UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT PURSUANT
TO SECTION 13 OR 15(D) OF THE
SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported): August 25, 2020

SIGYN THERAPEUTICS, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	**333-204486**	**47-2573116**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)
8880 Rio San Diego Drive Suite 800 San Diego, CA (Address of principal executive offices)		92108 (Zip Code)

Registrant's telephone number, including area code: 619.368.2000

Prior address and phone number:

9465 Wilshire Boulevard **Beverly Hills, CA** (Address of principal executive offices)	**90212** (Zip Code)

(213) 457-3772

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
None	None	None

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☒

As used herein, the terms, "we," "us," "our," and the "Company" refers to Sigyn Therapeutics, Inc., a Delaware corporation and its subsidiaries, unless otherwise stated.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Form 8-K and other reports filed by Sigyn Therapeutics, Inc. ("Sigyn" or the "**Company**") from time to time with the Securities and Exchange Commission (collectively, the "**Filings**") contain or may contain forward looking statements and information that are based upon beliefs of, and information currently available to, the Company's management as well as estimates and assumptions made by the Company's management. When used in the filings the words "anticipate", "believe", "estimate", "expect", "future", "intend", "plan" or the negative of these terms and similar expressions as they relate to the Company or Company's management identify forward looking statements. Such statements reflect the current view of the Company with respect to future events and are subject to risks, uncertainties, assumptions and other factors relating to the Company's industry, the Company's operations and results of operations and any businesses that may be acquired by the Company. Should one or more of these risks or uncertainties materialize, or should the underlying assumptions prove incorrect, actual results may differ significantly from those anticipated, believed, estimated, expected, intended or planned.

Although the Company's management believes that the expectations reflected in the forward looking statements are reasonable, the Company cannot guarantee future results, levels of activity, performance or achievements. Except as required by applicable law, including the securities laws of the United States, the Company does not intend to update any of the forward-looking statements to conform these statements to actual results. The following discussion should be read in conjunction with the Company's pro forma financial statements and the related notes filed with this Form 8-K.

Item 1.01 Entry into a Material Definitive Agreement.

Share Exchange Agreement

On August 25, 2020, Reign Resources Corporation, a Delaware corporation (the "Registrant") executed a Share Exchange Agreement (the "Agreement") with Sigyn Therapeutics, Inc., a Delaware corporation ("Sigyn"), whereby the Registrant will acquire 100% of the of the issued and outstanding shares of common stock of Sigyn, in exchange for a total of 75% of the fully paid and nonassessable shares of the Registrant's common stock outstanding immediately following the Closing of the Agreement (the "Acquisition"). The Closing Date for the Acquisition was October 19, 2020, at which date, upon FINRA approval, the Company's trading symbol changed to SIGY.

Upon the Closing of, and as a result of, the Acquisition, Sigyn will become a wholly-owned subsidiary of the Registrant, and following the consummation of the Acquisition and giving effect to the issuance of the Registrant's shares of common stock as part of the Acquisition, as well as additional shares of common stock to be issued to noteholders and warrant holders of both the Registrant and Sigyn, the stockholders of Sigyn will beneficially own approximately Seventy-five percent (75%) of the issued and outstanding Common Stock of the Registrant on a fully diluted basis. In addition, in connection with the Acquisition, the two principals of Sigyn will be appointed to serve as members of the Registrant's board of directors. The parties have taken the actions necessary to provide that the Acquisition is treated as a "tax free exchange" under Section 368 of the Internal Revenue Code of 1986, as amended. The Agreement contains customary representations, warranties and covenants of the Registrant and Sigyn for like transactions. The Acquisition will close upon the completion of various closing conditions as further described in the Agreement (the "Closing Date"). The shares of the Registrant's common stock to be issued in connection with the Acquisition will not be registered under the Securities Act, and will be issued in reliance upon the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"). Certificates representing these shares will contain a legend stating the restrictions applicable to such shares.

The Company intends to file financial statements of Sigyn in an amendment to this Current Report on Form 8-K no later than 71 days from the Closing Date. The foregoing descriptions of the above referenced agreements do not purport to be complete. For an understanding of their terms and provisions, reference should be made to the Agreement attached as Exhibit 10.1 to the Current Report on Form 8-K filed by us on August 31, 2020, announcing the Acquisition, and is incorporated herein by reference.

Item 2.01 Completion of Acquisition or Disposition of Assets.

