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Satellos Bioscience Inc.

(OTCQB: MSCLF)

MSCLF: SAT-3153 Granted Orphan Drug Designation and Rare Pediatric Disease Designation…

Based on our probability adjusted DCF model that takes into account potential future revenues in DMD, MSCLF is valued at $0.70/share. This model is highly dependent upon continued success of the development candidates and will be adjusted accordingly based on future clinical results.

Current Price (09/14/23)	$0.38
Valuation	**$0.70**

OUTLOOK

On August 29, 2023, Satellos Biosciences Inc. (MSCLF) announced financial results for the second quarter of 2023 and provided a business update. The U.S. FDA recently granted Orphan Drug Designation (ODD) and Rare Pediatric Disease Designation (RPDD) to SAT-3153, the company's lead development candidate, for the potential treatment of Duchenne muscular dystrophy (DMD). Ongoing and upcoming activities for the development of SAT-3153 include larger-scale and longer-duration in vivo studies, non-GLP and GLP dose ranging and toxicology studies, compilation of the Chemistry, Manufacturing and Controls (CMC) section of the IND, and evaluation and prioritization of several back-up candidate compounds. We expect an IND filing and initiation of a Phase 1 clinical trial in healthy volunteers in the 1H24.

SUMMARY DATA

52-Week High	**$0.67**
52-Week Low	**$0.12**
One-Year Return (%)	**14.51**
Beta	**0.75**
Average Daily Volume (sh)	**7,830**
Shares Outstanding (mil)	**113**
Market Capitalization ($mil)	**$34**
Short Interest Ratio (days)	**1**
Institutional Ownership (%)	**2**
Insider Ownership (%)	**17**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2022 Estimate	**-2.5**
P/E using 2023 Estimate	**-2.5**

Risk Level	**High**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	0.0 A	0.0 A	0.0 A	0.0 A	0.0 A
2023	0.0 A	0.0 A	0.0 E	0.0 E	0.0 E
2024					0.0 E
2025					0.0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	-$0.05 A	-$0.05 A	-$0.04 A	-$0.09 A	-$0.24 A
2023	-$0.03 A	-$0.04 A	-$0.02 E	-$0.02 E	-$0.09 E
2024					-$0.06 E
2025					-$0.06 E

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WHAT'S NEW

Business Update

Update on SAT-3153

Satellos Biosciences Inc. (MSCLF) is developing therapies for severe muscle conditions with a focus on muscle regeneration. The company's core technology derives from discoveries made in the laboratory of the Chief Scientific Officer, Dr. Michael Rudnicki, regarding the understanding of muscle stem cell function and its role in muscle regeneration. His research revealed that muscle stem cells are capable of regeneration and that deficiencies in muscle stem cell function contribute to the pathology of Duchenne muscular dystrophy (DMD) and that modulating their activity can potentially impact the disease.

Muscle stem cells can undergo symmetric or asymmetric division in response to injury stimuli. Symmetric division results in two identical copies of the stem cell through a process of self-renewal. Asymmetric division results in one stem cell and one daughter cell committed to differentiation (progenitor muscle cell). Progenitor muscle cells then undergo mitosis to potentially generate hundreds to thousands of new muscle cells that can be incorporated into functional muscle tissue. Dr. Rudnicki's research has identified links between deficits in either symmetric or asymmetric division that can lead to multiple muscle wasting and degenerative diseases, including DMD. His laboratory published results showing that muscle stem cells that lack dystrophin protein, a hallmark of patients with DMD, are unable to divide properly.

The company's lead development candidate, SAT-3153, is a protein kinase inhibitor that targets a particular protein in the Notch signaling pathway (codenamed "K9"). Following results obtained through genetic ablation of K9, Satellos hypothesized that targeting K9 could modulate asymmetric muscle stem cell division. Since K9 is already the target of other pharmaceutical interventions in a different disease setting, Satellos was able to synthesize existing K9 inhibitors to test the hypothesis. These studies showed that inhibiting K9 resulted in modulation of muscle stem cell division, enhanced muscle regeneration, and increased muscle mass/function.

