



NEWS RELEASE

SELLAS Life Sciences Reports Third Quarter 2021 Financial Results and Provides Business Update

11/12/2021

NEW YORK, Nov. 12, 2021 (GLOBE NEWSWIRE) -- **SELLAS Life Sciences Group, Inc.** (NASDAQ: SLS) ("SELLAS" or the "Company"), a late-stage clinical biopharmaceutical company focused on developing novel cancer immunotherapies for a broad range of indications, today reported its financial results for the quarter ended September 30, 2021 and provided a business update.

"During the third quarter of 2021, in addition to continuing to enroll patients in the United States and Europe for our Phase 3 REGAL study of galinpepimut-S (GPS) in acute myeloid leukemia (AML) patients, we also commenced clinical and regulatory preparations for a potential new Phase 2/3 study of GPS in AML patients following a bone marrow transplant (BMT) who harbor minimal residual disease (MRD)," said Angelos M. Stergiou, MD, ScD. h.c., President and Chief Executive Officer of SELLAS. "We are excited to begin exploring GPS as a treatment option for this post-BMT population which, based on the retrospective outcomes data published earlier in the summer, remains an area of unmet need. We believe there is significant opportunity for GPS to become the key antileukemic vaccine immunotherapy in various AML settings, with the potential to treat patients who have undergone a BMT as well as patients who have achieved second remission in AML (CR2), the indication of our REGAL study."

Dr. Yair Levy, Director of Hematologic Malignancies at the Baylor University Medical Center, stated "I look forward to a clinical trial in transplanted patients that would address the high relapse rate among MRD positive (MRD+) AML patients. Although BMT remains the only truly curative treatment for AML patients with any significant disease risk, its benefit is limited by relapses in about 50% of patients who enter transplant with MRD. The trial being planned by SELLAS would explore whether GPS could be a treatment option for a much larger population of AML patients – i.e., those patients who have undergone BMT whose chances of remaining in remission could significantly improve as well as the large number of MRD+ patients who have been shown to have a high relapse rate after BMT or who do

not undergo a BMT because they are considered unlikely to benefit from it.”

Pipeline Update and Corporate Highlights:

- Phase 3 REGAL Study:
 - Additional sites in the United States and European Union were activated during the third quarter with enrollment continuing. In addition, regulatory approval to commence the REGAL study was received in both Hungary and Taiwan during the quarter.
 - The final statistical analysis plan (SAP) for the REGAL study provides for a planned interim safety and futility analysis after 80 events (deaths) which the Company had anticipated would take place in the first half of 2022, provided that the ongoing COVID-19 pandemic did not significantly adversely impact our projected timeline for enrollment. Over the last 12 to 18 months, the Company has monitored the impact of the COVID-19 pandemic on the projected timeline for the REGAL study. During this period, the Company took several steps to mitigate possible and actual delays due to the COVID-19 pandemic, including increasing the number of clinical sites and the number of countries in which sites are located in order to maintain the original timeline. Despite these mitigation steps, the Company now anticipates that the interim analysis will take place in the second half of 2022, provided that the ongoing COVID-19 pandemic does not continue to adversely impact the projected timeline for enrollment. In addition to the planned interim analysis under the SAP, the final charter for the Independent Data Monitoring Committee for the REGAL study provides for enrollment-based safety, futility, and efficacy analyses prior to the planned interim analysis.
- Planning for Potential Phase 2/3 GPS Study in AML Post-Transplant Patients: In August 2021, SELLAS hosted a Virtual Investor Symposium which focused on the potential for GPS in AML patients following a BMT. SELLAS management, Dr. Stergiou and Dr. Dragan Cicic, SVP, Clinical Development, were joined by leading cancer researcher Dr. Yair Levy, Director of Hematologic Malignancies at the Baylor University Medical Center. To access the event replay, click [here](#). The Company is currently in the regulatory and clinical planning stages for a potential Phase 2/3 clinical trial of GPS in this patient population.
- Red Door Community Award: On November 11, 2021, Angelos M. Stergiou, MD, ScD. h.c., President and Chief Executive Officer of SELLAS, was honored on behalf of SELLAS by the Red Door Community (formerly Gilda's Club) with the Red Door Award for Advances in Research.

Financial Results for the Third Quarter 2021:

Licensing revenue: There was no licensing revenue for the third quarter of 2021 and \$7.6 million for the nine

months ended September 30, 2021, which consists of the recognition of revenue from the Company's license agreement with 3D Medicines. The Company did not record any licensing revenue for the first nine months of 2020.

