# SMSbiotech, Inc.

*A New Approach to Regenerative Medicine*

**PRIVATE OFFERING MEMORANDUM**

August 26, 2025

**TABLE OF CONTENTS**

## THE OFFERING

By means of this Private Offering Memorandum, SMSbiotech, Inc. is offering 560,000 shares of its common stock.

The Company's common stock is being offered at the following prices:

| Investment Range | Price per Share |
|---|---|
| $10,000 to $49,999 | $28.13 |
| $50,000 to $99,999 | $26.72 |
| $100,000 to $249,999 | $25.32 |
| $250,000 to $499,999 | $22.50 |
| $500,000 and above | $22.50 Plus warrants |

Amounts in the investment range are based upon the total investment by the investor, including members of the investor's immediate family.

For investments over $500,000, an investor will receive a warrant which will allow the investor to purchase a number of shares equal to the number of shares purchased by the investor. The warrant will be exercisable for 180 days after the investor's purchase of the Company's shares at an exercise price of $22.50 per share.

After $5,000,000 is raised in this Offering, no further warrants will be issued.

A minimum investment of $10,000 is required.

SMSbiotech, Inc. is a clinical-stage biotech company headquartered in San Diego County that has made a groundbreaking finding in the field of stem cells. The Company has discovered and named a unique type of stem cell known as the Small Mobile Stem (SMS) cell. This significant discovery has paved the way for the creation and production of Small Mobile Stem cells, which present an unprecedented opportunity for an off-the-shelf treatment and a potential cure for multiple chronic diseases, starting with Chronic Obstructive Pulmonary Disease (COPD), a currently incurable condition and the third leading cause of death worldwide.

Chronic Obstructive Pulmonary Disease (COPD), which encompasses emphysema and chronic bronchitis, is a deadly lung disease that currently has no cure. The patient's lungs gradually deteriorate, and so does their quality of life. Some estimates the global cost of COPD exceeds $2.1 trillion annually by 2030 if indirect costs are included. More than 16 million U.S. citizens have COPD (400 million worldwide), affecting at least one of every 4 families. Given that current treatments only address symptoms, experts believe a mere 10% improvement in lung functions would constitute a great achievement in the field of medicine.

SMS cells provide a potential regenerative solution to lung tissue degeneration. SMS cells that are bio-manufactured to a large scale may provide an off-the-shelf cell treatment solution. The cells are originally obtained from healthy human adult blood. The cells are not genetically modified and are grown while maintaining potency. SMS cells have been biomanufactured by SMSbiotech and optimized for large-scale production for over a decade. This process is protected by issued patents and trade secrets. In the lab and animal models, SMS cells have been shown to stimulate lung cells and restore lung air sacs that are damaged up to 100% physically and functionally in 10 days or less. Uniquely, SMS cells can be stored and shipped at 4°C for up to three weeks, overcoming a major logistical challenge in cell treatment. Furthermore, SMS

cells are the only human cells that can be administered directly to the lung without surgery, that is, by inhalation using a nebulizer.

SMS cells should be regarded as a platform technology with the potential to address a wide range of therapeutic indications. This view is supported by extensive bench research and preclinical studies conducted by SMSbiotech. Testing in diabetic animal models with impaired wound healing, along with studies in companion animals and horses, has demonstrated strong beneficial effects in wound healing and orthopedic applications, including osteoarthritis and tendon repair. These early findings suggest broader therapeutic potential, with additional applications currently under review as part of SMSbiotech's ongoing research and development efforts.

There is no minimum amount required to be raised in this offering. All amounts received from investors will be delivered to the Company. There is no commitment by any person to purchase any of the securities offered by the Company, and there can be no assurance that any securities offered will be sold.

The securities to be sold in this offering will be restricted securities as that term is defined in Rule 144 of the Securities and Exchange Commission.

Even if all securities offered are sold, the Company's future operations will be dependent upon its ability to obtain additional capital. Accordingly, following the completion of this offering, the Company may sell additional shares of common stock and/or other securities to raise capital for its operations. There can be no assurance that additional funds may be obtained in the future.

The Company will not pay any sales commissions or other form of compensation to any officer, director, or employee in connection with this offering.

The shares are being offered and sold on a "best efforts" basis. There is no firm commitment by any person to purchase or sell any of the shares, and there is no assurance that any shares offered will be sold. There is no minimum number of shares which are required to be sold in this offering. The Company may terminate this offering at any time.

**Use of proceeds:** This Offering is for a maximum amount of $15,752,800, assuming all shares are sold at a price of $28.13 per share. If we sell the maximum amount, our net proceeds (after payment of any sales commissions and after deducting our estimated offering expenses) will be approximately $14,177,800. See "Use of Proceeds" for our intended use of proceeds from this Offering.

Investing in our common stock involves a high degree of risk, including:

- Lack of revenue and, as a result, a history of losses, and
- No market for our common stock.

**THE SECURITIES OFFERED HAVE NOT BEEN REGISTERED WITH, NOR APPROVED OR DISAPPROVED BY, THE UNITED STATES SECURITIES AND EXCHANGE COMMISSION BY THE SECURITIES REGULATORY AUTHORITY OF ANY STATE, AND NO COMMISSION OR AUTHORITY HAS PASSED UPON OR ENDORSED THE MERITS OF THIS OFFERING OR THE ACCURACY OR ADEQUACY OF THIS PRIVATE PLACEMENT MEMORANDUM, NOR IS IT INTENDED THAT THEY WILL. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.**

**NO PERSON HAS BEEN AUTHORIZED TO MAKE ANY REPRESENTATIONS IN CONNECTION WITH THIS OFFERING OTHER THAN THOSE CONTAINED IN THIS CONFIDENTIAL PRIVATE PLACEMENT MEMORANDUM (THE "MEMORANDUM") AND, IF GIVEN OR MADE, SUCH INFORMATION OR REPRESENTATIONS MUST NOT BE RELIED UPON AS HAVING BEEN AUTHORIZED BY THE COMPANY. THE DELIVERY OF THIS MEMORANDUM AT ANY TIME DOES NOT IMPLY THAT THE INFORMATION HEREIN IS CORRECT AS OF ANY TIME SUBSEQUENT TO ITS DATE.**

**THIS OFFERING IS BEING MADE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933 FOR AN OFFER AND SALE OF SECURITIES THAT DOES NOT INVOLVE A PUBLIC OFFERING. BY ACCEPTANCE OF THIS MEMORANDUM, EACH OFFEREE AGREES THAT SUCH OFFEREE WILL NOT TRANSMIT, REPRODUCE, OR MAKE AVAILABLE TO ANY OTHER PERSON, EXCEPT SUCH OFFEREE'S AGENTS AND ADVISORS, THIS MEMORANDUM OR ANY APPENDICES OR DOCUMENTS SUPPLIED IN CONNECTION HEREWITH.**

**THIS MEMORANDUM DOES NOT CONSTITUTE AN OFFER TO SELL, OR A SOLICITATION OF AN OFFER TO BUY, ANY OF THE SECURITIES OFFERED HEREBY, EXCEPT TO OR FROM THE PERSON TO WHOM THIS MEMORANDUM WAS DELIVERED BY, OR ON BEHALF OF, THE COMPANY. THIS MEMORANDUM DOES NOT CONSTITUTE AN OFFER TO SELL, OR A SOLICITATION OF AN OFFER TO BUY IN ANY STATE OR OTHER JURISDICTION IN WHICH SUCH OFFER OR SOLICITATION IS UNLAWFUL OR UNAUTHORIZED.**

**THIS MEMORANDUM HAS BEEN PREPARED SOLELY FOR, AND SHOULD BE USED ONLY IN CONNECTION WITH, A PROSPECTIVE INVESTOR'S CONSIDERATION OF AN INVESTMENT IN THE SECURITIES OF THE COMPANY DESCRIBED HEREIN.**

**THIS OFFER MAY BE WITHDRAWN AT ANY TIME AND IS SPECIFICALLY MADE SUBJECT TO THE TERMS DESCRIBED IN THIS MEMORANDUM. THE COMPANY RESERVES THE RIGHT TO REJECT ANY SUBSCRIPTION, IN WHOLE OR IN PART, OR TO ALLOT TO ANY PROSPECTIVE INVESTOR LESS THAN THE NUMBER OF SHARES SUBSCRIBED FOR BY SUCH PROSPECTIVE INVESTOR. ANY REPRESENTATION TO THE CONTRARY IS UNAUTHORIZED AND MUST NOT BE RELIED UPON.**

**PROSPECTIVE INVESTORS SHOULD NOT CONSTRUE THE CONTENTS OF THIS MEMORANDUM, ANY OTHER DOCUMENTS DELIVERED HEREWITH, IF ANY, OR ANY OTHER COMMUNICATION FROM THE COMPANY AS INVESTMENT OR LEGAL ADVICE. THIS MEMORANDUM, ANY OTHER DOCUMENTS DELIVERED HEREWITH, AND ANY SUCH OTHER MATERIALS, AS WELL AS THE NATURE OF AN INVESTMENT IN THE SECURITIES OFFERED HEREBY, SHOULD BE REVIEWED BY EACH PROSPECTIVE INVESTOR AND SUCH INVESTOR'S INVESTMENT, TAX, LEGAL, ACCOUNTING AND OTHER ADVISORS.**

**NO GENERAL SOLICITATION WILL BE CONDUCTED AND NO OFFERING LITERATURE OR ADVERTISING IN ANY FORM WILL OR MAY BE EMPLOYED IN THE OFFERING OF THE SECURITIES OFFERED HEREBY, EXCEPT FOR THIS MEMORANDUM (INCLUDING AMENDMENTS AND SUPPLEMENTS HERETO) AND THE DOCUMENTS SUMMARIZED HEREIN OR ENCLOSED HEREWITH. NO PERSON IS AUTHORIZED TO GIVE ANY INFORMATION OR TO MAKE ANY REPRESENTATION NOT CONTAINED IN THIS MEMORANDUM OR IN THE DOCUMENTS SUMMARIZED HEREIN OR ENCLOSED HEREWITH AND, IF GIVEN OR MADE, SUCH OTHER INFORMATION OR REPRESENTATION MUST NOT BE RELIED UPON.**

## FLORIDA RESIDENTS

**ANY SALE TO A RESIDENT OF FLORIDA IS VOIDABLE BY THE PURCHASER WITHIN THREE DAYS AFTER THE FIRST TENDER OF CONSIDERATION IS MADE BY SUCH PURCHASER TO THE COMPANY, ANY AGENT OF THE COMPANY, OR TO ANY ESCROW AGENT.**

## PENNSYLVANIA RESIDENTS

**PENNSYLVANIA RESIDENTS' MAY NOT, UNDER ANY CIRCUMSTANCES, SELL THE SECURITIES PURCHASED IN THIS OFFERING FOR A PERIOD OF TWELVE MONTHS FOLLOWING THE DATE OF PURCHASE, EXCEPT IN ACCORDANCE WITH RULE 204.11 OF THE PENNSYLVANIA SECURITIES COMMISSION**

## FORWARD LOOKING STATEMENTS

This Private Offering Memorandum contains various forward-looking statements that are based on the Company's beliefs as well as assumptions made by and information currently available to the Company. When used in this Private Offering Memorandum, the words "believe", "expect", "anticipate", "estimate", and similar expressions are intended to identify forward-looking statements. Such statements may include statements regarding and are subject to certain risks, uncertainties, and assumptions which could cause actual results to differ materially from projections or estimates. Factors which could cause actual results to differ materially are discussed at length under the heading "Risk Factors." Should one or more of the enumerated risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, estimated, or projected. Investors should not place undue reliance on forward-looking statements, all of which speak only as of the date made.

## USE OF PROCEEDS

We plan to use these net proceeds from this Offering for the following, depending upon the amount raised in this Offering:

| Use of Proceeds | Amount Raised | | | |
|---|---|---|---|---|
| | **$3,000,000** | **$5,000,000** | **$8,000,000** | **$15,750,000[(1)]** |
| Offering Expenses | $300,000 | $500,000 | $800,000 | $1,575,000 |
| Clinical Trials | $600,000 | $1,000,000 | $2,800,000 | $5,040,000 |
| Preclinical Research (Other Indications) | $600,000 | $750,000 | $1,200,000 | $1,890,000 |
| Biomanufacturing | $600,000 | $1,000,000 | $1,200,000 | $1,890,000 |
| General | $300,000 | $350,000 | $400,000 | $3,465,000 |
| Compassionate Use Application | $600,000 | $1,400,000 | $1,600,000 | $1,890,000 |

(1) Assumes all shares are sold at a price of $28.13 per share.

The precise amounts that we will devote to each of the foregoing items, and the timing of expenditures, will vary depending on numerous factors. Any line item amounts not expended completely shall be held in reserve as working capital and subject to reallocation to other line-item expenditures as required for ongoing operations.

