



July 1, 2025

SIGYN THERAPEUTICS, INC.

(OTC – SIGY)

Industry: Medical Devices

6 Mo. Price Target: \$9.00

SIGYN THERAPEUTICS, INC.

Near Term Milestones to Drive Shares to New Highs

Rob Goldman
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COMPANY SNAPSHOT

Sigyn Therapeutics, Inc. is developing next-generation blood purification therapies to address life-threatening conditions with no FDA-approved treatments. *Sigyn Therapy™* is a first-in-class device to address severe inflammatory disorders. It has been demonstrated to reduce the presence of bacterial toxins (including endotoxin), inflammatory cytokines, hepatic toxins, and infectious viral pathogens from human blood plasma. The Company is also developing medical devices to optimize the benefit of drugs to treat cancer.

KEY STATISTICS

Price as of 6/30/25	\$2.75
52 Week High – Low	\$5.75 - \$2.49
Est. Shares Outstanding	1.6M
Market Capitalization	\$4.4M
Average Volume	100
Exchange	OTCQB

COMPANY INFORMATION

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INVESTMENT HIGHLIGHTS

Sigyn is poised to change the way acute, life-threatening inflammatory conditions induced by endotoxemia and other concurrent inflammation. Many of these conditions have no approved therapy and represent billions in market size.

Primary targeted conditions include end stage renal disease and sepsis, the #1 cause of deaths in hospitals worldwide. The Company also has a deep oncology portfolio.

Sigyn has reported favorable in vitro results and is poised to submit multiple Breakthrough Device submissions this year. The Company could be awarded these designations in the coming quarter.

A planned ESRD feasibility study should commence in the next 12 months. Data could be derived from this trial within 6 months following the end of the study.

Our six-month price target of \$9.00 reflects both the current undervalued and underfollowed status of Sigyn versus peers, but also the value of future milestones. In our view, Sigyn's primary platform offers valuable, hidden features which could serve as a valuation driver. Looking ahead, future milestones could eventually lead to an M&A event.

COMPANY OVERVIEW

The View from 30,000 Feet

When we initiated coverage of **Sigyn Therapeutics (OTCQB: SIGY)** in March 2021, we were still in the throes of Covid-19, fears of infectious diseases, etc. However, even then, management had the vision to target a therapy to treat sepsis. Following strong in vitro data, and with improvements in the industry, Sigyn is continuing on this path, along with developing a treatment for other critically ill patients that face another condition that has a high level of mortality, end stage renal disease (ESRD) patients. In our view, milestones and events should serve as a series of valuation drivers for these shares over the next six months, and with even greater potential in the next 12-18 months.

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. The Company's current focus is for treating for two of the most challenging indications. These include sepsis and the treatment of endotoxemia and concurrent inflammation in dialysis patients, specifically those with ESRD.



Sepsis plays a role in nearly 1 in 3 of the 1.7 million patients diagnosed with sepsis. It is the biggest culprit of deaths in hospital settings and there is no FDA approved treatment for the condition. A peer is set to announce results of its latest study that they hope will indicate that it can deplete endotoxins, which is a driver of the condition. This would be great news for the industry and Sigyn, given the fact that in vitro studies indicate an even broader capability.

On the ESRD side, 550,000 are on dialysis each year and the mortality rate is a daunting 70% after 5 years. Again, endotoxins and excessively produced inflammatory cytokines are hallmarks of the condition. Given its foundation in blood purification technology, ESRD treatment is a no-brainer for Sigyn, in our view.

Looking Ahead

The Company has a highly targeted development pathway for its led platform. These include two Breakthrough Device submissions, feasibility study and other events. Thus, the Company will have an active 12-18 months.

Our price target of \$9.00 is roughly 3x the current share price and we believe it could be reached within six months, if not sooner. This thesis is based upon industry events we outline in this report, the submissions, and potential awards. The small 1.6 million share count and fewer than 250,000 shares in the public float also make these shares susceptible to a big move on favorable news. At the end of the day, a \$4.4 million market valuation for a company with a deep product portfolio and a series of favorable events ahead is the definition of undervalued. However, we believe that a higher profile will be afforded the Company and therefore the shares and investors will be the beneficiary. Moreover, our price target could prove to be conservative when compared with a proper peer who trades at a significantly higher valuation. As future milestones are met, we believe the

shares will emerge at a more normalized valuation. Furthermore, if data from a potential, future human ESRD trial is favorable in the next 2-3 years, we believe that Sigyn would emerge as a takeover candidate.

