May 16, 2022

Zacks Small-Cap Research

Sponsored – Impartial - Comprehensive

Brad Sorensen
312-265-9574
email@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

Emmaus Life Sciences, Inc. (OTCQX: EMMA)

EMMA: Emmaus suffers revenue decline but future looks promising.

EMMA is a commercial stage biopharma company bringing relief to sickle cell sufferers and looking to expand their reach. Using a discounted cash flow model and a discount rate of 25% we arrive at a valuation for EMMA of $4.50.

Current Price (05/13/22)	$0.25
Valuation	**$4.50**

OUTLOOK

Emmaus Life Sciences, Inc. has a product on the market that is helping to ease the symptoms of sickle cell disease using the amino acid L-glutamine and going by the commercial name of Endari.

The company recently announced 1Q 2022 results that showed revenues declined from a year ago, while cash balances also decreased. We still have a positive view of EMMA but adjusted our valuation modestly downward to reflect these issues.

SUMMARY DATA

52-Week High	**$2.15**
52-Week Low	**$0.25**
One-Year Return (%)	**-81.39**
Beta	**1.98**
Average Daily Volume (sh)	**21,643**
Shares Outstanding (mil)	**49**
Market Capitalization ($mil)	**$12**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**28**
Insider Ownership (%)	**36**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**232.6**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2022 Estimate	**N/A**
P/E using 2023 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High**
Type of Stock	**N/A**
Industry	**Med-Biomed/Gene**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	5 A	6 A	6 A	6 E	23 A
2022	3 A	6 E	6 E	6 E	21 E
2023	6 E	6 E	7 E	7 E	26 E
2024	7 E	7 E	7 E	7 E	28 E

Earnings per share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2021	-$0.17A	$0.05A	-$0.06A	$0.05E	$0.03 E
2022	-$0.03A	$0.01E	$0.01E	$0.01E	$0.00 E
2023	$0.03E	-$0.01E	$0.01E	$0.01E	$0.04 E
2024	$0.01E	$0.01E	$0.01E	$0.02E	$0.05E

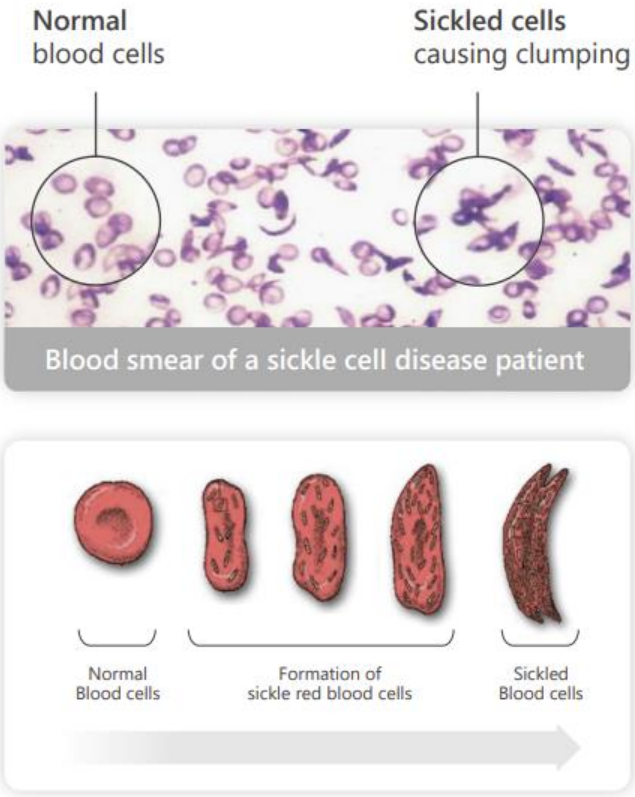
© Copyright 2022, Zacks Investment Research. All Rights Reserved.

