



March 4, 2021

SIGYN THERAPEUTICS, INC.

(OTC – SIGY)

Industry: Medical Devices

Price Target: \$9.00

SIGYN THERAPEUTICS, INC.

Redefining Treatment of Life-Threatening Conditions

Rob Goldman
rob@goldmanresearch.com

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COMPANY SNAPSHOT

Sigyn Therapeutics™ is a development-stage therapeutic technology company targeting a significant unmet need in global health; the treatment of life-threatening inflammatory conditions that are precipitated by Cytokine Storm Syndrome and not addressed with an approved therapy. Cytokine storm syndrome is the hallmark of sepsis, the most common cause of in-hospital deaths. Virus induced cytokine storm is a leading cause of COVID-19 deaths. Other therapeutic opportunities include bacteria induced cytokine storm, acute respiratory distress syndrome and acute forms of liver failure, such as hepatic encephalopathy.

KEY STATISTICS

Price as of 3/4/21	\$2.00
52 Week High – Low	\$3.50 - \$1.00
Est. Shares Outstanding	35.2M
Market Capitalization	\$70.6M
Average Volume	3,071
Exchange	OTCPK

COMPANY INFORMATION

Sigyn Therapeutics, Inc.
8880 Rio San Diego Drive
Suite 800
San Diego, CA 92108

Web: www.SignTherapeutics.com
Email: info@sigyntherapeutics.com
Phone : 619-368-2000

INVESTMENT HIGHLIGHTS

Sigyn is poised to change the way acute, life-threatening inflammatory conditions induced by Cytokine Storm Syndrome are treated. Many of these conditions have no approved therapy and represent billions in market size.

Primary targeted conditions include COVID-19 and sepsis, the #1 cause of deaths in hospitals worldwide. We believe the Company's sepsis opportunity is \$17B in the US alone.

Sigyn has reported favorable in vitro results and is poised to file an IDE with the FDA later this year. The Company could be awarded Breakthrough Device designation and Emergency Use Authorizations in the coming quarters which could make Sigyn an attractive M&A target by Tier 1 medical device players. .

The Company boasts enviable leadership that is second to none in this therapeutic category. The CEO has led NASDAQ-listed device companies and co-authored submissions that resulted in two FDA Breakthrough Device awards. The co-founders oversaw the development of three devices that were approved by the FDA to treat COVID-19.

Our six-twelve-month price target for Sigyn is \$9.00, more than 4x its recent closing price. This target reflects the value of prospective milestone achievements as Sigyn transitions from a development stage company to a clinical stage firm. It is affirmed by using a discounted potential value of revenue generated as an FDA-approved Breakthrough Device and EUA treatment for sepsis alone.

COMPANY OVERVIEW

San Diego-based **Sigyn Therapeutics, Inc. (OTC – SIGY)** is poised to change the way clinicians approach the treatment of acute, inflammatory conditions, in particular those precipitated by Cytokine Storm Syndrome (CSS), for which there is no approved therapy. Moreover, we believe that Sigyn's elegant, therapeutic process may prove to emerge as the most efficacious approach to treating a broad-based set of life-threatening conditions. These range from sepsis, the leading cause of death in hospitals, to virus induced cytokine storm (VICS) such as COVID-19, (BICS) bacteria induced cytokine storm (BICS), acute respiratory distress syndrome (ARDS) and acute forms of liver failure, such as hepatic encephalopathy. Based on our estimates, the market for the Sigyn-designed anti-cytokine blood purification therapy for these acute conditions reaches tens of billions per year for sepsis alone.

A New Lens for a New Paradigm



For years, we have been conditioned to view therapeutic treatment for life-threatening conditions in the form of a single targeted mechanism via biopharma, immunotherapy, etc. In contrast, we have viewed the multi-targeted mechanism capabilities of medical devices as a complementary tool rather than affording it due value as a potentially broad-based therapy. Perhaps it is a function of the hundreds of millions spent to move drugs through FDA process, along with follow-on marketing versus the lower bar for regulatory clearance of devices.

Sometimes it takes a calamitous event or a major technological advancement to change perception and therefore drive the early adoption of new or varied approaches. We proffer that such an event has occurred in the form of the current COVID-19 pandemic, coupled with technology catching up by improving upon previous designs, utilization, and modalities. Against this backdrop, we find Sigyn Therapeutics. To paraphrase an old commercial, "this is not your father's medical device company."

