



NEWS RELEASE

## Satellos Reports Q3 2024 Financial Results and Provides Clinical Update

2024-11-13

- Completed enrollment for SAT-3247 in Duchenne muscular dystrophy (DMD) in the first three (of five) single-ascending dose (SAD) cohorts with no safety concerns and initiated enrollment of first multiple-ascending-dose (MAD) cohort
- Presented canine data for SAT-3247 at the 2024 World Muscle Society Annual Congress showing improved measures of strength reaching near normal levels
- Cash balance of \$23.4 million as of September 30, 2024

TORONTO--(BUSINESS WIRE)-- **Satellos Bioscience Inc. (TSX: MSCL, OTCQB: MSCLF)** (“**Satellos**” or the “**Company**”), a clinical-stage biotechnology company developing life-improving medicines to treat degenerative muscle diseases, announced today its financial results and corporate highlights for the three months ended September 30, 2024. All references to currency in this press release are in Canadian dollars unless otherwise noted.

“Throughout the third quarter, we made important progress marked by the dosing of our first 24 (of 72) participants in our Phase 1 SAD and MAD trial of SAT-3247 in healthy volunteers,” said Co-founder and Chief Executive Officer Frank Gleeson. “We also reported key data from the open-label study of SAT-3247 in a preclinical canine model of DMD at the 2024 World Muscle Society Annual Congress in Prague. Building on this momentum, we remain on track to complete enrollment in the healthy volunteer single-ascending-dose arm by year end, complete enrollment in the multiple-ascending-dose healthy volunteer arm in the first quarter of 2025, and dose the first patient in the Phase 1a adult DMD trial in the fourth quarter of 2024. The SAT-3247 first-in-human clinical trial progress is a critical step in achieving our mission to develop life-improving medicines to treat degenerative

muscle diseases.”

## **CLINICAL UPDATE:**

Satellos announced that the first three cohorts (of five) of the single-ascending-dose (SAD) arm of the Phase 1 clinical healthy volunteer trial for SAT-3247 have been successfully completed and enrollment in the fourth cohort has commenced and is ongoing. Satellos has also completed enrolment in the food effect dose cohort. No drug-related adverse events have been reported to date.

Based on the positive safety data from the first three SAD cohorts, enrollment was initiated in the first cohort (of four) in the multiple-ascending dose (MAD) arm of the Phase 1 study. The Company remains on track to complete enrollment of the SAD cohorts by year-end 2024 and MAD cohorts in the first quarter of 2025, respectively.

## **PROGRAM AND BUSINESS UPDATE:**

Highlights for the quarter ended September 30, 2024, along with recent developments include:

### **SAT-3247 Development**

On July 11, 2024, the Company announced submission 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. Satellos announced on August 19, 2024, that the HREC submission had been approved.

On August 8, 2024, Satellos announced that the U.S. FDA had granted Rare Pediatric Disease Designation to SAT-3247 for the potential treatment of DMD after receiving Orphan Drug Designation earlier this year.

On September 18, 2024, Satellos announced that the first participant in the first-in-human healthy volunteer Phase 1 clinical trial had been dosed.

The Phase 1 clinical trial is comprised of two portions. In the first portion of the trial, 72 healthy volunteers are being enrolled in a blinded, randomized, placebo-controlled, staggered, parallel design study to assess the safety and pharmacokinetic properties of SAT-3247. Participants are being randomized across five SAD cohorts, four MAD cohorts, and one food effect dose cohort. In the second portion of the trial, which is expected to begin in late Q4 2024, 10 adult volunteers with genetically confirmed DMD are expected to be enrolled in a 28-day, open-label, single daily dose cohort designed primarily to confirm safety and assess pharmacokinetic properties of SAT-3247 in a patient population, and secondarily to explore potential pharmacodynamic markers for possible utility in future clinical trials.