Updates

- Emmaus Life Sciences announced 1Q 2022 earnings of -$0.03 per share-while revenues in the first quarter declined to $3.2 million from $5.3 million the year before.
    - Management noted that the decrease in revenue in the first quarter was largely due to a overstocking of the company's signature drug—Endari—in prior periods.
    - Management also noted that they saw sell through of Endari by distributors in the first three months of 2022 that was “substantially higher than in the same period in 2021.
- Emmaus also announced in April the launch of a full-service telehealth solution with several strategic partners. Management also noted that this online access is not available for competing brands.
- Other quarterly result highlights:
    - Selling expenses rose versus the same period a year ago due to a loosening of travel restrictions due to Covid-19. We believe this is a good trend and one we want to see continue in order to expand the market for Endari.
    - Emmaus had and ending cash and cash equivalent balance of $0.8 million at the end 1Q 2022—down from $2.3 million at the end of 2021. Management noted that it believes the company’s working capital is “insufficient to meet its needs for 2022” without obtaining additional loans or equity financing or curtailing operations. We believe the promise and potential of Endari is such at the company will be able to obtain the needed funding but this is the area we are most concerned with at the moment and are watching developments closely.

Sickle Cell Disease

Sickle cell disease is a genetic mutation that causes an individual’s blood cell to distort into a C, or sickle, shape. This mutation reduces the blood cells’ ability to transport oxygen throughout the body. Another problem arising from sickle cell disease is that the sickled blood cells tend to break down rapidly and becoming very “sticky”, resulting in patients with sickle cell disease having a propensity to have blood cells that clump together. This clumping causes the blood cells to become stuck and cause damage within blood vessels.



Source: https://www.emmausmedical.com/ May 13, 2022

As a result of this clumping and damage to the blood vessels, sufferers of sickle cell can have reduced blood flow to distal organs, which leads to physical symptoms such as incapacitating pain, tissue and organ damage and even early death. Other symptoms of sickle cell disease can include painful swelling of the feet and hands, fatigue from anemia due to the reduced blood cell count, and a potential yellowing of the skin or whites of the eyes.

Sickle cell disease impacts approximately 100,000 people in the US and an estimated 20-25 million people worldwide, a disease for which there is no cure and few effective treatments. And it appears to impact the black community in an outsize fashion with the CDC reporting that about 1 in 13 black babies born are born with the sickle cell trait. This results in 1 out of every 365 black babies being born with sickle cell disease, while only 1 in every 16,300 Hispanic-American births are born with sickle cell.

Endari

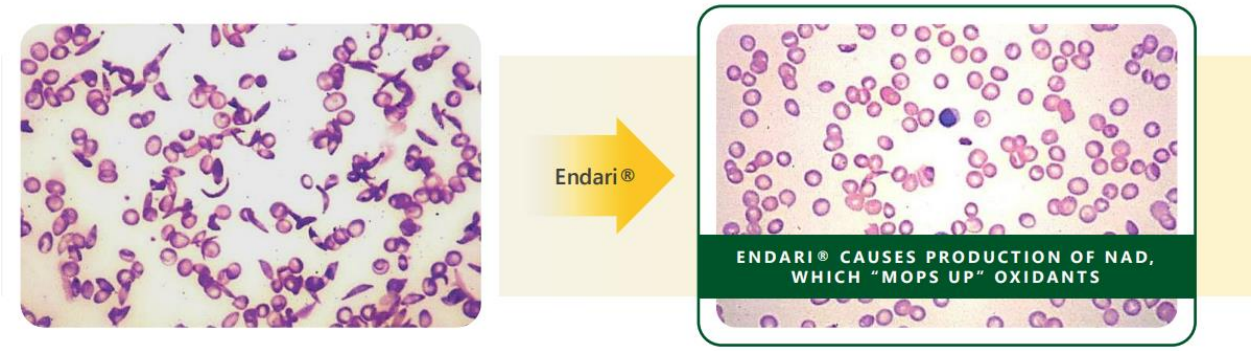
As mentioned, there are no official cures for sickle cell disease, although there have been reported cases, by the CDC, of stem cell transplants being used to “cure” sickle cell. This potential cure is an exciting new potential option but will likely not be appropriate for many sickle cell victims. The risks that come along with stem cell transplants, according to the CDC, including life-threatening illness or death and it can be quite difficult to find a matching donor. For most sickle cell sufferers, being able to manage and control symptoms would likely be a much preferrable, and more readily available, option. And that’s what Endari, the therapy for treatment of sickle cell disease created by Emmaus, can provide.