We believe that Sigyn is not just poised to be awarded a potential Breakthrough Device designation in its category or a possible Emergency Use Authorization (EUA) by the FDA in the coming year for key indications. Our thesis remains that Sigyn could eventually be the first company to advance a medical device to treat Cytokine Storm Syndrome as its own categorical indication. Therefore, the aforementioned life-threatening conditions could come under the CSS condition, offering clinicians a new weapon to fight this difficult to treat disorder. In the meantime, much of our focus is on the use of Sigyn Therapy to treat sepsis, given its large unmet need, with no approved therapy, despite the best efforts of dozens of firms. Moreover, if cleared just for sepsis, this incredibly lucrative event would be a boon to the company and its investors.

The Problem: Cytokine Storm Syndrome

Triggered by a wide range of infectious and non-infectious diseases, CSS refers to a group of related medical conditions in which the immune system produces too many inflammatory signals leading to the substantial production of pro-inflammatory cytokines. The pro-inflammatory cytokines start “storming” out of control, without enough aid from the anti-inflammatory cytokines. In people experiencing this condition, these pro-inflammatory cytokines are present in the blood at higher-than-normal amounts, wreaking havoc. This condition can lead to organ failure and death.



CSS has become a more widely known condition due to its frequent occurrence in acute COVID-19 patients. Perhaps this is why in response to COVID-19, the FDA appears to have established inflammatory cytokine reduction as a clinical endpoint to ameliorate cytokine storms that are induced by viral infections.

“Based on the totality of scientific evidence available, the removal of pro-inflammatory cytokines may ameliorate the cytokine storm due to the overabundance of pro-inflammatory cytokines and, in turn, provide clinical benefit.”

Clearly, this FDA comment may have a favorable impact on Sigyn’s future product submissions.

Anti-cytokine drug mechanisms are limited to single cytokine targets and broad efficacy of existing devices are little better. Two devices used to treat life-threatening inflammatory conditions are currently approved for sale outside of the U.S. only. While one device incorporates an adsorbent bead to address inflammatory cytokines that circulate freely in the blood, it does not address endotoxin, which is a potent activator of CSS. The second device depletes the presence of circulating endotoxin but does not address pro-inflammatory cytokines. As a result, on their own, efficacy and prospective utilization is limited.

Sigyn’s Approach: Target, Isolate, Deplete, Return

Sigyn Therapy’s innovative mechanism combines the therapeutic intent of the two devices and melds it into one offering. Leveraging a novel blood purification technology design and its founders extensive experience in developing therapeutic devices, SIGY has created a single-use (blood-in-blood-out) disposable device designed for use on the existing hemodialysis infrastructure found in hospitals and clinics worldwide. In vitro studies have demonstrated that Sigyn Therapy, which incorporates a cocktail of adsorbent components, is able to deplete the presence of a broad-spectrum of inflammatory cytokines and endotoxin from the bloodstream. As a result, the cytokines may return to their typical immune response function.

Using data from previous and forthcoming studies, Sigyn plans to submit an Investigational Device Exemption, or IDE with the FDA, later this year. Separately, Sigyn plans to submit its flagship as a candidate for an FDA “Breakthrough Device” designation, along with an EUA for one of its key indications such as HE, COVID-19, or sepsis. The IDE submission is designed to support the initiation of a human feasibility study for hepatic encephalopathy, whose protocol is designed to demonstrate safety of its therapy in health-compromised individuals suffering from acute CSS-related conditions. Management could also elect to conduct a concurrent

or subsequent study for sepsis. Following the completion of the HE feasibility study, management plans to leverage the data to support a modular regulatory strategy that would permit pivotal studies (necessary for FDA market clearance) to be conducted in life-threatening disease conditions precipitated by CSS. Upon clearance of the IDE, Sigyn may also submit an IDE supplement request to treat COVID-19 infected individuals or drug-resistant bacteria infections in a clinical setting.