THE SIGYN PIPELINE

Sigyn Therapeutics, Inc. is developing next-generation medical devices to address life-threatening conditions with no FDA-approved treatments. In our view, *Sigyn Therapy*[™], the Company's core platform, is on track to achieve breakthrough results for two of the most challenging indications. These include sepsis and the treatment of endotoxemia and concurrent inflammation in dialysis patients, specifically those with end stage renal disease (ESRD).

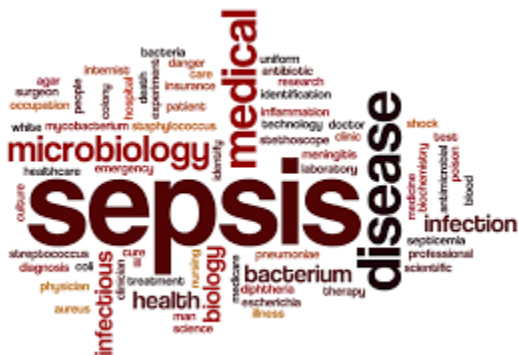
Sigyn Therapy™: A High-Level View

Sigyn Therapy™ is a formulation of adsorbent components that provide 200,000+ square meters (~50 acres) of surface area on which to bind and eliminate circulating therapeutic targets. *Sigyn Therapy™* is highly efficient, capable of processing the entire bloodstream of an average-sized person approximately 15 times during a four-hour treatment.

Key features of this therapy could be considered without a peer. These include its breadth and capacity to eliminate circulating therapeutic targets; the rate at which it processes the bloodstream; and its ability to be deployed on dialysis and CRRT machines already located in hospitals and clinics. However, throughput and ease of deployment are just highlights of the hardware's general functionality. The use of *Sigyn Therapy*[™] during in vitro studies have validated the clearance of bacterial toxins (including endotoxin), inflammatory cytokines, hepatic toxins, and infectious viral pathogens from human blood plasma.

Sepsis Treatment

Each year, 1.7 million patients in the U.S. are stricken with sepsis, a severe condition usually contracted while in the hospital. Sepsis is the leading cause of death in U.S. hospitals and a \$62 billion annual healthcare burden. Sepsis is a life-threatening condition triggered by the body's overwhelming response to bacterial components such as endotoxin (endotoxemia) and it continues to be a major global health issue, impacting millions. If not recognized and treated promptly, sepsis can result in multiple organ failure, shock, and death.



Yet, it has not been addressed with an FDA-approved therapy since Xigris was withdrawn from market in 2011. According to the CDC, 350,000 patients die from sepsis during hospitalization and the CDC estimates that sepsis plays a role in the deaths of 1 in 3 patients. Clearly, this is the textbook case for the definition of an unmet need but early treatment can likely improve outcomes.

The leading FDA candidate to treat a sepsis-related indication is an endotoxin-depletion device being advanced by Canadian firm **Spectral Medical, Inc. (EDT.TO, OTC-EDTXF)** will enable improved outcomes for patients with Endotoxic Septic Shock (ESS). ESS is a life-

threatening condition that arises when the body's response to infection spirals into a storm of systemic inflammation. It is characterized by a dangerous drop in blood pressure and a cascade of multiple organ failure caused by the presence of endotoxin. Spectral Medical believes that "ESS affects approximately 140,000 patients each year with a mortality rate > 50%."

Not to be outdone, *Sigyn Therapy*[™] in vitro studies have validated the ability of to deplete endotoxin, just like Spectral Medical. However, the Sigyn studies validated the ability to deplete **nine other sepsis-related targets from human blood plasma as well.** Sigyn Therapy's ability to target a broad range of harmful agents highlights its potential to treat sepsis and other inflammatory disorders.

End Stage Renal Disease Treatment

Endotoxemia and concurrent inflammation contribute to shorten the lives of end-stage renal disease (ESRD) dialysis patients. Sadly, during dialysis treatment, this can occur when bacterial products contaminate dialysis fluid or pass through dialysis membranes. On the heels of the aforementioned in vitro studies regarding endotoxemia depletion, *Sigyn Therapy*[™] aims to extend the lives of dialysis patients.