Satellos is currently conducting larger-scale and longer-duration *in vivo* studies to gain greater insight into the mechanism of SAT-3153. The company is also conducting the requisite non-GLP and GLP dose ranging and *in vitro*/*in vivo* safety studies, including toxicology studies, that are necessary for IND/CTA applications. In addition, several back-up development compounds have been identified and recently the company identified a chemical entity that is structurally closely related to SAT-3153, named SAT-3247, that may have enhanced pharmaceutical properties.

During the second quarter of 2023, the company began Chemistry, Manufacturing and Controls (CMC) development activities in support of an IND filing, which is currently planned for the first half of 2024. We then anticipate a Phase 1 clinical trial in healthy human volunteers initiating before the end of the second quarter of 2024, pending approval of the IND.

Granted Orphan Drug Designation and Rare Pediatric Disease Designation

On August 1, 2023, Satellos announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) and Rare Pediatric Disease Designation (RPDD) to SAT-3153 for the potential treatment of Duchenne muscular dystrophy (DMD). SAT-3153 is the company's lead development candidate that is a first-in-class oral, small molecule therapeutic designed to restore the innate muscle regeneration process independent of dystrophin and regardless of exon mutation status.

ODD is granted to support the development of therapeutics for diseases or disorders that affect fewer than 200,000 individuals in the U.S. The designation provides a number of benefits, including the

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potential for seven years of market exclusivity following approval, exemption from FDA application fees, and tax credits for qualified clinical trials. RPDD is granted for serious and life-threatening diseases that primarily affect children ages 18 years or younger and fewer than 200,000 people in the U.S. Upon approval, a sponsor may receive a priority review voucher (PRV). A PRV allows an applicant to receive an expedited drug application review (6 months as opposed to the traditional 10 months). PRVs are fully transferable and a number of them have sold in the past couple of years for approximately $100 million each.

New Chief Medical Officer

In June 2023, Satellos announced the appointment of Alan K. Jacobs, MD as Chief Medical Officer (CMO). Prior to joining Satellos, Dr. Jacobs was Vice President, Clinical Development, Neuroscience at Boston Pharmaceuticals, where he was responsible for early and late-stage clinical development programs. Before that, he held progressively senior leadership roles with Immunovant and Sanofi Genzyme, including strategic coordination of multiple successful IND submissions and execution of clinical trials.

Financial Update

On August 29, 2023, Satellos announced financial results for the second quarter of 2023. Net loss for the second quarter of 2023 was CAD$4.1 million compared to CAD$2.2 million for the second quarter of 2022. The increase in net loss was primarily due to increased spending on R&D contracting, professional fees, interest on long term debt, and foreign exchange loss. R&D expenses for the second quarter of 2023 were $0.87 million compared to $0.62 million for the second quarter of 2022. The increase was due to increased R&D contractor activity.

As of June 30, 2023, Satellos had approximately CAD$48.7 million in cash and cash equivalents. This was due in part to the equity offering in May 2023 that raised gross proceeds of $55 million. As of June 30, 2023, Satellos had approximately 112.8 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 136.3 million.

Conclusion

Satellos continues to execute its business plan as it works toward an IND filing in the first half of 2024 and a subsequent Phase 1 clinical trial in healthy volunteers. We look forward to additional updates from the company throughout the rest of the year as it completes the necessary requirements for the IND filing. With no changes to our model our valuation remains at $0.70.

