

# SIGYN THERAPEUTICS, INC.

## SIGY Hitting on All Cylinders; Shares Represent Rare Value

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### SIGYN THERAPEUTICS, INC. (OTC – SIGY - \$0.45)

Industry: Medical Technology

12-18 Month Price Target: \$9.00

#### COMPANY SNAPSHOT

Sigyn Therapeutics is a medical technology company focused on the treatment of pathogen-associated conditions that precipitate sepsis, the leading cause of hospital deaths worldwide. Sigyn Therapy™ is a multi-function blood purification technology that extracts pathogen sources of life-threatening inflammation in concert with the broad-spectrum elimination of inflammatory mediators from the bloodstream. Therapeutic opportunities for Sigyn Therapy also include emerging bioterror and pandemic threats; drug-resistant pathogens; hepatic encephalopathy; and community-acquired pneumonia, the leading cause of death in children under five years of age, and a catalyst for approximately 50% of sepsis cases.

#### KEY STATISTICS

Price as of 3/1/22	\$0.45
52 Week High – Low	\$3.49 - \$0.30
Est. Shares Outstanding	36.9M
Market Capitalization	\$16.6M
Average Volume	2,177
Exchange	OTC

#### COMPANY INFORMATION

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#### INVESTMENT HIGHLIGHTS

**SIGY Stock Offers Rare Upside, Entry Point.** Since our coverage initiation almost exactly a year ago, SIGY has successfully executed its development plans, thereby dramatically de-risking the stock, in our view. Plus, upcoming milestones may lead to a return to its 52-week high of \$3.49 in Q3, a nearly tenfold rise from current prices.

**SIGY Completes Animal Study-a Major Event.** Last week, SIGY reported the successful completion of an in vivo animal study (8 porcines) that demonstrated Sigyn Therapy to be safe and well tolerated. Also, SIGY reported the completion of in vitro blood plasma studies that validated the ability of Sigyn Therapy to address a broad-spectrum of relevant therapeutic targets.

**Go-To Therapy for Life-Threatening Inflammatory Conditions?** Based on its demonstrated ability to extract pathogens, toxins and inflammatory mediators from blood plasma, management believes its therapy may hold promise for addressing significant unmet needs in global health that remain beyond the reach of drugs, including sepsis, the leading cause of hospital deaths.

**FDA Submission, Human Clinical Studies Lie Ahead.** Data resulting from the in vivo study will be incorporated into an Investigational Device Exemption (IDE) that the Company plans to submit to the FDA in Q3 to support the potential initiation of human clinical studies.

**Recent Deals Support Our Price Target.** A review of dozens of medical device investments and M&A in 2021 by SVB affirm our investment thesis and price target, regarding SIGY's possible future value. With the potential to treat multiple unmet bacterial and viral life-threatening conditions such as sepsis, we maintain SIGY may ultimately be worth a premium to the medical device arena.

## KEY POINTS

### *The Sigyn Therapy*

Sigyn Therapy is a novel blood purification technology designed to perform functions that are beyond the reach of drugs and overcome the limitations of current devices to treat life-threatening inflammatory conditions, including sepsis, the leading cause of hospital deaths. Sigyn Therapy is a single-use disposable device designed for use on the established infrastructure of hemodialysis and continuous renal replacement therapy (CRRT) machines located in hospitals and clinics worldwide. Incorporated within Sigyn Therapy is a formulation of adsorbent components that provide more than 200,000 square meters (~50 acres) of surface area on which to adsorb and remove bloodstream targets. Unlike devices that concentrate therapeutic targets in the blood-path, Sigyn Therapy extracts targets from the bloodstream, thereby eliminating their ability to interact with blood cells during treatment.

### *Animal Study Background*

The Company's most recent animal study protocol was evaluated in the first-in-mammal use of Sigyn Therapy and assessments of treatment safety occurred in conjunction with the refinement of pre-treatment and operating procedures. In the study, an adult version of Sigyn Therapy was administered via standard dialysis machines utilizing conventional blood-tubing sets, for periods of up to six hours. Important criteria for treatment safety – including hemodynamic parameters, serum chemistries and hematologic measurements – were stable across all subjects. The study was conducted by an expert extracorporeal devices clinical team at Innovative BioTherapies, Inc. under a contract with the University of Michigan. The treatment protocol of the study was reviewed and approved by the University of Michigan Institutional Animal Care and Use Committee (IACUC).

### *Key Milestone, Company Valuation*

Clearly, the next landmark event for the Company is submission of an IDE to the FDA in Q3 to support the potential initiation of human clinical studies. Once the IDE and protocols are approved, human subject enrollment for the pivotal human study will commence. As pre-revenue health care companies are typically valued based on the achievement of development milestones, we believe that the IDE filing could serve as a catalyst to reach the \$3.49 mark, SIGY's 52-week high. Subject enrollment and favorable results also represent key stages on the road to higher stock prices. Given the potential broad use, and ability to meet unmet needs of a series of life-threatening conditions, we believe that SIGY is poised to ultimately reach premium valuations as compared with typical 510(k) pathway medical device companies.

A recent SVB Health Care Investment report on the health care industry's investment and M&A transactions for 2021 serve to affirm our thesis, in our view. After all, SIGY's indications category is a likely outlier in the medical device segment, given its potentially unmatched reach. According to the report, the 2021 median M&A deal value for device companies closed was \$268M. At the \$3.49 mark, SIGY would be valued at \$128M, essentially half of the M&A deal value and a figure akin to SIGY's development stage status. At our \$9.00 target, which we believe could occur upon receiving FDA clearance, but prior to commercialization, SIGY would be valued at \$332.1M, a premium to the \$268M M&A value. As we get closer to IDE submission and additional indications and feasibility studies are considered, we plan to review our thesis and targets.

## 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

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