As described in Item 1.01 above, and effective October 19, we acquired all the issued and outstanding shares of Acquiree pursuant to the Exchange Agreement and Acquiree became our wholly-owned subsidiary. The acquisition was accounted for as a recapitalization effected by a share exchange. The assets and liabilities of Acquiree have been brought forward at their book value and no goodwill has been recognized.

As a result of the acquisition of all the issued and outstanding shares of common stock of Acquiree, we have now assumed Acquiree's business operations as well as our own. The acquisition of Acquiree is treated as a reverse acquisition, and the business of Acquiree became the business of the Company.

Business Plan

Sigyn was established to address a significant unmet need in global health; the treatment of life-threatening inflammatory conditions precipitated by Cytokine Storm Syndrome ("the Cytokine Storm"), a hyperactive immune response that can induce multiple organ failure and cause death. The annual market opportunity for a therapeutic strategy to prevent or mitigate the Cytokine Storm exceeds $20 billion.

Sigyn Therapy™ is a development-stage blood purification therapy created to overcome the limitations of previous drugs and devices to treat life-threatening inflammatory conditions, including sepsis, the #1 cause of in-hospital deaths. Mechanistically, Sigyn Therapy is designed to deplete the presence of a broad-spectrum of inflammatory factors from the human circulatory system. This includes pro-inflammatory cytokines, cytokine aggregates, endotoxin and larger CytoVesicles that transport cytokines and other inflammatory cargos in the bloodstream.

Beyond sepsis, Cytokine Storm related therapeutic opportunities may include, but are not limited to virusinduced Cytokine Storm (a leading cause of COVID-19 deaths), bacteria-induced Cytokine Storm, acute respiratory distress syndrome (ARDS) and acute forms of liver failure, including hepatic encephalopathy. Sigyn Therapy may also be a candidate to stabilize or extend the life of patients waiting for the identification of a matched liver for transplantation. In such a scenario, Sigyn Therapy™ would serve as a bridge-to-liver transplant. Cytokine Storm Syndrome may also be induced by trauma, severe burns, acute pancreatitis, adverse drug reactions, cancer immunotherapies, cancer cachexia, acute kidney injury (AKI) and severe pneumonia.

We are focused on a significant unmet need in global health; the treatment of life-threatening inflammatory conditions that are precipitated by Cytokine Storm Syndrome ("The Cytokine Storm" or "CSS") and not addressed with a drug therapy. Our mission is to save lives.

Summary Highlights

- We designed Sigyn Therapy™ to overcome the limitations of previous drugs and devices to treat life-threatening inflammatory conditions, including sepsis.
- Our annual market opportunity is reported to exceed $20 billion.
- Cytokine Storm Syndrome is a hallmark of sepsis, the #1 cause of hospital deaths, which also claims more lives each year than all forms of cancer combined.
- Virus induced Cytokine Storm (VICS) is a leading cause of COVID-19 deaths and is associated with high mortality across a broad-spectrum of viral infections.
- Our co-founders have overseen the development of three therapeutic devices that have been cleared by the U.S. Food and Drug Administration (FDA) to treat COVID-19 in a clinical setting.
- In response to COVID-19, the FDA established inflammatory cytokine reduction as a clinical endpoint to ameliorate the Cytokine Storm induced by a viral infection.
- Our CEO has two decades of public company CEO and Board leadership experience.
- Other therapeutic opportunities include, but are not limited to bacteria induced Cytokine Storm (BICS), acute respiratory distress syndrome (ARDS) and acute forms of liver failure.
- We plan to submit Sigyn Therapy™ as an FDA “Breakthrough Device” candidate. Our CEO previously co-authored two regulatory submissions that each resulted in a “Breakthrough Device” award from FDA.
- We believe that Sigyn Therapy™ aligns with U.S. government initiatives to support broad-spectrum treatment countermeasures that mitigate life-threatening conditions resulting from pandemic outbreaks such as COVID-19.

About Sigyn Therapy™

We designed Sigyn Therapy™ to overcome the limitations of previous drugs and devices to treat life-threatening inflammatory conditions, including sepsis. In our quest to save lives, we recognized that Sigyn Therapy™ would require the capability to address a broad-spectrum of inflammatory targets that circulate in the bloodstream. These targets include inflammatory cytokines, cytokine aggregates, endotoxin and CytoVesicles that transport cytokines and other inflammatory cargos.

