation will not preclude the FDA from granting Orphan Drug designation to another sponsor developing the same drug for the same indication, approving such other drug before our drug would receive FDA approval, granting Orphan Drug designation and approving such other drug after we would 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;

- 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 β 0-thalassemia, two of the most common forms of SCD. SCD is a genetic blood disorder that affects 20 million - 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, the majority of people 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 profitability may be adversely impacted if we are unable to access markets with greater prevalence of SCD, or if there are insufficient 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 recent coronavirus (COVID-19) disease outbreak.
- 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 our potential 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®.

Our sales of Endari® can be greatly affected by the inventory levels our distributors carry. We monitor inventory of Endari® using a combination of methods. However, our estimates of specialty 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), 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. 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, at times we offer discounts to our customers in advance of Endari® price increases 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. 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 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.

Although Endari® was found to be safe and generally well tolerated in clinical trials, 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 all of our 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®. A successful product liability claim or series of claims brought against us could cause the value of our common stock to decline and, if judgments exceed our insurance coverage, could decrease 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.

Our management and personnel, systems and facilities currently in place may not be adequate to support our business plan and future growth. Continued operations and growth require that we manage our commercialization activities for Endari® and product development efforts effectively 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 expand our scientific, sales and marketing, managerial, operational, financial and other resources to support our planned commercialization activities.

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 our Chairman and Chief Executive Officer. Since inception, we have been dependent upon Dr. Niihara, who was one of the initial inventors on the patents for the method underlying Endari®. While Dr. Niihara and the rest of our executive officers are parties to confidentiality agreements that prevent them from soliciting our existing customers or disclosing information deemed confidential to us, we do not have any agreement with Dr. Niihara or any key members of management that would prohibit them from joining our competitors or forming competing companies. If Dr. Niihara or any key management personnel resign to join a competitor or form a competing company, the loss of such personnel, together with the loss of any customers or potential customers due to such executive's departure, could materially and adversely affect our business and results of operations. In addition, we do not maintain key man life insurance policies on any of our 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 a material weakness 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 2018 fiscal year had not been fully remediated and our disclosure controls and procedures were not effective. These matters are described in more detail in Part II – Item 9A “Controls and Procedures” in this Annual Report. 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®. As a result, competitors who obtain the requisite regulatory approval (subject to any regulatory exclusivity period, such as for Orphan Drug status) can offer products with the same active ingredients as Endari®.

In addition to licensing patent rights and seeking patents for our intellectual property, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, in our business. Our competitors may also use our methods, or acquire similar expertise, which could impair our ability to commercialize similar products.

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 of our employees to assign their inventions to us, and all of 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 held 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.

In particular, the patent for the use of L-glutamine to treat SCD expired in May 2016, and our license to the patent terminated with the expiration of the patent. This also 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. Many of our competitors have greater resources than we do and may be able to develop competing products more quickly than we can. 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 operations and our ability to commercialize our products.

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 of 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. 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.

We will incur significant ongoing expenses in maintaining our patent portfolio. Should we lack the funds to maintain our patent portfolio or to enforce our rights against infringers, we could be adversely impacted.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability, and the ability of our collaborators, to develop, manufacture, market and sell our products without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. We may become party to, or be threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates and products which could impede our ability to make, use, sell, distribute or market our products in such jurisdiction. Even if claims of infringement are without merit, any such action could divert the time and attention of management and impair our ability to access additional capital and/or cost us significant funds to defend.

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing our product candidates and manufacturing and marketing any of our products. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Alternatively, we could be ordered to cease commercializing any of our products that is found to infringe a third party's intellectual property right. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a third party's patent. A finding of infringement could prevent us from developing our product candidates and commercializing our products or force us to cease some of our business operations. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

We may be subject to claims by third parties asserting that we or our employees have misappropriated their intellectual property or claiming ownership of what we regard as our own intellectual property.

Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these employees or we have used or disclosed intellectual property, including

trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the U.S. Patent and Trademark Office, or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of or invalidate our patent rights, allow third parties to commercialize products similar or identical to our product candidates or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

We may become involved in lawsuits to protect or enforce any patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our issued patents, trade secrets, know-how or other intellectual property. To counter infringement or unauthorized use or to determine the scope and validity of our intellectual property rights, we may be required to file infringement claims or pursue other proceedings, which can be expensive and time consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that our patent is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology. An adverse result in any litigation or other proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly, subject us to significant liabilities, require us to cease using the subject technology or require us to license the subject technology from the third party, any or all of which could have a material adverse effect on our business.

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

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the trading price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

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

Filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U.S. can be less extensive than those in the U.S. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U.S. Consequently, we may not be able to prevent third parties from practicing our inventions in countries outside the U.S., or from selling or importing products made using our inventions in and into the U.S. or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products or export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as in the U.S. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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 submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with good clinical practices and good laboratory practices or cGMPs. In addition, our product labeling, 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 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. The FDA and the Federal Trade Commission ("FTC") also have the authority to regulate the claims we make in marketing our dietary supplement AminoPure. Failure to comply with FDA or FTC 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 any particular product candidate or to complete the clinical trials for a product candidate in the projected time frame could have a significant negative 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 conduct an investigation properly, ensuring proper monitoring of the investigations, and ensuring 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, our business, and our financial condition.

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 “FDCA”) 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;
- 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 favorable or 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.

Our business is subject to extensive government regulation, which could cause delays in the development of our product candidates and commercialization of any resulting products, impose significant costs on us or provide advantages to our larger competitors.

The FDA and similar regulatory authorities in foreign countries impose substantial requirements upon the development, manufacture and marketing of therapeutic products, such as drugs, biologics, and cell-based therapies. Failure to obtain marketing approval for any of our product candidates in any jurisdiction will prevent us from commercializing it as a product in that jurisdiction. The FDA and most other regulatory authorities impose requirements for laboratory and clinical testing, manufacturing, labeling, registration, marketing, storage, distribution, recordkeeping, reporting, and advertising and promotion, and other costly and time-consuming processes and procedures applicable to therapeutic products. In some cases, as a condition for approval to market any of our product candidates, the FDA or other regulatory authorities may impose commitments that we must satisfy following any such approval. These post-approval commitments could vary substantially from country to country depending upon the type, complexity and novelty of the applicable therapeutic product. Satisfaction of any such post-approval commitments (including the requirement to conduct additional clinical studies), if imposed by the FDA or other regulatory authorities, could take several years or more. In addition, post-approval requirements regarding safety surveillance, cGMP compliance, advertising and promotion, adverse event reporting, and recordkeeping must be met.

The effect of government regulation may be to delay marketing approval of our product candidates for a considerable or indefinite period of time, to impose costly processes and procedures upon our activities and to furnish a competitive advantage to companies that compete with us. There can be no assurance that marketing approval for any of our product candidates would be granted by the FDA or other regulatory authority on a timely basis, if at all, or, once granted, that the marketing authorization would not be withdrawn or other regulatory actions taken which might limit our ability to market our proposed products. Any such delay in obtaining or failing to obtain such approvals or imposition of regulatory actions would adversely affect us, the manufacturing and marketing of the products resulting from marketing approval of any of our product candidates, and our ability to generate product revenue.

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 EMA determines that the request for designation was materially defective or if the manufacturer is unable to ensure sufficient quantity 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 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; 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.

Our current and future relationships with customers and third-party payors in the U.S. and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Our industry is highly regulated and changes in law may adversely impact our business, operations or financial results. Any present or future arrangements with third-party payors, healthcare providers and professionals and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may restrict certain marketing and contracting practices. We are subject to various federal and state laws pertaining to healthcare fraud and abuse, including inducing, facilitating or encouraging submission of false claims to government programs and prohibitions on the offer or payment or acceptance of kickbacks or other remuneration for the purchase of our products. Healthcare providers, physicians and third-party payors in the U.S. and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with customers and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, which may constrain the business or financial arrangements and relationships through which we sell, market and distribute any products. In addition, we may be subject to transparency laws aimed at controlling healthcare costs and patient privacy regulation by the U.S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include (but are not limited to):

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs, such as Medicare and Medicaid;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil qui tam actions (commonly referred to as “whistleblower actions”), against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- provisions under the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) that impose criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- provisions under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (“HITECH”) and their respective implementing regulations, that impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Open Payments program under the federal Physician Payments Sunshine Act, which requires manufacturers of drugs, biologics, cell based therapies, medical devices and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program, with specific exceptions, to report annually to the CMS, information related to “payments or other transfers of value” made to physicians, which is defined to include doctors, dentists, optometrists, podiatrists and chiropractors, and teaching hospitals and applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by the physicians and their immediate family members;

- state and foreign laws and regulations analogous to those described above, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by nongovernmental third-party payors, including private insurers;
- state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers;
- state and foreign laws that require pharmaceutical and biopharmaceutical manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and
- state and foreign 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 sweeping language of the federal Anti-Kickback Statute, many potentially beneficial business arrangements would be prohibited if the statute were strictly applied. To avoid this outcome, the Department of Health and Human Services has published regulations, known as "safe harbors," that identify exceptions to or exemptions from the statute's prohibitions. Arrangements that do not fit within the safe harbors are not automatically deemed to be illegal but must be evaluated on a case by case basis for compliance with the statute and may be subject to scrutiny (and ultimately prosecution) by enforcement agencies. We seek to comply with the Anti-Kickback Statute and, if necessary, to fit within one of the defined safe harbors. We may be less willing than some of our competitors to take actions or enter into business arrangements that do not clearly satisfy the safe harbors. As a result, this unwillingness may put us at a competitive disadvantage. However, due to the breadth of the statutory provisions and the absence of uniform guidance in the form of regulations or court decisions, there can be no assurance that our practices fit within the safe harbors or that they will not be challenged under anti-kickback or similar laws. Further, liability may be established without a person or entity having actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it. Violations of such restrictions may be punishable by civil or criminal sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from U.S. federal healthcare programs (including Medicaid and Medicare). Any such violations could have a material adverse effect on our business, financial condition, results or operations and cash flows.

Under the False Claims Act, drug manufacturers have been held responsible for claims filed by physicians for reimbursement of the cost of medical services related to uses of a pharmaceutical product that are not on the approved labeling, known as "off-label use," if the manufacturer promoted the product for such off-label use. If the FDA or other government agencies determine that our promotional materials, trainings or other activities constitute off-label promotion of any of our products, it could request that we modify our training or promotional materials or other activities or subject us to regulatory enforcement actions, including the issuance of a warning letter, injunction, seizure, civil fine, and criminal penalties. Violations of the False Claims Act may result in treble damages based on the amount of overpayment and additional civil fines of \$5,000 to \$10,000 for each false claim. Drug manufacturers could also be held responsible for reimbursement claims submitted by any physician for pharmaceutical products that were knowingly not manufactured in compliance with cGMP regulations.

In addition to the state laws previously described, we also are subject to other state fraud and abuse statutes and regulations. Many of the states in which we operate or plan to expand to have adopted a form of anti-kickback law, self-referral prohibition, and false claims and insurance fraud prohibition. The scope of these laws and the interpretations of them vary from state to state and are enforced by state courts and regulatory authorities, each with broad discretion. Generally, state laws reach to all healthcare services and not just those covered under a governmental healthcare program. A determination of liability under any of these laws could result in fines and penalties and restrictions on our ability to operate in these states. There is no assurance that our arrangements or business practices will not be subject to government scrutiny or be found to violate applicable fraud and abuse laws.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. Further, we cannot guarantee that our arrangements or business practices will not be subject to government investigations and prosecutions which, even if we are ultimately found to be without fault, can be costly and disruptive to our business. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we and our employees, officers, or directors may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could have a material adverse effect on our business. If any of the physicians or other healthcare providers or entities with whom we expect to do

business, including our collaborators, is found not to be in compliance with applicable laws, such person or entity may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our business.

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 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 our potential product candidates 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 manufacturers 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.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers’ compensation insurance for costs we may incur due to injuries to our employees resulting from the use of hazardous materials, the insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research and, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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 \$17.8 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 experienced, and may continue to experience, significant volatility in our stock price that is uncorrelated to our results of operations or prospects.

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 July 18, 2019 and December 31, 2020, 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 \$6.86 and may continue to exhibit volatility. Factors such as the following may affect the volatility in our stock price:

- 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.

Stockholders may experience future dilution as a result of future equity offerings.

In order 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 our stockholders.

The outstanding convertible debentures and warrants may result in further dilution to our stockholders.

Our outstanding Second Amended and Restated 10% Senior Secured Convertible Debentures in the aggregate principal amount of \$7.2 million as of December 31, 2020 and related warrants to purchase a total of up to 1,537,200 shares of our common stock include 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 conversion price of the debentures and 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 \$2.00 per share based upon our issuance and sale of 100,000 shares of our common stock at a price of \$2.00 per share in March 2020. Since March 2020, we have issued additional warrants to purchase a total of 2,070,000 shares of our common stock with identical anti-dilution adjustments. These anti-dilution adjustments also would be triggered by future issuances by us of shares of our common stock or common stock equivalents at an effective price per share below the then-conversion and exercise prices of the debentures and such warrants, which adjustments would have a further dilutive effect on our 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 could cause the market price of our common stock to decline. A substantial majority of the outstanding shares of our common stock are, and the shares of common stock which may be sold in future offerings by us will be, freely tradable without restriction or further registration under the Securities Act.

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.

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 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.

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, 2019 and 2018 was approximately \$926,000 and \$669,000 respectively.

We lease 21,293 square feet of office space for our headquarters in Torrance, California, at a base rental of \$78,908 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 \$8,479 per month, which the lease will expire on December 31, 2022.

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, 2020, November 29, 2020, 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 was listed for trading on The Nasdaq Capital Market under the symbol "MYND" until July 17, 2019 and the symbol "EMMA" from then until the opening of the market on September 11, 2019, after which it became eligible for quotation on the OTCQB market. On August 3, 2020, our common stock was relegated to trading on the OTC Pink tier of the OTC Markets Group, Inc. The following table sets forth the high and low sales price for our common stock as reported on The Nasdaq Capital Market and high and low bid information for our common stock as reported on OTCQB or OTC Pink tier for the periods indicated. The information reported on the OTCQB and OTC Pink tier reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

	<u>High</u>	<u>Low</u>
Year Ended December 31, 2019		
First Quarter	\$ 12.91	\$ 3.90
Second Quarter	\$ 9.30	\$ 6.00
Third Quarter	\$ 11.76	\$ 1.33
Fourth Quarter	\$ 3.25	\$ 1.69
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 January 5, 2021)	\$ 1.45	\$ 1.31

Holders

As of January 5, 2021, we had approximately 394 stockholders of record.

Dividends

We did not pay cash dividends on our common stock in either of the years ended December 31, 2019 and 2018, 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

None.

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

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.

Overview of Restatement

As previously disclosed in the company's Current Report on Form 8-K filed with the SEC on July 8, 2020, the board of directors of the company, based on the recommendation of the audit committee and in consultation with management and the company's predecessor independent public accounting firm, concluded that, because of errors identified in the previously issued financial statements for the year ended December 31, 2018 and the quarterly periods ended June 30, 2019 and September 30, 2019, the company would restate the previously issued financial statements.

The restated financial statements correct the following errors:

1. Warrants issued by EMI in October 2018 and accounted for as equity should have been treated as derivative liabilities and accounted for at fair value with changes in fair value recorded in earnings. This error resulted in \$7.8 million, \$8.6 million, and \$7.5 million understatements of the fair value of warrant derivative liabilities as of June 30, 2019, March 31, 2019 and December 31, 2018, respectively. It also resulted in understatements of stockholder's deficit of \$5.6 million as of September 30, 2019 and \$9.7 million as of June 30, 2019, March 31, 2019 and December 31, 2018. This error also resulted in \$0.2 million and \$1.0 million understatements of net loss for the six months and three months ended June 30, and March 31, 2019, respectively, and in a \$2.4 million overstatement of net loss for the year ended December 31, 2018. In connection with the completion of our merger transaction with EMI on July 17, 2019, the exercise price of the warrants was adjusted and the warrants were reclassified to equity.
2. EMI's interest in EJ Holdings, which was consolidated as a Variable Interest Entity, should have been accounted for based upon the equity method. This error is resulted in \$13.2 million and \$0.2 million overstatements of cash and other current assets, respectively, and a \$13.6 million understatement of the equity method investment as of December 31, 2018. The error also resulted in a \$0.2 million overstatement of loss from operations and a \$0.1 million overstatement of loss before income taxes for the year ended December 31, 2018.
3. Fair value of cashless warrants exercised in September 2018 upon expiration of warrants should have been recorded in additional paid-in capital. The error resulted in \$18.3 million of an overstatement of change in fair value of warrant derivative liabilities and an understatement of additional paid-in cash for the year ended December 31, 2018.
4. Other adjustments consist of the following:
Period adjustments of variable considerations resulted in \$1.4 million and \$436,000 understatements of revenue and accounts receivable and \$945,000 overstatement of accounts payable as of December 31, 2018 and \$1.3 million overstatement of revenue as of September 30, 2019.

An error in accounting for on the financing of insurance premium resulted in \$141,000 and \$598,000 understatements of prepaid expenses and current liabilities as of December 31, 2018 and September 30, 2019, respectively.

Adjustments of the stock modification accounting resulted in \$52,000 understatements of additional paid-in capital and general and administrative expense for the year ended December 31, 2018 and an overstatement of general and administrative expenses for the nine months ended September 30, 2019.

An error in the accounting for conversion feature of securities resulted in \$172,000 and \$249,000 understatements of additional paid-in capital and interest expenses, respectively and \$543,000 and \$466,000 overstatements of loss on debt extinguishment and change in fair value of embedded conversion option, respectively, for the year ended December 31, 2018.

An error in the classification of shipping cost and royalty expenses resulted in a \$229,000 understatement of cost of sales and \$80,000 and \$141,000 overstatements of selling cost and general and administrative expense, respectively for the year ended December 31, 2019. The error also resulted in a \$71,000 understatement of cost of sales and \$11,000 and \$60,000 overstatements of selling cost and general and administrative expense.

An error in the debt modification accounting resulted in a \$1.1 million understatement of additional paid-in capital as of September 30, 2019. The error also resulted in \$320,000 overstatements of loss on debt extinguishment for the three months and nine months ended September 30, 2019 and a \$1.3 million understatement of interest expense for nine months ended September 30, 2019.

An error in the GBP warrant liability classification resulted in a \$91,000 understatement of warrant derivative liabilities and a \$776,000 overstatement of additional paid-in capital as of December 31, 2019. The error also resulted in a \$685,000 understatement of change in fair value of warrant derivative liabilities for the three months and the nine months ended September 30, 2019.

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. 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, 2019, our accumulated deficit was \$226.2 million and we had cash and cash equivalents of \$1.8 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. 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 enter 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 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: We provide our customers prompt payment and large order discounts and from time to time offer additional discounts that are recorded as a reduction of revenue in the period the revenue is recognized. Sales attributable to one-time discounts offered by us increased in 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 raw materials, packaging, shipping and distribution of Endari®.

Research and Development Expenses

Research and development costs 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 supplies. 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 costs, including share-based compensation for our directors and executive officers, of our employees, including our in-house commercialization team. 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 and administrative 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 material, 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, 2019 and 2018 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 and/or 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 convertible debentures and promissory notes and debentures 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 convertible debentures and promissory 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, 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.

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. 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.

The 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 and 2018. 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 8 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

	Year Ended December 31,	
	2019	2018 (As Restated)
CONSOLIDATED STATEMENTS OF OPERATIONS (\$ in thousands)		
REVENUES, NET	\$ 22,752	\$ 16,459
COST OF GOODS SOLD	1,094	993
GROSS PROFIT	21,658	15,466
OPERATING EXPENSES		
Research and development	2,183	1,723
Selling	6,975	4,733
General and administrative	17,012	17,464
Total operating expenses	26,170	23,920
LOSS FROM OPERATIONS	(4,512)	(8,454)
OTHER INCOME (EXPENSE)		
Loss on debt extinguishment	(438)	(2,702)
Change in fair value of warrant derivative liabilities	3,545	4,476
Change in fair value of embedded conversion option	131	—
Net losses on investment in marketable securities and long-term investment	(21,947)	(43,977)
Net losses on equity method investment	(414)	(97)
Miscellaneous reverse merger costs	(309)	—
Notes conversion costs	(3,341)	—
Interest and other income	232	1,002
Interest expense	(27,625)	(22,796)
Total other expense	(50,166)	(64,094)
LOSS BEFORE INCOME TAXES	(54,678)	(72,548)
INCOME TAXES	164	39
NET LOSS	(54,842)	(72,587)
NET LOSS PER COMMON SHARE	\$ (1.30)	\$ (1.97)
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING	42,259,460	36,857,995

Years ended December 31, 2019 and 2018

Net Loss. Net loss was \$54.8 million for the year ended December 31, 2019 compared to \$72.6 million for the year ended December 31, 2018, representing a decrease of \$17.7 million, or 24.4%. The decrease in net loss was primarily a result of a \$6.3 million increase in net revenue and a \$13.9 million decrease in other expenses partially offset by a \$2.3 million increase in operating expenses, as discussed below. As of December 31, 2019, we had an accumulated deficit of approximately \$226.2 million. We anticipate that our net loss will narrow in the foreseeable future.

Revenues, Net. Net revenues increased by \$6.3 million, or 38% to \$22.8 million for the year ended December 31, 2019 compared to 2018. Substantially all net revenues were attributable to Endari® sales. We afforded customers a higher level of price discounts related to large volume orders in 2019 than in 2018. This resulted in an offset to the growth in net revenues compared to the higher growth in gross sales and boxes of Endari® sold in 2019. We expect Endari® revenues to increase as we expand our commercialization efforts in the U.S. and abroad.

Cost of Goods Sold. Cost of goods sold increased by \$0.1 million, or 10% to \$1.1 million for the year ended December 31, 2019 compared to 2018 as net revenues increased. Cost of goods sold consist primarily of costs for raw materials, packaging, shipping and distribution of Endari®.

Research and Development Expenses. Research and development expenses increased by \$0.5 million, or 27%, to \$2.2 million for the year ended December 31, 2019 compared to 2018. 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 increased \$2.2 million, or 45%, to \$7.0 million for the year ended December 31, 2019 compared to 2018. The increase was primarily due to an increase of \$1.5 million in contract sales organization (CSO) fees for Endari® and \$0.7 million in salaries and other marketing activities including public relations, sales meetings and sponsorships. We anticipate that our selling expenses will continue to increase as we expand Endari® marketing and sales activities both in the U.S. and outside the U.S. In January 2020, we terminated the relationship with our CSO and established our in-house sales force.

General and Administrative Expense. General and administrative expense decreased \$0.5 million, or 3%, to \$17.0 million for the year ended December 31, 2019 compared to 2018. General and administrative expense includes share-based compensation expenses, professional fees, office rent and payroll expenses. Of the \$17.0 million in total general and administrative expenses in 2019, \$2.4 million were one-time expenses attributable to stock option and warrant modifications relating to the merger transaction. We expect on-going general and administrative expenses to remain substantially the same for the foreseeable future.

Other Income and Expense. Total other expense decreased by \$13.9 million, or 21.7%, to \$50.2 million for the year ended December 31, 2019 compared to 2018. The decrease was primarily due to by a reduction in net loss on investment in marketable securities of \$22.5 million and a decrease in loss on debt extinguishment of \$2.3 million, which were partially offset by an increase in interest expense of \$4.8 million and \$3.3 million in note conversion expense related to the convertible notes converted in connection with the Merger.

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 recent 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

Based on our losses to date, anticipated future net revenues and operating expenses, debt repayment obligations, funding commitment to EJ Holdings and cash and cash equivalents balance of \$1.8 million as of December 31, 2019, we do not have sufficient operating capital for our business without raising additional capital. While we look to expand our commercialization of Endari® in the U.S. and expand or commence early access programs and eventual marketing and commercialization abroad, there is no assurance that our net revenues will increase in the future.

We continue to incur expenses for the expanded commercialization of Endari®, research costs for our pilot study of our prescription grade L-glutamine oral powder in the treatment of diverticulosis and CAOMECS technology and expenses relating to EJ Holdings' startup and operation of its Ube, Japan manufacturing facility. We have previously relied on private equity offerings, debt financings, and loans, including loans from related parties and other investors as discussed below. As of December 31, 2019, we had outstanding consolidated notes payable in an aggregate principal amount of \$17.1 million, consisting of \$3.9 million of non-convertible promissory notes and \$13.2 million of senior secured convertible debentures and convertible notes. All \$17.1 million aggregate principal amount of notes payable outstanding as of December 31, 2019 was either due on demand or was to become due and payable within the next twelve months. Subsequent to December 31, 2019, our outstanding senior secured convertible debentures were amended and restated to extend the maturity date to August 31, 2021 subject to monthly redemption payments under the convertible debentures, and the maturity date of an outstanding convertible promissory note in the principal amount of \$3.0 million as of December 31, 2019 was extended to June 15, 2023. The notes payable bear interest at annual rates ranging from 10% to 12%. The net proceeds of the notes were used for working capital purposes.

Until we can generate sufficient revenue, our future cash requirements are expected to be financed through public or private equity or debt offerings, loans or corporate collaboration and licensing arrangements or other financing arrangements. We have no current understanding or arrangements with respect to future financings, and there can be no assurance that we can

raise needed capital on terms acceptable to us (or at all). Due to the uncertainty of our ability to meet our current and future operating and capital expenses, there is substantial doubt about our ability to continue as a going concern.

Subsequent to the year ended December 31, 2019, the company issued shares of common stock as follows:

Common Shares Issued after December 31, 2019	Dollar Amount	Number of Shares Issued
Common shares	\$ 200,000	100,000

Cash Flows

Net cash used in operating activities

Net cash used in operating activities of \$4.5 million in 2019 related to net loss of \$54.8 million adjusted for non-cash items of \$50.0 million primarily related to the amortization of discount on notes payable and convertible notes payable, net losses on investment in marketable securities, loss on debt settlement, shared-based compensation and fair value of replacement equity award, and notes conversion expenses.

Net cash used in investing activities

Net cash used in investing activities decreased by \$5.9 million, or 80%, to \$1.5 million for the year ended December 31, 2019 from \$7.4 million for the years ended December 31, 2018. The decrease was primarily due to \$13.3 million used to fund the purchase by EJ Holdings, Inc. of the manufacturing plant in Ube, Japan in 2018, which was partially offset by \$6.2 million decrease of cash proceeds from sales of marketable securities and \$1.6 million of transaction costs relating to the merger transaction.

Net cash from financing activities

Net cash from financing activities increased by \$9.6 million, or 168%, to a positive \$3.9 million for the year ended December 31, 2019 from a negative \$5.7 million for the year ended December 31, 2018, primarily as a result of a \$7.3 million increase in cash proceeds from the issuance of common stock and a \$14.7 million decrease in repayment of convertible notes partially offset by a \$17.6 million decrease of cash proceeds from the issuance of convertible debentures and convertible note.

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

On September 10, 2020, our Audit Committee determined to engage Squar Milner LLP (“Squar Milner”) as our independent registered public accounting firm and to dismiss BDO USA, LLP (“BDO”) as our independent registered public accounting firm. Effective as of November 1, 2020, Squar Milner became part of Baker Tilly US, LLP (“Baker Tilly”).

BDO was engaged by us on January 8, 2020 to audit our annual financial statements as of and for the year ended December 31, 2019 (the “2019 Annual Financials”) and to review our unaudited quarterly financial statements for 2020, but as of September 10, 2020 had not completed its audit for 2019 or issued any audit or review reports on our financial statements. At the time of BDO’s dismissal, there were no (1) disagreements (as that term is defined in Item 304(a)(1)(iv) of Regulation S-K under the Securities Act of 1933, as amended (“Regulation S-K”) and related instructions), between management of the company and BDO on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedures which disagreements, if not resolved to the satisfaction of BDO, would have caused BDO to refer to the disagreements in its reports on the financial statements for 2019, or (2) reportable events as set forth in Item 304(a)(1)(v) of Regulation S-K, except as described below:

We reported in a Current Report on Form 8-K filed with the Securities and Exchange Commission, or SEC, on July 8, 2020 (the “July 2020 8-K”) that the previously filed audited consolidated financial statements of our EMI Holding, Inc. subsidiary, or EMI, for the year ended December 31, 2018 (the “2018 Annual Financials”), as well as EMI’s unaudited consolidated financial statements for the three months ended March 31, 2019 and the three and six months ended June 30, 2019 and our previously filed unaudited consolidated financial statements for the three and nine months ended September 30, 2019 (together with the 2018 Annual Financials, the “Affected Financials”), can no longer be relied upon as the result of accounting errors identified in the course of the preparation of the company’s Annual Report on Form 10-K for the year ended December 31, 2019 related to (1) the misclassification as equity of warrants issued in October 2018 and (2) the erroneous consolidation as a Variable Interest Entity of our interest in EJ Holdings, Inc., a 40%-owned Japanese corporation (the “Reported Errors”). BDO advised management that BDO concluded that the Reported Errors materially impact the fairness and reliability of the 2018 Annual Financials and other Affected Financials and that, unless resolved to BDO’s satisfaction, would prevent BDO from rendering an audit report on our 2019 Annual Financials. As reported in the July 2020 8-K, management agreed with BDO’s conclusion regarding the Reported Errors. BDO also advised management that information had come to BDO’s attention regarding (1) the accounting for two revenue adjustments recorded in 2019 that should have been recorded in 2018, (2) the accounting for certain debt and related warrants issued in 2018 that also impacted 2019, and (3) the accounting for certain debt modifications in 2019 which BDO concluded impacted the Affected Financials in immaterial ways and which, unless resolved to BDO’s satisfaction, would prevent BDO from rendering an audit report on our 2019 Annual Financials. BDO advised management that it would be necessary to re-audit the 2018 Annual Financials to make all adjustments regarding these errors, as well as the Reported Errors, to BDO’s satisfaction. Management disagreed with BDO’s advice regarding the need to re-audit the 2018 Annual Financials for immaterial errors but agreed to consult with SingerLewak, LLP (“SingerLewak”), EMI’s predecessor auditor, and to consider engaging SingerLewak to re-audit the 2018 Annual Financials if the parties could agree upon the appropriate scope of the re-audit. After considering the matter further and discussing it with management and BDO, SingerLewak advised management that, in accordance with its practices, any re-audit of the 2018 Financials by SingerLewak would include accounts affected by the Reported Errors only and that accounts affected by immaterial errors affecting the 2019 Annual Financials should be audited by BDO as the successor auditor. Since the parties were unable to agree on the scope of a re-audit of the 2018 Financials, the Audit Committee determined to dismiss BDO and to retain Squar Milner to audit both the 2019 Annual Financials and the 2018 Financials and to review our quarterly financial statements for 2020 and adjustments to our unaudited quarterly financial statements for 2019. Accordingly, the disagreement was not resolved prior to BDO’s dismissal. BDO also advised management that the Reported Errors necessarily meant that we did not maintain effective controls over certain aspects of the financial reporting process, which we previously reported in our Annual Report on Form 10-K for the year ended December 31, 2018.

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, 2019. 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, 2019, 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, 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 of 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, 2019, 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, 2019.

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 and a smaller reporting company.

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, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

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	Vice-Chairman and Chief Operating Officer
Yasushi Nagasaki, C.P.A.	53	Interim Chief Financial Officer
Lan T. Tran, M.P.H.	45	Chief Administrative 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 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.

Lan T. Tran, M.P.H. served as Chief Administrative Officer since May 2011 and as President from January 2018 until July 2019 of EMI Holding. She previously served as EMI Holding's Corporate Secretary from May 2011 until September 2018 and Co-President from January 2016 until being named President. Prior to April 2011, she held various senior executive management positions with Emmaus Medical. Prior to joining Emmaus Medical, Ms. Tran was with for many years part of the executive management team at LA BioMed, a non-profit medical research and education company. Ms. Tran holds a B.S. degree in Psychobiology and a Master of Public Health degree from UCLA.

Yasushi Nagasaki, C.P.A. served as 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 the officers and 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 shareholders
- 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, 2019 the directors, 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 late reports on Form 3 were filed on July 29, 2019 on behalf of Dr. Niihara, Ms. Tran and Mr. Dickey due to delays in signing the reports or administrative errors by the Company's personnel assisting with the filing. A late report on Form 3 also was filed on September 11, 2019 on behalf of Dr. Osato after company personnel discovered the Form 3 had previously been signed but not filed on his behalf. Late reports on Form 4 were filed on behalf of Mr. Zen on September 3, 2019 and on September 9, 2019 due to delays in signing the report resulting from the difference in time zones between Hong Kong, where he resides, and California, where our offices are located.

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 all 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. 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 in writing to Emmaus License Sciences, Inc., Attention: Secretary, 21250 Hawthorne Boulevard, Suite 800, Torrance, California 90503.

ITEM 11. EXECUTIVE COMPENSATION

Summary Compensation Table

On July 17, 2019 we completed our merger transaction with EMI Holding. On September 25, 2019, our board of directors approved a change in our fiscal year end from September 30 to December 31. Since the merger transaction occurred

prior to our former fiscal year end of September 30, 2019, in accordance with SEC rules, the following table sets forth information regarding all compensation paid for services to us in all capacities for our former fiscal years ended September 30, 2019 and 2018 by (i) each person who served as our principal executive officer during our former fiscal year ended September 30, 2019 and (ii) up to two additional individuals who were our two most highly compensated executive officers other than our principal executive officer during our former fiscal year ended September 30, 2019 and whose total compensation exceeded \$100,000 (collectively referred to as our "former named executive officers"). The employment of each of our former named executive officers who were then employed by us was terminated in conjunction with the completion of the merger transaction.

Name and Position	Twelve Months Ended September 30,	Salary	Bonus	Stock Awards	Option Awards	All Other Compensation	Total
Patrick Herguth	2019	\$ 190,359	\$ —	\$ —	\$ 246,000	\$ —	\$ 436,359
Chief Executive Officer	2018	—	—	—	—	—	—
George C. Carpenter IV	2019	163,281	—	216,594	134,758	—	514,633
President and Chief Executive Officer	2018	238,125	—	127,300	102,900	—	468,325
Donald D'Ambrosio	2019	170,208	25,000	—	82,965	—	278,173
Chief Financial Officer	2018	215,015	—	29,700	27,200	16,835	288,750

The following table sets forth information concerning the compensation earned by our Chief Executive Officer, and our two other most highly compensated executive officers for the twelve months ended September 30, 2018 and 2019:

Name and Position	Twelve Months Ended September 30,	Salary	Bonus	Stock Awards	Option Awards	All Other Compensation	Total
Yutaka Niihara, M.D., MPH	2019	\$ 80,208	\$ —	\$ —	\$ —	\$ —	\$ 80,208
Chairman and Chief Executive Officer	2018	—	—	—	—	—	—
Joseph (Jay) C. Sherwood III	2019	52,083	—	—	—	—	52,083
Chief Financial Officer	2018	—	—	—	—	—	—
Willis C. Lee	2019	50,000	—	—	—	—	50,000
Vice-Chairman and Chief Operating Officer	2018	—	—	—	—	—	—

The following table sets forth information concerning the compensation earned by our Chief Executive Office and our next two most highly compensated executive officers, whom we refer to as our "named executive officers," for the three months ended December 31, 2019:

Name and Position	Year ended December 31	Salary	Bonus	Stock Awards	Option Awards	All Other Compensation	Total
Yutaka Niihara, M.D., MPH	2019	\$ 96,250	\$ —	—	\$ —	—	\$ 96,250
Joseph (Jay) C. Sherwood III	2019	62,500	—	—	—	—	62,500
Willis C. Lee	2019	60,000	—	—	—	—	60,000

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 2019, in part, to preserve available capital to fund operating expenses. Additionally, no specific performance criteria were established for our executive officers for 2019. As of this date, the Compensation Committee also has made no determination regarding any discretionary cash bonuses for 2019.

Outstanding Equity Awards at 2019 Fiscal Year End

The table below sets forth information regarding outstanding options held by the former named executive officers as of September 30, 2019:

NAME	Option Awards				Stock Awards		
	Number of Securities Underlying Unexercised Options (#)		Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price	Option Expiration Date	Number of Shares of Stock That Have Not Vested (#)	Market Value of Shares of Stock That Have Not Vested (\$)
	Exercisable	Non-Exercisable					
Patrick Herguth	33,332	—	—	\$ 7.68	12/12/2028	—	—
George Carpenter	5,333	—	—	\$ 36.00	09/22/2026	—	—
	362	—	—	\$ 300.00	10/08/2023	—	—
	1,020	—	—	\$ 56.64	12/10/2022	—	—
	11,330	—	—	\$ 9.30	04/04/2028	—	—
	6,831	—	—	\$ 8.28	10/08/2028	—	—
	4,998	—	—	\$ 8.76	12/03/2028	—	—
	4,861	—	—	\$ 7.68	12/12/2028	—	—
Donald D'Ambrosio	3,000	—	—	\$ 35.40	03/31/2027	—	—
	3,000	—	—	\$ 9.30	04/04/2028	—	—
	4,165	—	—	\$ 8.28	10/8/2028	—	—
	4,416	—	—	\$ 8.76	12/03/2028	—	—
	1,666	—	—	\$ 7.08	06/25/2029	—	—

The following table sets forth information regarding outstanding equity awards held by our named executive officers as of December 31, 2019:

Name	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price	Option 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
Joseph (Jay) C. Sherwood III	20,420	32,087	\$ 9.80	6/19/2029
Willis C. Lee	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 31 of 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 that 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 that 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, 2018 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 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 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

During our former fiscal year ended September 30, 2019, our former non-employee directors received cash compensation, as well as grants of common stock, restricted stock and stock options for their service on our Board of Directors or Board committees. The values of the option and restricted share grants were determined using the Black-Scholes Model and the closing price of the stock on the day of grant. All our former non-employee directors resigned as directors in conjunction with the completion of our merger transaction with EMI Holding in July 2019, with the exception of Dr. Smith, who resigned as a director effective September 30, 2019.

The following table sets forth information regarding our former non-employee director compensation for the former fiscal year ended September 30, 2019:

Name	Fees Earned or Paid in Cash	Option Awards	Stock Awards	All Other Compensation	Total
Robin Smith, M.D.(1)	\$ 195,000	\$ 59,500	\$ 178,240	\$ —	\$ 432,740
John Pappajohn	—	—	18,919	—	18,919
Geoffrey Harris	18,750	—	28,378	—	47,128
Michal Votruba	—	—	198,720	—	198,720
Peter Unanue	—	—	18,919	—	18,919

- (1) On July 14, 2017, the Board approved a Chairman Services Agreement with Robin L. Smith, M.D. pursuant to which Dr. Smith provided non-exclusive advisory and management services to the Company, which may include advice and assistance concerning: strategic vision and planning; identification of growth and expansion opportunities; financial planning; and corporate partnering and business development (collectively, the “Services”). Under the Agreement, Dr. Smith was entitled to an annual cash fee of \$300,000, payable in equal monthly installments, which reduced to \$250,000 for calendar year 2018. In conjunction with the merger transaction, the Chairman Services Agreement terminated in accordance with its terms and Ms. Smith ceased to serve as Chairman of the Board. In conjunction with the termination, the Company paid Ms. Smith a \$150,000 bonus as called for in the Chairman Services Agreement.

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

- \$100,000 per year cash compensation, payable in quarterly installments;
- \$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 during the period July 17, 2019 when our non-employee directors other than Ms. Wood became directors in conjunction the

completion of the merger transaction with EMI Holding, and December 31, 2019. 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	\$ 50,000	\$ —	\$ 50,000
Masaharu Osato, M.D.	50,000	—	50,000
Wei Peu Zen	50,000	—	50,000
Robert Dickey IV	50,000	—	50,000
Total	<u>\$ 200,000</u>	<u>\$ —</u>	<u>\$ 200,000</u>

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

The following table sets forth certain information as of December 31, 2020 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 December 31, 2020 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)	25.9 %
Willis C. Lee	Vice-Chairman and Chief Operating Officer	1,434,636 (3)	2.9 %
Yasushi Nagasaki	Interim Chief Financial Officer	1,169,753 (4)	2.3 %
Lan T. Tran, M.P.H.	Chief Administrative Officer	1,129,213 (5)	2.3 %
Masaharu Osato, M.D.	Director	735,396 (6)	1.5 %
Wei Peu Zen	Director	2,278,048 (7)	4.7 %
Ian Zwicker	Director	217,029	*
Robert Dickey IV	Director	—	*
Jane Pine Wood	Director	—	*
Officers and Directors as a Group (9 persons)		20,296,455 (8)	39.6 %
5% or More Owners			
Telcon RF Pharmaceutical, Inc.		4,147,491 (9)	8.5 %

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

(1) Based on 48,987,189 shares of common stock issued and outstanding as of December 31, 2020.

(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 1,102,651 shares underlying stock options.