In the United States, 550,000 ESRD patients receive ~85 million dialysis treatments each year. Tragically, the first-year mortality rate of ESRD patients on dialysis is 20-25% and 60-70% die within 5-years of dialysis initiation. Surprisingly, the leading cause of ESRD patient deaths is cardiovascular disease, with a prevalence of 70–80%. *Sigyn Therapy*[™] targets hallmark drivers of cardiovascular disease, including endotoxin and excessively produced inflammatory cytokines.

Dual Development Path

Going forward, Sigyn may elect to run two generally simultaneous development pathways. To accelerate clinical development, the Company plans to submit documentation with the FDA to receive a Breakthrough Device designation for the treatment of sepsis and one for the treatment of endotoxemia and concurrent inflammation in dialysis patients. Management brings relevant experience, including oversight of the first therapy to receive two Breakthrough Device designations from FDA.

Beyond an opportunity to obtain a Breakthrough Device designation, the Company will submit an Investigational Device Exemption (IDE) to FDA to support a feasibility study whose target enrollment is 12–15 ESRD patients. The study will integrate *Sigyn Therapy*[™] in series with regularly scheduled dialysis treatments to evaluate safety and monitor changes in endotoxin and inflammatory cytokine levels during treatment. Favorable results could advance first in-human studies as well.

Higher Sigyn Valuations

It is instructive to review how industry events and milestones along Sigyn's development pathways can provide a series of materially positive boosts in the Company's valuation. Spectral Medical may be a year or so ahead of Sigyn with respect to its development of sepsis treatment as it relates to the presence of endotoxins. Sometime in this quarter, Spectral Medical will announce results from a recent study and we believe they could be favorable.

If they are, we believe that Sigyn would be a beneficiary of such an event.

As we noted above, Sigyn's in vitro studies have already indicated the presence of endotoxins in sepsis patients similar to Spectral Medical. However, Sigyn was found to have validated the ability to deplete nine other sepsis-related targets as well. As of this writing, Sigyn's low market cap is a small fraction of the Spectral Medical's market cap. Not only could a rising tide Sigyn's valuation but its profile as well, given the Company's current pathway.

In the ESRD arena, the valuation drivers may be even more pronounced, considering there is no other peer following the Company's development path. If Sigyn study results are favorable, we believe that would provide a major boost to overall valuation. Advancement in ESRD treatment offers a real benefit for patients and a business case for the industry as well.

A therapy that extends ESRD patient lives would offer significant quantifiable value to a U.S. dialysis industry dominated by Fresenius Medical Care and DaVita, Inc. Based on the size of their in-network patient populations, each month of extended life represents a revenue opportunity of approximately \$1 billion to each company. Likewise, each week of reduced hospitalization (patients are out of network when hospitalized) could enable Fresenius and DaVita to each recoup approximately \$250 million in what would have been lost revenues.

A Clear Milestone Path

Looking ahead, investors should take notice of the Sigyn-driven and other industry-driven milestone and events. Sigyn has a clear development path. These include two Breakthrough Device submissions, which we believe could be granted with 60 days following the submission. Such events would be followed by the ESRD feasibility study, which if favorable, could lead to a unique IDE submission.

Interestingly, such a submission could be aided by a tactical approach by Sigyn management. The Company has also identified several candidate opportunities for *Sigyn Therapy*[™] to be designated as a Humanitarian-Use Device (HUD). An HUD designation provides an alternative regulatory pathway for a medical device to treat a disease or condition that manifests in fewer than 8,000 individuals in the United States each year. Upon receipt of a HUD designation, a Company is permitted to submit a Humanitarian Device Exemption (HDE) marketing application that is exempt from FDA effectiveness requirements. In the absence of efficacy data, Sigyn Therapeutics will seek to leverage safety data from its ESRD study in combination with results from in vitro studies already conducted.

Other, Valuable Pipeline Therapies

While *Sigyn Therapy*[™] remains management's core focus, we believe value exists for the Company's oncology portfolio.

In our view, the full lineup of the Company's therapeutic candidates is enviable and represents a deep portfolio in the field of extracorporeal blood purification. To optimize the benefit of drugs to treat cancer, the Company invented the *ImmunePrep*[™] platform to enhance the performance of immunotherapeutic

antibodies; *ChemoPrep™* to improve the delivery of chemotherapy; and *ChemoPure™* to reduce chemotherapy toxicity.