Based on its expansive mechanism of action, we believe that Sigyn Therapy™ will emerge as a candidate to prevent or mitigate Cytokine Storm Syndrome (CSS), a life-threatening immune response precipitated by a wide-range of infectious and non-infectious conditions. Among the hallmarks of CSS is the excessive or uncontrolled release of pro-inflammatory cytokines, which can lead to multiple organ failure and cause death.

Our Cytokine Storm related therapeutic opportunities include, but are not limited to sepsis, virus induced Cytokine Storm (VICS), bacteria induced Cytokine Storm (BICS), acute respiratory distress syndrome (ARDS) and acute forms of liver failure, including hepatic encephalopathy. We also believe there is an opportunity for Sigyn Therapy™ to stabilize or extend the life of patients waiting for the identification of a matched liver for transplantation. In such a scenario, Sigyn Therapy™ would serve as a bridge to liver transplant. Cytokine Storm Syndrome may also result from trauma, severe burns, acute pancreatitis, adverse drug reactions, cancer immunotherapies, cancer cachexia, acute kidney injury (AKI) and severe pneumonia.

To optimize the broad-spectrum depletion of inflammatory targets from the bloodstream, Sigyn Therapy™ incorporates a cocktail of three different adsorbent components, each with unique binding and capture characteristics.

To optimize safety and performance, we designed Sigyn Therapy™ to isolate inflammatory cytokines, cytokine aggregates, endotoxin and CytoVesicles from essential blood cells to minimize adverse cellular reactions and enhance the interaction of these targets with our adsorbent cocktail in a low-shear force environment. Thus, maximizing our ability to safely deplete a broad-spectrum of inflammatory targets from the bloodstream.

Implementation and Manufacturing

To support the potential for widespread implementation, Sigyn Therapy™ is a single-use (blood-in-blood-out) disposable device designed for use on the established infrastructure of hemodialysis and continuous renal replacement therapy (CRRT) machines already located in hospitals and clinics worldwide. Sigyn Therapy™ does not require additional pumps or separation cartridges, yet is compatible for use with industry standard connectors and blood tubing sets.

To optimize scalability and control manufacturing costs, Sigyn Therapy™ is comprised of non-biological components whose supply is readily available from various industry vendors. Our management team has experience in establishing “Quality Systems” and “current Good Manufacturing Practices”(cGMP) that are necessary to support market clearance of medical device technologies in the United States and abroad.

Our Therapeutic Targets

To calm the Cytokine Storm, we deplete the presence of inflammatory cytokines, cytokine aggregates, endotoxin, and CytoVesicles from the bloodstream.

Inflammatory Cytokines & Cytokine Aggregates

Human cytokine production plays a central role to stimulate and regulate the innate and adaptive immune response to inflammation, trauma and infection. Cytokines represent a family of more than 100 different immunomodulation agents, which can exist in both peptide and protein forms. Included within the cytokine family are chemokines, interferons, interleukins, lymphokines and tumor necrosis factor. The excess production or dysregulation of inflammatory cytokines (Cytokine Storm Syndrome) has been demonstrated to play a role in the pathogenesis of a wide-range of life-threatening conditions, including septic shock and sepsis-associated organ dysfunction. Cytokine Aggregates result when two or more biologically active cytokines fuse together in the circulatory system.

About Endotoxin

Endotoxin resulting from bacterial infections is a potent driver of Cytokine Storm Syndrome and is associated with a wide-range of antibiotic resistant species. 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. Endotoxin is a primary activator of septic shock and multiple organ failure. Once in circulation, endotoxin induces the production of monocytes and macrophages that produce and release cytokines and other systemic mediators of life-threatening inflammatory conditions.

About CytoVesicles

Beyond endotoxin and inflammatory cytokines, CytoVesicles transport a wide-range of biologically active cytokines that participate in concert with freely circulating cytokines to promote both acute and chronic inflammatory disease conditions. We believe that the simultaneous depletion of circulating cytokines, cytokine aggregates, endotoxin and CytoVesicles establish Sigyn Therapy™ as a first-in-industry approach to alleviate the symptoms or severity of a multitude of inflammatory disorders. We define CytoVesicles to be inclusive of microparticles (MPs) and microvesicles (MVs) classified as Extracellular Vesicles (EVs) with cytokines bound to their surface as well as EVs that transport cytokines as encapsulated cargo. CytoVesicle populations may also include platelet-derived MVs, endothelial-derived MVs and leukocyte-derived MVs, which are prevalent in the blood of those suffering from acute and chronic inflammatory disorders.

