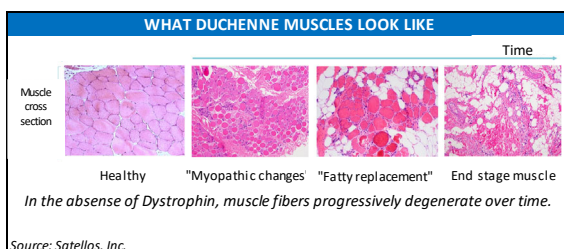




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Ticker (Exchange)	MSCL-TSXV/MSCLF-OTCQB
Recent Price (10/05/2023)	Cdn\$0.41
52-week Range	Cdn\$0.215 to 0.85
Shares Outstanding	112.8 mm
Market Capitalization	Cdn\$46.2 mm
Average 10-day volume	18,200
Insider Ownership +>5%	19%
Institutional Ownership (est.)	50%
EPS (Qtr. ended 6/30/2023)	(\$0.05)
Employees	20



COMPANY DESCRIPTION

Satellos Bioscience Inc. (“Satellos” or “the Company”) is a biotechnology company dedicated to developing life-changing medicines to treat degenerative muscle conditions. The Company’s scientists have discovered what could possibly be a previously unrecognized root cause of skeletal muscle degeneration, which may transform how muscle disorders are treated. Satellos’ scientific founder, Dr. Michael Rudnicki, is a thought leader who discovered and has shown how muscle stem cells regulate muscle repair and growth throughout life. He has demonstrated how defects in a process known as stem cell “polarity”, which controls how muscle stem cells divide to create muscle **progenitor†** cells, lead to a failure of muscle regeneration in patients with **Duchenne muscular dystrophy (DMD)**—a rare genetic disorder of progressive muscular weakness that affects boys almost exclusively. As a result of this ongoing inability to produce sufficient numbers of new muscle cells, the muscles of individuals living with Duchenne are unable to keep up with and repair the continuous and accumulating damage to their muscles. Satellos is developing a small molecule oral therapeutic intended to correct muscle stem cell polarity and restore the body’s innate muscle repair and regeneration process. This unique therapeutic approach could prove to be a disease modifying treatment for patients with Duchenne as well as other muscular dystrophies. To expand its programs into other degenerative muscle conditions or disorders, Satellos has created MyoReGenX™, a proprietary discovery platform, which the Company utilizes to identify disease situations where deficits in muscle stem cell polarity and regeneration occur and are open to therapeutic treatment.

KEY POINTS

- Duchenne affects an estimated 1 in 4,000 live male births worldwide per year and is 100% fatal.
- Current Duchenne treatment approaches share one common aspect—they are all focused on existing muscle fibers and attempting to lessen the impact of muscle damage that has already occurred. This includes both standard of care corticosteroid treatment, or more recent genetic approaches, such as **exon skipping**, with Exondys 51 approved in the U.S. and indicated for patients with an exon 51 mutation (which is 12% of Duchenne patients), or gene therapy where Elevidys received U.S. FDA approval in June 2023 for the treatment of pediatric patients through the ages of 4 through 5 (only).
- Satellos is focused on restoring, repairing, and regenerating muscle fibers. Based on the unique mechanism of action of its drug candidates, the Company believes its approach may have applicability across a broad range of degenerative conditions, from lethal genetic diseases to age-related muscle loss—areas where the medical need for new treatments is significant.
- The Company holds numerous issued and pending patents related to the manipulation, modulation, and use of muscle stem cells for experimental and therapeutic purposes, including four patent families, which represent core intellectual property for Satellos.
- The Company recently raised Cdn\$55 million from healthcare-focused institutional investors to advance its lead drug candidate towards an IND filing in mid-2024 and bolstered its senior management team to support this objective.
- As of June 30, 2023, Satellos had cash and cash equivalents of Cdn\$48.7 million, providing a cash runway through 2025.

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Executive Overview

Satellos Bioscience Inc. (“Satellos” or “the Company”) is a biotechnology company focused on skeletal muscle regeneration science. The Company seeks to develop medications to reset the body’s innate ability to self-repair as a new approach for treating devastating muscle disorders.

The origin of the Company’s science is a seminal 2007 Cell paper by Company co-founder and Chief Scientific Officer, Dr. Michael Rudnicki (biography on page 8), in which he identified and defined a sub-population of muscle (aka “satellite”) stem cells capable of self-renewal and regeneration. In a subsequent paper in *Nature Medicine*, Dr. Rudnicki made a landmark discovery concerning the nature of Duchenne muscular dystrophy (“Duchenne” or “DMD”)—a lethal, inherited disorder in which the dystrophin gene is mutated. Specifically, Dr. Rudnicki recognized for the first time that the **dystrophin** protein (produced by the dystrophin gene) has a fundamentally basic role to play in the regeneration capacity of muscles. Its absence in the bodies of individuals living with DMD severely impairs their ability to repair and regenerate muscle as they grow, thereby leading to the progressive muscle damage and loss that is a hallmark of this disease. Until Dr. Rudnicki’s finding, Duchenne was known as a degenerative condition in which muscle fibers simply broke down, also due to the protein’s absence, rather than one in which muscles failed to regenerate. This new, more complete understanding of the underlying nature of Duchenne offers the potential for a new avenue for treatment.

Duchenne is a multi-systemic genetic condition affecting many parts of the body, resulting in deterioration of the skeletal, heart, and lung muscles. As the most common childhood onset muscular dystrophy, it is caused by mutations in the gene that codes for dystrophin, a protein that contributes to the function of muscle cells. The gene is carried on the X chromosome and affects approximately 1 in 4,000 male births worldwide per year. Duchenne appears irrespective of geography or socio-economic conditions and causes muscle stem cell dysfunction, progressive degeneration of muscle, functional decline, and ultimately loss of life.

Dr. Rudnicki uniquely identified that the protein expressed in muscle stem cells has a role to trigger regeneration. Without that regenerative boost, the muscle stem cells do not know how to properly divide, do not make new muscle cells, do not go on to repair and restore muscle fibers, and do not regenerate muscle fibers. The reason for the massive destruction and ongoing degradation of muscle in patients with Duchenne is perhaps more due to the fact the body cannot keep up with the effects of the disease and cannot repair itself, as it is intended to. What appears to be damaged muscle fiber is actually muscle fiber that cannot repair itself and cannot regenerate. This is a drastically different way of approaching this disease, such that the focus becomes fixing the restorative capacity of the body (versus fixing the fibers).

Satellos believes that the concept of repair and regeneration applies to many other conditions, which may be identified over time. In the near term, the Company is focused on working to develop therapeutic agents that can interact with the muscle cells and correct the problem of Duchenne patients. Satellos believes that the science is not just sound but that it truly is transformative as it is looking at diseases in a completely unique way in that there is an underlying biochemical deficit that is occurring in children as a result of not having the dystrophin protein. Satellos believes that this deficit can be improved, if not corrected. In some cases, the Company’s technology may actually be synergistic with other approaches that make the muscle fiber more conducive to repair, which would be positive for these patients.

Current standard of care for Duchenne patients consists of corticosteroid treatment with either prednisone or branded Deflazacort (with Deflazacort priced at \$100,000 annually). While playing an important role in alleviating inflammation and modestly modifying the course of this disease, corticosteroids do not treat the underlying causes of the disease and are associated with a myriad of serious side effects. A newer treatment approach is exon skipping, which attempts to address a root cause through the technique of skipping over the mutated exon. One recently approved exon-skipping drug therapy, Exondys 51 (Sarepta Therapeutics, Inc.), which carries an annual cost of approximately \$600,000, is approved in the U.S. and indicated only for patients with an exon 51 mutation, which represents roughly 12% of the Duchenne population. The latest product approval for Duchenne, Elevidys (delandistrogene moxeparovect-rokl), also comes from Sarepta and is the first ever micro-dystrophin expressing

gene therapy, which aims to produce a surrogate version of the dystrophin protein in mature muscle fibers. Elevidys was approved through the FDA accelerated approval pathway for ambulatory children aged 4 through 5 with Duchenne muscular dystrophy. Verification of clinical benefit is pending as of the publication date of this document. The publicly listed pricing for this therapy is \$3.2 million.

Muscular Dystrophies and Muscle-Wasting Disorders

Muscular dystrophy (dystrophies) include(s) over 160 unique diseases that display progressive muscle degeneration, which often lead to weakness, loss of ambulation, and potentially loss of life. These diseases affect tens of thousands of people every year and are largely inadequately served by current therapeutic approaches. Dystrophies occur as a result of mutations in genes that code for important muscle proteins, leading to the alteration or complete loss of their contribution toward ensuring a healthy, functional muscle tissue.

Satellos is working to develop first-in-class regenerative therapeutics that seek to reset proper muscle stem cell function, restore productive muscle regeneration, improve muscle strength and functionality, and eventually enhance the quality and duration of patient lives. The Company's scientists were the first to discover that the loss of dystrophin in muscle stem cells underlies the classically observed, but previously not understood, impaired regeneration response in Duchenne patients. Satellos was also the first to discover an alternative signaling pathway that can be therapeutically targeted to restore regeneration (independent from and in the absence of the dystrophin protein). In both *in vitro* and *in vivo* preclinical studies, Satellos has shown that the targeting of this pathway results in significantly improved muscle quantity, quality, and function. The Company intends to expand into other muscular dystrophies and wasting syndromes where similar mechanisms may be at play and diminished regeneration has been detected.

Aging and Trauma-Induced Muscle Disorders

As humans age, there is a loss in skeletal muscle mass and strength—a phenomena known as **sarcopenia**. Individuals that suffer from sarcopenia are at higher risk for slips, trips, and falls, reduced independent mobility, and mortality. Although the exact underlying cause of sarcopenia is not fully understood, scientists at Satellos have discovered a clear deficit in the muscle regeneration process during aging. These deficits not only may cause the onset of sarcopenia, but they may also hinder recovery in individuals who have undergone mobility related operations following injury or joint replacements. Onset of sarcopenia and impaired injury recovery are both factors that contribute to the potential for overall frailty in the elderly population and are therefore areas of high unmet need.

The Company has identified multiple candidate pathways that can be targeted to improve muscle quality, quantity, and function in aged muscle tissue. The plan is to develop regenerative therapeutics, which may prevent or treat sarcopenia linked to skeletal muscle loss, as well develop a locally delivered therapeutic designed to enhance post-surgical skeletal muscle recovery in the elderly.

Development Status

Satellos is developing a strategy for submitting an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) and subsequent conduct of clinical trials with its drug candidates. Over the next two years, the Company seeks to move its lead program for Duchenne through early clinical development with submission of an IND application to the FDA by mid-2024, followed by initiation of clinical trials in humans. As part of its planning and preparations, the Company has recently hired Dr. Alan Jacobs as Chief Medical Officer, who is engaging expert advisors experienced in the FDA review process in areas of relevance to products the Company is working to develop, and has sought input from individuals and groups with clinical trial expertise in Duchenne.

The Company announced on August 1, 2023, that the FDA had granted **Orphan Drug Designation** and Rare Pediatric Disease Designation to SAT-3153 for the potential treatment of Duchenne. These designations provide certain benefits, including the potential for a seven-year market exclusivity upon regulatory approval, exemption from FDA application fees, tax credits for qualified clinical trials, and a priority review voucher and a Rare Pediatric Disease Priority Review Voucher. The FDA grants Orphan Drug Designation to support development of medicines for underserved patient populations, or rare disorders, that affect fewer than 200,000 people in the U.S.

The FDA grants Rare Pediatric Disease Designation for serious and life-threatening diseases that primarily affect children ages 18 years or younger and fewer than 200,000 people in the United States. The Rare Pediatric Disease Priority Review Voucher Program is intended to address the challenges that drug companies face when developing treatments for these unique patient populations. Under this program, a sponsor who receives an approval for a drug or biologic for a “rare pediatric disease” may be eligible for a voucher that can be redeemed to receive priority review of a subsequent marketing application for a different product or sold to another sponsor for priority review of their marketing application.

The Company has identified multiple regulatory pathways affecting muscle stem cell polarity, has prioritized two of those pathways and identified drug targets in each of them, and has filed new intellectual property around these pathways and targets. Satellos has engaged the well-known intellectual property firms Cooley LLP and Wilson Sonsini Goodrich and Rosati and has been very active filing patents and building its intellectual property estate (further described on page 7). Satellos has generated novel intellectual property that is believed to be patentable and is working with its patent counsel on filing for intellectual property protection around its biological and chemical discoveries, including but not limited to novel classes of compounds and specific compounds that the Company has invented.

Université de Sherbrooke Agreement

To uncover the drug candidates’ potential in other dystrophic conditions, Satellos announced in December 2021 that it had entered into a scientific research agreement with Université de Sherbrooke in Quebec, Canada to collaborate on activities to identify further disease indications for the Company’s muscle regeneration technology in select preclinical models of rare muscular dystrophies. Beyond Duchenne, there are more than 30 types of muscular dystrophies that affect humans, each with different causes that manifest into conditions, which range the spectrum of severity—from benign, small impairments in motor function to full loss of ambulation and death.

MyoReGenX™ Discovery Platform

Satellos has created a proprietary MyoReGenX™ Discovery Platform (described below and in greater detail on page 17), which the Company utilizes to identify disease situations where deficits in muscle stem cell polarity and regeneration occur and are open to therapeutic treatment. The Company’s lead drug program in Duchenne, where Satellos has shown that impaired stem cell function severely compromises muscle regeneration throughout life, intends to correct this stem cell deficiency to enable muscle regeneration throughout a patient’s life. This unique therapeutic approach may offer possibilities for addressing the progressive muscle loss not only in Duchenne but other serious disorders, including debilitations of aging, potentially enhancing the quality and duration of life for patients with muscular dystrophies and muscle wasting disorders.

The MyoReGenX™ Discovery Platform, which is unique to Satellos, provides three core functions based on decades of muscle stem cell knowledge, including:

- (1) Recapitulation of the muscle stem cell micro-environment (the “niche”);
- (2) Identification, classification, and confirmation of regenerative deficits in serious muscle diseases; and
- (3) Discovery and development of therapeutic solutions for those cases where regeneration is found to be impaired.

MyoReGenX™ was designed specifically to recreate the specialized muscle stem cell niche *in vitro*. Maintaining this micro-environment is necessary for sustaining the identity and functionality of muscle stem cells outside of the body. MyoReGenX™ uniquely enables the Company to map pathways that modulate muscle repair and regeneration, identify and confirm drug targets, and test drug candidates for their ability to restore muscle stem cell repair mechanisms that have been impaired by genetic mutations, disease, or injury.

Corporate Overview and History

Satellos was founded in 2018 by biotechnology entrepreneurs Mr. Frank Gleeson (biography on page 8) and Dr. Michael Rudnicki in partnership with Bloom Burton & Co., Canada’s largest specialty biotechnology advisors and bankers. In 2021, Satellos executed a reverse takeover (“RTO”) of iCo Therapeutics Inc., undertook a concurrent capital raise, and began trading on the TSX-V under the ticker MSCL (MSCLF-OTC)—the ticker symbol being the short form for muscle (the Company’s therapeutic interest). Coinciding with the reverse takeover, Satellos completed a concurrent capital raise of \$7.25 million and converted a \$1 million debt instrument by Parent Project Muscular Dystrophy into an equity investment in the Company.

In May 2023, Satellos closed an equity offering, issuing a total of 110 million equity securities for gross proceeds of \$55 million and included participation from funds managed by Avidity Partners, Qiming Venture Partners USA, Perceptive Advisors, Soleus Capital, FMB Research, Allosterly Investments, and other leading healthcare specialized institutional investors.

Following the RTO, the Company has three wholly-owned subsidiaries, Satellos Biosciences US, Inc. (an entity incorporated under the laws of Delaware), Amphotericin B Technologies, Inc. (an entity incorporated under the Business Corporations Act [British Columbia] (Amp B), and iCo Therapeutics Australia Pty Ltd. (an entity incorporated under the laws of Australia). Satellos is headquartered at 200 Bay Street, Suite 2800, Toronto, Ontario M5J 2J1. The Company employs twenty (20) full and part-time staff and five (5) full-time equivalent staff under a sponsored research agreement with the Ottawa Hospital Research Institute (“OHRI”) from whom it has licensed foundational technology.

Intellectual Property

Satellos has a portfolio of issued patents as well as multiple new patent applications that the Company is preparing on a regular basis. Specifically, this includes multiple issued patents related to polarity modulator Wnt7a, which it licensed from the Ottawa Hospital Research Institute (OHRI), as described below. Multiple mechanistic patent filings surrounding the regulation of polarity via modulating specific pathways and drug targets are being drafted, are in the filing process, or are under review by patent offices. Furthermore, composition of matter patent applications on multiple new chemical entities (NCEs) as modulators of specific polarity regulating pathways and targets are in development. A description of these efforts, where information has been made available, is provided in the accompanying section.

Muscle Stem Cells

Satellos holds numerous issued and pending patents related to the manipulation, modulation, and use of muscle stem cells for experimental and therapeutic purposes, including four patent families:

- (1) ‘A method of stimulating asymmetric division of satellite stem cells’ patent family (patents/applications derived from PCT/US2018/027920);
- (2) ‘Wnt7a compositions and methods of using the same’ patent family (patents/applications derived from PCT/US2012/055396);
- (3) ‘Compositions and methods for modulating stem cells and uses thereof’ patent family (patents/applications derived from PCT/CA2010/000601); and
- (4) Modulation of satellite cell polarity and asymmetric division (application 63/447,807)

These patents represent core intellectual property for Satellos. The Company’s strategy is to maintain these patents and aggressively pursue protection as it makes new discoveries or inventions. Satellos has engaged one of North America’s leading intellectual property firms—Cooley LLP (<https://www.cooley.com/>)—to assist with developing its intellectual property strategy, drafting and filing patent filings, and maintaining its international portfolio of filings. The Company has engaged Osler (<https://www.osler.com>), one of Canada’s leading intellectual property firms, to handle its portfolio of Wnt7a patents and to assist in strategic developments, filing, and patent prosecution.

Satellos believes it has invented novel chemical matter and intends to file patent applications on a timely basis, seeking to obtain protection while optimizing patent life. The Company’s approach is to seek intellectual property protection by making filings in major markets, including but not limited to the U.S., EU, Japan, China, and Canada. Satellos believes it will be better positioned to arrange for the manufacture, distribution, and sale of its drug candidates in the named jurisdictions (at the very least) upon receipt of regulatory approvals.

Satellos seeks to explore strategies to extend the useful life of its patents through follow-on filings and other means, along with regulatory strategies to obtain accelerated market access or additional market exclusivity for its drug candidates. Also, the Company intends to ensure that its knowledge and expertise is guarded by trade secrets or trade-mark filings. Its MyoReGenX™ Discovery Platform is one such example.

In-Licensing of New Patent Application

In June 2022, the Company announced that it had licensed a provisional patent application, recently filed with the United States Patent and Trademark Office and titled “Modulation of Satellite Cell Polarity and Asymmetric Cell Division,” from the OHRI. This helps the Company accelerate its discovery and development efforts for a novel treatment for Duchenne muscular dystrophy and potentially other dystrophies and muscle disorders. Under terms of the Amending Agreement, Satellos will pay cash and common share consideration to OHRI.

Company Leadership

Directors and officers of Satellos possess a range of expertise and knowledge in which to develop and execute on its business strategy and support its technical capabilities. The Company believes it possesses the ability to execute on its commercial and operational strategy and expects to continue to build out its team with additional specialists and expert consultants that support its business goals in a timely and cost-effective manner.

Frank Gleeson, MBA, Co-founder, Chief Executive Officer, Board Member

Mr. Gleeson is an accomplished business leader with a depth of experience as a business executive, venture capitalist, and start-up entrepreneur. During his career, Mr. Gleeson has been involved in over 20 biomedical companies and has negotiated numerous financing and merger and acquisition (M&A) transactions valued in excess of \$500 million. Prior to founding Satellos in 2018, he spent four years with the Centre for Probe Development and Commercialization (CPDC), where, as Chief Commercial Operations, Mr. Gleeson was instrumental in building a global radiopharmaceutical manufacturing business and supporting the creation of two spin-out companies. Prior to CPDC, he served as an Executive-in-Residence with the Fight Against Cancer Innovation Trust (FACIT), an innovative nucleator, where he supported or led the creation, financing, and exits of three new entities. In 2008, Mr. Gleeson co-founded, with Dr. Rudnicki, a stem-cell biotechnology company which they successfully merged into Fate Therapeutics Inc. (FATE-NASDAQ) in 2010. Earlier, Mr. Gleeson was founding chief executive officer of MDS Proteomics Inc., a strategic corporate play focused on mapping the proteome, where he made and integrated three acquisitions, built leading-edge sequencing infrastructure, a 200-person team, and raised in excess of \$100 million. From 1994-2000, Mr. Gleeson was a senior vice president and venture partner with MDS Capital Corp. (now Lumira), where he was lead partner on a fund with over \$250 million under management and focused on creating drug discovery companies based on novel Canadian science. Prior to his tenure with MDS, Mr. Gleeson enjoyed a 17-year career with ICI plc (now Zeneca), a global chemicals, pharmaceuticals, and advanced materials company, during which he was involved in technology commercialization in several fields both in Canada and internationally. Mr. Gleeson has served on numerous Boards of private and public companies and not-for profit entities. He is a member of the investment advisory committee of Fighting Blindness Canada.