The expected use of net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve and change. The amounts and timing of our actual expenditures, specifically with respect to working capital, may vary significantly depending on numerous factors. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

In the event we do not sell all of the shares being offered, we may seek additional financing from other sources in order to support the intended use of proceeds indicated above. If we secure additional equity funding, investors in this offering would be diluted. In all events, there can be no assurance that additional financing would be available to us when wanted or needed and, if available, on terms acceptable to us.

## BUSINESS

SMS Cells

We are a clinical-stage biotech company headquartered in California that has made a groundbreaking finding in the field of regenerative medicine and stem cells. The Company has discovered and named a unique type of stem cell known as the Small Mobile Stem (SMS) cell. This significant discovery has paved

the way for the isolation and production of Small Mobile Stem cells, which present an unprecedented opportunity for an off-the-shelf allogeneic cell therapy and a potential cure for multiple chronic diseases, starting with Chronic Obstructive Pulmonary Disease (COPD), a currently incurable condition and the third leading cause of death worldwide.

**SMSbiotech** Technology:

- Our patented, regenerative platform technology promotes the restoration and healing of damaged and diseased cells and tissues
- The platform technology creates multiple solutions for multiple diseases
- This newly discovered technology is ethically sourced from living, human adults, and these cells can be used to treat most human beings without the need for custom stem cell generation.
- While other stem cells exist, none have the capabilities of Small Mobile Stem (SMS) cells
- First inhalable nebulized stem cell therapy for COPD
- No genetic manipulation required. Allogeneic therapy
- Provides a multi-targeted, orchestrated process
- Our platform manufactures a mixture of proteins and carbohydrates that surrounds cells and provides structural and biochemical support for therapeutic purposes, such as wound healing, which can have multiple uses.
- Off-the-Shelf Therapy: Consistent potency of cells derived from a healthy donor. No patient-derived cells or genetic engineering is required, ensuring scalability and low cost.
- Rapid and Safe: Preclinical studies show complete recovery both structurally and functionally in damaged animal lungs in 10 days or less with no adverse effects.
- SMS cells are a naturally occurring population of stem cells found in peripheral blood circulation, suggesting their physiological relevance and potential importance in tissue maintenance and repair throughout the body.
- Platform Technology: A regenerative orchestrated process that addresses fundamental mechanisms such as inflammation and fibrosis creates multiple regenerative solutions for various diseased organs.
- Scalability: A patented, proprietary, large-scale biomanufacturing production process that has demonstrated functionality with scalability
- Stability and potency: SMS cells present extraordinary stability in adverse conditions and can be preserved at refrigerator temperature for more than 3 weeks with consistent potency

<u>COPD Statistics</u>

- 3rd leading cause of death worldwide after heart disease and cancer
- 140,000 deaths per year in the US alone and around 3 million worldwide
- Affecting 15 million people in the US and 400 million worldwide
- Around $50 billion economic burden in the US just in 2020
- For severe COPD, the 2-year survival rate is just 50%
- Between 20% and 40% of all COPD patients in the world are never smokers
- The 5-year life expectancy for people with COPD ranges from 40% to 70%, depending on disease severity

- Nearly 90% of COPD deaths in those under 70 years of age occur in low- and middle-income countries.
- COPD is the seventh leading cause of poor health worldwide (measured by disability-adjusted life years)

COPD encompasses emphysema and chronic bronchitis, and is a deadly lung disease that currently has no cure. The patient's lungs gradually deteriorate, and so does their quality of life. Some estimates the global cost of COPD exceeds $2.1 trillion annually by 2030 if indirect costs are included. More than 16 million U.S. citizens have COPD (400 million worldwide), affecting at least one of every 4 families. Given that current treatments only address symptoms, experts believe a mere 10% improvement in lung function would constitute a great achievement in the field of medicine.

SMS cells provide a potential organ regenerative solution to lung tissue degeneration. SMS cells that are bio-manufactured on a large scale may provide an off-the-shelf cell therapy solution. The cells are originally obtained from healthy human adult blood. The cells are not genetically modified and are grown extensively while maintaining potency. In the lab and animal models, SMS cells have been shown to stimulate lung cells and restore lung air sacs that are damaged up to 100% physically and functionally in 10 days or less. SMS cells present extraordinary stability in adverse conditions and can be preserved at refrigerator temperature for at least 3 weeks with consistent potency. Furthermore, SMS cells are the only cells that can be administered directly to the lung periphery without surgery, that is, by inhalation using a nebulizer.

SMS cells discovered in human peripheral blood have shown promising potential for lung tissue regeneration without genetic modification, and they retain their native phenotype even after a plethora of cell culture generations. Our in vitro studies indicate that SMS cells possess low immunogenicity due to minimal major proteins that govern an immune reaction, corroborated historically by their undetected presence in blood transfusions. Our preclinical in vivo studies have demonstrated their safety, showing **no** toxicity, migration, immunogenicity, or tumorigenicity when administered to animals systemically via intravenous injections and via the respiratory tract. Specifically, in rats, SMS cells were well-tolerated, with no adverse effects observed in a range of administration methods and doses. These data were consistent with results obtained for other adult stem cells, such as mesenchymal stem cells derived from adult donors, where animal and human studies reported no discernible toxicity.

Furthermore, studies in mice confirmed that SMS cells remain localized in the lungs without migrating to other tissues. The human SMS cells were detectable in the lungs of healthy mice for about two weeks and in the lungs of immunocompromised mice for about three weeks. Human SMS cells, when applied to animal lungs, remained at the treatment site for several weeks without triggering an adverse response. This is supported by the biodistribution studies in rabbits showing no antibody (immune) reaction and lab tests confirming the cells have very low levels of proteins that typically cause immune rejection. It is consistent with the paucity of immunogenic proteins detected in vitro. Proof-of-concept studies showed that SMS cells significantly promoted lung tissue regeneration in COPD model rats with enzyme-induced lung injury. The study demonstrated both complete structural and functional recovery of lung tissue in rats with induced lung injury, that is in less than ten days after treatment with SMS cells administered via the oral tracheal route. Enzyme-treated rats that received SMS cells exhibited rapid regeneration of lung tissue up to 100% or more, as demonstrated through morphometric histologic analysis and functional exercise testing on a treadmill. In contrast, rats treated with elastase and did not receive SMS cells showed severe lung damage on histologic analysis and poor exercise performance. These preclinical results suggest that SMS cells have the potential to offer safe and effective cell therapy for COPD with a high therapeutic index.

SMS cells can bind selectively to various cells that are key to tissue regeneration, including Mesenchymal Stem Cells, endothelial cells, Alveolar Type 2 progenitor cells, chondrocytes, and other biological cells that play a critical role in wound healing. The binding causes stimulation of cell proliferation of endogenous

target cells or their inhibition (which occurs in fibroblasts). SMS cells have been demonstrated in vitro, to induce gene expression changes in the target cell. With respect to endothelial cells, the extracellular matrix from SMS cells exerts a strong angiogenic effect, leading to the formation of small and large blood vessels. SMS cells secrete various proteins that are important for tissue regeneration and repair.

The anticipated cost of the patient of one COPD SMS Cell Treatment is $20,000. More than one treatment may be required, which will be determined during the Phase 2 and 3 trials.

The Company expects its cost for one stem cell treatment will be approximately 10% to 15% of the cost to the patient.

Stem Cell Therapy in the Animal Market

The regenerative capacity of human SMS cells has been tested in animals other than rats. Single Joint Intraarticular Injection of SMS cells alleviated the symptoms of osteoarthritis in five companion dogs, within only a few days of administration. In three elderly dogs (both approximately 12 years old), systemic (intravenous) administration of SMS cells led to enhanced vitality, appetite, and energy level, again only several days after treatment. In diabetic mice, selected as a model of impaired wound healing, the application of proteins secreted by cells, derived from SMS cells, into induced wounds was able to promote and enhance the healing of the wounds, as compared with controls. The success of varied applications in animals across different species highlights the broad potential applications for SMS cell-based therapy.

The veterinary regenerative medicine sector is rapidly evolving, with stem cell therapy emerging as a transformative treatment for companion animals, particularly dogs and horses. The increasing prevalence of chronic conditions such as osteoarthritis, degenerative myelopathy (DM), and canine cognitive decline (CCD), as well as general aging-related diseases, has created a strong demand for advanced therapeutic interventions.

Current stem cell therapies only offer a minimally invasive, regenerative approach with long-term benefits compared to traditional pharmaceuticals like NSAIDs and corticosteroids. It is used for treating joint repair, osteoarthritis, degenerative myelopathy, skin and surgical wounds, organ fibrosis, spinal cord injuries, and inflammatory diseases of the skin and gut. In horses, it is gaining traction for tendon and ligament injuries, especially in the equine performance and racing industries, where musculoskeletal conditions are a leading cause of early retirement and decreased performance.

The global animal stem cell therapy market was valued at approximately $125–$150 million in 2023, with companion animals—primarily dogs and horses—comprising over 70% of the market. This segment is projected to grow at a compound annual growth rate (CAGR) of 10–14%, reaching an estimated $300–$400 million by 2030. Growth is driven by increasing pet healthcare expenditures, particularly in North America, Europe, and parts of the Asia-Pacific region. The United States dominates the market, accounting for over 50% of total revenues due to high pet ownership rates and access to advanced veterinary care.

Canine Market:

With approximately 80 million pet dogs in the U.S., the demand for advanced veterinary treatments continues to grow. Osteoarthritis, one of the leading conditions treated with stem cell therapy, affects an estimated 16 million dogs. Additionally, canine cognitive dysfunction (CCD) impacts between 14% and 35% of senior dogs, representing a significant unmet medical need. Degenerative myelopathy (DM), a progressive neurological disorder, has a prevalence of 0.19% across all dogs but disproportionately affects certain breeds, such as German Shepherds, with an incidence of 2.4%.

The anticipated cost of Stem Cell Treatment for dogs is $3,000, although pricing will vary depending on the indication of the disease, the organ affected by the disease, and the size of the dog.

Equine Market:

The U.S. equine industry comprises approximately nine million horses, with 60% involved in recreational and competitive activities. Musculoskeletal injuries, particularly tendon and ligament damage, are common in performance horses, affecting 30–50% of racehorses. Stem cell therapy is increasingly recognized as a valuable regenerative solution, facilitating faster recovery and reducing reinjury rates. The cost of stem cell treatment in the industry for equine ligament and tendon injuries ranges from $3,000 to $6,000 per treatment, positioning it as a premium therapeutic option in sports medicine. Notably, 70% of equine veterinarians report using or considering regenerative therapies for orthopedic conditions.

The anticipated cost of Stem Cell Treatment for horses is $4,000, although pricing will vary depending on the indication of the disease and the organ affected by the disease.

Regulatory Path

Results of Pre-Clinical Animal Testing:

Safety: 19 rats and 12 mice were used to demonstrate the safety of the cells using different injection routes and for up to a 4-month waiting period. No adverse reactions were detected with any of the large numbers of cells injected.

Efficacy: 21 rats were used to demonstrate efficacy using multiple regimens (different doses and time intervals). Regeneration exceeded 60% up to more than 100% in 10 days or less.

In the study, 19 rats and 12 mice were used to assess the safety of the cells through various injection routes over a 4-month period, with no adverse reactions observed. Additionally, 21 rats were utilized to evaluate efficacy using different doses and time intervals. Initially, rats treated with damaging enzymes exhibited damaged lungs, destroyed air sacs (emphysema), and lower performance during exercise tests. However, after a single injection of SMS cells into the lungs, significant improvements were noted. One week post-injection, lung air sacs (alveoli) regenerated by more than 60%, and with an additional dose, regeneration reached up to 100% in less than 10 days. Furthermore, the treated animals performed as well as or better than healthy rats in exercise tests.

Next Steps

SMSbiotech has received all necessary regulatory approvals from the Australian Therapeutic Goods Administration (TGA) and the Australian Human Research Ethics Committee (HREC), the equivalents of the US FDA and IRB, respectively, to move forward with our COPD human clinical trial in Australia. Our Phase I clinical trial commenced on April 22, 2025, with patient enrollment currently underway. The trial, structured to include 18 mild to moderate COPD patients in accordance with pre-IND guidance from the US FDA, aims to establish the safety and tolerability of our therapy. A significant milestone was achieved on July 11, 2025, with the successful administration of treatment to our first two sentinel patients. Over the course of their therapy, both patients were closely monitored, and we are pleased to confirm that no safety concerns were observed. The total projected cost for this Phase I trial is approximately $800,000.

The Phase I trial is a first-in-human, open-label, non-randomized, dose-escalation safety study of 18 COPD patients qualified as severe (oxygen dependent), with a life expectancy of about 5 years, including end-stage. Participants between 39 and 69 years of age with mild to moderate chronic obstructive pulmonary disease treated with SORT-COPD. A dose-escalation committee currently oversees the dose escalation.