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

(7) Includes 1,270,214 shares owned by Profit Preview International Group Limited, a Hong Kong limited company wholly owned by Mr. Zen. Excludes 375,308 shares owned by Smart Start investments Limited, a Hong Kong corporation, of which the Mr. Zen is a director and 9.93% 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 24.71% shareholder, as to which shares Mr. Zen disclaims beneficial ownership.

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

(9) 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, 2019 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	7,245,350	\$ 4.68	2,167,150

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

Except as follows in the below items, since the beginning of our last fiscal year, there has not been, nor is there currently proposed, any transaction or series of similar transactions to which we are or will be 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, lend or re-lend 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, 2019, the outstanding balance under the revolving line of credit agreement of \$600,000 was reflected on our consolidated balance sheet. With the tax-gross up, the effective interest rate on the outstanding balance as of December 31, 2019 was 10.4%. The revolving line of credit agreement will expire on November 22, 2022.

The following table sets forth information relating to our promissory notes payable and convertible notes payable from related persons outstanding at any time during the years ended December 31, 2018 and 2019 (amounts in thousands).

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	Shares Underlying Notes December 31, 2019
Current, Promissory notes payable to related parties:										
	Hope International Hospice, Inc. (1)	10%	6/3/2016	Due on Demand	—	250	250	78	—	—
	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	43	159	—	—		
				Subtotal	\$ 43	\$ 1,313	\$ 277	\$ 80		—
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		—
				Total	\$ 43	\$ 16,113	\$ 15,077	\$ 1,633		—

(1) Dr. Niihara, our Chairman and Chief Executive Officer, is a co-owner with his wife and a director and the Chief Executive Officer of Hope International Hospice, Inc.

(2) Officer

(3) Director

(4) Mr. Zen, one of our directors, is the sole owner of Profit Preview International Group, Ltd.

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, Inc., or EMI, 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 up to 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 an affiliated company, 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.

On September 1, 2020, we issued a promissory note to Soomi Niihara, Dr. Niihara's wife, in the amount of \$395,000. The note bore interest at the rate of 12% per annum, with principal and accrued interest due upon demand. The note was repaid on October 1, 2020.

On September 1, 2020, we issued a promissory note to Hope International Hospice, Inc., of which Dr. Niihara and his wife are the sole shareholders and directors, in the amount of \$189,000. The note bore interest at the rate of 12% per annum, with principal and accrued interest due upon demand. The note was repaid on October 1, 2020.

On October 28, 2020, we issued a promissory note to Soomi Niihara in the amount of \$685,000. The note bore interest at the rate of 12% per annum, with principal and accrued interest due upon demand. The note was repaid on December 21, 2020.

On January 20, 2021, we issued a promissory note to Soomi Niihara in the amount of \$700,000. The note bore interest at the rate of 12% per annum, with principal and accrued interest due upon demand.

Guarantee by Officer

On January 15, 2018, EMI Holding issued a convertible promissory note to Wealth Threshold Limited in the original principal amount of \$5,000,000, repayment of which is personally guaranteed by Dr. Niihara. The unpaid principal amount of the note was \$3,150,000 as of December 31, 2020.

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, 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, 2019 and 2018:

	Years ended December 31, 2019 and 2018	
Audit Fees (1)	\$	275
Audit-Related Fees		—
Tax Fees		—
All Other Fees		—
Total	\$	<u>275</u>

(1) Audit fees consisted of fees for services performed in the audits of our annual financial statements.

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 2019 and 2018, 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, 2010	
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.					*
3.2	Amended and Restated By-Laws.	8-K	001-35527	3.4	July 22, 2019	
4.1	Specimen Common Stock Certificate.					*
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.	DEF 14A	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	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	January 28, 2019	
4.21	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	
4.22	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	
4.23	Form of Second Amended and Restated Common Stock Purchase Warrant.	8-K	001-35527	4.2	February 27, 2020	
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	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished
		Form	File No.	Exhibit	Filing Date	
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					*
10.12	Promissory Note dated May 26, 2019					*
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	
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	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished
		Form	File No.	Exhibit	Filing Date	
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 1, 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.					*
10.24	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.)					*

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished
		Form	File No.	Exhibit	Filing Date	
10.26	<u>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.)</u>					*
10.27	<u>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.)</u>					*
10.28	<u>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.)</u>					*
10.29	<u>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 asterix in Filed/Furnished column.</u>					*
10.30	<u>Agreement dated December 23, 2019 between Telcon RF Pharmaceutical Inc. and Emmaus Life Sciences, Inc.</u>					*
10.31	<u>Securities Purchase Agreement dated as of February 28, 2020 between Emmaus Life Sciences, Inc. and Lincoln Park Capital Fund, LLC</u>	8-K	001-35527	1.1	March 3, 2020	
10.32	<u>Registration Rights Agreement dated as of February 28, 2020 between Emmaus Life Sciences, Inc. and Lincoln Park Capital Fund, LLC.</u>	8-K	001-35527	10.1	March 3, 2020	
10.33	<u>Letter of Commitment dated December 23, 2019 between EMI Holding, Inc. (formerly, Emmaus Life Sciences, Inc) and Telcon RF Pharmaceutical, Inc.</u>					*
10.34	<u>Convertible Bond Purchase Agreement between Emmaus Life Sciences, Inc. and Telcon RF Pharmaceutical, Inc.</u>					*
10.35	<u>Right to Sell (Call Option) Agreement between Emmaus Life Sciences, Inc. and Telcon RF Pharmaceutical, Inc.</u>					*
10.36	<u>Loan Agreement Dated October 28, 2020 Between Emmaus Life Sciences, Inc. and EJ Holdings, Inc.</u>	8-K	001-35527	10.1	November 13, 2020	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished
		Form	File No.	Exhibit	Filing Date	
10.37+	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.					*
21.1	List of Subsidiaries.					*
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	XBRL Instance Document					
101.SCH	XBRL Taxonomy Extension Schema Document					
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					
101.PRE	XBRL Taxonomy Extension Presentation Linkbase 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 January 22, 2021.

Emmaus Life Sciences, Inc.

By: /s/ Yutaka Niihara

Name: Yutaka Niihara, M.D., M.P.H.

Title: *Chairman and Chief Executive Officer*

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Company in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
<u>/s/ Yutaka Niihara</u> Yutaka Niihara, M.D., M.P.H.	Chairman of the Board and Chief Executive Officer (Principal Executive Officer)	January 22, 2021
<u>/s/ Yasushi Nagasaki</u> Yasushi Nagasaki	Interim Chief Financial Officer (Principal Financial and Accounting Officer)	January 22, 2021
<u>/s/ Willis C. Lee</u> Willis C. Lee	Director	January 22, 2021
<u>/s/ Robert Dickey IV</u> Robert Dickey IV	Director	January 22, 2021
<u>/s/ Masaharu Osato</u> Masaharu Osato, M.D.	Director	January 22, 2021
<u>/s/ Ian Zwicker</u> Ian Zwicker	Director	January 22, 2021
<u>/s/ Jane Pine Wood</u> Jane Pine Wood	Director	January 22, 2021

INDEX TO FINANCIAL STATEMENTS

EMMAUS LIFE SCIENCES, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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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 subsidiaries (collectively, the Company) as of December 31, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity (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 as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Matter

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses from operations and does not have sufficient liquidity to meet its expected operating and capital cash flow requirements. This raises substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters also are described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Restatement of Previously Issued Financial Statements

When originally issued, the Company's December 31, 2018 consolidated financial statements were audited by another independent registered accounting firm whose report (dated March 21, 2019) expressed an unqualified opinion thereon and expressed substantial doubt as to the ability of the Company to continue as a going concern. Management subsequently determined that such financial statements included material departures from accounting principles generally accepted in the United States of America; accordingly, the accompanying December 31, 2018 consolidated financial statements have been restated as more fully explained in Note 3.

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.

/s/ BAKER TILLY US, LLP

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

San Diego, California
January 22, 2021

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

	As of	
	December 31, 2019	December 31, 2018 (As Restated)
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 1,769	\$ 3,905
Accounts receivable, net	2,150	1,788
Inventories, net	7,971	4,705
Investment in marketable securities	27,929	49,343
Marketable securities, pledged to creditor	—	238
Prepaid expenses and other current assets	1,402	634
Total current assets	41,221	60,613
Property and equipment, net	151	152
Long-term investment at cost	—	538
Equity method investment	13,325	13,569
Right of use assets	4,474	—
Other assets	285	406
Total assets	\$ 59,456	\$ 75,278
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	\$ 11,498	\$ 8,235
Deferred rent, current portion	—	19
Operating lease liabilities, current portion	991	—
Other current liabilities	5,748	5,342
Revolving line of credit to related party	600	—
Warrant derivative liabilities	38	8,939
Notes payable, net of discount	3,749	6,212
Notes payable to related parties	193	468
Convertible debentures, net of discount	7,015	—
Convertible notes payable, net of discount	2,995	11,253
Convertible notes payable to related parties, net of discount	—	5,089
Total current liabilities	32,827	45,557
Deferred rent, less current portion	—	268
Operating lease liabilities, less current portion	3,932	—
Other long-term liabilities	33,750	36,222
Notes payable, net of discount, less current portion	—	925
Convertible notes payable, net of discount, less current portion	—	5,485
Convertible notes payable to related parties, net of discount	—	8,529
Total liabilities	70,509	96,986
STOCKHOLDERS' EQUITY (DEFICIT)		
Preferred stock — par value \$0.001 per share, 15,000,000 shares authorized, no shares issued or outstanding	—	—
Common stock — par value \$0.001 per share, 250,000,000 shares authorized, 48,471,446 shares and 37,341,393 shares issued and outstanding at December 31, 2019 and at December 31, 2018, respectively	48	37
Additional paid-in capital	215,207	149,682
Accumulated other comprehensive income (loss)	(79)	(69)
Accumulated deficit	(226,229)	(171,358)
Total stockholders' deficit	(11,053)	(21,708)
Total liabilities and stockholders' deficit	\$ 59,456	\$ 75,278

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

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

	Years Ended December 31,	
	2019	2018 (As Restated)
REVENUES, NET	\$ 22,752	\$ 16,459
COST OF GOODS SOLD	1,094	993
GROSS PROFIT	21,658	15,466
OPERATING EXPENSES		
Research and development	2,183	1,723
Selling	6,975	4,733
General and administrative	17,012	17,464
Total operating expenses	26,170	23,920
LOSS FROM OPERATIONS	(4,512)	(8,454)
OTHER INCOME (EXPENSE)		
Loss on debt extinguishment	(438)	(2,702)
Change in fair value of warrant derivative liabilities	3,545	4,476
Change in fair value of embedded conversion option	131	—
Net losses on investment in marketable securities and long-term investment	(21,947)	(43,977)
Net losses on equity method investment	(414)	(97)
Miscellaneous reverse merger costs	(309)	—
Notes conversion costs	(3,341)	—
Interest and other income	232	1,002
Interest expense	(27,625)	(22,796)
Total other expense	(50,166)	(64,094)
LOSS BEFORE INCOME TAXES	(54,678)	(72,548)
INCOME TAXES	164	39
NET LOSS	(54,842)	(72,587)
COMPONENTS OF OTHER COMPREHENSIVE INCOME (LOSS)		
Foreign currency translation adjustments	(10)	16
Other comprehensive income (loss)	(10)	16
COMPREHENSIVE LOSS	(54,852)	(72,571)
NET LOSS PER COMMON SHARE - BASIC and DILUTED	(1.30)	(1.97)
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING	42,259,460	36,857,995

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

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

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity / (Deficit)
	Shares	Amount				
Balance, December 31, 2017, as restated	36,634,856	\$ 37	\$ 117,107	\$ 41,276	\$ (140,132)	\$ 18,288
Cumulative effect adjustment on adoption of ASU 2016-01	—	—	—	(41,361)	41,361	—
Beneficial conversion feature relating to convertible and promissory notes payable	—	—	13,374	—	—	13,374
Exercise of warrants	1,741,720	1	18,455	—	—	18,456
Stock issued for cash	131,268	—	1,275	—	—	1,275
Repurchase and cancellation of common stock	(1,254,924)	(1)	(5,075)	—	—	(5,076)
Share-based compensation	—	—	4,546	—	—	4,546
Exercise of common stock options	88,473	—	—	—	—	—
Foreign currency translation effect	—	—	—	16	—	16
Net loss	—	—	—	—	(72,587)	(72,587)
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)

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

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

	Year ended December 31,	
	2019	2018 (As Restated)
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	\$ (54,842)	\$ (72,587)
Adjustments to reconcile net loss to net cash flows used in operating activities		
Depreciation and amortization	73	61
Impairment loss on long-term investment	515	—
Amortization of discount of notes payable and convertible notes payable	23,781	18,234
Foreign exchange adjustments	(115)	(297)
Net losses on investment in marketable securities	21,432	43,977
Loss on equity method investment	414	97
Loss on debt extinguishment	438	2,702
Share-based compensation and fair value of replacement equity award	3,805	4,545
Notes conversion costs	3,341	—
Change in fair value of warrant derivative liabilities	(3,545)	(4,476)
Change in fair value of embedded conversion option	(131)	—
Net changes in operating assets and liabilities		
Accounts receivable	(361)	(1,761)
Inventories	(3,267)	(4,079)
Prepaid expenses and other current assets	(720)	(332)
Other non-current assets	(4,364)	(241)
Income tax receivable and payable	(64)	24
Accounts payable and accrued expenses	6,527	3,572
Deferred rent	(317)	245
Other current liabilities	426	5,312
Other long-term liabilities	2,451	(630)
Net cash flows used in operating activities	(4,523)	(5,634)
CASH FLOWS FROM INVESTING ACTIVITIES		
Cash paid in connection with the Merger	(1,645)	—
Sale of marketable securities	221	6,439
Purchases of property and equipment	(60)	(94)
Purchase of marketable securities and investment at cost	—	(469)
Capital contributions and loan to equity method investees	—	(13,316)
Net cash flows used in investing activities	(1,484)	(7,440)
CASH FLOWS FROM FINANCING ACTIVITIES		
Repurchase of common stock and warrants	—	(11,262)
Proceeds from notes payable issued, net of issuance cost and discount	600	11,560
Proceeds from convertible notes payable issued, net of issuance cost and discount	—	17,816
Payments of notes payable	(143)	(5,077)
Payments of convertible notes	(5,348)	(20,000)
Proceeds from exercise of warrants	186	111
Proceeds from issuance of common stock	8,589	1,275
Net cash flows provided by (used in) financing activities	3,884	(5,577)
Effect of exchange rate changes on cash	(13)	—
Net decrease in cash and cash equivalents	(2,136)	(18,651)
Cash, cash equivalent, beginning of period	3,905	22,556
Cash, cash equivalents, end of period	\$ 1,769	\$ 3,905
SUPPLEMENTAL DISCLOSURES OF CASH FLOW ACTIVITIES		
Interest paid	\$ 1,543	\$ 2,178
Income taxes paid	\$ 227	\$ 3
NON-CASH INVESTMENT AND FINANCING ACTIVITIES		
Warrant liabilities reclassified to equity	\$ 6,337	\$ —
Exercised of warrants and options on cashless basis	\$ —	\$ 18,345
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.

Notes to 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 Holding”) 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 Telemetrynd, Inc. (“Telemetrynd”), 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 Telemetrynd 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. 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— The accompanying consolidated financial statements have been prepared on the basis that the Company will continue as a going concern. The Company had net loss of approximately \$54.8 million and \$72.6 million for the years ended December 31, 2019 and 2018, respectively. In addition, the Company has a significant amount of notes payable and other obligations due within the next twelve months and is projecting that its operating losses and expected capital needs, including the expected costs relating to the commercialization of Endari®, will exceed its existing cash balances and cash expected to be generated from operations for the foreseeable future. In order to meet the Company’s expected obligations, the Company will need to raise additional funds through equity and debt financings or licensing or other strategic agreements. The Company has no understanding or arrangement for any additional financing, and there can be no assurance that the Company will be able to complete any additional equity or debt financings on favorable terms, or at all, or enter into licensing or other strategic arrangements. Due to the uncertainty of the Company’s ability to meet its current operating and capital expenses, there is substantial doubt about the Company’s ability to continue as a going concern, as the continuation and expansion of its business is dependent upon obtaining further financing, successful and sufficient market acceptance of its products, and achieving a profitable level of operations. The consolidated financial statements do not include any adjustments that might result from the outcome of these uncertainties.

Principles of consolidation—The consolidated financial statements include the accounts of the Company (and EMI Holding 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’s 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— Effective January 1, 2018, the Company adopted ASC 606, *Revenue from Contracts with Customers* using the modified retrospective transition methods. The adoption of ASC 606 did not have a material impact on the measurement or on the recognition of revenue of contracts for which all revenue had not been recognized as of January 1, 2018, therefore no cumulative adjustment has been made to the opening balance of accumulated deficit at the beginning of 2018. Since January 2018, the Company has generated 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 enter 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 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 become 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 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 our 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 ASU 2016-02, 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 are valued based on first-in, first-out and 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. All raw material purchases during the years ended December 31, 2019 and 2018 were from 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, 2019 and 2018.

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, 2019 and December 31, 2018, the Company had no 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 to measure all 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 6 for additional details.

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 countries 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, accounts receivable, note receivable, warrant derivative liabilities, accounts payable, certain accrued liabilities, convertible notes payable, notes payable, conversion feature liabilities and other contingent liabilities. The carrying amounts of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities approximate their fair values due to the short-term nature of those instruments.

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.

The 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, and. The fair value of the Company's debt instruments is not materially different from their carrying values as presented. 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 8.

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 fair 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.

Net 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, 2019 and December 31, 2018, there were 12,933,664 shares and 17,406,715 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, 2019, including interim periods within those annual reporting periods. Early adoption is permitted. The Company is evaluating the impact of this new standard on its financial statements and related disclosures.

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 Company is assessing the impact the adoption of ASU 2018-13 will have on its consolidated financial statements and accompanying footnote disclosures.

NOTE 3 – RESTATEMENT OF PREVIOUSLY ISSUED FINANCIAL STATEMENTS

As previously disclosed in the Company's Current Report on Form 8-K filed with the SEC on July 8, 2020, the board of directors of the Company, based on the recommendation of the audit committee and in consultation with management and the Company's predecessor independent registered public accounting firm, concluded that, because of errors identified in the previously issued audited financial statements of EMI Holding, Inc. as of and for the year ended December 31, 2018, the Company would restate the previously issued financial statements.

The restated financial statements correct the following errors:

1. The common stock purchase warrants issued in connection with the 10% Senior Secured Debentures in October 2018 and accounted for as equity should have been treated as derivative liabilities and accounted for at fair value with changes in fair value recorded in earnings. This error resulted in \$75 million and \$9.7 million understatement of the fair value of warrant derivative liabilities and stockholder's deficit, respectively, as of December 31, 2018. This error also resulted in a \$2.4 million overstatement of net loss for the year ended December 31, 2018. In connection with the completion of the Merger on July 17, 2019, the warrants were reclassified as equity.
2. EJ Holdings was incorrectly consolidated as a VIE and the Company's variable interest in EJ Holdings should have been accounted for using the equity method. This error resulted in \$13.2 million and \$0.2 million overstatements of cash and other current assets, respectively, and a \$13.5 million understatement of the equity method investment as of December 31, 2018. The error also resulted in a \$0.2 million overstatement of loss from operations and a \$0.1 million overstatement of loss before income taxes for the year ended December 31, 2018.
3. The fair value of cashless warrants exercised in September 2018 upon their expiration of warrants should have been recorded in additional paid-in capital. The error resulted in a \$18.3 million overstatement of change in fair value of warrant derivative liabilities and an understatement of additional paid-in capital for the year ended December 31, 2018.
4. Other adjustments: The restated financial statements also include adjustments to correct certain insignificant errors to the financial statements as of and for the year ending December 31, 2018.

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

	As of December 31, 2018		
	Previously Reported	Adjustments	As Restated
ASSETS			
CURRENT ASSETS			
Cash and cash equivalents	\$ 17,080	\$ (13,175) (b)	\$ 3,905
Accounts receivable, net	1,351	437 (d)	1,788
Inventories, net	4,705	—	4,705
Investment in marketable securities	49,343	—	49,343
Marketable securities, pledged to creditor	238	—	238
Prepaid expenses and other current assets	743	(109) (b)(d)	634
Total current assets	73,460	(12,847)	60,613
Property and equipment, net	152	—	152
Long-term investment	538	—	538
Equity method investment	—	13,569 (b)	13,569
Other assets	406	—	406
Total assets	\$ 74,556	\$ 722	\$ 75,278
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)			
CURRENT LIABILITIES			
Accounts payable and accrued expenses	9,122	(887) (b)	8,235
Deferred rent, current portion	19	—	19
Other current liabilities	5,181	161 (d)	5,342
Warrant derivative liabilities	—	8,939 (a)(d)	8,939
Notes payable, net of discount	6,394	(182) (a)	6,212
Notes payable to related parties	468	—	468
Convertible notes payable, net of discount	11,253	—	11,253
Convertible notes payable to related parties, net of discount	5,089	—	5,089
Total current liabilities	37,526	8,031	45,557
Deferred rent, less current portion	268	—	268
Other long-term liabilities	36,222	—	36,222
Warrant derivative liabilities	1,399	(1,399) (d)	—
Notes payable, net of discount, less current portion	1,021	(96) (a)	925
Convertible notes payable, net of discount, less current portion	5,485	—	5,485
Convertible notes payable to related parties, net of discount, less current portion	8,529	—	8,529
Total liabilities	90,450	6,536	96,986
STOCKHOLDERS' EQUITY (DEFICIT)			
Preferred stock — par value \$0.001 per share, 15,000,000 shares authorized, no shares issued or outstanding	—	—	—
Common stock — par value \$0.001 per share, 250,000,000 shares authorized, 37,341,393 shares issued and outstanding at December 31, 2018	37	—	37
Additional paid-in capital	140,903	8,779 (a)(c)(d)	149,682
Accumulated other comprehensive loss	(69)	—	(69)
Accumulated deficit	(156,668)	(14,690)	(171,358)
Stockholders' deficit	(15,797)	(5,911)	(21,708)
Noncontrolling interests	(97)	97 (b)	—
Total liabilities and stockholders' deficit	\$ 74,556	\$ 722	\$ 75,278

(a) Warrant adjustments: The correction of this misstatement resulted in an increase of \$7.5 million in warrant derivative liabilities and decreases of \$182,000 in short-term notes payable, \$96,000 in long-term notes payable and \$9.7 million in additional paid-in capital.

(b) EJ Holdings adjustments: The correction of this misstatement resulted in increases of \$13.6 million in equity method investment, \$58,000 in accounts payable and accrued expenses, and \$97,000 in non-controlling interest and decreases of \$13.2 million in cash and cash equivalent and \$240,000 in prepaid expenses and other current assets.

(c) Cashless warrants adjustments: The correction of this misstatement resulted in an increase of \$18.3 million in additional paid-in capital.

(d) Corrections of other misstatement were as follows: (i) period adjustment and reclassification of variable consideration resulted in an increase of \$436,000 in accounts receivable and a decrease of \$946,000 in accounts payable and accrued expense. It also resulted a decrease of \$10,000 in income tax receivable and an increase of \$24,000 in income tax payable; (ii) correction of financing of insurance premium resulted in an increase of \$141,000 in each of prepaid expenses and current liabilities; (iii) correction of stock modification accounting resulted in an increase of \$52,000 in additional paid-in capital; and (iv) correction of accounting treatment for conversion feature of senior secured convertible promissory note resulted in an increase of \$172,000 in additional paid-in capital.

Emmaus Life Sciences, Inc.
Consolidated Statement of operations and Comprehensive Loss
(In thousands, except share and per share amounts)

	Years Ended December 31, 2018		
	Previously Reported	Adjustments	As Restated
CONSOLIDATED STATEMENTS OF LOSS			
REVENUES, NET	\$ 15,077	\$ 1,382 (d)	\$ 16,459
COST OF GOODS SOLD	764	229 (d)	993
GROSS PROFIT	14,313	1,153	15,466
OPERATING EXPENSES			
Research and development	1,723	—	1,723
Selling	4,813	(80) (d)	4,733
General and administrative	17,877	(413) (b)(d)	17,464
Total operating expenses	24,413	(493)	23,920
LOSS FROM OPERATIONS	(10,100)	1,646	(8,454)
OTHER INCOME (EXPENSE)			
Loss on debt extinguishment	(3,245)	543 (d)	(2,702)
Change in fair value of warrant derivative liabilities	20,674	(16,198) (a) (c)	4,476
Change in fair value of embedded conversion option	466	(466) (d)	—
Net losses on investment in marketable securities	(43,977)	—	(43,977)
Net losses on equity method investment	—	(97) (b)	(97)
Interest and other income (loss)	969	33 (b)	1,002
Interest expense	(22,825)	29 (a)(d)	(22,796)
Total other income (expense)	(47,938)	(16,156)	(64,094)
LOSS BEFORE INCOME TAXES	(58,038)	(14,510)	(72,548)
INCOME TAXES	6	33 (d)	39
NET LOSS INCLUDING NONCONTROLLING INTEREST	(58,044)	(14,543)	(72,587)
Net loss attributable to noncontrolling interest	146	(146)	—
NET LOSS ATTRIBUTABLE TO THE COMPANY	(57,898)	(14,689)	(72,587)
COMPONENTS OF OTHER COMPREHENSIVE INCOME (LOSS)			
Foreign currency translation adjustments	17	(1) (b)	16
Other comprehensive income (loss)	17	(1)	16
COMPREHENSIVE LOSS	(58,027)	(14,544)	(72,571)
Amounts attributable to noncontrolling interest:			
Net loss attributable to noncontrolling interest	146	(146) (b)	—
Foreign currency translation adjustments	—	—	—
COMPREHENSIVE INCOME (LOSS) ATTRIBUTABLE TO THE COMPANY	\$ (57,881)	\$ (14,690)	\$ (72,571)
NET LOSS PER COMMON SHARE - BASIC AND DILUTED	(1.57)	(0.40)	(1.97)
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING	36,857,995	36,857,995	36,857,995

(a) Warrant adjustments: The correction of this misstatement resulted in an increase of \$2.1 million in change in fair value of warrant derivative liabilities and a decrease of \$278,000 in interest expense.

(b) EJ Holdings adjustments: The correction of this misstatement resulted in a decrease of \$211,000 in general and administrative expense, an increase of \$97,000 in loss on equity method investment and an increase in \$32,000 in interest income.

(c) Cashless warrant adjustments: The correction of this misstatement resulted in a decrease of \$18.3 million in change in fair value of warrant derivative liabilities.

(d) Corrections of other misstatement were as follows: (i) period adjustment of variable consideration resulted in increases of \$1.4 million in revenue, net and \$33,000 in income tax provision; (ii) reclassification of shipping cost and royalty expense to cost of sales resulted in an increase of \$229,000 in cost of sales and decreases of \$80,000 and \$141,000 in selling expense and general and administrative expense, respectively; (iii) correction of stock modification accounting resulted in a decrease of \$52,000 in general and administrative expense; and (iv) correction of accounting treatment for conversion feature resulted in an increase of \$249,000 in interest expense and decreases of \$543,000 and \$466,000 in loss on debt extinguishment and change in fair value of embedded conversion option, respectively.

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

	Year ended December 31, 2018		
	Previously Reported	Adjustments	As Restated
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	\$ (58,044)	\$ (14,543)	\$ (72,587)
Adjustments to reconcile net loss to net cash flows used in operating activities			
Depreciation and amortization	61	—	61
Amortization of discount of notes payable and convertible notes payable	18,263	(29) (d)	18,234
Foreign exchange adjustments	53	(350) (b)	(297)
Net losses on investment in marketable securities	43,977	—	43,977
Loss on equity method investment	—	97 (b)	97
Loss on debt extinguishment	3,245	(543) (d)	2,702
Share-based compensation and fair value of replacement equity award	4,597	(52) (d)	4,545
Change in fair value of warrant derivative liabilities	(20,674)	16,198 (a)(c)	(4,476)
Change in fair value of embedded conversion option	(466)	466 (d)	—
Net changes in operating assets and liabilities			
Accounts receivable	(1,324)	(437) (d)	(1,761)
Inventories	(4,079)	—	(4,079)
Prepaid expenses and other current assets	(431)	99 (b)(d)	(332)
Other non-current assets	(241)	—	(241)
Income tax receivable and payable	(10)	34 (d)	24
Accounts payable and accrued expenses	4,631	(1,059) (b)(d)	3,572
Deferred rent	245	—	245
Other current liabilities	5,174	138 (d)	5,312
Other long-term liabilities	(630)	—	(630)
Net cash flows used in operating activities	(5,653)	19	(5,634)
CASH FLOWS FROM INVESTING ACTIVITIES			
Sale of marketable securities	6,439	—	6,439
Purchases of property and equipment	(94)	—	(94)
Purchase of marketable securities and investment at cost	(469)	—	(469)
Capital contributions and loan to equity method investees	—	(13,316) (d)	(13,316)
Net cash flows provided by (used in) investing activities	5,876	(13,316)	(7,440)
CASH FLOWS FROM FINANCING ACTIVITIES			
Repurchase of common stock and warrants	(11,262)	—	(11,262)
Proceeds from notes payable issued, net of issuance cost and discount	11,560	—	11,560
Proceeds from convertible notes payable issued, net of issuance cost and discount	17,645	171 (d)	17,816
Payments of notes payable	(5,077)	—	(5,077)
Payments of convertible notes	(20,000)	—	(20,000)
Proceeds from exercise of warrants	111	—	111
Proceeds from issuance of common stock	1,275	—	1,275
Proceeds from noncontrolling interest	48	(48) (b)	—
Net cash flows provided by (used in) financing activities	(5,700)	123	(5,577)
Effect of exchange rate changes on cash	—	—	—
Net increase (decrease) in cash, cash equivalents and restricted cash	(5,477)	(13,174)	(18,651)
Cash, cash equivalents, beginning of period	22,556	—	22,556
Cash, cash equivalents, end of period	\$ 17,079	\$ (13,174)	\$ 3,905
SUPPLEMENTAL DISCLOSURES OF CASH FLOW ACTIVITIES			
Interest paid	\$ 2,178	\$ —	\$ 2,178
Income taxes paid	\$ 3	\$ —	\$ 3
Exercised of warrants and options on cashless basis	\$ 1,712	\$ 16,633 (c)	\$ 18,345

Refer to the descriptions of the adjustments and their impact on net loss in the Consolidated Balance Sheet and Statement of Comprehensive Loss as of and for the year ended December 31, 2018 above except for those below:

Cash flow classification adjustment related to EJ Holdings resulted in a net increase to cash flows provided by operating activities of \$0.1 million and a decrease in net cash flows provided by investing activities of \$13.3 million for the year ended December 31, 2018.

(d) Correction of unpaid deferred financing cost included in proceeds from convertible notes payable issued, net of issuance cost and discount resulted in a net increase to cash flow from financing activities and a net decrease to cash flow provided by operating activities of \$171,000.

NOTE 4—REVENUES

Revenues by category were as follows (in thousands):

	Year ended December 31,	
	2019	2018
Endari®	\$ 22,311	\$ 15,953
Other	441	506
Revenues, net	<u>\$ 22,752</u>	<u>\$ 16,459</u>

The following table summarizes the revenue allowance and accrual activities for the years ended December 31, 2019 and 2018 (in thousands):

	Trade Discounts, Allowances and Chargebacks	Government Rebates and Other Incentives	Returns	Total
Balance as of December 31, 2017	\$ —	\$ —	\$ —	\$ —
Provision related to sales in the current year	926	1,535	99	2,560
Credit and payments made	(842)	(737)	—	(1,579)
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	<u>228</u>	<u>1,354</u>	<u>315</u>	<u>1,897</u>

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

	Revenue for year ended December 31,		Accounts receivables as of December 31,	
	2019	2018	2019	2018
AmerisourceBergen Specialty Group	58 %	78 %	56 %	57 %
McKesson Plasma and Biologics LLC	23 %	14 %	31 %	25 %

The Company is party to a distributor agreement with Telcon pursuant to which it granted Telcon exclusive rights to the Company's 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, 2019 and 2018. Refer Note 13 for related party transaction details.

The Company received an upfront payment 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. The upfront payment of \$500,000 is included in other long-term liabilities as unearned revenue as of December 31, 2019 and 2018.

NOTE 5—SELECTED FINANCIAL STATEMENT CAPTIONS - ASSETS

Inventories consisted of the following (in thousands):

Inventories by category	As of December 31,	
	2019	2018
Raw materials and components	\$ 1,145	\$ 171
Work-in-process	2,187	2,471
Finished goods	4,639	2,063
Total	<u>\$ 7,971</u>	<u>\$ 4,705</u>

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

	As of December 31,	
	2019	2018 (As Restated)
Prepaid insurance	\$ 735	\$ 223
Other prepaid expenses and current assets	667	411
	<u>\$ 1,402</u>	<u>\$ 634</u>

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

	As of December 31,	
	2019	2018
Equipment	\$ 335	\$ 306
Leasehold improvements	77	70
Furniture and fixtures	95	79
Total property and equipment	507	455
Less: accumulated depreciation	(356)	(303)
Property and Equipment, net	<u>\$ 151</u>	<u>\$ 152</u>

During the years ended December 31, 2019 and 2018, depreciation expenses were approximately \$59,000 and \$47,000, respectively.

NOTE 6 — 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 and December 31, 2018, the closing prices per Telecon share on the Korean Securities Dealers Automated Quotations ("KOSDAQ") were approximately \$4.20 and \$7.43, respectively.

As of December 31, 2019 and December 31, 2018, 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 the Company's agreement that a portion of the net sale proceeds will be used to purchase at face value a 10-year convertible bond of Telcon in the principal amount of approximately \$31.8 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.

As of December 31, 2018, the Company held 39,250 shares of capital stock of CellSeed, Inc., Japanese Corporation ("CellSeed"), which shares were the remainder part of 147,100 shares acquired by the Company in January 2009 for approximately \$1.1 million or \$7.69 per share. As of December 31, 2018, the closing price per CellSeed share on the Tokyo Stock Exchange was approximately \$6.07 and all the Company's CellSeed shares were pledged to secure a \$300,000 convertible note issued to Mitsubishi UFJ Capital III Limited Partnership that was due on demand and was classified as marketable securities, pledged to creditor in current assets. In June 2019, all the CellSeed shares were sold for net cash proceeds of approximately \$221,000 after repayment of the secured convertible note.

Effective January 1, 2018, the Company adopted ASU 2016-01 which requires the Company to measure all 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 attributable to an investment in KPS Co., Ltd. No impairment loss was recognized during the year ended December 31, 2018. The Company recognized a cumulative effect adjustment of \$41.4 million, net of \$12.3 million income tax benefit, to increase the opening balance of accumulated deficit with an offset to accumulated other comprehensive income as of January 1, 2018, in connection with the adoption of ASU 2016-01.

The fair values of our equity securities were included in the following line items in the Consolidated Balance Sheets (in thousands):

	As of December 31, 2019		As of December 31, 2018	
	Fair Value with Changes Recognized in Income	Measurement Alternative - No Readily Determinable Fair Value	Fair Value with Changes Recognized in Income	Measurement Alternative - No Readily Determinable Fair Value
Marketable securities	\$ 27,929	\$ —	\$ 49,581	\$ —
Long-term investment at cost	—	—	—	538
Total equity securities	<u>\$ 27,929</u>	<u>\$ —</u>	<u>\$ 49,581</u>	<u>\$ 538</u>

Net unrealized losses on available-for-sale marketable securities held as of December 31, 2019 and 2018 were \$21.4 million and \$43.2 million, respectively.

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 was valued at \$13.8 million and \$13.6 million as of December 31, 2019 and December 31, 2018 respectively. The loan proceeds were used by EJ Holdings to purchase the Ube facility in December 2019 and pay related taxes. The loan matures on September 30, 2028 and bears interest at the rate of 1% payable annually. 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.

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 financial information of EJ Holdings for years ended December 31, 2019 and 2018 (in thousands):

	As of	
	December 31, 2019	December 31, 2018
ASSETS		
CURRENT ASSETS	\$ 2,310	\$ 13,505
OTHER ASSETS	10,654	—
Total assets	<u>12,964</u>	<u>13,505</u>
LIABILITIES		
CURRENT LIABILITIES	\$ 296	\$ 33
LONG-TERM LIABILITIES	13,870	13,634
Total liabilities	<u>14,166</u>	<u>13,667</u>
NONCONTROLLING INTEREST	<u>(721)</u>	<u>(97)</u>
REVENUES, NET		
	<u>\$ 229</u>	<u>\$ 57</u>
NET LOSS	<u>\$ (1,035)</u>	<u>\$ (243)</u>

NOTE 7—SELECTED FINANCIAL STATEMENT CAPTIONS - LIABILITIES

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

	December 31, 2019	December 31, 2018 (As Restated)
Accounts payable:		
Clinical and regulatory expenses	\$ 232	\$ 83
Professional fees	1,183	2,157
Selling expenses	1,303	382
Manufacturing cost	4,541	—
Other vendors	18	844
Total accounts payable	7,277	3,466
Accrued interest payable, related parties	42	842
Accrued interest payable	991	2,138
Accrued expenses:		
Payroll expenses	891	713
Government rebates and other rebates	1,355	933
Due to EJ Holdings	238	57
Other accrued expenses	704	86
Total accrued expenses	3,188	1,789
Total accounts payable and accrued expenses	\$ 11,498	\$ 8,235

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

	As of December 31,	
	2019	2018
Trade discount	\$ 23,242	\$ 26,222
Unearned revenue	10,500	10,000
Other long-term liabilities	8	—
Total other long-term liabilities	\$ 33,750	\$ 36,222

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 pharmaceutical grade L-glutamine (“PGLG”). The Company purchased \$4.5 million and \$1.0 million of PGLG from Telcon during years ended December 31, 2019, and 2018, respectively, of which \$3.7 million and zero were reflected in accounts payable as of December 31, 2019 and 2018, respectively. See Note 12 for additional details.

NOTE 8—NOTES PAYABLE

Notes payable consisted of the following at December 31, 2019 and 2018 (in thousands except for conversion price and shares):

Year Issued	Interest Rate Range	Term of Notes	Conversion Price	Principal Outstanding December 31, 2019	Discount Amount December 31, 2019	Carrying Amount December 31, 2019	Shares Underlying Notes December 31, 2019	Principal Outstanding December 31, 2018	Discount Amount December 31, 2018 As Restated	Carrying Amount December 31, 2018 As Restated	Shares Underlying Notes December 31, 2018
Notes payable											
2013	10%	Due on demand	—	\$ 920	\$ —	\$ 920	—	\$ 909	\$ —	\$ 909	—
2015	10%	Due on demand	—	—	—	—	—	10	—	10	—
2016	10% - 11%	Due on demand	—	—	—	—	—	843	—	843	—
2017	5% - 11%	Due on demand	—	—	—	—	—	2,575	—	2,575	—
2018	10% - 11%	Due on demand - 18 months	—	—	—	—	—	12,311	9,511	2,800	—
2019	11%	Due on demand - 6 months	—	2,829	—	2,829	—	—	—	—	—
				<u>\$ 3,749</u>	<u>\$ —</u>	<u>\$ 3,749</u>	<u>—</u>	<u>\$ 16,648</u>	<u>\$ 9,511</u>	<u>\$ 7,137</u>	<u>—</u>
		Current		\$ 3,749	\$ —	\$ 3,749	—	\$ 12,448	\$ 6,236	\$ 6,212	—
		Non-current		\$ —	\$ —	\$ —	—	\$ 4,200	\$ 3,275	\$ 925	—
Notes payable - related party											
2016	10% - 11%	Due on demand	—	\$ 20	\$ —	\$ 20	—	\$ 270	—	\$ 270	—
2017	10%	Due on demand	—	—	—	—	—	39	—	39	—
2018	11%	Due on demand	—	159	—	159	—	159	—	159	—
2019	10%	Due on demand	—	14	—	14	—	—	—	—	—
				<u>\$ 193</u>	<u>\$ —</u>	<u>\$ 193</u>	<u>—</u>	<u>\$ 468</u>	<u>\$ —</u>	<u>\$ 468</u>	<u>—</u>
		Current		\$ 193	\$ —	\$ 193	—	\$ 468	\$ —	\$ 468	—
Convertible debentures											
2019	10%	18 months	\$ 9.52	\$ 10,200	\$ 3,185	\$ 7,015	1,080,415 (a)	\$ —	\$ —	\$ —	—
				<u>\$ 10,200</u>	<u>\$ 3,185</u>	<u>\$ 7,015</u>	<u>1,080,415</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>—</u>
		Current		\$ 10,200	\$ 3,185	\$ 7,015	1,080,415	\$ —	\$ —	\$ —	—
Convertible notes payable											
2011	10%	5 years	\$ 3.05	\$ —	\$ —	\$ —	—	\$ 300	\$ —	\$ 300	98,285
2014	10%	Due on demand - 2 years	\$3.05 - \$3.60	—	—	—	—	519	—	519	183,648
2016	10%	1 year	\$ 4.50	—	—	—	—	61	—	61	16,753
2017	10%	Due on demand - 1 year	\$3.50 - \$4.50	—	—	—	—	2,820	349	2,471	899,613
2018	6% - 10%	Due on demand - 2 years	\$3.50 - \$10.00	3,000	5	2,995	363,876 (b)	19,556	6,169	13,387	3,661,427
				<u>\$ 3,000</u>	<u>\$ 5</u>	<u>\$ 2,995</u>	<u>363,876</u>	<u>\$ 23,256</u>	<u>\$ 6,518</u>	<u>\$ 16,738</u>	<u>4,859,726</u>
		Current		\$ 3,000	\$ 5	\$ 2,995	363,876	\$ 16,604	\$ 5,351	\$ 11,253	3,981,232
		Non-current		\$ —	\$ —	\$ —	—	\$ 6,652	\$ 1,167	\$ 5,485	881,210
Convertible notes payable - related party											
2012	10%	Due on demand	\$ 3.30	\$ —	\$ —	\$ —	—	\$ 200	\$ —	\$ 200	74,182
2015	10%	2 years	\$ 4.50	—	—	—	—	200	—	200	58,350
2017	10%	2 years	\$ 10.00	—	—	—	—	5,000	311	4,689	532,671
2018	10%	2 years	\$ 10.00	—	—	—	—	9,400	871	8,529	971,963
				<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>—</u>	<u>\$ 14,800</u>	<u>\$ 1,182</u>	<u>\$ 13,618</u>	<u>1,637,166</u>
		Current		\$ —	\$ —	\$ —	—	\$ 5,400	\$ 311	\$ 5,089	665,203
		Non-current		\$ —	\$ —	\$ —	—	\$ 9,400	\$ 871	\$ 8,529	971,963
		Grand Total		<u>\$ 17,142</u>	<u>\$ 3,190</u>	<u>\$ 13,952</u>	<u>1,444,291</u>	<u>\$ 55,172</u>	<u>\$ 17,211</u>	<u>\$ 37,961</u>	<u>6,496,892</u>

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

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

The average stated interest rate of notes payable was 10% for the years ended December 31, 2019 and 2018. The average effective interest rate of notes payable for the years ended December 31, 2019 and 2018 was 66% and 35%, respectively, after giving effect to discounts relating to beneficial conversion features and deferred financing cost in connection with these notes.