Dr. Michael Rudnicki, OC, PhD, FRS, FRSC, Co-founder and Chief Scientific Officer

An acknowledged world thought leader and scientific authority on muscle stem cell function and their role in muscle regeneration, in a landmark 2007 cell paper, Dr. Rudnicki was the first to define so called muscle stem cells (a.k.a. 'satellite cells') and characterize a subpopulation as bona fide multipotent stem cells capable of both self-renewal and regeneration. Building on this work, Dr. Rudnicki has established a continuous record of foundational findings and discoveries spanning a 25-year research career. In so doing, he has transformed the field's understanding of the nature and role muscle stem cells play in the lifelong repair and growth processes of skeletal muscle, the body's largest organ. Of significance, Dr. Rudnicki and his team made the breakthrough identification of a signaling role for dystrophin in orienting muscle stem cells to divide asymmetrically to produce muscle progenitor cells. This seminal discovery transforms the classical understanding of Duchenne muscle dystrophy as a disease of muscle fragility to a new paradigm in which defective muscle regeneration can be seen as a root cause of the progressive muscle loss experienced by patients living with Duchenne. These findings offer new hope for the development of an entirely novel potential therapeutic approach to treating Duchenne and possibly other incurable and fatal muscle disorders. Dr. Rudnicki is the Scientific Director of the Canadian Stem Cell Network, Director of the Regenerative Medicine Program at the Ottawa Hospital Research Institute (OHRI), a Professor in the Faculty of Medicine at the University of Ottawa, and an Associate Editor of the *Journal of Cell Biology* as well as *Cell Stem Cell*. He has published 235 scientific articles, authored 14 patents, with an h-Index of 96 based on 44,000+ citations of his work. Dr. Rudnicki's contributions have been recognized with numerous honors, including being named a Tier 1 Canada Research Chair, a Fellow of both the Royal Society and the Royal Society of Canada, a past International Research Scholar of the Howard Hughes Medical Institute for the maximum allowable two consecutive terms, and an Officer of the Order of Canada. He received a Ph.D. at the University of Ottawa and trained at the postdoctoral level at the Massachusetts Institute of Technology in the Whitehead Institute under Dr. Rudolf Jaenisch. On June 22, 2022, the Company announced that Dr. Rudnicki had been admitted as a Fellow of

the Royal Society, the UK's national science academy and a Fellowship of the world's most revered scientists. With admission to the Royal Society, founded in 1660 by grant of royal charter by King Charles II, Dr. Rudnicki joins an exclusive collective of Fellows, including some of the most influential and respected scientists of all time, including Sir Isaac Newton and Charles Darwin.

Dr. Alan K. Jacobs, MD, Chief Medical Officer

Dr. Jacobs joins Satellos from Boston Pharmaceuticals, where as Vice President, Clinical Development, Neuroscience he oversaw early and late-stage development programs, led integrated development and biomarker plan creation, created and oversaw clinical trials, and contributed to business development collaborations. Prior to that he held progressively senior leadership roles with Immunovant and Sanofi Genzyme, including strategic coordination of multiple successful IND submissions and development and execution of Phase 2 and 3 clinical trials. Previously, Dr. Jacobs was Medical Director with both the Ohio Center for Treatment and Research in Multiple Sclerosis and the Center for Neuroscience Research in Dayton, Ohio. He was concurrently a Professor of Neurology at the Wright State University Boonshoft School of Medicine. Dr. Jacobs is a Fellow of the American Academy of Neurology.

Philip D. Lambert, Ph.D., Chief Technology Officer

Dr. Lambert brings more than two decades of experience in pharmaceutical research and development to Satellos. He is a well published researcher, a serial entrepreneur, and a leader who has held senior positions in academia, biotechnology, non-profit, large pharmaceutical, and contract research organizations (CROs). Dr. Lambert is an experienced drug finder, who has provided the necessary preclinical data to support the entrance of more than twenty small and large molecule therapeutics into clinical trials for multiple diseases. He was a member of the management team that conducted the due diligence and sale of Sirtris Pharmaceuticals to GlaxoSmithKline for \$720 million. He further cofounded, effectively grew, and sold VivoPath, a CRO, to Charles River Laboratories. Dr. Lambert received a Ph.D. in neuroendocrinology from Imperial College London and was a faculty member in the Department of Psychiatry at Emory University School of Medicine.

Elizabeth Williams CPA, CA, Chief Financial Officer

Ms. Williams has nearly 20 years of experience in biotech, working with publicly listed entities in both Canada and the United States. Prior to joining Satellos, Ms. Williams was CFO of Medicenna (MDNA-NASDAQ), where she was responsible for all financial, legal, and investor relations functions and led the graduation of the company from the TSXV to the TSX main board and subsequently the Nasdaq. Previous to Medicenna, she was Vice President of Finance and Administration at Aptose Biosciences Inc. (APTO-NASDAQ), previously Lorus Therapeutics Inc., a biotechnology company listed on both the TSX and NASDAQ capital markets. While at Aptose, Ms. Williams held several positions, including Acting CFO, and was responsible for a broad range of activities, including financings, financial reporting, and regulatory compliance. She serves as Director and Chair of the Audit Committee of Triumvira Immunologics Inc. Ms. Williams is a Chartered Professional Accountant (CPA) and Chartered Accountant (CA).

J. Robert Hall, Vice President, Finance and Administration

Mr. Hall has been with Satellos since January 2020, serving in various finance and administration related roles. In his new role, he will continue to support both the CEO and CFO of Satellos. Mr. Hall brings thirty years of progressive financial management experience in the Canadian biotechnology industry, and has worked in biomanufacturing, research, venture capital, and debt financing, and with start-up firms. He holds BSc (Biochemistry) and MBA degrees and is a Chartered Financial Analyst charter holder.

Dr. Ryan Mitchell, Vice President, Business Development

Prior to joining Satellos, Dr. Mitchell worked with Bloom Burton Securities Inc. as a scientific consultant, where he contributed to monetization planning efforts for clients ranging from pre-seed start-ups to large multinational pharmaceutical companies. Dr. Mitchell completed his graduate work at the McMaster University Stem Cell and Cancer Research Institute, where he authored numerous publications in high impact journals, such as *Nature* and *Cell*.

Warren Whitehead, Head of Strategy

Mr. Whitehead is a Chartered Professional Accountant (CPA) and Certified Management Accountant (CMA) who has held multiple senior financial management positions in several biotechnology and pharmaceutical companies, and is currently a Board Member of Aptose Biosciences (APTO-NASDAQ). Mr. Whitehead was the former Chairman and Board Member of Plantform Corporation and a former Board Member of Telesta Therapeutics (TSX), which was acquired by Prometic Life Sciences in 2016. He served as the Chief Financial Officer of ProMIS Neurosciences Inc. (formerly Amorfix Life Sciences Ltd.) from 2013 to 2015, a TSX-listed company targeting detection and effective treatment of Alzheimer's disease and amyotrophic lateral sclerosis (ALS). Previously, from 2006 to 2008, he was the chief financial officer of Arius Research Inc., a TSX-listed company developing anti-cancer antibodies, where he provided financial guidance and leadership during the acquisition of Arius by Roche in 2008. He was also the former chief financial officer of Labopharm Inc. from 2000 to 2006, where he completed a series of public equity financings, including a cross-border NASDAQ offering. Other positions include chief financial officer of Resolution Pharmaceuticals Inc., and a position in finance and business development at Glaxo Canada (now GlaxoSmithKline). Mr. Whitehead holds an MBA and BComm from the University of Windsor and a BA from the University of Western Ontario.

Board of Directors

Chair, Geoff MacKay, President and Chief Executive Officer of AVROBIO, Inc.

Mr. MacKay is a pioneer in cell and gene therapy, with a track record of successful leadership at innovative biotechs. He is the former chief executive officer of Organogenesis Inc., the world's leading cell therapy company. During his tenure, the company treated 1 million patients with living cell therapies, received the first approval of an allogeneic cell therapy from the FDA's Center for Biologics Evaluation and Research, and led the field of regenerative medicine. Mr. MacKay is also the founding chief executive officer of eGenesis, a biotech dedicated to applying CRISPR Cas-9 gene editing to xenotransplantation. Earlier in his career, he spent 11 years at Novartis in senior leadership positions within the global transplantation and immunology franchise. Mr. MacKay sits on the boards of Talaris Therapeutics and Satellos Bioscience. Past activities include chairman of the board of MassBio, chairman of the board of the Alliance of Regenerative Medicine, and a member of the advisory council to the Health Policy Commission for Massachusetts.

Adam Mostafa, Board Member and Chair, Audit Committee

Mr. Mostafa is a seasoned and accomplished financial leader. He is the current chief financial officer of X4 Pharmaceuticals, working closely with the chief executive officer and Board of Directors on all strategic and financial matters, including the close of its 2019 reverse merger with Arsanis and subsequent NASDAQ public listing and follow-on financings. In his role, Mr. Mostafa oversees teams, including finance, business development, commercial, and corporate communications, leading all investor relations (IR) and public relations (PR) initiatives and building strong ties with the investor and investment banking communities. Prior to joining X4, Mr. Mostafa served as chief financial officer of Abpro Corporation, a biotechnology company focused on antibody therapeutics. Previously, Mr. Mostafa was a managing director in the healthcare investment banking group at Cantor Fitzgerald, and a senior banker in the healthcare investment banking group at Needham & Company. Mr. Mostafa has also held positions of vice president in the investment banking group at CRT Capital Group, portfolio management associate in the global stock selection group at AQR Capital, and analyst in the healthcare investment banking group at Salomon Smith Barney. Mr. Mostafa holds an A.B. in Economics from Brown University.

Dr. Rima Al-awar, PhD, Board Member

Dr. Al-awar is an accomplished pharmaceutical executive with expertise spanning target discovery to lead identification and clinical candidate nomination. Dr. Al-awar is a member of the leadership team at the Ontario Institute for Cancer Research (OICR), a collaborative research institute that conducts and enables high-impact translational cancer research. Dr. Al-awar joined the OICR in 2008 to establish the Drug Discovery Program, whose purpose is to seek out and translate the most promising ideas from Ontario's academic community into new therapeutic treatments for the benefit of cancer patients. Under Dr. Al-awar's leadership, the group has grown to a team of more than 30 multi-disciplinary researchers who have identified and validated two promising new cancer targets, BCL6 and WDR5, invented and advanced lead drug candidates against each target, and, through the OICR's investment and commercialization arm FACIT, entered into substantial pharmaceutical development partnerships. Prior to joining OICR, Dr. Al-awar had a 13-year career with Eli Lilly and Company. Hired as a senior organic chemist, Dr. Al-awar progressed through multiple positions of increasing breadth and responsibility, culminating as Head in the Route Selection Group, Chemical Product Research and Development from 2005-2008 at the Lilly Corporate Center, Indiana. Dr. Al-awar earned a PhD in synthetic organic chemistry from North Carolina State University and did a post-doctoral fellowship at the University of North Carolina at Chapel Hill before joining Lilly in 1995.

Franklin M. Berger, Board Member

Mr. Berger currently serves on the Board of Directors of Essa Pharma Inc., Bellus Health, Inc., Atreca, Inc., Kezar Life Sciences, Inc., Rain Therapeutics, Inc., and ATEA Pharmaceuticals. He spent 12 years in sell-side equity research, most recently as a Managing Director, U.S. Equity Research at J. P. Morgan Securities, Inc., where he was involved with the issuance of over \$12 billion in biotechnology company equity or equity-linked securities covering 26 publicly traded biotechnology companies. Mr. Berger has participated in several notable biotechnology financings, including Genentech's initial public offering, the first large Celgene Corporation financings, as well as financings of several large-cap companies in their rapid growth phase. Mr. Berger began his career as a sell-side analyst at Josephthal & Co. and Salomon Smith Barney. Mr. Berger received a B.A. in International Relations from Johns Hopkins University, an M.A. in International Economics from Johns Hopkins University School of Advanced International Studies, and an MBA from Harvard University.

Brian Bloom, Board Member

Co-founder, Chairman, and chief executive officer of Bloom Burton & Co, Mr. Bloom serves on the Board of Directors of Triumvira Immunologics, Appili Therapeutics, and Qing Bile Therapeutics. He is also on the Faculty of Science Dean's Advisory Board at McMaster University. Mr. Bloom was formerly the Chairman of the Board of Grey Wolf Animal Health, a member of the Life Sciences Advisory Board at the National Research Council of Canada and on the Boards of BIOTECanada and the Baycrest Foundation. Before co-founding Bloom Burton in 2008, Mr. Bloom spent six years at Dundee Securities in the healthcare and biotechnology institutional sales and equity research groups. He started his career at New York-based investment banking firms SCO Financial Group and Molecular Securities. Mr. Bloom received an Honors Bachelor of Science in Biochemistry from McMaster University and subsequently studied at the Mount Sinai Graduate School for Biological Sciences of New York University, with a focus in molecular endocrinology and biophysics. Mr. Bloom received the McMaster University 2017 Distinguished Alumni Award in Science.

Bill Jarosz, Board Member

Mr. Jarosz was the chief executive officer of iCo Therapeutics, Inc. from 2020 until 2021 and currently the President of Satellos' subsidiary Amphotericin B Technologies, Inc. He is currently a Founding Partner at Cartesian Capital Group, LLC, a global investment management firm. From 1997 until 2005, Mr. Jarosz served as Managing Director and General Counsel of AIG Capital Partners, a subsidiary of American International Group, Inc., and as Managing Director of the AIG-Brunswick Millennium Fund. While at AIG Capital Partners, Mr. Jarosz oversaw global private equity transactions for the firm's various private equity funds. Prior to joining AIG in 1997, Mr. Jarosz practiced law at Debevoise & Plimpton, specializing in international private equity investment and Russian corporate and securities laws. He also served as a consultant to the World Bank on the regulation of Foreign Direct

Investment in emerging markets. Mr. Jarosz is a graduate of the University of Montana and received an MA in Law and Diplomacy from the Fletcher School at Tufts University, and a JD from Harvard Law School.

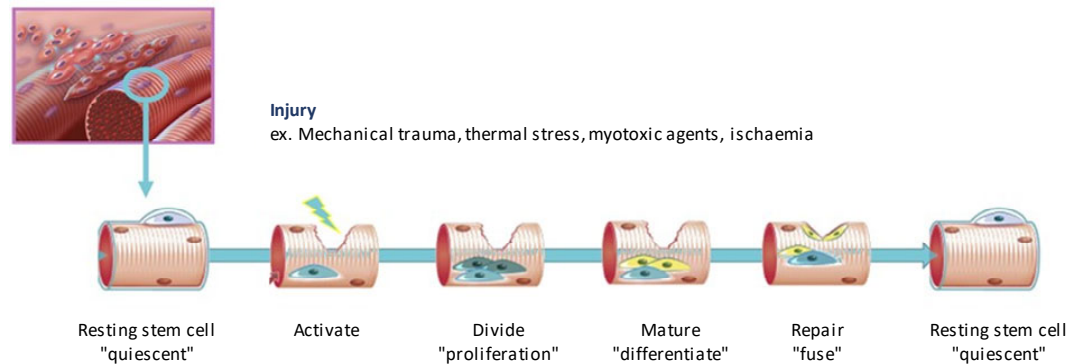
Dr. William McVicar, Board Member

Dr. McVicar's career in the pharmaceutical industry spans more than 30 years. He has held numerous high ranking positions, leading teams at Sandoz, Novartis, RPR Gencell, Sepracor, Innotek Pharmaceuticals, Flex Pharmaceuticals, and Salarius pharmaceuticals. During his career, Dr. McVicar has overseen the development of multiple drug candidates from early testing all the way through to approval, including BROVANA[®], XOPENEX MDI[®], and XOPENEX's pediatric approval. As a C-suite executive, Dr. McVicar has raised over \$100 million in venture financing, lead numerous licensing transactions, and has successfully executed the merger of Flex and Salarius Pharmaceuticals, where he remains Chair of the Board of Directors. Dr. McVicar earned a B.S. in Chemistry from SUNY College at Oneonta and a Ph.D. in Chemistry from the University of Vermont. He is an author on numerous peer-reviewed scientific publications and an inventor on 15 issued U.S. patents.

Core Story

Muscle is a regenerating organ and the largest organ in the body with the capacity to self-regenerate and self-repair throughout life. Muscle stem cells (aka satellite cells) are the creators of cells that fuse into muscle fibers, with skeletal muscles composed of bundles of fibers. Muscle stem cells remain on the muscle fibers they create and can repair and regenerate the fiber upon injury (shown in Figure 1).

Figure 1
HOW DOES MUSCLE REGENERATE



Source: Satellos, Inc.

Satellos has made groundbreaking discoveries into the body's regenerative processes and is in the process of developing a novel category of medicines. Based on its findings, the Company's drug products may be able to reset the body's natural ability to self-repair skeletal muscle to treat degenerative muscle diseases. Degenerative muscle conditions have devastating impacts on the daily lives of millions of individuals and are inadequately served by current treatments. Satellos believes that the medicines being developed by the Company hold great potential for benefits in many disease situations, including rare genetic orphan conditions, such as Duchenne muscular dystrophy (a disease of failed repair and regeneration), as well as large market disease conditions associated with chronic illnesses and ageing. The market size for these treatments is estimated to be over \$20 billion, with a number of companies within this sector in early development stages valued over \$500 million (see Competition section, page 32), demonstrating the importance being placed within this therapeutic category.

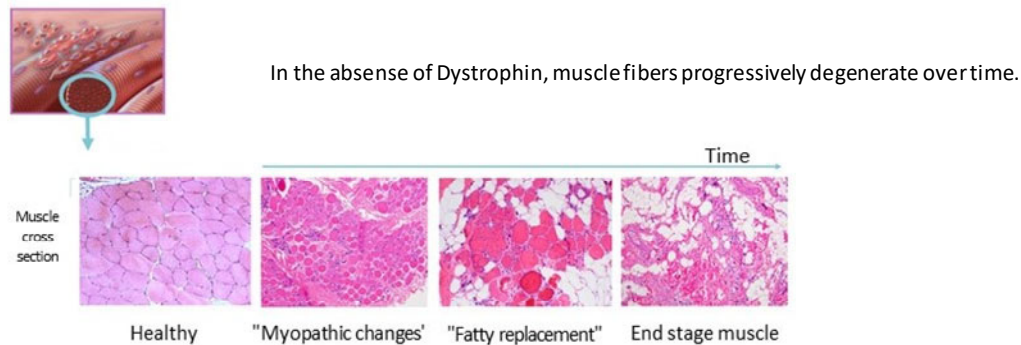
Satellos' lead drug program is focused on treating Duchenne muscular dystrophy (DMD), a fatal genetic disease with insufficient treatment options. Beginning early in childhood, Duchenne progressively destroys muscle tissue, a process that Satellos has discovered is due to a failure of the body's regenerative processes to self-repair. The Company believes that by resetting the self-repair and regeneration process, its therapeutics may have the potential to transform the treatment paradigm and create better outcomes for individuals living with Duchenne. There is tremendous value to be created in muscular dystrophy given the potential for an accelerated approval for a drug candidate that goes into Duchenne patients since to date, a truly effective treatment for these patients does not exist.

Duchenne Muscular Dystrophy Overview

Muscular dystrophies consist of progressive muscle wasting and weakness and are caused by deletion, duplication, or mutations in the dystrophin gene, resulting in either the absence of or very low levels of the dystrophin protein. As depicted in Figure 2 (page 14), Duchenne muscular dystrophy is a rare, rapidly progressive form of muscular dystrophy that affects boys almost exclusively and causes progressive weakness and degeneration of the muscles, generally leading to death by the third decade of life. As the most common and most severe type of muscular dystrophy, Duchenne can be inherited in families in an X-linked recessive fashion. It often occurs in people from families without a known family history of the condition.

Dystrophin is a muscle membrane associated protein and is vital to the structural and membrane stability of muscle fibers in the skeletal, diaphragm, and heart muscle. The lack of normally functioning dystrophin causes muscle fragility. It was Dr. Rudnicki's discovery that dystrophin also plays a regulatory role in muscle stem cells where it enables ongoing muscle repair and regeneration. As muscle damage evolves and cannot be efficiently repaired by normal processes, connective tissue and fat replace muscle fibers, causing inevitable muscle weakness and ultimately, destruction.

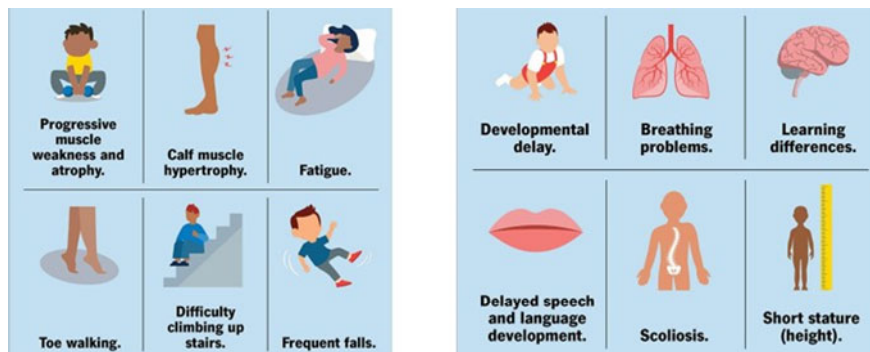
Figure 2
WHAT DUCHENNE MUSCLES LOOK LIKE



Source: Satellos, Inc.

Figure 3 depicts some of the common symptoms experienced by patients with Duchenne, where patients typically lose their ability to walk by the early teens, require ventilation support in their late teens, and eventually die due to heart and lung failure.

Figure 3
COMMON SYMPTOMS OF DUCHENNE MUSCULAR DYSTROPHY



Source: The Cleveland Clinic.

The average life expectancy for patients with Duchenne is mid-twenties (noting that with comprehensive healthcare intervention patients can reach mid-thirties). The disease occurs in approximately one in 4,000 male births, with approximately 20,000 babies worldwide born with it every year. Patients with Duchenne face a unique set of challenges due to psychosocial issues and transitions of care, including to their mental health and independence, functionality, and quality of life in critical domains, such as education, employment, and personal interactions.

Current treatment approaches share one common aspect—they are focused on existing muscle fibers, where the emphasis is on trying to repair the damage that has already occurred to these fibers or lessen/slow the impact of the damage on those fibers (Figure 4). This includes gene therapy and exon skipping in their current iterations. To the Company’s knowledge, Satellos is the only company focused on the idea of repairing and regenerating muscle by correcting muscle stem cell division to reset the body’s innate ability for self-repair and regeneration. The Company has been at the forefront of describing this disease as a disease of failed regeneration as opposed to a disease of muscle degeneration. The reason the fibers become so damaged is that they are not able to repair themselves in the normal fashion. Satellos believes that this can be corrected.