Endari has been proven to reduce complications of sickle cell disease in adults and children 5 years and older and gained the orphan drug designation from the FDA, which is reserved for those drugs and therapies targeted at conditions affecting fewer than 200,000 Americans. This designation provides the company that receives it with the possibility of receiving tax credits for qualified clinical

trials, an exemption from user fees, and, most importantly for Emmaus at this point, 7 years of market exclusivity after approval of the drug or therapy. The effectiveness of Endari in the fight against sickle cell disease is demonstrated by the results from recent clinical studies, which included 230 patients with sickle cell anemia or sickle thalassemia. Importantly, prior to the study, all 230 patients had at least two painful crises within 12 months of entering the trial. Among the encouraging results:

- Endari was shown to lower the frequency of sickle cell crises by 45%--annualized.
- Endari was shown to lower the frequency of hospitalizations by 33%.
- Cumulative days spent in the hospital by those on Endari were reduced by 41%.
- The time to the first sickle cell crisis in patients was delayed by 30 days.
- There was a reduced occurrence of acute chest syndrome (ACS). ACS is an acute complication of sickle cell disease and a major cause of morbidity and mortality. Once acquired, immediate intervention is required—regardless of age.
- Analysis by the company indicates that patients requiring blood transfusions and receiving Endari required about 43% fewer units of red blood cells.

A pictorial representation of what happens with the red blood cells and Endari is below, the details of which will be discussed in the following section.



Source: https://www.emmausmedical.com/ May 13, 2022

It can seem a bit heartless to look at the financial benefits of a treatment like Endari when quality of life issues are involved, but it is the financial picture that helps motivate further treatments such as Endari. As seen above, patients that take Endari have fewer hospitalization days, resulting in lower costs to patients and their insurance companies. According to a study in the *American Journal of Hematology* (*March 2009, Kauf, Coates, Huazhi, Mody-Patel, Hartzema*), the potential savings on treatment costs could reach more than $2 billion annually in the US alone.

Other important aspects of a drug or therapy is how complicated it is to use, how accessible it is and how many patients it is approved for. There are several other types of treatment for sickle cell disease, with the main one being hydroxyurea, which is a drug produced by several companies, including Bristol Myers Squibb. While hydroxyurea has proven effective in reducing crisis episodes in some sickle cell patients, it is only approved for those over 18 years of age and, more seriously, has a black box warning from the FDA noting that, "Hydroxyurea is mutagenic and clastogenic, and causes cellular transformation to a tumorigenic phenotype. Hydroxyurea is thus unequivocally genotoxic and a presumed transspecies carcinogen which implies a carcinogenic risk to humans. In patients receiving long-term hydroxyurea for myeloproliferative disorders, such as polycythemia vera and thrombocythemia, secondary leukemias have been reported. It is unknown whether this leukemogenic effect is secondary to hydroxyurea or is associated with the patient's underlying disease." Endari is approved for those 5 year of age and older and carries no black box label for

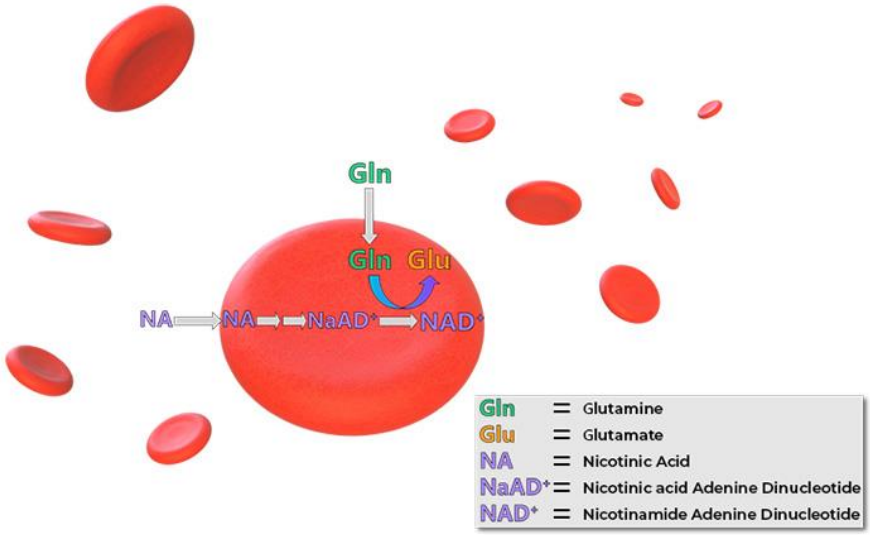
patients to be concerned about. Additionally, Endari is easy for patients to take with it being in powder form and able to take easily orally and has other convenience benefits including:

- No preliminary bloodwork or follow-up testing is needed.
- Endarii can be delivered to the patient's front door and taken at home.
- Endari can be administered via being mixed into food or drinks.
- The company believes that Endari, due to the above factors, has a high potential for to be the first choice for medication for patients using telemedicine services.

Endari—how it works

Endari consists of the amino acid glutamine, which is a naturally occurring amino acid in the human body and is a key sickle cell disease treatment that can be used alone or alongside other treatments. For those of us in the analyst world, lack of complete understanding of anything is frustrating, but that can often be the case with the human body and how and why it interacts with therapies, both drug and otherwise and that's the case here. The mechanism of action of the amino acid glutamine in treating sickle cell disease is not fully understood but the company has a general idea on why it works:

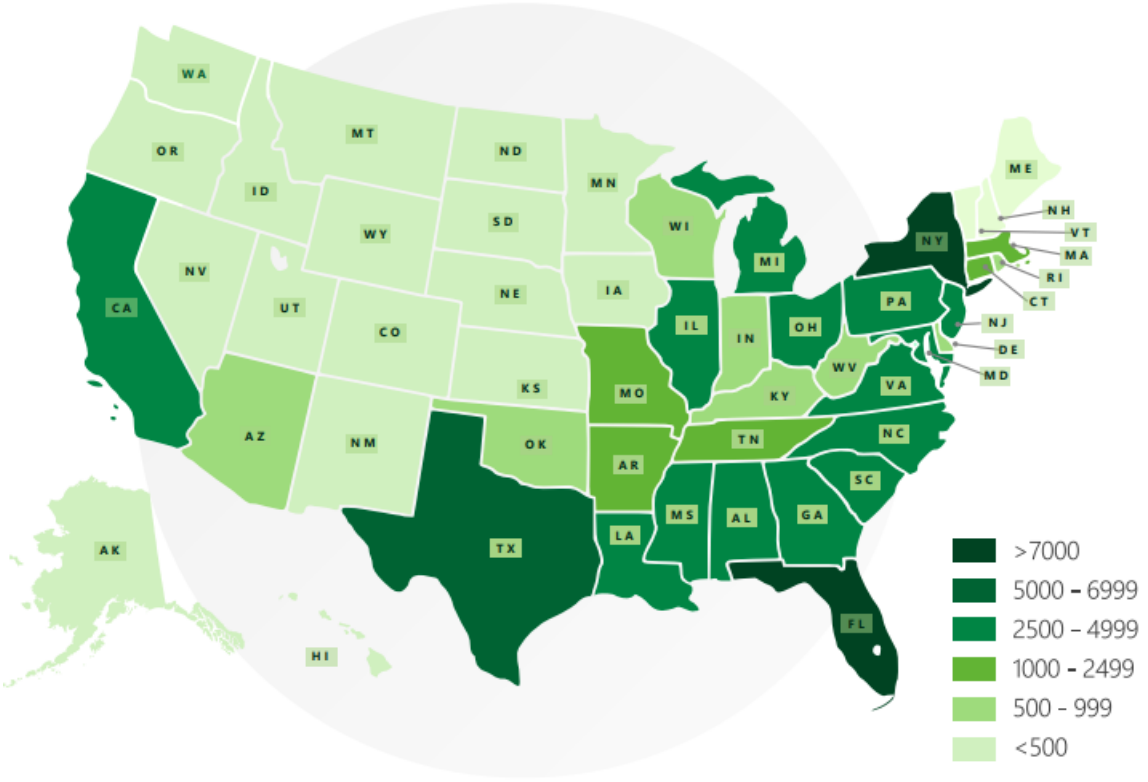
1. Oxidative stress is caused by an imbalance in cells between reactive oxygen and the cell's ability to detoxify oxygen. Oxidative stress phenomena are involved in the pathophysiology (functional changes that accompany a particular syndrome or disease) of sickle cell disease.
2. Sickle red blood cells are more susceptible to oxidative damage than normal red blood cells, which may contribute to the chronic hemolysis (damage or destruction of red blood cells) and vaso-occlusive (when blood flow is blocked to an area because sickle-shaped cells have become stuck in the blood vessel) events associated with sickle cell disease.
    - Stuck blood cells increase the risk of heart attacks, strokes and frequent infections.
3. It is believed that Endari helps to restore the ratio of NADH/NAD (total) in the red blood cells. NADH is a natural antioxidant in the cell and is involved in regulating and preventing oxidative damage in red blood cells. In individuals with sickle cell disease, the ratio of NAD+ and NADH may be altered. Endari improves and restores the ratio of NADH to NAD total, which may help sickle cell red blood cells tolerate increased oxidative stress.
4. NAD is nicotinamide adenine dinucleotide—a critical coenzyme found in every cell in the body—involved in hundreds of metabolic processes.
    - Exists in two form-NAD+ and NADH+
    - Higher levels of oxidants experienced by SCD patients tilts the NAD+/NADH equilibrium toward NAD+ production.