Our Co-founders Have Relevant Industry Experience

Our co-founders (Jim Joyce and Craig Roberts) are also the inventors of Sigyn Therapy™. They have more than 50 years combined experience in medical technology field. Their experience in developing medical technologies is especially relevant.

Mr. Joyce is the founder, former Chairman and CEO of Aethlon Medical, Inc. During his tenure, Mr. Joyce oversaw the development of the Aethlon Hemopurifier®, a first-in-class blood purification technology to address life-threatening viruses and cancer-promoting exosomes. At present, the Hemopurifier® is the subject of FDA studies to treat severe COVID-19 infection and cancer.

Under Mr. Joyce's leadership, the Hemopurifier® became the first therapeutic candidate to be awarded two FDA "Breakthrough Device" designations and is the first and only device to receive "Emergency Use Authorization" (EAU) approval from both the FDA and Health Canada to treat Ebola virus. Prior to the EAU award, the Hemopurifier® was deployed to treat Ebola in Germany. Additionally, the Hemopurifier® was the recipient of an FDA cleared "Investigational Device Exemption" to support clinical programs to treat a broad-spectrum of life-threatening viruses that are not addressed with antiviral drugs. 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. Readers Digest Magazine placed the Hemopurifier® on its "Top 10 Medical Breakthroughs" award list. During Mr. Joyce's tenure, the Hemopurifier® was the subject of two contract awards from the Department of Defense (DOD) as well as a contract award from the National Cancer Institute (NCI).

Mr. Roberts is an inventor of several life-saving therapeutic device technologies. This includes the Percutaneous Adult Extracorporeal Membrane Oxygenation (ECMO) system, which was licensed and subsequently sold to C.R. Bard. During the current pandemic, ECMO is being 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 successfully 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 incorporated a series of cartridges, which included an adsorbent-based column to deplete endotoxin and inflammatory cytokines from human blood plasma. The adsorbent-based column of the IMPACT system has been incorporated into an extracorporeal system configuration that received FDA Emergency Use Authorization (EAU) to treat severe COVID-19 infections.

Our Therapeutic Opportunities

Cytokine Storm Syndrome underlies a wide-range of infectious and non-infectious disease conditions that are not addressed with anti-cytokine drugs. The potential therapeutic opportunities for Sigyn Therapy™ include, but are not limited to sepsis, virus induced Cytokine Storm (VICS) underlying COVID-19 and other virulent infections, bacteria induced Cytokine Storm (BICS), acute respiratory distress syndrome (ARDS) and acute forms of liver failure, including hepatic encephalopathy. We also believe there is an opportunity for Sigyn Therapy™ to stabilize or extend the life of patients waiting for the identification of a matched liver for transplantation. In such a scenario, Sigyn Therapy™ is proposed to serve as a bridge to liver transplant.

The Sepsis Treatment Opportunity

Sepsis is defined as a life-threatening organ dysfunction caused by a dysregulated host response to infection. The precipitation of sepsis as the result of Cytokine Storm Syndrome is common. In January of 2020, a report entitled; *"Global, Regional, and National Sepsis Incidence and Mortality, 1990-2017: Analysis for the Global Burden of Disease Study,"* was published in the Journal Lancet. The publication reported 48.9 million cases of sepsis and 11 million deaths in 2017. In that same year, an estimated 20.3 million sepsis cases and 2.9 million deaths were among children younger than 5-years old. The report referenced that sepsis kills more people around the world than all forms of cancer combined. In the United States, sepsis was reported to be the most common cause of in-hospital deaths 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. In the 191 patient analysis, 137 (72%) patients recovered from COVID-19 infection and were released, while 54 (28%) died during their hospital care. The study reported the diagnosis of sepsis in all 54 (100%) 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.

As a result, an increased focus has been directed toward extracorporeal blood purification, with an emphasis on devices that improve immune homeostasis through the depletion of circulating inflammatory mediators. Given the pivotal role of endotoxin and cytokine production in sepsis, it is anticipated that the simultaneous depletion of these inflammatory factors may establish the basis for an efficacious strategy. We also believe that cytokine aggregates and inflammatory cargos being transported by circulating CytoVesicles represent novel yet important therapeutic targets.