As the lead candidate *Sigyn Therapy™* gains development traction, it is possible that management may seek a partner to further development of the oncology portfolio, thereby monetizing these underdeveloped assets.

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.

Annette Marleau, Ph.D. Chief Scientific Officer

Dr. Marleau is a recognized thought leader in the development of therapeutic blood purification technologies to address cancer. Prior to joining Sigyn Therapeutics, Dr. Marleau was Chief Technology Officer at Immunicom, Inc., where she led R&D endeavors to establish a pipeline of blood purification candidates to treat cancer. She also served as Director of Research at Aethlon Medical, Inc., where she oversaw preclinical programs that facilitated the first-in-human clinical investigation of the Aethlon Hemopurifier® as an adjunct cancer therapy.

Dr. Marleau has been awarded more than \$6 million in NIH grants and contracts to serve as Principal Investigator for pre-clinical and clinical programs to advance blood purification technologies. Additionally, she co-authored two FDA-cleared Investigational Device Exemptions, co-authored a regulatory submission that resulted in an FDA "Breakthrough Device" award, and is an inventor on pending and issued patents underlying blood purification therapies targeting cancer, inflammatory disorders, and life-threatening infectious diseases.

Dr. Marleau completed a fellowship in immunology at Scripps Research Institute in La Jolla, CA. She is a graduate of Western University (PhD), Ontario Veterinary College at University of Guelph (Master of Science), and University of Waterloo (Bachelor of Science) in Canada.

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.

Craig P. Roberts, Co-Founder, Board Member

Mr. Roberts is an inventor of life-saving therapeutic technologies, which includes a Percutaneous Adult Extracorporeal Membrane Oxygenation (ECMO) system that was licensed and subsequently sold to C.R. Bard.

Mr. Roberts is also an 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 associated 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. 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 continuous renal replacement therapy.

Richa Nand, Board Member

Richa Nand is a senior legal executive with more than 20 years of experience as an intellectual property ("IP") attorney and strategic business advisor for biotechnology and medical device companies. She is the founder of Insight Patents, a legal and consulting firm providing IP and transactional corporate services for the life sciences industry. Ms. Nand previously served as Vice President of Corporate Development and Legal at Bird Rock Bio – a Johnson & Johnson-backed biopharmaceutical company in San Diego – and Vice President of Intellectual Property and Licensing; Director of Business Development; and In-House Patent Counsel at Cytori Therapeutics. Prior to law school, she was a biomedical researcher at Cedars Sinai Medical Center in Beverly Hills, California. Ms. Nand received a Bachelor of Science degree in Microbiology and Molecular Genetics from the University of California, Los Angeles, and a Juris Doctor degree from Boston University School of Law.

Jim Dorst, Board Member

Jim Dorst has more than 30 years of senior management experience in finance, operations, planning and business transactions at both private and public companies. He was most recently Director of Corporate Development at SYNnex/Concentrix, where he was primarily responsible for mergers and acquisitions. Mr. Dorst was previously Chief Operating Officer ("COO") and Chief Financial Officer ("CFO") at SpectraScience, Inc.; CFO of Aethlon Medical, Inc. and Vice President of Finance and Operations for Verdisoft Corporation. In addition, he previously served as Senior Vice President of Finance and Administration at SeeCommerce; CFO and COO of Omnis Technology Corp; and CFO and Senior Vice President of Information Technology at Savoir Technology Group, Inc. Mr. Dorst practiced as a Certified Public Accountant with Coopers & Lybrand (now PricewaterhouseCoopers LLP); and holds a Master of Science degree in Accounting and a Bachelor of Science degree in Finance from the University of Oregon.

Christopher Wetzel, Board Member

Christopher Wetzel has more than 25 years of leadership experience in various aspects of the healthcare delivery system and since 2004, has served as Chief Executive Officer for the Surgery Center at Hamilton in New Jersey. His career has focused on building organizations, increasing operational efficiency, increasing profitability, maximizing revenue, and managing change in the complex and high-growth healthcare environment. Mr. Wetzel applied his broad background in strategy, finance, and operations to guide various entities starting new ventures, entering new markets, and reengineering business processes. He is a long-term investor in the extracorporeal therapy space. Mr. Wetzel received a Master of Business Administration degree

in Healthcare Management and a Bachelor of Science degree in Nursing from Thomas Jefferson University (formerly Philadelphia University).