Source: https://www.endarirx.com/how-ENDARI-works May 13, 2022

Endari-How It's Sold

Having a drug or therapy that works isn't much good unless the company can get that solution into people's hands. Emmaus has a good start at that challenge with Endari and is continuing to work to improve access and distribution. Through research the company has done, they've recognized that about 86% of sickle cell patients in the US live in the major metropolitan areas in 18 states—as seen in the map below. This allows Emmaus to have a more targeted sales approach and to concentrate the company's sales resources in specific areas. To that end, Emmaus transitioned from a contract sales force to an internal sales team, which we believe better aligns with the company's goals, and have since added to their sales staff and the expenses for sales and marketing have increased to support more salespeople and the associated travel required. For now, we believe that spending more money to get the word out on the benefits of Endari is money well spent and we will be watching to see if the results follow the investment.



Source: https://www.emmausmedical.com/ March 28, 2022

Additionally, in the US, Emmaus is more aggressively attempting to expand the reach of Endari. The salespeople we mentioned above are targeting hematologists, physicians and treatment centers, while also working with local and national sickle cell disease foundations to get the word about Endari out. Importantly, Endari is well covered by various insurance programs, including Managed Medicare, the Children's Health Insurance Program (CHIP), commercial insurance and Medicare, while also providing patient assistance where required. The result is that Emmaus has a network of over 600 pharmacies distributing Endari, with the big 3 distributors involved—AmerisourceBergen, Cardinal and McKesson. And there are more opportunities to expand Endari's reach through pharmacy benefit managers, group purchasing organizations and specialty pharmacies.
But we view one of the real opportunities for an expansion of Endari in treating sickle cell disease to be in the global area—and that is an area where Emmaus is being quite aggressive. The first step is getting Endari approved by the various regulatory agencies in the relevant countries and, according to the company, of the 20-25 million global cases of sickle cell—the predominant concentration of them are in Africa, the Middle East, India, South America and Mediterranean regions. Currently, Endari is approved for use in the US and Israel. Endari is submitted for approval in Saudi Arabia, Kuwait, and Bahrain, while the United Arab Emirates has approved Endari for use for the treatment of sickle cell disease. The process for gaining approval has started in other Gulf Cooperation Council countries and Early Access programs are underway or planned in the UK, France and Turkey. Additionally, Emmaus has opened an office in Dubai and has distribution partners in place in the Middle East and North Africa (MENA) region.

Finally, Emmaus announced that they have launched a full-service telehealth solution that will provide online access to Endari—something that Endari's competitors don't have the ability to provide at this point.