The primary objective of this study is to determine the safety of SORT-COPD at three doses in people with chronic obstructive pulmonary disease. The study will include three cohorts, each comprising six participants. Each cohort will consist of two sentinel participants (1 male, 1 female) and four additional participants (2 male, 2 female), resulting in a total of 18 participants across all cohorts.

Upon collection of safety data from the initial patients in the Phase I clinical trial, the Company plans to apply for Compassionate Use (Expanded Access) in the U.S. at the FDA. If granted, the treatment will be made available for Compassionate Use in patients with severe COPD. The Company has already obtained approval from a US-based Institutional Review Board (IRB) for SMS cell therapy in Compassionate Use (Expanded access). Compassionate Use (Expanded Access) will allow patients with debilitating or life-threatening diseases, such as COPD, for whom there is no other efficient approved drug treatment; access to early investigational drug treatments. This will generate early revenue for SMSbiotech, broaden the application of our expanding platform technology, and provide additional critical data, well in advance of US FDA commercial drug approval.

SMSbiotech will pursue compassionate use worldwide (officially termed expanded access in the USA), which eventually provides access to a huge pool of patients. The regulations regarding access to compassionate use in different countries are quite diverse, and they are significantly easier or more difficult than the United States. SMSbiotech will benefit from charging patients for compassionate use, providing early access to revenue during Phase I and prior to commercialization

The key objectives of the Phase I trial include:

1. Safety Assessment: The primary goal of this phase is to ensure that the SMS cell treatment is safe for human application. This will be determined through close monitoring of adverse effects, laboratory tests, and health evaluations of the trial participants. The safety data will be collected and analyzed to identify any potential risks and to establish the treatment's safety profile.

2. Dosage Determination: The Phase I trial will also be used to help determine the safe dosage of SMS cell treatment. Patients will be administered varying doses of the treatment, and their responses will be closely monitored. The results will help identify the dose that offers therapeutic benefit while ensuring patient safety.

3. Initial Efficacy Indication: Although the primary focus of Phase I trials is usually safety, given the FDA's request for efficacy data, we will also track and document any signs of efficacy during this phase. Even though the sample size is relatively small, any positive indication can be an encouraging sign of the treatment's potential to treat COPD.

4. Regenerative Medicine Advanced Therapy (RMAT) Designation: SMSbiotech intends to pursue a US FDA RMAT designation using human safety data obtained during our Phase 1 trial.

Once the Phase I trial is completed, the data will be systematically collected, analyzed, and compiled into a comprehensive report for submission. Any indications of efficacy observed in trial participants will be promptly communicated to regulatory authorities. This is a critical step that may facilitate the acceleration of subsequent clinical trial phases, potentially enabling an earlier market entry than originally projected.

The overall timeline for the Phase I trial is as follows:

1. Regulatory Approval and Trial Initiation: After receiving approval from the TGA, the Company began a Phase I Clinical Trial on April 22, 2025 (volunteer enrollment).

2. Patient Enrollment: The process of patient enrollment will take approximately 3-4 months. The company plans to have all 18 patients with mild or moderate COPD enrolled during the Phase I initiation.

3. Therapy Administration and Patient Monitoring: Patients enrolled will be administered the SMS cell therapy in sequential cohorts and closely monitored within a period of about 8 months.

4. Data Analysis and Report Compilation: After the monitoring period, the data will be analyzed, and a report will be compiled for submission to the FDA. This process is anticipated to be completed by Q4 2025–Q1 2026

5. Reporting to the regulators and preparing for the next phase: The final report will be submitted to the FDA/TGA, and based on their feedback, the Company will make necessary adjustments and preparations for the Phase II Clinical Trial. This is expected to occur in the first quarter of 2026 - second quarter

Once we gather preliminary safety data during the Phase I Trial, we anticipate filing for Expanded Access (Compassionate Use) with about 10 individuals. Expanded Access is a potential pathway for a patient with a serious or immediately life-threatening disease or condition to gain access to an investigational medical product for treatment outside of clinical trials when no comparable or satisfactory alternative therapy options are available. Being granted Expanded Access to our COPD treatment will open the door for us to provide SMS cells to patients with the greatest requirement for them and provide early revenue.

If Phase I is successful, we will apply to the FDA for approval to conduct a Phase II trial, the purpose of which will be to establish safety and efficacy. We anticipate the Phase II trial will cost approximately $13,000,000 and take approximately 12 months to complete.

If Phase II is successful, we will apply to the FDA for approval to conduct a Phase III trial, the purpose of which will establish efficacy. We anticipate the Phase III trial will cost approximately $38,000,000 and take approximately 12 months to complete.

While we have limited prior experience in navigating the regulatory approval process, we are actively building a robust regulatory strategy aligned with requirements in both the United States and Australia and we are working closely with experienced regulatory consultants to guide the preparation and management of submissions to the FDA.

Regulation

We are pursuing a strategic approach that leverages early-stage clinical trials in Australia under the oversight of the Therapeutic Goods Administration (TGA), while concurrently preparing for regulatory approval in the United States through the Food and Drug Administration (FDA). Australia is a preferred location for Phase I trials by U.S. pharmaceutical companies due to its rigorous compliance with Good Clinical Practice (GCP) standards and efficient regulatory timelines. Importantly, the FDA recognizes data generated from Australian Phase I studies conducted under TGA guidelines, allowing for a smoother transition into the U.S. regulatory pathway. This strategy not only accelerates clinical development but also represents a cost-effective and globally credible foundation for building future value and partnerships.

Therapeutic Goods Administration (TGA) – Australia

We received approval from the TGA to initiate a Phase I clinical trial in patients with 18 mild to moderate COPD under the Clinical Trial Notification (CTN) scheme on April 22, 2025. This regulatory pathway allows for a streamlined approval process, reducing the time required to initiate first-in-human studies.

The approval process includes:

- Preclinical data submission, demonstrating the safety and efficacy of SMS cells in animal models.
- Manufacturing and quality assurance review.
- Clinical trial protocol approval, outlining the study design, safety monitoring, and patient eligibility criteria.
- Volunteer/Patient Informed Consent Form

Food and Drug Administration (FDA) – United States

If the Phase I trial in Australia is successful, SMSbiotech plans to file an Investigational New Drug (IND) application with the FDA to conduct Phase II clinical trials in the United States.

The IND submission will include:

- Preclinical safety and efficacy data, incorporating findings from both laboratory and animal studies. Manufacturing and quality control data, ensuring the scalability and reproducibility of SMS cell production.
- Results from the Phase I trial in Australia
- Clinical trial protocols, detailing study design, dosing regimens, safety monitoring, and patient selection criteria.
- Volunteer/Patient Informed Consent Form

Upon IND approval, SMSbiotech will proceed with U.S.-based clinical trials, advancing its development program toward regulatory approval.

**Expanded Access and Accelerated Approval Pathways in the U.S.**

As mentioned earlier, to provide early access to patients with severe COPD, SMSbiotech plans to apply for Compassionate Use (Expanded Access) in the U.S. after obtaining human safety data from the Phase I clinical trial, allowing patients who do not qualify for clinical trials to receive investigational treatment.

Additionally, the Company intends to seek:

- Fast-Track Designation, which facilitates expedited interactions with the FDA and enables a rolling review process.
- Regenerative Medicine Advanced Therapy (RMAT) Designation, which allows for accelerated approval and fast track priority review, if early clinical data demonstrates safety in human subjects

**Final Commercial Approval Requirements in the US.**

In the United States, the FDA regulates a number of products, including foods, drugs, biologics, medical devices, and stem cell therapy under the Federal Food, Drug, and Cosmetic Act, or FDCA, and the Public Health Service Act, or PHSA, and their implementing regulations. The process required by the FDA before these product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA's Good Laboratory Practice, or GLP, regulations;
- submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical trials may begin and must be updated annually;
- approval by an independent Institutional Review Board (or IRB) or ethics committee at each clinical site before the trial is initiated;
- performance of adequate and well-controlled human clinical trials in compliance with Good Clinical Practice, or GCP, regulations to establish the safety, purity, and potency of the proposed product candidate for its intended purpose;
- preparation of and submission to the FDA of a Biologics License Application, or BL,A after completion of clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with current Good Manufacturing Practice, or cGMP, requirements and to assure that the facilities, methods, and controls are adequate to preserve the product's continued safety, purity, and potency, and of selected clinical investigations to assess compliance with GCPs; and
- FDA review and approval of the BLA to permit commercial marketing of the product for particular indications for use in the United States.

Prior to commencing the first clinical trial with a product candidate in the U.S., the Company must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human studies. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin in the US. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold, and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefor,e may or may not result in FDA authorization to commence a clinical trial.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and

for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial commences at that site, and must monitor the study until completed. Regulatory authorities, the IRB, or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board (DSMB) or independent data monitoring committee (IDMC), which provides recommendations for whether or not a study should move forward at designated check points based on access to certain data from the study and may suggest halting the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

For purposes of approval of a BLA, human clinical trials are typically conducted in three or four sequential phases that may overlap.

- Phase 1 — The investigational product is initially introduced into healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans and the side effects associated with increasing doses.
- Phase 2 — The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages, and dosing schedule, and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- Phase 3 — The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.
- Phase 4 — In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. The FDA may also make these so-called Phase 4 or post-marketing studies a condition to approval of the BLA.

Phase 1, Phase 2, and Phase 3 testing may not be completed successfully within a specified period, if at all, and there can be no assurance that the data collected will support FDA approval or licensure of the product. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality, and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

Biologics License Application (BLA) Submission and Review by the FDA

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies, and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent preclinical and clinical studies, including negative

or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of the use of the product, or from a number of alternative sources, including studies initiated by investigators.

In most cases, the submission of a BLA is subject to a substantial application user fee. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, for original BLAs, the FDA's goal is to review the BLA within ten months after it accepts the application for filing, or, if the product relates to an unmet medical need in a serious or life-threatening indication and has received a priority review designation, six months after the FDA accepts the application for filing.

After filing the marketing application, the FDA reviews a BLA to determine, among other things, whether a product is safe, pure, and potent, and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity, and potency. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve a biological product for marketing unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to ensure compliance with GCPs. If the FDA determines that the data provided in the application, or the manufacturing process or manufacturing facilities for the product are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. The FDA also may refer applications for novel candidates which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation, and a recommendation as to whether the application should be approved and under what conditions, if any. The FDA is not bound by recommendations of an advisory committee, but it considers such recommendations when making decisions on approval.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the product will be produced, the FDA may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, but the application is not ready for approval. A Complete Response Letter may request additional information or clarification, including new clinical studies. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information, and/or require post-marketing testing and surveillance to monitor the safety or efficacy of a product. If a Complete Response Letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the resubmitted BLA does not satisfy the criteria for approval.

If a product receives regulatory approval, such approval is limited to the conditions of use (e.g., patient population, indication) described in the application. Further, depending on the specific risk(s) to be addressed, the FDA may require that contraindications, warnings or precautions be included in the product labeling, require that post-approval trials, including Phase 4 clinical trials, be conducted to further assess a product's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a Risk Evaluation and Mitigation Strategy, or REMS, plan if it determines that a REMS is necessary to ensure that the benefits of the product outweigh its risks and to assure the safe use of the product, which can materially affect the potential market and profitability of the product. The REMS plan could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries, and other risk minimization tools. The FDA

also may condition approval on, among other things, the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards are not maintained or if problems occur after the product reaches the marketplace. The FDA may prevent or limit further marketing of a product based on the results of post-marketing trials or surveillance programs. After approval, some types of changes to the approved product are subject to further testing requirements and FDA review and approval.

Expedited Review and Approval in the U.S.

A sponsor may seek approval of its product candidate under programs designed to accelerate the FDA's review and approval of new products that meet certain criteria. Specifically, new products are eligible for fast-track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. For a fast-track product, the FDA may consider sections of the BLA for review on a rolling basis before the complete application is submitted if relevant criteria are met. A fast-track designated product candidate may also qualify for priority review. A Priority Review designation means the FDA's goal is to take action on an application within 6 months (compared to 10 months under standard review). A drug application (NDA or BLA) must demonstrate the potential to provide a significant improvement in the safety or effectiveness of treating, diagnosing, or preventing a serious condition, according to the FDA.

Under the accelerated approval program, the FDA may approve a BLA on the basis of either a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Post-marketing studies or completion of ongoing studies after marketing approval are generally required to verify the biologic's clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit. In addition, the Food and Drug Administration Safety and Innovation Act, or FDASIA, established the new Breakthrough Therapy designation. A sponsor may seek FDA designation of its product candidate as a breakthrough therapy if the product candidate is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Sponsors may request the FDA to designate a breakthrough therapy at the time of or any time after the submission of an IND, but ideally before an end-of-phase 2 meeting with the FDA. If the FDA designates a breakthrough therapy, it may take actions appropriate to expedite the development and review of the application, which may include holding meetings with the sponsor and the review team throughout the development of the therapy; providing timely advice to, and interactive communication with, the sponsor regarding the development of the product to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable; involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review; assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and considering alternative clinical trial designs when scientifically appropriate, which may result in smaller trials or more efficient trials that require less time to complete and may minimize the number of patients exposed to a potentially less efficacious treatment.