Michael Ryan, Board Member

Mr. Ryan is a seasoned executive, entrepreneur and investor within the early-stage technology and life science industry. Mr. Ryan is one of the Founder Directors of Irrus Investments, Ltd., a role he has held since 2011. Irrus Investments is the largest angel investment syndicate in Ireland with an emphasis on life science companies. To date, Irrus has invested over €40million in 35 early-stage life science and technology companies in Ireland, UK, Sweden and USA. Mr. Ryan previously served as Chief Executive Officer and Board Member of Sedana Medical, from 2011 until shortly before the Company launched on the Nasdaq owned First North stock exchange in Stockholm in 2017. Prior to this, he was the main shareholder and Chief Executive Officer of Artema Medical AB, where he helped orchestrate the Company's acquisition by Datascope Corporation. Mr. Ryan holds a B.Eng in Mechanical Engineering and a Masters in Industrial Engineering from University College Dublin.

Scientific Advisory Board

H. David Humes, MD

David Humes, MD is an internationally recognized nephrologist and physician scientist. He received his B.A. in mathematics/physics from University of California, Berkeley and his M.D. from University of California, San Francisco as a Regent Scholar. He completed further training at UCSF, University of Pennsylvania and Harvard. He has been appointed to the faculty at Harvard Medical School and University of Michigan. Currently he is Professor of Internal Medicine at University of Michigan after serving as Chairman of the Department. He is considered a world-renowned scholar in the areas of nephrology, acute renal failure, cell therapy, biomaterials, device formulation, tissue engineering, and extracorporeal therapy. He has published over 250 scientific articles and book chapters, edited 6 medical textbooks, and has over 70 issued or applied patents. He has served on numerous editorial boards of scientific and medical journals. He has founded 4 spinout biomedical companies raising over \$100 million of private equity. His research has been funded with over \$40 million of grants from federal agencies and foundations. His accomplishments have been recognized as an Established Investigator of the American Heart Association, President's Award of National Kidney Foundation, A.N. Richards Distinguished Achievement Award in Nephrology, Special Recognition Award from Association of Professors of Medicine, and Kolff Award in Regenerative Medicine. He is an elected member of the American Society of Clinical Investigation and the American Association of Physicians and a Fellow of American Association for the Advancement of Science and American Institute for Biological and Medical Engineering.

Alexander S. Yevzlin, MD, FASN

Dr. Yevzlin graduated magna cum laude from Dartmouth College. He did his residency in Internal Medicine at the University of Michigan and fellowship in Nephrology at Northwestern. Dr. Yevzlin is currently Professor of Medicine and director of Interventional Nephrology at the University of Michigan. Dr. Yevzlin has presented and published over 150 abstracts, invited lectures, and manuscripts. He is an internationally recognized leader

in the field of Interventional Nephrology, having edited the first three textbooks on the subject, and is a past President of the American Society of Diagnostic and Interventional Nephrology. In addition to his academic contributions, Dr. Yevzlin has been involved the invention, design, and reduction to practice of multiple medical devices in his role as chief medical officer, chief science officer, and founder of multiple start-up biotech companies.

Ajay Verma, MD, PhD

Ajay Verma is a neurologist, neuroscientist, drug developer, inventor and biotech science advisor. Ajay most recently headed R&D efforts at Yumanity Therapeutics, developing drugs against novel targets for treating neurodegenerative diseases. Prior to that he was the EVP of Research and Experimental Medicine at Codiak Biosciences. He has also served as CMO at United Neuroscience (now called Vaxxinity), VP of Neurology at Biogen and Novartis, and Director of Neuroscience Experimental Medicine at Merck. His drug development experience spans small molecule, peptide/protein, antibody, oligonucleotide, vaccine and exosome drug platforms. He has largely focused on translational and early clinical development in neurology indications using precision drug development approaches that leverage biomarkers and experimental medicine paradigms. Ajay is interested in developing drugs for established as well as novel targets in Neurology. Prior to his Biopharma career, Ajay was a Professor of Neurology at the Uniformed Services University of the Health Sciences. He also worked as a staff neurologist at the Walter Reed Army Medical Center for 11 years after completing his neurology residency there. Ajay received his M.D. and Ph.D. from Johns Hopkins University, where he trained in the laboratory of Dr. Solomon Snyder. Ajay received his B.S. in Zoology from the University of Maryland.