Figure 4

DUCHENNE: A FATAL DISEASE WITH NO CURE

Satellos is focused on restoring, repairing, and regenerating



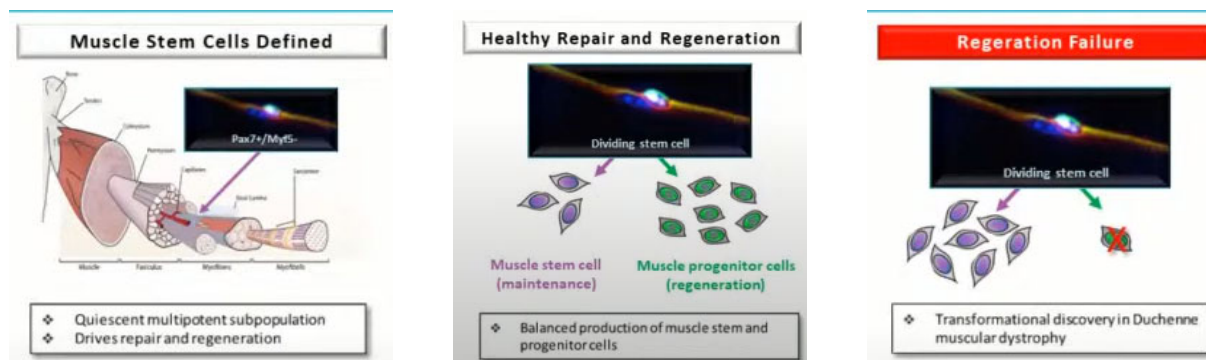
Source: Satellos, Inc.

Foundational Discoveries

The significant discoveries upon which Satellos is based are depicted in Figure 5. The first discoveries (left side) illustrate Dr. Rudnicki (biography on page 8) and his team’s seminal identification and characterization of muscle stem cells as a specialized sub-population of pluripotent stem cells, residing deep within the muscle fiber and capable of differentiation to produce muscle progenitor cells (middle), and subsequently, in healthy situations throughout life, drive ongoing muscle repair and regeneration. Muscle stem cells, in response to damage, produce both a stem cell and a differentiated cell, called a muscle progenitor cell, in a balanced fashion to both preserve the stem cell pool for future use and enable the generation of new muscle cells. That elegant and regulated process is what enables the repair and regeneration of muscle fiber. In a paper published in *Nature Medicine* in 2015, Dr. Rudnicki identified that in muscular dystrophy, this regulated process of producing progenitor cells goes awry. Due to the absence or defects in the dystrophin protein, the body’s stem muscle cells are unable to produce sufficient progenitor cells to allow muscle repair and regeneration to occur as needed throughout life (right side of Figure 5). Satellos believes that this fundamentally profound discovery changes the entire nature and potential narrative of how to treat this disease.

Figure 5

FOUNDATIONAL DISCOVERIES: GROUNDBREAKING DISCOVERIES INTO REGENERATION IN HEALTH AND DISEASE



Source: Satellos, Inc.

Development Pipeline

Overview

Satellos' development pipeline is based on biological discoveries in the area of muscle stem cell regulation and muscle regeneration made by Dr. Rudnicki. The Company believes these discoveries and advances may have relevance to understanding and treating a range of degenerative muscular disorders and conditions. Satellos is focused on developing new classes of therapeutic drugs that may help damaged muscles repair and regenerate themselves. The Company has obtained rights to granted patents and patent applications with respect of this portfolio from the Ottawa Hospital Research Institute (OHRI), further described on page 7.

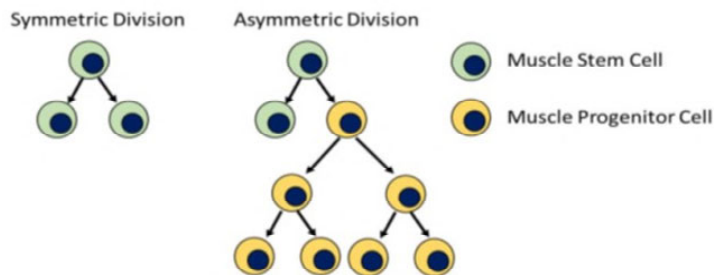
Satellos believes that Dr. Rudnicki's discoveries in muscle stem cell regulation offer insight into a possible cause of degenerative muscle disorders (that have previously not been recognized), which can be treated therapeutically. The Company is building on these discoveries to invent and develop new classes of small molecule therapeutics (i.e., drugs which ideally can be taken by mouth) designed to address this root cause in which it can help muscle fibers repair and regenerate. Satellos believes this approach may have applicability across a broad range of degenerative conditions, from lethal genetic diseases to aging-related muscle loss—areas where the medical need for new treatment is significant. Satellos intends to pursue multiple applications for its technology to treat muscle degeneration diseases and muscle loss associated with aging and injury.

The Company's first application of its technology is directed towards the discovery and development of a small molecule drug for the treatment of Duchenne muscular dystrophy, a disease with no known cure and one in which and treatments are largely palliative or partially effective. Duchenne is an orphan disease with a significant medical need for new therapeutic approaches that have the potential to improve quality and duration of life.

Science of Muscle Stem Cells

Two decades ago in a landmark publication, Dr. Rudnicki was the first to define so called muscle stem cells ('satellite cells') and characterize a sub-population as legitimate multipotent stem cells capable of both self-renewal and regeneration. Since this publication, Dr. Rudnicki's laboratory, based out of the OHRI, has pursued a singular research campaign under his direction to discover the regulatory underpinnings of muscle stem cell biology. These efforts have led the Rudnicki Lab to effectively 'crack the code' on how muscle stem cells functionally contribute to muscle regeneration and homeostasis through highly orchestrated processes involving the regulation of 'symmetric' and 'asymmetric' division by specific biological stimuli or conditions, as illustrated in Figure 6.

Figure 6
MUSCLE STEM CELLS UNDERGO SYMMETRIC OR ASYMMETRIC DIVISIONS IN RESPONSE TO INJURY STIMULI
MUSCLE PROGENITOR CELLS ARE GENERATED TO PRODUCE NEW MUSCLE TISSUE OR REPAIR INJURED MUSCLE



Source: Satellos, Inc.

Essentially, symmetric divisions result in two identical copies of the stem cell through the process of self-renewal. By contrast, asymmetric stem cell divisions result in one stem cell being produced and one differentiated daughter cell, called a progenitor muscle cell. Progenitor muscle cells then undergo normal **mitosis** to generate potentially thousands of new cells that eventually incorporate into functional muscle tissue.

The Rudnicki Lab was the first to explain how these specialized muscle stem cells reacted to cues from their environment triggering them to spring into action and begin producing fast dividing progenitor cells. These initial findings have made an important contribution to the current understanding that a multipotent stem cell population exists within the muscle environment (known colloquially as the “niche”) and is responsible for maintaining muscle growth, regeneration, and repair throughout an individual’s lifetime. Furthermore, they have significant implications for understanding disease processes and developing new therapeutic approaches to treat them. Dr. Rudnicki has connected deficits in either symmetric or asymmetric division to multiple muscle wasting and degenerative diseases. For these and other contributions to the field, he was recently given one of the highest scientific honors in the world, inducted as a Fellow into the Royal Society (an independent scientific academy in the United Kingdom, dedicated to promoting excellence in science for the benefit of humanity <https://royalsociety.org/>).

MyoReGenX™ Discovery Platform

The muscle stem cell ‘niche’ resides deep within the muscle tissue. Muscle stem cells respond to signaling molecules and stimuli from this environmental niche to physically orient themselves in space and undergo either a symmetric or asymmetric division. To better study and identify these processes as well as advance the translation of these findings to humans as potential therapies, Dr. Rudnicki developed a proprietary muscle stem cell screening platform, the MyoReGenX™ Discovery Platform, which is an automated microscopy system that can track and identify the divisions of individual muscle stem cells in response to various stimuli. The Rudnicki Lab determined how to sustain the muscle stem cell in as near a natural setting as possible (i.e. preserving the muscle bundle in order to reliably study their function). Developing this technology has taken years and represents a trade secret to which Satellos has exclusive commercial access to pursuant to the Company’s relationship with the OHRI.

Using MyoReGenX™, Satellos has identified several biochemical pathways and drug targets by which muscle stem cells are amenable to modulation and tested numerous potential drug candidates for their potential to regulate muscle stem regeneration capacity. This work has also led to the identification of disease specific deficiencies in either symmetric and asymmetric stem cell divisions, including sarcopenia, **cachexia**, and Duchenne. The Company is building on these and other findings and actively implementing MyoReGenX™ in its drug discovery and development programs, beginning with Duchenne, its lead development program.

Lead Development Program: Duchenne Muscular Dystrophy

As the most common fatal genetic disorder diagnosed during childhood, Duchenne affects approximately one in 4,000 male births per year with approximately 20,000 babies worldwide born with it every year. Early signs of motor impairment and delays in motor-related milestones begin between the ages of two to five. Rapid disease progression and muscle weakening typically follow, resulting in patients usually being wheelchair-bound by age 12. In their late teenage years, Duchenne patients begin to suffer from **cardiomyopathy**, a condition that reduces the heart’s ability to pump blood. Eventually, these patients may experience respiratory failure, the inability to breathe due to weakness in the muscles of the diaphragm, and heart failure, which is the leading causes of death in these patients. There is no known cure for Duchenne and existing treatments are only moderately effective.

Duchenne is triggered by a change or mutation in the dystrophin gene that results in the loss of the dystrophin protein. Dr. Rudnicki recently discovered that muscle stem cells, as a direct result of the loss of the dystrophin protein, are unable to properly divide. In addition to its commonly recognized role in stabilizing muscle, the dystrophin protein has a second, previously unrecognized role as a signal transduction molecule. In this role, the dystrophin protein is expressed in muscle stem cells where it directs muscle stem cells to ‘polarize’ (i.e., change their spatial orientation) to enable the stem cell to divide in an ‘asymmetric’ fashion whereby it:

- a) preserves the muscle stem cells that initiate repair and regeneration (green cells in Figure 6, page 16) while
- b) simultaneously creates an entirely different cell, namely, a muscle progenitor cell (yellow cells in Figure 6, page 16), through which multiple rounds of conventional cell mitosis generates new muscle.

Dr. Rudnicki's hypothesis is that in Duchenne patients, the process of 'asymmetric' division is severely impaired; thus, the production of muscle progenitor cells to repair muscle is dramatically reduced. Because of this, these patients are unable to keep up with the continuous damage to their muscles throughout their lives. These are induced by the most basic physiological muscle contractions requiring repair and regeneration of muscle, including basic functions, such as standing, walking, lifting, breathing, and climbing stairs.

Dr. Rudnicki believes that he has identified a root cause of the progressive nature of Duchenne which, to date, had not been well understood. Noteworthy is that recently published independent findings from the Duchenne research community have demonstrated support for his hypothesis in humans. The researchers conducted a genetic analysis of a large cohort of Duchenne patients (some of whom maintained ambulation for a decade or longer than the majority of their peers) in an attempt to identify genetic factors that could explain this phenomenon.

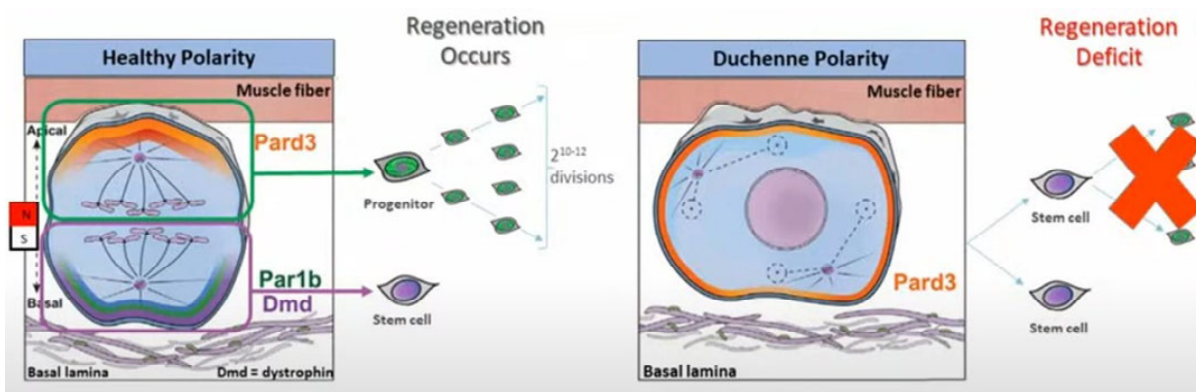
After describing several believed factors, one was theorized by the study findings to have the ability to affect polarity and alter the regulation of muscle stem cell regeneration capacity in a similar fashion as the small molecule drugs that Satellos is developing. These findings may be seen as third-party evidence in humans for the potential value of the Company's approach. In a healthy muscle stem cell, the muscle stem cell repair and regenerate normally throughout life by a process of cell division no different than any other cell, with the exception that in the case of a stem cell, it has to produce the tissue type it is going to become. It does that when it divides by creating a cell that is like itself and then a cell that is unlike a stem cell.

The role that the dystrophin protein plays, which is Dr. Rudnick's fundamental discovery, is that it is responsible for helping the stem cell to properly establish and orient itself against the muscle fiber in a perpendicular fashion. These cells actually change their spatial orientation and become oriented North South between the muscle fiber and the **basal lamina**. Before Dr Rudnicki's discovery, the dystrophin protein was not known to be expressed in the muscle stem cells. In its normal course existing in the muscle stem cell, it establishes polarity that allows the cell to create a stem cell when it divides. As shown in Figure 7 (page 19), these are the two centrosomes of what become nuclei of the two new cells; one becomes a stem cell or remains a stem cell and one becomes a muscle progenitor cell that then goes on to divide as muscle progenitor cells and these cells ultimately fuse into or become new fibers.

As it relates to muscular dystrophy, when a Duchenne muscle stem cell attempts to divide, it does not have the Duchenne protein to anchor the South pole. Thus, it proceeds to flop around deep in the muscle fiber as it attempts to divide and occasionally produces a progenitor cell, but for the most part dividing to create two stem cells (Figure 7, page 19, right side).

Figure 7

MUSCLE REGENERATION FAILS WHEN STEM CELLS DO NOT ESTABLISH 'POLARITY'



Source: Satellos, Inc.

Nationwide Children's Hospital Study

There is now human data that was generated from the largest study ever done in Duchenne patients by the most well-known center for treating Duchenne patients in the world, Nationwide Children's Hospital (<https://www.nationwidechildrens.org/>) in Columbus, Ohio. Nationwide Children's Hospital is the epicenter for Duchene muscular dystrophy treatment, where these patients go to get treated and where the geneticists are the physicians. The study was conducted completely unrelated to Satellos by geneticists and physicians at Nationwide who treat Duchenne patients. What they observed was that there has always been some boys who walk a little longer than their peer group. In this case, they identified boys, many of whom continued to walk well into their twenties and some into their 30s.

A group of these physician geneticists (with the lead author being Dr. Kevin Flanagan) noticed outlier boys with Duchene could keep walking despite having the disease. It is logical to think that if a patient is able to keep walking with this disease, then his legs must have enough muscle to bear the patients' weight (otherwise he could not keep walking). So with a leap of faith, these physicians undertook a retrospective analysis of 419 boys with Duchenne—the largest cohort ever studied—to ask the question: Why could these boys keep walking? This was a big departure in the Duchene community since the question usually is: Why are they in a wheelchair?

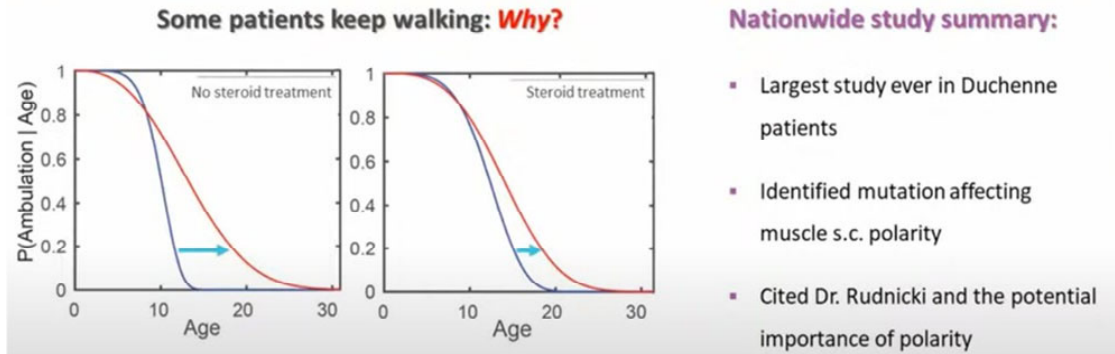
Based on this question, the physicians undertook **genome-wide association studies (GWAS)** to help scientists identify genes associated with a particular disease (or another trait). This method studies the entire set of DNA (the genome) of a large group of people, searching for small variations, called single nucleotide polymorphisms or SNPs (pronounced "snips"). In their paper, which they published in an online journal, the physicians concluded that there could be a number of genetic explanations, but the most likely was a particular mutation called a SNP, which directly affected the muscle stem cells in these boys and would appear to have restored their regenerative capacity by altering the polarity of the stem cells. The physicians concluded that studying muscle stem cells was key for the long term when considering this disease. Furthermore, this meant that studies needed to continue to look at Dr. Rudnicki's work as it proved genetically that dystrophin is not needed in the muscle fibers to be able to keep walking and this was genetic proof in humans.

With this information and based on facts from the physicians' work at Nationwide Children's Hospital stating that they have studied this group of 419 boys diagnosed with Duchene who are able to keep walking without dystrophin, this study showed that something else was happening that was regenerative based and likely related to these patients stem cells. Figure 8 (page 20) depicts the children in this study becoming young adults (red line), where the chart is showing how these boys continue to walk and have a normal sort of outcome from the disease condition (blue line).

Figure 8

EVIDENCE IN PATIENTS: DUCHENNE STUDY CITES POLARITY AS POTENTIAL DISEASE MODIFIER

Represents human proof of concept for Satellos' approach



Source: Satellos, Inc.

When looking at the difference of what would explain why some boys can walk 10 to 20 years longer than their peers (and well past any expectations), the most common characteristic was that these children had a mutation that affected the polarity of their stem cells. Specifically, a particular genetic change that led directly to the muscle stem cells being able to continue to produce progenitor cells.

Satellos' Unique Approach

Figure 9 summarizes the problem and Satellos' approach. The left side shows that in Duchenne patients, the muscle stem cells do not properly orient themselves and do not produce enough progenitor cells. Satellos has identified biochemical pathways (i.e. the protein networks that talk to and give signals to muscle stem cells), to where there are ways to intervene in those pathways and reset polarity and re-establish that North-South orientation, leading to the production of progenitor cells. The Company has identified small molecule drug candidates that act on those biochemical pathways in order to make that outcome occur. Satellos has identified more than one pathway, prioritized these biochemical pathways, and picked one of them, the **Notch pathway**. They further have identified a specific protein target within this pathway and codenamed it K9.

Figure 9

SATELLOS APPROACH: CORRECT POLARITY WITH DRUG TO RESTORE MUSCLE REGENERATION



Source: Satellos, Inc.

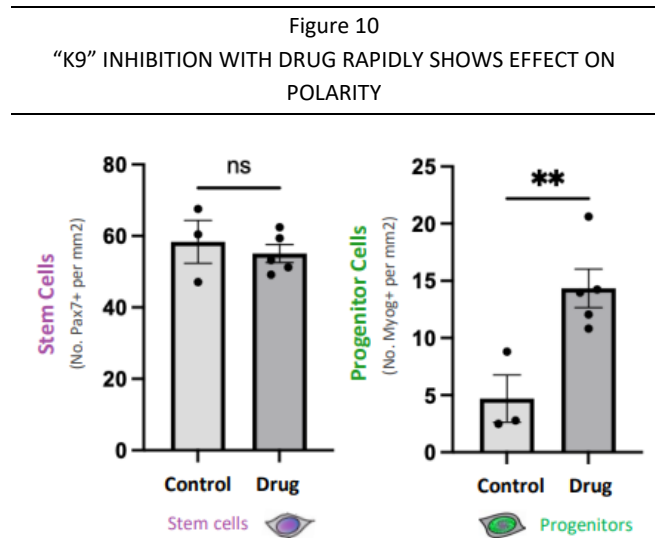
Recent Update

In January 2023, Satellos announced that it had designated SAT-3153 as its lead development candidate. SAT-3153 is a protein kinase inhibitor that targets a particular protein in the Notch signaling pathway (codenamed "K9"). Subsequent to results obtained through genetic ablation of K9, Satellos theorized that targeting K9 could modulate asymmetric muscle stem cell division. Because K9 is already the target of other pharmaceutical interventions in a different disease setting, the Company was able to synthesize existing K9 inhibitors to test the hypothesis. These studies showed that inhibiting K9 caused a modulation in muscle stem cell division, enhanced muscle regeneration, and increased muscle mass/function. Satellos expects to begin IND-enabling studies for SAT-3153 in the near term.

Preclinical Studies Support Targeting K9

Satellos recently provided additional preclinical data supporting the targeting of K9. Using a compound that is already under clinical investigation that targets K9, the Company performed preclinical proof-of-concept experiments to determine the effect of inhibiting K9 on muscle stem cell polarity and division. Importantly, these results were not performed with SAT-3153; rather they were performed with a completely separate compound also targeting K9.

Figure 10 shows the result of treating **Mdx mice**, which are used as a model for studying Duchenne, with the K9 inhibitor. The graph on the left shows that following treatment of the mice, there is no change in the number of muscle stem cells between mice treated with drug and those treated with placebo. The graph on the right shows that mice treated with drug had a significantly higher percentage of progenitor cells than mice treated with placebo, suggesting that the drug is pushing the muscle stem cell population toward asymmetric division. In patients with DMD, it is the lack of asymmetric division in muscle stem cells that ultimately leads to muscle degeneration; therefore any treatment that can increase the number of asymmetric divisions could lead to a restoration of muscle tissue and function.