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 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 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, 2019 (in thousands):

Conversion feature liabilities—Amended and Restated 10% Senior Secured Convertible Debentures	December 31, 2019
Balance, beginning of period	\$ —
Fair value at issuance date	132
Change in fair value	(131)
Balance, end of period	<u>\$ 1</u>

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, 2019 and as of the Merger date were based upon following assumptions:

	December 31, 2019	July 17, 2019
Stock price	\$ 1.97	\$ 7.02
Selected yield	16.77 %	19.82 %
Expected volatility (peer group)	50.00 %	55.00 %
Expected life (in years)	0.81	1.26
Expected dividend yield	—	—
Risk-free rate	Term structure	Term structure
Balance, end of period:		
Conversion feature liabilities (in thousands)	\$ 1	\$ 132

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, including \$600,000 loaned by him 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, 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, 2019, the outstanding balance under the revolving line of credit agreement of \$600,000 was 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, 2019 was 10.4%. The revolving line of credit agreement will expire on November 22, 2022. Refer to Note 13 for related party transaction details.

NOTE 9—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. In the events of a “dilutive issuance” of common stock, the exercise price is to be adjusted on a one-time basis to a 10% premium to the dilutive issuance price and the number of shares issuable under the GPB Warrant will be increased on a full ratchet basis. 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, 2019 and 2018 (in thousands):

Warrant liability—GPB	December 31, 2019	December 31, 2018
Balance, beginning of period	\$ 1,399	\$ 1,882
Change in fair value included in the statement of comprehensive income (loss)	(1,361)	(483)
Balance, end of period	<u>\$ 38</u>	<u>\$ 1,399</u>

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, 2019	December 31, 2018
Stock price	\$ 1.97	\$ 9.10
Risk-free interest rate	1.64 %	2.48 %
Expected volatility (peer group)	60.00 %	70.00 %
Expected life (in years)	3.50	4.00
Expected dividend yield	—	—
Number outstanding	252,802	240,764
Balance, end of period:		
Warrant derivative liabilities (long-term) (in thousands)	\$ 38	\$ 1,399

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. The net proceeds of the sale of the debentures and warrants were used to fund EMI’s loan to EJ Holdings, Inc in October 2018 reflected in the Company’s consolidated financial statements.

The debentures were amended and restated in their entirety in conjunction with the Merger on July 17, 2019 as described in Note 12. As originally issued, the debentures bore interest at the rate of 10% per annum, payable monthly commencing November 1, 2018, and were to mature on April 21, 2020. EMI was to be obligated to redeem \$1 million principal amount of debentures monthly, commencing in May 2019 and to redeem the debentures in full upon a “subsequent financing” of at least \$20 million, subject to certain exceptions, or in the “event of default” (as defined). EMI’s obligations

under the debentures are secured by a security interest in substantially all EMI assets and guaranteed by EMI's U.S. subsidiaries.

The common stock purchase warrants also were amended and restated in their entirety in conjunction with the Merger. As originally issued, the common stock purchase warrants were exercisable for five years beginning April 22, 2019 at an initial exercise price of \$11.30 per share, which was to be subject to reduction if EMI became a listed company or its common stock became listed or quoted on a trading market based upon the public offering price or "VWAP" of the common stock. The exercise price also was subject to adjustment in certain other customary circumstances. In accordance with the fee agreement, EMI paid the placement agent a cash fee equal to 5% of the gross proceeds received from the purchasers, granted the warrants to purchase up to 120,000 shares of EMI common stock on the same terms as the common stock purchase warrants sold to the purchasers and reimbursed the agent for certain legal fees and expenses. Effective as of March 5, 2019, EMI entered into a securities amendment agreement with the debenture and warrant holders which amended in certain respects the original securities purchase agreement provided that the debentures and warrants were to be amended in certain respects and restated in their entirety immediately prior to and subject to the completion of the then-pending Merger. Pursuant to the terms of the securities amendment agreement, (i) the debenture holders waived their right to the monthly redemption of \$1,000,000 principal amount of the debentures that was due May 1, 2019 and their right to accelerate the repayment of the debentures in connection with the proposed Merger and (ii) the provision of the debentures requiring their mandatory redemption in connection with any "subsequent financing" was eliminated. The debenture holders subsequently waived their rights to the monthly redemptions due June 1 and July 1, 2019 respectively.

The amended and restated debentures provide that the mandatory monthly redemption of \$1,000,000 principal amount thereof would commence in November 2019 and that they would mature on October 21, 2020, six months later than the original maturity date of the debentures. Unlike the debentures, the amended and restated debentures were convertible at the option of each holder into shares of EMI common stock at a conversion price of \$10.00 a share, subject to adjustment for stock splits, merger reorganizations and other customary events. The amended and restated warrants will be exercisable for up to an aggregate of up to 1,460,000 shares of EMI common stock, or 244,000 more shares than were previously purchasable under the original warrants, at an initial exercise price of \$10.00 per share, or \$1.30 less than the original exercise price of the warrants. 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. The exercise price also will be subject to adjustment for stock splits and other customary events. Upon completion of the Merger, the 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. Subsequent to the Merger, the exercise price of the warrants was 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.

The Company evaluated common stock purchase warrants issued in connection with the original issuance in October 2018 of the Company's outstanding 10% Senior Secured Debentures 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 Company common stock immediately prior to completion of the Merger, which resulted in the related warrants being reclassified to equity. The following table presents information regarding the warrants measured at fair value when reclassified to equity and as of December 31, 2018 (in thousands):

Liability instrument—10% Senior Secured Convertible Debentures	July 19, 2019	December 31, 2018
Balance, beginning of period	\$ 7,540	\$ —
Fair value at issuance date		9,686
Change in fair value included in the statement of comprehensive income (loss)	(1,204)	(2,146)
Fair value at reclassification to equity	(6,336)	—
Balance, end of period	\$ —	\$ 7,540

The fair value and change in fair value of warrant derivative liabilities are determined using a Binominal Monte-Carlo Cliquet Option Pricing Model prior to the Merger. The model is similar to Black-Scholes option pricing models, except that the exercise price resets at certain dates in the future.

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

	July 19, 2019	December 31, 2018 (As Restated)
Stock price	\$ 6.86	\$ 9.00
Risk-free interest rate	1.79 %	2.51 %
Expected volatility (peer group)	65.00 %	70.00 %
Expected life (in years)	4.26	4.81
Expected dividend yield	—	—
Balance, end of period:		
Warrant liabilities (in thousands)	\$ 6,336	\$ 7,540

A summary of outstanding warrants as of December 31, 2019 and 2018 is presented below:

	Year ended December 31, 2019	Year ended December 31, 2018
Warrants outstanding, beginning of period	3,436,431	5,265,432
Assumed as part of Merger	1,044,939	—
Deemed Granted	500,729 (a)	1,542,000
Exercised	(51,000)	(2,385,317)
Cancelled, forfeited and expired	—	(985,684)
Warrants outstanding, end of period	4,931,099	3,436,431

(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, 2019 is presented below.

			Outstanding Weighted Average Remaining Contractual Life (Years)		Exercisable	
Year issued	Exercise Price	Number of Warrants Issued		Weighted Average Exercise Price	Total	Weighted Average Exercise Price
Prior to January 1, 2018						
	\$4.29-\$10.28	1,937,407	1.57	\$ 5.43	1,937,407	\$ 5.43
	Total	1,937,407			1,937,407	
At December 31, 2018						
	\$ 10.76	210,553	3.61	\$ 10.76	210,553	\$ 10.76
	\$ 5.87	1,407,000	3.81	\$ 5.87	1,407,000	\$ 5.87
	2018 Total	1,617,553			1,617,553	
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 (a)	174,999	3.24	\$ 14.04	174,999	\$ 14.04
	\$ 31.50 (a)	737,975	2.57	\$ 31.50	737,975	\$ 31.50
	\$ 36.24 (a)	22,333	2.57	\$ 36.24	22,333	\$ 36.24
	\$ 60.00 (a)	666	1.00	\$ 60.00	666	\$ 60.00
	\$ 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	1,376,139			1,376,139	
	Grand Total	4,931,099			4,931,099	

(a) The exercise price of these warrants was reduced to \$12 per share for the one-year period following the Merger.

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. On February 28, 2013, the number of shares of common stock authorized for issuance under the 2011 Stock Incentive Plan was increased from 3,000,000 shares to 6,000,000 shares. On July 14, 2014, the number of shares of common stock authorized for

issuance under the 2011 Stock Incentive Plan was increased from 6,000,000 shares to 9,000,000 shares. 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 of three years, all based on 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 maintains a 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 options under the 2012 Omnibus Incentive Compensation Plan were fully vested prior to the Merger.

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 to 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.

	6/19/2019	9/27/2018	8/8/2018	2/27/2018
Stock Price	\$ 10.30	\$ 11.10	\$ 11.30	\$ 11.40
Exercise Price	\$ 10.30	\$ 11.10	\$ 11.30	\$ 11.40
Term	6 years	6 years	6 years	6 years
Risk-Free Rate	1.83%	2.99%	2.88%	2.75%
Dividend Yield	—	—	—	—
Volatility	67.16%	69.14%	66.09%	68.18%

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, 2019, the Company granted options to purchase 50,000 shares of common stock. The options have an exercise price of \$10.30 per share. During the year ended December 31, 2018, the Company granted stock option to purchase up to 357,000 common stock. 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, 2019 and 2018 is presented below

	December 31, 2019		December 31, 2018	
	Number of Options	Weighted-Average Exercise Price	Number of Options	Weighted-Average Exercise Price
Options outstanding, beginning of period	6,642,200	\$ 4.40	6,775,200	\$ 4.12
Granted or deemed issued	636,683 (a)	\$ 10.10	357,000	\$ 11.28
Exercised	(167)	\$ 5.00	(170,000)	\$ 4.59
Cancelled, forfeited and expired	(33,366)	\$ 11.29	(320,000)	\$ 6.06
Options outstanding, end of period	7,245,350	\$ 4.68	6,642,200	\$ 4.40
Options exercisable at end of year	7,001,680	\$ 4.47	5,958,783	\$ 3.87
Options available for future grant	2,167,150		2,357,800	

(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, 2019 and 2018, the Company recognized \$3.7 million and \$4.6 million, respectively, of share-based compensation cost arising from stock option grants including \$1.9 million of one-time adjustments resulting from the Merger. As of December 31, 2019, there was \$1.4 million 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 1.8 years.

NOTE 10—INCOME TAXES

The provision for income taxes consists of the following for the years ended December 31, 2019 and 2018 (in thousands):

	2019	2018
Current U.S.	\$ 164	\$ 38
International	—	1
Deferred U.S.	—	—
International	—	—
	<u>\$ 164</u>	<u>\$ 39</u>

Deferred tax assets consist of the following as of December 31, 2019 and 2018 (in thousands):

	2019	2018
Net operating loss carryforward	\$ 16,773	\$ 19,573
General business tax credit	9,888	9,342
Stock options	5,723	5,997
Charitable contribution	81	139
Accrued expenses	166	364
Unearned revenue	175	1,396
Allowance for bad AR	2,373	173
Unrealized gain/ (loss) on LT investment	1,400	—
Other	1,629	352
Total gross deferred tax assets	38,208	37,336
Less valuation allowance	(38,019)	(34,193)
Net deferred tax assets	<u>\$ 189</u>	<u>\$ 3,143</u>

Deferred tax liabilities consist of the following as of December 31, 2019 and 2018 (in thousands):

	2019	2018
Unrealized loss on long-term investment	\$ —	\$ (2,965)
Unrealized loss on foreign exchange translation and others	(185)	(176)
Unrealized gain on marketable securities	—	—
Other	(4)	(2)
Total deferred tax liabilities	<u>\$ (189)</u>	<u>\$ (3,143)</u>

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 increased by approximately \$3.8 million and \$20.8 million for the years ended December 31, 2019 and 2018 respectively.

As of December 31, 2019 and December 31, 2018, the Company had net operating loss carryforwards for federal income tax purposes of approximately \$62.9 million and \$63.5 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 \$55.9 million and \$55.1 million respectively, which expire in various years through 2039. As of December 31, 2019 and December 31, 2018, the Company has general business tax credits of \$9.9 million and \$9.3 million, respectively, for federal income tax purposes. The tax credits are available to offset future tax liabilities, if any, through 2039. 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):

	2019	2018
Tax benefit at statutory federal rate	\$ (11,365)	\$ (15,195)
State taxes, net of federal tax benefit	(666)	(3,695)
Increase in valuation allowance	3,411	6,340
Permanent items	5,710	4,130
General business tax credit	(545)	(431)
Other	3,619	8,890
	<u>\$ 164</u>	<u>\$ 39</u>

As of December 31, 2019 and December 31, 2018, 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, 2019, all federal tax returns since 2016 are subject to audit. The expiration of the state returns varies by state, but the 2015 and subsequent years' returns generally are subject to audit. No tax returns are currently being examined by taxing authorities.

NOTE 11—LEASES

Operating leases — During the years ended December 31, 2019 and 2018, 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 \$78,908 per month, which the lease will expire on September 30, 2026, and leased an additional 1,600 square feet office space in Torrance, California, at a base rent of \$2,240 per month and 2,986 square feet office space in New York, New York, at a base rent of \$5,500, which leases expired on January 31, 2020 and December 30, 2019, respectively. Upon expiration of New York office lease in December 2019, the Company leased 1,850 square feet of new office space in New York, New York, at base rent of \$8,479 per month, which the lease will expire on January 31, 2023.

The Company leased 1,322 square feet of office space in Tokyo, Japan, which the lease expired on September 30, 2020.

The rent expense for the years ended December 31, 2019 and 2018 amounted to approximately \$926,000 and \$669,000, respectively.

Future minimum lease payments were as follows as of December 31, 2019 (in thousands):

	Amount
2020	\$ 991
2021	1,080
2022	1,110
2023	1,043
2024 and thereafter	2,983
Total lease payments	7,207
Less: Interest	(2,284)
Operating lease liabilities	<u>\$ 4,923</u>

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 carry forward 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, 2019, the Company had an operating lease right-of-use asset of \$4.5 million and lease liability of \$4.9 million in the balance sheet. The weighted average remaining term of the Company's leases as of December 31, 2019 was 6.1 years and the weighted-average discount rate was 11.8%.

Prior to the adoption, future minimum lease payments under non-cancellable leases at December 31, 2018 were as follows (in thousands):

	Amount
2019	\$ 730
2020	974
2021	973
2022	1,003
2023 and thereafter	3,665
Total	\$ 7,345

NOTE 12—COMMITMENTS AND CONTINGENCIES

Management Control Acquisition Agreement — On June 12, 2017, the Company entered into a Management Control Acquisition Agreement (the "MCAA") with Telcon Holdings, Inc. ("Telcon Holdings"), a Korean corporation, and Telcon RF Pharmaceuticals, Inc. (formerly Telcon Inc.), ("Telcon"), a Korean-based public company whose shares are listed on KOSDAQ, a trading board of Korea Exchange in South Korea. In accordance with the MCAA, the Company invested approximately \$31.8 million to purchase 6,643,559 shares of Telcon common stock at a purchase price of approximately \$4.79 per share.

The MCAA was amended in certain respect and supplemented by an Agreement, dated as of September 29, 2017, among the parties. Pursuant to the September 2017 Agreement, among other things, Telcon purchased 4,444,445 shares of Company common stock from KPM Tech Co., Ltd and Hanil Vacuum Co., Ltd. at a price of \$6.60 per share.

On July 2, 2018, the Company entered into an Additional Agreement with Evercore Investment Holdings Co., Ltd. (formerly Telcon Holdings Co., Ltd.), ("Evercore"), and Telcon. In the Additional Agreement, the Company agreed to use the proceeds from the sales of its KPM shares to repurchase shares of Company common stock from Telcon at a price of \$7.60 a share, subject to certain exceptions, and Telcon granted the Company the right to purchase from Telcon all or a portion of its shares of the Company at a price of \$7.60 a share until October 31, 2018 and at a price to be agreed upon after October 31, 2018. The Company repurchased 495,000 shares of the Company common stock from Telcon at a price of \$7.60 a share in 2018.

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 13 for related party transaction details.

NOTE 13—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, 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	Shares Underlying Notes December 31, 2019
Current, Promissory note payable to related parties:										
	Lan T. Tran (2)	10%	4/29/2016	Due on Demand	\$ 20	\$ 20	—	—	—	—
	Hope International Hospice, Inc. (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		—
				Total	\$ 193	\$ 16,159	\$ 15,077	\$ 1,635		—

The following table sets forth information relating to our loans from related persons outstanding at any time during the year ended December 31, 2018 (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, 2018	Highest Principal Outstanding	Amount of Principal Repaid	Amount of Interest Paid	Conversion Rate	Shares Underlying Notes at December 31, 2018
Current, Promissory note payable to related parties:										
	Masaharu & Emiko Osato (3)	11%	12/29/2015	Due on Demand	\$ —	\$ 300	\$ 300	\$ 76	—	—
	Lan T. Tran (2)	11%	2/10/2016	Due on Demand	—	131	131	29	—	—
	Masaharu & Emiko Osato (3)	11%	2/25/2016	Due on Demand	—	400	400	94	—	—
	Lan T. Tran (2)	10%	4/29/2016	Due on Demand	20	20	—	—	—	—
	Hope International Hospice, Inc. (1)	10%	6/3/2016	Due on Demand	250	250	—	—	—	—
	Lan T. Tran (2)	10%	2/9/2017	Due on Demand	12	12	—	—	—	—
	Yutaka Niihara (2)(3)	10%	9/14/2017	Due on Demand	27	904	877	95	—	—
	Lan T. Tran (2)	11%	2/10/2018	Due on Demand	159	159	—	—	—	—
				Subtotal	\$ 468	\$ 2,176	\$ 1,708	\$ 294		—
Current, Convertible notes payable to related parties:										
	Yasushi Nagasaki (2)	10%	6/29/2012	Due on Demand	200	200	—	—	\$ 3.30	74,182
	Yutaka & Soomi Niihara (2)(3)	10%	11/16/2015	2 years	200	200	—	—	\$ 4.50	58,350
	Wei Peu Zen (3)	10%	11/6/2017	2 years	5,000	5,000	—	250	\$ 10.00	532,671
				Subtotal	\$ 5,400	\$ 5,400	\$ —	\$ 250		665,203
Non Current, Convertible notes payable to related parties:										
	Profit Preview International Group, Ltd. (4)	10%	2/1/2018	2 years	4,037	4,037	—	202	\$ 10.00	420,456
	Profit Preview International Group, Ltd. (4)	10%	3/21/2018	2 years	5,363	5,363	—	268	\$ 10.00	551,507
				Subtotal	\$ 9,400	\$ 9,400	\$ —	\$ 470		971,963
				Total	\$ 15,268	\$ 16,976	\$ 1,708	\$ 1,014		1,637,166

(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 8 for a discussion of the Company's revolving line of credit agreement with Dr. Niihara.

See Notes 4 and 12 for a discussion of the Company's distribution and supply agreements with Telcon, which holds 4,844,622 shares of the Company common stock, or approximately 8.5% of the common stock outstanding as of December 31, 2019. As of December 31, 2019, the Company held 6,643,559 shares Telcon stock as discussed in Note 6.

NOTE 14—SUBSEQUENT EVENTS

Subsequent to the year ended December 31, 2019, the Company issued the following securities:

	Dollar Amount	Number of Shares Issued
Common stock	\$ 200,000	100,000

On February 27, 2020, the Company and EMI entered into a securities amendment agreement (the “February 2020 Amendment”) with the holders of \$9.2 million principal amount of EMI’s outstanding amended and restated 10% Senior Secured Convertible Debentures and related outstanding amended and restated common stock purchase warrants to purchase up to 1,663,200 shares of the Company common stock. Pursuant to the terms of the February 2020 Amendment, the debenture holders waived their rights to the monthly redemption of \$1,000,000 in principal amount of the debentures for the six-month period beginning February 2020 and ending July 2020. The monthly redemptions were to resume beginning in August 2020. In connection with the February 2020 Amendment, the maturity date of the Debentures was extended by six months to April 21, 2021, and the conversion price of the debentures and the exercise price of the related warrants were reduced to \$3.00 per share from \$9.52 and \$5.87, respectively, per share. The debentures and related 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 debentures and the exercise price of the related warrants were reduced to \$2.00 a share as a result of the Company’s sale of 100,000 shares of common stock at a price of \$2.00 a share under the Purchase Agreement Lincoln Park Capital LLC described below. The conversion price of the debenture and the exercise prices of the related warrants are also subject to adjustment for stock splits and other customary events.

On February 28, 2020, the Company 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 of shares of the Company 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 in connection with entering into the Purchase Agreement. Pursuant to the Purchase Agreement, on any business day over the 36-month term of the Purchase Agreement the Company has the right at our discretion and subject to certain conditions to direct LPC to purchase up to 20,000 shares of the Company common stock, which amount is subject to increase under certain circumstances based upon increases in the market price of the common stock. The purchase price of the common stock will be based upon the prevailing market price of the 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).

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 was 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. 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 amount of loan forgiveness would be reduced if the Company were to terminate employees or reduce salaries during such period. The Company believes it has used the entire loan amount for purposes consistent with the PPP and has applied for forgiveness of the loan.

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. The interest for the note was increased from 11% 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.

On September 22, 2020, the Company and EMI entered into a securities amendment agreement (the “September 2020 Amendment”) with the holders of EMI’s outstanding debentures described above. The September 2020 Amendment amends in

certain respects the securities purchase agreement among EMI and the debenture holders originally entered into on September 8, 2018, as amended by the February 2020 Amendment, and provides that the debentures are to be amended in certain respects as set forth in the form of Allonge Amendment No. 1 to the debentures included in the September 2020 Agreement (the “Allonge”). Pursuant to the Allonge, the aggregate monthly redemption payments under the debentures were reduced to \$500,000 from \$1,000,000 in principal amount and the maturity date of the debentures was extended from April 21, 2021 to August 31, 2021. The monthly redemption payments resumed in September 2020 and will continue on the first day of each month thereafter commencing October 1, 2020. The remaining principal balance of the debentures will be due and payable upon maturity, subject to mandatory prepayment in connection with certain “Capital Events” as defined.

In consideration of the debenture holder’s financial accommodations to the Company, the Company issued to the holders, pro rata based upon the relative principal amounts of their debentures, five-year common stock purchase warrants to purchase a total of up to 1,840,000 shares of the Company common stock at an exercise price of \$2.00 a share. The warrants provide for so-called full-ratchet anti-dilution adjustments in the event the Company sells or issues shares of common stock or common stock equivalents at an effective price per share less than the exercise price of the warrants, subject to certain exceptions. The exercise price also remains subject to adjustment for stock splits and other customary events. In October 2018, the Company granted to T.R. Winston and its affiliates for services relating to the September 2020 Amendment common stock purchase warrants to purchase up to 75,000 shares of the Company common stock at an exercise price of \$2.10 a share and otherwise on terms identical to the warrants issued to the debenture holders described above.

On September 28, 2020, the Company entered into a convertible bond purchase agreement with Telcon pursuant to which it purchased on October 16, 2020 at face value a convertible bond of Telcon in the principal amount of approximately \$26.1 million, on the terms described in the purchase agreement. The Company purchased the convertible bond with a portion of the net proceeds from the sale of Telcon common shares owned by us as reported in our October 14, 2020 press release announcing the sale of the Telcon shares. The sale of the Telcon shares and purchase of the Telcon convertible bond was in accordance with our December 23, 2019 agreement with Telcon. As contemplated by the December 23, 2019 agreement, the convertible bond and any proceeds therefrom, including proceeds from any exercise of the call option or early redemption right described below, replace the Company’s former Telcon shares and proceeds therefrom as collateral under the revised API Supply Agreement with Telcon.

The Telcon convertible bond matures on October 16, 2030 and bears interest at the rate of 2.1% a year, payable quarterly. Beginning on October 16, 2021, the holder of the convertible bond 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. To the extent not previously redeemed, the principal amount of the bond will be due upon maturity. 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.

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.

On October 28, 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, including approximately \$4.0 million, loaned through December 31, 2020. 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 as described under “Equity Method Investment” in Note 6 above.

NOTE 15—QUARTERLY FINANCIAL STATEMENTS (UNAUDITED)

Below are the Consolidated Financial Statement of the Company as previously reported and as restated to reflect adjustments:

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

	As of September 30, 2019 (Unaudited)		
	Previously Reported	Adjustments	As Restated
ASSETS			
CURRENT ASSETS			
Cash and cash equivalents	\$ 13,546	(12,220) (b)	\$ 1,326
Accounts receivable, net	1,900	82 (c)	1,982
Inventories, net	7,491	—	7,491
Investment in marketable securities	27,643	—	27,643
Marketable securities, pledged to creditor	—	—	—
Prepaid expenses and other current assets	1,194	347 (b)(c)	1,541
Total current assets	51,774	(11,791)	39,983
Property and equipment, net	163	—	163
Equity method investment	—	13,407 (b)	13,407
Right of use assets	4,118	—	4,118
Other assets	427	—	427
Total assets	\$ 56,482	\$ 1,616	\$ 58,098
LIABILITIES AND STOCKHOLDERS' DEFICIT			
CURRENT LIABILITIES			
Accounts payable and accrued expenses	\$ 10,706	220 (b)	\$ 10,926
Operating lease liabilities, current portion	844	—	844
Other current liabilities	5,676	357 (a)(c)	6,033
Warrant derivative liabilities	—	91 (a)	91
Notes payable, net of discount	3,886	—	3,886
Notes payable to related parties	193	—	193
Convertible debentures, net of discount	11,000	(4,530) (a)	6,470
Convertible notes payable, net of discount	2,928	—	2,928
Total current liabilities	35,233	(3,862)	31,371
Operating lease liabilities, less current portion	3,714	—	3,714
Other long-term liabilities	34,585	(29) (a)	34,556
Convertible debentures, net of discount less current portion	1,200	(494) (a)	706
Total liabilities	74,732	(4,385)	70,347
STOCKHOLDERS' DEFICIT			
Preferred stock — par value \$0.001 per share, 15,000,000 shares authorized, no shares issued or outstanding	—	—	—
Common stock — par value \$0.001 per share, 250,000,000 shares authorized, 47,671,446 shares issued and outstanding at September 30, 2019	47	1	48
Additional paid-in capital	199,395	13,224 (a)(b)	212,619
Accumulated other comprehensive income (loss)	(51)	—	(51)
Accumulated deficit	(216,916)	(7,949)	(224,865)
Stockholders' deficit	(17,525)	5,276	(12,249)
Noncontrolling interests	(725)	725	—
Total liabilities and stockholders' deficit	\$ 56,482	\$ 1,616	\$ 58,098

(a) Senior secured debentures adjustments: The correction of this misstatement resulted in decreases of \$4.5 million in short-term convertible notes payable and \$0.5 million in long-term convertible notes payable. Also, it resulted in a decrease of \$5.6 million in additional paid-in capital, \$263,000 million in short-term conversion feature liabilities and \$29,000 in long-term conversion feature liabilities.

(b) EJ Holdings adjustments: The correction of this misstatement resulted in increases of \$13.4 million in equity method investment, \$220,000 in accounts payable and accrued expenses, and \$725,000 in non-controlling interest, as well as decreases of \$12.2 million in cash and cash equivalents and \$241,000 in prepaid expenses and other current assets.

(c) Corrections to other misstatements were as follows: (i) period adjustment and reclassification of variable consideration resulted in increases of \$82,000 in accounts receivable and \$22,000 in current liabilities; (ii) correction of financing of insurance premium resulting in an increase of \$598,000 in prepaid expenses and other current liabilities; (iii) correction relating of debt modification resulting in an increase of \$1.1 million in additional paid-in capital; (iv) correction relating to GPB warrant classification resulting in an increase of \$91,000 in warrant derivative liabilities and a decrease of \$776,000 in additional paid-in capital.

Emmaus Life Sciences, Inc.
Consolidated Statement of operations and Comprehensive Loss
(In thousands, except share and per share amounts)

	Three months ended September 30, 2019		
	(Unaudited)		
	Previously Reported	Adjustments	As Restated
REVENUES, NET	\$ 6,084	\$ (324) (c)	\$ 5,760
COST OF GOODS SOLD	178	70 (c)	248
GROSS PROFIT	5,906	(394)	5,512
OPERATING EXPENSES			
Research and development	725	—	725
Selling	1,789	(11)	1,778
General and administrative	6,991	65 (b)(c)	7,056
Total operating expenses	9,505	54	9,559
LOSS FROM OPERATIONS	(3,599)	(448)	(4,047)
OTHER INCOME (EXPENSE)			
Loss on debt extinguishment	(6,427)	5,989 (a)(c)	(438)
Change in fair value of warrant derivative liabilities	424	3,152 (a)(c)	3,576
Change in fair value of embedded conversion option	342	(211) (a)	131
Net losses on equity investment in marketable securities and long-term investment	(5,248)	—	(5,248)
Net loss on equity method investment	—	36 (b)	36
Miscellaneous reverse merger costs	(309)	—	(309)
Note conversion costs	(3,906)	565 (c)	(3,341)
Interest and other income (loss)	(17)	35 (b)	18
Interest expense	(7,318)	(1,396) (a)	(8,714)
Total other income (expenses)	(22,459)	8,170	(14,289)
LOSS BEFORE INCOME TAXES	(26,058)	7,722	(18,336)
INCOME TAXES	25	—	25
NET LOSS INCLUDING NONCONTROLLING INTEREST	(26,083)	7,722	(18,361)
Net loss attributable to noncontrolling interest	(54)	54 (b)	—
NET LOSS ATTRIBUTABLE TO THE COMPANY	(26,137)	7,776	(18,361)
COMPONENTS OF OTHER COMPREHENSIVE INCOME (LOSS)			
Foreign currency translation adjustments	11	(6)	5
Other comprehensive loss	11	(6)	5
COMPREHENSIVE LOSS	(26,072)	7,716	(18,356)
Amounts attributable to noncontrolling interests:			
Net loss attributable to noncontrolling interest	(54)	54	—
Foreign currency translation adjustments	(6)	6	—
Comprehensive loss attributable to noncontrolling interest	(60)	60	—
COMPREHENSIVE LOSS ATTRIBUTABLE TO THE COMPANY	\$ (26,132)	\$ 7,776	\$ (18,356)
NET LOSS PER COMMON SHARE - BASIC and DILUTED	\$ (0.57)	\$ 0.17	\$ (0.40)
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING	46,020,507	45,986,629	45,986,629

(a) Senior secured debentures adjustments: The correction of this misstatement resulted in decreases of \$6.3 million in loss on debt extinguishment and \$211,000 in change in fair value of embedded conversion option and increases of \$2.4 million in change in fair value of warrant derivative liabilities and \$1.4 million in interest expenses.

(b) EJ Holdings adjustments: The correction of this misstatement resulted in increases of \$125,000 in general and administrative expense, \$36,000 in loss on equity method investment and an increase in \$35,000 in interest and other income (loss).

(c) Corrections to other misstatement were as follows: (i) period adjustment of variable consideration resulted in a decrease of \$324,000 in revenue, net; (ii) reclassification of shipping cost and royalty expense to cost of sales resulted in an increase of \$71,000 in cost of sales and decreases of \$11,000 and \$60,000 in selling cost and general and administrative expense, respectively; (iii) correction relating to stock modification accounting resulted in an increase of \$52,000 in general and administrative expense; (iv) correction relating to accounting for debt modification resulted in a decrease of \$320,000 in loss on debt extinguishment; and (v) correction relating to the GPB warrant classification resulted in an increase of \$685,000 in change in fair value of warrant derivative liabilities.

Nine months ended September 30, 2019 (Unaudited)				
	Previously Reported	Adjustments		As Restated
REVENUES, NET	\$ 17,260	\$ (1,300)	(c)	\$ 15,960
COST OF GOODS SOLD	573	198	(c)	771
GROSS PROFIT	16,687	(1,498)		15,189
OPERATING EXPENSES				
Research and development	1,778	—		1,778
Selling	5,177	(29)		5,148
General and administrative	14,523	(1,048)	(b)(c)	13,475
Total operating expenses	21,478	(1,077)		20,401
LOSS FROM OPERATIONS	(4,791)	(421)		(5,212)
OTHER INCOME (EXPENSE)				
Loss on debt extinguishment	(6,427)	5,989	(a)(c)	(438)
Change in fair value of warrant derivative liabilities	623	2,869	(a)(c)	3,492
Change in fair value of embedded conversion option	342	(211)	(a)	131
Net losses on equity investment in marketable securities and long-term investment	(22,242)	—		(22,242)
Net loss on equity method investment		(413)	(b)	(413)
Miscellaneous reverse merger costs	(309)	—		(309)
Note conversion costs	(3,906)	565	(c)	(3,341)
Interest and other income (loss)	146	102	(b)	248
Interest expense	(22,757)	(2,396)	(a)(c)	(25,153)
Total other income (expenses)	(54,530)	6,505		(48,025)
LOSS BEFORE INCOME TAXES	(59,321)	6,084		(53,237)
INCOME TAXES	242	(1)	(c)	241
NET LOSS INCLUDING NONCONTROLLING INTEREST	(59,563)	6,085		(53,478)
Net loss attributable to noncontrolling interest	620	(620)		—
NET LOSS ATTRIBUTABLE TO THE COMPANY	(58,943)	5,465		(53,478)
COMPONENTS OF OTHER COMPREHENSIVE INCOME (LOSS)				
Foreign currency translation adjustments	10	8		18
Other comprehensive loss	10	8		18
COMPREHENSIVE LOSS	(59,553)	6,093		(53,460)
Amounts attributable to noncontrolling interests:				
Net loss attributable to noncontrolling interest	620	(620)		—
Foreign currency translation adjustments	8	(8)		—
Comprehensive loss attributable to noncontrolling interest	628	(628)		—
COMPREHENSIVE LOSS ATTRIBUTABLE TO THE COMPANY	\$ (58,925)	\$ 5,465		\$ (53,460)
NET LOSS PER COMMON SHARE - BASIC and DILUTED	\$ (1.46)	\$ 0.14		\$ (1.32)
WEIGHTED-AVERAGE COMMON SHARES OUTSTANDING	40,474,847	40,443,124		40,443,124

(a) Senior secured debentures adjustments: The correction of this misstatement resulted in decreases of \$6.3 million in loss on debt extinguishment and \$211,000 in change in fair value of embedded conversion option as well as in increases of \$2.1 million in change in fair value of warrant derivative liabilities and \$1.0 million in interest expenses.

(b) EJ Holdings adjustments: The correction of this misstatement resulted in a decrease of \$930,000 in general and administrative expense, and increases of \$36,000 in loss on equity method investment and \$102,000 in interest income.

(c) Corrections to other misstatement were as follows: (i) period adjustment of variable consideration resulted in decreases of \$1.3 million in revenue, net and \$1,000 income tax provision (ii) reclassification of shipping cost and royalty expense to cost of sales resulted in an increase of \$199,000 in cost of sales and decreases of \$29,000 and \$170,000 in selling cost and general and administrative expense, respectively; (iii) correction relating to stock modification accounting resulted in an increase of \$52,000 in general and administrative expense; (iv) correction relating to accounting for debt modification resulted in an increase of \$1.3 million in interest expenses and a decrease of \$320,000 in loss on debt extinguishment; and (v) correction relating to GPB warrant classification resulted in an increase of \$685,000 in change in fair value of warrant derivative liabilities.

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

	Nine Months Ended September 30, 2019 (Unaudited)		
	Previously Reported	Adjustments	As Restated
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	\$ (59,563)	\$ 6,085	\$ (53,478)
Adjustments to reconcile net loss to net cash flows used in operating activities			
Depreciation and amortization	54	—	54
Impairment loss on long-term investment	524	—	524
Amortization of discount of convertible notes and notes payable	19,479	2,396	21,875
Foreign exchange adjustments on convertible notes and notes payable	49	(256)	(207)
Net losses on equity investment in marketable securities	21,718	—	21,718
Loss on equity method investment	0	413	413
Loss on debt extinguishment	6,427	(5,989)	438
Share-based compensation and fair value of replacement equity award	3,541	52	3,593
Note conversion costs	3,906	(565)	3,341
Change in fair value of warrant derivative liabilities	(623)	(2,869)	(3,492)
Change in fair value of embedded conversion option	(342)	211	(131)
Net changes in operating assets and liabilities			
Accounts receivable	(548)	355	(193)
Inventories	(2,787)	—	(2,787)
Prepaid expenses and other current assets	(426)	(599)	(1,025)
Other non-current assets	(4,150)	—	(4,150)
Accounts payable and accrued expenses	4,857	1,109	5,966
Deferred revenue	500	—	500
Deferred rent	(287)	—	(287)
Other current liabilities	230	598	828
Other long-term liabilities	2,363	—	2,363
Net cash flows used in operating activities	(5,078)	941	(4,137)
CASH FLOWS FROM INVESTING ACTIVITIES			
Cash paid in connection with the Merger	(1,641)	—	(1,641)
Purchases of property and equipment	(55)	—	(55)
Sales of marketable securities	221	—	221
Net cash flows provided by (used in) investing activities	(1,475)	—	(1,475)
CASH FLOWS FROM FINANCING ACTIVITIES			
Payments of convertible notes	(3,368)	—	(3,368)
Proceeds from exercise of warrants	186	—	186
Proceeds from issuance of common stock	6,210	—	6,210
Net cash flows provided by (used in) financing activities	3,028	—	3,028
Effect of exchange rate changes on cash	(8)	13	5
Net decrease in cash and cash equivalents	(3,533)	954	(2,579)
Cash and cash equivalents, beginning of period	17,079	(13,174)	3,905
Cash and cash equivalents, end of period	<u>\$ 13,546</u>	<u>\$ (12,220)</u>	<u>\$ 1,326</u>
SUPPLEMENTAL DISCLOSURES OF CASH FLOW ACTIVITIES			
Interest paid	\$ 1,239	\$ —	\$ 1,239
Income taxes paid	\$ 242	\$ —	\$ 242
Warrant liabilities reclassified to equity	\$ 776	\$ 5,561	\$ 6,337
Conversion of convertible notes and notes payable to common stock	\$ 33,777	\$ —	\$ 33,777
Conversion of accrued interest payable to common stock	\$ 2,381	\$ —	\$ 2,381
Initial recognition of right-of-use lease asset	\$ —	\$ 2,922	\$ 2,922

Refer to descriptions of the adjustments and their impact on net loss in the Consolidated Statement of Operation and Comprehensive Loss for the nine months ended September 30, 2018 above.