Fast Track designation, accelerated approval, priority review and breakthrough therapy designation do not change the standards for approval but may expedite the development or approval process.

The Company may pursue various expedited regulatory pathways that are available for products addressing serious or life-threatening conditions, including Fast Track designation, Accelerated Approval, Priority Review, and Breakthrough Therapy designation. These programs do not alter the FDA's standards for

safety and efficacy but may significantly accelerate the development and review process by facilitating earlier engagement with the FDA, enabling rolling submissions, and potentially shortening review timelines.

The U.S. Congress and the government have recently introduced regulatory frameworks supportive of regenerative therapies, such as the Regenerative Medicine Advanced Therapy (RMAT) designation. We expect this trend to continue, as advanced regenerative therapies hold significant promise in addressing chronic diseases that impact large patient populations.

Additionally, because the Company's platform is based on regenerative medicine technology, SMSbiotech may be eligible for Regenerative Medicine Advanced Therapy (RMAT) designation. RMAT status is intended for regenerative therapies targeting serious conditions and offering the potential to address unmet medical needs. If granted, the RMAT designation in the U.S. provides the following potential benefits:

- Expedited development and review processes
- Early and frequent interaction with the FDA to discuss development plans
- Rolling review of marketing applications.
- Consideration for accelerated approval based on surrogate or intermediate clinical endpoints
- Reduced clinical trial requirements in certain circumstances.
- The Company intends to evaluate and pursue these regulatory opportunities as appropriate, subject to the outcome of ongoing clinical development activities.

Post-Approval Requirements in the U.S.

All therapeutic products manufactured or distributed pursuant to FDA approval or licensure are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There are also continuing, annual user fee requirements under the Prescription Drug User Fee Act (PDUFA) for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications containing clinical data. Manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements, which impose significant procedural and documentation requirements. Changes to the manufacturing process are strictly regulated and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements on manufacturers. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance. The Company cannot be certain that it will be able to comply with the cGMP regulations and other FDA regulatory requirements. If the Company is not able to comply with these requirements, the FDA may, among other things, take enforcement action or seek sanctions against use, impose restrictions on a product or its manufacturer, require the Company to recall its stem cell treatment from distribution, or withdraw approval of the BLA. The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market, or product recalls;
- fines, warning letters, or holds on post-approval clinical studies;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal healthcare programs; or mandated modification of promotional materials and labeling, and the issuance of corrective information.

The FDA closely regulates the marketing, labeling, advertising, and promotion of the products it regulates. A company can make only those claims relating to safety and efficacy, purity, and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of unapproved, or "off-label," uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising, and potential civil and criminal penalties. The FDA does restrict manufacturers' communications on the subject of off-label use of their products.

Other U.S. Health Care Laws

The Company's sales, promotion, medical education and other activities following product approval will be subject to regulation by numerous regulatory and law enforcement authorities in the United States in addition to the FDA, including potentially the Federal Trade Commission, the Department of Justice, the Centers for Medicare and Medicaid Services, other divisions of the Department of Health and Human Services and state and local governments. The Company's promotional and scientific/educational programs must comply with the anti-kickback provisions of the Social Security Act, the Foreign Corrupt Practices Act, the False Claims Act, the Physician Payments Sunshine Act, the Veterans Health Care Act and similar state laws.

Depending on the circumstances, failure to meet these applicable regulatory requirements can result in criminal prosecution, fines or other penalties, exclusion from government health care programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private "qui tam" actions brought by individual whistleblowers under the False Claims Act in the name of the government or refusal to allow the Company to enter into supply contracts, including government contracts.

Coverage, Pricing and Reimbursement in the U.S.

Sales of products depend significantly on the availability of third-party coverage and reimbursement. Third-party payors include government health administrative authorities, managed care providers, private health insurers, and other organizations. These third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products, including the Company's stem cell treatment. The Company may need to conduct expensive clinical studies to demonstrate the comparative cost-effectiveness of its stem cell treatment. The Company's stem cell treatment may not be considered cost-effective. Reimbursement may not be available or sufficient to allow the Company to sell its stem cell treatment on a competitive and profitable basis.

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect the Company's ability

to sell its stem cell treatment profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality, and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

Product Liability Insurance

The Company is in the process of obtaining product liability insurance. The successful prosecution of a product liability case against the Company could have a materially adverse effect upon its business if the amount of any judgment exceeds the insurance coverage. Any claim that may be brought against the Company could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by the Company's insurance or that is in excess of the limits of the insurance coverage. The Company's insurance policies also have various exclusions, and the Company may be subject to a claim for which the Company has no coverage. The Company may have to pay any amounts awarded by a court or negotiated in a settlement that exceed the coverage limitations or that are not covered by its insurance, and the Company may not have, or be able to obtain, sufficient capital to pay such amounts.

Intellectual Property

As of the date of this Private Offering Memorandum, we have filed fifteen patent applications. We obtained our first patent in 2018 and have been **issued seven** patents since 2018. Patents protect our technology and prevent anyone from using our technology without our permission. We will also seek patents in other areas of our technology, such as the processes utilized to apply SMS cells for other indications.

In addition to filing patents, the Company has taken appropriate steps to protect its intellectual property. The Company has rules and processes to protect its trade secrets, private information, and other intellectual property. Access to sensitive information is restricted, non-disclosure agreements (NDAs) are used, and potential infringement is monitored. In addition, we use Egnyte, a cloud encryption-based data management platform structured to comply with FDA regulations, to store and share any documents or files. The platform includes general data protection and compliance for storing files, documents, and data securely. The Company will also undertake IP audits regularly to identify areas of risk and verify that the relevant legal safeguards are in place.

Keys to Success

- Successful Completion of Phase I Trial: The trial's outcome is dependent on patient selection, research methodology, and precautionary measures. If the Phase I Trial is successful, it will lay the groundwork for further clinical development, regulatory approval, and possible early revenues from Compassionate Use.
- Product Introduction: The introduction of the treatment for compassionate use is a significant advance toward the goal of providing access to SMS cells for patients who could benefit from them. To ensure the product is utilized appropriately and safely, it will be necessary to work closely with regulatory agencies and healthcare practitioners.
- Strong Supply Chain: The success of bringing SMS cells to market requires the creation or establishment of a robust supply chain. This requires having reliable, large-scale production methods that yield cells of sufficient quality, potency, and safety.
- Strategic Partnerships: The most efficient and successful method of bringing SMS cells to market is to form alliances and collaborate with important stakeholders, including pharmaceutical companies, regulatory bodies, government sectors (including military), healthcare providers, and

patient advocacy groups. These collaborations will aid in understanding and managing healthcare and regulatory landscapes.

- Establishing SMS cell therapy as a platform technology that can address future multiple indications and diseases, allowing us access to larger human and animal health markets.
- Strategic Licensing for Global Expansion: We are actively pursuing licensing partnerships with pharmaceutical companies. Our primary focus is on licensing our technology specifically for our COPD indication to various countries or regions, potentially including Southeast Asia, South America, Australia, and the Middle East. In addition, we are considering expanding our scope to other indications and diseases, which would allow us to begin licensing our technology to some of the major pharmaceutical companies for these indications and diseases.

Market/ Marketing

In 2020, COPD caused a $50 billion economic burden in the US. The global COPD treatment market was valued at US$18.1 billion in 2022. The global COPD therapeutic market is expected to grow at a 5% CAGR from 2023 to 2032. Considering the size of the market, acquiring a 2.5% US market share would generate $500 million in sales and $350 million in EBITDA for the Company.

The following will be used to increase sales and revenue:

ONLINE

- Website Development
- SEO
- Webinars, Podcasts, Conferences
- Email & Social Media Marketing

OFFLINE

- Signage & Print Media
- Word of Mouth Marketing or Relationship Building
- Direct Marketing

- Strategic Partnerships: Collaborate with complementary companies, US government, research institutions, and healthcare organizations to amplify marketing efforts and expand reach. This can involve joint marketing campaigns, co-branded content, or cross-promotion to leverage each other's networks and expertise. For example through website announcements of collaborations.
- Expanded Access (Compassionate Use) Programs: As indicated, upon the collection of safety data from the initial patients during our Phase I clinical trial, the Company plans to apply for Compassionate Use (Expanded Access) in the U.S. and worldwide.
- Key Opinion Leader (KOL) Engagement: Engage with influential healthcare professionals and industry experts who have a strong presence and following in the regenerative medicine field. Collaborating with KOLs can help raise awareness of the Company’s SMS cell therapy and enhance its reputation.
- Digital Marketing: We will develop a comprehensive digital marketing strategy to reach and engage with target audiences. This includes creating a user-friendly website, implementing search engine optimization techniques, running targeted online advertising campaigns, and utilizing social media platforms to share informative content and engage with followers, and most importantly, possible investors or shareholders.
- Content Marketing: Produce high-quality and educational content, such as blog articles, LinkedIn posts, and videos, to position the Company as a thought leader in the field of regenerative medicine. Focus on providing valuable information about SMS cells, their potential applications, and their benefits to both healthcare professionals and patients.

- Thought Leadership: Identify opportunities for the Company's experts to speak at industry conferences, participate in panel discussions, and contribute articles to reputable publications. Establishing thought leadership can help build credibility and visibility for the company.
- Physician Education Programs: Develop targeted educational programs and materials to educate healthcare providers about the benefits and potential applications of SMS cells. Offer workshops, webinars, and training sessions to ensure physicians are well-informed and confident in recommending the Company's therapy.
- Patient Advocacy: Collaborate with patient advocacy groups and organizations related to diseases that could potentially benefit from SMS cell therapy. Engage with these groups to raise awareness, provide educational resources, and support patients in accessing the therapy.
- Regulatory Compliance: Ensure strict adherence to all regulatory requirements and maintain open communication with regulatory bodies, such as the FDA. Highlight the Company's commitment to safety, ethical practices, and compliance, as this can instill trust in both healthcare providers and patients.
- Patient Testimonials and Case Studies: Share success stories, testimonials, and case studies of patients who have benefited from SMS cell therapy. This can help build trust and demonstrate the therapy's effectiveness to potential customers.
- Market Research and Monitoring: Continuously monitor market trends, competitor activities, and customer feedback to identify opportunities and refine marketing strategies. Conduct market research to understand the needs, preferences, and challenges of target audiences, and tailor marketing messages accordingly.

Competition

**COPD**

At present, the Company does not have any competition since current treatments target COPD's detrimental symptoms but not the fundamental cause of the disease. They may slow the progress, but do not reverse or cure the disease. Current treatments include short-acting and long-acting Bronchodilator Inhalers (albuterol, levalbuterol, and ipratropium) and Corticosteroids. Non-drug treatments include supplemental oxygen and surgery such as lung volume reduction and lung transplantation.

**Animal Market**

**Key Players in Veterinary Regenerative Medicine:**

The companion animal stem cell therapy market comprises specialized biotech firms in veterinary regenerative medicine and major animal health corporations expanding into this sector.

- VetStem – A pioneer in autologous stem cell therapy for arthritis and orthopedic conditions in dogs and horses.
- Ardent Animal Health– Specializes in allogeneic stem cell therapies for a broad range of veterinary applications.
- StemCell X – A European firm focused on equine regenerative medicine on arthritis.

Major Animal Health Corporations Expanding into Regenerative Medicine:

- Zoetis – The world's largest animal health company, investing heavily in regenerative and biologic therapies.
- Dechra Pharmaceuticals – Expanding into companion animal therapeutics, including stem cell treatments.
- Elanco & Boehringer Ingelheim Animal Health – Developing stem cell-based orthopedic and neurological therapies for dogs.

However, none of the competitors listed above are using SMS type stem cells.

Future Plans

As of June 2025, we started a separate dedicated facility for cGMP biomanufacturing, scaling up of SMS cell production. In Q4 2025, we plan to finish and fully establish the cGMP biomanufacturing facility in San Diego County which will allow us to produce a significant number of cells at the highest quality that would serve the interim need for different worldwide clinical research projects and that of compassionate use patients. Having a manufacturing plant is essential to ensuring that we can meet the growing demand for treatments through clinical trials and into compassionate use. The facility will allow for scalable production of SMS cells at a low cost, optimizing production efficiency and maximizing revenue potential. By producing in-house, we retain control over the supply chain, reduce dependency on external manufacturers, and ensure a high level of quality and consistency in every batch. Manufacturing costs are estimated to be 10-15% of revenues. The estimated cost to build this facility and operate it for one year is approximately $2.5 million.

As previously mentioned, during our clinical trials, we plan to pursue the Compassionate Use application, both in the US and internationally. This initiative aims to generate early worldwide revenues and will pave the way for establishing a bio-production plant dedicated to manufacturing and multiplying SMS cells, leveraging the company's patents and trade secrets on producing SMS cells at high quality, an optimized production with approximate manufacturing costs at 10-15% of revenues. The facility will allow for scalable production of SMS cells at a low cost, optimizing production efficiency and maximizing revenue potential. By producing in-house, we retain control over the supply chain, reduce dependency on external manufacturers, and ensure a high level of quality and consistency in every batch.