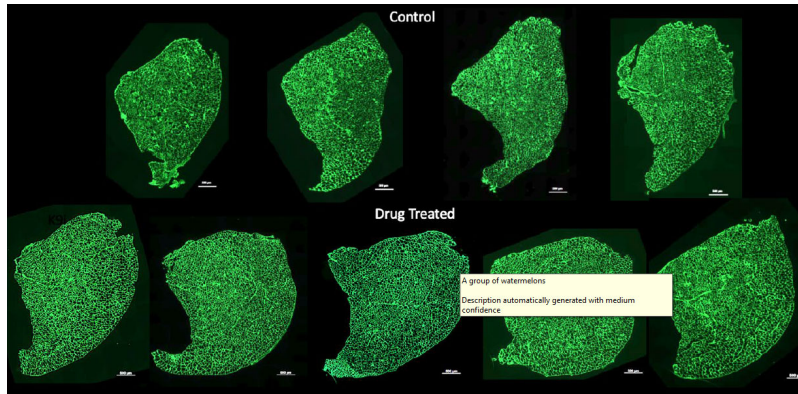
Source: Satellos, Inc.

Significant Increase in Muscle Size and Function in Duchenne Muscular Dystrophy Disease Model

Satellos announced in early February 2023 that its proprietary MyoReGenX™ assay platform identified a protein kinase (K9) as a potential drug target to modulate polarity in muscle stem cells. Using a known inhibitor of this kinase target as a reference compound for generating proof of concept to guide future drug development efforts with its own compounds, Satellos treated Mdx mice, a gold-standard experimental model for studying Duchenne, for a period of two weeks. Drug treated muscles were larger in size than untreated control muscles by an average of 40% and displayed about a 25% increase in ability to generate force, approaching levels seen in normal mice (Figure 11, page 22).

Satellos believes that a dysfunction in the normal process of stem cell polarity in response to muscle damage represents a previously unrecognized root cause of Duchenne. The goal of correcting polarity in Duchenne is to restore the body’s innate ability to regenerate muscle in response to the ongoing damage experienced by people living with Duchenne.

Figure 11
DRUG TREATED MUSCLES WERE LARGER IN SIZE THAN UNTREATED CONTROL MUSCLES BY AN AVERAGE OF 40% & DISPLAYED ABOUT A 25% INCREASE IN ABILITY TO GENERATE FORCE

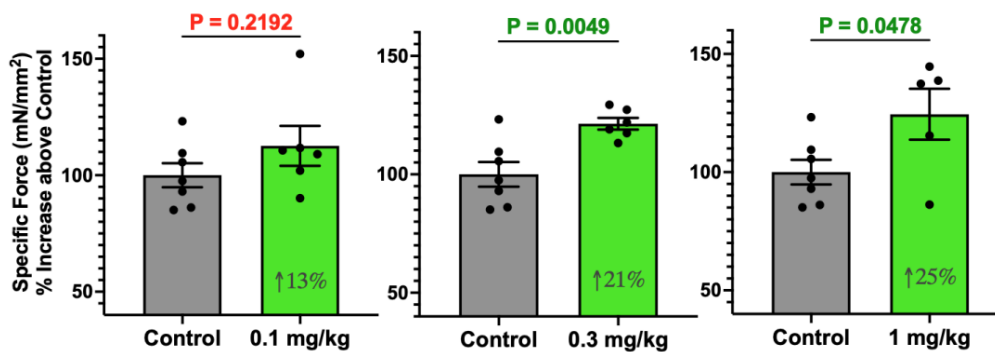


Source: Satellos, Inc.

Rapid increase in muscle force in dose dependent manner

In addition, the increase in muscle size shown in Figure 11 (above) is also accompanied by a dose-dependent increase in muscle force. Figure 12 (below) illustrates the specific muscle force for drug-treated and placebo-treated mice. As the dose of drug increases, those mice experience a proportionate increase in their muscle force. These results indicate that not only are the mice generating muscle tissue, but that this muscle tissue is functional and leads to an increase in muscle strength.

Figure 12
RAPID INCREASE IN MUSCLE FORCE IN DOSE DEPENDENT MANNER



Source: Satellos, Inc.

Create, Prioritize, and Advance Novel Small Molecule Drug Candidates Into Further Preclinical Studies

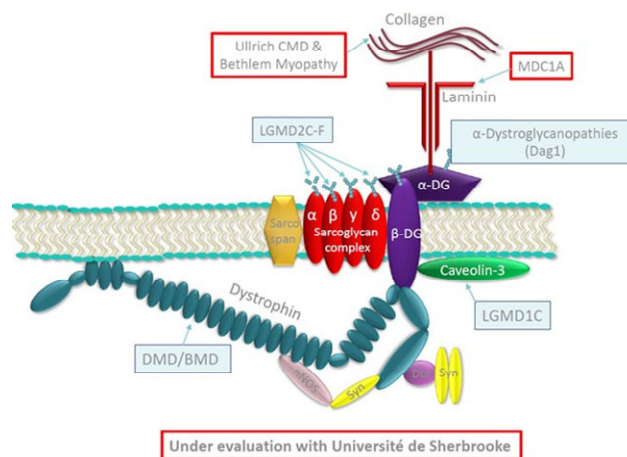
Satellos' compounds have been designed to be potent and selective inhibitors of a particular kinase protein in the Notch pathway (which the Company is calling K9 for confidentiality purposes).

On January 3, 2023, the Company indicated that results from preclinical ADME, PK, and in vivo studies led to designation of SAT-3153 as its lead development candidate for the treatment of Duchenne. In a subsequent study with SAT-3153, in an acute injury model intended to determine if drug is acting rapidly on mechanism, Mdx mice treated with SAT-3153 displayed a statistically significant effect on polarity through new progenitor muscle cell formation versus placebo controls (n=5 per group) after one (1) week. In a further in vivo study, Mdx mice treated with SAT-3153 four times per week versus placebo controls (n=8 per group) showed a 19% increase in muscle force after two weeks. Additional preclinical studies have shown SAT-3153 to have no binding of the hERG channel (a key requirement to rule out possible cardiac toxicity), a plasma protein binding level of < 90% (indicating significant levels of free drug are available to initiate a therapeutic effect), and oral bioavailability. The Company is continuing to conduct preclinical studies to confirm the drug candidates' suitability for further development and establish the appropriate dosing regimens, including oral dosing, to be used in its pre-IND toxicology studies and to inform its plans for dosing in clinical trials in humans. In addition, the Company has identified numerous potential back-up compounds.

Follow-On Program(s)

Beyond Duchenne, there are more than 30 types of muscular dystrophy that affect humans. The Company believes that some of these forms of muscular dystrophy may show potential as follow-on programs using the same development candidate intended to treat Duchenne, which could expand market demand. Every form of muscular dystrophy has a unique cause that manifests into conditions ranging in severity from benign, small impairments in motor function to the full loss of ambulation or even death. Satellos is interested in a subset of dystrophies associated with a multiprotein complex expressed in muscle and other tissues, known as the **Dystrophin-associated Glycoprotein Complex (DGC)**, as shown in Figure 13.

Figure 13
DYSTROPHIN ASSOCIATED PROTEIN COMPLEX



Source: Satellos, Inc.

Satellos has identified several forms of muscular dystrophy where the mechanism of action may provide a therapeutic benefit to patients, believing these conditions may represent opportunities to expand indications and perhaps grow the market for its therapeutics. The Company expects to evaluate these forms of muscular dystrophy to determine the extent to which impaired muscle stem cell divisions arise and whether the Company's therapeutic drug candidates may be of benefit.

Other dystrophies are known to be characterized by an underlying disease gene, which normally produces a protein that interacts via the DGC with dystrophin. In diseased individuals where the function of these proteins is disrupted, the function of the DGC complex may be disrupted as well. Satellos has prioritized several of these dystrophies where it believes the mechanism of action may provide a therapeutic benefit to patients. These indications are summarized in Figure 14. These estimates are based on the current information known to health experts, patient registries, and advocacy groups and are subject to change, and may or may not reflect the actual prevalence of these conditions. As these diseases represent orphan or ultra-orphan indications, generally with few if any viable treatment options, reliable market data does not exist.

Figure 14

Condition	Epidemiology
Collagen VI MD (Ullrich & Bethlem)	1 in 143,000
LAMA2 MD (MDC1A)	1 in 50-400,000
Limb Girdle MD (LGMD)	1 in 15-120,000
Dyostroglycanopathies	1 in 50-100,000

Source: Satellos, Inc.

Université de Sherbrooke (UdeS) Agreement

On January 3, 2022, as part of Satellos’ plan to investigate the potential for its drug candidates in other dystrophic conditions, the Company entered into the Université de Sherbrooke (UdeS) Agreement. Under this Agreement, the parties will assess Satellos’ candidate drug molecules in disease models of rare or ultra-rare dystrophies, which are believed to display signs of muscle regeneration failure, including **Lama-2 Related Muscular Dystrophy** (prevalence estimates of between one in 50,000 and one in 400,000 births) and **Collagen-VI Related Muscular Dystrophy** (prevalence of severe form of the disease estimated to be one in 1,000,000 births). Both disease indications are highly underserved and may provide tremendous opportunities for early clinical trial readouts as well as afford the potential for nondilutive funding avenues along with obtaining orphan and rare pediatric disease designations.

Disease Expansion Indication: Congenital Muscular Dystrophy Type 1A

On October 12, 2022, Satellos reported new data generated under its Sponsored Research Agreement with the Université de Sherbrooke showing preliminary proof of concept in a second rare disease, Congenital muscular dystrophy type 1. In this study, collaborators showed the potential for treatment with a Satellos drug candidate to modulate the muscle stem cell division process and restore regeneration. Satellos presented this preclinical proof of concept data at the World Muscle Society Congress in Halifax, Canada on October 14, 2022.

Second Drug Development Program

In addition to the lead program, which is centered on the promotion of muscle stem cell asymmetric division in Duchenne, Satellos has licensed a large body of intellectual property related to compositions and methods for promoting symmetric division of muscle stem cells through the action of a naturally occurring protein called Wnt7a. Previous to discovering the specific deficits related to muscle stem cell asymmetric division in Duchenne, Dr. Rudnicki made several discoveries surrounding the signaling pathway that controls symmetric division of muscle stem cells, specifically the Wnt7a planar cell polarity pathway. Research from Dr. Rudnicki’s laboratory demonstrated that administration of Wnt7a protein to muscle stem cells regulates the ‘planar cell polarity pathway’ and results in stimulation of symmetric stem cell division. Stimulation of muscle stem cell symmetric expansion serves to expand the resident pool of muscle stem cells, effectively enhancing the substrate material available to participate in muscle regeneration, producing a large stronger muscle tissue.

Through the use of recombinant protein engineering, Dr. Rudnicki successfully produced a modified Wnt7a protein that can be injected into muscle tissue to enhance the muscle regeneration process. As well as promoting symmetric stem cell division, delivery of Wnt7a protein also stimulates the physical migration, proliferation, and differentiation of muscle progenitor cells—all aspects of the muscle regenerative process. While not suitable for correcting the asymmetric division deficit observed in Duchenne, stimulating symmetric division of muscle stem

cells for the purposes of enhancing regeneration with Wnt7a may be an effective treatment strategy in other muscle wasting conditions. In particular, indications where significant muscle damage and/or atrophy (loss) has occurred due to physical trauma or disease may represent opportunities for evaluation of Wnt7a therapeutic modality. Satellos has identified a number of potential indication areas that may justify future follow up through the design and execution of preliminary preclinical experimentation. Figure 15 summarizes some of these findings.

Figure 15
TARGET INDICATIONS FOR A SYMMETRIC DIVISION PROGRAM

Condition	Epidemiology	Potential Approach
Hip/Knee Replacement Surgery	Nearly 1 million knees and hips are replaced each year in the US (Source: Kremers et al. 2015. The Journal of Bone and Joint Surgery.)	Improve muscle recovery time, prevent slips, trips, falls
Stress Urinary Incontinence	Observed prevalence between 4-35% of adult women (Source: Luber et al. 2004. Reviews in Urology.)	Enhance muscle function, restore bladder control
Fascioscapulohumeral M. Dystrophy	1 in 20,000 persons Enhance or prevent further loss of muscle function	Enhance or prevent further loss of muscle function

Source: Satellos, Inc.

Potential Market

Satellos is developing novel drug candidates to treat degenerative, life altering, and lethal muscle disorders. Its lead therapeutic program is focused on the discovery and development of a novel, disease modifying treatment for the genetic pediatric disease, Duchenne muscular dystrophy. The Company estimates the combined Duchenne patient population across all ages to be approximately 21,500 individuals in the major pharmaceutical markets of Canada, the U.S., the EU, and Japan (using prevalence estimations and census data). Based on approved product sales data, the current market for therapeutics to treat Duchenne is estimated at \$700 million with projected growth estimates ranging from \$2 billion to \$13 billion (Source: Drugs.com/price-guide/emflaza) as newer therapeutics intended to be disease modifying, such as microdystrophin gene replacement therapies, are developed and come to market.

Current standard of care for Duchenne patients consists of corticosteroid treatment with either prednisone or branded Deflazacort (with Deflazacort priced at \$100,000 annually). While playing an important role in alleviating inflammation and modestly modifying the course of this disease, corticosteroids do not treat the underlying causes of the disease and are associated with a myriad of serious side effects.

A newer approach is exon skipping, which attempts to address a root cause through the technique of skipping over the mutated exon. One recently approved exon-skipping drug therapy, Exondys 51, carries an annual cost of approximately \$600,000 (Source: Drugs.com/pricguide/exondys-51). It is approved in the U.S. and indicated only for patients with an exon 51 mutation, which represents roughly 12% of the Duchenne population. Despite these factors and its modest efficacy, sales of Exondys 51 in 2019 were \$380 million. The latest product approval for Duchenne; the first ever micro-dystrophin expressing gene therapy which aims to produce a surrogate version of the dystrophin protein in mature muscle fibers, is indicated for use in ambulatory children aged 4 through 5 with Duchenne, and carries an estimated \$3.2 million price tag.

A second genetics-based therapy (which alters ribosome activity during translation), Translarna, is indicated for approximately 15% of the Duchenne population that carry a nonsense mutation and is currently only approved in the EU. It is also only modestly effective yet its sales in 2019 were \$180 million (Source: PTC Therapeutics 2019 Annual Report). Despite efficacy issues, growth estimates by market analysts are high, with an estimated compound annual growth rate of ~41% (Source: Grandview Research Market Analysis Report Duchenne Muscular Dystrophy Drugs Market Size) for these and other products in late-stage development. Satellos believe these positive estimates are due, in part, to the lack of effective treatment alternatives and, to some extent, to the desire of patients and their families to have relief from this devastating, progressive, and eventually fatal disease. A summary of drug approvals that are expected to drive Duchenne market growth during the next decade is provided in Figure 16 (page 26).

Figure 16

NEW DRUG APPROVALS EXPECTED TO DRIVE DMD MARKET GROWTH DURING THE NEXT DECADE

(Q3 2016) Sarepta Therapeutics' Exondys 51 received FDA approval

• *First-in-class exon-skipping therapy, it is currently the only novel disease modifying therapy approved in U.S.*

(Q1 2017) PTC Therapeutics' Emflaza received FDA approval

• *Emflaza is the first corticosteroid that has received FDA approval to treat DMD in U.S.*

(Q3 2021) Santhera Pharmaceuticals' Raxone Received FDA Approval

• *Potential therapy for patients who are not amenable to Translarna or exon-51 skipping therapies*

(Q1 2022) Italfarmaco Givinostat Received FDA & EMA Approval

• *Givinostat's novel MOA is a histone deacetylases inhibitor that helps to prevent fibrosis*

(Q1 2022) PTC Therapeutics' Translarna Received FDA Approval

• *Translarna is a disease-modifying drug that will compete for a high price against Exondys 51*

(Q2 2023) Sarepta Therapeutics' Elevidys received FDA accelerated approval.

• *The first ever micro-dystrophin expressing gene therapy which aims to produce a surrogate version of the dystrophin protein in mature muscle fibers.*

Source: GlobalData.

To date, there have not been any treatment options for Duchenne that have demonstrated long-lasting disease-modifying potential. Based on the possible transformative nature of Satellos' technology in treating a root cause of the disease, the Company views significant market potential for its products. Satellos believes that a novel therapeutic with disease modifying potential could be priced in excess of \$100,000 annually—which is significantly less than exon skipping drugs. Based on these estimates, with a potential patient population of 21,500 persons, Satellos believes that the annual revenue potential for an effective, disease modifying drug treatment for Duchenne could potentially exceed \$1 billion annually.

The Company's method is unique in an alternative manner. All current treatment approaches (of which Satellos is aware), include gene correction and target mature muscle tissue. Thus, they may not be effective in addressing the inherent deficits in muscle regeneration (i.e., repairing and regenerating muscle fibers), which Satellos has identified as a potential root cause of the progressive, ongoing muscle loss experienced by people living with Duchenne.

In contrast, Satellos is attempting to restore the regenerative capacity of muscle stem cells in Duchenne patients with its drug candidates. The goal of the Company's treatment is not to simply increase the bulk of muscles but instead to boost the ability of Duchenne patients to self-repair and regenerate functional muscle, increasing muscle strength, and enhancing both the quality and duration of their lives. Based on the unique mechanism of action of its drug candidates, Satellos believes its therapeutic approach has the potential to be disease modifying as a stand-alone treatment for Duchenne, as well as complementary to other treatment methods.

Development Strategy

Since the Company is developing therapeutics to treat a number of rare diseases, it is eligible and intends to apply for specific government sponsored development programs that could offer strategic assistance during the regulatory review process, accelerated approval timelines and speed to market, as well as offer enhanced market exclusivity. These programs, when awarded, can be of great value to the receiving parties and include:

- **Orphan Drug Designation.** Satellos announced that it had received Orphan Drug Designation on August 1, 2023. The Orphan Drug Designation program provides status to drugs that are defined as those intended to treat, prevent, or diagnosis a rare disease or condition, such as Duchenne. Benefits for drugs that are bestowed ‘orphan status’ may include tax credits on clinical testing, waiving of the new drug application (NDA) user fee, and eligibility for a seven-year market exclusivity upon drug approval.
- **Rare Pediatric Disease Designations.** Satellos announced that it had received Rare Pediatric Disease Designation on August 1, 2023. As a developer of a therapeutic for Duchenne, Satellos is eligible and intends to apply for Rare Pediatric Disease Designation. Benefits for this designation include the potential for receiving a priority review voucher that is awarded after approval of the drug. This priority review voucher can be utilized to reduce the review process timeframe for a separate future drug development program. There is also an aftermarket for these vouchers, which have been monetized by others for substantial sums.
- **Accelerated Approval.** The FDA instituted its Accelerated Approval Program to allow for earlier approval of drugs that treat serious conditions and that fill an unmet medical need based on a surrogate endpoint. A surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. The use of a surrogate endpoint can considerably shorten the time required prior to receiving FDA approval. Drug companies are still required to conduct studies to confirm the anticipated clinical benefit. These studies are known as Phase 4 confirmatory trials. If the confirmatory trial shows that the drug provides an actual clinical benefit, then the FDA grants traditional approval for the drug. If the confirmatory trial does not show that the drug provides a clinical benefit, the FDA has regulatory procedures in place that could lead to removing the drug from the market.

Business Strategy

To further advance its development candidates and possibly speed up its regulatory approvals, Satellos seeks to first demonstrate the safety and potential efficacy for treating Duchenne patients in early clinical trials (i.e., Phase I/II). The Company is developing predictive biomarkers of efficacy, which could have the potential to shorten the timeline to approval for sale, subject to further clinical study. At the same time, Satellos expects to file for all applicable FDA designations where criteria can be met that could benefit its workflow, including orphan drug and rare pediatric disease designations, along with accelerated approval. This could enable the Company’s ability to explore and evaluate three broad approaches for optimizing value creation and monetization:

- (1) leveraging market demand into development and commercialization partnerships with biopharmaceutical companies in risk-reward sharing arrangements;
- (2) continuing to advance development and commercialization of the Company’s lead clinical product for Duchenne; and
- (3) exploring merger and acquisition (M&A) transactions.

The above may include a mix of joint venture arrangements, regional partnerships, or co-development and co-marketing collaborations (depending on clinical trial outcomes, market, and environmental conditions, and risk/reward trade-offs). With these relationships, Satellos expects to pursue having its products approved and registered for sale globally.

Drug Development Infrastructure

Satellos is working to create the first ever therapy intended to regulate muscle stem cell driven regeneration capacity and possibly address what could be the root cause of the progressively degenerating nature of Duchenne. In particular, the Company seeks to discover and develop a first-in-class, small molecule drug that can be taken by mouth. To achieve this goal, Satellos has established and continues to enhance a customized drug development infrastructure comprising an interleaved cascade of proprietary assays and a network of specialized **contract research organizations (CROs)**.

These assays span from procurement and generation of chemical matter through to establishing preclinical efficacy. Chemical compounds that progress through this process are evaluated for: (1) specific inhibition of the particular drug target, which Satellos finds as being of interest; (2) the ability to regulate the associated signal transduction cascade that affects asymmetric stem cell division and progenitor cell production; (3) the physico-chemical behavior once injected into living animals; and (4) the ability to alter the disease course in typical Duchenne preclinical models. Satellos' CROs were selected following a competitive process for their unique expertise in a range of drug development skills, including: (a) drug fragment screening; (b) in silico drug screening; (c) chemical synthesis; (d) biomolecular assay development; (e) x-ray crystallography; and (f) DNA encoded library screening.

The Company has established an in-house team of drug development professionals to oversee its workplan and manage its infrastructure. Heading up the team is Dr. Phil Lambert, Chief Technology Officer (biography on page 9), who is a neuroscientist by training and a high-performing preclinical executive with over twenty-five years of drug discovery and development expertise. In addition, the Company has hired Dr. Alan Jacobs (biography on page 9) as Chief Medical Officer to lead and oversee the clinical development strategy.