Cash flow classification adjustment related to EJ Holdings in 2019 resulted in a net increase to cash flows provided by operating activities of \$940,000.

No other misstatements impacted the classifications between net operating, net investing or net financing cash flow activities for the nine months ended September 30, 2019.

**RESTATED CERTIFICATE OF INCORPORATION
OF
EMMAUS LIFE SCIENCES, INC.**

(Originally incorporated on March 20, 1987
under the name of AGE RESEARCH, INC.)

ARTICLE I

The name of the corporation is Emmaus Life Sciences, Inc. (the “Corporation”).

ARTICLE II

The registered office of the Corporation in the State of Delaware is 9 E. Loockerman Street, Suite 311, Dover, Delaware 19901, County of Kent. The registered agent in charge thereof at such address is Registered Agent Solutions, Inc.

ARTICLE III

The nature of the business, and the objects and purposes proposed to be transacted, promoted and carried on, are to do any or all things herein mentioned, as fully and to the same extent as natural persons might or could do, and in any part of the world, viz.:

“The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of Delaware.”

ARTICLE IV

CAPITAL STOCK

Section 4.A. The total number of shares of stock which the Corporation shall have authority to issue is Two Hundred Sixty Five Million (265,000,000).

Section 4.B. Common Stock. The total number of shares of Common Stock which the Corporation shall have authority to issue is Two Hundred and Fifty Million (250,000,000), with a par value of \$0.001 per share. Stockholders shall not have preemptive rights or be entitled to cumulative voting in connection with the shares of the Corporation’s Common Stock.

Section 4.C. Blank-Check Preferred Stock. The total number of shares of undesignated preferred stock which the Corporation shall have the authority to issue is Fifteen Million (15,000,000) shares, with a par value of \$0.001 per share. The Board of Directors is hereby expressly authorized to provide, out of the unissued shares of preferred stock, for one or more series of preferred stock and, with respect to each such series, to fix the number of shares constituting such series and the designation of such series, the voting powers, if any, of the shares of such series, and the preferences and relative, participating, optional or other special rights, if

any, and any qualifications, limitations or restrictions thereof, of the shares of such series. The powers, preferences and relative, participating, optional and other special rights of each series of preferred stock, and the qualifications, limitations or restrictions thereof, if any, may differ from those of any and all other series at any time outstanding.

ARTICLE V

[Reserved.]

ARTICLE VI

The number of members of the Board of Directors shall be fixed from time to time by the Board of Directors. If any vacancy occurs, the remaining directors, by an affirmative vote of a majority thereof, may elect a director to fill the vacancy until the next annual meeting of stockholders.

ARTICLE VII

No contract or transaction between the Corporation and one or more of its directors or officers, or between the Corporation and any other corporation, partnership, association, or other organization in which one or more of its directors or officers are directors or officers, or have a financial interest, shall be void or voidable solely for this reason, or solely because the director or officer is present at or participates in the meeting of the Board of Directors or committee thereof which authorizes the contract or transaction, or solely because his or their votes are counted for such purpose, if:

1. The material facts as to his interest and as to the contract or transaction are disclosed or are known to the Board of Directors or the Committee, and the Board or committee in good faith authorizes the contract or transaction by a vote sufficient for such purpose without counting the vote of the interested director or directors; or
2. The material facts as to his interest and as to the contract or transaction are disclosed or are known to the stockholders entitled to vote thereon, and the contract or transaction is specifically approved in good faith by vote of the stockholders; or
3. The contract or transaction is fair as to the Corporation as of the time it is authorized, approved or ratified, by the Board of Directors, a committee thereof, or the stockholders.

Interested directors may be counted in determining the presence of a quorum at a meeting of the Board of Directors or of a committee which authorizes the contract or transaction.

ARTICLE VIII

The Board of Directors shall have the power to make, adopt, amend or repeal the Bylaws of the Corporation.

ARTICLE IX

Section 1. Elimination of Certain Liability of Directors. A director of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except for liability (i) for any breach of the director's duty of loyalty to the Corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law (iii) under Section 174 of the Delaware General Corporation Law, or (iv) for any transaction from which the director derived an improper personal benefit.

Section 2. Indemnification and Insurance.

(a) Right to Indemnification. Each person who was or is made a party or is threatened to be made a party or is involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative (hereinafter a "proceeding"), by reason of the fact that he or she, or a person of whom he or she is the legal representative, is or was a director or officer of the Corporation or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust or other enterprise, including service with respect to employee benefit plans, whether the basis of such proceeding is alleged action in an official capacity as a director, officer, employee or agent or in any other capacity while serving as a director, officer, employee or agent, shall be indemnified and held harmless by the Corporation to the fullest extent authorized by the Delaware General Corporation Law, as the same exists or may hereafter be amended (but, in the case of any such amendment, only to the extent that such amendment permits the Corporation to provide broader indemnification rights than said law permitted the Corporation to provide prior to such amendment), against all expense, liability and loss (including attorney's fees, judgments, fines, ERISA excise taxes or penalties and amounts paid or to be paid in settlement) reasonably incurred or suffered by such person in connection therewith and such indemnification shall continue as to a person who has ceased to be a director, officer, employee or agent and shall inure to the benefit of his or her heirs, executors and administrators; provided, however, that, except as provided in paragraph (b) hereof, the Corporation shall indemnify any such person seeking indemnification in connection with a proceeding (or part thereof) initiated by such person only if such proceeding (or part thereof) was authorized by the Board of Directors of the Corporation. The right to indemnification conferred in this Section shall be a contract right and shall include the right to be paid by the Corporation the expenses incurred in defending any such proceeding in advance of its final disposition; provided, however, that, if the Delaware General Corporation Law requires, the payment of such expenses incurred by a director or officer in his or her capacity as a director or officer (and not in any other capacity in which service was or is rendered by such person while a director or officer including, without limitation, service to an employee benefit plan) in advance of the final disposition of a proceeding, shall be made only upon delivery to the corporation of an undertaking, by or on behalf of such director or officer, to repay all amounts so advanced if it shall ultimately be determined that such director or officer is not entitled to be indemnified under this Section or otherwise. The Corporation may, by action of its Board of Directors, provide indemnification to employees and agents of the Corporation with the same scope and effect as the foregoing indemnification of directors and officers.

(b) Right of Claimant to Bring Suit. If a claim under paragraph (a) of this Section is not paid in full by the Corporation within 30 days after a written claim has been received by the Corporation, the claimant may at any time thereafter bring suit against the Corporation to recover the unpaid amount of the claim and, if successful in whole or in part, the claimant shall be entitled to be paid also the expense of prosecuting such claim. It shall be a defense to any such action (other than an action brought to enforce a claim for expenses incurred in defending any proceeding in advance of its final disposition where the required undertaking, if any is required, has been tendered to the Corporation) that the claimant has not met the standards of conduct which make it permissible under the Delaware General Corporation Law for the Corporation to indemnify the claimant for the amount claimed, but the burden of proving such defense shall be on the Corporation. Neither the failure of the Corporation (including its Board of Directors, independent legal counsel, or its stockholders) to have made a determination prior to the commencement of such action that indemnification of the claimant is proper in the circumstances because he or she has met the applicable standard of conduct set forth in the Delaware General Corporation Law, nor an actual determination by the Corporation (including its Board of Directors, independent legal counsel, or its stockholders) that the claimant has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that the claimant has not met the applicable standard of conduct.

(c) Non-Exclusivity of Rights. The right to indemnification and the payment of expenses incurred in defending a proceeding in advance of its final disposition conferred in this Section shall not be exclusive of any other right which any person may have or hereafter acquire under any statute, provision of the Certificate of Incorporation, bylaw, agreement, vote of stockholders or disinterested directors or otherwise.

(d) Insurance. The Corporation may maintain insurance, at its expense, to protect itself and any director, officer, employee or agent of the Corporation or another corporation, partnership, joint venture, trust or other enterprise against any such expense, liability or loss, whether or not the Corporation would have the power to indemnify such person against such expense, liability or loss under the Delaware General Corporation Law.

[Signature Page Follows]

In witness whereof, this Restated Certificate of Incorporation which only restates and integrates and does not further amend the provisions of the Certificate of Incorporation of the Corporation as heretofore amended or supplemented, there being no discrepancies between those provisions and the provisions of this Restated Certificate of Incorporation, and it having been duly adopted by the Corporation's Board of Directors in accordance with Section 245 of the Delaware General Corporation Law, has been executed by its duly authorized officer this 5th day of November, 2019.

EMMAUS LIFE SCIENCES, INC.

By: /S/YUTAKA NIIHARA

Name: Yutaka Niihara, M.D., M.P.H.

Title: Chairman and Chief Executive Officer

<div style="border: 1px solid black; padding: 2px; margin-bottom: 5px;"> NUMBER EMM </div>	 <p style="font-size: small;">INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE</p>	<div style="border: 1px solid black; padding: 2px; margin-bottom: 5px;"> SHARES SPECIMEN </div> <p style="font-size: small;">COMMON STOCK</p>	<p style="font-size: x-small;">SEE REVERSE FOR CERTAIN DEFINITIONS</p> <div style="border: 1px solid black; padding: 2px;"> CUSIP 29137T 10 1 </div>
<p>THIS CERTIFIES THAT:</p> <p style="font-size: 1.5em; font-weight: bold; color: red;">SPECIMEN - NOT NEGOTIABLE</p> <p>IS THE OWNER OF</p>			
<p>FULLY PAID AND NON-ASSESSABLE SHARES OF COMMON STOCK OF \$0.001 PAR VALUE EACH OF</p> <p>EMMAUS LIFE SCIENCES, INC.</p> <p>transferable on the books of the Corporation in person or by attorney upon surrender of this certificate duly endorsed or assigned. This certificate and the shares represented hereby are subject to the laws of the State of Delaware, and to the Certificate of Incorporation and Bylaws of the Corporation, as now or hereafter amended. This certificate is not valid until countersigned by the Transfer Agent.</p> <p>WITNESS the facsimile signatures of its duly authorized officers.</p>			
<p>DATED:</p>			
<p style="color: red; font-weight: bold;">SPECIMEN NOT NEGOTIABLE</p>		 <p style="font-size: x-small;">SECRETARY</p>	 <p style="font-size: x-small;">CHAIRMAN</p>
<p style="font-size: x-small;">© COLUMBIA PRINTING SERVICES, LLC</p>			

COUNTERSIGNED AND REGISTERED
 AMERICAN STOCK TRANSFER & TRUST COMPANY, LLC
 BROOKLYN, NY
 TRANSFER AGENT AND REGISTRAR
 AUTHORIZED SIGNATURE

THE CORPORATION WILL FURNISH TO ANY STOCKHOLDER, UPON REQUEST AND WITHOUT CHARGE, A FULL STATEMENT OF THE DESIGNATIONS, RELATIVE RIGHTS, PREFERENCES AND LIMITATIONS OF THE SHARES OF EACH CLASS AND SERIES AUTHORIZED TO BE ISSUED, SO FAR AS THE SAME HAVE BEEN DETERMINED, AND OF THE AUTHORITY, IF ANY, OF THE BOARD TO DIVIDE THE SHARES INTO CLASSES OR SERIES AND TO DETERMINE AND CHANGE THE RELATIVE RIGHTS, PREFERENCES AND LIMITATIONS OF ANY CLASS OR SERIES. SUCH REQUEST MAY BE MADE TO THE SECRETARY OF THE CORPORATION OR TO THE TRANSFER AGENT NAMED ON THIS CERTIFICATE.

The following abbreviations, when used in the inscription on the face of this certificate, shall be construed as though they were written out in full according to applicable laws or regulations:

TEN COM	- as tenants in common	UNIF GIFT MIN ACT -Custodian.....
TEN ENT	- as tenants by the entireties		(Cust) (Minor)
JT TEN	- as joint tenants with right of survivorship and not as tenants in common		under Uniform Gifts to Minors
			Act.....
			(State)

Additional abbreviations may also be used though not in the above list.

For Value Received, _____ hereby sell, assign and transfer unto

PLEASE INSERT SOCIAL SECURITY OR OTHER
IDENTIFYING NUMBER OF ASSIGNEE

(PLEASE PRINT OR TYPEWRITE NAME AND ADDRESS, INCLUDING ZIP CODE, OF ASSIGNEE)

_____ Shares
of the stock represented by the within Certificate, and do hereby irrevocably constitute and appoint

_____ Attorney
to transfer the said stock on the books of the within named Corporation with full power of substitution in the premises.

Dated _____

NOTICE: THE SIGNATURE(S) TO THIS ASSIGNMENT MUST CORRESPOND WITH THE NAME(S) AS WRITTEN UPON THE FACE OF THE CERTIFICATE, IN EVERY PARTICULAR, WITHOUT ALTERATION OR ENLARGEMENT OR ANY CHANGE WHATSOEVER.

Signature(s) Guaranteed

By _____
The Signature(s) must be guaranteed by an eligible guarantor institution (Banks, Stockbrokers, Savings and Loan Associations and Credit Unions with membership in an approved Signature Guarantee Medallion Program), pursuant to SEC Rule 17Ad-15.

EMMAUS LIFE SCIENCES, INC.

Promissory Note

Principal Amount: US\$1,500,000 Loan Date: 04/24/2019
Currency: US dollars Term: Two years
Interest Rate: 11.0% per year Loan Due Date: Due on demand
Interest Payment Period: Interest is payable annually

Lender: Eastwind Ltd.

FOR VALUE RECEIVED, Emmaus Life Sciences, Inc., a Delaware corporation, located at 21250 Hawthorne Blvd., Suite 800, Torrance, CA 90503 (“Borrower”) agrees to pay to Lender the sum of the Principal Amount in the stated Currency, together with any accrued interest at the stated Interest Rate, under the following terms and conditions of this this Promissory Note (“Note”).

1. Terms of Repayment (Balloon Payment): The entire unpaid Principal Amount and any accrued interest shall become immediately due and payable upon the stated Loan Due Date. Simple interest at the stated Interest Rate will accrue on the outstanding Principal Amount commencing on the Loan Date of this Note and the Borrower shall make payments of interest only as per the stated Interest Payment Period.

2. Prepayment: This Note may be prepaid in whole or in part at any time after six months of the Loan Date without premium or penalty. All prepayments shall first be applied to interest, and then to principal payments.

3. Place of Payment: All payments due under this Note shall be sent to the Lender's address, as noted in Attachment 1 hereto, or at such other place as the Lender or subsequently assigned holder of this Note may designate in writing in the future.

4. Default: In the event of default, the Borrower agrees to pay all costs and expenses incurred by the Lender, including all reasonable attorney fees as permitted by law for the collection of this Note upon default.

5. Acceleration of Debt: If the Borrower (i) fails to make any payment due under the terms of this Note or seeks relief under the U.S. Bankruptcy Code, (ii) fails to deliver shares to the Lender by the deadline set forth in Section 4 hereof, (iii) suffers an involuntary petition in bankruptcy or receivership that is not vacated within thirty (30) days, (iv) consents to the appointment of a receiver, trustee, assignee, liquidator or similar official or such appointment is not discharged or stayed within 30 days, (v) makes a general assignment for the benefit of its creditors or (vi) admits in writing that it is generally unable to pay its debts as they become due.

the entire balance of this Note and any interest accrued thereon shall be immediately due and payable to the holder of this Note.

6. Modification: No modification or waiver of any of the terms of this Note shall be allowed unless by written agreement signed by the parties. No waiver of any breach or default hereunder shall be deemed a waiver of any subsequent breach or default of the same or similar nature.

7. Complete Note: This Note is the complete and exclusive statement of agreement of the parties with respect to matters in this Note. This Note replaces and supersedes all prior written or oral agreements or statements by and among the parties with respect to the matters covered by it. No representation, statement, condition or warranty not contained in this Note is binding on the parties.

8. Transfer of the Note: This Note may be transferred, in whole or in part, at any time or from time to time, by the Lender. The Borrower hereby waives any notice of the transfer of this Note by the Lender or by any subsequent holder of this Note, agrees to remain bound by the terms of this Note subsequent to any transfer, and agrees that the terms of this Note may be fully enforced by any subsequent holder of this Note. If this Note is to be transferred, the Lender shall surrender this Note to the Borrower, whereupon the Borrower will forthwith issue and deliver upon the order of the Lender a new Note registered as the Lender may request, representing the outstanding Principal Amount being transferred by the Lender and, if less than the entire outstanding Principal Amount is being transferred, a new Note to the Lender representing the outstanding Principal Amount not being transferred. This Note may not be transferred by the Borrower, by operation of law or otherwise, without the prior written consent of the Lender.

9. Lost, Stolen or Mutilated Note: Upon receipt by the Borrower of evidence reasonably satisfactory to the Borrower of the loss, theft, destruction or mutilation of this Note, and, in the case of loss, theft or destruction, of any indemnification undertaking by the Lender to the Borrower in customary form and, in the case of mutilation, upon surrender and cancellation of this Note, the Borrower shall execute and deliver to the Lender a new Note representing the outstanding Principal Amount and accrued and unpaid interest thereon.

10. Remedies: The remedies provided in this Note shall be cumulative and in addition to all other remedies available under this Note at law or in equity (including a decree of specific performance and/or other injunctive relief), and nothing herein shall limit the Lender's right to pursue actual and consequential damages for any failure by the Borrower to comply with the terms of this Note.

11. Severability of Provisions: If any portion of this Note is deemed unenforceable, all other provisions of this Note shall remain in full force and effect.

12. Insufficient Authorized Shares: The Borrower shall take all reasonable best action necessary to increase the Borrower's authorized shares of common stock to an amount sufficient to allow Borrower to reserve the Required Reserve Amount for the Note.

13. Choice of Law: All terms and conditions of this Note shall be interpreted under the laws

of California, U.S.A., without regard to conflict of law principles.

Signed Under Penalty of Perjury, this 24th day of April, 2019

Emmaus Life Sciences, Inc.

By: Yutaka Niihara, M.D., CEO

By: Lender

ATTACHMENT 1

Lender's Name: Eastwind ltd.

Lender's Address:

5. Acceleration of Debt: If the Borrower (i) fails to make any payment due under the terms of this Note or seeks relief under the Japanese Bankruptcy Code, (ii) fails to deliver shares to the Lender by the deadline set forth in Section 4 hereof, (iii) suffers an involuntary petition in bankruptcy or receivership that is not vacated within thirty (30) days, (iv) consents to the appointment of a receiver, trustee, assignee, liquidator or similar official or such appointment is not discharged or stayed within 30 days, (v) makes a general assignment for the benefit of its creditors or (vi) admits in writing that it is generally unable to pay its debts as they become due, the

entire balance of this Note and any interest accrued thereon shall be immediately due and payable to the holder of this Note.

6. Modification: No modification or waiver of any of the terms of this Note shall be allowed unless by written agreement signed by the parties. No waiver of any breach or default hereunder shall be deemed a waiver of any subsequent breach or default of the same or similar nature.

7. Complete Note: This Note is the complete and exclusive statement of agreement of the parties with respect to matters in this Note. This Note replaces and supersedes all prior written or oral agreements or statements by and among the parties with respect to the matters covered by it. No representation, statement, condition or warranty not contained in this Note is binding on the parties.

8. Transfer of the Note: This Note may be transferred, in whole or in part, at any time or from time to time, by the Lender. The Borrower hereby waives any notice of the transfer of this Note by the Lender or by any subsequent holder of this Note, agrees to remain bound by the terms of this Note subsequent to any transfer, and agrees that the terms of this Note may be fully enforced by any subsequent holder of this Note. If this Note is to be transferred, the Lender shall surrender this Note to the Borrower, whereupon the Borrower will forthwith issue and deliver upon the order of the Lender a new Note registered as the Lender may request, representing the outstanding Principal Amount being transferred by the Lender and, if less than the entire outstanding Principal Amount is being transferred, a new Note to the Lender representing the outstanding Principal Amount not being transferred. This Note may not be transferred by the Borrower, by operation of law or otherwise, without the prior written consent of the Lender.

9. Lost, Stolen or Mutilated Note: Upon receipt by the Borrower of evidence reasonably satisfactory to the Borrower of the loss, theft, destruction or mutilation of this Note, and, in the case of loss, theft or destruction, of any indemnification undertaking by the Lender to the Borrower in customary form and, in the case of mutilation, upon surrender and cancellation of this Note, the Borrower shall execute and deliver to the Lender a new Note representing the outstanding Principal Amount and accrued and unpaid interest thereon.

10. Remedies: The remedies provided in this Note shall be cumulative and in addition to all other remedies available under this Note at law or in equity (including a decree of specific performance and/or other injunctive relief), and nothing herein shall limit the Lender's right to pursue actual and consequential damages for any failure by the Borrower to comply with the terms of this Note.

11. Severability of Provisions: If any portion of this Note is deemed unenforceable, all other provisions of this Note shall remain in full force and effect.

12. Insufficient Authorized Shares: The Borrower shall take all reasonable best action necessary to increase the Borrower's authorized shares of common stock to an amount sufficient to allow Borrower to reserve the Required Reserve Amount for the Note.

13. Choice of Law: All terms and conditions of this Note shall be interpreted under the laws in Japan.

Signed Under Penalty of Perjury, this 26th day of May, 2019

Emmaus Medical, Japan

By: Yutaka Niihara, MD, Board of Director

By: Lender

ATTACHMENT 1

Lender's Name: Shigeru Matsuda

Lender's Address:

EXHIBIT CFORM OF THIRD AMENDMENT TO OFFICE LEASE AGREEMENTTHIRD AMENDMENT TO OFFICE LEASE AGREEMENT

THIS THIRD AMENDMENT TO OFFICE LEASE AGREEMENT (this "**Second Amendment**") is made and entered into effective as of September 10, 2019 (the "**Effective Date**"), by and between RREF II PACIFIC CENTER LLC, a Delaware limited liability company ("**Landlord**"), and EMMAUS LIFE SCIENCES, INC., a Delaware corporation ("**Tenant**").

R E C I T A L S:

- A. Bixby Torrance, LLC, a Delaware limited liability company ("**Bixby**") and Tenant entered into that certain Office Lease Agreement dated October 17, 2014 (the "**Original Lease**"), as amended by that certain (i) Statement of Tenant Regarding Lease Commencement (the "**Tenant Statement**") executed by Tenant, (ii) First Amendment to Office Lease Agreement dated February 1, 2018 (the "**First Amendment**") between Landlord (as successor-in-interest to Bixby) and Tenant, and (iii) Second Amendment to Office Lease Agreement dated December 6, 2018 (the "**Second Amendment**").
- B. The Original Lease, the Tenant Statement, the First Amendment and the Second Amendment are collectively referred to herein as the "**Lease**".
- C. Pursuant to the Lease, Landlord currently leases to Tenant and Tenant currently leases from Landlord (i) that certain space (collectively, the "**Original Premises**") containing approximately 13,374 rentable square feet commonly known as Suite 800 and located on the eighth (8th) floor of that certain office building located at 21250 Hawthorne Blvd., Torrance, CA 90503 (the "**Building**"), and (ii) that certain space (the "**Expansion Space**") containing approximately 7,559 rentable square feet (consisting of a portion of that certain space previously commonly known as Suite 850) and located on the eighth (8th) floor of the Building. The Original Premises and the Expansion Space, together, are commonly known as Suite 800.
- D. Landlord and Tenant desire to confirm the Expansion Space Commencement Date, the Revised Expiration Date and the Base Rent payable by Tenant for (i) the Expansion Space during the Expansion Space Term prior to the Second Extended Term Commencement Date, and (ii) the entire Premises during the Second Extended Term (as defined in the Second Amendment).
- E. All capitalized terms when used herein shall have the same meaning as is given such terms in the Lease unless expressly superseded by the terms of this Third Amendment.

A G R E E M E N T :

NOW, THEREFORE, in consideration of the foregoing Recitals and the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. Confirmation of Dates. The parties hereby confirm that: (i) the Expansion Space is Ready for Occupancy; and (ii) the Expansion Space Term commenced as of September 4, 2019 (the "**Expansion Space Commencement Date**") for a term of seven (7) years ending co-terminously with the Second Extended Term (as defined in the Second Amendment) on September 30, 2026 (the "**Revised Expiration Date**") (unless sooner extended or terminated as provided in the Lease, as amended hereby).
2. Base Rent for Expansion Space Prior to Second Extended Term Commencement Date; Base Rent for Entire Premises During Second Extended Term. The Base Rent payable by Tenant (i) for the Expansion Space during that certain period of the Expansion Space Term prior to March 1, 2024 (which shall be calculated separate and apart from the Base Rent payable for the Original Premises), and (ii) for the entire Leased Premises (i.e., the Expansion Space and the Original Premises) from and after March 1, 2024, shall all be as set forth in the following schedules:

Base Rent Payable for Expansion Space Prior to March 1, 2024:

<u>Period Prior to 3/1/24</u>	<u>Monthly Base Rent Rate</u> <u>per Rentable Square Foot of Expansion</u> <u>Space</u>	<u>Annual Base Rent</u>	<u>Monthly Installment of Base Rent</u>
<u>09 / 04 / 19</u> - <u>09 / 30 / 20</u>	\$3.65	\$ 331,084.20	\$27,590.35
<u>10 / 01 / 20</u> - <u>09 / 30 / 21</u>	\$ 3.76	\$ 341,062.08	\$28,421.84
<u>10 / 01 / 21</u> - <u>09 / 30 / 22</u>	\$ 3.87	\$351,039.96	\$29,253.33
<u>10 / 01 / 22</u> - <u>09 / 30 / 23</u>	\$ 3.99	\$ 361,924.92	\$30,160.41
<u>10 / 01 / 23</u> - <u>02 / 09 / 24</u>	\$ 4.11	\$ 372,809.88	\$31,067.49

Basic Rent Payable for entire Leased Premises From and After March 1, 2024:

<u>Period From and After 3/1/24</u>	<u>Monthly Base Rent Rate</u> <u>per Rentable Square Foot of Entire</u> <u>Premises</u>	<u>Annual Base Rent</u>	<u>Monthly Installment of Base Rent</u>
<u>03 / 01 / 24</u> - <u>09 / 30</u> <u>/ 24</u>	\$4.11	\$1,050,170.76	\$ 87,514.23
<u>10 / 01 / 24</u> - <u>09 /</u> <u>30 / 25</u>	\$ 4.23	\$ 1,080,832.68	\$ 90,069.39

Exhibit C

10/01/25 - 09/30/26 (i.e., the Revised Expiration Date)

\$ 4.36

\$ 1,114,049.76

\$ 92,837.48

[TO BE COMPLETED PURSUANT TO THE PROVISIONS OF SECTION 3.2 OF THE SECOND AMENDMENT]

3. No Further Modification. Except as set forth in this Third Amendment, all of the terms and provisions of the Lease shall remain unmodified and in full force and effect.
4. Counterparts. This Third Amendment may be executed in multiple counterparts, each of which is to be deemed original for all purposes, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the parties have caused this Third Amendment to be duly executed by their duly authorized representatives as of the date first above written.

LANDLORD:

RREF II PACIFIC CENTER LLC,
a Delaware limited liability company

By: /s/ Jason Murrow
Name: Jason Murrow
Title: Authorized signatory

TENANT:

EMMAUS LIFE SCIENCES, INC.,
a Delaware corporation

By: /s/ Willis Lee
Name: Willis Lee
Title: COO

By:
Name:
Title:

Exhibit C
-3-

Distributor Agreement

This Agreement (this "Agreement"), is made and entered into this 15 day of 6, 2017 (the "Effective Date") by and between Emmaus Life Sciences, Inc., a Delaware corporation with offices at 21250 Hawthorne Blvd., Suite 800, Torrance, California 90503, the United States of America (hereinafter called "Manufacturer") and Telcon Inc., Korea corporation ("Distributor"), with offices at 684, Dongtangiheung-ro, Giheung-gu, Yongin-si, Gyeonggi-do.

The parties hereto agree as follows:

I. ASSOCIATION

Distributor shall act as the exclusive (as provided in Exhibit A) distributor of Manufacturer's Products as described in attached Exhibit A ("Products") throughout the countries set forth in Exhibit A (each, a "Territory" and collectively, the "Territories") upon the Products being approved to be sold in the Territories.

II. DUTIES

1. Distributor agrees to make an upfront payment of \$5 million by June 19, 2017 and a follow-up payment of \$5 million within 1 months from December 27, 2017. Manufacturer agrees to grant Distributor a distribution right to Manufacturer's Products in the Territories.
2. Distributor agrees to use commercially reasonable best efforts to actively and diligently promote the sale of the Products in the Territories during the Term hereof.
3. Distributor shall purchase the minimum quantities of the Product from Manufacturer as set forth in Exhibit C (the "Minimum Purchase Requirement"). Distributor shall have the sole authority to determine the prices of the Products sold by it during the Term hereof and to establish its own pricing policy for the Products in the Territories, including price increases or decreases and the timing thereof as determined solely by Distributor.
4. Distributor agrees to promote in the Territory the Manufacturer's name and the Products during the Term hereof. Distributor shall use its reasonable efforts to provide appropriate and professional application advice and counseling for the Products sold by Distributor, and provide prompt follow-up service and advice to purchasers of Products when so requested by the purchaser; provided, that, if requested by Distributor, Manufacturer shall provide reasonable assistance and cooperation directly and only to Distributor's personnel with respect to providing such counseling and services, and Manufacturer shall not be obligated to provide any assistance or cooperation services directly to any patients, consumers, sub-distributors, retailers, resellers or dispensers of the Products.

5. Distributor shall not solicit orders for any Product from or market the Products to any prospective purchaser outside the Territories. If Distributor receives an order for any Product from a prospective purchaser outside the Territories, Distributor shall immediately refer that order to Manufacturer or Manufacturer's designated distributor in such territory. Distributor shall not accept any such orders. Distributor shall not deliver or tender (or cause to be delivered or tendered) any Product outside of the Territories. Distributor shall not sell any Product to a purchaser in the Territories if Distributor actually knows that such purchaser intends to remove that Product from the Territories. Distributor shall not knowingly give, offer, advertise, market or otherwise provide Product for any use or application other than one specifically authorized by Manufacturer in writing or in literature accompanying the Product.

6. (a) Distributor covenants that all of its activities under or pursuant to this Agreement shall comply, in all material respects, with all applicable laws, rules and regulations in the Territory. Distributor shall be responsible for obtaining all licenses, permits and approvals which are necessary for the importation and sale of the Products in the Territories and for the performance of its duties hereunder; provided, that Manufacturer shall use its reasonable best efforts to cooperate with Distributor and provide any assistance requested by Distributor in obtaining such licenses, permits and approvals as expeditiously as reasonably practicable. To the extent necessary and required, Manufacturer, at its sole cost and expense, shall have the sole responsibility of obtaining and maintaining the registrations and approvals of the Products with the U.S. Food and Drug Administration (the "U.S. Product Registration"). To the extent the U.S. Product Registration is necessary and required and has not been obtained as of the date hereof, Manufacturer agrees to use its reasonable best efforts to obtain the U.S. Product Registration as promptly as practicable after the date hereof. To the extent necessary and required, Distributor, at its sole cost and expense, shall have the sole responsibility of obtaining and maintaining the registrations and approvals of the Product, in the name of Manufacturer (except to the extent prohibited by applicable law), with any non-U.S. applicable Governmental Authority (defined below) that regulates the import, marketing, labeling, distribution, use or sale of Products in each Territory (the "Product Registrations"). To the extent such Product Registrations are necessary and required and have not been obtained in any of the Territories as of the date hereof, Distributor agrees to use its reasonable best efforts to obtain such necessary Product Registrations, in the name of Manufacturer (except to the extent prohibited by applicable law), as promptly as practicable after the date hereof. Each party hereto shall keep the other party hereto informed on a timely basis as to any developments that would have a material effect on any Product Registration and the U.S. Product Registration. Manufacturer shall use its reasonable best efforts to assist Distributor in obtaining the Product Registration, in the name of Manufacturer (except to the extent prohibited by applicable law), with Distributor's local regulatory agencies and Governmental Authorities of the other Territories. "Governmental Authority" shall mean any nation or government, any foreign or domestic federal, state, county, municipal or other political instrumentality or subdivision thereof and any foreign or domestic entity or body exercising executive, legislative, judicial, regulatory, administrative or taxing functions of or pertaining to government, including any court.

(b) Except as otherwise set forth herein, each party shall use commercially reasonable efforts to maintain in full force and effect all necessary licenses, permits and other authorizations required

by applicable law or Governmental Authorities to fully perform its duties and obligations under this Agreement. Furthermore, each party hereby agrees to use commercially reasonable efforts to take, or cause to be taken, all actions and to do, or cause to be done, all things necessary or proper to make effective the transactions contemplated by this Agreement.

7. In the event (x) any applicable Governmental Authority in any Territory should issue a request, directive or order that the Products be recalled, (y) a court of competent jurisdiction orders such a recall or (z) either party reasonably determines that any Product presents a risk of injury or gross deception or is otherwise defective, misbranded and/or adulterated (as evidenced by appropriate supporting documentation) and that recall of such Product is appropriate (each such event, a "Recall"), each party shall give telephonic notice (to be confirmed in writing) to the other party within one day after becoming aware of an event described in clauses (x) or (y) or after making the determination described in clause (z). Manufacturer shall have the sole responsibility for taking all corrective and remedial actions and implementing a Recall in accordance with all applicable Laws or requirements of applicable Governmental Authorities; provided, that Distributor shall be responsible for taking such remedial actions and implementing such Recall to the extent such Recall relates to any damages caused by storage or handling of the Product (i) by Distributor or its agents or subdistributors and/or (ii) that is not in accordance with the instructions provided by Manufacturer to Distributor pursuant to Section III(2) hereof, on Manufacturer's brochures, inserts, labels or other documentation provided to Distributor (such handling of the Products by Distributor hereinafter referred to as "improper storage or handling"). Manufacturer and Distributor shall confer with each other and keep the other party informed on a regular basis of Manufacturer's and Distributor's (to the extent Distributor is responsible for taking any actions pursuant to the terms hereof) progress in planning and implementing such Recall. Distributor shall use commercially reasonable efforts to assist in promptly executing Product Recalls as directed by Manufacturer, in which event Manufacturer will promptly reimburse Distributor for all documented, reasonable, out-of-pocket expenses reasonably incurred by Distributor in connection such Recall, including any costs and expenses incurred by Distributor in complying with Manufacturer's directives in connection with repurchasing Product subject to such Recall, except to the extent that costs and expenses relate to improper storage or handling and Product Recalls resulting therefrom. Manufacturer shall provide to Distributor replacement Products for the recalled Product at Manufacturer's sole costs and expenses; provided, that Distributor shall pay for the replacement Products to the extent the Recall is attributable to any damages caused by improper storage or handling of the Product by Distributor or sub-distributors. Distributor shall be responsible, and shall promptly reimburse Manufacturer, for all documented, reasonable, out-of-pocket expenses reasonably incurred by or on behalf of Manufacturer in connection any Recall to the extent attributable to any damages caused by improper storage or handling of the Product by Distributor or sub-distributors.

8. Each party shall promptly advise the other party of each material complaint that such party may receive or become aware of concerning the Product; provided that, in the case of Manufacturer, such obligation is limited to those material complaints that may impact or involve Distributor's activities hereunder. Each party shall cooperate with the other party to provide any information that the other party, in good faith, deems necessary to respond to such complaints. Manufacturer shall have the sole responsibility at its own expense of addressing any complaints

relating to the Product Registrations and the development, manufacture, supply and use of the Product, including any adverse drug experience reports.

9. Distributor may translate, at its own expense, all user and technical manuals and advertising and marketing information with respect to the Product into local languages in the Territories. Distributor shall provide Manufacturer with copies of drafts of all such materials prior to use of such materials and copies of final versions of all such materials prior to use of such materials. Manufacturer shall own all copyrights in all translations and Distributor hereby irrevocably assigns to Manufacturer any right, title or interest therein. Manufacturer shall not be liable for translation errors made by Distributor or at Distributor's direction or for the non-conformance of such translations with the laws and regulations in force from time to time in the Territories.

10. Distributor shall provide Manufacturer with written quarterly reports, which shall include sales data and forecasts with respect to the Product. Distributor will also participate in quarterly meetings, with Manufacturer, in person or by telephone, to discuss sales volumes and future marketing strategies.

11. Distributor agrees that any material publicity or advertising which shall be released by it in connection with the Product shall be in accordance with the terms of this Agreement and with any information or data which Manufacturer has furnished in connection with this Agreement, including, without limitation, any minimum pricing established by Manufacturer for inclusion in publicity or advertising for the Products, which, for the avoidance of doubt, is a material term of this Agreement, the failure of Distributor's strict compliance with which shall be grounds for termination under Section X(2)(c). Copies of all such publicity and advertising shall be forwarded to Manufacturer prior to dissemination, and shall not be disseminated without Manufacturer's prior written approval thereof, not to be unreasonably withheld, conditioned or delayed.

12. Distributor may not customize, modify or have customized or modified any Product, including but not limited to the packaging of any Product, unless it obtains the prior written consent of Manufacturer, which consent may not be unreasonably withheld, conditioned or delayed by Manufacturer. If any customization or modification of the Product or any packaging of the Product is required by any applicable law or Governmental Authorities in any of the Territories, Distributor shall immediately notify Manufacturer and Manufacturer shall cooperate with Distributor to comply with such requirements. Distributor acknowledges and agrees that any unauthorized customizing or modification of any Product, including but not limited to, the packaging or label of any Product by Distributor or any subdistributor, shall automatically void any Manufacturer warranty with respect to such Product, shall automatically eliminate any indemnification obligation Manufacturer would have otherwise owed with respect to such Product under this Agreement, and shall be deemed a breach of this Agreement.

13. Distributor shall use all reasonable efforts to sell to its customers only Products of saleable quality and shall remove any Products either known to it to be unmerchantable or of distressed quality from its or any retailer's inventory in the Territory, in accordance with applicable law. Manufacturer shall sell and deliver to Distributor only Products of saleable quality and not any

Products either known to it to be unmerchantable or of distressed quality, in accordance with applicable law.

14. Each party shall conduct its business, including, but not limited to the obligations set forth herein, in a professional and lawful manner and otherwise in a manner that does not violate the terms of this Agreement.

15. Distributor shall pay all of its expenses, including without limitation all travel, lodging and entertainment expenses, incurred in connection with its activities hereunder, except as otherwise provided herein and/or agreed between the Parties.

III. ASSISTANCE BY MANUFACTURER

1. In conjunction with the initial Product launch in the Territories, Manufacturer agrees to furnish Distributor with reasonable quantities of Manufacturer's catalogs, manuals, advertising literature and other sales aids that may be available by Manufacturer; provided, that, after the initial Product launch, Manufacturer shall provide to Distributor reasonable quantities of such catalogs, manuals, advertising literature and other sales aids to the extent reasonably requested by Distributor. Furthermore, if any such catalogs, manuals, advertising literature or other sales aids are updated or revised by Manufacturer, Manufacturer shall promptly provide such updates or revisions to Distributor. Distributor shall be responsible for preparing sales and marketing materials after the initial Product launch. Any materials provided pursuant to this Section shall be in English.

2. Prior to the initial launch of Products in the Territories, Manufacturer shall provide Distributor with necessary initial training for marketing, promotion, handling, maintenance, sale and use of the Products. Following Product launch, Manufacturer will provide follow up training once a year as mutually agreed by the parties or, if any new developments or updates occur with respect to the Product, as soon as practicable after the occurrence of such development or update, each, at a location to be mutually agreed to by the parties. Sales samples will not be provided to Distributor. Notwithstanding the foregoing, Distributor shall have the primary responsibility to promote, market and sell the Products in the Territories, with the training and assistance of Manufacturer as provided in this Section.

IV. INTELLECTUAL PROPERTY RIGHTS

1. Distributor acknowledges and agrees that all trademarks, trade names, trade dress, designs, service marks, service names, images, logos or identifying slogans affixed to Products or any accompanying labels, containers, and cartons, whether or not registered, including, without limitation, the "Products" trademark (collectively, the "Trademarks"), constitute the exclusive property of Manufacturer or its licensors and shall be used by Distributor only in connection with promoting the sale of Products hereunder. During the term of this Agreement, Distributor is authorized by Manufacturer to use the Trademarks, on a royalty-free basis, solely in connection with Distributor's promotion, marketing, sale and distribution of Products and to otherwise perform its obligations hereunder, provided that Distributor's use of such Trademarks shall be in

accordance with Manufacturer's policies from time to time communicated to Distributor (such policies which are in effect as of the date hereof have been made available by Manufacturer to Distributor prior to the date hereof). Distributor shall have no interest in such Trademarks by virtue of this Agreement except as herein expressly provided, and Distributor's right to use of such Trademarks shall cease immediately upon termination or expiration of this Agreement. Manufacturer reserves the right to change the Trademarks without notice, provided, that Manufacturer shall provide prompt notification of such change to Distributor. Distributor shall not change or remove any Trademarks or third-party trademarks or other proprietary notices on or contained within the Products.