VALUATION

We are slightly adjusting the valuation of EMMA to $4.50 from $5.70 to reflect our slightly increased concern about the current liquidity situation as well as the decline in revenues seen in 1Q 2022. The major factors in determining the valuation of EMMA involve the growth rate of Endari for the treatment of sickle cell, while also projecting the potential income from expanding the use of Endari into other treatments of conditions such as diverticulosis. With Emmaus management bringing the sales function in house, demonstrating to us their commitment to improving sales, while also considering the loosening of opportunities for the salespeople to speak and meet with potential clients due to fewer Covid-related restrictions, we are assigning a 7% growth rate for Endari through 2025 before leveling off at 3% thereafter as the market becomes saturated and new competition may enter the market. That higher growth rate in effect until 2025 also includes the assumption that some of that growth comes from expansion of Endari into some international markets. The real game-changer for Emmaus, in our view, would be for Endari to expand for use in treating other conditions.

We assume that Endari is approved for treatment of diverticulosis in 2024 with sales beginning in 2025 at a rate of 0.1% of the projected US market of $480 million. Admittedly, this is a very rough estimate but we think a reasonable one based on the condition and lack of effective treatments currently available. After the initial year of sales, we assume a 5% growth rate of sales of Endari for the treatment of diverticulosis in the following years. We are also adding a measure of conservatism to our estimates as we assume the growth rates of Endari for sickle cell diseases and diverticulosis will also include any other uses that may be approved for Endari in the next 10 years.

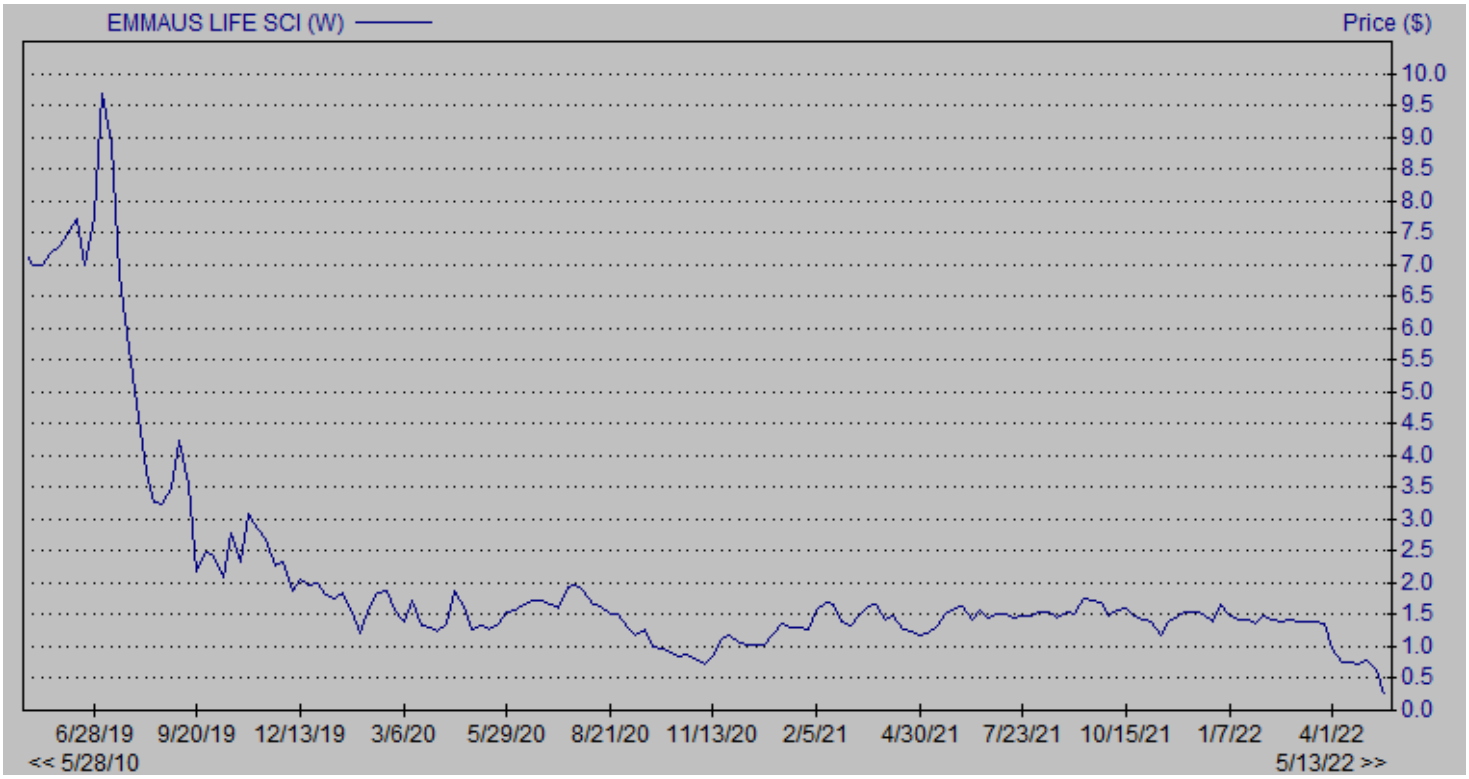
On the expense side, we assume that sales expenses expand at 7% annualized rate, which they will likely need to do, in our view, in order to meet the sales growth assumptions we are making. Further, we assign a 5% growth rate to both administrative expenses and research and development as that is the growth rate we assume will be needed in order to achieve the goals outlined. Finally, a major benefit that we believe exists for potential shareholders of EMMA is that Emmaus is already making sales and meeting expenses without getting additional financing. We believe this will continue and that the dilution of current shareholders due to the issuance of additional shares will be de minimis in the coming years.