Our Take

In our view, Sigyn offers a rare opportunity in the health care arena, and one that offers substantial upside potential. Our conclusion is based upon a variety of factors. These include management's inimitable history of success in this blood purification category, pubco leadership experience, market size, and most important, the potential for Sigyn to emerge as the go-to treatment for CSS-related conditions. Our 6–12-month price target of \$9.00 (\$317M market cap) reflects the value of a series of prospective milestone achievements as Sigyn transitions from a development stage company to a clinical stage firm.

This target is further bolstered by comp **Cytosorbents Corp. (NASDAQ – CTSO)**, which currently carries a \$388M market cap and trades 7.6x this year's sales, along with a discounted potential value of revenue generated as an FDA-approved Breakthrough Device and EUA treatment for sepsis alone. If the FDA clears the device for use to treat CSS conditions via removal of pro-inflammatory cytokines as an endpoint then all bets are off and we believe that the Company would be the prettiest girl at the dance for Tier 1 med device companies on the prowl for new acquisitions.

THE SIGYN DIFFERENCE



Figure 1: Model Depiction of Sigyn Therapy

Sigyn's flagship platform, Sigyn Therapy, is a proprietary blood purification technology designed to overcome the limitations of previous drug and device candidates to treat acute inflammatory conditions, notably those preceded by Cytokine Storm Syndrome. The applications and potential indications represent unmet needs and, in many cases, there is no approved drug therapy. Given that the FDA established inflammatory cytokine reduction as a clinical endpoint to ameliorate cytokine storms that are induced by viral infections, we believe that Sigyn's therapy could be cleared to treat VICS, sepsis, or acute COVID-19—all representing vast markets.

Against this backdrop, Sigyn may also be positioned to receive EUA for use of its therapy for other indications including HE, COVID-19, and others, making Sigyn Therapy the go-to therapy to treat acute, life-threatening inflammatory conditions.

Why Sigyn is Poised to Succeed

Favorable Early Study Results

In December 2020, Sigyn reported in vitro study results that validated the ability of Sigyn Therapy to simultaneously clear both inflammatory cytokines and endotoxin from human blood plasma. A month later, the Company reported the results of an in vitro pilot study that successfully modeled the ability of Sigyn Therapy to address inflammatory CytoVesicles, which have been elusive targets for previous therapeutic candidates. These results were critical as management gained valuable insight indicating that the platform can address a broad-spectrum of inflammatory targets, including inflammatory cytokines, endotoxin and CytoVesicles that participate in concert with freely circulating cytokines to escalate Cytokine Storm Syndrome. Other studies including animal studies are expected to commence throughout 2021, heading into the IDE submission in 3Q/4Q of this year.

Enviably Leadership

Investors would be hard pressed to find a leadership team that matches the type of experience and success of the Sigyn team. The Chairman and CEO has considerable experience specifically in the blood purification space, and two decades of pubco and Board experience. Plus, he co-authored two regulatory submissions that resulted in two Breakthrough Device awards from the FDA. The co-founders previously oversaw the development of three devices that were approved by the FDA to treat COVID-19. Sigyn is leveraging these devices and previous experience to design a device that may demonstrate similar safety and efficacy profiles in the HE and COVID-19 indications.

Improving Existing Approaches

The Sigyn Therapy was designed to overcome the limitations of previous drug and device therapies. This includes two industry-pioneering devices that are currently prevalent in the marketplace outside of the United States.

The Toraymyxin device, a product developed and owned by \$9B in market cap **Toray Industries, Inc. (OTC - TRYIY)** Toraymyxin has a high specificity to bind circulating endotoxin, a potent activator of cytokine storm syndrome induced by bacterial infections. However, Toraymyxin does not address inflammatory cytokines or CytoVesicles. The CytoSorb device, the lead product of CytoSorbents incorporates an adsorbent component to deplete inflammatory cytokines below 5 nanometers in diameter from the bloodstream but does not address endotoxin or CytoVesicles.

Both products are market cleared and often deployed to treat a variety of inflammatory conditions in more than 40 countries. Toraymyxin has been safely administered to more than 150,000 patients and the CytoSorb device has been safely administered to more than 100,000 patients. In the United States, both devices are being evaluated in the treatment of COVID-19 infected individuals.