Our Virus Induced Cytokine Storm (VICS) Treatment Opportunity

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.

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.

Beyond COVID-19, virus induced Cytokine Storm is associated with many of the 250,000 to 500,000 global deaths that result from severe influenza infections each year. In some years, the death toll resulting from influenza rises to pandemic proportions. In modern history, the best known example is the H1N1 Spanish Flu of 1918 which caused the deaths of more than 50 million individuals. Other deadly influenza outbreaks included the 1957 H2N2 Asian influenza, the 1968 H3N2 Hong Kong influenza, and the 2009 H1N1 pandemic influenza. Between 1997 and 2014, several epizootic avian influenza viruses (e.g., H5N1, H7N9, and H10N8) crossed the species barrier to cause increased human death tolls.

In recent years, virus induced Cytokine Storm was associated with high mortality resulting from the 2003 SARS virus outbreak and the 2014-15 Ebola virus outbreak. VICS is also reported to play a role in mosquito-borne viral infections, including severe Dengue infections, which result in approximately 40,000 deaths each year.

In the absence of an antiviral drug or vaccine to combat a severe viral infection, there is an urgent need for therapies to address life-threatening inflammatory conditions that manifest in individuals after infection.

In this regard, Sigyn Therapy™ is positioned to be a first-line countermeasure to mitigate Cytokine Storm Syndrome in emerging viral outbreaks that are increasingly being fueled by the confluence of global warming, urban crowding and intercontinental travel. As it is improbable for disease-specific drugs and vaccines to be developed, proven effective, manufactured and then delivered within a time frame necessary to combat an emerging pandemic threat, there will be a continued need for therapies to address virus induced Cytokine Storm Syndrome.

Furthermore, we believe that Sigyn Therapy™ aligns with U.S. Government initiatives that support the development of broad-spectrum medical countermeasures that mitigate the impact of emerging pandemic threats, yet also have viability in established disease indications. In this regard, Sigyn Therapy depletes a wide-range of circulating inflammatory factors that underly a broad-spectrum of life-threatening disease indications.

Our Bacteria Induced Cytokine Storm (BICS) Treatment Opportunity

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.

Our Acute Respiratory Distress Syndrome (ARDS) Treatment Opportunity

Acute respiratory distress syndrome (ARDS) is a form of respiratory failure characterized by the rapid onset of widespread inflammation in the lungs. ARDS is often associated with multiple organ failure and is known to be precipitated by a variety of clinical disorders, including Cytokine Storm Syndrome. Globally, ARDS is associated with approximately 3 million deaths each year and has a mortality rate of 30-50%.

Our Hepatic Encephalopathy (HE) Treatment Opportunity

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.

Our Bridge-To-Liver Transplant Opportunity

There is a significant need for a medical device that can reduce and control the presence of inflammatory cytokines and toxins from the bloodstream. Based on these requirements, Sigyn Therapy™ is a candidate strategy to stabilize or extend the life of a patient prior to the identification of a matched liver for transplantation. Otherwise known as a bridge-to-liver transplant. In 2017, 8,082 U.S. patients received a liver transplant and 13,885 patients were on the waiting list for a liver transplant. The average cost associated with a liver transplant is $577,100 USD.

Other Potential Treatment Opportunities

Cytokine Storm Syndrome may also result from trauma, severe burns, acute pancreatitis, adverse drug reactions, cancer immunotherapies, cancer cachexia, acute kidney injury (AKI) and severe pneumonia.

Our Therapeutic Device Competition

We are advancing Sigyn Therapy™ to mitigate life-threatening conditions that are precipitated by Cytokine Storm Syndrome and not addressed with an FDA approved therapy. Should we receive regulatory approval to market Sigyn Therapy™ in or outside of the United States, we anticipate the market environment for therapeutic blood purification technologies may be competitive.

We designed Sigyn Therapy™ to overcome the limitations of previous drug and device therapies. This includes two industry pioneering medical devices that are currently prevalent in the marketplace outside of the United States. Specifically, the Toraymyxin device, a product developed and owned by Toray Industries, Inc. and the CytoSorb device, developed by CytoSorbents Corporation. 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 is the subject of more than 200 publications. CytoSorb has been safely administered to more than 100,000 patients. Both devices are currently being evaluated in the treatment of COVID-19 infected individuals.