We believe in the prospects of Emmaus to expand the use rate of Endari but acknowledge that there are many uncertainties surrounding the growth rates and approvals for the expansion of the uses of Endari. Additionally, there are concerns we have about the ability to obtain additional funding at favorable terms in the current environment. Therefore, we are assigning a discount rate of 25% to Emmaus when applied to the discounted cash flow model, which is what we are using to come up with the $4.50 valuation. We believe that valuation, given the factors above, is a fair one and that investors considering EMMA for their portfolio should recognize that the risk level is elevated as the future cash flows are certainly not assured. But we believe there are solid prospects and good odds for success as we've laid out and believe EMMA is worth a look at the current levels for investors with a higher risk tolerance.

PROJECTED INCOME STATEMENT & BALANCE SHEET

Emmaus Life Sciences Income Statement and Balance Sheet (in thousands, except share data)	3Q2021A	4Q2021E	1Q2022A	2022E	2023E	2024E	2025E
Net Revenues	5,766	6,631	3,234	24,610	26,333	28,176	30,148
Cost of goods sold	445	450	1,007	2,461	2,633	2,818	3,015
Gross profit	5,321	6,181	2,227	22,149	23,699	25,358	27,133
Operating expenses							
Research and development	470	484	466	2,625	2,756	2,894	3,039
Selling	1,518	1,450	1,460	5,350	5,725	6,125	6,554
General and administrative	3,364	2,000	3,369	14,175	14,884	15,628	16,409
Total operating expenses	5,352	3,934	5,295	22,150	23,365	24,647	26,002
Gain/(loss) from operations	(31)	2,247	(3,068)	(1)	335	711	1,131
Other income/(expense)							
Net gain/(loss) on investment	0	-	-	-	-	-	-
Net gain/(loss) on equity method investment	(663)	-	(566)	-	-	-	-
Interest expense	(683)	-	(737)	-	-	-	-
Other income/(expense)	(1,542)	-	2,726	2,300	2,000	2,000	2,300
Total other income/(expense)	(2,888)	0	1,423	2,300	2,000	2,000	2,300
Income/(loss) before income taxes	(2,919)	2,247	(1,645)	2,299	2,335	2,000	3,431
Income taxes/(benefit)	232	0	(103)	0	0	0	0
Net Income/(loss)	(3,151)	2,247	(1,542)	2,299	2,335	2,000	3,431
Earnings/(loss) per common share	($0.06)	$0.05	($0.03)	$0.04	$0.04	$0.04	$0.06
Weighted average of shares outstanding	49,311,864	49,311,864	49,311,864	51,777,457	54,366,330	57,084,647	59,938,879
Current Assets							
Cash and Cash Equivalents	2,321	2,344	813	2,391	2,439	2,488	2,537
Inventories, net	6,252	6,315	3,453	6,378	6,441	6,506	6,571
Other Current assets	3,901	3,800	2,182	3,800	3,800	3,800	3,800
Total current assets	12,474	12,459	6,448	12,569	12,680	12,794	12,908
Property, plant and equipment	97	102	138	107	112	118	124
Equity method investment	17,835	17,835	17,771	17,835	17,835	17,835	17,835
Investment in convertible bond	25,716	25,716	23,521	25,716	25,716	25,716	25,716
Other assets	3,935	3,935	3,615	3,935	3,935	3,935	3,935
Total Assets	60,057	60,047	51,493	60,162	60,279	60,397	60,518
Current Liabilities							
Accounts payable	6,973	7,112	9,718	7,255	7,400	7,548	7,699
Notes payable	3,269	3,285	2,286	3,302	3,318	3,335	3,352
Other current liabilities	14,784	15,000	22,547	15,450	15,450	15,450	15,450
Total current liabilities	25,026	25,398	34,551	26,006	26,168	26,333	26,500
Operating lease liabilities, less current portion	3,449	3,450	3,084	3,451	3,452	3,453	3,454
Other long-term liabilities	46,683	46,683	36,157	46,683	46,683	46,683	46,683
Total Liabilities	75,158	75,531	73,792	76,140	76,303	76,469	76,637
Paid in Capital	220,066	220,066	220,027	220,066	220,066	220,066	220,066
Accumulated other comprehensive income	(763)	(763)	482	(763)	(763)	(763)	(763)
Accumulated deficit	(234,404)	(234,404)	(242,808)	(234,404)	(234,404)	(234,404)	(234,404)
Total Stockholder deficit	(15,101)	(15,101)	(22,299)	(15,101)	(15,101)	(15,101)	(15,101)
Total Liabilities and stockholder deficit	60,057	60,430	51,493	61,039	61,202	61,368	61,536