Many Shots on Goal

Virus Induced Cytokine Storm (VICS) is associated with high mortality rates and is defined by an excess production of inflammatory cytokines in response to a virulent viral infection. As the vast majority of human viruses are not addressed with a corresponding drug or vaccine, there is an urgent and ongoing need for therapies that mitigate the Cytokine Storm that can be initiated by a broad-spectrum of viral pathogens. At present, VICS is a leading cause of COVID-19 deaths and often precipitates other life-threatening conditions including acute respiratory distress syndrome (ARDS) and sepsis, which are highly prevalent in hospitalized COVID-19 patients.

COVID-19 & Influenza

In March of 2020, Yale University researchers reported that elevated levels of pro-inflammatory cytokines correlated with the severity of COVID-19 infection and increased mortality rates. Inversely, the researchers reported that declining levels of these same cytokines are associated with patient recovery. In April of 2020, the FDA established pro-inflammatory cytokine reduction as a clinical endpoint to ameliorate the cytokine storm induced by a viral infection.

Given the optimistic current environment for COVID-19 we are hesitant to assign a firm target market forecast. Still, we believe if an EUA is awarded for this indication, we believe the near-term market opportunity could approach \$3B or higher in the US alone, depending upon hospitalization rates and the number of treatments. It is clearly a market that represents low-hanging fruit.

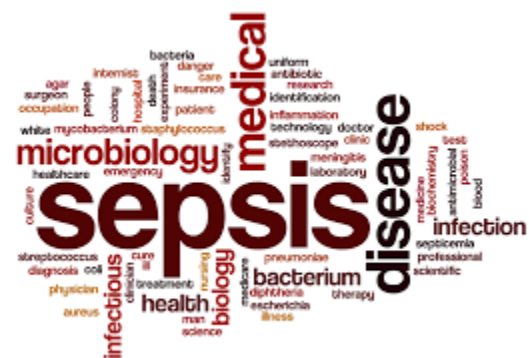
Influenza is a huge potential market as well for Sigyn and given the periodic major viral outbreaks, Sigyn could position its therapy as a first line of defense. We believe once the COVID-19 pandemic abates, attention could return to this category and a market size billions in prospective business abroad is not out of the question.

Sepsis

Noted medical publication *The Lancet* reported 48.9M cases of sepsis and 11M deaths in 2017. The report referenced that sepsis kills more people around the world than all forms of cancer combined, as it is responsible for one in five deaths worldwide. In the U.S. sepsis was reported to be the most common cause of in-hospital deaths (35%) with annual costs exceeding \$24 billion.

Sepsis is also a significant risk factor in virulent virus infections, including COVID-19. In March of 2020, the Journal Lancet published the first and largest study (at the time) of risk factors linked to COVID-19 infection and death in hospitalized adults who either died or were released from two hospitals in the Wuhan, China region. The study reported the diagnosis of sepsis in all patients who died.

To date, more than 100 human studies have been conducted to evaluate the safety and benefit of candidate drugs to treat sepsis. With one brief exception (Xigris, Eli Lilly), none of these studies resulted in a market



approved therapy. As the treatment of sepsis remains elusive for therapeutic drug agents, an increased understanding of the complex mechanisms that underlie sepsis support the potential of therapeutic strategies that modulate a broad-spectrum of inflammatory factors.

While the \$24B for market size in this segment is a commonly cited figure, we believe this reflects cost of *care* versus cost of *treatment*. For Sigyn, we believe the domestic opportunity is around \$17B with global market 5-10 times that figure. While management will surely look to receive clearance abroad, we are focused on US FDA approval at this time.

BICS

Gram-negative bacteria infections are a significant global health issue due to their resistance to antibiotic therapy. In severe infections, bacteria shed endotoxins into the circulatory system, which are potent drivers of Cytokine Storm Syndrome. According to the Centers for Disease Control and Prevention (CDC), over two million infections are caused by antibiotic-resistant bacteria each year in the United States, resulting in approximately 23,000 deaths. From a national biodefense perspective, four species of bacteria have been classified as "Category A" biological threats as they pose a high risk to national security and public health. These include *Bacillus anthracis* (anthrax), *Clostridium botulinum* toxin (botulism), *Yersinia pestis* (plague) and *Francisella tularensis* (tularemia). The extracorporeal elimination of circulating endotoxin has previously been demonstrated to help rebalance the innate immune system, decrease levels of inflammatory mediators and improve vascular function and hemodynamics. This segment remains a wild card for Sigyn and we expect that much like viral outbreaks, biological threats may dominate the opportunity for the Company and we believe government (military) related revenue is in the cards, although the runway is fairly long.