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, cytokine aggregates or CytoVesicles. Conversely, the CytoSorb device incorporates an adsorbent component to deplete inflammatory cytokines from the bloodstream, but does not address endotoxinor CytoVesicles.

To effectively treat Cytokine Storm driven conditions, we recognized that Sigyn Therapy™ would need to address a broader spectrum of circulating inflammatory particles, which includes targets that have been beyond the reach of previous drugs and devices, including the Toraymxyin and CytoSorb device.

To optimize our broad-spectrum depletion of these inflammatory particles, we incorporate a cocktail of three different adsorbent components within Sigyn Therapy™, each with unique binding and capture characteristics.

In the medical field, the term cocktail often refers to the simultaneous administration of multiple drugs (a drug cocktail) with differing mechanisms of actions. While drug cocktails have proven to be life-saving therapies for HIV, Hepatitis-C and cancer patients, dosing is often limited by toxicity and adverse events that may result from deleterious drug interactions.

Sigyn Therapy™ is not constrained by such limitations as the active components within our device are not introduced into the body. As a result, we are able to incorporate a substantial dose of multiple adsorbents, each with differing mechanisms and capabilities to optimize the ability of Sigyn Therapy™ to calm the cytokine storm that underlies life-threatening inflammatory conditions.

Beyond an advantageous dosing strategy, the components of our adsorbent cocktail have surface pore structures that allow us to address inflammatory targets whose size may range up to 100 nanometers in diameter. Whereas, previous blood purification therapies have often been limited to addressing small molecular targets.

Despite their differing capabilities, Sigyn Therapy™ and CytoSorb are both single-use (blood-in-blood-out) cartridges deployed for use on the established infrastructure of hemodialysis and CRRT machines located in hospitals and clinics worldwide. Neither device requires additional pumps or separation cartridges, which is a significant advancement over previous blood purification techniques to treat life-threatening inflammatory disorders.

In the case of CytoSorb, whole blood is circulated directly over an adsorbent bead resin to capture circulating cytokines. Whereas, Sigyn Therapy™ incorporates porous membranes to isolate blood plasma from cellular components. The plasma then interacts with a cocktail of adsorbent components in a low shear force environment to optimize the adsorption of cytokines and a broad-spectrum of other inflammatory targets.

Potential Anti-Cytokine Drug Competition

At present, Cytokine Storm related indications are not addressed with an approved anti-cytokine drug. However, the COVID-19 pandemic has prompted the clinical evaluation of several anti-cytokine drugs as the excess production of inflammatory cytokines (Cytokine Storm Syndrome) is a leading cause of death in COVID-19 infected individuals. The Cytokine Storm precipitates a wide range of life-threatening conditions, including acute respiratory distress syndrome (ARDS) and sepsis, which have been reported to be highly prevalent in hospitalized COVID-19 patients.

Much of the drug focus is being directed toward the interleukin-6 (IL-6) cytokine. Tocilizumab (Actemra: Roche), sarilumab (Kevzara: Sanofi/Regeneron) and siltuximab (Sylvant: EUSA Pharm) are each being evaluated in COVID-19 subjects. Additionally, anakinra (Kineret: Sobi) is being tested as an interleukin-1 (IL-1) inhibitor and etanercept (Enbrel; Amgen) is being advanced to inhibit tumor necrosis factor alpha (TNF-a) in COVID-19 patients. Other anti-cytokine drug candidates are also being evaluated.

Emerging and historic evidence reveal the considerable challenge to temper the Cytokine Storm through the inhibition of a single cytokine target. In April of 2020, an article in the Journal Nature reported 14 different inflammatory cytokines to be highly elevated in bloodstream of COVID-19 patients. In May of 2020, Stanford researchers reported that elevated levels of inflammatory cytokines in COVID-19 patients are consistent with those observed in critically ill (non COVID-19) sepsis and ARDS patients, which are conditions for which anti-cytokine drugs were previously unable to demonstrate benefit in clinical studies. Specific to sepsis, more than 70 human studies have been conducted to evaluate the safety and benefit of candidate drugs. With one brief exception (Xigris, Eli Lilly), none of these studies resulted in a market approved therapy.

In the absence of a safe and effective drug agent, there is a critical global need for a therapeutic strategy to mitigate life-threatening conditions that are precipitated by Cytokine Storm Syndrome. We believe the broad-spectrum depletion of inflammatory cytokines, cytokine aggregates, endotoxin and CytoVesicles from the bloodstream provides the greatest hope to address this critical unmet need in healthcare.