2. All representations of Manufacturer's Trademarks that Distributor intends to use shall first be submitted to Manufacturer for approval, which approval shall not be unreasonably withheld by Manufacturer, of design, color and other details or shall be exact copies of those used by Manufacturer. All uses of the Trademarks shall reproduce faithfully the design and appearance of the Trademarks as represented in or on the labels and packaging or as is otherwise provided by Manufacturer, including claims of copyright or trademark protection and/or registration. The Trademarks shall not be used in juxtaposition or conjunction with intellectual property associated with any product or service other than the Products, and shall always be used in a non-offensive manner, and in a manner which is not in any way denigrating to the Manufacturer or the Product or the Trademarks, in each case, taking into account the cultural and social standards and customs of the Territory in which the Trademarks are being used. If any of Manufacturer's Trademarks are to be used in conjunction with another trademark on or in relation to the Products, then Manufacturer's mark shall be presented equally legibly and separated from the other mark so that each appears to be a mark in its own right, distinct from the other mark.

3. At no time during the term of this Agreement shall Distributor attempt or assist others to register any trademarks, logos, slogans, designs or trade names substantially similar to those of Manufacturer, or challenge or assist others to challenge Manufacturer's Trademarks or registrations thereof. Distributor shall have no right to sublicense to any third party the right to reproduce the Trademarks for any purpose, except in connection with media advertising or otherwise to perform its obligations hereunder, which shall first be reviewed and approved in writing by Manufacturer, provided, that Manufacturer's consent shall not be unreasonably withheld.

4. Distributor shall not remove, alter or deface any Manufacturer Trademark appearing on any Product or documentation without the express written permission of Manufacturer. Except as otherwise set forth herein, Distributor shall not use Manufacturer's trade names and/or trademarks without the prior, express written consent of Manufacturer.

5. Under no circumstances shall Distributor, at any time, use Manufacturer's Trademarks as part of Distributor's corporate or trade name. Upon termination of this Agreement, Distributor shall remove all references to Manufacturer and Manufacturer's Trademarks from its letterheads, advertising literature and places of business, and shall not thereafter use any similar or deceptive name or trademark intending to give the impression that there is any relationship between the parties.

V. SALES FORCE

1. Distributor shall use commercially reasonable best efforts to maintain a competent and experienced sales force sufficient to adequately serve each Territory.
2. Distributor shall be allowed to appoint sub-distributors, dealers, retailers or other non-employee representatives to work in connection with the promotion, distribution and sales of Products in the Territories, provided that Distributor shall be responsible for the agreement of and the observance by any such sub-distributor, dealer, retailer or other non-employee representative of the covenants and agreements, and shall otherwise be responsible for the performance of any such sub-distributors, dealers, retailers or other non-employee representatives; and provided further that Distributor will be responsible for any and all termination or other compensation claims that any such sub-distributor, dealer, retailer or other non-employee representative may have against Manufacturer under any sub-distributorship or similar agreement it may have with Distributor or under any applicable law.

VI. CUSTOMER SERVICING

Distributor shall maintain in the Territory sufficient inventory of the Products so as to permit filling and shipping against current customer orders normally shipped from Distributor's warehouse stock. Manufacturer shall maintain a sufficient inventory of Products. Distributor agrees to notify Manufacturer if it opens any new offices or branches or closes or ceases to operate through one of its offices or branches.

VII. ORDERS/ACCEPTANCE/PRICE AND TERMS

1. Distributor shall order Products from Manufacturer by submitting a written purchaser order on a form specified by Manufacturer identifying the Products ordered, requested delivery date(s) and any export/import information required to enable Manufacturer to fill the order; provided, that nothing in such purchase order forms shall be construed to modify or amend the terms and conditions of this Agreement, and, in the case of any conflict therewith, the terms and conditions of this Agreement shall control. All orders from Distributor are subject to approval and final acceptance by Manufacturer, which shall not be unreasonably withheld, conditioned or delayed. Price lists to Distributor and any royalty payable to Manufacturer shall be as set forth in Exhibit B (as revised from time to time by Manufacturer in its sole discretion) in effect on date of shipment.
2. Manufacturer will invoice Distributor within five (5) days after receipt and acceptance of a purchase order. Distributor shall make 50% payment within five (5) days after receipt of the invoice. The balance shall be due and payable to Manufacturer within five (5) days after the product delivery. Manufacturer shall be responsible for freight shipping and insurance costs, U.S. customs duties and taxes and any other charges imposed by U.S. Governmental Authorities and Distributor shall be responsible for all other costs, including but not limited to any non-U.S. customs duties and taxes. Payment to Manufacturer by Distributor shall be in United States currency.

3. A service charge at the rate that is the lower of (i) two percent (2%) over the rate of interest announced by Bank of America in Los Angeles, California (or any successor in interest thereto or any commercially equivalent financial institution if no such successor exists) to be its "prime rate", and (ii) the highest rate permitted by applicable law, shall be payable by Distributor on any portion of Distributor's outstanding undisputed amounts payable by Distributor hereunder that are not paid to Manufacturer within thirty (30) days past the due date

VIII. WARRANTY; FORCE MAJEURE; LIMITATION OF LIABILITY

1. (a) Manufacturer warrants to Distributor that (i) all Products delivered hereunder shall be of Manufacturer's standard quality, (ii) all Products delivered hereunder shall be developed and manufactured in accordance with the applicable labeling and all applicable Product Registrations and the U.S. Product Registration, (iii) all Products delivered shall be developed and manufactured in accordance with all applicable laws, rules or regulations, (iv) to the best of its actual, current knowledge, Manufacturer owns or holds licenses to all intellectual property rights relating to the Products that are required for Manufacturer to grant the rights granted to Distributor under this Agreement and all required registrations for such intellectual property rights are in full force and effect.

(b) Distributor represents and warrants that it and its principals are not debarred, suspended or proposed for debarment by the U.S. Government, and further represents and warrants that it will immediately notify Manufacturer in writing if any such debarment or suspension occurs, is commenced or, to Distributor's knowledge, is threatened. Distributor represents and warrants that it will not engage, directly or indirectly, any person to perform or participate in the services contemplated by this Agreement if (a) that person is debarred by the U.S. Government or the U.S. Food and Drug Administration under 21 U.S.C. § 335a or any foreign equivalent or to Distributor's knowledge is threatened with debarment by a pending proceeding, action, or investigation, (b) that person is excluded from participation in any federal health care program under 42 C.F.R. Part 1001 *et seq.* or is the subject of an exclusion proceeding, or (c) that person is otherwise disqualified under federal, state, local or other law, or to Distributor's knowledge is threatened with such disqualification by a pending proceeding, action, or investigation, from performing or participating in the services contemplated by this Agreement. Distributor represents and warrants that it will immediately notify Manufacturer in writing if any such debarment, exclusion, or disqualification occurs, or if any such debarment, exclusion, or disqualification proceeding, action, or investigation is commenced or, to Distributor's knowledge, is threatened, with respect to any such person.

(c) The parties each represent a warrant that, as of the Effective Date: (i) it is a corporation duly incorporated, validly existing and in good standing under the laws of its jurisdiction of incorporation; (ii) it has the corporate power and authority and the legal right to enter into this Agreement free from any conflicting right owed to a third party and to perform its obligations hereunder; (iii) it has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder and that this Agreement has been duly executed and delivered on behalf of such party, and constitutes a legal, valid, binding obligation, enforceable against such party in accordance with its terms; (iv) all

necessary consents, approvals and authorizations of all applicable competent authorities and other persons required to be obtained by such party in order to execute and perform this Agreement on behalf of such party have been obtained; and (v) the execution and delivery of this Agreement and the performance of such party's obligations do not constitute a default or require any consent under any other contractual obligation of such party.

2. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, MANUFACTURER MAKES NO OTHER WARRANTIES, ORAL, STATUTORY, EXPRESS OR IMPLIED: THERE ARE NO IMPLIED WARRANTIES INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR NONINFRINGEMENT.

3. Manufacturer shall not be liable for damages resulting from inability to ship due to, and shipment delays resulting from any of the Force Majeure Events (as defined below) and (b) Distributor shall not be liable for damages resulting from performance delays hereunder (other than with respect to payment of obligations) and such performance delays shall not be considered a breach of this Agreement if caused by or resulting from a Force Majeure Event. "Force Majeure Event" shall mean any acts of God, fires, floods, hurricanes, typhoons, earthquakes, tsunamis, wars, sabotage, material accidents, labor disputes or shortages, plant shutdown or equipment failure (only if such shutdown or failure is attributable to a Force Majeure Event suffered by such party), delays caused by shipping companies, voluntary or involuntary compliances with any law, order, rule or regulation of Governmental Authority; or inability to obtain material (including raw materials, power and fuel, equipment or transportation, only if such inability is attributable to a Force Majeure Event suffered by such party) (each, a "Force Majeure Event"). The party suffering such Force Majeure Event shall promptly notify the other party and of the period for which such inability is expected to continue, and any time for performance hereunder shall be extended by the actual time delay caused by such event; provided, that the parties shall use commercially reasonable efforts to mitigate the effect of any such event and to resume the performance of their respective obligations hereunder; provided, further, that Manufacturer may terminate this Agreement if the Force Majeure Event continues for more than ninety (90) days.

4. EXCEPT FOR THE PARTIES' OBLIGATIONS TO INDEMNIFY EACH OTHER PURSUANT TO THIS AGREEMENT, NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR SPECIAL, CONSEQUENTIAL OR INCIDENTAL DAMAGES ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT, EVEN IF ADVISED OF THE POSSIBILITY OF THE SAME.

IX. RELATIONSHIP BETWEEN MANUFACTURER AND DISTRIBUTOR

Distributor is not an agent, employee or legal representative of Manufacturer, but an independent contractor. Except as set forth herein, Distributor or Manufacturer does not have any authority to assume or create any obligation or responsibility on behalf of the other party or bind the other party in any manner whatsoever. The relationship between Manufacturer and Distributor is that of vendor and vendee.

X. TERM/CANCELLATION/NON-REFUNDABLE PAYMENT

1. This Agreement shall become effective as of the Effective Date and shall remain in effect for two (2) years (the “Term”). Thereafter the Term shall automatically renew for additional one (1) year periods unless terminated by either party by written notice given no less than thirty (30) days prior to the date of renewal of the Term.
2. The following events shall constitute grounds for termination by Manufacturer:
 - (a) if Distributor shall file or have filed against it a petition in bankruptcy or insolvency or if Distributor shall make an assignment for benefit of its creditors or if Distributor's viability as a going concern should, in Manufacturer's sole judgment, become materially and adversely impaired, in which event Manufacturer may terminate this Agreement by giving written notice to Distributor and such termination shall be effective immediately upon delivery of such notice;
 - (b) if Distributor materially degrades or places in bad repute the name and reputation of Manufacturer (as supported by evidentiary documentation);
 - (c) if Distributor breaches, in any material respect, any of its representations, warranties or covenants hereunder, or fails to meet any other of its material obligations hereunder, and such breach is not cured within thirty (30) days after receipt of notice of such breach; or
 - (d) if Distributor has not ordered the minimum quantities, as per Exhibit C, for year one in the first 12 months after signing, and such breach is not cured within thirty (30) days after receipt of notice of such breach.
3. The following events shall constitute grounds for termination by Distributor:
 - (a) if Manufacturer shall file or have filed against it a petition in bankruptcy or insolvency or if Manufacturer shall make an assignment for benefit of its creditors or if Manufacturer's viability as a going concern should, in Distributor's sole judgment, become materially and adversely impaired, in which event Distributor may terminate this Agreement by giving written notice to Manufacturer and such termination shall be effective immediately upon delivery of such notice;
 - (b) if Manufacturer materially degrades or places in bad repute the name and reputation of Distributor (as supported by evidentiary documentation); or
 - (c) if Manufacturer breaches, in any material respect, any of its representations, warranties or covenants hereunder, or fails to meet any other of its material obligations hereunder, and such breach is not cured within thirty (30) days after receipt of notice of such breach.
4. Termination of the Agreement shall be without prejudice to any rights or claims of the terminating party for any breach and such terminating party's right to recover damages, loss and all sums payable under this Agreement. Notwithstanding any provision herein to the contrary, the rights and obligations of the parties set forth in Sections II(6), II(7), XI and XIII as well as

any rights or obligations otherwise accrued hereunder (including any accrued payment obligations), shall survive the expiration or termination of this Agreement.

XI. NONDISCLOSURE

All information disclosed, transferred or otherwise revealed to Distributor or Manufacturer (the "Receiving Party") by the other party (the "Disclosing Party") under this Agreement, including but not limited to, engineering information, manufacturing information, technology, know-how and price books or lists, shall at all times remain the Disclosing Party's sole and exclusive proprietary and confidential property and information. The Receiving Party shall at all times hold such information confidential and shall not disclose any such information (a) if not otherwise within the public domain, other than as a result of the Receiving Party's violation of any of the terms hereof, (b) unless such information is required to be disclosed pursuant to any applicable law, rule or regulation or requested by any Governmental Authority or (c) other than to the Receiving Party's agents and representative who need to know such information in connection with the performance of the Receiving Party's obligations under this Agreement and who are bound by obligations of confidentiality at least as stringent as those set forth herein. The Receiving Party shall use such information only as required for the performance of its obligations under this Agreement and for no other purpose. Upon any termination or expiration of this Agreement in accordance with the terms hereof, or as the Disclosing Party directs from time to time, the Receiving Party shall promptly return to the Disclosing Party or destroy all such information together with any copies or reproductions thereof. The parties' obligations under this section shall survive any termination or expiration of this Agreement

XII. CERTAIN PRACTICES

Distributor acknowledges that certain laws of the United States applicable to the Manufacturer, including but not limited to the Foreign Corrupt Practices Act of 1977 (15 U.S.C. §§ 78dd-1, *et seq.*) and export control laws, but which may not be applicable to Distributor, impose fines or penalties on Manufacturer in the event Manufacturer makes payments to foreign government officials for the purpose of influencing those officials in making a business decision favorable to Manufacturer. In addition, Manufacturer and Distributor may be subject to similar laws or requirements of the country of destination of the Products.

Distributor and Manufacturer shall not take any actions or omit to take any actions that may cause liability to the other party under the above mentioned laws. Without limiting the generality of the foregoing, in performing the services contemplated by this Agreement, Distributor (i) agrees that Distributor has not and shall not, directly or indirectly, offer to make, promise, authorize or accept any payment or anything of value, including bribes, gifts and/or donations to or from any public official, regulatory authorities or anyone else for the improper purpose of influencing, inducing or rewarding any act, omission or decision in order to secure an improper advantage, including to obtain or retain business, and (ii) shall comply with all applicable anti-corruption and anti-bribery laws and regulations. Distributor shall notify Manufacturer or its representatives or agents immediately upon becoming aware of any breach under this Section. For the purpose of ensuring compliance with applicable anti-bribery laws and

regulations, Distributor agrees that Manufacturer or its representatives or agents shall have the right to conduct an investigation or audit during the term of this Agreement to monitor compliance with the terms of this Section. Distributor shall cooperate fully with such investigation or audit, the timing of which shall be at the sole discretion of Manufacturer.

XIII. INDEMNIFICATION

1. Distributor shall indemnify, defend, and hold Manufacturer, its subsidiaries and Affiliates and their respective officers, directors, shareholders, employees, and agents (collectively, "Distributor Indemnitees") harmless against any and all liabilities, suits, claims, proceedings, costs, fines, penalties, and expenses ("Losses") brought or threatened against any such Distributor Indemnitee, whether known or unknown, contingent or otherwise, to the extent attributable to:

(a) any untruth, inaccuracy, misrepresentation, or breach of any warranty, representation, covenant, or agreement made by Distributor in this Agreement;

(b) the distribution, marketing, advertisement, promotion or sale of any of the Products by Distributor in the Territories after the Effective Date, whether during or after the Term of this Agreement, including but not limited to errors in translation of technical manuals, advertising and marketing information, or other materials with respect to the Products, but not however, with respect to the use of the Products (including, without limitation, any Claims (as defined below) based on, arising out of or relating to product liability), except to the extent that such use was in any way encouraged by Distributor but inconsistent with Product Registrations and/or the instructions provided by Manufacturer to Distributor pursuant to Section III(2) hereof, on Manufacturer's brochures, inserts, labels or other documentation provided to Distributor; or

(c) infringement of a third party's intellectual property rights by Distributor, except to the extent such infringement was caused by Distributor's exercise of any of the rights granted by Manufacturer to Distributor in this Agreement, including the right to distribute, market, advertise, promote or sell Products under this Agreement, or by Distributor's breach of this Agreement.

Distributor shall pay all litigation costs, reasonable attorney's fees, settlement payments, and such damages awarded or resulting from any such suit, claim or proceeding (collectively, "Claims").

2. Manufacturer shall indemnify, defend, and hold Distributor, its subsidiaries and Affiliates and their respective officers, directors, shareholders, employees, and agents (collectively, "Manufacturer Indemnitees") harmless against any and all Losses, whether known or unknown, contingent or otherwise, to the extent attributable to:

(a) any untruth, inaccuracy, misrepresentation, or breach of any warranty, representation, covenant, or agreement made by Manufacturer in this Agreement;

(b) the distribution, marketing, advertisement, promotion or sale of any of the Products by Manufacturer, its Affiliates or any third party with whom Manufacturer has a direct or indirect agreement (whether oral or written) to distribute, manufacture, market, advertise, promote, sell, import, export or otherwise deal in the Products, excluding any third party who is a subdistributor of Distributor or who otherwise has a distribution relationship with Distributor, solely in its capacity as such, and any use of any of the Products (including, without limitation, any Claims based on, arising out of, or relating to product liability) prior to the Effective Date or following the termination or expiration of this Agreement, except to the extent that such use was in any way encouraged by Distributor but inconsistent with Product Registrations and/or the instructions provided by Manufacturer to Distributor pursuant to Section III(2) hereof, on Manufacturer's brochures, inserts, labels or other documentation provided to Distributor;

(c) the distribution, marketing, advertisement, promotion or sale of any of the Products by Manufacturer, its Affiliates or any third party with whom Manufacturer has a direct or indirect agreement (whether oral or written) to distribute, manufacture, market, advertise, promote, sell, import, export or otherwise deal in the Products, excluding any third party who is a subdistributor of Distributor or who otherwise has a distribution relationship with Distributor, solely in its capacity as such, outside the Territories or inside the Territories, and any use of any such Products inside and outside the Territories that were sold by Manufacturer, its Affiliates or any third party with whom Manufacturer has a direct or indirect agreement (whether oral or written) to distribute, manufacture, market, advertise, promote, sell, import, export or otherwise deal in the Products, excluding any third party who is a subdistributor of Distributor or who otherwise has a distribution relationship with Distributor, solely in its capacity as such (including, without limitation, any Claims based on, arising out of, or relating to product liability), whether sold by Manufacturer, its Affiliates or any third party, prior to, on or following the Effective Date;

(d) infringement of a third party's intellectual property rights by reason of Distributor's exercise of any of the rights granted by Manufacturer to Distributor in this Agreement, including the right to distribute, market, advertise, promote or sell Products under this Agreement; or

(e) manufacture, labeling or packaging of the Products by Manufacturer, its Affiliates or any third party with which Manufacturer has a direct or indirect agreement (whether oral or written) to manufacture, label or package the Products, and any use of the Products (including, without limitation, any Claims based on, arising out of, or relating to product liability). Manufacturer shall pay all litigation costs, reasonable attorney's fees, settlement payments, and such damages awarded or resulting from any such Claim.

Distributor acknowledges and agrees that use of the Product in a manner not authorized by Manufacturer or any unauthorized customizing or modification of any Product, including but not limited to the packaging or labeling of any Product by Distributor or any subdistributor, may provide grounds for Manufacturer to disclaim or reduce its indemnification liabilities.

3. Third Party Claims.

(a) If either Manufacturer or any Distributor Indemnitee, on the one hand, or Distributor or a Manufacturer Indemnitee, on the other hand (in either case, an “Indemnitee”) receives notice or otherwise obtains knowledge of any matter or any threatened matter arising from the claim of a third party that may give rise to an indemnification claim against the party from whom indemnification is sought (the “Indemnitor”), then the Indemnitee shall promptly deliver to the Indemnitor a written notice describing, to the extent practicable, such matter in reasonable detail. The failure to make timely delivery of such written notice by the Indemnitee to the Indemnitor shall not relieve the Indemnitor from any liability with respect to such matter, except to the extent the Indemnitor is actually materially prejudiced by failure to give such notice on a timely basis. The Indemnitor shall have the right, at its option, to assume the defense of any such matter with its own counsel, but only if the Indemnitor simultaneously agrees to indemnify the Indemnitee for such matter.

(b) If the Indemnitor elects to assume the defense of and indemnification for any such matter, then:

(A) notwithstanding anything to the contrary contained in this Agreement, the Indemnitor shall not be required to pay or otherwise indemnify the Indemnitee against any attorneys’ fees or other expenses incurred on behalf of the Indemnitee in connection with such matter following the Indemnitor’s election to assume the defense of such matter, unless (x) the Indemnitor fails to defend diligently the Claim within ten days after receiving notice of such failure from the Indemnitee, (y) the Indemnitee reasonably shall have concluded (upon advice of its counsel) that there may be one or more legal defenses available to such Indemnitee or other Indemnities that are not available to the Indemnitor, or (z) the Indemnitee reasonably shall have concluded (upon advice of its counsel) that, with respect to such claims, the Indemnitee and the Indemnitor may have different, conflicting, or adverse legal positions or interests;

(B) the Indemnitee shall make available to the Indemnitor all books, records and other documents and materials that are under the control of the Indemnitee or any of the Indemnitee’s agents and that the Indemnitor considers necessary or desirable for the defense of such matter, and cooperate in all reasonable ways with, and make its employees and advisors available or otherwise render reasonable assistance to, the Indemnitor and its agents; and

(C) the Indemnitor shall not, without the written consent of the Indemnitee, which shall not be unreasonably withheld or delayed, settle or compromise any pending or threatened Claim in respect of which indemnification may be sought hereunder (whether or not the Indemnitee is an actual or potential party to such Claim) or consent to the entry of any judgment (x) which does not, to the extent that the Indemnitee may have any liability with respect to such Claim, include as an unconditional term thereof the delivery by the claimant or plaintiff to the Indemnitee of a written release of the Indemnitee from all liability in respect of such Claim, (y) which includes any statement as to or an admission of fact, culpability or a failure to act, by or on behalf of the Indemnitee, or (z) in any manner that involves any injunctive relief against the Indemnitee or may materially and adversely affects the Indemnitee.

(c) If the Indemnitor elects not to assume the defense of and indemnification for such matter, then the Indemnitee shall proceed diligently to defend such matter with the assistance of counsel

reasonably satisfactory to the Indemnitor; provided, that the Indemnatee shall not settle, adjust or compromise such matter, or admit any liability with respect to such matter, without the prior written consent of the Indemnitor, such consent not to be unreasonably withheld or delayed. The procedures in this Section XIV(4) shall not apply to direct claims of Manufacturer or its Indemnitees against Distributor or Distributor or its Indemnitees against Manufacturer.

XIV. VARIOUS

1. This Agreement constitutes the entire and only agreement between the Manufacturer and Distributor with respect to its subject matter and there are no understandings or representations of any kind, express, implied, oral, written statutory or otherwise, not expressly set forth herein. All express or implied representations, agreements and understandings, either oral or written, heretofore made are expressly superseded by this Agreement. No alteration or modification of this Agreement shall be binding unless in writing and signed by the all of the parties hereto.

2. Except as otherwise expressly set forth, this Agreement is not assignable in whole or in part by either party without express written consent of the other party; provided, however, that either party may, without such consent, assign this Agreement and its rights and obligations hereunder in connection with the transfer or sale of all or substantially all of its business, or in the event of its merger, consolidation, change in control or similar transaction. This Agreement and the provisions hereof shall be binding upon each of the parties, their successors and permitted assigns. Nothing in this Agreement, whether express or implied, shall be construed to give any person or entity (other than parties hereto and their respective legal representatives, successors and assigns and as expressly provided herein) any legal or equitable right, remedy or claim under or in respect of this Agreement or any covenants, conditions or provisions contained herein, as a third party beneficiary or otherwise; provided, that the Indemnitees who are entitled to indemnification pursuant to Section XIII and who are not otherwise a party to this Agreement shall be third party beneficiaries of this Agreement.

3. This Agreement shall be governed by and interpreted and enforced in accordance with the laws of the State of California, United States of America, without regard to the conflicts of law principles thereof, and the official language of this Agreement for all purposes shall be English.

4. The parties shall attempt to resolve all disputes arising out of or in connection with this Agreement, including disputes or claims relating to the interpretation or application of the provisions of this Agreement (a "Dispute"), through mutual good faith consultations. If any Dispute cannot be resolved by the parties within 30 business days from the date when a party serves a written notice on the other party requesting such good faith consultation, such Dispute shall be resolved by arbitration pursuant to the Rules of Arbitration of the International Chamber of Commerce (the "ICC Rules of Arbitration"). The place of arbitration shall be Los Angeles, California. The arbitration shall be the sole and exclusive forum for resolution of any such Dispute, and the award rendered in such arbitration shall be final and binding. Judgment on the award rendered may be entered in any court having jurisdiction thereof. Notwithstanding, each party hereto acknowledges that money damages would not be an adequate remedy in the event

that certain of the covenants or agreements in this Agreement are not performed by the parties in accordance with their terms, and it is therefore agreed that in addition to and without limiting any other remedy or right each party may have, each party will have the right to an injunction, temporary restraining order or other equitable relief in any court of competent jurisdiction enjoining any such breach and enforcing specifically the terms and provisions hereof.

5. Should any provision of this Agreement be found to be void, invalid, or unenforceable by a court of competent jurisdiction, that finding shall only affect the provisions found to be void, invalid, or unenforceable and shall not affect the remaining provisions of this Agreement.

6. No waiver of any breach of any agreement or provision herein contained shall be deemed a waiver of any proceeding or succeeding breach thereof or of any other agreement or provision herein contained. No extension of time for performance of any obligations or acts shall be deemed an extension of the time for performance of any other obligations or acts.

7. Should any party institute any action or proceeding (including arbitration) to enforce this or any provision hereof or for damages by reason of any alleged breach of this Agreement or of any provision hereof or for a declaration of rights hereunder, the substantially prevailing party in any such action or proceeding shall be entitled to receive from the other party all costs and expenses, including reasonable attorneys' fees, incurred by the prevailing party in connection with such action or proceeding.

8. The parties agree to do such further acts and things to execute and deliver such additional agreements and instruments as the other may reasonably be required to consummate, evidence or confirm the agreements contained herein in the manner contemplated hereby.

To Distributor: Telcon Inc.

684, Dongtangiheung-ro,
Giheung-gu, Yongin-si, Gyeonggi-do
Korea
Attention:
Fax No.: 82-2-515-8804

To Manufacturer: Emmaus Life Sciences, Inc.
21250 Hawthorne Blvd., Suite 800

Torrance, California 90503
United States of America
Attention: _____
Fax No.: 310-214-0075

9. Counterparts. This Agreement may be executed in counterparts and by facsimile, each of which shall be deemed an original but all of which together shall constitute but one and the same instrument

MANUFACTURER:
Emmaus Life Sciences, Inc.

_____/s/Willis Lee_____
By: Willis Lee Date _____
Title: COO

_____/s/ Ji Hoon Kim_____
By: Ji Hoon Kim Date _____
Title: CEO of Telcon Inc.

Exhibit A

Product(s): _____ (L-glutamine powder for diverticulosis treatment)

Territory: South Korea, Japan, China

Exhibit B

Distributor Product Price List in US Dollars

Product	Distributor Price
L-glutamine powder for diverticulosis treatment	TBD

The price to Distributor is: TBD

The royalty payable to Manufacturer is: TBD

Minimum order amount for each purchase order from Distributor is: TBD

Expected delivery of Product is _____ days from the purchase order.

Freight charges will be paid by Manufacturer. Title and risk of loss with the respect to the Products shall pass from Manufacturer to Distributor upon the delivery of the Products to Distributor at Distributor's shipping address designated on its purchase order and Manufacturer shall be responsible for procuring insurance for the transport of the Products to Distributor's shipping address designated on its purchase order.

Payment Terms: Manufacturer will invoice Distributor within five (5) days after receipt and acceptance of a purchase order. Distributor shall make 50% payment within five (5) days after receipt of the invoice. The balance shall be due and payable to Manufacturer within five (5) days after the product delivery. Manufacturer shall be responsible for freight shipping and insurance costs, U.S. customs duties and taxes and any other charges imposed by U.S. Governmental Authorities and Distributor shall be responsible for all other costs, including but not limited to any non-U.S. customs duties and taxes. Payment to Manufacturer by Distributor shall be in United States currency.

Wire Instructions:

Exhibit C
Minimum Purchase Requirement

Minimum Purchase Requirement - Minimum purchase order amount for each purchase order from Distributor is: TBD

**Amendment for Distribution Agreement on June 15, 2017
between Emmaus Life Sciences Inc. and Telcon Inc.**

Emmaus Life Sciences Inc.와 Telcon Inc.는 2017년 6월15일 체결된 Distribution Agreement 중 하기와 같이 내용을 수정 또는 추가함을 합의 한다.

Emmaus Life Sciences Inc. and Telcon Inc. agree to amend or add to the following content in the Distribution Agreement on June 15, 2017.

1. II. 의무에서 다음 16항을 추가한다.

Add the following Paragraph 16 to the obligation.

“16. “제조사”는 부록 A 상 상품에 대해서신약등록을 위한 3차임상TEST를 시작하고, FDA로부터 승인을 받아야만 한다. 제조자가 2017년7월에 FDA 승인받은 신약 ENDARI의 유사적응증으로 임상3차만 하면 신약을 신청 할 수 있다.

“16. The "manufacturer" must commence a third clinical trial for new drug registration for the products in Appendix A and obtain approval from the FDA. It is possible to apply for a new drug only after the third phase of clinical trials,because it is similar to ENDARI, a new drug approved by the FDA in July 2017.”

2. X. 계약기간/계약해제/환불불가 지불액에서 1항을 다음과 같이 수정한다.

계약기간/계약해지/환불불가/지불액에서 제1항을 다음과 같이 수정한다.

2. In the term of a contract/ cancellation / non-refundable payment (X), Section 1 shall be amended as follows.

“1. 본 계약은 발효일로부터 효력을 발생하며 상품등록이 완료된 시점부터 2년간 유효하다. 30일전 서면통지로 해지하지 않으면 자동 1년씩 연장된다.”

“1. This Agreement shall become effective from the effective date and shall be valid for two (2) years from the date the product registration on FDA is completed. If not canceled by written notice 30 days ago, it will be automatically extended by one year.

3. 2. “X.계약기간/계약해제/환불불가 지불액에서 3항에서 다음 (d)를 추가한다.

3. 2. “Add the following (d) in Section 3 of the term of a contract/ cancellation / non-refundable payment (X).

“(d) “제조사”가 Ⅱ조16항의 의무를 위반하는 경우 발효일로부터 (3) 년 이내에 판매점은 본 계약을 해지할 수 있다.”

In the event that the "Manufacturer" breaches the obligations of Article Ⅱ Section 16, the distributor may terminate this contract within three years from the effective date.

4. XIII 보상에서 2항에서 다음 (f)를 추가한다.

In paragraph 2 of the compensation (XIII), the following (f) is added.

“(f) “제조사”가 FDA 승인을 받지 못하여 “판매점”이 X조 3에 따라 판매점이 본 계약을 해지하면 “제조사”는 Ⅱ 1 에 따라 수령한 금액과 기타 발생한 손해를 배상한다.”

If the "manufacturer" is not approved by the FDA and the "distributor" terminates agreement under Article X Section 3, the "manufacturer" shall reimburse the amount received .

계약당사자는 2부를 발행하여 각1부씩 보관한다.
The parties to the contract shall issue two copies and keep one copy each.

2018년 01월11일
January 11, 2018

“EMMAUS LIFE SCIENCES INC”
BY: /s/ WILLIS C LEE
NAME: WILLIS C LEE
TITLE : COO/VICE CHAIRMAN

“TELCON INC”
BY: /s/ Ji Hoon Kim
NAME: Ji Hoon Kim
TITLE: CEO

Raw Material Supply **Agreement**

**Pharmaceutical Grade L-glutamine
(PGLG)**

Emmaus Life Sciences, Inc.

Telcon Inc.

Raw Maerial Supply Agreement

This Agreement (this "Agreement"), is made by and between Emmaus Life Sciences. Inc. (hereinafter called "Manufacturer") and Telcon Inc. ("Supplier") in order to clarify the contractual rights and obligations between the parties regarding the supply of pharmaceutical grade L-glutamine ("PGLG").

I. PURPOSE

The purpose of this Agreement is to provide the necessary details in Supplier's supplying PGLG to Manufacturer and to promote mutual benefit.

II. DUTIES

1. Supplier's duties are as follows:
 - 1) Supplier shall supply PGLG to Manufacturer.
 - 2) Supplier shall use its reasonable best efforts to assure the quality of PGLG.
 - 3) Supplier shall provide necessary information requested by Manufacturer to solve problems regarding PGLG quality and reasonable best efforts to cooperate with Manufacturer.
2. Manufacturer's duties are as follows:
 - 1) Manufacturer shall produce, promote, distribute, and sell products made from PGLG
 - 2) Manufacturer shall investigate, accept, and resolve problems which arise in distribution and sales processes
3. Each party shall conduct its business, including, but not limited to the obligations set forth herein, in a professional and lawful manner and otherwise in a manner that does not violate the terms of this Agreement. When issues which have not been agreed upon arise, two companies shall resolve the issues in good faith.

III. SUPPLY ITEM TYPE / PRICE

1. The specification of the quantity, standard, and price of PGLG with which Supplier provides Manufacturer shall be as set forth in Exhibit (Annex to this Agreement), and Supplier shall clearly indicate contents required by the relevant laws, such as the characteristics and the use of PGLG, how to use it, cautions, and others.
2. If there is fluctuations of manufacturing costs (more than 10%) due to political, economic, social conditions such as changes in the raw material cost, insurance price, economic situations, Manufacturer and Supplier can readjust the supply price after a written consultation.

IV. PAYMENTS

1. Within 30 days after the completion of the delivery of PGLG, Manufacturer shall make payment to the account designated by Supplier.
2. If Manufacturer fails to fulfill the payment by the payment date set forth in the Paragraph 1 above, Manufacturer shall pay Supplier 5% annual delay interest rate calculated on a daily basis.

V. DUTY OF CARE

1. Supplier shall use its reasonable best efforts in the contract with Manufacturer by managing PGLG permissions and producing PGLG in good faith during the term of the contract.

VI. TERM

1. This Agreement shall become effective as of the contract start date and shall remain in effect for five (5) years (the "Term").
2. Manufacturer and Supplier shall give a written notice to the other party three (3) months prior to the contract end date if the party does not wish to renew this Agreement.
3. The Term may renew for additional one (1) year periods unless terminated by either party by a written notice as set forth in Paragraph 2, and it is valid for 15 years. If either party has requested the other party to change the terms and conditions of this Agreement in a written form, Manufacturer and Supplier may change the terms and conditions of this Agreement by mutual agreement.

VII. ORDERS/DELIVERY

1. Manufacturer shall order PGLG from Supplier by submitting a written purchaser order identifying the product name, standard, quantity, and place of delivery and any other information sixty (60) days before the delivery date.
2. Manufacturer shall submit a purchaser order after a prior consultation with Supplier, and Supplier shall deliver PGLG to the place of delivery in the United States designated by Manufacturer (or another place designated by Manufacturer) within 60 days from the receipt of the purchase order. However, if the delivery is delayed, Supplier shall notify Manufacturer of the reasons for delay and the delivery schedule shall be adjusted by mutual consultation.
3. The delivery date shall be the date on which PGLG enter into the place designated by Manufacturer, by Supplier.
4. Supplier shall deliver PGLG requested by Manufacturer in a written purchase order to the place in the United States designated by Manufacturer, and Manufacturer shall pay the additional expenses in the case where the designated place is a different place.
5. Manufacturer shall notify Supplier of the expected order quantity for the next 6 months.

VIII. QUALITY CONTROL / RETURNS

1. Supplier shall warrant that PGLG is managed in accordance with the cGMP regulations and other national and international regulations.
 2. Supplier shall be responsible for the management of the delivery and the delivery processes. Supplier shall bear the responsibility and expenses for return, exchange, and disposal due to the problems in the delivery process, and Manufacturer shall be responsible for storage and distribution after the delivery of PGLG and general returns in the distribution processes.
 3. Manufacturer shall accept the problems of PGLG which has been delivered and resolve the consumer complaints arising from the distribution and sales processes as the responsibility of Manufacturer, but if there is a reasonable cause that Manufacturer cannot resolve the problems about PGLG due to the lack of information and others, Supplier shall provide Manufacturer with information necessary to resolve the problems as requested by Supplier.
-

4. Manufacturer shall complete the inspection within 15 days after the completion of delivery by Supplier, and Manufacturer may request a return or replacement of damaged or defective PGLG delivered by Supplier in a written form within one month after the receipt of PGLG. Manufacturer shall not require Supplier to exchange or return PGLG if Manufacturer failed to notify Supplier in a written form within the allowed period or if the problems was caused due to the negligence of Manufacturer.

IX. CANCELLATION

1. If Supplier or Manufacturer breaches, in any material respect, any of its representations, warranties or covenants hereunder, or fails to meet any other of its material obligations hereunder without reasonable cause, Manufacturer or Supplier shall notify the other party of the action or the fulfillment of the breach, and if such breach or failure is not cured within thirty (30) days after the receipt of the notice of such breach, this Agreement and the annex to this Agreement may be terminated in whole or in part.
2. The following events shall constitute grounds for termination of this Agreement and the annex to this Agreement in whole or in part without a prior notification by either party.
 - 1) If the other party is forcibly seized, seized provisionally, disposed, or auctioned by a third party or has filed bankruptcy, Vergleich, or commencement of company reorganization procedure.
 - 2) If the other party is defaulted or suspended from the bank
 - 3) If this Agreement shall not be continued due to the Authority or related laws
 - 4) If this Agreement shall not be continued because force majeure such as natural disasters, riot, war, large fire, and blackout persists for more than 6 months
3. The termination under the provisions of Paragraph 1 and Paragraph 2 shall be in a written form to the other party.
4. The termination under Paragraph 2 shall not affect claims for damages.
5. If this Agreement is terminated, Manufacturer shall bear the responsibility for the inventory that it holds as of the date of termination, and Manufacturer shall receive products ordered in written purchase orders submitted as of the termination date and pay for Supplier.
6. The fact that Supplier or Manufacturer has not claimed or asserted rights regarding violations or defaults shall not be construed as a waiver of the violations or defaults of this Agreement or any future violations or defaults of this Agreement.

X. INDEMNIFICATION

If Manufacturer or Supplier breaches this Agreement or any agreement between the two parties and causes damages to the other party, or this Agreement is terminated because of the breach, Manufacturer or Supplier shall compensate the other party for the full amount of the damages.

XI. PROHIBITION OF TRANSFER OF RIGHTS AND OBLIGATIONS

Manufacturer and Supplier shall not transfer, collateralize, lend, or dispose of all or part of the rights and obligations set forth in this Agreement to a third party, without a prior written consent from the other party.

XII. NONDISCLOSURE

1. In order to facilitate the supply of PGLG, Manufacturer and Supplier shall provide mutually beneficial technical information and data if necessary, and treat them as strictly confidential.

2. Supplier shall not disclose the technical information and other important information regarding the contents of this Agreement, the supply of raw materials, and the quality control of PGLG provided by Manufacturer to a third party.
3. "Confidentiality" as defined in Paragraph 1 and Paragraph 2 shall be supplied as a mutual document, in which case the word "confidential" shall be inserted in the document.

XIII. COMPETENT COURT

If a dispute arises regarding this Agreement, Manufacturer and Supplier shall resolve the dispute on the basis of mutual trust, but unless an agreement is reached, the California courts of the United States of America shall be the court having exclusive jurisdiction under the California law as applicable law.

XIII. SPECIAL PROVISIONS

The matters not specified in this Agreement shall be in conformity with general and customary terms.

In order to prove the establishment of the above Agreement, two (2) copies of this Agreement shall be completed, signed and sealed, and Manufacturer and Suppliers shall keep each copy.