On October 1, 2024, Satellos reported data at the World Muscle Society annual meeting. The presentation provided

an overview of key data collected during the open-label pilot study of SAT-3247 in a preclinical canine model of DMD. The data presented from the pilot study showed improved measures of muscle strength to near normal levels in the two DMD canines treated with SAT-3247.

An initial summary of the data is presented below. After four months of treatment (from ~nine to ~thirteen months of age) with a daily oral dose of SAT-3247:

- Treatment with SAT-3247 resulted in improvements in every force parameter measured over baseline. The average force improvement following four months of treatment, across all measures, was 195% (i.e., 2.95x) compared to baseline.
- Treated animals showed a return to muscle function near healthy, non-diseased, age-matched animal levels when evaluated against historical comparator data.
- The animals showed increases in the Regenerative Index (RI), a measure of the ratio of new muscle to dying muscle, in the diaphragm, gastrocnemius medialis (calf), and vastus lateralis (quadriceps) skeletal muscles. This is in addition to previously reported improvements in RI demonstrated in the bicep femoris.
- There were no adverse events and no significant changes in hematology or clinical chemistry observed.
- Trends to lower creatine kinase levels were noted, a finding that could be consistent with a Duchenne disease-modifying treatment.

## Financial Results (in \$C)

Satellos had cash and cash equivalents and short-term investments of \$23.4 million as of September 30, 2024, compared to \$39.6 million as of December 31, 2023. The decrease in cash and cash equivalents and short-term investments is due to cash used in operating activities in the nine months ended September 30, 2024.

For the three months ended September 30, 2024, Satellos reported a net loss of \$9.0 million (\$0.08 loss per share), compared to a net loss of \$3.6 million (\$0.03 loss per share) for the three months ended September 30, 2023. The increase in net loss for the three-month period ended September 30, 2024, compared with the same period in 2023 was a result of increased research and development (R&D) expenses related to the initiation of a Phase 1 clinical trial, higher headcount and R&D activities associated with SAT-3247. In addition, during the period ended September 30, 2024, management determined that it was no longer likely that the sale of AmpB (and its component assets, OralTrans and the investment in NWMT) would be completed through the exercise of the call option or completion of the put option. As such, the Company recognized a non-cash impairment charge of \$3.9 million to fully write down the remaining carrying value of the intangible asset.

Research and development expenses increased by approximately \$529 thousand to \$3.3 million for the three months ended September 30, 2024, compared to \$2.7 million for the three months ended September 30, 2023. The increase in R&D expenses was primarily the result of increased preclinical IND-enabling costs and chemistry,

manufacturing, and controls expenses 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 incurred to prepare for and initiate a Phase 1 clinical trial in Q3 2024. These increases were partially offset by a decrease in non-cash stock-based compensation due to the forfeiture of stock options in the current period related to staffing changes.

General and administrative expenses were relatively consistent, at \$1.8 million for the three months ended September 30, 2024, as compared to \$1.8 million for the three months ended September 30, 2023.

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

## About Satellos Bioscience Inc.

Satellos is a clinical-stage drug development company dedicated to developing life-improving medicines to treat degenerative muscle diseases. Satellos has invented SAT-3247 as a first-of-its-kind, orally administered small molecule drug designed to restore skeletal muscle regeneration initially in Duchenne muscular dystrophy (DMD). Satellos has generated a significant body of preclinical evidence in DMD to support that correcting muscle stem cell polarity with SAT-3247 has the potential to restore skeletal muscle regeneration to repair and strengthen muscle that has been damaged. The Company's lead drug candidate SAT-3247 is currently in clinical development as a potential disease-modifying treatment DMD. Additionally, Satellos is leveraging its breakthrough research in muscle stem cell polarity and proprietary discovery platform MyoReGenX™, to identify degenerative muscle diseases where deficits in muscle regeneration occur that are amenable to therapeutic intervention for future clinical development. For more information, visit [www.satellos.com](http://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; expected timing regarding enrollment and dosing with respect to the Company's programs; 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; 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](http://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

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