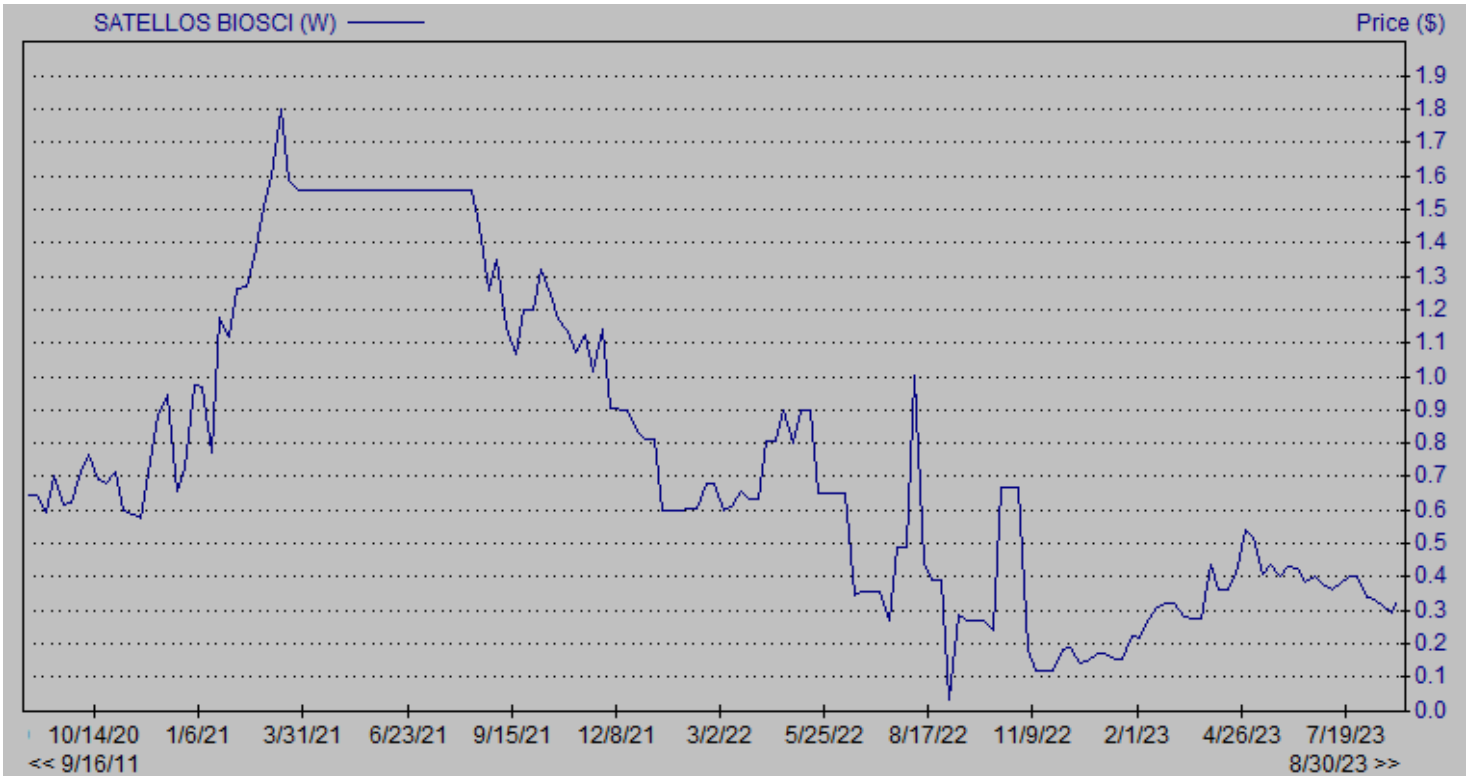
PROJECTED FINANCIALS

Satellos Biosciences Inc. (in $USD)	2022 A	Q1 A	Q2 A	Q3 E	Q4 E	2023 E	2024 E	2025 E
DMD Program	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Additional Indication	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Other Income	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Total Revenues	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**
CoGS	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
R&D	$1.9	$0.5	$0.6	$0.5	$0.5	$2.2	$2.2	$2.4
SG&A	$3.0	$0.6	$1.3	$0.8	$0.9	$3.6	$3.3	$3.5
Stock-based compensation	$1.1	$0.2	$0.3	$0.3	$0.4	$1.1	$1.3	$1.4
Depreciation and Amortization	$0.2	$0.0	$0.0	$0.1	$0.1	$0.2	$0.3	$0.3
Other expenses	$0.1	$0.0	$0.0	$0.0	$0.0	$0.1	$0.1	$0.1
Operating Income	($6.3)	($1.3)	($2.3)	($1.7)	($1.9)	($7.1)	($7.3)	($7.7)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	$2.1	$0.0	$0.8	$0.0	$0.0	($0.8)	$0.1	$0.1
Pre-Tax Income	($8.4)	($1.3)	($3.1)	($1.7)	($1.9)	($7.9)	($7.2)	($7.6)
Taxes & Other	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($8.4)	($1.3)	($3.1)	($1.7)	($1.9)	($7.9)	($7.2)	($7.6)
Reported EPS	**($0.23)**	**($0.03)**	**($0.04)**	**($0.02)**	**($0.02)**	**($0.09)**	**($0.06)**	**($0.06)**
Weighted Shares Outstanding	35.7	41.9	78.2	112.8	113.0	86.5	115.0	125.0

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

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