July 12, 2017

Emmaus Life Sciences. Inc.
21250 Hawthorne Blvd., Suite 800
Torrance CA 90503, USA

Signature: /s/ Willis Lee

Name: Willis C. Lee

Title: COO and CFO

Telcon Inc.
684 Dongtangiheung-ro, Giheung-gu
Yongin-si, Kyungki-do 17102, Korea

Signature:

Name: Baxon Kim

Title: Chairman, CEO

<Exhibit: Annex to the Agreement>

The annex to this Agreement (hereinafter called this "Annex") regarding PGLG supply is made by and between Emmaus Life Sciences, Inc. ("Manufacturer") and Telcon Inc. ("Supplier")

1. API Name: Pharmaceutical Grade L-glutamine (PGLG)
2. Unit price: USD 50.00/Kg
3. Quantity to be ordered: 940,000 Kg(Total supply amount USD47,000,000)
4. Terms and conditions
 - A. Conditions for establishment: the contract for this item is made by agreement on this Annex between the parties.
 - B. Term of agreement: This Agreement shall become effective as of the signing date and shall remain in effect for five (5) years. The Term will be automatically renewed for additional one (1) year periods unless terminated by either party with a written notice, and valid for total 15 years.
 - C. Ordering unit: 1 Batch
Ordering management: Manufacturer shall notify Supplier in writing of the expected order quantity for six (6) months, and shall notify Supplier in writing of the supply request quantity two (2) months before the date of requested delivery date.
 - D. Packaging unit: 25 Kg
 - E. Terms of payment: Within 30 days after the completion of the delivery of PGLG, Manufacturer shall make payment to the account designated by Supplier.
 - F. Other
 - i. The confidentiality established by documents and mutual agreement shall be mutually protected by the two companies.
 - ii. The two parties shall establish mutual strategic cooperation system to exchange information and cooperate with each other.
 - iii. The incurred costs not specified in the Agreement shall be settled at the actual cost in consultation between the two companies.
 - iv. The right to this transaction shall not be transferred to a third party.
5. Supplier may adjust the supply price to reflect the increase of raw material prices or the increase rate of production costs.
6. However, when adjusting supply price, prior consultations and coordination between two companies shall be required.

When issues which have not been agreed upon arise, two companies shall resolve the issues in good faith. To prove the contract, two (2) copies of Annex shall be completed, and Manufacturer and Suppliers shall keep each copy.

12th July, 2017

Emmaus Life Sciences, Inc.
21250 Hawthorne Blvd., Suite 800
Torrance CA 90503, USA

Telcon Inc.
684 Dongtangiheung-ro, Giheung-gu
Yongin-si, Kyungki-do 17102, Korea

Signature:

Signature:

Name: Willis C. Lee

Name: Baxon Kim

Title: COO and CFO

Title: Chairman, CEO

API Supply Agreement

This Agreement (this "Agreement"), is made and entered into this 16 day of 6, 2017 (the "Effective Date") by and between Emmaus Life Sciences, Inc., a Delaware corporation with offices at 21250 Hawthorne Blvd., Suite 800, Torrance, California 90503, the United States of America (hereinafter called "Manufacturer") and Telcon Inc., Korea corporation ("Supplier"), with offices at 684, Dongtangiheung-ro, Giheung-gu, Yongin-si, Gyeonggi-do.

The parties hereto agree as follows:

I. ASSOCIATION

Supplier shall act as an API Supplier of Manufacturer's Products as described in attached Exhibit A ("Products") upon the Products being approved to be marketed by U.S. and other regulatory agencies.

II. DUTIES

1. Upon completing the Telcon acquisition agreement by Manufacturer, Manufacturer agrees to purchase from Supplier the minimum quantities of Manufacturer's API needs for its Endari product, as set forth in Exhibit C (the "Minimum Purchase Requirement").

"Supplier" shall pay 36 billion Won (36,000,000,000) to "Manufacturer" by June 19, 2017 in consideration of the supply rights in this agreement.
2. Supplier covenants that all of its activities under or pursuant to this Agreement shall comply, in all material respects, with all applicable laws, rules and regulations. Supplier shall be responsible for obtaining all licenses, permits and approvals which are necessary for the performance of its duties hereunder; provided that Manufacturer shall use its reasonable best efforts to cooperate with Supplier and provide any assistance requested by Supplier in obtaining such licenses, permits and approvals as expeditiously as reasonably practicable.
 - (1) API Supply Quantity
 - Manufacturer shall purchase 25% or more of raw API material from Supplier every year for 15 years, and Manufacturer directly takes all actions.
 - Manufacturer guarantees that Supplier receives more than annual revenue of USD 5 million (US\$ 5,000,000) and annual profit of USD 2.5 million (US\$2,500,000) starting year 2018. The cumulative calculations shall be made on December 31 each year.

(2) Manufacturer shall provide a security for revenue and profit targets as follows:

- Manufacturer provides new stocks obtained in Article 3 and all common stocks of KPM TECH to Supplier as a collateral to secure annual revenue and profit targets in Article 2 . In the event that annual revenue and profit targets are not met, “Supplier” may sell a part of new stocks or KPM TECH stocks to cover for the shortfall, provided that a method of collateral pledge and disposition shall be decided by Board of Director of Supplier.
- The duration of the collateral pledge shall be until Supplier has received cumulative profit equaling 36 billion Won (36,000,000,000). However, the pledged KPM TECH stocks shall be released to Manufacturer when the first USD \$5,000,000 revenue and USD \$2,500,000 profit are reached.

(3) Manufacturer’s obligations related to the above (1), (2)

Annual sales amount up to US\$5,000,000	---	50%
Annual sales amount from US\$5,000,000 to US\$10,000,000	---	40%
Annual sales amount from US\$10,000,000 to US\$20,000,000	---	35%
Annual sales amount more than US\$20,000,000	---	30%

3. Each party shall conduct its business, including, but not limited to the obligations set forth herein, in a professional and lawful manner and otherwise in a manner that does not violate the terms of this Agreement.

III. ORDERS/ACCEPTANCE/PRICE AND TERMS

1. Manufacturer shall order API from Supplier by submitting a written purchaser order on a form specified by Manufacturer identifying the Products ordered, requested delivery date(s) and any export/import information required to enable Supplier to fill the order; provided, that nothing in such purchase order forms shall be construed to modify or amend the terms and conditions of this Agreement, and, in the case of any conflict therewith, the terms and conditions of this Agreement shall control. Price lists shall be as set forth in Exhibit B in effect on date of shipment.

2. Supplier will invoice Manufacturer upon completing the order. Supplier shall be responsible for freight shipping and insurance costs, U.S. customs duties and taxes and any other charges imposed by U.S. Governmental Authorities.

IV. TERM/CANCELLATION

1. This Agreement shall become effective as of the Effective Date and shall remain in effect for 15 years (the "Term"). Thereafter the Term may renew for additional one (1) year periods unless terminated by either party by written notice given no less than thirty (30) days prior to the date of renewal of the Term.

2. The following events shall constitute grounds for termination by Manufacturer:

(a) if Supplier shall file or have filed against it a petition in bankruptcy or insolvency or if Supplier shall make an assignment for benefit of its creditors or if Supplier's viability as a going concern should, in Manufacturer's sole judgment, become materially and adversely impaired, in which event Manufacturer may terminate this Agreement by giving written notice to Supplier and such termination shall be effective immediately upon delivery of such notice;

(b) if Supplier materially degrades or places in bad repute the name and reputation of Manufacturer (as supported by evidentiary documentation);

(c) if Supplier breaches, in any material respect, any of its representations, warranties or covenants hereunder, or fails to meet any other of its material obligations hereunder, and such breach is not cured within thirty (30) days after receipt of notice of such breach;

3. The following events shall constitute grounds for termination by Supplier:

(a) if Manufacturer shall file or have filed against it a petition in bankruptcy or insolvency or if Manufacturer shall make an assignment for benefit of its creditors or if Manufacturer's viability as a going concern should, in Supplier's sole judgment, become materially and adversely impaired, in which event Supplier may terminate this Agreement by giving written notice to Manufacturer and such termination shall be effective immediately upon delivery of such notice;

(b) if Manufacturer materially degrades or places in bad repute the name and reputation of Supplier (as supported by evidentiary documentation); or

(c) if Manufacturer breaches, in any material respect, any of its representations, warranties or covenants hereunder, or fails to meet any other of its material obligations hereunder, and such breach is not cured within thirty (30) days after receipt of notice of such breach.

4. Termination of the Agreement shall be without prejudice to any rights or claims of the terminating party for any breach and such terminating party's right to recover damages, loss and all sums payable under this Agreement.

V. NONDISCLOSURE

All information disclosed, transferred or otherwise revealed to Supplier or Manufacturer (the "Receiving Party") by the other party (the "Disclosing Party") under this Agreement, including but not limited to, engineering information, manufacturing information, technology, know-how and price books or lists, shall at all times remain the Disclosing Party's sole and exclusive proprietary and confidential property and information. The Receiving Party shall at all times hold such information confidential and shall not disclose any such information (a) if not otherwise within the public domain, other than as a result of the Receiving Party's violation of any of the terms hereof, (b) unless such information is required to be disclosed pursuant to any applicable law, rule or regulation or requested by any Governmental Authority or (c) other than to the Receiving Party's agents and representative who need to know such information in connection with the performance of the Receiving Party's obligations under this Agreement and who are bound by obligations of confidentiality at least as stringent as those set forth herein. The Receiving Party shall use such information only as required for the performance of its obligations under this Agreement and for no other purpose. Upon any termination or expiration of this Agreement in accordance with the terms hereof, or as the Disclosing Party directs from time to time, the Receiving Party shall promptly return to the Disclosing Party or destroy all such information together with any copies or reproductions thereof. The parties' obligations under this section shall survive any termination or expiration of this Agreement

VI. CERTAIN PRACTICES

Supplier acknowledges that certain laws of the United States applicable to the Manufacturer, including but not limited to the Foreign Corrupt Practices Act of 1977 (15 U.S.C. §§ 78dd-1, *et seq.*) and export control laws, but which may not be applicable to Supplier, impose fines or penalties on Manufacturer in the event Manufacturer makes payments to foreign government officials for the purpose of influencing those officials in making a business decision favorable to Manufacturer. In addition, Manufacturer and Supplier may be subject to similar laws or requirements of the country of destination of the Products.

Supplier and Manufacturer shall not take any actions or omit to take any actions that may cause liability to the other party under the above mentioned laws. Without limiting the generality of the foregoing, in performing the services contemplated by this Agreement, Supplier (i) agrees that Supplier has not and shall not, directly or indirectly, offer to make, promise, authorize or accept any payment or anything of value, including bribes, gifts and/or donations to or from any public official, regulatory authorities or anyone else for the improper purpose of influencing, inducing or rewarding any act, omission or decision in order to secure an improper advantage, including to obtain or retain business, and (ii) shall comply with all applicable anti-corruption

and anti-bribery laws and regulations. Supplier shall notify Manufacturer or its representatives or agents immediately upon becoming aware of any breach under this Section. For the purpose of ensuring compliance with applicable anti-bribery laws and regulations, Supplier agrees that Manufacturer or its representatives or agents shall have the right to conduct an investigation or audit during the term of this Agreement to monitor compliance with the terms of this Section. Supplier shall cooperate fully with such investigation or audit, the timing of which shall be at the sole discretion of Manufacturer.

VII. INDEMNIFICATION

1. Supplier shall indemnify, defend, and hold Manufacturer, its subsidiaries and Affiliates and their respective officers, directors, shareholders, employees, and agents (collectively, "Supplier Indemnitees") harmless against any and all liabilities, suits, claims, proceedings, costs, fines, penalties, and expenses ("Losses") brought or threatened against any such Supplier Indemnitee, whether known or unknown, contingent or otherwise, to the extent attributable to:

(a) any untruth, inaccuracy, misrepresentation, or breach of any warranty, representation, covenant, or agreement made by Supplier in this Agreement;

(b) the distribution, marketing, advertisement, promotion or sale of any of the Products by Supplier in the Territories after the Effective Date, whether during or after the Term of this Agreement, including but not limited to errors in translation of technical manuals, advertising and marketing information, or other materials with respect to the Products, but not however, with respect to the use of the Products (including, without limitation, any Claims (as defined below) based on, arising out of or relating to product liability), except to the extent that such use was in any way encouraged by Supplier but inconsistent with Product Registrations and/or the instructions provided by Manufacturer to Supplier pursuant to Section III(2) hereof, on Manufacturer's brochures, inserts, labels or other documentation provided to Supplier; or

(c) infringement of a third party's intellectual property rights by Supplier, except to the extent such infringement was caused by Supplier's exercise of any of the rights granted by Manufacturer to Supplier in this Agreement, including the right to distribute, market, advertise, promote or sell Products under this Agreement, or by Supplier's breach of this Agreement.

Supplier shall pay all litigation costs, reasonable attorney's fees, settlement payments, and such damages awarded or resulting from any such suit, claim or proceeding (collectively, "Claims").

2. Manufacturer shall indemnify, defend, and hold Supplier, its subsidiaries and Affiliates and their respective officers, directors, shareholders, employees, and agents (collectively, "Manufacturer Indemnitees") harmless against any and all Losses, whether known or unknown, contingent or otherwise, to the extent attributable to:

(a) any untruth, inaccuracy, misrepresentation, or breach of any warranty, representation, covenant, or agreement made by Manufacturer in this Agreement;

(b) the distribution, marketing, advertisement, promotion or sale of any of the Products by Manufacturer, its Affiliates or any third party with whom Manufacturer has a direct or indirect agreement (whether oral or written) to distribute, manufacture, market, advertise, promote, sell, import, export or otherwise deal in the Products, excluding any third party who is a subSupplier of Supplier or who otherwise has a distribution relationship with Supplier, solely in its capacity as such, and any use of any of the Products (including, without limitation, any Claims based on, arising out of, or relating to product liability) prior to the Effective Date or following the termination or expiration of this Agreement, except to the extent that such use was in any way encouraged by Supplier but inconsistent with Product Registrations and/or the instructions provided by Manufacturer to Supplier pursuant to Section III(2) hereof, on Manufacturer's brochures, inserts, labels or other documentation provided to Supplier;

(c) the distribution, marketing, advertisement, promotion or sale of any of the Products by Manufacturer, its Affiliates or any third party with whom Manufacturer has a direct or indirect agreement (whether oral or written) to distribute, manufacture, market, advertise, promote, sell, import, export or otherwise deal in the Products, excluding any third party who is a subSupplier of Supplier or who otherwise has a distribution relationship with Supplier, solely in its capacity as such, outside the Territories or inside the Territories, and any use of any such Products inside and outside the Territories that were sold by Manufacturer, its Affiliates or any third party with whom Manufacturer has a direct or indirect agreement (whether oral or written) to distribute, manufacture, market, advertise, promote, sell, import, export or otherwise deal in the Products, excluding any third party who is a subSupplier of Supplier or who otherwise has a distribution relationship with Supplier, solely in its capacity as such (including, without limitation, any Claims based on, arising out of, or relating to product liability), whether sold by Manufacturer, its Affiliates or any third party, prior to, on or following the Effective Date;

(d) infringement of a third party's intellectual property rights by reason of Supplier's exercise of any of the rights granted by Manufacturer to Supplier in this Agreement, including the right to distribute, market, advertise, promote or sell Products under this Agreement; or

(e) manufacture, labeling or packaging of the Products by Manufacturer, its Affiliates or any third party with which Manufacturer has a direct or indirect agreement (whether oral or written) to manufacture, label or package the Products, and any use of the Products (including, without limitation, any Claims based on, arising out of, or relating to product liability). Manufacturer shall pay all litigation costs, reasonable attorney's fees, settlement payments, and such damages awarded or resulting from any such Claim.

Supplier acknowledges and agrees that use of the Product in a manner not authorized by Manufacturer or any unauthorized customizing or modification of any Product, including but not limited to the packaging or labeling of any Product by Supplier or any subSupplier, may provide grounds for Manufacturer to disclaim or reduce its indemnification liabilities.

3. Third Party Claims.

(a) If either Manufacturer or any Supplier Indemnitee, on the one hand, or Supplier or a Manufacturer Indemnitee, on the other hand (in either case, an “Indemnitee”) receives notice or otherwise obtains knowledge of any matter or any threatened matter arising from the claim of a third party that may give rise to an indemnification claim against the party from whom indemnification is sought (the “Indemnitor”), then the Indemnitee shall promptly deliver to the Indemnitor a written notice describing, to the extent practicable, such matter in reasonable detail. The failure to make timely delivery of such written notice by the Indemnitee to the Indemnitor shall not relieve the Indemnitor from any liability with respect to such matter, except to the extent the Indemnitor is actually materially prejudiced by failure to give such notice on a timely basis. The Indemnitor shall have the right, at its option, to assume the defense of any such matter with its own counsel, but only if the Indemnitor simultaneously agrees to indemnify the Indemnitee for such matter.

(b) If the Indemnitor elects to assume the defense of and indemnification for any such matter, then:

(A) notwithstanding anything to the contrary contained in this Agreement, the Indemnitor shall not be required to pay or otherwise indemnify the Indemnitee against any attorneys’ fees or other expenses incurred on behalf of the Indemnitee in connection with such matter following the Indemnitor’s election to assume the defense of such matter, unless (x) the Indemnitor fails to defend diligently the Claim within ten days after receiving notice of such failure from the Indemnitee, (y) the Indemnitee reasonably shall have concluded (upon advice of its counsel) that there may be one or more legal defenses available to such Indemnitee or other Indemnities that are not available to the Indemnitor, or (z) the Indemnitee reasonably shall have concluded (upon advice of its counsel) that, with respect to such claims, the Indemnitee and the Indemnitor may have different, conflicting, or adverse legal positions or interests;

(B) the Indemnitee shall make available to the Indemnitor all books, records and other documents and materials that are under the control of the Indemnitee or any of the Indemnitee’s agents and that the Indemnitor considers necessary or desirable for the defense of such matter, and cooperate in all reasonable ways with, and make its employees and advisors available or otherwise render reasonable assistance to, the Indemnitor and its agents; and

(C) the Indemnitor shall not, without the written consent of the Indemnitee, which shall not be unreasonably withheld or delayed, settle or compromise any pending or threatened Claim in respect of which indemnification may be sought hereunder (whether or not the Indemnitee is an actual or potential party to such Claim) or consent to the entry of any judgment (x) which does not, to the extent that the Indemnitee may have any liability with respect to such Claim, include as an unconditional term thereof the delivery by the claimant or plaintiff to the Indemnitee of a written release of the Indemnitee from all liability in respect of such Claim, (y) which includes any statement as to or an admission of fact, culpability or a failure to act, by or on behalf of the Indemnitee, or (z) in any manner that involves any injunctive relief against the Indemnitee or may materially and adversely affects the Indemnitee.

(c) If the Indemnitor elects not to assume the defense of and indemnification for such matter, then the Indemnitee shall proceed diligently to defend such matter with the assistance of counsel

reasonably satisfactory to the Indemnitor; provided, that the Indemnitee shall not settle, adjust or compromise such matter, or admit any liability with respect to such matter, without the prior written consent of the Indemnitor, such consent not to be unreasonably withheld or delayed. The procedures in this Section XIV(4) shall not apply to direct claims of Manufacturer or its Indemnitees against Supplier or Supplier or its Indemnitees against Manufacturer.

VIII. VARIOUS

1. This Agreement constitutes the entire and only agreement between the Manufacturer and Supplier with respect to its subject matter and there are no understandings or representations of any kind, express, implied, oral, written statutory or otherwise, not expressly set forth herein. All express or implied representations, agreements and understandings, either oral or written, heretofore made are expressly superseded by this Agreement. No alteration or modification of this Agreement shall be binding unless in writing and signed by the all of the parties hereto.

2. Except as otherwise expressly set forth, this Agreement is not assignable in whole or in part by either party without express written consent of the other party; provided, however, that either party may, without such consent, assign this Agreement and its rights and obligations hereunder in connection with the transfer or sale of all or substantially all of its business, or in the event of its merger, consolidation, change in control or similar transaction. This Agreement and the provisions hereof shall be binding upon each of the parties, their successors and permitted assigns. Nothing in this Agreement, whether express or implied, shall be construed to give any person or entity (other than parties hereto and their respective legal representatives, successors and assigns and as expressly provided herein) any legal or equitable right, remedy or claim under or in respect of this Agreement or any covenants, conditions or provisions contained herein, as a third party beneficiary or otherwise; provided, that the Indemnitees who are entitled to indemnification pursuant to who are not otherwise a party to this Agreement shall be third party beneficiaries of this Agreement.

3. This Agreement shall be governed by and interpreted and enforced in accordance with the laws of the State of California, United States of America, without regard to the conflicts of law principles thereof, and the official language of this Agreement for all purposes shall be English.

4. The parties shall attempt to resolve all disputes arising out of or in connection with this Agreement, including disputes or claims relating to the interpretation or application of the provisions of this Agreement (a "Dispute"), through mutual good faith consultations. If any Dispute cannot be resolved by the parties within 30 business days from the date when a party serves a written notice on the other party requesting such good faith consultation, such Dispute shall be resolved by arbitration pursuant to the Rules of Arbitration of the International Chamber of Commerce (the "ICC Rules of Arbitration"). The place of arbitration shall be Los Angeles, California. The arbitration shall be the sole and exclusive forum for resolution of any such Dispute, and the award rendered in such arbitration shall be final and binding. Judgment on the award rendered may be entered in any court having jurisdiction thereof. Notwithstanding, each party hereto acknowledges that money damages would not be an adequate remedy in the event

that certain of the covenants or agreements in this Agreement are not performed by the parties in accordance with their terms, and it is therefore agreed that in addition to and without limiting any other remedy or right each party may have, each party will have the right to an injunction, temporary restraining order or other equitable relief in any court of competent jurisdiction enjoining any such breach and enforcing specifically the terms and provisions hereof.

5. Should any provision of this Agreement be found to be void, invalid, or unenforceable by a court of competent jurisdiction, that finding shall only affect the provisions found to be void, invalid, or unenforceable and shall not affect the remaining provisions of this Agreement.

6. No waiver of any breach of any agreement or provision herein contained shall be deemed a waiver of any proceeding or succeeding breach thereof or of any other agreement or provision herein contained. No extension of time for performance of any obligations or acts shall be deemed an extension of the time for performance of any other obligations or acts.

7. Should any party institute any action or proceeding (including arbitration) to enforce this or any provision hereof or for damages by reason of any alleged breach of this Agreement or of any provision hereof or for a declaration of rights hereunder, the substantially prevailing party in any such action or proceeding shall be entitled to receive from the other party all costs and expenses, including reasonable attorneys' fees, incurred by the prevailing party in connection with such action or proceeding.

8. The parties agree to do such further acts and things to execute and deliver such additional agreements and instruments as the other may reasonably be required to consummate, evidence or confirm the agreements contained herein in the manner contemplated hereby.

To Supplier: Telcon Inc.
 684, Dongtangiheung-ro,
 Giheung-gu, Yongin-si, Gyeonggi-do

Korea

 Attention:
 Fax No.: 82-2-515-8804

To Manufacturer: Emmaus Life Sciences, Inc.
 21250 Hawthorne Blvd., Suite 800
 Torrance, California 90503
 United States of America
 Attention: _____
 Fax No.: 310-214-0075

9. Counterparts. This Agreement may be executed in counterparts and by facsimile, each of which shall be deemed an original but all of which together shall constitute but one and the same instrument

MANUFACTURER:
Emmaus Life Sciences, Inc.
_____/s/ Willis Lee_____
By: Willis Lee Date
Title: COO

SUPPLIER:

By: Date
Title:

Exhibit A

Product: bulk containers of Pharmaceutical Grade L-glutamine (API) for Sickle Cell Disease treatment

Exhibit B

API Price List in US Dollars

Product	Supplier Price
25 kg container of Pharmaceucal Grade L-glutamine for SCD treatment	\$1250 (\$50 per kg)

Minimum order amount for each purchase order from Supplier is: TBD

Expected delivery of Product is _____ days from the purchase order.

Freight charges will be paid by Supplier.

Wire Instructions:

Exhibit C
Minimum Purchase Requirement

Minimum Purchase Requirement - Minimum purchase order amount for each year from Supplier is: 25% of Manufacturer's total needs (annual basis) for its Endari product.

추 가 합 의 서
ADDITIONAL AGREEMENT

본 추가합의서는 대한민국에 소재한 1) [주식회사 에버코어인베스트먼트홀딩스(구 텔콘홀딩스(주))(이하 “에버코어”)], 2) 주식회사 텔콘알에프제약(구 주식회사 텔콘, 이하 “텔콘”) 및 미합중국에 소재한 3) Emmaus Life Sciences, Inc. (이하 “엠마우 스”)간에 2018. 7. 2. 체결되었다.

This ADDITIONAL AGREEMENT (this “**Agreement**”) is made as of July 2, 2018 by and among (1) Evercore Investment Holdings Co., Ltd. (formerly Telcon Holdings Co. Ltd., “**Evercore**”), a company with its place of business in the Republic of Korea (“**Korea**”), (2) Telcon RF Pharmaceutical Inc. (formerly Telcon Inc., “**Telcon**”), a company with its place of business in Korea and (3) Emmaus Life Sciences, Inc. (“**Emmaus**”), a company with its place of business in U.S.A.

에버코어, 텔콘 및 엠마우스(이하 총칭하여 “당사자들”)는 아래와 같이 본 추가합 의서의 내용에 대하여 합의한다.
Evercore, Telcon and Emmaus (collectively, the “**Parties**”) hereby agree as follows:

제 1 조 [목적]

ARTICLE 1 OBJECTIVE

본 추가합의서는, (1) 당사자들 간에 체결된 (i) 2017. 6. 12.자 경영권인수계약서, (ii) 2017. 9. 29.자 합의서 및 (iii) 텔콘과 엠마우스 간에 체결된 2017. 6. 16.자 API Supply Agreement(이하 (i), (ii), (iii)을 총칭하여 “기존 계약”)에 따른 당사자들의 법 률관계를 명확 하게 하고, (2) 현재 텔콘이 소유한 엠마우스 주식 및 엠마우스가 보유한 주식회사 케이피엠테크(이하 “케이피엠테크”) 주식의 처 리방법을 정하기 위하여 체결한다.

This Agreement (1) clarifies the rights and obligations of the Parties under (i) the Management Control Acquisition Agreement by and among the Parties dated as of June 12, 2017 (the “**MCSA**”), (ii) the Agreement by and among the Parties dated as of September 29, 2017 (the “**9/29 Agreement**”) and (iii) the API Supply Agreement by and between Telcon and Emmaus dated as of June 16, 2017 (the “**API Supply Agreement**”), (contracts under (i), (ii) and (iii) collectively referred to as “Existing Contracts”) and (2) sets forth the matters related to the disposal of the shares of Emmaus owned by Telcon and the shares of KPM Tech Co., Ltd. (“**KPM Tech**”) owned by Emmaus.

제 2 조 [게실병 치료제의 호주 판권관련 합의내용 해지]

ARTICLE 2 TERMINATION OF AGREEMENT ON THE DISTRIBUTION RIGHT FOR DIVERTICULOSIS TREATMENT IN AUSTRALIA

텔콘과 엠마우스는 2017. 9. 29.자 합의서 제3조[게실병 치료제의 아시아 판권 잔금

지급] 제2항을 이행하기 위하여 게실병 치료제 호주 판권의 가치에 대한 외부평가를 진행하였으며, 외부평가금액 한도 내에서 상호 협의하여 가치를 산정하여 계약을 체결하려고 노력하였으나, 당사자들간 상호 협의가 이루어지지 않음에 따라, 본 추가합의서를 통하여 게실병 치료제의 호주 판권 계약을 체결하지 않는 것으로 합의한다. 당사자들은 텔콘과 엠마우스가 더 이상 게실병 치료제 호주 판권에 관한 계약을 협상하거나 체결할 의무를 부담하지 않는다는 점을 확인하며, 이와 관련하여 다른 당사자(들)에게 위 합의서에 규정된 위약벌을 포함한 일체의 책임을 묻지 않기로 한다.

Pursuant to Article 3(2) (Payment of Remaining Consideration for Asian Distribution Right for Diverticulosis Treatment) of the Sep. 29, 2017 Agreement, Telcon and Emmaus conducted appraisal of the value of the Australian distribution right and exercised their best efforts to agree on a value not exceeding the appraisal value. However, the Parties failed to reach an agreement and hereby agree not to enter into a distribution agreement for the distribution right for diverticulosis treatment in Australia. The Parties acknowledge and agree that (i) Telcon and Emmaus have no further obligation to negotiate for or enter into an agreement related to the distribution right for diverticulosis treatment in Australia and (ii) the Parties shall exempt the other Parties from any liability in relation to the said obligation including the penalty provided for in the Sept. 29, 2017 Agreement.

제 3 조 [SCD원료공급 관련 질권변경]

ARTICLE 3 CHANGE OF PLEDGE RELATED TO SCD RAW MATERIAL SUPPLY

1. 2017. 6. 16.자 API Supply Agreement 제2조 제2항 제2호에 따라 엠마우스는 텔콘에 엠마우스가 소유한 텔콘 발행 보통주식 6,643,559주 및 케이피엠테크 발행 보통주식 4,248,720주를 담보로 제공한 바 있으며, 담보제공기한은 텔콘이 위 API Supply Agreement의 별첨(Exhibit A)에 규정된 Product 공급권 취득을 위하여 지급한 360억원과 동일한 금액의 총 매출이익이 텔콘에게 발생된 때까지로 하되, USD 5,000,000 이상의 총매출액과 USD 2,500,000 이상의 총매출이익이 모두 텔콘에게 발생된 때에는 엠마우스 소유 케이피엠테크 주식에 관해 설정된 담보를 해제하기로 한 바 있다.
1. Pursuant to Article 2(2)(ii) of the API Supply Agreement, Emmaus pledged its (i) 6,643,559 common shares of Telcon and (ii) 4,248,720 common shares of KPM Tech to Telcon as collateral. The duration of pledge is until such time as Telcon realizes total profits of KRW 36 billion, which is the amount Telcon paid for the acquisition of supply right for the products set forth in Exhibit A of the API Supply Agreement; provided that, if Telcon achieves total revenue of USD 5,000,000 or more AND total profit of USD 2,500,000 or more, the pledge on KPM Tech shares owned by Emmaus is to be cancelled.
2. 상기 1항과 관련하여, 텔콘은 엠마우스가 담보로 제공한 케이피엠테크 주식

4,248,720주에 대한 질권을 본 추가합의서 체결 즉시 해당주식에 대한 종목 질권에서 해당주식이 입고된 계좌에 대한 질권으로 변경하기로 한다. 단, 이 와 같은 질권 변경은 2017. 6. 16.자 API Supply Agreement의 다른 조항을 변경 하거나 그 밖에 어느 당사자의 의무를 경감시키는 효력을 갖지 아니한다.

2. With respect to Paragraph 1 above, Telcon shall change the pledge on KPM Tech shares owned by Emmaus which were provided by Emmaus as collateral, to a pledge on the account in which the shares are held, immediately upon the execution of this Agreement; provided that such cancellation of pledge shall not have the effect of amending any other provision of the API Supply Agreement, or otherwise reducing the obligations of any Party thereunder.

제 4 조 [텔콘이 소유한 엠마우스 주식의 매각]

ARTICLE 4 SALE OF EMMAUS SHARES OWNED BY TELCON

1. 텔콘은 2017. 9. 29.자 합의서에 따라 케이피엠테크 및 주식회사 한일진공으 로부터 엠마우스 발행 보통주식 4,444,445주를 1주 당 USD 6.60으로 매수하여 소유하고 있는 바, 엠마우스는 본 추가합의서 제3조 제2항에 따라 질권이 설정된 계좌에 입고 되어 있는 케이피엠테크 주식을 2018. 8. 31.까지 합리적 인 가격에 매각하여, 매각대금 중 이백만불을 제외한 금액으로 텔콘이 소유 한 엠마우스 주식을 1주당 매매가액을 USD 7.60으로 하여 매수하기로 하며, 텔콘은 매매대금을 수령하는날 제3조 제2항에 따라 설정된 계좌질권을 해지 하기로 한다. 엠마우스는 2018. 12. 15.까지 매각대금 중 남은 이백만불을 텔 콘 소유의 잔여 엠마우스 주식을 1주당 매매가액을 USD 7.60으로 매수하는 데에 사용하여야 한다.
1. Pursuant to the 9/29/2017 Agreement, Telcon purchased 4,444,445 common shares of Emmaus from KPM Tech and Hanil Vacuum Co., Ltd. at the price of USD 6.60 per share. Emmaus shall exercise its best efforts to sell the KPM Tech shares entered into the pledged account pursuant to Article 3(2) hereof at commercially reasonable prices by August 31, 2018, and to the extent that such sale is actually made, shall use the proceeds from such sale, except \$2,000,000, to purchase Emmaus shares owned by Telcon at the price of USD 7.60 per share, and Telcon shall release the pledge on account effected under Article 3(2) on the date of receipt of the purchase price. Emmaus shall use \$2,000,000 to purchase remaining Emmaus shares at \$7.60 share price by December 15, 2018.
2. 엠마우스는 2018. 10. 31.까지 텔콘이 소유한 엠마우스 주식의 전부 또는 일 부를 1주당 매매가액을 USD 7.60으로 하여 추가로 매수할 권리를 가진다. 엠마우스가 본 항에 따른 매수권을 행사할 경우, 텔콘과 엠마우스 간에는 엠마우스가 매 수권을 행사한 주식에 관해 1주당 USD 7.60의 매매가액으로 주식매매계약이 체결된 것으로 간주되며, 텔콘과 엠마우스 는 그로부터 10일

내에 주식매매계약에 따른 이행을 종결하여야 한다. 2018. 11. 1. 이후에도 엠 마우스는 텔콘이 소유한 엠마우스 주식에 대한 매수권을 보유하되, 다만 그 매매가액은 매수권을 행사한 이후 별도의 외부평가를 거쳐 텔콘과 엠마우스 가 상호 협의한 가격으로 정하기로 한다. 엠마우스는 외부평가기관이 외부 평가에 필요한 자료를 요구하는 경우 적시에 제공하여 최대한 빠른 시간 내 에 주식의 매각이 완료될 수 있도록 노력하여야 한다.

2. Until October 31, 2018, Emmaus shall have a right to additionally purchase all or parts of Emmaus shares owned by Telcon at the price of USD 7.60 per share (the “**Call Option**”). In case where Emmaus exercises the Call Option, a share purchase agreement shall be deemed to have been executed between Telcon and Emmaus in respect of the shares for which Emmaus exercised the Call Option, at the price of USD 7.60 per share, and Telcon and Emmaus shall close the transaction pursuant to such share purchase agreement within ten (10) days thereafter. Emmaus shall continue to have a call option in respect of Emmaus shares owned by Telcon from and after November 1, 2018, provided that the purchase price in such case shall be the price agreed by Telcon and Emmaus based on a separate appraisal process, to be conducted following exercise of such call option. If the appraiser requests information necessary for the appraisal, Emmaus shall exercise its best effort in providing the requested information so that the share sale and purchase can be completed as soon as practicable.
3. 상기 제1항 또는 제2항에 따른 엠마우스 주식 매매가 이루어지는 경우, 텔 콘은 매매대상 엠마우스 주식의 완전한 소유 권을 담보권 등 일체의 제한이 나 부담이 없는 상태로 엠마우스에게 이전하여야 한다. 엠마우스는 엠마우 스 주식의 소유권을 이전 받음과 동시에, 자신의 선택에 따라 매매대금을 미화 또는 원화로 지급하되, 미화를 원화로 환산하거나 원화를 미화로 환산 하는 경우 그 적용환율은 실제 지급일 전날 하나은행(KEB Hana Bank)의 홈 페이지에 최종 게시된 매매기준율로 한다.
3. Upon consummation of the sale and purchase transaction in respect of Emmaus shares pursuant to Paragraph 1 or 2 above, Telcon shall deliver clean title to the Emmaus shares subject to sale and purchase, free and clear of lien, encumbrances and adverse claims including security interests. Simultaneously with the receipt of title to the Emmaus shares, Emmaus shall pay the purchase price in either KRW or USD in its discretion. In case where USD is exchanged for KRW or vice versa, the applicable exchange rate shall be the final basic exchange rate announced on the website of KEB Hana Bank on the day preceding the payment date.
4. 상기 2항에 규정된 매수권과 별도로, 텔콘은 자신이 소유하는 엠마우스 주 식의 전부 또는 일부를 제3자(이하 “양수 인”)에게 매각, 양도 또는 이전(이하 “양도 등”) 하거나, 엠마우스가 나스닥에 상장된 이후 장내매각 하고자 하는 경우, 아래와 같이 엠마우스에게 우선매수권을 보장하여야 한다. 엠마우스의 본 우선매수권은 2019. 6. 30까지 보장된다.

4. In addition to the call options set forth in Paragraph 2 above, if Telcon wishes to sell, assign or transfer (“**Transfer**”) all or part of Emmaus shares owned by Telcon, or sell such shares on the market subsequent to listing of the shares on NASDAQ, Telcon shall grant a right of first refusal (the “**ROFR**”) to Emmaus until June 30, 2019, as follows:
- (a) 텔콘은 자신이 소유하는 엠마우스 주식의 전부 또는 일부를 양도 등을 하고자 하는 경우 (i) 양도 등을 하고자 하는 주식(이하 “양도대상주식”)의 매도의사, (ii) 매매대금, (iii) 매도예정일 및 (iv) 매매대금의 지급방법 등과 같은 매도조건을 엠마우스에게 통지(이하 “매도통지”)하여 엠마우스에게 매도통지에 기재된 매도조건에 따른 양도 대상주식에 관한 우선 매수의 기회를 부여하여야 한다.
 - (a) In case where Telcon intends to Transfer all or part of its Emmaus shares, Telcon shall send a notice (the “**ROFR Notice**”) to Emmaus stating (i) the intention to sell the Emmaus shares subject to transfer (the “**ROFR Shares**”), (ii) the purchase price, (iii) the expected closing date of the sale, (iv) the method of payment of the purchase price, and other material terms of the Transfer, thereby providing a prior opportunity for Emmaus to purchase the ROFR Shares on the terms stated in the ROFR Notice.
 - (b) 매도통지를 받은 엠마우스는 그 수령일로부터 10일(이하 “우선매수권 행사기간”) 이내에 우선매수권을 행사할 것인지 여부를 텔콘에게 통지 하여야 한다. 엠마우스가 우선매수권 행사기간 내에 우선매수권을 행사 한다는 사실을 텔콘에게 통지하지 않는 경우, 엠마우스가 양도대상주식 에 대하여 우선매수권의 행사를 포기한 것으로 본다.
 - (b) Emmaus shall notify Telcon as to whether Emmaus will exercise the ROFR or not within ten (10) days following receipt of the ROFR Notice (the “**ROFR Period**”). If Emmaus does not notify Telcon of its intention to exercise the ROFR within the ROFR Period, Emmaus shall be deemed to have waived its ROFR with respect to the ROFR Shares.
 - (c) 매도통지를 받은 엠마우스가 우선매수권 행사기간 내에 우선매수권을 행사한다는 사실을 텔콘에게 통지한 경우, 매도통지에 기재된 거래조건 에 따라 엠마우스와 텔콘 간에 양도대상주식에 관한 매매계약이 체결 된 것으로 간주되며, 텔콘과 엠마우스는 그로부터 10일 내에 주식매매 계약에 따른 이행을 종결하여야 한다.
 - (c) Following receipt of the ROFR Notice, if Emmaus notifies Telcon of its intent to exercise the ROFR within the ROFR period, a share purchase agreement shall be deemed to have been executed in respect of the ROFR Shares by and between Emmaus and Telcon under the terms set forth in the ROFR Notice, and Telcon and Emmaus shall close the transaction under such share purchase agreement within ten (10) days of such notice by Emmaus.
 - (d) 매도통지를 받은 엠마우스가 우선매수권 행사기간 내에 우선매수권을 행사하지 아니한다는 의사를 표시하거나, 상기 (b)항에 따라 우선매수

권을 포기한 것으로 간주되는 경우, 텔콘은 엠마우스 이외의 제3자에게 매각하는 경우에는 매도통지에 기재된 매도조건과 같거나 그보다 양수 인에게 불리한 조건으로 양도대상주식에 대하여 양도 등을 할 수 있다. 다만 엠마우스가 나스닥에 상장되는 경우, 나스닥상장 이후의 장내매각 하는 경우에는 매도통지에 기재된 매도조건과 관계없이 매각할 수 있다. 단, 제3자에 대한 양도 등이 엠마우스의 매수통지 수령일로부터 30 일 이내에 종결되지 않는 경우 텔콘은 본 항에 규정된 절차를 다시 이 행하여 엠마우스에게 우선매수권 행사 기회를 또 한번 부여하여야 한다.