HE

The lowest hanging fruit for the Company, Hepatic Encephalopathy (HE) is a life-threatening complication of liver cirrhosis that results in 25,000-40,000 U.S. hospital admissions each year. The three-year survival rate following the first episode of HE is approximately 15%. HE severity has been correlated with highly elevated serum concentrations of pro-inflammatory cytokines and toxins. We view the significance of clearance for HE as a bridge to substantial sepsis and COVID-19 treatment revenue rather than HE-related revenue which appears to have a market size of around \$500M per year, based on the number of late-stage patients with the condition.

SIGYN LEADERSHIP TEAM

James A. Joyce, Co-Founder, Chairman, Chief Executive Officer

James "Jim" Joyce has 30+ years of diverse public market experience, which includes two decades of public company CEO and Corporate Board leadership roles. He is also an inventor or co-inventor underlying 18 pending or issued patents.

Prior to establishing Sigyn Therapeutics, Mr. Joyce was the founder and former Chairman and CEO of **Aethlon Medical (NASDAQ – AEMD)**, a therapeutic technology company that he navigated from single shareholder start-up to Nasdaq-traded Company with 8000+ shareholders. During his tenure at Aethlon, Mr. Joyce oversaw

the development of the *Hemopurifier®*, a first-in-class blood purification technology to address life-threatening viruses and cancer-promoting exosomes. Under his leadership, the *Hemopurifier®* became the first therapeutic candidate to be awarded two FDA “Breakthrough Device” designations and was the first and only device to receive “Emergency Use Authorization” (EAU) approval from both the FDA and Health Canada to treat Ebola virus. Time Magazine named the *Hemopurifier®* one of the “11 Most Remarkable Advances in Healthcare” and designated the device to its “Top 25 Best Inventions” award list. The *Hemopurifier®* has since been cleared by the FDA to treat severe COVID-19 infections in a clinical setting.

Under Mr. Joyce’s leadership, the *Hemopurifier®* was the subject of two Department of Defense (DOD) contract awards and a National Cancer Institute (NCI) contract. Mr. Joyce led the completion of approximately \$100 million of equity financings on behalf of Aethlon Medical and established preclinical and clinical collaborations with more than twenty government and non-government research institutes.

Based on the use of the *Hemopurifier®* to treat HIV and Hepatitis-C infected individuals in India, Mr. Joyce was the recipient of the “Spirit of India Award” sponsored by the Bill & Melinda Gates Foundation and awarded each year by the American India Foundation to the American business leader who has demonstrated a commitment to accelerate social and economic change in India.

Mr. Joyce testified before Congress and lobbied Capitol Hill to promote the *Hemopurifier®* as a broad-spectrum countermeasure against bioterror and pandemic threats, which contributed to expanding the government-wide definition of treatment countermeasure to be inclusive of medical devices under U.S. law.

Mr. Joyce is also the founder and former Executive Chairman of Exosome Sciences, Inc. (ESI), a company focused on the discovery of exosomal biomarkers to diagnose and monitor cancer and neurological disorders. Inspired by the death of a former teammate, Mr. Joyce established a collaboration with the Boston University CTE Center to test his hypothesis that circulating exosomes transported tau protein cargos (exosomal tau or TauSome) that could provide a basis for a non-invasive blood test to diagnose and monitor neurological tauopathies, including chronic traumatic encephalopathy (CTE) and Alzheimer’s disease. As a result, ESI was invited to participate in the first NIH funded clinical study of CTE, which revealed TauSome levels to be approximately 9x higher in 78 former NFL players as compared to the same age group control subjects. The study results (co-authored by Mr. Joyce) were published in the Journal of Alzheimer’s Disease. Follow-on clinical studies are being conducted. Mr. Joyce established a collaboration with the Boston University Alzheimer’s Disease Center that also demonstrated TauSome levels to be significantly elevated in diagnosed Alzheimer’s patients.