Outsourced Research and Development Agreements

To optimize Satellos' product development candidates, the Company outsources certain of its research and product development activities. Considerations for determining which activities are outsourced include (but are not limited to): cost, expertise, capacity, track record, communications, relationships, and quality assurance. Descriptions of these relationships (where information has been made available) are provided in the accompanying section.

HD Bioscience Co., Limited (a subsidiary of WuXi AppTec (Hong Kong) Limited)

Satellos has entered into a contractual arrangement with HD Bioscience Co., Limited, under which, in exchange for payments made, HD Bioscience performs various critical drug development activities at the request of Satellos. Specifically, per Satellos' request, HD Bioscience performs chemical synthesis, evaluates biochemical and cell-based activity, as well as establishes pharmacokinetic profiles of all its newly synthesized chemical matter.

Wuxi Biortus Biosciences Co., Limited

Satellos has entered into a contractual arrangement with Wuxi Biortus Biosciences Co., Limited under which, in exchange for payment made, Wuxi Biortus Biosciences performs activities related to the generation of a protein crystal structure of Satellos' drug target, as well as various biophysical experiments related to the evaluation of drug-target binding. These experiments aim to develop an understanding of how the Company's compounds interact with its drug target for the purposes of compound structure refinement towards a potent and selective drug-like molecule with known target binding properties.

Charles River Laboratories

Satellos has entered into contractual agreements with Charles River Laboratories, under which, in exchange for payments made, Charles River Laboratories performs various critical drug development activities at the behest of Satellos. Under the guidance of Satellos, Charles River Laboratories performs non-clinical studies in the areas of analytical and bioanalytical method development, safety, and toxicology that are required for IND submission.

Eurofins CDMO Alphora Inc

Satellos has entered into contractual agreements with Eurofins CDMO Alphora Inc., under which, in exchange for payments made, Eurofins CDMO Alphora Inc. performs various critical drug development and manufacturing activities for Satellos. Under the guidance of Satellos, Eurofins CDMO Alphora Inc. performs chemical manufacturing, scale-up, quality and control studies that are required for IND submission.

Myologica, LLC

Satellos has entered into contractual agreements with Myologica LLC, under which, in exchange for payments made, Myologica LLC will independently perform various preclinical drug discovery activities for Satellos, which may include, but not be limited to, specialized preclinical modelling studies in which Myologica's has expertise and which support the Company's drug discovery program for Duchenne muscular dystrophy.

Hospital Research Institute (OHRI)

Effective May 1, 2018, Pre-Arrangement Satellos and the OHRI entered into a sponsored research agreement, during the term of which OHRI agreed to carry out specific research and development activities according to a prescribed statement of work under the direction of the Company's co-founder, Dr. Rudnicki (the OHRI SRA). Under the OHRI scientific research agreement, Dr. Rudnicki leads a dedicated R&D team who are engaged solely to execute the agreed R&D program of Satellos.

Université De Sherbrooke (UdeS) To Study Rare Muscular Dystrophies

Satellos entered into a scientific research agreement with Université de Sherbrooke in December 2021. The Université de Sherbrooke is in the heart of one of Quebec's three major research hubs. Known for its sense of innovation, the Université de Sherbrooke is a key partner of senior and regional governments in the promotion of economic, cultural, and social development. Under the Agreement, Satellos and Université de Sherbrooke will collaborate on research activities to identify additional disease indications for Satellos' novel muscle regeneration technology in select preclinical models of rare muscular dystrophies. The workplan commenced January 3, 2022, for an initial period of 12 months. Together, the parties will assess Satellos' candidate drug molecules in disease models of rare or ultra-rare dystrophies, which are believed to display signs of muscle regeneration failure, including: Lama-2 Related Muscular Dystrophy (prevalence estimates between 1 in 50,000 and 1 in 400,000 births) and Collagen-VI Related Muscular Dystrophy (prevalence of severe form of the disease estimated to be 1 in 1,000,000 births).

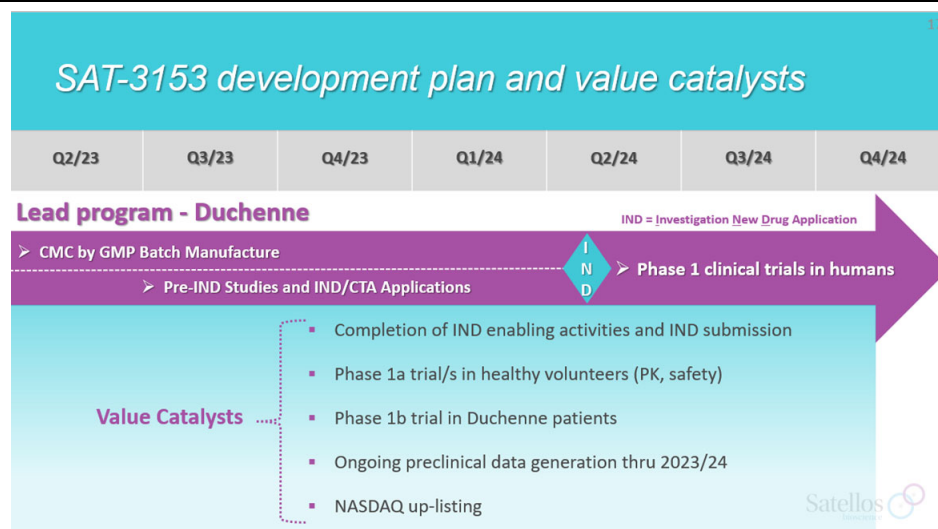
Milestones

Potential 12-Month Milestones

Satellos expects to advance the following initiatives in the coming twelve months:

- R&D program in the Company’s research lab under the direction of the CSO, Dr. Michael Rudnicki, focused on supporting the preclinical development plan, assessing and validating new drug targets and new disease indications, and continuing to generate new IP.
- Larger-scale and longer-duration in vivo studies to establish a range of pharmaceutical and competitive benchmarks with the Company’s drug candidates that will inform clinical trial development.
- Conduct of requisite non-GLP and GLP dose ranging and in vitro and in vivo safety (including toxicology) studies to support clinical trial development and IND/CTA applications.
- Execution of prescribed studies; compilation of the Chemistry, Manufacturing and Controls (CMC) section of the Investigational New Drug Application (IND)/Clinical Trial Authorization (CTA) applications and Good Manufacturing Practice (GMP) manufacturing of drug candidate substance to be used in Phase I clinical trials.
- Initiation of a first-in-human Phase 1 clinical trial in healthy volunteers to evaluate the safety and pharmacokinetics of the Company's lead drug candidate.
- In Q2 2023, the Company’s ongoing efforts demonstrated that a chemical entity closely related structurally to SAT-3153, named SAT-3247, showed what the Company believes to be particularly attractive and possibly enhanced pharmaceutical properties to SAT-3153.

Figure 17
SAT-3153 DEVELOPMENT PLAN & VALUE CATALYSTS



Source: Satellos, Inc.

Strategic Development Plan

Going forward, the Company's strategic development plan is based on the following three components:

- (1) A focus initially on rare diseases of significant need and limited treatment options, where Satellos believes its approach can be impactful, beginning with Duchenne.
- (2) Broadening into additional rare disease indications, which is where its research relationship with Université de Sherbrooke may contribute (described further on pages 24 and 29).
- (3) Expanding into disease conditions with greater numbers of patients, such as those related to aging, injuries and trauma, and degeneration associated with chronic illness.

Satellos has identified several biochemical pathways and drug targets by which muscle stem cells are amenable to modulation and has generated numerous potential drug candidates with chemical structures and properties that could yield suitable drug-like properties. The Company is now able to select and advance a number of these candidates into further research and development experiments to test their effect in its predictive MyoReGenX™ Discovery Platform and affirm their potential suitability as drug candidates for treating Duchenne.

The Company's objective is to optimize the top prospective candidate(s) and advance the lead development candidate through the requisite IND enabling studies and submit an IND with the FDA in Q2 2024 with the intention of initiating the Phase 1 clinical trial mid-2024.

Competition

The Company faces competition from pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies, as well as academic institutions, government agencies, and other public and private research organizations that conduct research in Duchenne muscular dystrophy. Many of these competitors or potential competitors have greater financial resources as well as development, selling, and marketing capabilities than Satellos. Numerous therapeutic approaches and product candidates, including but not limited to exon skipping, gene therapy and CRISPR-CAS, antifibrosis, myostatin inhibition, mitochondrial and metabolic modulation, and others are in or close to commencing clinical development in humans.

While the Company believes its approach is distinctive and may complement other approaches due to its different mechanisms of action, there can be no guarantee that this proves to be the case and one or more competing products may get to market faster with better outcomes for patients, thus reducing the potential market opportunity for the Company's product candidates.

Currently Marketed Products

There are currently four leading products globally for Duchenne muscular dystrophy, with Translarna and Exondys 51 (eteplirsen) being the only disease modifying mutation-specific therapies approved for the condition (Figure 18).

Figure 18
LEADING MARKETED PRODUCTS FOR DMD

Generic Name	Brand	Company	Approved Indication	Availability
ataluren	Translarna	PTC Therapeutics	DMD	5EU*
deflazacort	Emflaza	PTC Therapeutics	DMD	US
eteplirsen	Exondys 51	Sarepta Therapeutics	DMD	US
prednisolone	Prednisolone	Asahi Kasei Pharma; Mylan Seiyaku	DMD	Japan

Source: GlobalData, Pharma Intelligence Center [Accessed January 30, 2018]

PTC Therapeutics is the leading therapeutic within the Duchenne marketplace, with Translarna in the EU and Emflaza in the U.S. (and no other therapies in the pipeline) with future participants seeking to capitalize on gaps in the treatment landscape concentrated on disease-modifying mutation specific therapies. Sarepta Therapeutics has a very promising product channel with the accelerated approval of Exondys 51 in the U.S. There are also two Phase III exon skipping therapies in its pipeline, which could enhance the Company's profile.

PTC Therapeutics

PTC Therapeutics is a science-driven, global biopharmaceutical company focused on the discovery, development, and commercialization of clinically differentiated medicines that provide benefits to patients with rare disorders. PTC currently has two approved medicines for treating Duchenne resulting from a nonsense mutation in the dystrophin gene in ambulatory patients aged two years and older: Translarna™ (ataluren) and Emflaza™ (deflazacort). Emflaza® (deflazacort) is approved in the U.S. for the treatment of Duchenne in patients two years of age and older. Translarna™ (ataluren) has been approved in the UE and Brazil for ambulatory patients aged two years and older with Duchenne resulting from a nonsense mutation in the dystrophin gene. The Company has headquarters in South Plainfield, New Jersey.

Sarepta Therapeutics

Sarepta Therapeutics is focused on engineering precision genetic medicine for rare diseases. The company holds leadership positions in Duchenne and limb-girdle muscular dystrophies (LGMDs), and currently has more than 40 programs in various stages of development. Sarepta's pipeline is driven by its multi-platform Precision Genetic Medicine Engine in gene therapy, RNA, and gene editing. The company currently has one approved medicine,

Exondys 51, which is the first FDA-approved Duchenne muscular dystrophy treatment for patients who have a confirmed genetic mutation in the dystrophin gene that can be treated by skipping exon 51. In some patients, it helps the body make a shorter form of the dystrophin protein. The drug was approved under accelerated approval, which allows it to be approved based on a marker that is considered reasonably likely to predict a clinical benefit. Exondys 51 treatment increased the marker, dystrophin, in skeletal muscle in some patients. Verification of a clinical benefit may be needed for Exondys 51 to continue to be approved. The latest product approval for Duchenne is also from Sarepta; the first ever micro-dystrophin expressing gene therapy, which aims to produce a surrogate version of the dystrophin protein in mature muscle fibers. Elevidys (delandistrogene moxeparvec-rokl) was approved through the FDA accelerated approval pathway for ambulatory children aged 4 through 5 with Duchenne muscular dystrophy. Verification of clinical benefit is pending as of the publication date of this document. The publicly listed pricing for this therapy is \$3.2 million.

Asahi Kasei Pharma; Mylan Seiyaku

Prednisone is a synthetic corticosteroid currently used off-label to delay muscle weakness progression in Duchenne patients. The treatment was approved by the FDA in the 1950s and is prescribed due to its anti-inflammatory properties.

Pipeline for Products Addressing Duchenne Muscular Dystrophy

The Duchenne pipeline currently contains 108 products, with more than 70% of pipeline drugs for this indication in discovery or preclinical development. Sarepta Therapeutics has the highest number of pipeline drugs for Duchenne with 14 pipeline drugs, 8 in pre-clinical, and one in pre-registration. Small molecules targeting glucocorticoid receptors are the most popular drugs currently on the market for Duchenne, with development of new therapies focused on antisense oligonucleotide drugs that target dystrophin. However, there is still a high number of small molecule candidates for Duchenne. Figure 19 summarizes the more promising late stage drugs in development.

Figure 19
THERAPEUTIC CANDIDATES IN LATER-STAGE CLINICAL DEVELOPMENT FOR DMD

Drug	Company	Phase
Eteplirsen (Exondys 51)	Sarepta Therapeutics Inc	Approved* (US); Phase III (5EU)
Idebenone (Catena / Sovrima / Raxone)	Santhera Pharmaceuticals	Phase III
Casimersen (SRP-4045 or Exon 45 PMO)	Sarepta Therapeutics Inc	Phase III
Givinostat	Italfarmaco SpA	Phase III
Golodirsen (SRP-4053)	Sarepta Therapeutics Inc	Phase III
RG-6206 (BMS-986089)	F. Hoffmann-La Roche	Phase II/III

*Given Accelerated FDA approval in US.

Source: GlobalData, Pharma Intelligence Center [Accessed January 30, 2018]

- Exondys 51 is the first-in-class exon skipping therapy that has been granted accelerated approval in the U.S. and was launched in 2016. It is currently in Phase III in the EU. It could potentially become a market leader in Duchenne.
- Givinostat, an inhibitor of histone deacetylases, is the first treatment to show histological improvement of muscle fibers.
- Roche and Bristol Myers Squibb have entered into a licensing agreement for the development of RG-6206, a myostatin inhibitor for Duchenne.

The early stage pipeline for Duchenne has a higher proportion of antisense oligonucleotides versus other genetic disorder indications due to their action on dystrophin, Duchenne’s main drug target. This is a change from current marketed drug focus, glucocorticoid receptors. Almost half of pipeline drugs for genetic disorders are small molecules, however, only a third of Duchenne pipeline drugs are small molecules. Duchenne has a higher proportion of antisense oligonucleotide drugs than other genetic disorder indications due to antisense oligonucleotides acting on dystrophin mRNA, currently the main drug target against Duchenne. Currently, there is only one marketed drug for Duchenne that is an antisense oligonucleotide and targets dystrophin. The remaining marketed drugs are small molecules and predominantly target glucocorticoid receptor.

Preclinical Pipeline Efforts Within Muscular Dystrophy Arena

Preclinical companies within the muscular dystrophy space include Avidity Bioscience, Inc. (RNA-NASDAQ), Fulcrum Therapeutics, Inc. (FULC-NASDAQ), Solid Biosciences Inc. (SLDB-NASDAQ), and Edgewise Therapeutics, Inc. (EWTX-NASDAQ), which are all companies with pre-clinical or early clinical development efforts. These companies are perhaps a year to two ahead of where Satellos may be considered, noting the valuations among these companies underscore the importance the market has placed withing this therapeutic category.

Investment Highlights

- **Satellos Bioscience Inc. is pioneering discoveries into the body's regenerative processes and developing a novel category of small molecule drugs that have the capacity to reset the body's innate ability to rebuild muscle from within.** Based on its findings, the Company's drug products are expected to be able to reset the body's natural ability to self-repair skeletal muscle to treat degenerative muscle diseases.
- **Degenerative muscle conditions have devastating impacts on the daily lives of millions of patients and are inadequately served by current treatments.** Satellos believes that its development efforts may have potential benefits in many disease situations, including rare genetic conditions, such as Duchenne muscular dystrophy—an incurable disease that affects an estimated 1 in 4,000 live male births per year worldwide—as well as diseases associated with chronic illnesses and aging. The market size for these treatments is estimated at over \$20 billion, with a number of companies in early stages of development within this sector valued at over \$500 million.
- **Satellos' lead drug program is focused on treating Duchenne muscular dystrophy, a fatal genetic disease with insufficient treatment options.** Beginning early in childhood, Duchenne progressively destroys muscle tissue, a process that Satellos has discovered is due to a failure of the body's regenerative processes to self-repair. The Company believes that by resetting the self-repair and regeneration process, its therapeutics may have the potential to transform the treatment paradigm and create better outcomes for individuals living with the disease.
- **There is tremendous value to be created in muscular dystrophy as there is the potential for accelerated approval of a drug candidate that goes into Duchenne patients since to date, there is no truly effective treatment for these patients other than corticosteroids, which only delays the inevitable by a couple of years.**
- **Satellos has the capital needed, having recently raised \$55 million from world class healthcare institutional investors to advance its lead clinical candidate through Phase 1 clinical trial and meaningful data readouts.** Cash runway is currently projected through 2025.
- **Satellos' directors and officers possess a range of expertise and knowhow in which to develop and execute on its business strategy and support its technical capabilities.** The Company believes it possesses the ability to execute on its commercial and operational strategy with an experienced team in place to drive the strategy forward.
- **Satellos has licensed a large body of intellectual property related to compositions and methods of use of a naturally occurring protein called 'Wnt7a', which plays a role in the symmetric stem cell division central to muscle regeneration.** It is believed that Wnt7a may be an effective treatment strategy in muscle wasting conditions other than Duchenne, including indications where significant muscle damage and/or atrophy (loss) has occurred due to physical trauma or disuse. Satellos expects to explore the use of Wnt7a as a therapeutic modality for these cases.

Recent Highlights

September 20, 2023—Satellos Bioscience Inc. announced that management will participate in the Cantor Fitzgerald Global Healthcare Conference 2023 taking place September 26-28th in New York City.

September 7, 2023—Announced that it has entered into an agreement with ICP Securities Inc., a dealer member in good standing with the Canadian Investment Regulatory Organization, to provide market making services for the securities of Satellos Bioscience Inc. in accordance with TSX Venture Exchange policies, subject to the receipt of approval by the TSXV. The services agreement aims to assist in maintaining a reasonable market and improving the liquidity of Satellos securities.

September 5, 2023—Announced that it had appointed Elizabeth Williams, CPA, CA as Chief Financial Officer of the Company. Warren Whitehead, CPA, CMA transitioned to Head of Strategy. Ms. Williams has nearly 20 years of expertise leading corporate finance and strategy for public biotech companies listed on Nasdaq and TSX.

August 1, 2023—Announced that that U.S. Food and Drug Administration (FDA) had granted Orphan Drug Designation and Rare Pediatric Disease Designation to SAT-3153 for the potential treatment of Duchenne. These designations provide certain benefits including the potential for a seven-year market exclusivity upon regulatory approval, exemption from FDA application fees, tax credits for qualified clinical trials, and a priority review voucher and a Rare Pediatric Disease Priority Review Voucher.

June 29, 2023—Following the Company's Annual General Meeting, Mr. Franklin Berger was appointed to the Board of Directors of Satellos. Mr. Berger spent 12 years in sell-side equity research, most recently as a Managing Director, U.S. Equity Research at J.P. Morgan Securities, Inc., where he was involved with the issuance of over \$12 billion in biotechnology company equity or equity-linked securities covering 26 publicly traded biotechnology companies.

June 7, 2023—Appointed Alan K. Jacobs, MD as Chief Medical Officer (CMO) of the Company. Dr. Jacobs is an accomplished and experienced clinical development professional with an extensive and impressive track record in both early and late-stage therapeutic development in the neuroscience and rare disease spaces.

May 17, 2023—Closed an equity offering, issuing a total of 110 million equity securities for gross proceeds of \$55 million and included participation from funds managed by Avidity Partners, Qiming Venture Partners USA, Perceptive Advisors, Soleus Capital, FMB Research, Allosterly Investments and other leading healthcare specialized institutional investors.

March 19, 2023—Announced that Ryan Mitchell, PhD and Vice President of Business Development would present preclinical proof of concept data in a poster presentation at the Muscular Dystrophy Association (MDA) Clinical and Scientific Conference being held in Dallas, TX from March 19-23, 2023.

March 9, 2023—Announced a new study with SAT-3153, in an acute injury model intended to determine if the drug is acting rapidly on mechanism, Mdx mice treated with SAT-3153 displayed a statistically significant effect on polarity through new progenitor muscle cell formation vs placebo controls (n=5 per group), after one (1) week. In a further in vivo study, Mdx mice treated with SAT-3153 four times per week vs. placebo controls (n=8 per group) showed a 19% increase in muscle force after two weeks. Additional preclinical studies have shown SAT-3153 to have no binding of the hERG channel (a key requirement to rule out possible cardiac toxicity), a plasma protein binding level of < 90% (indicating significant levels of free drug are available to initiate a therapeutic effect), and oral bioavailability.

February 6, 2023—Announced results from multiple preclinical studies in a disease model of Duchenne muscular dystrophy demonstrating a significant increase in muscle size and function in Duchenne disease model, 40% increase in muscle size compared to control mice and 25% increase in muscle force, approaching levels seen in normal mice.

January 03, 2023—Announced that it has designated SAT-3153 for development towards an IND filing for the treatment of Duchenne after evaluating results from preclinical ADME, PK, and in vivo studies.

Historical Financial Results

Figures 20, 21, and 22 (pages 37-39) provide a summary of Satellos' most recent key financial statements for the quarter ended June 30, 2023. All dollar amounts are expressed in Canadian currency unless otherwise noted.