U.S. Regulatory Strategy

In the United States, Sigyn Therapy™ is expected to be classified as a medical device whose primary regulatory jurisdiction is the Center for Devices and Radiological Health (CDRH), the FDA branch that oversees the market approval of medical devices. Based on the following statement published by FDA in April 2020, we believe the regulatory environment for an anti-cytokine blood purification device has significantly improved: *"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."*

In response, we plan to submit an investigational device exemption (IDE) to support the initiation of a human feasibility study, whose protocol is designed to demonstrate safety of Sigyn Therapy™ in health-compromised individuals suffering from acute Cytokine Storm related disorders.

Upon completion of our feasibility study, we would plan to leverage the resulting study 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 that are initiated and sustained by Cytokine Storm Syndrome.

Additionally, we believe the characteristics of Sigyn Therapy™ align with FDA's "Breakthrough Device" program to facilitate access to technologies that address life-threatening conditions for which no available treatment alternative exists. There is no assurance that FDA will award a "Breakthrough Device" designation to Sigyn Therapy™.

Item 3.02 Unregistered Sales of Equity Securities.

Reference is made to the disclosure made under Item 1.01 and 2.01 which are incorporated herein by reference to this Item 3.02.

Item 5.01 Changes in Control of Registrant

The information set forth in Item 1.01 and Item 2.01 of this Current Report on Form 8-K is incorporated by reference to this Item 5.01.

Item 5.02 Departure of Directors and Principal Officers, Election of Directors, Appointment of Principal Officers

In connection with the Agreement, on October 19, the current officers and directors of the Company resigned, and concurrently, the Company appointed new officers and a new board of directors as follows:

Name	Age	Position	Commencement of Service As Officer/Director
James Joyce	59	Chairman and CEO and Director	2020
Craig Roberts	67	CTO and Director	2020

Set forth below are brief accounts of the business experience during the past five years of each director and executive officer of the Company.

About our Management Team

James A. Joyce ("Jim"), Chairman and CEO and Director

Jim Joyce has 30+ years of diverse public market experience, which includes two decades of public company CEO and Corporate Board leadership roles. In the field of medical technology, Mr. Joyce has founded and led organizations that have achieved several first-in-industry milestones. He is also an inventor or co-inventor underlying 18 issued or pending patent applications worldwide.

Prior to establishing Sigyn Therapeutics, Mr. Joyce was the founder, Chairman and CEO of Aethlon Medical, a therapeutic device company that he navigated from a single shareholder start-up to Nasdaq-traded Company with 8000+ shareholders and a peak market value that exceeded $200 million.

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 Mr. Joyce's leadership, the Hemopurifier® became the first therapeutic candidate to be awarded two FDA "Breakthrough Device" designations and is the first and only device to receive "Emergency Use Authorization" (EAU) approval from both the FDA and Health Canada to treat Ebola virus. Prior to the EAU award, the Hemopurifier® was cleared to treat Ebola in Germany. Additionally, the Hemopurifier® was the recipient of an FDA approved "Investigational Device Exemption" to support clinical programs to treat a broad-spectrum of life-threatening viruses that are not addressed with antiviral drugs. 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. Readers Digest Magazine placed the Hemopurifier® on its "Top 10 Medical Breakthroughs" award list.

Under Mr. Joyce's leadership, the Hemopurifier® was the subject of two Department of Defense (DOD) contract awards, a National Cancer Institute (NCI) contract award and a grant from the National Institutes of Health (NIH). He also led the completion of approximately $100 million of equity financings on behalf of Aethlon. To validate the broad-spectrum utility of the Hemopurifier®, Mr. Joyce originated preclinical and clinical research collaborations with more than twenty leading 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 received 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 also testified before Congress and lobbied Capital Hill to promote the Hemopurifier® as a broad-spectrum countermeasure against bioterror and pandemic threats, which contributed to expand the government-wide definition of treatment countermeasure to be inclusive of medical devices under U.S. law.

He is also the founder and former Executive Chairman of Exosome Sciences, Inc. (ESI). ESI's focus is directed toward 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 (BU) CTE Center to test his hypothesis that exosomes transported tau protein cargos (exosomal tau or TauSome) that could serve as the 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 same age control group subjects. The study results (co-authored by Mr. Joyce) were published in the Journal of Alzheimer's Disease. Based on these outcomes, a follow-on clinical study is being conducted through a collaboration that Mr. Joyce established with the Translational Genomics Research Institute (TGEN).

