Satellos Announces Q2 2024 Financial Results and Updated Canine Data

- Updated data in a canine model of Duchenne muscular dystrophy (DMD) show further increased improvement in muscle force over baseline of 195% at four-month point

- Receipt of Orphan Drug and Rare Pediatric Disease designations from US FDA

- On track to dose first participant in Phase 1 clinical trial with SAT-3247 in Q3 2024

- Cash balance of $27.7 million at June 30, 2024

TORONTO--(BUSINESS WIRE)--August 12, 2024--**Satellos Bioscience Inc. (TSX: MSCL, OTCQB: MSCLF)** ("**Satellos**" or the "**Company**"), a public biotech company developing new small molecule therapeutic approaches to improve the treatment of muscle diseases and disorders, announced today its financial results and operational highlights for the three months ended June 30, 2024. All references to currency in this press release are in Canadian dollars unless otherwise noted.

"The second quarter continued to be momentous for Satellos," said Frank Gleeson, Co-founder and CEO, Satellos. "In addition to advancing SAT-3247 through preclinical development and on July 10 filing a regulatory application in Australia to commence a Phase 1 clinical trial, we received Orphan Drug and Rare Pediatric Disease Designations from the FDA and presented positive interim muscle regeneration data in a canine model of DMD at the annual PPMD conference. We ended the quarter with a cash balance of $27.7 million and are on track to initiate a Phase 1 clinical trial with SAT-3247 in Q3 of 2024."

Phil Lambert, PhD, Chief Scientific Officer of Satellos, said, "Today, we are proud to announce additional data from the now completed canine study in which we show that the interim positive effects on the function of muscle in these animals were further increased over the full four months of the study. We believe these data are consistent with the positive results SAT-3247 treatment has demonstrated in numerous mdx mouse models and other studies and provide evidence in a large animal model of the potential for SAT-3247 to represent a disease-modifying therapeutic approach for people living with Duchenne."

CANINE DATA UPDATE:

On July 2, 2024, Satellos announced data in a canine model of DMD showing improved muscle repair and regeneration and improved muscle force from SAT-3247 treatment. After treatment with SAT-3247 the animals showed an increase in Regenerative Index (RI), a measure of the number of newly regenerated muscle fibers versus the number of damaged and dying muscle fibers, suggesting that muscle repair and regeneration is occurring. These results were updated today, the results of which can be seen in our corporate presentation here.

The highlighted results in the corporate presentation are from two dystrophic animals in a pilot study in which each animal was treated for four months (from eight to 12 months of age) with an oral dose of SAT-3247. In addition to showing an improved RI, treatment with SAT-3247

resulted in improvements in every force parameter measured over baseline. The average force improvement across all measures was 111% at two months and increased to 195% at four months as compared with baseline.

PROGRAM AND BUSINESS UPDATE:
Highlights for the quarter ended June 30, 2024, along with recent developments include:

Advanced SAT-3247
On May 28, 2024, Satellos announced the formation of a Clinical Advisory Board to support the advancement of SAT-3247 in clinical trial development for DMD. Further details on the members of the Advisory Board can be found here.

On June 27, 2024, the Company announced that Frank Gleeson, Satellos CEO, would join leading members of the Duchenne medical and scientific community during a panel discussion at Parent Project Muscular Dystrophy's 30th Annual Conference that was held June 27-29, 2024, in Orlando, Florida.

Subsequent to the quarter end, on July 11, 2024, the Company announced submission on July 10, 2024, of a clinical research proposal to a Human Research Ethics Committee (HREC) in Australia seeking regulatory authorization under their Therapeutic Goods Administration's (TGA's) Clinical Trial Notification (CTN) scheme to conduct a first-in-human Phase 1 clinical trial of SAT-3247. Subject to approval by the HREC and acceptance of the CTN by Australia's TGA, the Phase 1 clinical trial is intended to enroll healthy volunteers to assess the safety and pharmacokinetic properties of SAT-3247. Following completion of this portion of its program, if successful, Satellos plans to advance SAT-3247 into clinical trials with DMD patients commencing in early 2025.

Subsequent to the quarter end, on August 7, 2024, Satellos announced that the U.S. Food and Drug Administration (FDA) had granted Rare Pediatric Disease Designation to SAT-3247 for the potential treatment of DMD after receiving Orphan Drug Designation earlier this year.

The company further updated that Satellos conducted all preclinical and toxicology studies to the standards of relevant global regulatory bodies and expect to be able to leverage the results for additional Phase 1 and subsequent clinical trials in Australia and further jurisdictions including the United States and Canada.

The Company expects to dose the first participant in a Phase 1a clinical trial in Q3 2024 to evaluate the safety and pharmacokinetic ("PK") properties of SAT-3247 in healthy human volunteers.

Financial Results
Satellos had cash and cash equivalents and short-term investments of $27.7 million as of June 30, 2024, compared with $39.6 million at December 31, 2023. The decrease in cash and cash equivalents and short-term investments is due to cash used in operating activities in the six months ended June 30, 2024.

For the three months ended June 30, 2024, Satellos reported a net loss of $6.0 million ($0.05 loss per share), compared to a net loss $4.1 million ($0.05 loss per share) for the three months ended June 30, 2023. The increase in net loss for the three-month periods ended June 30, 2024, compared with the same period in 2023 was a result of increased research and development (R&D) expenses related to higher headcount and R&D activities associated with SAT-3247 as well as higher general and administrative expenses due to increased personnel and professional fees to support expanded operations.