- (d) Following receipt of the ROFR Notice, if Emmaus notifies Telcon of its intention not to exercise the ROFR within the ROFR Period or if Emmaus is deemed to have waived its ROFR pursuant to paragraph (b) above, Telcon may Transfer the ROFR Shares to a third party other than Emmaus on terms which are equal to or less favorable to the transferee than the terms set forth in the ROFR Notice, provided that, if the Emmaus shares are listed on NASDAQ, any Transfer on the market following the listing may be effected without consideration of the terms set forth in the ROFR Notice. If the transfer to the third party is not closed within thirty (30) days following Emmaus' receipt of the ROFR Notice, Telcon shall repeat the procedures set forth in this Article and grant another ROFR to Emmaus.

제 5 조 [위약벌]

ARTICLE 5 PENALTY FOR BREACH

어느 당사자가 본 추가합의서에서 정한 의무를 위반한 경우 해당 의무의 이행상 대방 당사자에게 금 오십억원을 위약벌로 지급하기로 한다. 단, 텔콘이 제4조 제4 항을 위반하여 제3자에게 엠마우스 주식을 양도하고 그로 인한 매각차익이 금 오 십억원을 초과하는 경우에는 그 매각차익 금액을 위약벌 금액으로 한다.

If any Party breaches any obligation hereunder, the breaching Party shall pay KRW 5 billion as a penalty for breach to the Party to whom such obligation is owed; provided that, if Telcon transfers its Emmaus shares to a third Party in violation of Article 4(4) hereof and the profits from such sale exceed KRW 5 billion, such greater amount shall be the penalty for breach.

제 6 조 [추가 의무]

1. 엠마우스, 에버코어, 텔콘은 기존 계약에 대하여 아무런 이의 제기를 하지 않는다.
1. Emmaus, Evercore, and Telcon shall not make any appeal of the existing contracts.
2. 엠마우스 및 텔콘은 SCD 원료 공급과 관련하여 2017. 6. 16.자 API Supply Agreement 및 본 계약이 규정하는 바에 따라 이행을 하여야 하며, 해당 계약

내용의 변경은 텔콘과 엠마우스의 동의 없이는 불가하다.

2. In relation to the supply of SCD raw materials, Emmaus and Telcon shall perform their respective obligations in accordance with the 6/16/2017 API Supply Agreement and this Agreement, and the terms of said agreements cannot be changed without the mutual agreement of Telcon and Emmaus.
3. 텔콘이 엠마우스와 아지노모토사의 지시에 따라 실행한다는 가정하에, 엠마우스는 텔콘이아지노모토사로부터 제공받은 원료를 [2018]. [8]. [31].까지 엠마우스에게 처음으로 납품할 수 있도록 최대한 협조한다.
3. Provided that Telcon follows the instructions from Emmaus and Ajinomoto, Emmaus shall provide utmost cooperation to enable Telcon to supply the first order of API to Emmaus by August 31, 2018.
4. 2017. 6. 16.자 API Supply Agreement에도 불구하고 엠마우스는 2018년까지 텔 콘의 최소 매출액 \$2,000,000과 최소 매출 이익 \$1,000,000를 보장한다.
4. Notwithstanding the 6/16/2017 API Supply Agreement, Emmaus guarantees Telcon minimum of USD 2,000,000 revenue and USD 1,000,000 profit in 2018.
5. 엠마우스는 관련 법률이 허용하는 한도 내에서 게실병 임상 관련 임상 신청 (IND)에 대한 결과 및 향후 진행사항 그리고 엠마우스의 나스닥 상장과 관련된 정보를 텔콘에게 신속히 제공하여야 한다.
5. To the extent permitted under applicable law, Emmaus shall promptly provide Telcon with the results and progress of the diverticulosis IND and the information related to Emmaus' NASDAQ IPO.

제 7 조 [기타]

ARTICLE 7 MISCELLANEOUS

1. 본 추가합의서는 당사자들이 기명날인 또는 서명한 날로부터 효력이 발생한 다.
1. This Agreement shall be effective as of the date on which the Parties signed or affixed the seals on this Agreement.
2. 본 추가합의서에서 규정한 사항들에 대해서는 본 추가합의서가 당사자들 간 에 체결된 기존 계약에 우선하여 적용된다.
2. With respect to the matters set forth herein, this Agreement shall supersede any prior agreement or contract among the Parties (including the MCSA, the 9/29 Agreement and the API Supply Agreement).
3. 본 추가합의서는 대한민국 법률에 따라 해석된다.
3. This Agreement shall be construed in accordance with the laws of Korea.

4. 본 추가합의서로부터 또는 이와 관련하여 발생하는 제반 분쟁에 대하여는 서울중앙지방법원을 제1심 관할법원으로 한다.
4. Any dispute arising under or related to this Agreement shall be submitted to the jurisdiction of the Seoul Central District Court as the court of first instance.

본 추가합의서는 3부로 작성되며, 본 추가합의서의 체결을 증명하기 위하여 각 당사자의 적법한 대리인이 서명날인한다(단, 한국 당사자의 경우 당사자들의 대표 자들이 각 회사의 법인인감도장을 날인 또는 서명하고 인감증명을 첨부키로 한 다).

IN WITNESS WHEREOF, the Parties have executed this Agreement in three (3) copies by their respective authorized representatives (for Korean Parties, the representatives shall sign or affix the corporate seal with attachment of the Certificate of Seal Impression).

2018년 7월 2일 July 2,
2018

주식회사 에버코어인베스트먼트홀딩스(구. 텔콘홀딩스(주))

주소 : 서울시 강남구 테헤란로 108길 25, 5층(대치동, 대치빌딩) 대표이사 : 김 지
훈 (인)

Evercore Investment Holdings Co., Ltd. (formerly, Telcon Holdings Co., Ltd.)

Address: 5th Floor, 25, Teheran-ro 108-gil (Daechi-dong, Daechi Building), Gangnam-gu, Seoul, Korea

Representative Director: Ji Hoon Kim (Seal)

주식회사 텔콘알에프제약

주소 : 경기도 용인시 기흥구 동탄기흥로 684

대표이사 : 김 지

훈 (인) Telcon RF

Pharmaceutical Inc.

Address: 684, Dongtandgiheung-ro, Giheung-gu, Youngin-si, Gyeonggi-do, Korea Representative Director: Ji Hoon

Kim (Seal)

Emmaus Life Sciences Inc.

주소 : 21250 Hawthorne Blvd. Suite 800 Torrance, CA 90503 CEO : Dr. Yutaka

Niihara (인)

Emmaus Life Sciences Inc.

Address: 21250 Hawthorne Blvd. Suite 800 Torrance, CA 90503 CEO: Dr. Yutaka

Niihara (Seal)

합 의 서(Agreement)

본 합의서는 대한민국에 소재한 1) 주식회사 텔콘알에프제약(구 주식회사 텔콘, 이하 “텔콘”) 및 미합중국에 소재한 2) Emmaus Life Sciences, Inc. (이하 “엠마우스”)간에 2019. 12. 23. 체결되었다.

텔콘 및 엠마우스(이하 총칭하여 “당사자들”)는 아래와 같이 본 합의서의 내용에 대하여 합의한다.

This agreement is executed on December 23, 2019 between 1) Telcon RF Pharmaceutical, Inc. (formerly Telcon Co., Ltd. And herein “Telcon”) in Republic of Korea and 2) Emmaus Life Sciences, Inc. (“Emmaus”) in the United States of America.

Telcon and Emmaus (herein “Parties”) hereby agree to each of the following:

제 1 조 [목적]

본 합의서는 당사자들간에 2019.12.23. 자로 체결된 확약서(이하 “확약서”)라고 하며 본 합의서에서 달리 정의되지 않는 한 각 용어의 정의는 “확약서”에서 정해진 바에 따름)에 따라 본건 질권을 종목질권에서 계좌질권으로 변경함에 따라 엠마우스가 보유한 텔콘 주식 처리방법 및 당사자들의 이행사항을 정하기 위하여 체결한다.

Article 1 [Objective]

In accordance with the December 23, 2019 Letter of Commitment (“Commitment Letter”), this agreement follows the definition of terms in the Commitment Letter and is entered to determine the handling of Telcon shares held by Emmaus and the Parties’ responsibilities upon changing the pledge on shares to the pledge on account.

제 2 조 [텔콘 발행 신규 전환사채의 취득]

1. 엠마우스는 확약서 제2조에 따라 계좌질권이 설정된 계좌에 입고되어 있는 텔콘 주식을 합리적인 가격에 매각하게 될 경우, 매각 대금 중 360억원으로은 텔콘이 신규로 발행할 사모전환사채(이하 “본건 신규전환사채”)를 인수하기로 하며, 인수대금 납입 완료에 따라 취득한 본건 신규 전환사채를 텔콘에 다시 담보로 제공하고 질권을 설정 하기로 한다. 단, 360억원과 매각대금의 차액은엠마우스가 사용하기로 하며, 텔콘 주식 매각과 본건 신규전환사채 인수대금 납입, 그 차액의 엠마우스 지급과 관련하여 계좌질권에 대한 해지와 설정 등의 절차는 동부증권과 협의하여 업무

에 차질 없도록 진행하기로 한다.

1. In order to facilitate Emmaus' sale of Telcon shares pursuant to Paragraph 2 of the Commitment Letter, the Parties will establish a brokerage account (the "Account") with DongbuSecurities into which the Telcon shares will be deposited. Upon the conclusion of Emmaus' sale of Telcon shares the Parties agree that KRW 36 billion of the net sale proceeds will be surrendered to Telcon in exchange for a new convertible bond of Telcon with a face amount equal to the market value of such Telcon shares and the balance of the net sale proceeds will be released to Emmaus free and clear of any pledge, encumbrance or restriction. The new convertible bond shall be pledged as a collateral under the API Supply Agreement. The termination of the pledge, the establishment of the Account, the sale of the Telcon shares, the payment of KRW 36 billion for the convertible bond, and the payment of the remaining net sale proceeds to Emmaus will be conducted in consultation with Dongbu Securities.

2. 본건 신규전환사채의 발행조건은 표면이자 2.1%, 만기보장수익률 2.1%, 만기 10년으로 하되, 세부사항은 추후 협의하기로 한다.

2. The new convertible bond shall bear 2.1% interest rate, 2.1% guaranteed return on maturity, and shall have a 10- year term. The bond shall be convertible at Emmaus option into Telcon shares on customary terms at a conversion price to be determined. Other conditions shall be negotiated in the future.

제 3 조 [콜옵션]

본건 신규전환사채와 관련하여 사채발행에 따른 인수계약서 체결 시 사채권면금액의 50%에 대한 콜옵션을 발행회사 또는 발행회사가 지정하는 자에게 부여하기로 하며, 콜옵션 행사가는 사채권면금액으로 하기로 한다. 이외 콜옵션에 관한 세부 사항은 추후 협의하기로 한다.

Article 3 [Call Option]

In accordance with Article 2 above, Emmaus shall grant the call option on 50% of the debenture amount to the issuer or the issuer's designated party. Additional details shall be determined by the Parties in the future.

제 4 조 [엠마우스가 보유한 텔콘 주식의 매각]

1. 엠마우스는 자신이 보유한 텔콘 주식을 매각할 경우 비보존, 이두현, 이두현 또는 비보존과 이해관계가 있는 자에게 매각할 수 없다. 단, 장내매각은 예외로 하며, 시간외 대량매매(통칭 "블럭딜")의 경우는 텔콘의 서면동의를 받는 경우에 한하여 예외로 한다.

2. 엠마우스는 자신이 보유한 텔콘 주식을 장외에서 제3자에게 매각할 경우, 제3자가 제1항의 매각제한사항을 준수하도록 계약서에 명시하여야 한다.

Article 4 [Sale of Telcon Shares Held By Emmaus]

1. Emmaus may not knowingly sell its Telcon shares to Vivozon, Doo Hyun Lee, or their related parties. Market sale is an exception. Large volume sale through block deal requires a written consent from Telcon.
2. In case of a sale to a third party buyer, its contract should state the sale limitation as in Paragraph 1 above.

제 5 조 [질권해지]

엠마우스는 텔콘에 연간 \$5,000,000의 매출과 \$2,500,000의 매출이익(이하 통칭하여 보장금액”)을 보장하기로 한바, 매년말 기준으로 보장금액이 실현됨을 조건으로 텔콘은 실현된 매출이익에 해당하는 금액만큼 매년 1월말일(공휴일인 경우 익일)에 본건 신규전환사채에 대한 담보를 해지하고 해지된 금액을 엠마우스에게 지불한다.

Article 5 [Termination of Pledge]

Emmaus agreed to guarantee Telcon \$ 5,000,000 sales revenue and \$ 2,500,000 sales profit annually. Provided that the guaranteed amount is realized at the end of each year, Telcon shall reduce the collateral amount by the actual annual sales profit amount and pay Emmaus the reduction amount on January 31 of each following year (the following day if it is a public holiday).

제 6 조 [엠마우스 보유 텔콘 주식에 대한 의결권]

엠마우스는 1) 협약서 제2조에 따라 텔콘 주식을 모두 매도하기 전까지 보유하고 있는 주식 및 2) 본건 신규전환사채를 전환할 경우 보유하게 되는 주식과 관련하여 텔콘의 요청이 있을 경우에는 그 시점에 엠마우스가 보유하고 있는 텔콘 주식에 대한 의결권을 텔콘이 요청하는 바에 따라 행사하여 주기로 한다.

Article 6 [Voting Rights to Emmaus Owned Telcon Shares]

Emmaus agrees to vote: 1) according to Paragraph 2 of this commitment letter until all Telcon shares are sold, the shares held by Emmaus and 2) the shares held by Emmaus, if the convertible bond is converted, in favor of Telcon’s request.

본 합의서는 2부로 작성되며, 본 합의서의 체결을 증명하기 위하여 각 당사자의 적법한 대리인이 서명날인한다(단, 한국 당사자의 경우 당사자들의 대표자들이 각 회사의 법인인감도장을 날인 또는 서명하고 인감증명을 첨부키로 한다).

2019년 12월 23일

주식회사 텔콘알에프제약

주소 : 경기도 용인시 기흥구 동탄기흥로 684

대표이사 : 김 지 훈 (인)

Telcon RF Pharmaceutical Inc.

Address: 684, Dongtandgiheung-ro, Giheung-gu, Youngin-si, Gyeonggi-do, Korea

Representative Director: Ji Hoon Kim (Seal)

Emmaus Life Sciences Inc.

주소 : 21250 Hawthorne Blvd. Suite 800 Torrance, CA 90503

CEO : Dr. Yutaka Niihara (인)

Emmaus Life Sciences Inc.

Address: 21250 Hawthorne Blvd. Suite 800 Torrance, CA 90503



확약서 (Letter of Commitment)

Emmaus Life Sciences, Inc. (이하 “엠마우스”)는 나스닥(또는 NYSE American)에 상장을 진행 중에 있으며, 상장을 위한 순수자본요건을 충족하기 위하여 엠마우스가 보유한 주식회사 텔콘알에프제약(구 주식회사 텔콘, 이하 “텔콘”) 발행 주식을 처분하기를 희망하는 바, 아래의 사항을 당사자들은 각각 확약하기로 한다.

Emmaus Life Sciences, Inc. (“Emmaus”) is in the process of seeking to up-list its common stock on NASDAQ (or NYSE American) and wishes to liquidate the shares of Telcon RF Pharmaceutical Inc. (formerly Telcon Co., Ltd. and herein “Telcon”) held by Emmaus in order to meet the listing requirements. The parties, therefore, hereby agree to each of the following:

1. 엠마우스는 2017. 6. 16.자 API Supply Agreement 제2조 제2항 제2호에 따라 엠마우스가 소유한 텔콘 발행 보통주식 6,643,559주에 대해 텔콘에게 담보(이하 “본건 질권”)로 제공한 바 있으며, 텔콘은 위 API Supply Agreement의 별첨(Exhibit A)에 규정된 Product 공급권 취득을 위하여 지급한 360억원과 동일한 금액의 총 매출이익이 텔콘에게 발생된 때 본건 질권을 해제하기로 합의한 바가 있다.
 1. 6,643,559 shares of Telcon issued to Emmaus were pledged as collateral in accordance with Article 2, Paragraph 2.2 of the June 16, 2017 API Supply Agreement. It was previously agreed that the collateral shall be released when the total cumulative sales profit paid to Telcon reaches KRW 36 billion for the API supply stated in Exhibit A of the API Supply Agreement.
2. 상기 제1조와 관련하여, 본 확약서 날인과 동시에 엠마우스는 대량보유변동보고 지분신고를 약식서식으로 변경하여 지분신고를 하고, 텔콘은 본건 질권을 해당 주식에 대한 종목질권에서 해당 주식이 입고된 계좌에 대한 질권(이하 “계좌질권”)으로 변경하여 주식 매도가 가능하도록 한다. 단, 이와 같은 질권 변경은 기존 계약의 다른 조항을 변경하거나 그 밖에 어느 당사자의 의무를 경감시키는 효력을 갖지 아니한다.
 2. With respect to Paragraph 1 above, Emmaus will file the short form to report its shareholder ownership and become second largest shareholder of Telcon. Telcon shall change the pledge on Telcon shares owned by Emmaus to a pledge on the account (herein “account pledge”) in which the shares are held to enable the stock sale by Emmaus, immediately upon the execution of this commitment letter. Provided, however, that such changes in pledge shall not have the effect of changing other provisions of existing contracts or reducing the obligations of any other party.

본 확약서는 2부로 작성되며, 본 확약서의 날인을 증명하기 위하여 각 당사자의 적법한 대리인이 서명날인한다(단, 한국 당사자의 경우 당사자들의 대표자들이 각 회사의 법인인감도장을 날인 또는 서명하고 인감증명을 첨부키로 한다).
This certificate shall be prepared in two copies, signed by a legitimate representative of each party.

2019년 12월 23 일

확약인

주식회사 텔콘알에프제약
주소 : 경기도 용인시 기흥구 동탄기흥로 684
대표이사 : 김 지 훈 (인)

Emmaus Life Sciences Inc.
주소 : 21250 Hawthorne Blvd. Suite 800 Torrance, CA 90503

/s/ Dr. Yutaka Niihara
CEO : Dr. Yutaka Niihara (인)

주식회사 텔콘알에프제약
제15회 무기명식 이권부 무보증 사모 전환사채 인수계약서
Telcon RF Pharmaceutical, Inc.
15th Bearer-type Interest Purchase Agreement for Unsecured Private Equity Convertible Bonds

발행금액 : 금 삼백억원
(₩30,000,000,000)
Principal Amount: KRW 30,000,000,000

2020. 09. 28.
September 28, 2020

[발행회사]
주식회사 텔콘알에프제약
Issuer: Telcon RF Pharmaceutical, Inc.

[인수인]
Emmaus Life Sciences, Inc. (엠마우스생명과학)
Purchaser: Emmaus Life Sciences, Inc.

전환사채 인수계약서 Convertible Bond Purchase Agreement

주식회사 텔콘알에프제약(이하 “발행회사”이라 한다)은 2020년 09월 28일 개최한 이사회 결의에 의하여 발행하는 권면총액 금 삼백억원 (₩30,000,000,000원)의 제15회 무기명식 이권부 무보증 사모 전환사채(이하 “본건 전환사채”라 한다)에 관하여 Emmaus Life Sciences, Inc.(이하 “인수인”이라 한다)를 인수인으로 하여 다음과 같이 인수계약을 체결한다.

Telcon RF Pharmaceutical Inc. (hereinafter referred to as the “issuer”) issues the 15th unsecured privately held convertible bond for a total of KRW 30 billion (KRW 30,000,000,000) upon the approval of the board of directors held on September 28, 2020 (hereinafter referred to as “the main convertible bond”). Emmaus Life Sciences Inc. (hereinafter referred to as the “purchaser”) is the purchaser, and the agreement is as follows.

- 다 음 - following

제1조 (계약의 목적) Article 1 (Nature of Agreement)

본 계약은 발행회사가 2020년 09월 28일 개최한 이사회결의에 의하여 발행하는 제15회 무기명식 이권부 무보증 사모 전환사채를 인수인이 인수함에 있어 당사자들이 합의한 사항을 명확히 함에

목적이 있다.

The purpose of this Agreement is to clarify what the parties have agreed on the 15th unsecured private equity convertible bond approved by the issuer's Board of Directors on September 28, 2020.

제2조 (정관 등 내용변경) Article 2 (Changes in Bylaws)

발행회사는 본 계약의 성실한 이행을 위하여 사채대금 납입 일의 전일까지 발행회사의 정관 및 내부규정 등 회사 운영에 관한 사항 중 본 계약에 반하는 부분을 본 계약내용에 부합하도록 변경하여야 하며 추후 본 계약이 변경되거나 전환권이 행사되어 변경할 필요가 있는 경우에도 그에 부합하도록 정관 및 내부규정 등을 변경하여야 한다.

In order to faithfully implement this agreement, the issuer shall make necessary changes to the bylaws and internal regulations of the issuing company to comply with the contents of this Agreement. In the event that this agreement is changed in the future or the right of conversion is exercised, the bylaws and internal regulations shall be changed as necessary.

제3조 (진술 및 보장) Article 3 (Statement and Guarantee)

1) 인수인은 발행회사에 대하여 아래와 같이 진술하고 보장한다.

The purchaser makes the following statement and guarantee to the issuer in this paragraph.

① 인수인은 미합중국 법률에 따라 적법하게 설립되어 유효하게 존속 중인 회사다.

The purchaser is a company that is legally established and valid under the laws of the United States of America.

② 인수인은 본 계약의 체결 및 유지를 위하여 인수인이 이행하여야 하는 모든 조치를 취하였다.

The purchaser has taken all measures that the purchaser should perform in order to enter into and maintain this agreement.

③ 인수인은 본 계약을 체결하고 본 계약에 따른 의무를 이행하는데 필요한 법률적 및 사실적인 모든 권한을 보유하고 있다.

The purchaser has all legal and factual rights required to enter into this agreement and to perform any obligations under this agreement.

④ 본 계약에 의한 인수인의 의무는 적법, 유효하고 인수인에 대하여 집행 가능한 법적 의무를 구성한다.

The obligations of purchaser under this agreement are lawful and valid, and they constitute legal obligations.

2) 발행회사는 인수인에게 아래와 같이 진술하고 보장한다.

The issuer makes the following statements and guarantees to the purchaser as below.

① 본 계약 및 본건 전환사채에 관한 사항

Matters on the agreement and convertible bonds

(1) 발행회사는 대한민국 법률에 따라 적법하게 설립되어 유효하게 존속 중인 회사로서 그 자산을 적법하게 소유하며, 상법 등 관계법령 및 정상적인 상관행에 따라 사업을 영위하고 있다.

The issuer, a company duly established and validly existing under the laws of the Republic of

Korea, lawfully owns its assets and engages in business in accordance with related laws and regulations including the Commercial Act and normal business practice.

(2) 발행회사는 본 계약을 체결하고 본 계약에 따른 의무를 이행하는데 필요한 법률적 및 사실적인 모든 권한을 보유하고 있다.

The issuer has all legal and factual rights required to enter into the agreement and perform any obligations under this agreement.

(3) 발행회사는 주주총회 및 이사회 승인을 비롯하여 본 계약의 체결 및 유지를 위하여 발행회사가 이행하여야 하는 모든 조치를 취하였으며, 파산, 지급불능, 회사 정리, 지급유예 및 채권자의 권리에 부정적 영향을 미치는 사실은 없다.

The issuer has taken all required measures for the execution and maintenance of the agreement such as by approving general meetings of shareholders and the board of directors, and the issuer is not in a state of bankruptcy, insolvency, liquidation, moratorium, and/or any fact negatively affects the rights of creditors.

(4) 본 계약에 의한 발행회사의 의무는 적법, 유효하고 발행회사에 대하여 집행 가능한 법적 의무를 구성한다.

The obligations of issuer under the agreement are lawful and valid, and they constitute legal obligations.

(5) 인수인이 본 계약서에 따라 인수하는 본건 전환사채는 적법, 유효하게 발행되었다.

The convertible bond to be purchased in accordance with the agreement by the purchaser have been lawfully and validly issued.

(6) 본 계약의 체결 및 본건 전환사채의 발행은 법률이나 규정 기타 관계법령을 위반하지 아니하며, 발행회사의 정관에 부합하고, 발행회사가 당사자인 계약 또는 기타 의무의 위반을 가져오지 아니한다.

Execution of the agreement and issuance of the convertible bond do not violate laws, regulations and other related statutes. They are in conformity to the issuer's articles of incorporation, and do not cause violation of any agreement or obligation which the issuer is a party to.

(7) 발행회사의 발행주식은 본 계약 체결일을 기준으로 주당 액면가가 금 100원인 보통주 85,377,382주이고, 그 외의 발행주식은 존재하지 아니한다.

Total outstanding shares issued by the issuer are 85,377,382 shares of common stock with a par value of KRW 100 per share as of this date of execution hereof and there exist no additional issued shares.

② 발행회사에 관한 사항 Matters on the Issuer

(1) 발행회사는 설립 이후 본 계약 체결일까지 주식의 발행에 있어서 가장납입을 한 사실이 없으며 발행회사의 주식은 첨부하는 주주명부의 기재와 같고 이를 자신의 계산으로 취득하였거나 가장납입 한 사실이 없다.

The issuer has not been involved in any fraudulent payment for share in connection with its issuance of shares from its incorporation through the execution hereof. The shares of the issuer are as specified in a stockholders' list, and the issuer has not acquired such shares on its own

account or engaged fraudulent payment for share.

(2) 발행회사가 인수인에게 제공하거나 통지한 것을 제외하고는 발행회사의 사업에 중요한 영향을 미치는 것으로서 분쟁의 결과에 따라 발행회사가 본 계약상의 의무를 이행할 수 없을 것으로 우려되는 현재 진행되는 소송, 중재 또는 행정절차 기타 분쟁은 없다.

Except as provided or notified to the purchaser by the issuer, there exist no lawsuit, arbitration, administrative procedures and/or other disputes which have a significant effect on the business of the issuer and are feared to prevent the issuer from fulfilling its obligations hereunder as a result thereof.

(3) 발행회사는 재산 및 기타 유무형의 자산에 관하여 적법한 권리를 보유하고 있고, 발행회사가 알고 있는 한 제3자의 권리를 침해하거나 침해 받고 있지 않다.

The issuer owns legitimate rights with regard to its assets and other tangible or intangible properties, and to the best knowledge of the issuer, such right is not violating or being violated by any third party's right.

(4) 발행회사가 보유하고 있는 모든 특허권 기타 지적재산권, 부동산, 동산, 기계, 차량, 사무실 기기 및 기타 영업에 필요한 모든 권리, 물건 등은 적법하게 발행회사의 소유로 되어 있거나, 발행회사가 사용할 수 있는 권한을 보유하고 있으며, 발행회사가 알고 있는 한 위 소유권 및 사용권을 중대하게 방해할 만한 어떠한 사유도 존재하지 아니하며, 발행회사의 지적재산권은 제3자의 권리를 침해하지 아니한다.

All patents, intellectual property rights, real estate, movable assets, machinery, vehicles, office devices, and any other rights and items for business owned by the issuer are under lawful ownership or license of the issuer. To the best knowledge of the issuer, there exists no cause whatsoever that may materially disturb the aforesaid ownership and license, and the intellectual property right of the issuer does not violate any third party's right.

(5) 발행회사는 발행회사 자신과 발행회사의 시설, 자산, 임차물 및 장비 등과 관련하여 환경관련 법률, 규정 또는 규칙을 중요한 점에 있어 준수하였다.

The issuer, in connection with itself, its facilities, assets, objects leased and equipment, has complied with environment-related laws, regulations or rules while putting great importance thereto.

(6) 발행회사가 제출한 발행회사의 주주명부, 등기부등본, 정관 등의 자료에는 발행회사에 관한 사항이 허위로 기재되거나 중요한 사항이 고의로 누락되지 않았다.

Materials submitted by the issuer such as the shareholders' list, certified copy of register, articles of incorporation do not contain false record or intentional omission of important details about the issuer.

제4조 (선행조건) Article 4 (Prerequisite)

인수인은 다음 각호의 사항이 모두 충족되는 경우에 한하여 제5조에 따라 본건 전환사채에 대한 사채대금을 납입하고 본건 전환사채를 인수하기로 한다.

The purchaser shall pay the principal amount of the convertible bond and take over the convertible bond pursuant to Article 5 only if all of the following Paragraphs are satisfied.

- 1) 본 계약 제3조 제2항에 따른 발행회사의 진술 및 보장이 본 계약 체결일 및 사채대금 납입일 현재 모두 진실하고 정확하며, 중요한 사항이 누락되지 않았을 것
The statements and guarantees of the issuer pursuant to Paragraph 2) of Article 3 of this agreement are true and accurate as of the execution date of this agreement and the payment date of the debenture payment, and no important matters are omitted.
- 2) 본 계약 체결일 이후 사채대금 납입일까지 발행회사의 경영 또는 재무상태에 중대한 악영향을 미칠 수 있는 변동이 없을 것
From the execution date of this agreement until the payment date of the debenture payment, there shall be no change that may have a significant adverse effect on the management or financial condition of the issuing company.
- 3) 사채대금 납입일 현재 발행회사의 본 계약상 의무위반이 없을 것
As of the payment date of debenture payment, there shall be no violation of duty under this agreement.
- 4) 사채대금 납입일 현재 발행회사의 정관 및 이사회 의사록 기타 인수인이 합리적으로 필요하다고 판단하여 요구하는 서류들이 인수인이 만족하는 내용과 형식으로 작성되어 제출될 것
As of the payment date of debenture payment, the articles of incorporation, the minutes of the board of directors, and other documents of the issuing company requested by the purchaser as deemed reasonably required shall be prepared and submitted in the content and format that the purchaser be satisfied.

제5조 (사채발행 및 인수) Article 4 (Issuance and Purchase of Bonds)

인수자 Purchaser	인수금액 Purchase Amount	권종 Volume
Emmaus Life Sciences, Inc. (엠마우스생명과학)	금 삼백억원 (₩30,000,000,000) KRW 30B (KRW 30,000,000,000)	10억원권 25매, 5억원권 10매 25 units of KRW 1B, 10 units of KRW 500M
합계 Total	금 삼백억원 (₩30,000,000,000) KRW 30B (KRW 30,000,000,000)	10억원권 25매, 5억원권 10매 25 units of KRW 1B, 10 units of KRW 500M

- 1) 발행회사는 본 계약 제6조 및 제7조에 정한 조건으로 본건 전환사채의 발행을 결의하고 이를 인수인에 배정하여야 한다.
The issuer shall decide and allocate to issue the convertible bonds to purchaser under the terms and conditions specified in Articles 6 and 7 of this agreement.
- 2) 인수인은 발행회사가 배정한 본건 전환사채를 인수하여야 한다.
The purchaser shall take over the convertible bonds allocated by the issuer.
- 3) 발행회사는 인수인이 사채대금을 납입한 즉시 본건 전환사채를 등록 발행 한다.
The issuer shall register and issue the convertible bonds as soon as the purchaser makes the payment of debenture payment.
- 4) 발행회사는 본건 전환사채를 발행함에 있어서 상법 및 자본시장 과 금융투자업에 관한 법률, 기타 관계법령에 위반되지 아니하도록 이사회결의, 주주총회 결의, 정관변경, 등기 기타 필요한

제반 조치를 취하여야 한다.

In issuing this convertible bonds, the issuer shall take all required measures, such as resolutions of the board of directors, resolutions at the general shareholders' meeting, amendment of the articles of incorporation, registration and other required measures so as not to violate the Commercial Act, the Capital Markets and Financial Investment Business Act, and other related laws.

5) 본건 전환사채의 원리금 지급에 대하여는 발행회사가 전적으로 책임을 진다.

The issuer is fully responsible for the payment of the principal amount and interest of the convertible bond.

6) 인수인은 인수한 본건 전환사채를 상환기일 전에 발행회사의 동의 없이 제3자에게 전매할 수 있다. 전매시 본 계약상 인수인의 권리는 본건 전환사채를 취득하는 당사자에게 자동 승계되는 것으로 한다. 단, 본건 전환사채는 1년 이내에 50인 이상의 자에게 전매하지 아니한다.

The purchaser may resell the purchased convertible bonds to a third party without the consent of the issuer prior to the redemption date. At the time of resale, the rights of the purchaser under this agreement shall be automatically transferred to a third party that purchases the convertible bond. However, this convertible bond shall not be resold to 50 or more persons within one year.

제6조 (본건 전환사채의 발행조건) Article 6 (Terms of Issuance)

본 계약에 따라 발행회사가 인수인에게 발행하는 전환사채(“본건 전환사채”)의 발행조건은 다음과 같다.

The terms and conditions of issuance of this convertible bonds issued by the issuer to the purchaser under this Agreement are as follows.

1) 회사의 상호 : 주식회사 텔콘알에프제약

Name of the Issuer : Telcon RF Pharmaceutical, Inc.

2) 사채의 명칭 : (주)텔콘알에프제약 제15회 무기명식 이권부 무보증 사모 전환사채

Name of the Bond : Telcon RF Pharmaceutical, Inc. 15th Bearer-type Interest Unsecured Private Equity Convertible Bonds

3) 사채의 종류 : 무기명식 이권부 무보증 사모 전환사채

Type of Bond : Bearer-type Interest Unsecured Private Equity Convertible Bonds

4) 사채의 권면총액 : 금 삼백억원 (₩30,000,000,000)

Total Amount of Bond : KRW 30 billion (KRW 30,000,000,000)

5) 사채의 발행가액 : 사채 권면총액의 100% (할인율 0.00%)

Issuance Amount of Bond : 100% of total amount of the debenture (discount rate 0.00%)

6) 사채권의 금액 및 권종 : 총 35매 (금 10억원권 25매, 금 5억원권 10매)

Amount and Volume of Bond : 35 units in total (25 units of KRW 1 billion, 10 units of KRW 500 million)

7) 사채권의 분할 및 병합금지 : 본 사채권은 발행일로부터 1년간 분할 또 는 병합이 금지된다. 단, 발행일로부터 1년 경과 시점부터는 본 사채권 소지자의 요청이 있을 경우 권면금액 및 권종을 분할할 수 있다.

Prohibition of Division and Consolidation of bonds: This bond is prohibited from division or

consolidation for one year from the date of issue. However, after one year from the date of issue, the amount and type of issue may be divided at the request of the holder of this bond.

8) 사채의 이율: 본 사채 발행일로부터 상환기일 전일까지 각 사채권면총액에 대하여 표면금리는 연 2.10%, 조기상환수익률 및 만기보장수익률은 3개월 단위 복리 연 2.10%로 한다.

Interest Rate of Bond : From the issue date of this debenture to the day before the redemption date, the surface interest rate is 2.10% per year, and the early redemption rate and the guaranteed maturity rate are three months based compound rate of 2.10% per year.

9) 사채의 상환방법과 기한 : 만기까지 보유하고 있는 본 사채의 원금에 대하여는 2030년 10월 16일에 권면금액의 만기보장수익률 100.0000%에 해당하는 금액을 일시 상환한다. 단, 상환 기일이 은행 영업일이 아닌 경우에는 그 다음 영업일에 상환하고 원금상환기일 이후의 이자는 계산하지 아니한다.

Redemption Method and Duration: With respect to the principal of this bond held until maturity, on October 16, 2030, the amount equivalent to the guaranteed maturity rate of 100.0000% of the debenture amount will be repaid. However, if the redemption due date is not the bank business day, redemption will be made on the following business day, and interest after the principal redemption date will not be calculated.

10) 이자의 지급방법과 기한 : 본 사채 발행일 익일부터 원금 상환기일까지 매 3개월마다 표면이자율에 1/4로 산정된 매 3개월분의 이자를 이자 지급기일에 후급한다. 다만, 지급기일이 은행 영업일이 아닌 경우에는 그 다음 영업일에 이자를 지급하기로 하고 이 경우 지급기일 이후의 이자는 계산하지 아니한다.

Interest Payment Method and Duration : Every three months after the issue date of this bond to the due date of repayment of the principal, interest for every three months calculated as 1/4 of the annual interest rate shall be paid the interest payment dates. However, if the payment due date is not a bank business day, interest will be paid on the following business day, and in this case, interest after the payment date will not be calculated.

[이자 지급기일] Interest Payment Dates

2021년 01월 16일, 2021년 04월 16일, 2021년 07월 16일, 2021년 10월 16일,
2022년 01월 16일, 2022년 04월 16일, 2022년 07월 16일, 2022년 10월 16일,
2023년 01월 16일, 2023년 04월 16일, 2023년 07월 16일, 2023년 10월 16일,
2024년 01월 16일, 2024년 04월 16일, 2024년 07월 16일, 2024년 10월 16일,
2025년 01월 16일, 2025년 04월 16일, 2025년 07월 16일, 2025년 10월 16일,
2026년 01월 16일, 2026년 04월 16일, 2026년 07월 16일, 2026년 10월 16일,
2027년 01월 16일, 2027년 04월 16일, 2027년 07월 16일, 2027년 10월 16일,
2028년 01월 16일, 2028년 04월 16일, 2028년 07월 16일, 2028년 10월 16일,
2029년 01월 16일, 2029년 04월 16일, 2029년 07월 16일, 2029년 10월 16일,
2030년 01월 16일, 2030년 04월 16일, 2030년 07월 16일, 2030년 10월 16일.

11) 조기상환청구권(Put Option)에 관한 사항 : 본 사채의 사채권자는 본 사채의 발행일로부터 1년이 경과한 날 및 이후 매 3개월에 해당되는 날(이하 "조기상환지급일"이라 한다.)에 본 사채의

원금에 해당하는 금액의 전부 또는 일부에 대하여 만기전 조기상환을 청구할 수 있다. 단, 조기상환지급일이 은행 영업일이 아닌 경우에는 그 다음 영업일에 상환하고 조기상환지급일 이후의 이자는 계산하지 아니한다.

Early Redemption Claim (Put Option) : The bond holders are entitled to early redemption right after one year of the issue date of this bond and every three months thereafter (hereinafter referred to as the "early redemption payment date"). Early repayment may be requested before maturity for all or part of the amount corresponding to the principal amount. However, if the early repayment payment date is not a bank business day, repayment is made on the following business day, and interest after the early repayment payment date is not calculated.

① 조기상환 수익률 및 조기상환 청구기간 : 사채권자는 조기상환지급일 2개월전부터 1개월전까지 발행회사에게 사채의 권면금액을 단위로 하여 조기상환 청구를 하여야 한다. 단, 조기상환청구기간의 종료일이 영업일이 아닌 경우에는 그 다음 영업일까지로 한다.

Early Redemption Claim Rate and Period: The bond holders should file a claim for early redemption to the issuer from 2 months to 1 month before the early redemption payment date in units of the amount of debentures for the bonds. However, if the end of the early redemption claim period is not a business day, it shall be until the next business day.

구분	조기상환청구기간 Early Redemption Claim Period		조기상환지급일 Early Redemption Claim Date	조기상환율 Early Redemption Rate
	FROM	TO		
1차	2021년 07월 25일	2021년 08월 25일	2021년 09월 25일	100.0000%
2차	2021년 10월 25일	2021년 11월 25일	2021년 12월 25일	100.0000%
3차	2022년 01월 25일	2022년 02월 25일	2022년 03월 25일	100.0000%
4차	2022년 04월 25일	2022년 05월 25일	2022년 06월 25일	100.0000%
5차	2022년 07월 25일	2022년 08월 25일	2022년 09월 25일	100.0000%
6차	2022년 10월 25일	2022년 11월 25일	2022년 12월 25일	100.0000%
7차	2023년 01월 25일	2023년 02월 25일	2023년 03월 25일	100.0000%
8차	2023년 04월 25일	2023년 05월 25일	2023년 06월 25일	100.0000%
9차	2023년 07월 25일	2023년 08월 25일	2023년 09월 25일	100.0000%
10차	2023년 10월 25일	2023년 11월 25일	2023년 12월 25일	100.0000%
11차	2024년 01월 25일	2024년 02월 25일	2024년 03월 25일	100.0000%
12차	2024년 04월 25일	2024년 05월 25일	2024년 06월 25일	100.0000%
13차	2024년 07월 25일	2024년 08월 25일	2024년 09월 25일	100.0000%
14차	2024년 10월 25일	2024년 11월 25일	2024년 12월 25일	100.0000%
15차	2025년 01월 25일	2025년 02월 25일	2025년 03월 25일	100.0000%
16차	2025년 04월 25일	2025년 05월 25일	2025년 06월 25일	100.0000%
17차	2025년 07월 25일	2025년 08월 25일	2025년 09월 25일	100.0000%
18차	2025년 10월 25일	2025년 11월 25일	2025년 12월 25일	100.0000%
19차	2026년 01월 25일	2026년 02월 25일	2026년 03월 25일	100.0000%

20차	2026년 04월 25일	2026년 05월 25일	2026년 06월 25일	100.0000%
21차	2026년 07월 25일	2026년 08월 25일	2026년 09월 25일	100.0000%
22차	2026년 10월 25일	2026년 11월 25일	2026년 12월 25일	100.0000%
23차	2027년 01월 25일	2027년 02월 25일	2027년 03월 25일	100.0000%
24차	2027년 04월 25일	2027년 05월 25일	2027년 06월 25일	100.0000%
25차	2027년 07월 25일	2027년 08월 25일	2027년 09월 25일	100.0000%
26차	2027년 10월 25일	2027년 11월 25일	2027년 12월 25일	100.0000%
27차	2028년 01월 25일	2028년 02월 25일	2028년 03월 25일	100.0000%
28차	2028년 04월 25일	2028년 05월 25일	2028년 06월 25일	100.0000%
29차	2028년 07월 25일	2028년 08월 25일	2028년 09월 25일	100.0000%
30차	2028년 10월 25일	2028년 11월 25일	2028년 12월 25일	100.0000%
31차	2029년 01월 25일	2029년 02월 25일	2029년 03월 25일	100.0000%
32차	2029년 04월 25일	2029년 05월 25일	2029년 06월 25일	100.0000%
33차	2029년 07월 25일	2029년 08월 25일	2029년 09월 25일	100.0000%
34차	2029년 10월 25일	2029년 11월 25일	2029년 12월 25일	100.0000%
35차	2030년 01월 25일	2030년 02월 25일	2030년 03월 25일	100.0000%
36차	2030년 04월 25일	2030년 05월 25일	2030년 06월 25일	100.0000%

② 조기상환 청구장소 : 발행회사의 본점 및 하나은행 삼성중앙역지점

Place of Claim for Early Redemption: Headquarter of the issuer and Samsung Central Station Branch of KEB Hana Bank.