Advantages of SMSbiotech having a Biomanufacturing facility (SMS-BPEA-1):

- Provides substantial revenues, as early as during the phase 1 clinical trial with compassionate use cases;
- Increases the valuation of the company;
- Provides outreach and network to the worldwide COPD market opportunities;
- Supports the outreach to other potential therapies using our platform technology;
- Ability to explore the SMS cells for multiple other applications and in many different regions of the world;
- Creates a foundation for potential partnerships with large institutions, including government agencies, academic research centers, and military health programs.

With a portion of the proceeds from this Offering the Company will investigate the potential of the Company's SMS cells to treat other diseases.

General

We were incorporated in California on November 19, 2015.

As of the date of this Private Offering Memorandum, we had 13 full-time and no part-time employees.

Address: 1825 Diamond Street, Suite 101, San Marcos, CA 92078
Telephone Number: 1 (760) 290-3406
Email Address: investorinfo@smsbiotech.com
Website: www.smsbiotech.com

## RISK FACTORS

Investors should be aware that this offering involves certain risks, including those described below, which could adversely affect the value of the Company's common stock. The Company does not make, nor has it authorized any other person to make, any representation about the future market value of the Company's common stock. In addition to the other information contained in this Private Offering Memorandum, the following factors should be considered carefully in evaluating an investment in the Company's common stock.

### Risks Related to Our Company

We are an early-stage company and have not yet achieved profitability.

As of the date of this Private Offering Memorandum and since our inception, we have not yet generated revenue and have incurred net losses, as expected for a company in the product development stage. Any forecasts we make concerning our operations may prove to be inaccurate. Our prospects must be considered in light of the risks, expenses, and difficulties frequently encountered by companies in the early stage of development. As a result of these risks, challenges, and uncertainties, the value of your investment could be significantly reduced or completely lost.

We may not be able to continue as a going concern.

Our expected continued future losses as we are continuing to develop our product raise doubt about our ability to continue as a going concern. Our ability to remain operational is contingent on obtaining additional financing and successfully executing our business plan.

### Risks Related to Clinical Development, Government Approvals and the Marketing of the Company's Stem Cell Treatment

The Company's Stem Cell Treatment Has Not Been Approved for Sale

The Company's stem cell treatment has not been approved for sale, and the Company cannot guarantee that it will ever be approved. Its stem cell treatment is subject to premarket approval from the FDA in the United States, the EMA in the European Union, and by comparable agencies in most foreign countries before it can be sold. Before obtaining marketing approval, its stem cell treatment must undergo costly and time-consuming clinical testing, which could subject the Company to unanticipated delays and may prevent the

Company from marketing its stem cell treatment in the future. There can be no assurance that such approvals will be granted on a timely basis, if at all.

Our stem cell treatment is currently under development.

While regulatory authorities in certain countries have created expedited programs for breakthrough therapies, our technology will still need to navigate the regulatory approval process, which can be time-consuming and costly. Obtaining regulatory approval can be a lengthy and complex process with no guarantee of success. Failure to obtain necessary approvals would significantly hinder market entry and commercialization. There is also the possibility of changes in regulations that might affect us.

The time required to obtain approvals from regulatory authorities in different countries may be shorter or longer than that required for FDA approval, and requirements may differ from FDA requirements. We may be unable to obtain requisite approvals from foreign regulatory authorities, and even if obtained, such approvals may not be on a timely basis. If we fail to obtain timely clearance or approval for our stem cell treatment, our ability to market and sell our stem cell treatment will be limited, which will hinder our ability to generate revenue.

While our pre-clinical animal tests showed promising results, the performance of our stem cell treatment needs to be further validated in larger, more diverse populations.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of our clinical trials may not be predictive of the results of later-stage clinical trials. A number of companies in our industry have suffered significant setbacks in advanced clinical trials due to a lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our current and future clinical trials may not be successful.

The cost of developing, validating, and commercializing a new treatment can be substantial.

We have started our Phase I clinical trial in Australia. If this trial is successful, we will apply to the Therapeutic Goods Administration ("TGA"), the Australian equivalent of the FDA, to start a Phase II Trial. If this trial is successful, we will apply to the TGA to start a Phase III clinical trial. We estimate the cost of these three clinical trials will be approximately $57,000,000. Accordingly, we must raise significant additional capital to pay for these clinical trials and support our operations until we are able to generate revenue.

The Company May Experience Delays in Completing its Clinical Trials

The Company may experience delays in the completion of its clinical trial, and the Company does not know whether its planned clinical trials will need to be redesigned. Clinical trials can be delayed for a variety of reasons, including delays related to:

- the availability of financial resources needed to commence and complete the planned trials;
- obtaining regulatory approval to commence a trial;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining Institutional Review Board, or IRB, approval at each clinical trial site;

- recruiting suitable patients to participate in a trial;
- having patients complete a trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of the product candidate for use in clinical trials.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the competence of the CRO running the study, size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the treatment being studied in relation to other available therapies. Furthermore, the Company will rely on CROs and clinical trial sites to ensure the proper and timely conduct of the clinical trials and while the Company will have agreements governing their committed activities, the Company has limited influence over their actual performance. The Company could also encounter significant delays and/or need to terminate a development program for its stem cell treatment if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials for its stem cell treatment, while existing treatments have established safety and efficacy profiles. Further, a clinical trial may be suspended or terminated by the Company, one or more of the IRBs, by the Company upon a final recommendation by the Independent Data Monitoring Committee, or IDMC, or by FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or the clinical protocols, as a result of inspection of the clinical trial operations or trial site(s) by FDA or other regulatory authorities, the imposition of a clinical hold or partial clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. The occurrence of any one or more of these events would have significant and severe material consequences for the Company and could impact the Company's ability to continue as a going concern.

If the Company experiences termination of, or delays in the completion of, any clinical trial of its stem cell treatment, the commercial prospects for its stem cell treatment will be harmed, and the ability to generate product revenues will be delayed. In addition, any delays in completing the clinical trials will increase the costs, slow the product development and approval process, and jeopardize the Company's ability to commence sales and generate revenues. Any of these occurrences may harm the Company's business, prospects, financial condition, and results of operations significantly. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to a delay or the denial of regulatory approval for the Company's stem cell treatment.

A variety of issues may delay the ongoing Phase I clinical trial or future clinical trials. Early trials for the other product candidates, or the plans for later trials, may not satisfy the requirements of regulatory authorities, such as the FDA. The Company may fail to find subjects willing to enroll in the trials. Accordingly, the future clinical trials may not be completed on schedule, the FDA or foreign regulatory agencies may order the Company to stop or modify research, or these agencies may not ultimately approve the Company's stem cell treatment for commercial sale. Varying interpretations of the data obtained from clinical testing could delay, limit, or prevent regulatory approval of the Company's stem cell treatment. The data collected from the clinical trials may not be sufficient to support regulatory approval of the Company's stem cell treatment. The failure to adequately demonstrate the safety and efficacy of the Company's stem cell treatment would delay or prevent regulatory approval of the Company's stem cell treatment in the United States, which could prevent the Company from achieving profitability.

The development and testing of product candidates, the process of obtaining regulatory approvals, and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process, or after approval may subject an applicant to administrative or judicial sanctions. FDA sanctions could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, termination of the clinical trials, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, and payment of civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on the Company.

The requirements governing the conduct of clinical trials, manufacturing, and marketing of the product candidates, outside the United States, vary from country to country. Foreign approvals may take longer to obtain than FDA approvals and can require, among other things, additional testing and different trial designs. Foreign regulatory approval processes include all of the risks associated with the FDA approval process. Some of those agencies also must approve prices for products approved for marketing. Approval of a product by the FDA or the EMA does not ensure approval of the same product by the health authorities of other countries. In addition, changes in regulatory requirements for product approval in any country during the clinical trial process and regulatory agency review of each submitted new application may cause delays or rejections.

The Company has only limited experience in filing and pursuing applications necessary to gain regulatory approvals. The lack of experience may impede its ability to obtain timely approvals from regulatory agencies, if at all. The Company will not be able to commercialize its stem cell treatment until the Company has obtained regulatory approval. In addition, regulatory authorities may also limit the types of patients to which the Company may market its stem cell treatment (if approved). Any failure to obtain or any delay in obtaining required regulatory approvals may adversely affect the Company's ability to successfully market its stem cell treatment if it is approved.

The Company's stem cell treatment may cause undesirable side effects or have other problems that could delay or prevent its regulatory approval, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by the Company's stem cell treatment could cause the Company or regulatory authorities to interrupt, delay, or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities. Results of the clinical trials could reveal a high and unacceptable severity and/or prevalence of these or other side effects. In such an event, the trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order the Company to cease further development of, or deny approval of, for any or all targeted indications. Any adverse side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm the Company's business, financial condition, and prospects significantly.

Additionally, if the Company's stem cell treatment receives marketing approval, and the Company or others later identify undesirable side effects caused by the Company's stem cell treatment, a number of potentially significant negative consequences could result, including but not limited to the following:

- regulatory authorities may withdraw approvals of such product or require product recalls;
- regulatory authorities may require additional warnings on the label or impose restrictions on product distribution or use;

- regulatory authorities may require the Company to conduct new post-marketing studies or clinical trials;
- the Company could receive warning or untitled letters from the FDA or comparable notice of violations from foreign regulatory authorities;
- the Company may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- the Company could be sued and held liable for harm caused to patients; and
- the Company's reputation may suffer.

Any of these events could prevent the Company from achieving or maintaining market acceptance of its stem cell treatment, if approved, and could significantly harm its business, results of operations and prospects.

The Company will rely on third parties to conduct its clinical trials. If these third parties do not successfully carry out their contractual duties and meet regulatory requirements, or meet expected deadlines, the Company may not be able to obtain regulatory approval for or commercialize its stem cell treatment and its business could be substantially harmed.

The Company does not have the ability to independently conduct large clinical trials. The Company will rely upon third-party CROs to prepare for, conduct, monitor, and manage data for its future clinical trials. The Company will rely upon these parties for all aspects of the execution of its clinical trials and although the Company will oversee and carefully manage the CROs, the Company will directly control only certain aspects of their activities and will rely upon them to provide timely, complete, and accurate reports on the conduct of the studies. Although such third parties will provide support and represent the Company for regulatory purposes in the context of the clinical trials, ultimately, the Company is responsible for ensuring that each of the studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards, and the reliance on the CROs does not relieve the Company of its regulatory responsibilities. The Company and the CROs acting on the Company's behalf, as well as principal investigators and trial sites, will be required to comply with Good Clinical Practice, or GCP, and other applicable requirements, which are implemented through regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, or EEA, and comparable foreign regulatory authorities for all of the products in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators, and trial sites. If the Company or any of the CROs fail to comply with applicable GCPs or other applicable regulations, the clinical data generated in the clinical trials may be determined to be unreliable and the Company may therefore need to enroll additional subjects in the clinical trials, or the FDA, EMA or comparable foreign regulatory authorities may require the Company to perform an additional clinical trial or trials before approving the marketing applications. Moreover, if the Company or any of the CROs, principal investigators, or trial sites, fail to comply with applicable regulatory and GCP requirements, the Company, the CROs, principal investigators, or trial sites may be subject to enforcement actions, such as fines, warning letters, untitled letters, clinical holds, civil or criminal penalties, and/or injunctions. The Company cannot assure that upon inspection by a given regulatory authority, such regulatory authority will determine that any of the clinical trials comply with cGCP regulations. In addition, Phases II and III of the clinical trials must be conducted with the product produced under cGMP regulations. The failure to comply with these regulations may require the Company to delay or repeat clinical trials, which would delay the regulatory approval process.

If any future relationships with the third-party CROs terminate, the Company may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. In addition, the CROs are not the Company's employees, and except for remedies available to the Company under the agreements

with such CROs, the Company cannot control whether or not they devote sufficient time and resources to the Company's clinical trials. If CROs do not successfully fulfill their regulatory obligations, carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to the clinical protocols, regulatory requirements or for other reasons, the clinical trials may be extended, delayed or terminated, and the Company may not be able to obtain regulatory approval for, or successfully commercialize, its stem cell treatment. As a result, the Company's results of operations and the commercial prospects for its stem cell treatment would be harmed, the costs could increase, and the ability to generate revenues could be delayed.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays may occur, which can materially impact the Company's ability to meet the desired clinical development timelines. Though the Company plans to diligently oversee and carefully manage its relationships with the CROs, there can be no assurance that the Company will not encounter challenges or delays in clinical development in the future or that these delays or challenges will not have a material adverse impact on the Company's business, financial condition, and prospects.