Prior to founding Aethlon Medical and Exosome Sciences, Mr. Joyce operated James Joyce & Associates. He was the founder and former CEO of Mission Labs, Inc. and a principal at London Zurich Securities. Upon graduating from the University of Maryland, Mr. Joyce was first employed as a member of the Denver Broncos Football Club of the National Football League.

Craig P. Roberts, Co-Founder, Chief Technology Officer

Mr. Roberts is an inventor of several life-saving therapeutic technologies. This includes the Percutaneous Adult Extracorporeal Membrane Oxygenation (ECMO) system, which was licensed and subsequently sold to C.R. Bard. During the COVID-19 pandemic, ECMO has been broadly deployed to treat critically ill COVID-19 patients. Additionally, Mr. Roberts is the inventor of the IMPACT System, which received CE Mark clearance in the European Union and was subsequently registered in 32 countries and deployed to treat cytokine storm-related conditions, including sepsis, acute respiratory distress syndrome (ARDS), acute liver failure, severe pneumonia, and H5N1 bird flu virus infection. The IMPACT system was comprised of multiple cartridges and designed to reduce the presence of inflammatory cytokines from human blood plasma. The active cartridge component of the IMPACT system was recently incorporated into an extracorporeal system that received FDA Emergency Use Authorization (EUA) to treat severe COVID-19 infections.

As a Clinical Perfusionist, Craig has conducted more than 4,000 extracorporeal procedures, including adult and pediatric cardiopulmonary bypass, cardiac assist devices, ECMO (artificial lung), vascular access catheter systems, and CRRT. He is a nominee to receive the 2020 John H. Gibbon, Jr. Award from the American Society of Extracorporeal Technology (AmSECT). The award is the industry's highest achievement.

Eric Lynam, Head of Clinical Affairs

Mr. Lynam, who has played key roles in developing, contracting and conducting over 190 clinical trials, will oversee clinical studies of *Sigyn Therapy*™ in the United States and abroad. Previously, Mr. Lynam was the Director of Scientific and Medical Affairs for Pharmatech Incorporated until its recent acquisition by Caris Life Sciences. While at Pharmatech, Mr. Lynam pioneered a high efficiency, patient centered clinical trials system, providing on-demand trial access to a network of more than 1,500 investigators.

FINANCIALS SNAPSHOT

Management runs a tight ship at Sigyn, given the series of studies and FDA submission preparation, along with prototyping and limited manufacturing. It is expected that Sigyn will reach a number of milestones throughout 2021, including, continued in vitro study reports, animal studies and an IDE submission, which should serve as catalysts for increased Company stock value. This may require an initial, nominal fund-raise of an estimated \$2-3 million, which would fund the trials, studies, IP, and limited G&A expenses for the next 12 months. On the heels of the recently concluded in vitro studies, future trial and study protocols, along with candidate sites, have been identified.

The current burn rate for the Company is approximately \$200,000 per month. An additional round is likely needed in the near future for additional studies/trials, albeit likely at substantially higher valuation. We believe this second round would potentially coincide with an up-listing to NASDAQ in 2022.

It is clear that the Company has multiple shots on goal. This is especially the case if the platform offering is cleared for use for CSS as an indication. From our standpoint, assuming efficacy in study and trial results, Sigyn could have the opportunity to generate revenue from "low-hanging fruit" via product sales for HE, COVID-19, and sepsis. We currently believe clearance could occur

as a Breakthrough Device and EUA for one or multiple indications perhaps as early as 2022 or 2023. It is difficult to ascertain potential revenue for HE and severe COVID-19 at this time; however, given the history and severity of the sepsis impact on society, our preliminary forecasts are for sepsis only. As noted earlier, the value of the first-ever clearance for sepsis has tremendous value and by itself would generate strong acquisition interest from Tier 1 medical device players.

Preliminary Sepsis Value

Our projections assume that the US market size alone is \$17 billion. To be conservative, we assume Sigyn could capture 4% of the U.S patient market in the next five years, which is far below the mortality rate for the condition. Achieving this patient penetration translates into \$850M in revenue. By discounting it back 5 years at a 20% discount rate, we arrive at a valuation of \$341M, which is a tad above our \$317M market cap target (and \$9.00 per share). It should be noted that this estimate is for sepsis alone and is subject to change depending on clearance timing.