Figure 20
SATELLOS BIOSCIENCE INC.
(Formerly known as iCo Therapeutics Inc.)
CONSOLIDATED STATEMENTS OF LOSS AND COMPREHENSIVE LOSS

	Notes	3 Months ended		6 months ended	
		2023	2022	2023	2022
		June 30,		June 30,	
EXPENSES					
Professional fees		849,044	508,099	1,080,127	892,581
Stock-based compensation (options)	9	369,443	419,071	570,301	880,820
Management fees		871,243	414,073	1,284,933	824,876
Research and development contracting		873,012	616,049	1,591,777	1,303,478
Insurance		8,066	7,575	16,132	15,501
Interest on long-term debt		112,265	-	120,653	-
Amortization of intangible asset	3	-	107,214	-	213,250
Depreciation of equipment	7	1,277	850	2,313	1,648
Licenses		5,198	38,880	21,396	54,010
Conferences		3,951	50,041	14,991	65,513
Travel		56,872	39,623	102,188	44,058
Other expenses		23,075	9,379	42,525	20,360
Foreign exchange loss		1,191,182	27,534	1,188,746	24,697
LOSS BEFORE THE FOLLOWING:		(4,364,628)	(2,238,388)	(6,036,082)	(4,340,792)
OTHER INCOME					
Interest income		250,455	2,066	257,311	5,099
Gain (loss) on derivatives	3	(700)	-	(1,758)	-
Research and development tax credits (reversal of claim)		-	-	-	(16,431)
NET LOSS		(4,114,873)	(2,236,322)	(5,780,529)	(4,352,124)
OTHER COMPREHENSIVE (LOSS)/GAIN					
Items that may be reclassified to net loss					
Foreign currency translation adjustments		(443)	3,191	(1,500)	1,500
TOTAL COMPREHENSIVE LOSS		(4,115,316)	(2,233,131)	(5,782,029)	(4,350,619)
Basic and diluted loss per share		(0.05)	(0.07)	(0.10)	(0.13)
Weighted average number of common shares (basic & diluted)		78,176,104	32,997,613	60,017,866	32,997,613

Source: Satellos, Inc.

Figure 21
SATELLOS BIOSCIENCE INC.
(Formerly known as iCo Therapeutics Inc.)
CONSOLIDATED STATEMENTS OF FINANCIAL POSITION

<u>As at</u>	<u>Notes</u>	<u>June 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
ASSETS			
Current			
Cash and cash equivalents	6	48,726,538	1,923,536
Accounts receivable and other receivables		177,591	-
Sales tax receivable		180,800	260,435
Prepaid expenses and deposits		13,041	45,559
Derivatives, net	3	1,224	2,982
Total current assets		49,099,194	2,232,512
Equipment	7	12,590	8,036
Assets held for sale			
Intangible asset	3	3,916,190	3,916,190
Investments	3	42,670	41,906
		3,958,860	3,958,096
TOTAL ASSETS		53,070,644	6,198,644
LIABILITIES			
Current			
Accounts payable and accrued liabilities	8	1,805,196	2,830,124
Current portion of debentures	4	178,875	-
Total current liabilities		1,984,071	2,830,124
Long term debt			
Non-current portion of debentures	4	1,896,777	-
Total Liabilities		3,880,848	2,830,124
SHAREHOLDERS' EQUITY			
Common shares	5	61,916,480	30,209,208
Pre-Funded Warrants	5	17,771,925	-
Warrants	10	3,658,798	2,104,991
Contributed surplus	9	3,245,588	2,675,287
Accumulated deficit		(37,394,228)	(31,613,699)
Accumulated other comprehensive loss		(8,767)	(7,267)
Total shareholders' equity		49,189,796	3,368,520
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY		53,070,644	6,198,644

Commitments and contingencies (Note 15)

Subsequent events (Note 16)

The accompanying notes are an integral part of these condensed consolidated interim financial statements.

Source: Satellos, Inc.

Figure 22
SATELLOS BIOSCIENCE INC.
 (Formerly known as iCo Therapeutics Inc.)
CONSOLIDATED STATEMENTS OF CASH FLOWS

For the six months ended June 30, 2023 and 2022	Notes	Six months ended	
		June 30, 2023	June 30, 2022
CASH AND CASH EQUIVALENTS PROVIDED BY (USED IN):			
OPERATING ACTIVITIES			
Net loss		(5,780,529)	(4,352,124)
Items not affecting cash:			
Accrued interest on long-term debt, net of cash interest paid to debentureholders	4	56,902	-
Amortization of intangible asset	3	-	213,250
Depreciation of equipment	7	2,313	1,648
Stock-based compensation (options)	9	570,301	880,820
Foreign exchange gain(loss) on investments		(764)	-
Foreign exchange gain(loss)		1,189,510	24,697
Gain(loss) on derivatives	3	1,758	-
Net change in non-cash working capital balances:			
Accounts receivable		(177,591)	-
Sales tax receivable		79,635	300,057
Research and development tax credits receivable		-	16,431
Prepaid expenses		32,267	20,186
Accounts payable and accrued liabilities	8	(1,039,741)	(46,955)
		<u>(5,065,939)</u>	<u>(2,941,990)</u>
FINANCING ACTIVITIES			
Proceeds from issuance of Debenture Units	4	2,385,000	-
Cost of issuance of Debenture Units	4	(140,528)	-
Proceeds from exercise of warrants	10	10,000	-
Cost of exercise of warrants		(17)	-
Proceeds from issuance of Common Shares	5	35,148,610	-
Cost of issuance of Common Shares	5	(2,685,568)	-
Proceeds from issuance of Pre-Funded Warrants	5	19,850,993	-
Cost of issuance of Pre-Funded Warrants	5	(1,516,737)	-
		<u>53,051,753</u>	<u>-</u>
INVESTING ACTIVITIES			
Purchase of equipment	7	(6,867)	(1,250)
		<u>(6,867)</u>	<u>(1,250)</u>
Effect of foreign currency exchange rates on cash and cash equivalents		(1,175,945)	2,497
INCREASE IN CASH AND CASH EQUIVALENTS		46,803,002	(2,940,743)
CASH AND CASH EQUIVALENTS – Beginning		<u>1,923,536</u>	<u>4,871,263</u>
CASH AND CASH EQUIVALENTS – Ending	6	<u>48,726,538</u>	<u>1,930,520</u>

Source: Satellos, Inc.

Risks and Disclosures

This Executive Informational Overview® (EIO) has been prepared by Satellos Bioscience Inc. (“Satellos” or “the Company”) with the assistance of Crystal Research Associates, LLC (“CRA”) based upon information provided by the Company. CRA has not independently verified such information. Some of the information in this EIO relates to future events or future business and financial performance. Such statements constitute forward-looking information within the meaning of the Private Securities Litigation Act of 1995. Such statements can only be predictions and the actual events or results may differ from those discussed due to the risks described in Satellos’ statements on forms filed from time to time.

The content of this report with respect to Satellos has been compiled primarily from information available to the public released by the Company through news releases and other filings. Satellos is solely responsible for the accuracy of this information. Information as to other companies has been prepared from publicly available information and has not been independently verified by Satellos or CRA. Certain summaries of activities and outcomes have been condensed to aid the reader in gaining a general understanding. CRA assumes no responsibility to update the information contained in this report. In addition, for year one of its agreement, CRA has been compensated by the Company in cash of forty two thousand for its services in creating this report and for quarterly updates.

Investors should carefully consider the risks and information about Satellos’ business, as described below. Investors should not interpret the order in which considerations are presented in this or other filings as an indication of their relative importance. In addition, the risks and uncertainties overviewed in the accompanying section are not the only risks that the Company faces. Additional risks and uncertainties not presently known to Satellos or that it currently believes to be immaterial may also adversely affect the Company’s business. If any of such risks and uncertainties develops into an actual event, Satellos’ business, financial condition, and results of operations could be materially and adversely affected.

This report is published solely for information purposes and is not to be construed as an offer to sell or the solicitation of an offer to buy any security in any state. Past performance does not guarantee future performance. For more complete information about the risks involved of investing in the Company, as well as for copies of this report, please contact Satellos by calling (647) 660-1780.

Risk factors relating to the Company

The Company’s principal business is fundamentally constituted on the discovery and development of new drug candidates to treat muscle wasting disorders, initially for Duchenne. Due to the nature of Satellos’ business as a biotechnology company, the Company may be subject to significant risks and uncertainties, including but not limited to technical and scientific, regulatory and clinical, and business and financial, discussed below. Investors should consider all such risks and uncertainties and be aware that additional risks and uncertainties not currently known or reasonably foreseeable may arise.

Satellos has incurred significant losses since inception, and the Company expects to incur losses for the foreseeable future and may never achieve nor sustain profitability.

Since its inception, Satellos has incurred significant losses. The Company expects these losses to increase considerably in the coming years as it continues to dedicate its resources to conducting R&D, clinical trials and regulatory filings, commercialization activities, and general business operations. To achieve profitability, Satellos must develop and eventually commercialize a product or products with significant market potential either on their own or in collaboration with a partner. These development and commercialization activities are challenging, and include successfully inventing a novel product or products, completing preclinical activities and clinical trials in humans, obtaining regulatory approval for product marketing, and going to market. The Company may never realize revenue from its products and even if it does, it may not generate sufficient revenue to be profitable.

It will be many years before the Company expects to generate revenues from product sales to fund its operations, if ever.

The Company does not expect to have a product candidate approved for sale for several years as it advances its technology through the various stages of the drug discovery, preclinical development, clinical trial evaluation, and regulatory approval process. As a result, and as is typical for biotechnology companies in such circumstances, the Company anticipates financing its on-going cash requirements for the foreseeable future through a combination of equity offerings, debt financings, government, or other third-party funding, marketing, and distribution arrangements and other collaborations, partnership agreements and licensing arrangements, and government or philanthropic programs. There is considerable market risk and uncertainties associated with securing such arrangements that may adversely affect the Company's ability to pursue its business plan as intended and negatively impact its stock price.

The Company will need substantial additional funding to develop and realize commercial value for its technologies and drug candidates. Raising additional capital may not be possible on a timely basis or at all due to market conditions, or may cause dilution to existing shareholders, or require undue restrictions on or rights in its technologies or drug candidates.

R&D efforts in the biotechnology sector, which include drug discovery, and preclinical, clinical and regulatory development activities, are capital intensive and require significant investment. The Company expects R&D expenses to increase substantially as it scales its drug discovery efforts and advances its ensuing product candidates through the standard stages of biotechnology product development.

To continue its current business activities, achieve its milestones and fund increasing future research and product development expenses, the Company will require additional capital. Securing financing, if available, will likely require the Company to sell additional Common Shares or other financial instruments that are exchangeable for or convertible into Common Shares, and/or enter into development, distribution or licensing relationships, and/or incur additional debt, which may or may not be convertible into equity shares.

It is likely that any future debt financing arrangements would contain restrictive covenants that would impose significant operating and/or financial restrictions on the Company or include a lien on its assets. It is uncertain if these types of equity or debt financing will be available on a timely basis or at all, or available on reasonably acceptable terms. If available, they will be dependent on, among other things, the results and perceived value of its R&D efforts and product candidates, its ability to obtain regulatory approvals, the state of the capital markets overall, agreements with partners, and other relevant commercial considerations.

Any future financing activity may be dilutive to existing shareholders. If the Company cannot obtain sufficient funding on a timely basis or on reasonably acceptable terms, its ability to continue as a going concern and realize the value of its assets as well as pay its liabilities as they become due may be at risk. Consequently, it may be forced to significantly change or limit current or planned operations in order to safeguard its cash until such time, if ever, that sufficient proceeds from operations are generated. This could also lead to, among other things, the Company not taking advantage of business development opportunities, the termination or delay of future clinical trials for one or more of its product candidates, and jeopardize its ability to continue as a going concern.

Company may not be able to maintain its TSXV listing.

The Company will require significant infusions of capital to advance its development programs. If Satellos is unable to raise capital on a timely basis or satisfactory terms, its business prospects could be harmed and its stock price negatively affected. A sustained failure to raise capital, whether due to market conditions or development setbacks or other factors, may further cause the Company to fall below the minimum listing standards, such as share price and financial ratios, set by the TSXV. In such an event, its ability to maintain its listing may be compromised and the Company could be delisted. Delisting could have serious consequences for investor liquidity.

Risks associated with the novelty and early stage of development of the Company's technologies and therapeutic products or programs

The Company's programs are subject to significant technical risks and scientific unknowns due to their novelty and stage of development.

The Company's technology is based on highly original discoveries and hypotheses, and its drug development programs are of an early stage, being in the preclinical stage of the drug development process. As such, R&D activities over the next 12 months are expected to focus on three principal areas: (1) continuing to validate the biological safety and efficacy of novel mechanisms of action discovered by Dr. Rudnicki; (2) lead optimization (i.e., modifying and optimizing the chemical structures of potential drug candidates) to invent and nominate a lead development candidate and a Back-up Lead series; and (3) filing for appropriate intellectual property protection.

Technical or scientific setbacks are likely due to the nature of the scientific process and general uncertainties associated with the drug development process. While the Company has anticipated the potential for setbacks in its resource and timeline plans, it is possible that serious unforeseen setbacks could occur in any or all of these three focal areas. This could cause the Company to incur additional costs or experience delays in completing its plans on a timely basis, or, depending on their severity, possibly preclude the development and subsequent commercialization of its product candidates. Depending on the gravity of delays or cost increases, the share price of the Company may be adversely affected and potentially, its business operations could be materially harmed.

The Company's lead optimization efforts may not produce a lead drug candidate on a timely basis.

The Company's drug candidates for treating Duchenne are in the lead optimization stage of the drug discovery process. Five chemical series have been identified, from which dozens of putative lead drug candidates have been designed, synthesized, and tested *in vitro* in the Company's proprietary assays for enzymatic and biochemical activity. Several of these candidates have been further tested *in vivo* to assess their PK suitability and efficacy. Before nominating a development candidate, the Company anticipates undertaking multiple medicinal chemistry cycles encompassing compound design, synthesis, and testing with the intent of optimizing the specific properties which will meet its target product profile. There is a high degree of uncertainty in the medicinal chemistry process and accordingly, there can be no guarantee that the Company's chemistry efforts will prove to be successful on a timely basis nor that a suitable development candidate meeting its target product profile will ever be identified. A significant delay in or failure to nominate a development candidate would increase costs and would likely have a material adverse effect on the Company's value and stock price, and potentially impair its ability to continue operations.

The Company's drug product candidates may display serious adverse or intolerable side effects during preclinical development.

The Company's drug product candidates are in the preclinical phase of development. On a statistical basis, drug candidates at this stage of development have a high risk of failure. It is not uncommon for toxicologic, serious adverse, or intolerable side effects to be identified during the development of the drug product candidates in the biotechnology industry. If such adverse effects arise, the Company may incur additional costs and/or time delays in attempting to address the underlying issue/s giving rise to the adverse effects. If the Company is unable to correct the problem on a timely basis or at a reasonable cost, it may need to abandon development of the drug candidate or limit its development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe, or more acceptable from a risk-benefit perspective. Any or all of these outcomes could adversely affect the value of the Company and its stock price, and potentially impair its ability to continue operations.

The Company may not be able to translate its novel discoveries into viable therapeutic treatments suitable for clinical development.

The Company is pioneering a new approach to treating muscle disorders. Satellos' muscle stem cell discoveries are unique and the mechanisms of action it has uncovered have never been modulated for therapeutic purposes in muscle regeneration. The pioneering of this new pharmacology has caused the Company to face certain transaction hurdles. Among other things, the Company will need to determine the appropriate dosing regimes (including dose levels and frequency/interval of dosing) that elicit desirable effects and for how long such effects endure. Determining appropriate dosing regimes may involve significant iterative efforts, take longer than anticipated, or not be achievable at all. Significant delays or a failure to establish the appropriate pharmacological parameters to translate the Company's discoveries may severely impede Satellos' product and clinical development progress, which may result in materially adverse effects on its value and stock price, and could impair its ability to continue operations.

Modulating the EGFR pathway may require additional safety studies.

Preclinical studies are often designed to highlight the potential for untoward safety issues that may be expected to hinder development. The Company is cognizant of a theoretical risk that inhibition of the PTPX enzyme to modulate **epidermal growth factor receptor (EGFR)** signaling may promote tumorigenesis in individuals with pre-existing cancer, or those at high risk for developing cancer. While no direct evidence of such outcomes has been seen in preclinical studies conducted to date by the Company, plans are being established to experimentally evaluate these concerns as exhaustively as is practical given the state of the art of using preclinical research tools and models. Information derived from these experiments will be presented to regulators prior to receiving approval to commence with human clinical trials. There can be no guarantee that these results of these experiments will be acceptable to regulators and additional experimental studies may be requested prior to receiving approval to commence clinical trials in humans. This would delay the commencement of clinical trials, likely introducing additional costs and risk, and may adversely affect the Company's value and share price.

The Company's development candidate may exhibit unexpected issues during IND enabling studies, which may delay or prevent the commencement of clinical trials on a timely basis.

Prior to commencing clinical trials in humans, successful completion of which are a precondition for ultimately obtaining a product registration and marketing approval, a sponsoring company must submit a prescribed dossier to regulatory authorities in jurisdictions in which it is seeking approval to conduct clinical trials. Typical choices include the FDA in the U.S., the EMEA in Europe and Health Canada (HC); the filing dossier is known as either an IND submission in the case of the FDA or a CTA in the case of the EMEA and HC.

Prior to submitting an IND/CTA dossier, a body of largely experimental work is undertaken in order to generate the requisite data set expected by the regulators. During the execution of IND-enabling studies, it is possible that untoward effects that had not previously been seen in preclinical studies, such as a dose-limiting toxicity or a manufacturing issue, will manifest. Such findings may introduce material delays or add additional costs to the Company's timelines and budgets for commencing clinical trials. Additional financing may be required, which may cause dilution to shareholders. Depending on the severity of the issues, the Company's share price may be negatively affected and the competitive viability of its Duchenne program impaired.

Risks to the Company associated with clinical and regulatory processes

There can be no guarantee that the Company will obtain the required regulatory authorization/s to commence clinical trials in humans on a timely basis, or at all.

Prior to obtaining regulatory approval to register and begin marketing a new drug candidate, a sponsoring company must conduct exhaustive clinical trials in humans, often over many years, to evaluate and determine the safety and efficacy of its drug candidates. The Company has not commenced clinical trials for any of its future drug candidates to treat Duchenne or other muscle wasting disorders, in any jurisdiction.

Generally, sponsoring companies will seek authorization to conduct clinical trials in humans in one or more jurisdictions, such as with the FDA in the U.S., the EMEA in Europe, or Health Canada once it has completed the requisite preclinical development work. Securing FDA or Health Canada authorization to commence human clinical testing requires the submission of extensive preclinical and supporting information to the FDA or Health Canada for each product candidate to be tested. The process of obtaining authorization to commence human clinical testing, both in the U.S. and Canada, as well as abroad, is expensive and lengthy and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Regulators, such as the FDA or Health Canada, have substantial discretion in the authorization process and may refuse to accept any application or may decide that the submitting the Company's data is insufficient for approval to commence human clinical testing and/or require additional preclinical or other studies. In addition, varying interpretations of the data obtained from preclinical testing could delay, limit, or prevent authorization to commence human clinical testing of a product candidate.

Efficacy or other positive results of the Company's drug candidate(s) seen in preclinical animal model testing may not translate to and be seen in human clinical trials, which would have a deleterious effect on the clinical development and potential for regulatory approval of the Company's drug candidates.

Evaluating drug candidates in human clinical testing can be very costly, challenging to design and implement, and take significant time to complete. These trials are done in a stepped fashion from Phase I to Phase II to Phase III with the intent to show safety on a continuing, progressive basis through exposure to increased populations of healthy patient volunteers while in parallel, exploring and demonstrating the potential for beneficial therapeutic effect.

Clinical trials are inherently risky and there can be no assurance that the desired outcomes will be achieved nor that a drug candidate will progress smoothly from one step to the next. It is not uncommon in the biotechnology industry that positive efficacy or other beneficial therapeutic results seen in preclinical testing in animal models of a disease does not translate in an equivalent manner, or at all, to humans during clinical trial testing as animals are not always predictive of humans. This is true in Duchenne as well, where numerous therapeutic approaches that showed promise in preclinical developments did not demonstrate sufficient promise in human clinical testing to warrant continued development or market approval. There can be no assurance that positive or beneficial results shown by the Company's drug candidates in preclinical animal model testing will translate to meaningful benefits in humans, which are sufficient to justify and support continued clinical development. Such an outcome could potentially lead to the cessation of clinical development of the drug candidate(s), and adversely affecting the Company's market value and possible viability.

Clinical trials in humans may exhibit previously undetected side-effects, which may cause additional costs or delays in conducting clinical trials and possibly impede the Company's ability to complete clinical development of its drug candidate(s).

Unexpected or more severe adverse side effects than seen from preclinical safety testing can occur in human clinical testing as the number patients treated or duration of treatments increase. There can be no assurance that the Company's product candidates will not be shown in human clinical testing to have unacceptable side effects or toxicities not seen or predicted from preclinical safety assessments. If clinical trials of the Company's development candidate/s fail to demonstrate adequate safety to the satisfaction of Health Canada and the FDA (or similar regulatory authorities outside the U.S.) on a progressive basis through the phases of clinical development, the Company may incur additional costs or experience delays in completing, or ultimately be unable to complete the clinical development of its product candidate(s). Such an outcome may severely impair the Company's value and ability to continue operations.

Clinical trials of the Company's lead drug candidate(s) may be protracted due to a limited number of patients available for recruitment and may not be completed on a timely basis.

Duchenne is a rare disease, with an estimated total prevalence in the U.S. of 4,000 individuals and therefore represents a disease with a small patient pool for clinical testing. This patient pool is further reduced to approximately 1,000 individuals when considering the most widely utilized age range of patients between 5 and 9 years, which are often enrolled in studies where effects on ambulation are to be evaluated. Although Duchenne patients are often motivated to participate in clinical trials, the small number of patients available, compounded with the growing number of development candidates entering clinical testing, creates competition for patient enrollment during clinical studies. Failure to enroll sufficient numbers of patients in a reasonable amount of time in a clinical trial can significantly delay the time to completion of the trial, subsequent outcome analysis of the trial, as well as any future trials that rely on the outcomes of these studies. Such delays or lack of patient enrollment in clinical trials may cause the Company to incur additional costs or experience delays in completing, or ultimately to be unable to complete the clinical development of its product candidate(s). Such an outcome may severely impair the Company's value and ability to continue operations.