The Company may face substantial competition, which may result in others discovering, developing or commercializing competing products more quickly or more successfully than the Company.

The development and commercialization of new biological products is highly competitive. The Company expects to face competition with respect to stem cell treatment from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

Many of the companies which the Company may compete with in the future have significantly greater financial resources and expertise in research and development, manufacturing, nonclinical studies, conducting clinical trials, obtaining marketing approvals, and marketing approved products than the Company. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of the Company's potential competitors. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties may compete with the Company in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to the Company's stem cell treatment.

The Company may be unable to successfully scale-up manufacturing of its stem cell treatment in sufficient quality and quantity, which would delay or prevent the Company from commercializing its stem cell treatment, if approved for marketing by the FDA or other regulatory agencies.

In order to commercialize its stem cell treatment, the Company will need to manufacture SMS cells in large quantities. Although, as of the date of this Private Offering Memorandum, the Company had several trillion SMS cells available for approximately 400 COPD patients (equivalent to approximately $8 million in revenue, the Company may be unable to successfully increase the manufacturing capacity for its stem cell treatment in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities.

Further, in order to release product and demonstrate stability of its stem cell treatment for future commercial use, the Company's analytical methods must be validated in accordance with regulatory guidelines. The Company may not be able to successfully validate, or maintain validation of its analytical methods during scale-up or demonstrate adequate purity, stability or comparability of its stem cell treatment in a timely or cost-effective manner, or at all. Even if the Company believes its manufacturing processes meets all of the regulatory manufacturing requirements, the FDA will review those processes and the manufacturing facility as part of the review of the future BLA if submitted after completion of future clinical trials. If the Company is unable to fully accommodate the FDA requirements for manufacturing of SMS cells in sufficient quality and quantity, the regulatory approval or commercial launch of its stem cell treatment may be delayed or may not be successfully achieved.

Failure to obtain or maintain adequate coverage and reimbursement for the Company' stem cell treatment, if approved, could limit the ability to market the Company's stem cell treatment and decrease the Company's ability to generate revenue.

Sales of the Company's stem cell treatment will depend substantially, both domestically and abroad, on the extent to which the costs of the Company's stem cell treatment will be paid by health maintenance, managed care, pharmacy benefit, and similar healthcare management organizations, or reimbursed by government authorities, private health insurers, and other third-party payors. The Company anticipates that government authorities and other third-party payors will continue efforts to contain healthcare costs by limiting the coverage and reimbursement levels for products. If coverage and reimbursement are not available, or are available only to limited levels, the Company may experience a reduction in sales of its stem cell treatment, specifically in countries where coverage or reimbursement are not available. Although the Company's Stem Cell Treatment has a high gross margin, even if coverage is provided, the approved reimbursement for the Company's stem cell treatment may not be high enough to allow the Company to establish or maintain pricing sufficient to realize a return on its investment. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for the Company's stem cell treatment.

The Company intends to seek approval to market its stem cell treatment in both the United States and foreign jurisdictions. If the Company obtains approval in one or more foreign jurisdictions, the Company will be subject to rules and regulations in those jurisdictions relating to its stem cell treatment. In some countries, particularly the countries of the European Union, the pricing of pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, the Company may be required to conduct a clinical trial that compares the cost-effectiveness of its stem cell treatment to other available therapies. If reimbursement of its stem cell treatment is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, the Company may be unable to achieve or sustain profitability.

Even if the Company's stem cell treatment receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community necessary for commercial success.

If the Company's stem cell treatment does not achieve an adequate level of acceptance, the Company may not generate significant product revenues, and the Company may not become profitable. The degree of market acceptance of the Company's stem cell treatment, if approved for commercial sale, will depend on a number of factors, including:

- the timing of the Company's receipt of any marketing approvals;
- the terms of any approvals and the countries in which approvals are obtained;

- the efficacy and safety, and potential advantages and disadvantages compared to alternative treatments, including future alternative treatments;
- the prevalence and severity of any side effects associated with the Company's stem cell treatment;
- adverse publicity about the Company's stem cell treatment or favorable publicity about competing products;
- the approval of other products for the same indications as the Company's stem cell treatment;
- The Company's ability to offer its stem cell treatment for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the strength of the Company's marketing and distribution support; and
- the availability of third-party coverage and adequate reimbursement.

If the Company's stem cell treatment fails to achieve market acceptance, it could have a material and adverse effect on the Company's business, financial condition, results of operation and prospects.

The Company currently has no marketing and sales force. If the Company is unable to establish effective sales or marketing capabilities or enter into agreements with third parties to sell or market its stem cell treatment, the Company may not be able to effectively sell or market its stem cell treatment, if approved, or generate product revenues.

The Company currently has no sales and marketing infrastructure due to the fact that its stem cell treatment is still in clinical development. To achieve commercial success for which the Company retains sales and marketing responsibilities, the Company must build its sales, marketing, managerial, and other non-technical capabilities or make arrangements with third parties to perform these services. The Company may determine that there is a need to build its own sales force in the United States for the future marketing of its stem cell treatment, if approved, rather than seeking a U.S. co-marketing partner or relying on a contracted sales force. There are risks involved with either establishing its own sales and marketing capabilities or entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming, and could delay any product launch. If the commercial launch of the Company's stem cell treatment, for which the Company recruits a sales force and establishes marketing capabilities, is delayed or does not occur for any reason, the Company would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and its investment would be lost if the Company cannot retain or reposition its sales and marketing personnel.

Factors that may inhibit the Company's efforts to commercialize its stem cell treatment on its own include:

- the Company's inability to recruit, hire, retain, and incentivize adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to use and administer its stem cell treatment;
- the lack of complementary products to be offered by sales personnel, which may put the Company at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with establishing an independent sales and marketing organization.

If the Company does not establish sales and marketing capabilities successfully, either on its own or in collaboration with third parties, the Company may not be successful in commercializing its stem cell treatment, if approved, or any such commercialization may experience delays or limitations.

Healthcare legislative reform measures may have a material adverse effect on the Company's business and results of operations.

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of the Company's stem cell treatment. The Company cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If the Company is slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if the Company is not able to maintain regulatory compliance, the Company may lose any marketing approval that it may have obtained and it may not achieve or sustain profitability.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs that may result in more limited coverage or downward pressure on the price the Company may otherwise receive for its stem cell treatment. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, expanded healthcare coverage through Medicaid expansion and the implementation of the individual mandate for health insurance coverage, which included changes to the coverage and reimbursement of products under federal healthcare programs. The ACA contains a number of provisions that affect coverage and reimbursement of drug and biological products and/or that could potentially reduce the demand for biological products.

The Company's industry continues to face potential changes in the legal and regulatory landscape on the federal, state, and international levels. Additional legislative actions to control U.S. healthcare or other costs have been passed. The Budget Control Act, as amended, resulted in the imposition of 2% reductions in Medicare (but not Medicaid) payments to providers in 2013 and will remain in effect through 2027 unless additional Congressional action is taken. Regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine which biopharmaceutical products and which suppliers will be included in their healthcare programs. In markets outside of the United States, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and control the prices of medicinal products for human use.

The Company expects that current or future healthcare reform measures may result in more rigorous coverage criteria and additional downward pressure on the price that it receives for its stem cell treatment if it is approved for commercialization. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent the Company from attaining profitability.

Legislative and regulatory proposals have also been made to expand post-approval requirements and restrict sales and promotional activities for biotechnology products. The Company cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance, or interpretations for biological products will be changed, or what the impact of such changes on the marketing approvals of its stem cell treatment, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's

approval and decision-making processes may significantly delay or prevent marketing approval, as well as subject the Company to more stringent product labeling and post-marketing testing, and other requirements.

If the Company fails to comply with environmental, health and safety laws and regulations, the Company could become subject to fines or penalties or incur costs that could harm its business.

The Company is subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes that may be generated in its manufacturing facility. The Company cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from its use of hazardous materials, the Company could be held liable for any resulting damages, and the amount of the liability could exceed its resources. The Company could also incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We may not be granted Expanded Access (Compassionate Use) for our stem cell treatment.

Once preliminary safety data is obtained from a few patients in our Phase I Trial, we anticipate filing for Expanded Access (Compassionate Use) with the FDA. Being granted Expanded Access for our COPD treatment will enable us to provide SMS cells to patients worldwide with the greatest requirement for them and provide early revenue. If we are not granted Expanded Access by one or more regulatory authorities, we may not be able to generate revenue in certain countries until our clinical trials are completed and we receive approval from a regulatory authority to sell our stem cell treatment on a commercial basis.

Even if we obtain regulatory approval for our stem cell treatment, we will be subject to stringent, ongoing government regulation.

If our stem cell treatment receives regulatory approval, either in the United States or in other countries, our stem cell treatment will be subject to limitations on the approved indicated uses for which the stem cell treatment may be marketed or to the conditions of approval and may contain requirements for potentially costly post-marketing testing, and surveillance of the safety and efficacy of our stem cell treatment. We will continue to be subject to extensive regulatory requirements. These regulations are wide-ranging and govern, among other things:

- product design, development, and manufacture;
- product application and use;
- adverse experience monitoring and reporting;
- product advertising and promotion;
- manufacturing, including compliance with good manufacturing practices;
- record keeping requirements;
- registration and listing of products with the FDA and other state and national agencies; and
- storage and shipping

We must continually adhere to federal regulations known as Current Good Manufacturing Practices, or cGMPs, and their foreign equivalents, which are enforced by the FDA and other national regulatory bodies through their facilities inspection programs. If our facilities cannot pass a pre-approval inspection by regulators or fail such inspections in the future, the FDA or other national regulators will not approve the marketing applications for our stem cell treatment, or may withdraw any prior approval. In complying with cGMP and foreign regulatory requirements, we will be obligated to expend time, money, and effort in

production, record-keeping, and quality control to ensure that our stem cell treatment meets applicable specifications and other requirements.

If we do not comply with regulatory requirements at any stage, whether before or after marketing approval is obtained, we may be subject to, among other things, license suspension or revocation, criminal prosecution, seizure, injunction, fines, be forced to remove our stem cell treatment from the market, or experience other adverse consequences. This could materially harm our financial results and reputation. If we identify adverse effects after our stem cell treatment is on the market, or if manufacturing problems occur, regulatory approval may be suspended or withdrawn. We may be required to conduct additional clinical trials. If we encounter any of the foregoing problems, our business and results of operations will be harmed.

The FDA and other governmental authorities' policies may change, and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our stem cell treatment. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects, and ability to achieve or sustain profitability. We cannot predict the extent of adverse government regulations which might arise from future legislative or administrative action. Without government approval, we will be unable to sell our stem cell treatment.

The current and future relationships with healthcare professionals and potential customers in the United States and elsewhere may be subject, directly or indirectly, to applicable healthcare laws and regulations.

If we begin selling our stem cell treatment, we will be subject to additional healthcare statutory and regulatory requirements and oversight by federal and state governments as well as foreign governments, in the jurisdictions in which we conduct our business. Healthcare providers and physicians in the United States and elsewhere will play a primary role in the recommendation and prescription of our stem cell treatment if we obtain marketing approval. The current and future arrangements with healthcare professionals and potential customers may expose us to broadly applicable healthcare laws, including, without limitation:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. In addition, the Affordable Care Act provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- federal civil and criminal false claims laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under

the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a healthcare offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

- HIPAA, which also imposes obligations on covered entities, including healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain, or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, securit,y and transmission of individually identifiable health information;
- the U.S. federal physicians payment transparency requirements, sometimes called the "Sunshine Act" and its implementing regulations, which requires certain manufacturers of drugs, devices, biologicals and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report to the Centers for Medicare & Medicaid Services, or CMS, information related to physician payments and "other transfers of value" to physicians and teaching hospitals and, for transfers of value to other healthcare providers, as well as the ownership and investment interests held by physicians and their immediate family members;
- analogous state and foreign laws, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government which otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts;
- the U.S. federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under federal healthcare programs; and
- state and foreign laws that govern the privacy and security of health information in certain circumstances, including state security breach notification laws, state health information privacy laws, and federal and state consumer protection laws, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our future business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that the business practices may not comply with current or future statutes, regulations, or case law involving applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of these laws or any other governmental regulations, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of the operations, all of which could significantly harm our business. If any of the physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusions from participation in government healthcare programs, which could also adversely affect our business.

**Risks Related to Our Intellectual Property**

Our patents and trade secrets might not protect our technology from competitors, in which case we may not have any advantage over competitors in selling our stem cell treatment.

Our commercial success will depend in part on our ability to obtain additional patents and protect our existing patent position, as well as our ability to maintain adequate intellectual property protection for our stem cell treatment in the United States and other countries. If we do not adequately protect our technology, competitors may erode or negate any competitive advantage we may have, which could harm our business and our ability to achieve profitability. The laws of some foreign countries do not protect the proprietary rights to the same extent or in the same manner as U.S. laws, and we may encounter significant problems in protecting and defending our proprietary rights in these countries. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our stem cell treatment is covered by valid and enforceable patents or are effectively maintained as trade secrets.