③ 조기상환 청구절차 : 사채권자가 고객계좌에 전자등록된 경우에는 거래하는 계좌관리기관을 통하여 한국예탁결제원에 조기상환을 청구하고 자기계좌에 전자등록된 경우에는 한국예탁결제원에 조기상환을 청구하면 한국예탁결제원이 이를 취합하여 청구장소에 조기상환 청구한다.

Early Redemption Claim Procedure: If the bond holders are electronically registered in the account of the customer, the bond holders shall request Early Redemption Claim to the Korea Securities Depository through the account management institution that transacts with, and In the case of the bond holders are electronically registered in the account of the bond holders, if the bond holders request Early Redemption Claim to the Korea Securities Depository, the Korea Securities Depository collects this Early Redemption Claim and requests Early Redemption Claim at the place of claim for Early Redemption.

12) 지연배상금 : 발행회사가 본건 전환사채에 대한 원금 또는 이자의 지급의무 기타 본 계약에 의한 금전지급의무를 지체한 때에는, 발행회사는 지급하여야 할 금액에 대하여 연 12%의 비율에 의한 지연배상금을 지급하기로 한다.

본 계약에 의한 지연배상금의 계산에 있어서는 1년을 365일로 하여 1일 단위로 계산하기로 한다.

Delayed Payment Penalty: When the issuer delays the obligation to pay principal or interest on the convertible bonds or other payment obligations under this agreement, the issuer pays delayed payment penalty at an annual rate of 12%. The penalty is prorated in daily increments based on 365 days a year.

- 13) 원금상환 및 이자지급 장소 : 하나은행 삼성중앙역지점
Place of Principal Redemption and Interest Payment: Samsung Central Station Branch of KEB Hana Bank.
- 14) 사채의 납입장소 : 하나은행 삼성중앙역지점
Place of Bond Payment: Samsung Central Station Branch of KEB Hana Bank.
- 15) 사채의 자금사용용도 : 운영자금 및 타법인증권취득 등
Use of Bond: Operating Capital and Purchase of Other Corporate Securities, etc.
- 16) 사채의 인수 계약체결일 : 2020년 9월 28일
Execution Date of Bond Purchase Agreement : September 28, 2020
- 17) 사채의 청약일 : 2020년 09월 28일
Subscription Date of Bond : September 28, 2020
- 18) 사채의 납입일 : 2020년 10월 16일
Payment Date of Bond : October 16, 2020
- 19) 사채의 발행일 : 2020년 10월 16일
Issue Date of Bond : October 16, 2020
- 20) 사채의 만기일 : 2030년 10월 16일
Maturity Date of Bond : October 16, 2030
- 21) 사채의 발행방법 : “주식·사채 등의 전자등록에 관한 법률”에 따라 한국예탁결제원 또는 계좌관리기관의 전자등록 계좌부에 전자등록한다.
Issuance Method of Bond : Electronically registered in the electronic registration account book of the Korea Securities Depository or an account management institution in accordance with the “Act on Electronic Registration of Stocks and Bonds, etc.”.
- 22) 전환권에 관한 사항
Matters on Stock Conversion
- ① 전환가액 : 1주당 [9,232]원 (#별첨 전환가액 산정표 - 본건 전환사채 발행을 위한 이사회 결의일 전일로부터 소급한 1개월 가중산술평균주가, 1주일 가중산술평균주가 및 최근일 가중산술평균주가를 산술평균한 가액과 최근일 가중산술평균주가 및 청약일(청약일이 없는 경우에는 납입일) 3거래일 전 가중평균산술평주가 중 높은 가액으로 하되, 원단위 미만은 절상한다.)
Conversion Price : KRW [9,232] (Appendix Conversion Price Calculation Table - This is the highest value of the mathematical average of the 1-month weighted average stock price, 1-week weighted average stock price and the most recent day weighted average stock price, and the most recent day weighted average stock price retroactively from the day before the resolution of the board of directors for issuance of convertible bonds, and the weighted average stock price from the 3-days before subscription date, (If there is no subscription date, the payment date) but less than KRW is rounded up to a whole number.
- ② 전환비율 : 각 사채 권면금액(2이상의 사채로 전환 청구하는 경우에는 그 권면금액의 합산금액)을 전환가액으로 나눈 주식수의 100%를 전환주식수로 하고, 그 단주수에 상당하는 금액을 전환주식의 전자등록(교부)시 명의개서대리인이 현금으로 지급하며 단주주 대금에 대한 해당기간 이자는 지급하지 아니한다.

Conversion Rate : 100% of the number of shares obtained by dividing the denomination amount of each bond (the sum of the denomination amount in case of requesting conversion to two or more bonds) by the conversion price is the number of convertible stocks, the amount equivalent to the single orders of less than one share is paid in cash by the transfer agent upon the electronic registration(issuance) of the stock conversion, and the interest on the single orders is not paid.

③ 전환으로 인하여 발행할 주식의 내용 : (주)텔콘알에프제약 기명식 보통주식

Stocks to be issued due to Stock Conversion: Registered Common Stock of Telcon RF Pharmaceutical, Inc.

④ 전환가액의 조정

Adjustment of Conversion Price

가. 본 사채를 소유한 자가 전환청구를 하기 전에 i)시가를 하회하는 발행가액으로 유상증자를 하거나, ii)무상증자를 하거나, iii)주식배당, 준비금 자본전입을 통하여 주식을 발행하거나, iv)주식분할을 하거나, v)시가를 하회하는 전환가액 내지 행사가액으로 전환사채 또는 신주인수권부사채를 발행하거나, vi)기타 방법으로 주식을 발행하는 경우에는 다음과 같이 전환가액을 조정한다.

Before the bond holders request stock conversion, i) make a paid-in capital increase at the issue price below the market price, ii) make a free paid-in capital increase, iii) issue stocks through stock dividends or capital transfer of reserves, iv) in the case of stock split, v) issuing convertible bonds or bonds with warrant at a conversion or exercise price below the market price, or vi) issuing stocks in other ways, the conversion price shall be adjusted as follows:

조정 후 전환가액 Conversion Price after Adjustment = 조정 전 전환가액 Conversion Price before Adjustment $\times \left[\frac{A+(B \times C/D)}{A+B} \right]$

A : 기발행주식수 Number of Shares Outstanding

B : 신발행주식수 Number of Newly Issued Shares

C : 1주당 발행가격 Issuance Price per Share

D : 시가 Market Price

또한, 발행회사가 본건 전환사채의 만기 이전에 본건 전환사채 외에 추가로 발행회사의 보통주식을 대상으로 하는 전환사채, 교환사채 및 신주인수권부사채를 발행하는 경우, 추가로 발행된 사채의 전환, 교환, 신주인수권의 가격을 비교하여 추가로 발행된 채권의 가격이 더 낮은 경우 “본건 전환사채”의 전환가격을 신규 추가 발행된 전환사채, 교환사채 및 신주인수권부사채의 전환, 교환 또는 신주인수권 가격으로 조정하기로 한다.

In addition, if the issuer issues convertible bonds, exchange bonds, and bonds with warrant to the issuer's common stock in addition to the convertible bonds prior to the maturity, and the price of the newly issued bonds are lower by comparing the prices of the conversion, exchange, or warrant for issued bonds, the conversion price of the “convertible bonds” shall be adjusted to the price of the newly issued convertible bonds, exchange bonds and bonds with warrant.

다만, 위 산식 중 “기발행주식수”는 당해 조정사유가 발생하기 직전일 현재의 발행주식총수로 하

며, 전환사채 또는 신주인수권부사채를 발행할 경우 “신발행주식수”는 당해 사채 발행시 전환가격으로 전부 주식으로 전환되거나 당해 사채 발행시 행사가액으로 신주인수권이 전부 행사될 경우 발행될 주식의 수로 한다.

However, in the above formula, “number of shares outstanding” shall be the total number of shares issued as of the date immediately before the cause for adjustment, and in the case of issuing convertible bonds or bonds with warrant, the “number of newly issued shares” shall be the number of shares to be issued when the bonds are all converted to stocks at the conversion price at the time of issuance of the bonds or when the bonds are issued at the exercise price.

위 산식 중 “1주당 발행가액”은 주식분할, 무상증자, 주식배당의 경우에는 영(0)으로 하고, 전환사채 또는 신주인수권부사채를 발행할 경우에는 당해 사채 발행시 전환가격 또는 행사가액으로 한다.

In the above formula, “Issuance price per share” shall be zero (0) in the case of stock split, free paid-in capital increase, or stock dividend, and in the case of issuing convertible bonds or bonds with warrant, it shall be the conversion price or exercise price at the time of issue of the bonds.

위 산식에서 “시가”라 함은 당해 발행가액 산정의 기준이 되는 기준주가 또는 이론 권리락 주가(유상증자 이외의 경우에는 조정사유 발생 전일을 기산일로 계산한 기준주가)로 하며, 위의 산식에 의한 조정 후 행사가액의 원단위 미만은 절상한다.

In the above formula, the term “market price” shall be the standard stock price or theoretical rights-exclusive stock price that is the basis for the calculation of the issuance price (if not a paid-in capital increase, the base price calculated from the date before the occurrence of the cause for adjustment). After adjustment, the exercise price less than the KRW basic unit shall be rounded up.

나. 합병, 자본의 감소, 주식분할 및 병합 등에 의하여 전환가액의 조정이 필요한 경우에는 당해 합병 또는 자본의 감소, 주식분할 및 병합, 주식 액면 변경 등 직전에 전환사채가 전액 주식으로 전환되었더라면 인수인이 가질 수 있었던 주식수가 전환주식수가 되도록 전환가액을 조정한다. 본항에 따른 전환가액 조정일은 합병, 자본의 감소, 주식분할 및 병합, 주식 액면 변경의 기준일로 한다.

If adjustment of the conversion price is required due to a merger, decrease in capital, stock split or reverse split, etc., the conversion price shall be adjusted that the number of stocks the purchaser could have is the number of convertible stocks as if the total amount of convertible bonds had been converted to stocks immediately before the merger or decrease in capital, stock split and reverse split, and stock par value change. The conversion price adjustment date pursuant to this subparagraph shall be the date of merger, decrease in capital, stock split and reverse split, and stock par value change.

다. 위 가목 내지 나목과는 별도로 본건 전환사채 발행일의 다음달 말일부터 매1개월 마다 전환가액을 조정하되 전환가액 조정 전일을 기산일로 하여 소급한 최근 1개월 가중산술평균주가, 1주일 가중산술평균주가, 최근일 가중산술평균주가를 산술평균한 가격과 최근일 가중산술평균주가 중 높은 가격이 직전 전환가액보다 낮은 경우, 둘 중 낮은 가격으로 전환가액을 조정한다. 단, 전환가격의 최저 조정 한도는 발행회사 정관에 따라 액면가까지로 한다. (단, 조정일 전에 신주의 할인 발행 등의 사유로 전환가격을 이미 조정한 경우에는 이를 감안하여 산정한다)

Separately, regardless of clause 가 or clause 나 above, the conversion price is adjusted every 1-month from the end of the month following the convertible bond issuance date, but if the higher of the mathematical average of the 1-month weighted average stock price, 1-week weighted average stock price and the most recent day weighted average stock price, retroactively from the day before the conversion price adjustment and the most recent day weighted average stock price is lower than the previous conversion price, the conversion price shall be adjusted to the lower of the two. However, the minimum adjustment limit for the conversion price is up to the face value in accordance with the issuer's articles of incorporation (Nevertheless, if the conversion price has already been adjusted for reasons such as issuance of discount for newly issued stocks before the adjustment date, it will be calculated in consideration of this)

라. 위 가목 내지 다목에 의하여 조정된 전환가액이 주식의 액면가 이하일 경우에는 액면가를 전환가액으로 하며, 각 전환사채의 전환으로 인하여 발행할 주식의 발행가액의 합계액은 각 전환사채의 발행가액을 초과할 수 없다.

If the conversion price adjusted under clause 가 or clause 다 above is less than the par value of the stock, the par value shall be the conversion price, and the sum of the issuance amount of stocks to be issued due to conversion of each convertible bond shall not exceed the issuance amount of each convertible bond..

마. 감자, 주식병합 등 주식가치 상승사유가 발생하는 경우 조정비율만큼 상향하여 반영한 가액을 전환가액으로 한다. 단, 감자, 주식병합 등을 위한 주주총회 결의 일 전일을 기산일로 하여 1개월 가중산술평균주가, 1주일 가중산술평균주가와 최근일 가중산술평균주가를 산술평균한 가액과 최근일(기산일) 가중산술평균주가 중 높은 가액이 액면가액 미만이면서 기산일 전에 전환가액을 액면가액으로 이미 조정한 경우에는 조정 후 전환가액은 산정가액을 기준으로 감자, 주식병합 등으로 인한 조정비율만큼 상향 조정한 가액 이상으로 할 수 있다.

In the event that there is a reason for an increase in the stock value, such as decrease in capital, reverse split of stocks, etc., the conversion price shall be the value reflected by raising the adjustment ratio. If the higher of the mathematical average of the 1-month weighted average stock price, 1-week weighted average stock price and the most recent day weighted average stock price, and the most recent day weighted average stock price, and the most recent day (calculation date) weighted average stock price, retroactively from the day before the resolution of the shareholders' meeting for decrease in capital, reverse split of stocks, etc., is less than the par value and the conversion price has already been adjusted to the par value before the calculation date, the conversion price after adjustment may be higher than the price raised by the adjustment ratio due to decrease in capital, reverse split of stocks, etc., based on the calculated value.

바. 본 호에 의한 조정 후 전환가액 중 원단위 미만은 절상한다.

After adjustment under this subparagraph, the conversion price less than KRW shall be rounded up to a whole number.

⑤ 전환의 효력발생 : 전환청구장소 국민은행 증권대행부(발행회사의 명의개서 대리인)에 전환청구서 및 관계서류 일체를 제출한 때에 효력이 발생한다. 전환에 의하여 교부된 주식은 전환청구일에 전환된 것으로 본다. 전환사채의 이자계산, 전환권 행사로 취득한 주식의 배당에 관하여는

그 청구를 한 날이 속하는 영업연도말에 전환된 것으로 보아 배당의 효력을 가지며 기지급된 이자에 대하여는 영향을 미치지 아니한다. 단, 전환 청구일까지 아직 도래하지 않은 이지지급일의 이자는 전환으로 인하여 소멸한다.

Effect of Conversion : It takes effect when the conversion request and all related documents are submitted to the Securities Agency of KB Kookmin Bank (Issuer's transfer agent), the place of conversion. Issued stocks by conversion shall be deemed to have been converted on the date of conversion. With respect to the interest calculation on convertible bonds and the dividend on stocks by exercise of conversion rights, there are effect on the dividend and not effect on the interest paid by treated as the conversion shall be deemed to have been converted at the end of the business year in which the date of the request is made. However, the interest on the interest payment date that has not yet reached the date of conversion will lapse due to the conversion.

⑥ 전환청구기간 : 발행일로부터 1년이 되는 날부터 만기 1개월 전까지(2021년10월16일부터 2030년09월16일까지)로 한다. 원리금 지급일 직전 2영업일부터 원리금 지급일까지는 전환청구를 할 수 없다.

Conversion Request Period : From the date one year after the issued date to one month before maturity date (from October 16, 2021 to September 16, 2030). The conversion request shall not be made from the two business days immediately before the principal and interest payment date to the principal and interest payment date.

⑦ 전환청구절차 : 사채권자가 고객계좌에 전자등록된 경우에는 거래하는 계좌관리기관을 통하여 한국예탁결제원에 전환청구하고 자기계좌에 전자등록된 경우에는 한국예탁결제원에 전환청구하면, 한국예탁결제원이 이를 취합하여 청구장소에 전환청구한다.

Conversion Request Procedure : If the bond holders are electronically registered in the account of the customer, the bond holders shall request the stock conversion to the Korea Securities Depository through the account management institution that transacts with, and In the case of the bond holders are electronically registered in the account of the bond holders, if the bond holders request the stock conversion to the Korea Securities Depository, the Korea Securities Depository collects these stock conversions and requests the stock conversion at the place of the stock conversion.

⑧ 기타사항 : Others

가. 미발행 수권주식의 보유 : 사채권 보유자가 주식으로 전환청구를 할 수 있는 기간까지 발행회사가 발행할 주식의 총수에 전환으로 인하여 발행될 주식수를 미발행 주식으로 보유한다.

Holding of Unissued Authorized Stocks : Until the period in which the bond holders can request for the stock conversion, the number of shares to be issued due to conversion to the total number of shares to be issued by the issuer shall be held as unissued stocks.

나. 전환청구일이 속하는 달의 말일로부터 2주 이내에 전환청구로 인한 신주의 발행에 대하여 등기절차를 이행하여야 하며, 등기 절차 완료 후 14영업일 이내에 신주를 상장하기로 한다.

For the issuance of new stocks resulting from the conversion request within two weeks from the end of the month with the conversion request date, the registration process shall be carried out, and the new stocks shall be listed within 14-business days after completion of the registration

process.

다. 전환주권의 교부방법 및 장소 : 전환으로 인하여 발행되는 주식은 한국예탁결제원에 예탁 발행되므로 그 주권을 교부하지 아니한다. 단, 전환권 행사로 인하여 발행되는 주식은 명의개서대리인과 협의하여 전환청구일로부터 15영업일 이내에 추가상장에 필요한 모든 절차를 완료하여야 한다.

Method and Place of Issuance of Converted Stocks : the issued stocks due to conversion are deposited and issued with the Korea Securities Depository, so the stock certificates are not issued. However, for the issued stocks due to the exercise of the conversion, all required procedures for additional listing shall be completed within 15 business days from the date of request for conversion in consultation with the transfer agent.

라. 본 계약서에 규정하고 있지 않은 사항에 대하여는 상법 제513조 내지 제516조의 규정에 따른다. 또한 전각호의 사항 외에 필요한 사항은 발행회사와 인수인간에 협의하여 처리한다.

For matters not specified in this agreement, the provisions of Articles 513 or 516 of the Commercial Code shall be followed. In addition, the required matters other than the matters in the previous subparagraphs are handled in consultation with the issuer and the purchaser.

마. 전환가격이 조정될 경우에 발행회사는 한국거래소, 한국예탁결제원에 통보한다.

When the conversion price is adjusted, the issuer shall notify the Korea Exchange and the Korea Securities Depository.

제7조 (전환사채 인수대금의 납입) Article 7 (Payment of Principal Purchase Amount)

전환사채 인수인은 전환사채 인수대금을 납입기일 및 납입장소에 지급한다.

The purchaser shall pay the convertible bond payment at the payment date and place of payment.

제8조 (자료제출의 의무) Article 8 (Responsibility of Document Submission)

발행회사는 본건 전환사채의 원리금이 상환될 때까지 인수인의 요구가 있을 때는 언제든지 분기별 재무제표 및 관련부속명세서 등 관련자료의 열람 및 제출의 요구에 응해야 한다.

The issuer shall comply with the request to view and submit related data such as quarterly financial statements and related documents whenever there is a request from the purchaser until the principal and interest of the convertible bond are repaid.

제9조 (특약사항) Article 9 (Special Agreement)

1) 질권설정 Establishment of Pledge

① 인수대금 납입 완료에 따라 취득한 본건 신규 전환사채를 텔콘에 다시 담보로 제공하고 질권을 설정하기로 한다.

Upon payment of the purchase amount, the new convertible bond shall be pledged as collateral.

2) 질권해지 Termination of Pledge

① 텔콘 및 인수인간 엔dari 원료공급권과 관련하여 체결된 계약 및 합의사항에 따르기로 한다.

Regarding the right of Endari API supply, both parties shall follow the agreement and the additional agreements between the issuer and the purchaser.

② 원료공급과 관련한 매출액과 매출이익이 보장한 대로 이루어 지지 않을 경우 발행회사는 그 부족분에 해당하는 만큼 담보물 전체 혹은 일부를 매도 하여 충당하기로 한다. 또한 담보제공의 방식, 처분 방식은 발행회사의 이사회에서 결정하기로 한다.

If the sales revenue and sales profits related to Endari API supply are not met, the issuer may sell all or part of the collateral to cover the shortfall. In addition, the method of providing collateral and disposition will be decided by the board of directors of the issuing company.

3) Put옵션 및 주식전환 Put Option and Stock Conversion

① 인수인은 본 조 2)항에 따라 담보가 해지된 부분에 한하여 조기상환청구권(Put Option) 행사 및 전환청구 행사가 가능하다.

The purchaser may exercise the early redemption option (Put Option) and the conversion request only for the equivalent amount that has been cancelled pursuant to paragraph 2) of this Article.

제10조 (비용부담) Article 10 (Cost Burden)

본 계약의 체결, 본건 전환사채의 발행 및 전환권의 행사와 관련하여 발생하는 비용은 발행회사가 부담한다.

Expenses incurred in connection with the execution of this agreement, the issuance of the convertible bonds and the exercise of the stock conversion shall be borne by the issuer.

제11조 (비밀유지) Article 11 (Confidentiality)

각 당사자는, 관계 법령 또는 법원의 판결/결정/명령이나 정부기관(감독기관 포함)의 요청에 따라 정보의 공개가 필요하거나 기 공개된 경우를 제외하고, 본 계약의 체결 및 본 계약의 내용을 제3자에게 공개하거나 누설하여서는 안된다.

Unless the disclosure of information is required or previously disclosed at the request of the government agency (including the supervisory authority) or Judgments/decisions/orders by relevant laws or courts, each party shall not disclose or reveal the execution and the contents of this agreement to any third party.

제12조 (통지) Article 12 (Notices)

1) 발행회사는 다음 각 호의 사항에 대하여 그 처리 결과를 즉시 인수인에게 통지하여야 한다. 단, 처리 결과에 대한 통지는 금융감독원 및 한국거래소에 전자공시를 진행 완료한 경우에는 이에 갈음한다.

The issuer shall immediately notify the purchaser of the result of processing for the following matters. However, notification of the result of the processing shall be replaced if electronic disclosure has been completed with the Financial Supervisory Service and the Korea Exchange.

① 정관의 변경

Change of articles of incorporation

② 발행회사가 제3자에게 당시의 행사가액 이하로 주식연계채권을 발행하는 경우

When the issuer issues stock-linked bonds to a third party at the exercise price or less at the time

③ 발행회사의 최대주주 등(자본시장과 금융투자업에 관한 법률에 따른 최대주주의 특수관계인

포함)이 경영권을 포함한 지분(총 발행주식의 5%이상)을 양도하고자 하는 경우

When the largest shareholder, etc. of the issuer (including those related to the largest shareholder in accordance with the Capital Markets and Financial Investment Business Act) intends to transfer its shares (more than 5% of the total outstanding shares) including management rights.

④ 대표이사의 변경

Change of CEO

⑤ 본 계약체결일 현재 정관상 영위하는 목적사업 이외의 신규사업에 대한 투자

Investment in new business other than the target business operated by the articles of incorporation as of the execution date of this agreement

⑥ 기타 발행인의 경영에 중대한 영향을 미치는 사항

Other matters that have a significant impact on the issuer's management

2) 본 계약에 따른 통지는 서면에 의하여야 하고, 다음 주소 또는 번호로 인편, 팩시밀리/이메일 송신 또는 등기우편에 의하여 전달되어야 한다.

Notifications under this agreement shall be in writing and delivered by personal mail, fax/email transmission or registered mail to the following address or number.

모든 통지는, (i) 인편에 의한 경우 전달일에, (ii) 팩시밀리 또는 이메일 전송에 의한 경우 송신일에, (iii) 등기우편에 의한 경우 발송일에 통지가 이루어진 것으로 간주된다. 등기우편에 의한 경우, 우편 영수증이 발송의 최종 증빙이 된다. 인편에 의한 경우, 수취인이 서명한 인수증이 최종 증빙이 된다. 팩시밀리 전송에 의한 경우 송신 확인서가 최종 증빙이 되며, 그의 효력에 영향을 주지 않으나, 팩시밀리 통지는 인편 또는 선납등기우편에 의한 서신으로 즉시 확인해야 한다.

All notifications shall be deemed to have been made (i) on the date of delivery, if by personal service, (ii) on the date of transmission, if by facsimile or e-mail, and (iii) on the date of dispatch, if by registered mail. In the case of registered mail, the postal receipt is the final proof of shipment. In the case of personal delivery, the receipt signed by the recipient is the final proof. In the case of facsimile transmission, the transmission confirmation form is the final proof and does not affect its validity, but the facsimile notification shall be immediately confirmed by a letter by personal or prepaid registered mail.

제13조 (분쟁해결) Article 13 (Arbitration)

본 계약의 체결, 이행 또는 본 계약의 위반과 관련한 분쟁에 대하여는 서울중앙지방법원을 제1심 전속관할법원으로 한다.

The Seoul Central District Court shall be the exclusive jurisdiction court for the first instance for disputes related to the execution or performance of this agreement or breach of this agreement.

제14조 (기타) Article 14 (Miscellaneous)

1) 완전합의. 본 계약은 본 계약의 주제에 관하여 당사자들의 완전 합의를 구성하며, 본 계약에 정해진 사항을 제외한 구두 또는 서면의 명시적인 또는 암시적인 약속, 조건 또는 의무는 존재하지 않는다.

Complete agreement. This agreement constitutes the entire agreement of the parties with respect

to the subject matter of this agreement, and there are no commitments, conditions or obligations, expressed or implied, orally or in writing, except as set forth herein.

2) 변경. 본 계약의 변경은 각 당사자가 서명한 서면으로만 이루어질 수 있다.

Amendment. Changes to this agreement may only be made in writing signed by each party.

3) 가분성. 본 계약 중 어느 조항(문장, 문구 또는 그 일부를 포함하여)이 어느 면에서든 불법, 무효 또는 집행불능으로 되는 경우, 나머지 조항들은 당사자들의 의도에 따라서 합리적으로 계속 의미를 가지게 되는 한 계속 유효하다. 그와 같이 불법, 무효 또는 집행불능으로 된 조항은 당사자들이 추가 조치를 하지 않더라도 동일한 효력과 집행가능성을 부여하는 범위 내에서 변경, 제한된 것으로 간주된다.

Severability. If any provision of this agreement (including text, phrase or any part thereof) becomes illegal, invalid or unenforceable in any way, the remaining provisions shall remain in force as long as they remain reasonably meaningful in accordance with the intentions of the parties. Any provision made so illegal, invalid or unenforceable is deemed to be modified or restricted to the extent that it gives the same effect and enforceability, even if the parties do not take further action.

4) 포기. 일방 당사자가 본 계약에 따른 권리를 행사하지 않거나 행사를 지연하거나, 동 권리를 일회 또는 일부 행사하더라도 동 권리를 추후 행사할 수 있는 권리는 배제되지 않는다.

Disclaimer. Even if either party does not exercise the right under this Agreement, delays the exercise, or exercises the right once or in part, the right to exercise the right in the future is not excluded.

이상의 내용을 증명하기 위하여 본 계약을 체결하고 계약서 3부를 작성하여 인수인과 발행회사는 정당한 수권을 가진 자로 하여금 각각 기명 또는 서명날인하게 한 후 각 당사자가 1부씩 보관하기로 한다.

In order to prove the above, this agreement is distributed in three copies, one each to each party. The corporate seals or official signatures shall authenticate the agreement.

2020년 9월 28일

September 28, 2020

발행회사 Issuer

(주)텔콘알에프제약 Telcon RF Pharmaceutical, Inc.

주소 : 경기도 용인시 기흥구 동탄기흥로 684

Address : 684, Dongtan Giheung-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea

대표이사 김지훈 (인)

CEO : Ji Hoon Kim (Seal)

인수인 Purchaser

Emmaus Life Sciences Inc.
주소 : 미합중국 21250 Hawthorne Blvd. Suite 800 Torrance, CA 90503
대표이사 Yutaka Niihara (인)

매도청구권(Call Option-콜옵션) 계약서 Right to Sell (Call Option) Agreement

다음 당사자들은 2020년 9월 28일 다음과 같이 매도청구권(Call Option-콜옵션) 계약(이하 “본 계약”)을 체결한다.
This “right to sell(Call Option) agreement” (hereinafter “this agreement”) is executed on September 28, 2020 between the following parties.

1. 발행회사 Issuer

주식회사 텔콘알에프제약 Telcon RF Pharmaceutical, Inc.
대표이사: 김 지 훈 Ji Hoon Kim
주 소: 경기도 용인시 기흥구 공세로 54 (고매동)
54, Gongse-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea

2. 인수인 또는 채권자 Purchaser or Creditor

Emmaus Life Sciences, Inc.
CEO: Dr. Yutaka Niihara
미합중국 21250 Hawthorne Blvd. Suite 800 Torrance, CA 90503, USA

발행회사와 인수인은 주식회사 텔콘알에프제약 제15회 무기명식 이권부 무보증 사모 전환사채(이하 “본건 전환사채”)에 대해 본건 전환사채 인수계약서(이하 “인수계약서”)를 2020년 10월16일 체결하였다.

The Convertible Bond Purchase Agreement (hereinafter “purchase agreement”) is executed on October 16, 2020 between the issuer and the purchaser as for 1st Bearer-type Interest Purchase Agreement for Unsecured Private Equity Convertible Bond (hereinafter “convertible bond”) issued by Telcon RF Pharmaceutical, Inc.

이와 관련하여 다음과 같이 매도청구권(Call Option-콜옵션) 계약(이하 “본 계약”)을 체결하고 이를 성실히 이행하기로 한다. 본계약에 별도로 언급되지 않은 사항에 대하여는 인수계약의 계약의 내용이 우선하며, 본계약은 적법하게 인수계약의 일부로서 구성된다.

In this regard, the parties agree to execute this agreement faithfully as follows. For matters not otherwise stated in this agreement, the purchase agreement shall prevail, and this agreement is legally treated as a part of the purchase agreement.

제1조 매도청구권(Call Option)에 관한 사항 Article 1 Right to Sell (Call Option)

본 사채의 발행회사는 사채권자로 하여금 발행회사 또는 발행회사가 지정하는 자(이하 “콜옵션

행사권자”)에게 본 사채의 최초 권면총액 금 삼백억원(30,000,000,000원)의 50% 한도 내에서 발행일로부터 1년이 되는 날부터 만기일 1개월 전(2021년 10월 16일부터 2030년 09월 16일)까지 권면금액으로 매도할 것을 청구할 수 있다.

또한, 본 사채를 제3자에게 양도할 경우 발행회사 및 발행회사가 지정하는 자의 콜옵션 행사를 보장하는 방법으로 양도해야 하며, 콜옵션 청구기간 중 콜옵션과 본 인수계약 제6조 제11항의 조기상환청구권이 동시에 행사 청구되는 경우 콜옵션이 우선한다.

The issuer of this bond may ask the issuer or a person designated by the issuer (hereinafter “call option exerciser”) to purchase up to a total of 30 billion won (30,000,000,000 won) of the convertible bond from the purchaser. The right to sell is limited up to 50% of the principal amount at the face value from one year after the issue date to one month before the maturity date (from October 16, 2021 to September 16, 2030).

In addition, if the convertible bond is transferred to a third party, it must be transferred in a way that guarantees the exercise of the call option by the issuer and the person designated by the issuer. During the call option claim period, if the right to claim early redemption is simultaneously exercised under Paragraph 11 of Article 6 on the purchase agreement, the call option takes precedence.

상기와 같이 본계약이 성립함을 증명하기 위하여 본계약서2부를 작성하여 각자 서명 또는 기명 날인한 후 각1부씩 보관한다.

This agreement is distributed in two copies, one each to each party. The corporate seals or official signatures shall authenticate the agreement.

2020년 9 월 28일

발행회사 주식회사 텔콘알에프제약

경기도 용인시 기흥구 공세로 54 (고매동)

김 지 훈

인수인 Emmaus Life Sciences Inc.

21250 Hawthorne Blvd. Suite 800 Torrance, CA 90503, USA

Yutaka Niihara

CREDIT ACCESS AND LOAN AGREEMENT

THIS CREDIT ACCESS AND LOAN AGREEMENT (this "Agreement") is made and entered into on January 10, 2020 by and between Yutaka Niihara, M.D., M.P.H. ("Lender") and Emmaus Life Sciences, Inc., a Delaware corporation ("Emmaus"), with reference to the following facts:

RECITALS:

Lender is the Chairman of the Board, Chief Executive Officer and the principal stockholder of Lender.

A. Lender is the Chairman of the Board, Chief Executive Officer and the principal stockholder of Lender.

B. Lender is party to that certain Advantage Line Loan Agreement entered into as of November 22, 2019 between Lender and California Bank & Trust, as lender ("Bank"), as it may be amended from time to time (as so amended, the "Bank Credit Agreement").

B. Lender has afforded, and Emmaus and Lender desire that Lender continue to afford, Emmaus access to the credit available to Lender under the Bank Credit Agreement in the form of advances by Lender to Emmaus of proceeds of borrowings by Lender under the Bank Credit Agreement, on the terms set forth in this Agreement.

NOW, THEREFORE, the parties hereto agree as follows:

SECTION 1. ADVANCES AND RE-ADVANCES

1.1 On December 27, 2019, Lender advanced to Emmaus a total of \$600,000 of proceeds from borrowings by Lender under the Bank Credit Agreement. At Emmaus's request at any time and from time to time during the term of this Agreement, Lender may, but shall not be obligated to, advance or re-advance to Emmaus proceeds of borrowings by Lender under the Bank Credit Agreement to be used by Emmaus in its discretion; provided that the aggregate outstanding principal amount of all advances and re-advances by Lender to Emmaus hereunder at any time shall not exceed \$1,000,000.

1.2 Advances and re-advances by Lender to Emmaus hereunder shall bear interest from the date made until paid in full at the variable interest rate payable by Lender under the Bank Credit Agreement, as it may vary from time to time. Except as otherwise provided in this Agreement, the principal amount of and accrued and unpaid interest thereon shall be due and payable when such amounts become due and payable, whether upon maturity, in the event of acceleration, or otherwise, under the Bank Credit Agreement, subject to Lender's right in his discretion to demand payment of any such amounts at any time and to Emmaus' right to prepay any such amounts, in whole or in part, at any time without premium or penalty. If it shall be found that any interest or other amount deemed interest due hereunder violates applicable laws governing usury, the applicable rate of interest due hereunder shall automatically be lowered to equal the maximum permitted rate of interest. Emmaus' liability and obligation to pay the principal amount of and accrued and unpaid interest on advances and re-advances by Lender to

Emmaus hereunder shall be evidenced by a Revolving Promissory Note of Emmaus in substantially the form attached hereto as Exhibit A (the "Revolving Note"). In addition to Emmaus' payment of the principal amount of and accrued and unpaid interest on advances and re-advances hereunder as aforesaid, within 90 days after the end of each calendar year during the term hereof in which accrued interest hereunder is paid to Lender, Emmaus shall pay to Lender an additional amount in cash (the "Gross-Up Payment ") to the extent necessary to make Lender approximately whole for the income and employment taxes payable by Lender on the interest income realized by Lender in respect of amounts paid to Lender hereunder for such year, including the Gross-Up Payment. The Gross-Up Payment shall be calculated by Emmaus in good faith, after consultation with Lender's personal tax preparer or other tax advisor, based on the estimated marginal tax rates applicable to Lender for the year in which the amounts were paid to Lender, taking into account federal, state and local income and employment taxes, including all such taxes payable on the Gross-Up Payment, itself.

SECTION 2. TERM AND TERMINATION

2.1 The term of this Agreement shall coincide with the term of the Bank Credit Agreement. Notwithstanding the foregoing, the term of this Agreement shall terminate automatically in any of the following events:

- (a) the filing of a voluntary bankruptcy or insolvency by Emmaus or an involuntary bankruptcy or insolvency petition against Emmaus which is not vacated within 60 days from the date of filing, or the entry of an order for relief in any bankruptcy proceeding in which Emmaus is a defendant, or the appointment of a receiver or trustee for Emmaus, or the execution of an assignment for the benefit of creditors of Emmaus, or the execution of a composition with creditors or any agreement of like import by Emmaus;
- (b) written notice by Lender to Emmaus in the event Emmaus is in material default in the performance of any of the terms of this Agreement, provided that such default or breach is not cured within 10 days after such notice; and
- (c) any determination by the Board of Directors or the stockholders of Emmaus to dissolve Emmaus.

Upon the expiration or termination of this Agreement, all outstanding advances and re-advances hereunder and any accrued and unpaid interest thereon shall immediately be and become due and payable, in full, without presentment or demand.

SECTION 3. ADDITIONAL TERMS

3.1 This Agreement and the Revolving Note contain the entire understanding of the parties hereto with respect to the subject matter herein and therein and supersede any and all prior written or oral agreements or understandings between the parties with respect to such subject matter hereof or thereof.

3.2 This Agreement may be amended only in a writing executed by all parties.

3.3 This Agreement shall be binding upon and inure to the benefit of the parties and their respective permitted successors and assigns; provided, however, that neither this Agreement nor any rights or obligations of Emmaus hereunder may be assigned or delegated by Emmaus.

3.4 Nothing in this Agreement shall be deemed or construed by the parties or by any third parties as creating the relationship of principal and agent, partnership or joint venture between the parties, it being understood and agreed that no provision contained herein, and no actions of the parties, shall be deemed to create any relationship between the parties other than the relationship of lender and borrower.

3.5 This Agreement shall be construed and enforced in accordance with the internal laws of the State of California, without regard to conflict-of-law principles.

3.6 In the event that any dispute between Lender and Emmaus should result in litigation or arbitration, the prevailing party in such dispute shall be entitled to recover from the other party all reasonable fees, costs, and expenses of enforcing any right of the prevailing party, including without limitation, reasonable attorneys' fees and expenses as may be awarded in such litigation or arbitration.

3.7 This Agreement may be executed in counterparts, each of which shall be deemed an original and both of which shall constitute one and the same agreement with the same effect as if both parties had signed the same signature page. Any signature page of this Agreement may be detached from any counterpart of this Agreement and reattached to any other counterpart of this Agreement identical in form hereto but having attached to it one or more additional signature pages. A facsimile or other electronic signature shall have the same force and effect as an original signature.

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the day and year first set forth above.

Yutaka Niihara, M.D., M.P.H.

Emmaus Life Sciences, Inc.

By: _____
Willis C. Lee, Chief Operating Officer

List of Subsidiaries

Name	Place of incorporation
EMI Holding, Inc.	Delaware
Emmaus Medical, Inc.	Delaware
Emmaus Medical Japan, Inc.	Japan
Newfield Nutrition Corporation	Delaware
Emmaus Medical Europe Limited	United Kingdom
Emmaus Medical Europe Limited	Ireland
Emmaus Life Sciences, Co. Ltd.	Korea
EJ Holdings, Inc. (40% consolidated under the Variable Interest Entity Model)	Japan

**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: January 22, 2021

**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: January 22, 2021

**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 for the year ending December 31, 2019, 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)

January 22, 2021

/s/ Yasushi Nagasaki

Yasushi Nagasaki

Interim Chief Financial Officer

(Principal Financial and Accounting Officer)

January 22, 2021