HISTORICAL STOCK PRICE



DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, Brad Sorensen, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESTMENT BANKING AND FEES FOR SERVICES

Zacks SCR does not provide investment banking services nor has it received compensation for investment banking services from the issuers of the securities covered in this report or article.
Zacks SCR has received compensation from the issuer directly, from an investment manager, or from an investor relations consulting firm engaged by the issuer for providing non-investment banking services to this issuer and expects to receive additional compensation for such non-investment banking services provided to this issuer. The non-investment banking services provided to the issuer includes the preparation of this report, investor relations services, investment software, financial database analysis, organization of non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per-client basis and are subject to the number and types of services contracted. Fees typically range between ten thousand and fifty thousand dollars per annum. Details of fees paid by this issuer are available upon request.

POLICY DISCLOSURES

This report provides an objective valuation of the issuer today and expected valuations of the issuer at various future dates based on applying standard investment valuation methodologies to the revenue and EPS forecasts made by the SCR Analyst of the issuer's business.
SCR Analysts are restricted from holding or trading securities in the issuers that they cover. ZIR and Zacks SCR do not make a market in any security followed by SCR nor do they act as dealers in these securities. Each Zacks SCR Analyst has full discretion over the valuation of the issuer included in this report based on his or her own due diligence. SCR Analysts are paid based on the number of companies they cover. SCR Analyst compensation is not, was not, nor will be, directly or indirectly, related to the specific valuations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports and articles are based on data obtained from sources that it believes to be reliable, but are not guaranteed to be accurate nor do they purport to be complete. Because of individual financial or investment objectives and/or financial circumstances, this report or article should not be construed as advice designed to meet the particular investment needs of any investor. Investing involves risk. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports or articles or tweets are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

CANADIAN COVERAGE

This research report is a product of Zacks SCR and prepared by a research analyst who is employed by or is a consultant to Zacks SCR. The research analyst preparing the research report is resident outside of Canada, and is not an associated person of any Canadian registered adviser and/or dealer. Therefore, the analyst is not subject to supervision by a Canadian registered adviser and/or dealer, and is not required to satisfy the regulatory licensing requirements of any Canadian provincial securities regulators, the Investment Industry Regulatory Organization of Canada and is not required to otherwise comply with Canadian rules or regulations.