Certain aspects of our technologies are covered by U.S. and foreign patents. In addition, we have a number of new patent applications pending. There is no assurance that the applications which are pending or which may be filed in the future will result in the issuance of any patents. Furthermore, there is no assurance as to the breadth and degree of protection any issued patents might afford us. Disputes may arise between us and others as to the scope and validity of these or other patents. Any defense of the patents could prove costly and time-consuming, and there can be no assurance that we will be in a position, or will deem it advisable, to carry on such a defense. A suit for patent infringement could result in increasing costs and delaying or halting the development of our stem cell treatment.

Some of our intellectual property is protected as trade secrets or confidential know-how, and our pending patent application may not result in an issued patent.

We consider proprietary trade secrets and/or confidential and unpatented know-how to be important to our business, certain aspects of which may not be suitable for patent filings and must be protected as trade secrets and/or confidential know-how. This type of information must be protected diligently by us to protect our disclosure to competitors, since legal protections after disclosure may be minimal or non-existent. Accordingly, much of the value of this intellectual property is dependent upon our ability to keep our trade secrets and know-how confidential.

Failure to obtain or maintain trade secrets and/or confidential know-how could adversely affect our competitive position. Moreover, competitors may independently develop substantially equivalent proprietary information and may even apply for patent protection in respect of the same. If successful in obtaining such patent protection, competitors could limit the use of our trade secrets and/or confidential know-how.

**Risks Related to this Offering**

The Company's offering is being conducted on a "best efforts" basis.

There is no minimum amount which is required to be raised in this offering, and all proceeds from the sale of the securities offered will be delivered to the Company as they are received. If only a small number of securities offered are sold, the amount received from this offering may provide little benefit to the Company. Even if all securities offered are sold, the Company may need additional capital.

The Company does not know what the terms of any future capital raising may be, but any future sale of the Company's equity securities will dilute the ownership of existing stockholders and could be at prices substantially below the offering price of the Company's common stock. The failure of the Company to

obtain the capital which it requires may result in the slower implementation of the Company's business plan.

Establishment of offering price:

The offering price of the Company's common stock has been established by the Company, considering such matters as past offerings, the state of the Company's product and business development and the general condition of the industry in which it operates. The offering price bears no relationship to the Company's assets, net worth, or operating results.

As a result, you may be unable to sell your shares of our common stock.

You may experience future dilution as a result of future equity offerings or other equity issuances.

We expect that significant additional capital will be needed in the future to continue our planned operations. To raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. These sales may result in material dilution to our existing stockholders, and new investors could gain rights superior to existing stockholders.

As of the date of this Private Offering Memorandum, there was no public market for our common stock, and it is not expected that a public market will develop in the near future.

The securities sold in this Offering will be "restricted securities" as that term is defined in Rule 144 of the Securities Act of 1933 (the "Act").

As such, the securities sold in this Offering may be sold only in compliance with Rule 144 or some other exemption from registration under the Act, unless the securities are covered by an effective registration statement under the Act.

## MANAGEMENT

| Name | Age | Position |
|---|---|---|
| Abdulkader Rahmo, Ph.D. | 61 | President, Chief Scientific Officer, and a Director |
| Harry Friedman | 89 | Chief Financial Officer and a Director |
| Ghassan Kassab | 60 | Director |
| Joseph Kiani | 60 | Director |
| Mohamed Diab | 67 | Director |

Our directors are appointed for a one-year term, holding office until the next annual general meeting of our shareholders or until their successors are elected or appointed. Our officers are appointed by our board of directors and serve at the discretion of the board.

**Abdulkader Rahmo, PhD,** has been a director of the Company since 2015. He is also the Co-Founder of the Company and serves as the Company's President and Chief Scientific Officer. From 2007 to 2013, Dr. Rahmo was Head of the Medical Biotechnology Section at the National Commission for Biotechnology. Prior to that, he conducted postdoctoral research in Munich and held academic and research roles in the

Middle East, Europe, and the United States. Dr. Rahmo has over 15 years of experience focused on SMS cell discovery, development, and technology.

**Harry Friedman** has been a director of the Company since 2021. He also serves as the Company's Chief Financial Officer. From 1990 to 2010, he was the Founder and CEO of a privately held technology company, which he successfully sold to a strategic acquirer. Since 2003, Mr. Friedman has been engaged in consulting and private investments through his own advisory practice based in San Diego, CA. He has also been an active angel investor and member of Tech Coast Angels, advising and participating in several early-stage ventures.

**Ghassan Kassab, PhD,** has been a director of the Company since 2021. Since 2014, Dr. Kassab has served as the President and Chief Scientific Officer of the California Medical Innovations Institute, a biomedical research institute he founded. He is also the founder of 3DT Holdings, a medical device incubator, and Acculab Lifesciences, a preclinical contract research organization. From 1993 to 2014, he was a professor at Purdue University, where he held appointments in Biomedical Engineering, Surgery, and Cellular & Integrative Physiology.

**Joseph Kiani** has been a director of the Company since 2019. Since 1998, Mr. Kiani has been the Chief Executive Officer of Willow Laboratories, a company that develops products and technologies to help people prevent and manage diabetes. From 1989 to 2024, Mr. Kiani served as the Chief Executive Officer of Masimo Corporation, a global medical technology company he co-founded. In 2012, Mr. Kiani founded the Patient Safety Movement Foundation (PSMF). He serves on the boards of various healthcare institutions, including Rady Children's Hospital, and has received multiple recognitions and awards for his work. Mr. Kiani was a director of Stereotax from 2016 to 2021, a director of Neuroptics from 2011 to 2020, and has been a director of CDX Medical Technologies since July 2025.

**Mohamed Diab** has served as a Director of the Company since 2017. He currently holds the position of Senior Research Scientist at Willow Laboratories, a role he assumed as of early 2025. From 1989 to 2024, he was the Chief Technical Officer and Senior Research Scientist at Masimo Corporation, a medical device company he co-founded. Earlier in his career, Mr. Diab held senior engineering positions at Galiso, Inc. and Newport Medical Electronics.

Ghassan Kassab, Joseph Kiani, and Mohamed Diab are independent directors, as that term is defined in Section 803 of the NYSE American Company Guide.

Our directors are appointed for a one-year term, holding office until the next annual general meeting of our shareholders or until their successors are elected or appointed. Our officers are appointed by our board of directors and serve at the discretion of the board.

As with many smaller companies, our Board of Directors does not have a standing audit, nominating, or compensation committees, committees performing similar functions, or charters for such committees. Instead, the functions that might be delegated to such committees are carried out by our directors, to the extent required. Our directors believe that the cost associated with such committees has not been justified under our current circumstances.

Our Board of Directors has the ultimate responsibility to evaluate and respond to risks facing us. Our Board of Directors fulfills its obligations in this regard by meeting on a regular basis and communicating, when necessary, with our officers.

As with many smaller companies, we have not adopted a Code of Ethics which is applicable to our principal executive, financial, and accounting officers and persons performing similar functions since we only have three executive officers.

Holders of our common stock can send written communications to our entire Board of Directors, or to one or more Board members, by addressing the communication to "the Board of Directors" or to one or more directors, specifying the director or directors by name, and sending the communication to our corporate office. Communications addressed to the Board of Directors as whole will be delivered to each Board member. Communications addressed to a specific director (or directors) will be delivered to the director (or directors) specified.

A security holder communication not sent to the Board of Directors as a whole is not relayed to Board members which did not receive the communication.

We do not have an Insider Trading Policy since, as of the date of this Private Offering Memorandum, there was no public market for our common stock and a market is not expected to develop for our common stock for at least the next twelve months.

Executive Compensation

Our executive officers will be compensated through the following four components:

- Base Salary
- Short-Term Incentives (cash bonuses)
- Long-Term Incentives (equity-based awards)
- Benefits

These components provide a balanced mix of base compensation and compensation that is contingent upon our executive officer's individual performance. A goal of the compensation program is to provide executive officers with a reasonable level of security through base salary and benefits. We want to ensure that the compensation programs are appropriately designed to encourage executive officer retention and motivation to create shareholder value. We believe that our shareholders are best served when we can attract and retain talented executives by providing compensation packages that are competitive but fair.

Base Salaries

Base salaries generally have been targeted to be competitive when compared to the salary levels of persons holding similar positions in other publicly traded companies of comparable size. The executive officer's respective responsibilities, experience, expertise, and individual performance are considered.

Short-Term Incentives

Cash bonuses may be awarded at the sole discretion of the Board of Directors based upon a variety of factors that encompass both individual and company performance.

Long-Term Incentives

Equity incentive awards help to align the interests of our employees with those of our shareholders. Equity based awards are made under our Equity Incentive Plan. Options are granted with exercise prices equal to the closing price of our common stock on the date of grant and may be subject to a vesting schedule as determined by the Board of Directors which administers the plan.

We believe that grants of equity-based compensation:

- enhance the link between the creation of shareholder value and long-term executive incentive compensation;
- provide focus, motivation, and retention incentive; and
- provide competitive levels of total compensation

In addition to cash and equity compensation programs, executive officers participate in the health and welfare benefit programs available to other employees.

The following summary compensation table sets forth all compensation earned by the Company's officers during the years ended December 31, 2024 and 2023.

EXECUTIVE COMPENSATION

| Name and Principal Position | Year | Salary (1) | Bonus (2) | Stock Awards (3) | Option Awards (4) | All Other Compensation (5) | Total |
|---|---|---|---|---|---|---|---|
| **Abdulkader Rahmo, Ph.D. President, Chief Scientific Officer, and Director** | **2024** | **$143,188.98** | **--** | **--** | **--** | **--** | **$143,188.98** |
| | **2023** | **$124,368.64** | **--** | **--** | **--** | **--** | **$124,368.64** |
| **Harry Friedman Chief Financial Officer and Director** | **2024** | **--** | **--** | **--** | **$50,000** | **--** | **$50,000.00** |
| | **2023** | **--** | **--** | **--** | **--** | **--** | **--** |

(1) The dollar value of base salary (cash and non-cash) earned.

(2) The dollar value of bonus (cash and non-cash) earned.

(3) The value of all stock awarded during the periods covered by the table is calculated according to ASC 718-10-30-3, which represented the grant date fair value.

(4) The fair value of all stock options granted during the periods covered by the table are calculated on the grant date in accordance with ASC 718-10-30-3 which represented the grant date fair value.

(5) All other compensation that could not be properly reported in any other column.

The following shows the amount we expect to pay to our officers and the amount of time these persons expect to devote to our business during the twelve months ending May 31, 2026.

| Name | Projected Monthly Compensation | Percent of Time Devoted to Our Business |
|---|---|---|
| Abdulkader Rahmo | $16,667.00 | 100% |
| Chief Financial Officer[(1)] | $8,333.33 | 50% |
| Chief Business Officer[(1)] | $11,666.66 | 50% |

*(1) We expect to appoint persons to these positions at a later date.*

Employment Agreements

We have not entered into any employment agreements with our executive officers or other employees to date. We may enter into employment agreements with such persons in the future.

Equity Incentive Plan

The Company has an Equity Incentive Plan (the "Plan") which provides for the grant of stock options to the Company's officers, directors, employees, and consultants. As of the date of this Private Offering Memorandum, the following officers and directors have been granted options pursuant to the Plan:

| Name | Shares Issuable Upon Exercise of Options | Option Exercise Price Per Share | Option Expiration Date |
|---|---|---|---|
| Harry Friedman | 8,000 | $6.25 | None |
| Joseph Kiani | 542,800 | $2.10 | January 31, 2033 |

There are no compensatory plans or arrangements, including payments to be received from the Company with respect to any executive Officer, that would result in payments to such person because of his or her resignation, retirement or other termination of employment with the Company, or its subsidiaries, any change in control, or a change in the person's responsibilities following a change in control of the Company.

## PRINCIPAL SHAREHOLDERS

The following table shows the ownership, as of the date of this Private Offering Memorandum, of those persons owning beneficially 5% or more of our common stock and the number and percentage of outstanding shares owned by each of our directors and officers and by all officers and directors as a group. Each owner has sole voting and investment power over their shares of common stock.

| Name and Address | Shares Owned | % of Outstanding Shares |
|---|---|---|
| Abdulkader Rahmo, Ph.D. | 2,570,000 | 41% |
| Harry Friedman | 67,200 | *1% |

| | | |
|---|---|---|
| Ghassan Kassab | -- | -- |
| Joseph Kiani | 578,800 | 9% |
| Mohamed Diab | 612,000 | 10% |
| Thomas Pistone | 408,000 | 6% |
| Amy Mousavi | 530,000 | 8% |
| Acculab | 428,800 | 7% |
| **All Officers and Directors as a group (6 Persons)** | 5,194,800 | 82% |

**Less than 1%*

1. Includes shares issuable upon the exercise of options granted to the following persons:

| **Name** | **Shares Issuable Upon Exercise of Options** |
|---|---|
| Harry Friedman | 8,000 |
| Joseph Kiani | 542,800 |

## PLAN OF DISTRIBUTION

This Offering is intended as a non-public offering, exempt from registration under Section 4(a)(2) of the Securities Act of 1933 ("the Act"), as amended, and/or Regulation D promulgated pursuant to the Act and the securities laws and regulations of certain states. The shares which are subject to the Offering have not been registered under the Securities Act of 1933, nor pursuant to the provisions of any state securities laws. Availability of the exemptions from the securities laws for the sale of the shares is dependent upon the investment intent of the investors. Accordingly, each investor will be required to acknowledge, among other things, that the purchase of the shares is for investment, for his own sole account, and without any view to resale or other distribution thereof. Since the sale of the shares is not registered, the shares will be restricted and may not be resold without registration, except under specific exemptions from the securities registration requirements.