Donald J. Hillebrand, MD

Dr. Hillebrand is the Associate Medical Director of Liver Transplantation at Saint Luke's Hospital of Kansas City and Associate Professor of Medicine at the University of Missouri Kansas City (UMKC). Dr. Hillebrand has authored more than 20 Papers (published or in press/preparation) as well as 7 books (and/or book chapters). He is a recognized leader in the field of Hepatology and Liver Transplantation. In addition to his academic and clinical contributions, Dr. Hillebrand has served as a Principal Investigator in various clinical studies to evaluate extracorporeal treatments for liver disorders. Previously, he served on the Editorial Board of ASAIO Journal, was a Section Editor for the ASAIO Journal-Liver Transplantation, and a Reviewer for the European Journal of Gastroenterology & Hepatology. Dr. Hillebrand graduated with distinction in Microbiology from Iowa State University. He did his residency in Internal Medicine at Iowa State University Hospitals and Clinics and fellowships in Gastroenterology, Hepatology and Liver Transplantation at Iowa State University Hospitals and Clinics.

Eric W. Stroup

Eric Stroup has nearly 30 years of experience in the medical device field. He spent 26 years with Fresenius Medical Care, in various research and development leadership roles, most recently as the Senior Vice President of the Dialyzers, Membranes and Adsorbers Product Engineering Center. During his career, Eric has made significant contributions as a member of Senior Management in R&D. Eric collaborated with regional and global stakeholders to develop innovative product pipelines, drive key product development, technical design, and engineering milestones with a fiscally disciplined, business-oriented approach in his execution.

Among many notable accomplishments, he has a demonstrated history of product delivery. During his leadership, the Dialyzer R&D team was responsible for eight 510(k) decisions from the FDA for submissions in the last ten years (16 cleared 510(k)'s since 2000). These submissions supported a product family that sold greater than 55 million units annually in North America, representing a >70% market share and providing >\$375Million in revenue annually.

Eric built the Fresenius Medical Care Dialyzer Global R&D team in North America from scratch (including the completion of the Ogden Design Center) and established a winning culture across its locations in the EMEA, NA, and AP regions. Eric has an extraordinary commitment to deliver results and an innovative approach to driving outcomes.

FINANCIALS

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 over the next 18 months, including two Breakthrough Device Designations, the ESRD feasibility study, along with other potential submissions and studies, based on *Sigyn Therapy*™ preliminary data. These events may require a nominal fund-raise of around \$1.5 million, which would fund the submissions and ESRD feasibility study. If the data is favorable, as expected, a first in-human study in late 2026 may be prepared for a launch, accompanied by a financing, and perhaps coincide with a NASDAQ uplisting.

RISK FACTORS

In our view, the Company's near-term risks are related to the award of one or two Breakthrough Device designations. The greater near-term clinical risk would be unfavorable or inconclusive data from the Company's upcoming ESRD study. 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.

VALUATION AND CONCLUSION

Sigyn is poised to change the way acute, life-threatening inflammatory conditions induced by endotoxemia and other concurrent inflammation. Many of these conditions have no approved therapy and represent billions in

market size. Primary targeted conditions include end stage renal disease and sepsis, the #1 cause of deaths in hospitals worldwide. The Company also has a deep oncology portfolio.

Sigyn has reported favorable in vitro results and is poised to submit multiple Breakthrough Device submissions this year. The Company could be awarded these designations in the coming quarter. A planned ESRD feasibility study should commence in the next 12 months. Data could be derived from this trial within 6 months following the end of the study.

Our six-month price target of \$9.00 reflects both the current undervalued and underfollowed status of Sigyn versus peers, but also the value of future milestones. In our view, Sigyn's primary platform offers valuable, hidden features which could serve as a valuation driver. Looking ahead, future milestones could eventually lead to an M&A event.

SENIOR ANALYST: ROBERT GOLDMAN

Rob Goldman founded Goldman Small Cap Research in 2009 and has over 20 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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