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.

James "Jim" Joyce is the co-founder, Chairman and CEO of Sigyn Therapeutics, Inc., which was established on October 29, 2019. Previously, Mr. Joyce founded Aethlon Medical (Nasdaq: AEMD) in May of 1998 and served as Chairman until November 29, 2017 and CEO until December 10, 2018. In 2009, Mr. Joyce founded Exosome Sciences, Inc. and served as Executive Chairman until December 10, 2018. Mr. Joyce graduated from of the University of Maryland in 1984.

Craig P. Roberts, Chief Technology Officer and Director

Mr. Roberts is an inventor of several life-saving therapeutic device technologies. This includes the Percutaneous Adult Extracorporeal Membrane Oxygenation (ECMO) system, which was licensed and subsequently sold to C.R. Bard. During the current pandemic, ECMO is being 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 successfully deployed 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 incorporated a series of cartridges, which included an adsorbent-based column to deplete endotoxin and inflammatory cytokines from human blood plasma. The adsorbent-based column of the IMPACT system has been incorporated into an extracorporeal system configuration that received FDA Emergency Use Authorization (EAU) 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.

Mr. Roberts is the co-founder and Chief Technical Officer of Sigyn Therapeutics, which was established on October 29, 2019. Previously during the last five years, Mr. Roberts has provided medical technology advisory services. Education: USAF Medical Service Specialist - Medic 1971-1975; Long Beach School of Clinical Perfusion - 1976-1977 and Board Certified Clinical Perfusionist - American Board of Cardiovascular Perfusion - 1978.

Reference is made to the disclosure made under Item 1.01 and Item 2.01 which is incorporated herein by reference to this Item 5.02.

Item 5.03 Amendments to the Articles of Incorporation of the Company

On October 12, 2020, the Company changed its name to Sigyn Therapeutics, Inc. from Reign Resources Corporation pursuant to an amendment to its articles of incorporation filed with the State of Delaware on that date.

Item 9.01 Financial Statements and Exhibits.

(a) Financial Statements of Business Acquired.

The Company intends to file the financial statements of Sigyn Medical, Inc. required by Item 9.01(a) as part of an amendment to this Current Report on Form 8-K not later than 71 calendar days after the date of this Current Report on Form 8-K is required to be filed.

(b) Pro forma Financial Information.

The Company intends to file the pro forma financial information required by Item 9.01(B) as part of an amendment to this Current Report on Form 8-K not later than 71 calendar days after the date of this Current Report on Form 8-K is required to be filed.

(d) Exhibits

Exhibit Number	Description
3.1	Amendment to the Articles of Incorporation of Issuer

SIGNATURES

Pursuant to the requirements of the Securities and Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SIGYN THERAPEUTICS, INC.

Date: October 23, 2020

By: /s/ James A. Joyce
James A. Joyce, Chairman and CEO

STATE OF DELAWARE
CERTIFICATE OF AMENDMENT
OF CERTIFICATE OF INCORPORATION

The corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware does hereby certify:

FIRST: That at a meeting of the Board of Directors of Reign Resources Corporation resolutions were duly adopted setting forth a proposed amendment of the Certificate of Incorporation of said corporation, declaring said amendment to be advisable and calling a meeting of the stockholders of said corporation for consideration thereof. The resolution setting forth the proposed amendment is as follows:

RESOLVED, that the Certificate of Incorporation of this corporation be amended by changing the Article thereof numbered "FIRST" so that, as amended, said Article shall be and read as follows:

The name of the corporation is Sigyn Therapeutics, Inc.

SECOND: That thereafter, pursuant to resolution of its Board of Directors, a special meeting of the stockholders of said corporation was duly called and held upon notice in accordance with Section 222 of the General Corporation Law of the State of Delaware at which meeting the necessary number of shares as required by statute were voted in favor of the amendment.

THIRD: That said amendment was duly adopted in accordance with the provisions of Section 242 of the General Corporation Law of the State of Delaware.

IN WITNESS WHEREOF, said corporation has caused this certificate to be signed this 12th day of October, 2020.

By: /s/ Joseph Segelman
Authorized Officer

Title: CEO

Name: Joseph Segelman
Print or Type

State of Delaware
Secretary of State
Division of Corporations
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