Research and development expenses increased by approximately $3.3 million to $4.9 million for the three months ended June 30, 2024, compared to $1.6 million for the three months ended June 30, 2023. The increase in R&D expenses was the result of higher salary and management fees related to new hires to advance our research programs, increased preclinical pre-IND-enabling expenses of approximately $1.6 million and increased chemistry, manufacturing, and controls expenses of $560 thousand for work ongoing in the current year as SAT-3247 advanced from the discovery stage to the pre-clinical stage of development as well as clinical expenses of $663 thousand incurred in preparation of initiating a Phase 1 clinical study in Q3 2024. Non-cash stock-based compensation increased in the current year due to higher amortization of grants in the current year period associated with new hires and increased headcount.

General and administrative expenses increased by approximately $311 thousand to $1.8 million for the three months ended June 30, 2024, as compared to $1.5 million for the three months ended June 30, 2023. The increase in general and administrative expenses in the current year period is primarily the result of higher salary and management fees related to increased headcount to support operations offset by lower professional fees due to recruitment costs incurred in the prior year period. Non-cash stock-based compensation increased due to new grants issued in the second, third and fourth quarters of fiscal 2023.

Satellos' condensed consolidated interim financial statements for the three and six months ended June 30, 2024, and the related management's discussion and analysis (MD&A) will be available on the Company's website at www.satellos.com and SEDAR+ at www.sedarplus.ca.

About Satellos Bioscience Inc.
Satellos is a publicly traded biotechnology company dedicated to developing life-improving medicines to treat degenerative muscle diseases. Satellos has incorporated breakthrough research in muscle stem cell polarity into a proprietary discovery platform, called MyoReGenX™, to identify degenerative muscle diseases where deficits in this process affect muscle regeneration and are amenable to therapeutic intervention. With this platform, Satellos is building a pipeline of novel therapeutics to correct muscle stem cell polarity and promote the body's innate muscle repair and regeneration process. The Company's lead program is an oral, small molecule drug candidate in development as a potential disease-modifying treatment for Duchenne muscular dystrophy. Satellos is headquartered in Toronto, Ontario. For more information, visit www.satellos.com.

Notice on Forward-Looking Statements
This press release includes forward-looking information or forward-looking statements within the meaning of applicable securities laws regarding Satellos and its business, which may include,

but are not limited to, statements regarding Satellos' momentum, the potential for SAT-3247 to represent a disease modifying approach to the therapeutic treatment of people living with Duchenne; anticipated benefits to patients from a small molecule treatment for Duchenne; the advancement SAT-3247 into clinical trials; the pharmacodynamic properties and mechanism-of-action of SAT-3247; the potential of our approach in other degenerative muscle diseases or in muscle injury or trauma; the general benefits of modulating stem cell polarity by administering small molecule drugs; its/their prospective impact on Duchenne patients, patients with other degenerative muscle disease or muscle injury or trauma, and on muscle regeneration generally; the utility of regenerating muscle by modulating polarity; adoption of Satellos' approach by the medical community; and Satellos' technologies and drug development plans. All statements that are, or information which is, not historical facts, including without limitation, statements regarding future estimates, plans, programs, forecasts, projections, objectives, assumptions, expectations or beliefs of future performance, occurrences or developments, are "forward-looking information or statements." Often but not always, forward-looking information or statements can be identified by the use of words such as "shall", "intends", "anticipate", "believe", "plan", "expect", "intend", "estimate", "anticipate", "potential", "prospective" , "assert" or any variations (including negative or plural variations) of such words and phrases, or state that certain actions, events or results "may", "might", "can", "could", "would" or "will" be taken, occur, lead to, result in, or, be achieved. Such statements are based on the current expectations and views of future events of the management of the Company. They are based on assumptions and subject to risks and uncertainties. Although management believes that the assumptions underlying these statements are reasonable, they may prove to be incorrect. The forward-looking events and circumstances discussed in this release, may not occur and could differ materially as a result of known and unknown risk factors and uncertainties affecting the Company, including, without limitation, risks relating to the pharmaceutical and bioscience industry (including the risks associated with preclinical and clinical trials and regulatory approvals), and the research and development of therapeutics, the results of preclinical and clinical trials, general market conditions and equity markets, economic factors and management's ability to manage and to operate the business of the Company generally, including inflation and the costs of operating a biopharma business, and those risks listed in the "Risk Factors" section of Satellos' Annual Information Form dated March 26, 2024 (which is located on Satellos' profile at www.sedarplus.ca). Although Satellos has attempted to identify important factors that could cause actual actions, events or results to differ materially from those described in forward-looking statements, there may be other factors that cause actions, events or results to differ from those anticipated, estimated or intended. Accordingly, readers should not place undue reliance on any forward-looking statements or information. No forward- looking statement can be guaranteed. Except as required by applicable securities laws, forward-looking statements speak only as of the date on which they are made and Satellos does not undertake any obligation to publicly update or revise any forward-looking statement, whether resulting from new information, future events, or otherwise.

Contacts

Investors: Liz Williams, ir@satellos.com
Business Development: Ryan Mitchell, Ph.D., bd@satellos.com
Media: Jessica Yingling, Ph.D., jessica@litldog.com, +1.858.344.8091