There is no firm commitment by any person to purchase or sell any of the shares, and there is no assurance that any shares offered will be sold. There is no minimum number of shares which are required to be sold in this offering. We may terminate this offering at any time.

The Company has agreed to pay Manhattan Street Securities (“MSC”) a service fee equal to $250 per investor that invests through its platform. The Company will also pay $250 in warrants per investment to MSC. The Company will pay $1000 in cash and warrants for each corporate or IRA investment and $5000 in cash and warrants for each professional investment entity investment.

The Company also pays a monthly fee of $14,000 of cash and warrants to MSC for services provided for this offering.

## INVESTOR SUITABILITY STANDARDS

The Company will offer and sell its shares of common stock only to Accredited Investors.

An accredited investor is:

- A natural person (as opposed to a corporation, partnership, trust or other legal entity) whose net worth, or joint net worth together with his/her spouse, exceeds $1,000,000 exclusive of such person's primary residence;
- Any trust, with total assets in excess of $5,000,000, not formed for the specific purpose of acquiring the securities offered, whose purchase is directed by a sophisticated person as described in Section 506(b)(2)(ii) of Regulation D;
- A natural person (as opposed to a corporation, partnership, trust or other legal entity) whose individual income was in excess of $200,000 in each of the two most recent years (or whose joint income with such person's spouse was at least $300,000 during such years) and who reasonably expects an income in excess of such amount in the current year; or
- A corporation, partnership, trust or other legal entity (as opposed to a natural person) and all of such entity's equity owners fall into one or more of the categories enumerated above.

Prior to the purchase of the Securities, each prospective investor will be required to represent in the Subscription Agreement that:

1. Such investor's overall commitment to investments which are not readily marketable is not disproportionate to his or her net worth, and such investor's investment in the Securities will not cause his or her overall commitment to become excessive;

2. Such investor has adequate means of providing for current needs and personal contingencies, has no need for liquidity in his or her investment in the Securities, and has no reason to anticipate any change in personal circumstances, financial or otherwise, which might cause or require any sale or distribution of the Securities;

3. Such investor has evaluated the risks of investing in the Securities;

4. Such investor can bear the economic risks of the investment and has the capacity to protect his or her own interests in connection with the transaction;

5. Such investor has substantial experience in making investment decisions of this type or is relying on his or her own advisor or qualified purchaser representative in making this investment decision;

6. Such investor is aware that the Securities have not been registered under the Securities Act of 1933, as amended, but rather are being offered in reliance upon an exemption from the registration requirements of that Act, and that the subsequent sale or other disposition of such Securities will require, in the absence of such registration, the satisfaction of such conditions as the Company may require;
7. Such investor is aware that there is no market for the Company's common stock at this time, and there is no assurance that a market will ever develop. The Securities being offered will not be transferable unless such Securities are registered or except with the prior written consent of the Company, which consent may be withheld under certain circumstances;

8. Such investor is aware that any person to whom the investor may subsequently wish to sell the Securities (if the Securities are not registered) may have to satisfy standards of suitability at least as stringent as those set forth herein and that, in addition, the prior written approval of any such sale by certain state securities regulatory authorities may be required; and

9. Such investor is purchasing the Securities for his or her own account, for investment, and not with a view to resale or distribution.

The Securities will be offered only to individuals who are able to represent that they meet the foregoing standards and who are residents of states in which the Securities have been qualified for sale or in which there is an available exemption from registration. Prospective investors which are not natural persons (e.g., corporations, trusts, or partnerships) will be required to meet the foregoing standards or such other more stringent standards, and to make such representations in connection therewith, as the Company may deem appropriate. If a purchaser representative is required, he must also execute a disclosure and acknowledgment form.

## RESALE RESTRICTIONS

The Securities issued in this Offering will be "restricted securities" as that term is defined in Rule l44 of the Securities and Exchange Commission, and may, in the future, be sold only in compliance with Rule l44 or some other exemption from registration under the Securities Act of 1933, the availability of which must be established by the holder to the satisfaction of the Company, unless the securities are covered by an effective registration statement under the Securities Act of 1933. Rule l44 provides, in essence, that a person who is not affiliated with the Company may, after six months from the date of acquisition, sell restricted securities without restriction, provided the Company files 10-K and 10-Q reports with the Securities and Exchange Commission and is current in its filings with the SEC. There can be no assurance that Rule l44 or any other exemption will be available for the resale of the Securities purchased by investors in this Offering.

In order to facilitate compliance with the limitations on the resale of the securities purchased by investors in this Offering: (i) a legend will be placed on the certificates stating that the securities have not been registered under the Act and setting forth the restrictions on transferability and sale; (ii) a stop transfer notation will be made with respect to the securities in the appropriate records of the Company; and, (iii) stop transfer instructions will be issued to the Company's transfer agent.

## DESCRIPTION OF SECURITIES

Common Stock

The Company is authorized to issue 9,000,000 shares of common stock (the "Common Stock"). Holders of common stock are each entitled to cast one vote for each share held of record on all matters presented to shareholders. Cumulative voting is not allowed; hence, the holders of a majority of the outstanding common stock can elect all directors.

Holders of common stock are entitled to receive such dividends as may be declared by the Board of Directors out of funds legally available therefor and, in the event of liquidation, to share pro rata in any distribution of the Company's assets after payment of liabilities. The board is not obligated to declare a dividend. It is not anticipated that dividends will be paid in the foreseeable future.

Holders of common stock do not have preemptive rights to subscribe to additional shares if issued by the Company. There is no conversion, redemption, sinking fund, or similar provisions regarding the common stock. All outstanding shares of common stock are fully paid and non-assessable.

As of the date of this Private Offering Memorandum, the Company had 7,598,800 outstanding shares of common stock.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We currently intend to retain any future earnings for use in the operation of our business and do not intend to declare or pay any cash dividends in the foreseeable future. Any further determination to pay dividends on our capital stock will be at the discretion of our Board of Directors, subject to applicable laws, and will depend on our financial condition, results of operations, capital requirements, general business conditions, and other factors that our Board of Directors considers relevant.

Warrants

Certain investors in this Offering will receive warrants which will allow for the purchase of additional shares of common stock. The warrants will be exercisable for 180 days after an investor's purchase of the Company's shares at an exercise price of $22.50 per share.

Transfer Agent

Our transfer agent is Colonial Stock Transfer, whose address is 7840 S 700 E, Sandy, UT 84070. The Transfer Agent's telephone number is (801)335-5740 and its website is https://www.colonialstock.com/index.htm

## INDEMNIFICATION

The Company's Bylaws authorize indemnification of a director, officer, employee or agent of the Company against expenses incurred by him in connection with any action, suit, or proceeding to which he is named a party by reason of his having acted or served in such capacity, except for liabilities arising from his own misconduct or negligence in performance of his duty. In addition, even a director, officer, employee, or agent of the Company who was found liable for misconduct or negligence in the performance of his duty may obtain such indemnification if, in view of all the circumstances in the case, a court of competent jurisdiction determines such person is fairly and reasonably entitled to indemnification.

**Those interested in subscribing to the securities offered by the Company should complete the Subscription Agreement that follows.**

**SMSBIOTECH, INC.**

**BALANCE SHEETS**

*As of December 31*

| ASSETS | 2024 | 2023 |
|---|---|---|
| **Current Assets:** | | |
| Bank Accounts | $51,248.95 | $336,519.23 |
| Prepaid Expenses | $42,303.07 | $7,297.79 |
| **Total Current Assets** | **$93,552.02** | **$343,817.02** |
| Fixed Assets | $53,674.55 | $11,285.76 |
| Deposits | $17,305.84 | $17,305.64 |
| Investment in SMSbiotech Australia PTY | $63,936.60 | — |
| **Total Assets** | **$228,469.01** | **$372,408.62** |

## LIABILITIES AND SHAREHOLDERS' DEFICIT

| Category | 2024 | 2023 |
|---|---|---|
| **Current Liabilities:** | | |
| Accounts Payable | $287,774.64 | $249,176.13 |
| Credit Cards | $129,978.33 | $40,713.19 |
| Security Deposit Payable | $2,000.00 | $2,000.00 |
| Shareholder Payable | $132,336.00 | $87,336.00 |
| Deferred Revenue | $2,000.00 | $2,000.00 |
| Interest Payable | $3,086.38 | $3,086.38 |
| Payroll Clearing | -$2,804.42 | $(1,000.00) |
| **Total Current Liabilities** | **$554,370.93** | **$383,311.70** |
| Convertible Note | $400,000.00 | $400,000.00 |
| **Total Liabilities** | **$954,370.93** | **$783,311.70** |

**SMSBIOTECH, INC.**

**BALANCE SHEETS (CON'T)**

*As of December 31*

| **Shareholders' Deficit:** | | |
|---|---|---|
| Retained Deficit | $(7,641,383.08) | $(5,967,036.50) |
| Net (Loss) | $(1,773,998.84) | $(1,674,346.58) |
| Common Stock | $8,689,333.00 | $7,230,333.00 |
| Additional Paid-In Capital | $147.00 | $147.00 |
| **Total Shareholders' Deficit** | **$(725,901.92)** | **$(410,903.08)** |
| **Total Liabilities and Shareholders' Deficit** | **$228,469.01** | **$372,408.62** |

**SMSBIOTECH, INC**
**STATEMENT OF OPERATIONS**
*For the Years Ended December 31*

| Category | 2024 | 2023 |
|---|---|---|
| **INCOME:** | $0.00 | $0.00 |
| **Expenses:** | | |
| Automobile Expense | $2,320.97 | $2,481.16 |
| Bank Charges | $1,650.07 | $1,667.68 |
| Commission | $93,120.00 | $117,500.00 |
| Computer and IT Services | -- | $85.00 |
| Contractors | $150.00 | $4,385.00 |
| Depreciation Expense | -- | $54,536.00 |
| Dues & Subscriptions | $11,657.04 | $8,086.36 |
| Employee Benefits | $54,257.53 | $43,428.70 |
| Entertainment | $51.30 | $422.34 |
| Liability Insurance | $3,301.48 | $4,046.37 |
| Interest Paid | $20,322.41 | $8,346.81 |
| Cleaning Expenses | $11,717.50 | $7,450.00 |
| Legal & Professional Services | $187,732.61 | $197,306.70 |
| Marketing | $750.04 | $14,711.85 |
| Meals | $4,248.56 | $4,214.68 |
| Office Expenses | $2,731.81 | $8,497.29 |
| Outside Services | -- | $393.87 |
| Payroll Processing Fees | $35,171.63 | $26,651.72 |
| Postage & Shipping | $10,491.18 | $8,780.52 |
| Recruiting | $3,502.54 | $19,653.35 |
| Rent - Buildings | $110,044.93 | $109,001.02 |
| Equipment Lease | $39,228.93 | $30,282.64 |
| Repairs & Maintenance | $3,376.40 | $2,433.22 |
| Software Subscriptions | $18,074.82 | $8,954.66 |
| Supplies - Office | $8,339.67 | $9,464.29 |
| Taxes & Fees | $64.31 | $442.79 |
| Telephone | $1,078.41 | $361.75 |
| Training and Certification | $694.69 | $2,240.00 |
| Parking | $703.10 | $717.89 |

| SMSBIOTECH, INC<br>STATEMENT OF OPERATIONS (CON'T)<br>*For the Years Ended December 31* | | |
|---|---|---|
| Utilities | $31,063.44 | $40,074.01 |
| Meeting and Conference | -- | $5,683.37 |
| Promotional | -- | $1,913.13 |
| **Total Travel** | $22,957.49 | $36,953.14 |
| **Total Regulatory** | $190,174.06 | $161,075.88 |
| **Research and Development Expenses** | $899,662.08 | $746,341.61 |
| **Total Expenses** | **$1,768,639.00** | **$1,688,584.80** |
| **Other Income** | $773,609.64 | ($15,038.22) |
| **Other Expenses** | $1,648.00 | $800.00 |
| **Net (Loss)** | **($1,773,896.64)** | **($1,674,346.58)** |
| | | |