RISK FACTORS

In our view, the Company's biggest near-term risk is related to the results of future clinical trials and studies, initially with an indication for HE, with potential EUA for sepsis, severe COVID-19 or drug-resistant bacteria infections. A "global" risk, and the greatest risk overall, relates to the FDA not providing clearance for inflammatory cytokine reduction as a clinical endpoint to ameliorate cytokine storms induced by viral or bacterial infections. Still, even clearance and EUA for even a narrow band of indications would represent considerable value to Sigyn and its shareholders. It is also possible that results are favorable, but not statistically significant related to efficacy or QoL.

A secondary risk is related to timing of the launch of the upcoming trials and studies. These risks are consistent with those facing firms of similar size and status to Sigyn. Moreover, we believe that prior study results, along with Sigyn's strategic approach reduces the risks outlined above.

Volatility and liquidity are typical concerns for microcap stocks that trade on the over the counter (OTC) stock market. It is also possible that the share count could increase to fund future clinical trials and studies. However, an overriding financial benefit as a public company is the favorable access to and the availability of capital to fund research and development, product studies and launches, and other initiatives. Since the proceeds of any future funding would be used, in large part, to advance major business development, we believe that any dilutive effect from such a funding could be offset by related increases in market value.

CONCLUSION

In our view, Sigyn is poised to change the way acute, life-threatening inflammatory conditions induced by Cytokine Storm Syndrome are treated. Many of these conditions have no approved therapy and represent billions in market size. The primary targeted conditions include COVID-19 and sepsis, the #1 cause of deaths in hospitals worldwide. We believe the Company's sepsis opportunity is \$17B in the US alone.

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GLOSSARY OF TERMS

Acute respiratory distress syndrome (ARDS) - Condition in which fluid collects in the lungs' air sacs, depriving organs of oxygen.

Breakthrough Device Designation – FDA grants this designation to novel medical devices that have the potential to provide more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.

Cytokines - Cytokines are cell signaling molecules that aid cell to cell communication in immune responses and stimulate the movement of cells towards sites of inflammation, infection and trauma.

Cytokine Storm Syndrome (CSS) - Triggered by a wide range of infectious and non-infectious diseases, CSS refers to a group of related medical conditions in which the immune system produces too many inflammatory signals leading to the substantial production of pro-inflammatory cytokines. This condition can lead to organ failure and death.

CytoVesicles - Extracellular vesicles that transport inflammatory cytokine cargos.

Emergency Use Authorization (EUA) - An EUA is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines, during public health emergencies, such as the current COVID-19 pandemic.

Endotoxin - A toxin that is present inside a bacterial cell and is released when the cell disintegrates. It is sometimes responsible for the characteristic symptoms of a disease.

Hepatic Encephalopathy (HE) - The loss of brain function when a damaged liver does not remove toxins from the blood. Hepatic encephalopathy generally occurs in people with chronic liver disease, such as cirrhosis or hepatitis.

Investigational Device Exemption (IDE) - An investigational device exemption allows an investigational device to be used in order to collect safety and effectiveness data required to support a premarket approval application or a premarket notification [510] submission to Food and Drug Administration.

Sepsis - Sepsis is the body's extreme response to an infection. It is a life-threatening medical emergency. Sepsis happens when an infection you already have triggers a chain reaction throughout your body. Without timely treatment, sepsis can rapidly lead to tissue damage, organ failure, and death.

RECENT TRADING HISTORY FOR SIGY

(Source: www.BigCharts.com)



SENIOR ANALYST: ROBERT GOLDMAN

Rob Goldman founded Goldman Small Cap Research in 2009 and has over 25 years of investment and company research experience as a senior research analyst and as a portfolio and mutual fund manager. During his tenure as a sell side analyst, Rob was a senior member of Piper Jaffray's Technology and Communications teams. Prior to joining Piper, Rob led Josephthal & Co.'s Washington-based Emerging Growth Research Group. In addition to his sell-side experience Rob served as Chief Investment Officer of a boutique investment management firm and Blue and White Investment Management, where he managed Small Cap Growth portfolios and *The Blue and White Fund*.

ANALYST CERTIFICATION

I, Robert Goldman, 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.

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