The FDA has not established a set of required or recommended clinical outcome measurements for studies in Duchenne.

The FDA has produced guidance on the development of drugs for the treatment of Duchenne; however there are no generally accepted criteria for how to design, implement, or evaluate clinical outcome measures that would provide any guarantee of a favorable review for the purpose of drug approval. The FDA has suggested that it will consider the use of existing outcomes measures developed for other clinical trials in Duchenne or related muscular dystrophies, as well as proposals for the use of novel outcome measures that are capable of measuring clinically meaningful effects in patients.

The FDA encourages sponsors to engage with them early to discuss use of previously utilized measures or the proposition of novel measures prior to submitting official clinical trial designs. The FDA suggests that sponsors should include an assessment of multiple efficacy endpoints, when feasible, to characterize the breadth of effects on dystrophin-related pathologies, including skeletal, respiratory, and cardiac muscle function, even if the primary endpoint is only one of these measures. The open-ended nature of these suggestions may result in selection of inappropriate endpoints that do not yield meaningful results, or a large number of endpoints that significantly increase the cost of clinical trials. Implementing open ended trial designs with multiple endpoints or having to redesign and execute additional trials due to inappropriate selection of clinical endpoints that do not yield meaningful results may cause the Company to incur additional costs or experience delays in completing, or ultimately be unable to complete the clinical development of its product candidate(s). Such an outcome may impair the Company's value and ability to continue operations.

Risks related to the Company's dependence on third-party service providers

The Company depends on timely access to highly skilled experts to conduct its drug discovery and development activities including in the areas of lead optimization, preclinical drug development, developing and submitting regulatory submissions necessary to obtain approval to conduct clinical trials, and conducting clinical trials. Many of these skills are quite specialized, costly to hire, and challenging to recruit, particularly at scale. The Company believes its core skills to be in muscle stem cell biology and the professional management of the drug development process. As high-quality expert resources are widely available in the biotechnology industry on a fee-for-service basis through third-party contract resource organizations (CROs), the Company intends to maintain a lean infrastructure focused on its core capabilities and engage CROs wherever it deems technically advantageous, timely and cost-effective to advance its drug discovery, and preclinical and clinical development activities.

The Company will engage specialized CROs on a fee-for-service basis to conduct its drug discovery and lead optimization chemistries and preclinical development, including pharmacology and IND-enabling studies; those third parties may not perform satisfactorily, including failing to meet deadlines.

By engaging CROs, the Company is implicitly relying on third-party entities to execute the agreed workplans and deliverables therein to a high skill level, on time, and within budget. While the Company intends to use due care in the selection, evaluating, and contracting of only the highest quality CROs with reputations for successfully meeting client needs, it is possible that one or more CROs may not meet their contractual obligations on a timely basis or at all. It may not be possible for the Company to effectively redirect their activities or resources to achieve the desired outcomes on time, within budget, or to the expected standard, thereby adding further uncertainty. Depending on the severity of the delays, performance deficiencies or cost overruns, the Company may be forced to change to a different CRO or CROs, which can be disruptive. If required to switch or add new CROs, management's attention and resources may be redirected and constrained until alternative service providers are in place. These changes may have undesirable knock-on effects to other components of the R&D plan and have the very real potential to extend timelines and increase costs by significant amounts.

The Company will rely on fee-for-service CROs to develop and submit its regulatory filings and to conduct and report on clinical trials for its development candidates, and those third parties may not perform satisfactorily, including failing to meet deadlines.

To submit regulatory applications to obtain approval for and to conduct clinical trials in humans for its development candidate or development candidates, the Company plans to engage third-party service providers with specialized domain expertise for: (1) drafting and submitting IND and CTA submission and interactions with key regulatory authorities, including the FDA and Health Canada; and/or (2) planning, executing, providing data management and analysis, and reporting of clinical trials with particular expertise in therapies to treat Duchenne. These may and likely will be different entities and could include academic institutions, CROs, hospitals, clinics, and other third-party collaborators. Should the Company be unable to maintain or enter into agreements with these third parties on acceptable terms, or if any such engagement is terminated prematurely, the Company may be unable to enroll patients on a timely basis or otherwise conduct the desired clinical trials in the manner and timeframe originally intended.

There is no guarantee that these third parties will devote adequate time and resources to the Company's clinical studies or perform as required by the agreed terms in the contract or in accordance with regulatory requirements. If these third parties fail to meet expected deadlines, fail to transfer the Company's regulatory information in a timely manner, fail to adhere to protocols or act in accordance with regulatory requirements, fail to perform in accordance with the agreed contract terms, or if they otherwise perform in a substandard manner or in a way that compromises the quality or accuracy of their activities or the data they obtain, then clinical trials of the Company's development candidates may be extended or delayed with additional costs incurred, or the clinical trial data may be rejected by the FDA, Health Canada, or other regulatory agencies. Such delays, cost increases, or rejections could impede or harm the development candidate's development and market potential and impair the market value and stock price of the Company.

Failure by CRO's to meet regulatory requirements, guidelines, and standards could be injurious to the Company.

The Company and its CROs are required to comply with Good Laboratory Practices (GLP) and current Good Clinical Practices (cGCP) regulations and guidelines enforced by the FDA, Health Canada, and comparable foreign regulatory authorities. Regulatory authorities enforce these GLP/cGCP regulations through periodic inspections of CRO laboratories, clinical services CROs, principal investigators, and clinical trial sites. Failure to comply with applicable cGCP regulations may result in the clinical data generated in clinical trials being deemed unreliable.

In addition, clinical trials must typically be conducted with products produced under the cGMP regulations per FDA, Health Canada, and other regulatory authorities. Failure to comply with these regulations may impede ongoing clinical development and ultimately, submission of marketing applications may be delayed. Depending on the gravity of the non-compliance, the FDA, HC, or other regulatory authorities may demand that clinical trials be repeated, which would cause significant delays and cost increases.

If any of the clinical trial sites terminate for any reason, the follow-up information on patients enrolled in an ongoing clinical trial may be lost unless the Company is successfully able to transfer the care of those patients to another qualified clinical trial site, which is not guaranteed. Further, if the Company must terminate the agreements with any of its CROs, it may not be possible to enter into arrangements with alternative CROs on a timely basis or on commercially reasonable terms, or at all. Redoing clinical trials and/or switching CROs during a clinical trial would impose serious pressures on management and could severely delay development and market potential of the Company's drug candidates, as well as adversely affect its market value and stock price.

Risks Related to competitive environment, drug development, challenges, partnering, market access issues, and registration and reimbursement of the Company's muscle regeneration drug candidates.

There are multiple therapeutic approaches and product candidates currently in clinical development for the treatment of Duchenne including but not limited to gene correction and gene therapy. These or other approaches not yet in clinical development may be approved faster or achieve far better results than anticipated or than the Company's product candidates.

The Company faces competition from pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies as well as academic institutions, government agencies and other public and private research organizations that conduct research in Duchenne. Many of these competitors or potential competitors have greater financial resources and development and selling and marketing capabilities than the Company. Numerous therapeutic approaches and product candidates including but not limited to: exon skipping, gene therapy and CRISPR-CAS, antifibrosis, myostatin inhibition, mitochondrial and metabolic modulation, and others are in or close to commencing clinical development in humans. While the Company believes its approach is distinctive and may well complement other approaches due to its different mechanism of action, there can be no guarantee that this proves to be the case and one or more competing products may get to market faster with better outcomes for patients, thus reducing the market opportunity for the Company's product candidates. If Satellos' products are ultimately not competitive, its revenue and financial results, and general business prospects, including market value, would be adversely affected.

The Company may not be successful in developing an oral form of delivery for its intended product candidate to treat Duchenne patients.

The Company is currently planning for its development candidate to be taken orally, by mouth, in the form of a pill. Preclinical data generated to-date has deployed an intraperitoneal injection of an early generation drug candidate, which was contained in a reagent solution. The Company's drug discovery program is currently focused on inventing next generation compounds with certain enhanced properties, including as an oral formulation. There is no certainty that the Company will be successful in developing its development candidate in pill form with similar or better levels of efficacy than a product delivered by injection. Failure to do so could reduce the market attractiveness of the Company's products or limit their use to a smaller sub-set of patients, thus lowering the product's revenue prospects.

If sufficient beneficial advantages for patients are not shown in clinical trials, the Company may be unable to secure development partners on favorable terms, or at all.

The Company may pursue development and commercialization partnership arrangements with third parties. Potential partners for any clinical development, co-marketing, licensing, or broader arrangements may include large and midsize pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies. Often partnership agreements are made to obtain up-front capital, offset development costs, increase the probability of success from leveraging the skill sets of a more experienced partner, and secure a royalty annuity. In return, the partner generally receives downstream commercialization rights (or co-rights) on a region-by-region basis, or globally. The Company may benefit from such a partnership/s particularly given the pediatric nature of Duchenne, complexity of disease progression, and its sequelae, and the specialization of the medical centers which treat patients. Failure to demonstrate sufficient patient benefit may make it more difficult or preclude the Company from being successful in establishing these agreements should it choose to do so. This may increase the

Company's business costs and risks, delay commercialization activities and revenue generation, and potentially impair the business.

Despite launching products in the future, the Company may experience limits in market access, unfavorable reimbursement or pricing, or healthcare policy reform initiatives, which would limit the value of the products.

The Company's ability to commercialize any products successfully will depend, in part, on the extent to which coverage and reimbursement for these products and related treatments will be available from government healthcare programs, private health insurers, managed care plans, and other organizations. Government authorities and third party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. The Company cannot be sure that coverage and reimbursement will be available on a timely basis for any product that it, or any of its partners, commercializes and, if reimbursement is available, the level of reimbursement may be reduced. Access to reimbursement may impact the demand for, or the price of, any product candidate for which the Company or its partner/s obtains marketing approval. If reimbursement is not available on a timely basis or is available only to limited levels or is delayed, the commercial potential for any product candidate for which the Company or its partner has obtained marketing approval may be reduced. Such an outcome could adversely affect the Company's profitability and share price.

Product liability lawsuits could cause reputational damage and legal liabilities for the Company, limiting the commercial prospects for its products.

There is an inherent risk of product liability exposure related to the future evaluation of the Company's product candidates in human clinical trials. The Company's current product candidates have not been tested in human clinical trials, and therefore, safety data is limited and the data which has been generated to-date may not translate to humans. If the Company cannot successfully defend itself against claims that its product candidates or products caused injuries, it will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in decreased demand for any product candidates or products that it may develop, reputational injury and negative attention, withdrawal of clinical trial participants, significant costs to defend the related litigation, potential monetary awards to trial participants or patients, and lost or delayed product revenues. Such outcomes would be injurious to the Company's business.

Liability Insurance may not be adequate.

The Company does not yet hold clinical trial liability insurance coverage, and any coverage that may be obtained in the future may not be adequate to cover all liabilities that it may incur. When the Company begins to commercialize its product candidates, it will need to increase its insurance coverage, which is increasingly expensive. The Company may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Risks related to the Company's intellectual property and privacy legislation

If the Company fails to comply with its obligations under its intellectual property licenses with third parties, it could lose license rights that are important to its business.

Satellos is party to intellectual property license agreements with the OHRI, UBC, and CAT and expects to enter into additional license agreements in the future. The Company's existing license agreements impose, and future license agreements will most likely impose, various milestone payments, royalties, insurance, indemnification, and other obligations on the Company. The Company's current agreement with the OHRI requires it to maintain its patents and pay annual license fees and research fees. If Satellos fails to comply with its obligations under this license, the OHRI may have the right to terminate this license agreement. In such event, the Company might not be able to market any product that is covered by such license, or to convert such license to a non-exclusive license. This could

materially adversely affect the value of the product candidate being developed under the OHRI License. Termination of any license agreement or reduction or elimination of the Company's licensed rights may result in Satellos having to negotiate new or reinstated licenses with less favorable terms.

If Satellos is unable to obtain and maintain patent protection for its technology and products, or if the Company's partners or licensors are unable to obtain and maintain patent protection for the technology or products that it licenses from them, or if the scope of the patent protection obtained is not sufficiently broad, the Company's competitors could develop and commercialize technology and products similar or identical to that of Satellos, and its ability to successfully commercialize its technology and products may be adversely affected.

The Company's success will depend on its ability to obtain and maintain patent and other intellectual property protection with respect to its product candidates. Satellos and its licensors have sought to protect the Company's proprietary position by filing patent applications in the U.S., Canada, and abroad related to its novel technologies and products that are important to its business. This process is expensive and time-consuming, and the Company may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, patents might not be issued or granted with respect to the Company's patent applications that are currently pending, and issued or granted patents might later be found to be invalid or unenforceable, be interpreted in a manner that does not adequately protect the Company's current product or any future products, or fail to otherwise provide Satellos with any competitive advantage.

The patent position of biotechnology and pharmaceutical companies is generally uncertain because it involves complex legal and factual considerations and in recent years has been the subject of much litigation. The standards applied by the United States Patent and Trademark Office and foreign patent offices in granting patents are not always applied uniformly or predictably. As a result, the issuance, scope, validity, enforceability and commercial value of the Company's and its partners' or licensors' patent rights are highly uncertain. The degree of future protection that the Company will have on its proprietary products and technology, if any, is uncertain and a failure to obtain adequate intellectual property protection with respect to Satellos' product candidates and proprietary technology could have a material adverse impact on the success of its business.

Even if the Company's owned and licensed patent applications issue as patents, they may not issue in a form that will provide Satellos with any meaningful protection, prevent competitors from competing with the Company or otherwise provide the Company with any competitive advantage, including not being listed in the FDA's Approved Drug Products With Therapeutic Equivalence Evaluations publication (commonly known as, the Orange Book). The Company's competitors may be able to circumvent its owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and the Company's owned and licensed patents may be challenged in the courts or patent offices in Canada, the U.S., and abroad. Such challenges may result in patent claims being narrowed, invalidated, or held unenforceable, which could limit Satellos' ability to or stop or prevent the Company from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of its technology and products. Given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, the Company's owned and licensed patent portfolio may not provide it with sufficient rights to exclude others from commercializing products similar or identical to the Company's.

Satellos may become involved in lawsuits to protect or enforce its patents, which could be expensive, time consuming and whether successful or unsuccessful, limit the commercial value of the Company's product or have a material adverse effect on the Company's business.

Competitors may infringe on any of the Company's current or future patents. To counter infringement or unauthorized use, Satellos may be required to file costly and time-consuming infringement claims. Also, the court may decide in an infringement proceeding that a specific patent held by the Company is not valid or enforceable or may refuse to stop the other party from using the Company's intellectual technology at issue on the grounds that its patents do not cover the intellectual property being disputed. An adverse result in any litigation proceeding could put one or more of the Company's patents at risk of being invalidated or interpreted narrowly. Additionally,

due to the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of the Company's confidential information could be compromised by disclosure during this type of litigation. Satellos' licensor may have rights to file and prosecute such claims and it is reliant on them.

The Company's commercial successes depend upon its ability and the ability of its partners and other collaborators to develop, manufacture, market, and sell its product candidates and use its proprietary technologies without infringing the proprietary rights of third parties. Third parties may assert infringement claims against the Company based on existing patents or patents that may be granted in the future, which at this time cannot be known to the Company. Satellos may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to its products and technology, including interference proceedings before the United States Patent and Trademark Office or other similar regulatory authorities.

If the third party is successful and the Company is found to infringe on their intellectual property rights, Satellos could be forced to negotiate the rights to the third party's intellectual property in order to continue to develop and market its products and technology. There is no guarantee that the Company will be able to obtain any required license on commercially reasonable terms or at all. Even if the Company was able to obtain a license, it could be non-exclusive, thereby giving its competitors access to the same technologies licensed to the Company.

If Satellos is not able to obtain a license for the rights to their technology, it could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, the Company could be found liable for additional monetary damages. A finding of infringement could prevent the Company from commercializing its product candidates, or delay commercialization during adjudication of a patent dispute, including a 30-month injunction, or force the Company to cease some of its business operations, pay royalties and/or damages to companies holding the patents that were infringed, all of which could materially harm the Company's business.

Claims that Satellos has misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on its business. Litigation or other legal proceedings relating to intellectual property claims may cause the Company to incur significant expenses and could distract its employees from their normal responsibilities, even if it is resolved in the Company's favor. Also, any public announcements of the results of hearings, motions, or other interim proceedings or developments could be perceived to be negative by securities analysts or investors, leading to a potential adverse effect on the price of the Common Shares.

These types of litigation or proceedings could substantially increase the Company's operating losses and reduce the resources available for product development activities. Satellos may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of the Company's competitors may be able to sustain the costs of such litigation or proceedings more effectively than it can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on Satellos' ability to compete in the marketplace.

The Company may be subject to claims that its employees have wrongfully used or disclosed alleged trade secrets of their former employers.

Satellos makes efforts to ensure that its employees do not use the proprietary information or know-how of others in their work for the Company; however, it may nonetheless be subject to claims that it or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. This would most likely result in Satellos having to enter litigation to defend against these claims. If the Company fails in defending any such claims, in addition to paying monetary damages, it may lose valuable intellectual property rights and/or personnel. Even if intellectual property is successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

If Satellos is unable to protect the confidentiality of its trade secrets, the Company's innovative capacity and competitive position could be harmed.

The Company relies on trade secrets, including unpatented know-how, technology, and other proprietary information, to maintain its competitive position, in addition to filing patents for some of its technology and products. The types of protections available for trade secrets are particularly important with respect to the Company's proprietary MyoRegenX technology platform, which involves significant unpatented know-how.

Satellos seeks to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as the Company's employees, corporate collaborators, outside scientific collaborators, sponsored researchers, contract manufacturers, consultants, advisors, and other third parties. The Company also enters into confidentiality and invention or patent assignment agreements with its employees and consultants.

Despite these efforts, any of these parties may breach the agreements and disclose the Company's proprietary information, including its trade secrets, and Satellos may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, costly, and time-consuming, and the outcome is unpredictable. In addition, courts in certain jurisdictions are less willing or unwilling to protect trade secrets. If any of the Company's trade secrets were to be lawfully obtained or independently developed by a competitor, it would have no right to prevent them from using that technology or information to compete with Satellos. If any of the Company's trade secrets were to be disclosed to or independently developed by a competitor, its competitive position would be harmed.

Satellos must protect and manage confidential personal health information, including reporting from marketed product adverse event reporting and clinical trials. Accidental release of information could harm the Company.

As the Company's programs advance in development, it expects to generate or otherwise obtain clinical data that may include personal information and personal health information. These data are required for successful development and commercialization of pharmaceutical products, such as clinical trial data to support regulatory submissions and pharmacovigilance data to monitor for potential adverse events following product launch. The Company recognizes the sensitivity of this data and will apply protections to minimize the risk of release, including strict data blinding protocols and secure information technology infrastructure. However, despite these measures, it is possible that personal information or personal health information could be released and may expose the Company to substantial reputational risk and legal liabilities. Regardless of merit or eventual outcome, liability claims may result in decreased demand for any product candidates or products that it may develop, injury to the Company's reputation and significant negative media attention, withdrawal of clinical trial participants, significant costs to defend the related litigation, substantial monetary awards to trial participants or patients, loss of revenue and the inability to commercialize any products that Satellos may develop.

Risks related to regulatory approval of the Company's product candidates and other legal compliance matters

The Company's future product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA, Health Canada, and by comparable authorities in other countries.

If the Company, one of its contractors, or license partners are not able to comply with regulations and guidelines governing pharmaceutical product development (including, but not limited to GMP, Good Clinical Practices, GLP, quality assurance/quality control, and guidelines set forth by the International Conference for Harmonization), it could impact the overall development and/or commercialization activities, the timing of development or result in a supply disruption of commercial product that would negatively impact the business.

The development and manufacturing of pharmaceutical products is strictly governed by a series of standardized regulations and guidelines to ensure data and product quality including, but not limited to GMP, GLP, and additional guidelines set forth by the International Conference for Harmonization. These guidelines are mandatory

standards for most regulatory agencies and designed to ensure the highest quality of research and manufacturing for pharmaceutical products. Satellos' team has experience in the development and commercialization of pharmaceutical products under these regulations. The Company aims to put in place infrastructure to ensure compliance with relevant guidelines, including standard operation procedures and third-party audits.

Despite these precautions, it is possible that activities conducted internally or by a third party may be non-compliant with industry standard regulations, with significant negative impact on the Company. During product development, non-compliance with standard guidelines and regulations may invalidate drug product and/or data such that they are not appropriate to support regulatory filings. The Company may be required to repeat development activities as a result, incurring additional development risk and costs. Repeating specific development activities could also delay overall development and commercialization timelines, negatively impacting a product's revenue potential. Adverse effects on timing and costs could lead to discontinuation of product development.

In the event that non-compliance with standard guidelines adversely impacts clinical trial activities and trial participants, Satellos could also be exposed to substantial reputational risk and legal liabilities. Regardless of merit or eventual outcome, liability claims may result in decreased demand for any product candidates or products that it may develop, injury to the Company's reputation and significant negative media attention, significant costs to defend the related litigation, substantial monetary awards to trial participants, loss of revenue and the inability to commercialize any products that the Company may develop.

For commercial products, non-compliance with standard guidelines and regulations may prevent the Company from releasing products to the market or require Satellos to withdraw products from the market. In either case, the Company would incur manufacturing costs for products without the potential to generate revenues. In addition, delays in delivery of products to the market could adversely impact long-term product utilization and drive substitution to competitor products. In the case where products released to the market is retroactively found to be non-compliant with existing guidelines, the Company could also incur significant costs related to the returns, refunds, and destructions of non-compliant products. As well, Satellos could be exposed to substantial reputational risk and legal liabilities with potential negative consequences.

In any situation of guideline non-compliance, Satellos will be required to undertake a comprehensive investigation and engage in activities to remedy and prevent future deviations. These activities could impose significant costs on the Company and draw resources away from other Company objectives.

Failure to obtain regulatory approval in international jurisdictions would prevent the Company's product candidates from being marketed abroad. Risk of a rejection, incomplete response, a poor approved label or pricing restrictions by a regulatory authority outside of the U.S. may adversely impact the U.S. market opportunity and limit the value of the asset to Satellos.

The Company intends to enter into agreements with third parties for the marketing of its products outside Canada and the U.S. In order to market and sell Satellos' products in the European Union and many other jurisdictions, the Company or its third parties must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA or Health Canada approval. The regulatory approval process outside the U.S. generally includes all the risks associated with obtaining FDA or Health Canada approval. In addition, in many countries outside the U.S. or Canada, it is required that the product be approved for reimbursement before the product can be approved for sale in that country.

Satellos may not obtain approvals from regulatory authorities outside the U.S. or Canada on a timely basis, if at all. Approval by the FDA or Health Canada does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the U.S. or Canada does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. Satellos may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize its products in any market, thus limiting its revenue potential.

The Company's direct and indirect relationships with healthcare customers, government, payors, and reimbursement/contract decision makers, will be subject to applicable anti-bribery anti-corruption and other healthcare laws and regulations, which could expose it to criminal sanctions, civil penalties, program exclusion, debarment, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians, and third-party payors play a primary role in the recommendation and prescription of any product candidates for which the Company obtains marketing approval. The Company's future arrangements with third-party payors and customers may expose it to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which it markets, sells and distributes its products for which it obtains marketing approval. Restrictions under applicable U.S. federal and state healthcare laws and regulations that may impact the Company's activities, include the following:

- the federal healthcare anti-kickback statute 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 either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs;
- civil penalties could be imposed against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, 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;
- criminal and civil liability could be imposed for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- manufacturers of drugs, devices, biologics and medical supplies are generally required to report information related to physician payments and other transfers of value and physician ownership and investment interests; and
- analogous laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures.

Costs will be substantial to ensure that the Company's business arrangements with third parties will comply with applicable healthcare laws and regulations in each jurisdiction when Satellos' products will eventually be offered.

It is possible that governmental authorities will conclude that the Company's business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If the Company's operations are found to be in violation of any of these laws or any other governmental regulations that may apply to it, Satellos may be subject to significant civil, criminal, and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid in the U.S., and the curtailment or restructuring of the Company's operations. If any of the physicians or other providers or entities with whom Satellos expects to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil, or administrative sanctions, including exclusions from government funded healthcare programs.

Market access, legislative and pricing policy changes may increase the difficulty and cost for the Company to obtain optimal marketing approval to commercialize its product candidates and affect the prices it may obtain.

In the U.S. and other foreign jurisdictions, there have been legislative and regulatory changes and proposed changes regarding, among other matters, biopharmaceutical product approvals and pricing that could prevent or delay marketing approval of and commercial prospects for the Company's product candidates, potentially having a negative impact on its ability to profitably sell any of its future product candidates. Such an outcome may have a materially adverse effect on the value and going concern prospects of the Company.

Risks Related to Employee Matters, Managing Growth, Natural Disasters and Armed Conflict

Satellos is highly dependent upon certain key executives and other key personnel and their loss could adversely affect its ability to achieve its business objectives.

The Company is highly dependent on its executive officers. Although Satellos has or will have formalized contractual agreements with each of its executive officers, these agreements do not prevent them from terminating their engagement with the Company at any time. The loss of the services of any of these persons could potentially harm the Company's research, development, and commercialization objectives and financial condition. Satellos' success is also dependent on its ability to recruit, retain, and motivate qualified scientific, drug development, clinical, project management, financial, and business personnel. The Company may not be able to attract and retain these personnel on a timely basis or on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. Satellos also experiences competition for the hiring of scientific and clinical personnel from universities and research institutions. The Company further depends on scientific and clinical collaborators and advisors, all of whom have outside commitments that may limit their availability.

Satellos expects to expand its research, preclinical drug development, project management and clinical planning capabilities, and as a result, may encounter difficulties in managing its growth, which could disrupt its operations. As the Company executes on its R&D plans and business strategy, it expects to experience significant growth in the number of CROs and full-time equivalent staff members it is funding through these operations, particularly in the areas of research, drug discovery and preclinical development, clinical planning, and project management. As a result, Satellos will need to identify, hire, and integrate personnel who have not worked together previously. This growth will also result in significant additional responsibilities on management, who may need to spend a disproportionate amount of its attention away from the business operations and spend a substantial amount of time to managing these growth activities. Managing this growth will further require the Company to continue to implement and improve its managerial, operational, and financial systems, and continue to recruit and train additional qualified personnel. Due to its limited financial resources, Satellos may not be able to effectively manage the expansion of its operations or recruit and train additional qualified personnel. If it is unable to effectively manage this growth, expenses may increase more than anticipated and Satellos may not be able to effectively implement its business strategy.

Failure to maintain adequate internal controls over financial processes and reporting may negatively impact the Company's results of operations or its ability to comply with its reporting obligations.

Effective internal controls are necessary for Satellos to provide reliable financial reports and to help prevent fraud. Although the Company intends to undertake a number of procedures in order to help ensure the reliability of its financial reports, including those imposed on it under Canadian securities laws, the Company cannot be certain that such measures will ensure that it will maintain adequate control over financial processes and reporting. Failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm Satellos' results of operations or cause it to fail to meet its reporting obligations once it becomes a reporting issuer.

Natural disasters such as continuing or new epidemic or pandemic outbreaks.

The Company, its employees, consultants and third-party contractors could be affected by an epidemic or pandemic outbreak, either within a facility or within the communities in which they operate. The Company will develop and adopt policies and procedures in order to deal with any potential epidemic or pandemic outbreaks impacting its facilities. There can be no assurance that such policies and procedures will ensure that the Company's operations would not be adversely affected.

Unless contained, epidemics such as the ongoing COVID-19 pandemic, could cause a slowdown in global economic growth and have a material adverse effect on the business, operations, financial condition, and share price of the Company and could cause delays or disruptions to the achievement of the Company's goals and milestones. The continued spread of the virus could have a material adverse effect on the economies of the countries in which the Satellos operates. In addition, the ongoing COVID-19 pandemic has caused volatility on the TSXV, on which the Common Shares are listed. The continued adverse effects of the spread of COVID-19, if not contained, could have a material adverse effect on the business, operations and financial condition of the Company; however, the full extent and impact of the ongoing COVID-19 pandemic on the Company's operations cannot currently be ascertained, as it depends upon future developments which cannot be predicted, and includes, among other matters: the continued duration of the outbreak, the severity of the virus and the ability to treat it, the ability to collect sufficient data to track the virus and the collective actions taken to curb the spread of the virus.

The international response to the COVID-19 pandemic has led to significant restrictions on travel, temporary business closures, quarantines, global stock market volatility, and a general reduction in consumer activity. Such public health measures have and continue to result in operating and supply chain delays and disruptions, global stock market and financial market volatility, declining trade and market sentiment, reduced movement of people and labor shortages, and travel and shipping disruption and shutdowns, or a fear of any of the foregoing, all of which could affect commodity prices, interest rates, credit ratings, credit risk, and inflation. For example, during the COVID-19 pandemic, global supply chain disruptions continue to be seen and have impacted the business of the Company.

Even though the Company has implemented business continuity measures to mitigate and reduce any potential impacts of the ongoing COVID-19 pandemic on its business, operations and financial condition, the continued spread of COVID-19, including the emergence of new variants, in the countries in which it and its consultants and third-party contractors operate could have a material adverse impact on the Company's workforce and its continued operations. In particular, the ongoing COVID-19 pandemic has the potential to delay or cause the termination of the drug development program, pre-IND studies, and subsequent clinical studies. This could lead to delayed advancement of research and development and significant costs to replace data lost in the termination of pre-IND studies or clinical studies. These studies have significant inherent operational risks and the ongoing COVID-19 pandemic adds to that uncertainty in ways that are not predictable. The following are some ways that the Company could be adversely impacted by the ongoing COVID-19 pandemic:

- Satellos and/or its third-party contractors may experience labor shortages caused by sickness and/or the need to quarantine, potentially delaying key study activities and the time to completion/data read out of the study;
- there has and may continue to be delays to the development of the Company's drug development program;
- Satellos may not be able to commence the pre-IND studies due to the foregoing, which would ultimately delay the commencement of clinical trials in humans;
- once clinical trials are underway, investigator sites may not be able to recruit and maintain clinical trial subjects, which may delay the time to begin, conduct, and complete the study. Clinical trial subjects may become infected with COVID-19 while participating in the study. This may result in the need for additional subjects to be recruited (increasing trial costs and delaying time to trial completion), or to an inability to make conclusions from the study data analyses;

- volatility of the global stock market and financial market may impact the Company's ability to raise capital; and
- it is not possible to estimate how long any delays might be, how much additional cost may be incurred, or the extent and impact of any missing data.

To date, Satellos has been able to continue its operations with limited disruptions. The Company is closely monitoring the impact of the COVID-19 pandemic, including the emergence of variant strains of the virus, on its business, however, it is difficult to predict the future impact COVID-19 may have on the business, results of operations, financial position, and cash flows.

Risk related to the conflict in Ukraine.

In February 2022, Russian military forces launched significant military action against Ukraine, and sustained conflict and disruption in the region continues. The war in Ukraine and the surrounding region has lead and could lead to further disruption, instability, and volatility in global markets, increase inflation and further disrupt supply chains, which may materially and adversely affect the Company's business. As a result of actions taken by Russia in Ukraine, actions have been taken by other countries and organizations, including new and stricter sanctions by Canada, the European Union, and the U.S. against officials, individuals, regions, and industries in Russia, Ukraine and Belarus and the effects of disruptive events could affect the global economy and financial and commodities markets in ways that cannot necessarily be foreseen at the present time. These events could also exacerbate other pre-existing political, social and economic risks, including those described elsewhere in this Annual Information Form.

Manufacturing Risks Related to the Company

If identified, product candidates may be inherently challenging to synthesize, manufacture, and/or formulate, and may prove unstable. If the Company is unable to have its products manufactured on a timely basis, it could face delayed clinical trial approvals.

Satellos currently does not own or operate any manufacturing facilities and does not have any significant inhouse manufacturing experience or personnel. Therefore, the Company intends to engage specialized contract manufacturing organizations (CMO or CMOs) to develop manufacturing processes and produce and package product for clinical trials in humans. If the CMO is unable to develop such processes on a timely basis, the Company's timelines to initiate pre-IND studies and the ensuing clinical trials in humans may be adversely affected, resulting in significant additional costs for the Company.

If a CMO of the Company's products or constituents experiences quality assurance/quality control issues or receives an inspection by a regulatory authority and is required to enact remediation which delay supply, it may impact the supply and timing of the initiation of clinical trials in humans or interrupt and delay their continuation.

Reliance on third-party CMOs entails risks to which Satellos would not be subject if the Company manufactured its product candidates, including the following:

- reliance on the third party for regulatory compliance and quality control and assurance;
- the possibility of breach of the manufacturing agreement by the third party because of factors beyond the Company's control (including a failure to synthesize and manufacture the Company's product candidates in accordance with the product specifications); and
- the possibility of termination or nonrenewal of the agreement by the third party at a time that is costly or damaging to the Company.

In addition, the FDA, Health Canada, EMA, and other regulatory authorities require that the Company's future product candidates be manufactured according to cGMP and similar foreign standards. Pharmaceutical manufacturers and their subcontractors are required to register their facilities and/or products manufactured at the time of submission of the marketing application and then annually thereafter with the FDA, EMA, and other regulatory agencies. They are also subject to periodic unannounced inspections by the FDA, EMA, and other regulatory agencies.

Any subsequent discovery of problems with a product, or a manufacturing or laboratory facility used by the Company or its collaborators, may result in restrictions on the product or on the manufacturing or laboratory facility, including product recall, suspension of manufacturing, product seizure or a voluntary withdrawal of the drug from the market. Any failure by its third-party manufacturers to comply with cGMP or any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approvals of any of Satellos' product candidates.

If the Company has to make changes in methods for formulation, manufacturing, or testing of the product candidates, it may result in additional costs or delay.

As product candidates are developed through preclinical to late-stage clinical trials towards approval and commercialization, various aspects of the development program, such as manufacturing methods and formulation, may be altered in an effort to optimize processes, product stability, and results. There is no certainty that these changes will achieve the intended objectives. Any of these changes could cause a significant delay in product candidates' development timeline and/or cause the product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of the Company's product candidates, and/or jeopardize its or its collaborators' ability to commence product sales and generate revenue.

Other Risk Factors

The Company's Director and Officer (D&O) insurance policies may be inadequate and potentially expose it to unrecoverable risks.

Satellos has limited D&O and commercial insurance policies. Any significant insurance claims could have a material adverse effect on its financial condition. Insurance availability, coverage terms, and pricing varies with market conditions. The Company expects to continue to obtain appropriate insurance coverage for insurable risks that it identifies; however, it may fail to correctly anticipate or quantify these risks, or may not be able to obtain appropriate insurance coverage, or insurers may not cover insurable events that may occur as the Company expects. Conditions in the insurance markets are rapidly changing, including those related to director and officer coverage. These conditions have resulted in rising premium costs, higher policy deductibles, and lower coverage limits. For some risks, Satellos may not be able to maintain insurance coverage because of cost or availability.

The Company's information technology (IT) and infrastructure may fail or suffer security breaches, which could result in significant disruption of its discovery and product development programs and its ability to operate its business effectively.

Satellos contracts IT services through internet service, web hosting, and data sharing service providers. The Company also engages with a wide range of collaborators, contractors or consultants, financial institutions and other business providers or partners. It is possible that any of its systems, whether in-house or contracted, and those of its current and future collaborators, contractors or consultants, financial institutions and other business providers or partners may be vulnerable to disruptive elements, including computer viruses, phishing attacks, espionage and hacking programs resulting in unauthorized access; or be damaged or compromised through natural disasters, terrorism, war, and telecommunication or electrical failures. Although the Company takes such steps to help protect sensitive information from unauthorized access or disclosure, its IT and infrastructure may be vulnerable in the future to attacks by hackers or viruses, failures, or breaches due to third-party action, employee or contractor negligence or error, malfeasance, or other incidents or disruptions.

If such an event were to occur and cause interruptions in the Company's operations or result in a loss of or damage to its data or inappropriate access to or disclosure of confidential or proprietary information, including trade secrets, Satellos could incur liability, its competitive position could be harmed, its reputation could be damaged, and the further development and commercialization of its product candidates could be significantly compromised or delayed.

Risks Related to the Company's Securities

The price of Satellos' common stock has experienced volatility and may be subject to fluctuation in the future based on market conditions.

The market prices for the securities of biotechnology companies, including Satellos has historically been highly volatile. The market has, from time to time, experienced significant price and volume fluctuations that are unrelated to the operating performance of any particular company. In addition, because of the nature of its business, certain factors such as the Company's announcements, competition from new therapeutic products or technological innovations, government regulations, fluctuations in operating results, results of clinical trials, public concern regarding the safety of drugs generally, general market conditions and developments in patent and proprietary rights can have an adverse impact on the market price of Satellos' common stock.

For example, from January 1, 2021 through December 31, 2021, the closing price of the Common Shares on the TSXV has ranged from a low of \$1.00 to a high of \$3.20. Any change in the public's perception of its prospects could cause the price of the Company's listed securities to change dramatically. Furthermore, any negative change in the public's perception of the prospects of biotechnology companies in general or the market in general could depress Satellos' share price regardless of its results. Volatility or depression in the capital markets, particularly with respect to biotechnology stocks, could also affect the Company's ability to raise additional capital.

The Company's shareholders may experience significant dilution from future sales of its securities.

Satellos anticipates that it will need to raise additional capital in the future. The sale of additional equity, including warrants or debt securities, if convertible into equity, and including the recent financing of units, will result in dilution to existing shareholders. Also, any debt financing, if available, may require the Company to pledge its assets as collateral or involve restrictive covenants, such as limitations on its ability to incur additional indebtedness, limitations on the Company's ability to acquire or license intellectual property rights and other operating restrictions that could negatively impact Satellos' ability to conduct its business. As a result, the Company's net income per share could decrease in future periods and the market price of its Common Shares could decline. The perceived risk of dilution may negatively impact the price of Satellos' shares and may cause its shareholders to sell their shares, which would contribute to a decline in the price of its Common Shares. Moreover, the perceived risk of dilution and the resulting downward pressure on the Company's share price could encourage investors to engage in short sales of its Common Shares, which could further contribute to progressive price declines in the Company's Common Shares.

Satellos may be subject to securities litigation, which is expensive and could divert management attention.

The market price of the Common Shares may be volatile, and in the past companies that have experienced volatility in the market price of their shares have been subject to securities class action litigation. Satellos may be the target of this type of litigation in the future. Litigation of this type could result in substantial costs and diversion of management's attention and resources, which could adversely impact Satellos' business. Any adverse determination in litigation could also subject Satellos to significant liabilities.

As a venture issuer, Satellos is not required to make representations relating to the establishment and maintenance of disclosure controls and procedures and internal control over financial reporting.

In contrast to the certificate required for non-venture issues under National Instrument 52-109 - *Certification of Disclosure in Issuers' Annual and Interim Filings* (NI 52-109), the certifying officers of Satellos, as a venture issuer, are not required to make representations relating to the establishment and maintenance of disclosure controls and procedures (DC&P) and internal control over financial reporting (ICFR), as defined in NI 52-109.

In particular, the certifying officers of Satellos are not required to make any representations that they have: designed, or caused to be designed, DC&P to provide reasonable assurance that information required to be disclosed by Satellos in its annual filings, interim filings or other reports filed or submitted under securities legislation is recorded, processed, summarized and reported within the time periods specified in securities legislation; and designed, or caused to be designed, ICFR to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with the Company's generally accepted accounting principles (GAAP). Investors should be aware that inherent limitations on the ability of certifying officers of a venture issuer to design and implement on a cost effective basis DC&P and ICFR may result in additional risks to the quality, reliability, transparency and timeliness of interim and annual filings and other reports provided under securities legislation.

Satellos has never paid dividends on the Common Shares and does not anticipate paying any dividends in the foreseeable future. Consequently, any gains from an investment in the Common Shares will likely depend on whether the price of the Common Shares increases.

Satellos has not paid dividends on the Common Shares to date and currently intends to retain its future earnings, if any, to fund the development and growth of the Company's business. As a result, capital appreciation, if any, of the Common Shares will be an investors sole source of gain for the foreseeable future. Consequently, in the foreseeable future, an investor will likely only experience a gain from an investment in the Common Shares if the price of the Common Shares increases.

Glossary

Basal Lamina—A layer of extracellular matrix secreted by the epithelial cells, on which the epithelium sits. It is often incorrectly referred to as the basement membrane, though it does constitute a portion of the basement membrane.

Cachexia—A complex syndrome associated with an underlying illness, causing ongoing muscle loss that is not entirely reversed with nutritional supplementation.

Cardiomyopathy—A disease of the heart muscle that makes it harder for the heart to pump blood to the rest of the body. Cardiomyopathy can lead to heart failure.

Chronic obstructive pulmonary disease (COPD)—Refers to a group of diseases that cause airflow blockage and breathing-related problems. It includes emphysema and chronic bronchitis.

Collagen-VI Related Muscular Dystrophy—A group of disorders that affect skeletal muscles (which are the muscles used for movement) and connective tissue (which provides strength and flexibility to the skin, joints, and other structures throughout the body).

Contract research organizations (CROs)—An organization contracted by another company to take the lead in managing that company's trials and complex medical testing responsibilities.

Duchenne muscular dystrophy—A genetic disorder characterized by progressive muscle degeneration and weakness due to the alterations of a protein called dystrophin that helps keep muscle cells intact.

Dystrophin—A protein located between the sarcolemma and the outermost layer of myofilaments in the muscle fiber (myofiber). It is a cohesive protein, linking actin filaments to other support proteins that reside on the inside surface of each muscle fiber's plasma membrane (sarcolemma).

Dystrophin-associated Glycoprotein Complex (DGC)—DGC is a multiprotein complex that includes dystrophin and the dystrophin-associated proteins. It is one of the two protein complexes that make up the costamere in striated muscle cells. The other complex is the integrin-vinculin-talin complex.

Epidermal growth factor receptor (EGFR)—A transmembrane protein that is a receptor for members of the epidermal growth factor family of extracellular protein ligands.

Exon skipping—In molecular biology, exon skipping is a form of RNA splicing used to cause cells to “skip” over faulty or misaligned sections of genetic code, leading to a truncated but still functional protein despite the genetic mutation.

Genome-wide association studies (GWAS)—In genomics, a genome-wide association study, also known as whole genome association study, is an observational study of a genome-wide set of genetic variants in different individuals to see if any variant is associated with a trait.

Lama-2 Related Muscular Dystrophy—A disorder that causes weakness and wasting (atrophy) of muscles used for movement (skeletal muscles). This condition varies in severity, from a severe, early-onset type to a milder, late-onset form.

Mdx Mice—The Mdx mouse is a popular model for studying Duchenne muscular dystrophy (DMD). The Mdx mouse has a point mutation in its DMD gene, changing the amino acid coding for a glutamine to STOP codon. This causes the muscle cells to produce a small, nonfunctional dystrophin protein. As a result, the mouse has a mild form of DMD where there is increased muscle damage and weakness.

Mitosis—In cell biology, mitosis is a part of the cell cycle in which replicated chromosomes are separated into two new nuclei. Cell division by mitosis gives rise to genetically identical cells in which the total number of chromosomes is maintained.

Notch pathway—A highly conserved cell signaling system present in most animals.

Orphan Drug Designation—Orphan Drug Designation provides certain benefits, including the potential for a seven-year market exclusivity upon regulatory approval, exemption from FDA application fees, tax credits for qualified clinical trials, and a priority review voucher.

Progenitor—A person or thing from which a person, animal, or plant is descended or originates.

Sarcopenia—An age related, involuntary loss of skeletal muscle mass and strength.



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