R&D Expenses: Research and development expenses for the third quarter of 2021 were \$4.5 million, as compared to \$2.4 million for the same period in 2020. Research and development expenses for the nine months ended September 30, 2021 were \$12.3 million as compared to \$6.5 million for the same period in 2020. The increase was primarily due to an increase in clinical trial expenses related to the Company's Phase 3 REGAL clinical trial of GPS in AML patients and a ramp up of the manufacture of clinical trial materials and registration batches of GPS, a technology transfer to a new contract manufacturer, clinical drug supply purchase costs in the European Union in preparation for opening sites and enrolling patients in EU countries, and personnel related expenses due to increased headcount.

G&A Expenses: General and administrative expenses for the third quarter of 2021 were \$2.4 million, as compared to \$2.1 million for the same period in 2020. General and administrative expenses for the nine months ended September 30, 2021 were \$8.8 million, as compared to \$6.3 million for the same period in 2020. The increase was primarily due to amortization expense associated with the capitalized contract acquisition costs of the 3D Medicines license agreement, an increase in legal fees as compared to the same period in 2020 during which the majority of legal expenses were offset by a reimbursement credit, and personnel related expenses due to increased headcount.

Net Loss: Net loss attributable to common stockholders was \$7.1 million for the third quarter of 2021, or a basic and diluted loss per share attributable to common stockholders of \$0.45, as compared to a net loss attributable to common stockholders of \$4.5 million for the same period in 2020, or a basic and diluted loss per share attributable to common stockholders of \$0.53. Net loss attributable to common stockholders was \$14.1 million for the nine months ended September 30, 2021, or a basic and diluted loss per share attributable to common stockholders of \$0.92, as compared to a net loss attributable to common stockholders of \$13.1 million for the same period in 2020, or a basic and diluted loss per share attributable to common stockholders of \$1.83.

Cash Position: As of September 30, 2021, cash and cash equivalents totaled approximately \$26.3 million.

About SELLAS Life Sciences Group, Inc.

SELLAS is a late-stage clinical biopharmaceutical company focused on developing novel cancer immunotherapeutics for a broad range of indications. SELLAS' lead product candidate, GPS, is licensed from Memorial Sloan Kettering Cancer Center and targets the WT1 protein, which is present in an array of tumor types. GPS has potential both as a monotherapy and in combination to address a broad spectrum of hematologic malignancies and solid tumor indications. SELLAS' second product candidate, nelipepimut-S (NPS), is a HER2-directed cancer immunotherapy with potential to treat patients with early-stage breast cancer with low to intermediate HER2 expression, otherwise

known as HER2 1+ or 2+, which includes TNBC patients, following the standard of care.

For more information on SELLAS, please visit www.sellaslifesciences.com.

Forward-Looking Statements

This press release contains forward-looking statements. All statements other than statements of historical facts are “forward-looking statements,” including those relating to future events. In some cases, forward-looking statements can be identified by terminology such as “plan,” “expect,” “anticipate,” “may,” “might,” “will,” “should,” “project,” “believe,” “estimate,” “predict,” “potential,” “intend,” or “continue” and other words or terms of similar meaning. These statements include, without limitation, statements related to the clinical development of GPS for AML, and the potential for GPS as a drug development candidate. These forward-looking statements are based on current plans, objectives, estimates, expectations, and intentions, and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks and uncertainties associated with the COVID-19 pandemic and its impact on the Company’s clinical plans, risks and uncertainties associated with immune-oncology product development and clinical success thereof, the uncertainty of regulatory approval, and other risks and uncertainties affecting SELLAS and its development programs as set forth under the caption “Risk Factors” in SELLAS’ Annual Report on Form 10-K filed on March 23, 2021 and in its other SEC filings. Other risks and uncertainties of which SELLAS is not currently aware may also affect SELLAS’ forward-looking statements and may cause actual results and the timing of events to differ materially from those anticipated. The forward-looking statements herein are made only as of the date hereof. SELLAS undertakes no obligation to update or supplement any forward-looking statements to reflect actual results, new information, future events, changes in its expectations or other circumstances that exist after the date as of which the forward-looking statements were made.

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SELLAS LIFE SCIENCES GROUP, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(Amounts in thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Licensing revenue	\$ —	\$ —	\$ 7,600	\$ —
Operating expenses:				
Cost of licensing revenue	—	—	200	—
Research and development	4,541	2,367	12,281	6,511
General and administrative	2,436	2,125	8,794	6,312
Total operating expenses	<u>6,977</u>	<u>4,492</u>	<u>21,275</u>	<u>12,823</u>
Operating loss	(6,977)	(4,492)	(13,675)	(12,823)
Non-operating income (expense), net:				
Change in fair value of warrant liability	30	6	(29)	25
Change in fair value of contingent consideration	(140)	13	(403)	(268)
Interest income	2	—	6	25
Total non-operating income (expense), net	<u>(108)</u>	<u>19</u>	<u>(426)</u>	<u>(218)</u>
Net loss	(7,085)	(4,473)	(14,101)	(13,041)
Deemed dividend arising from warrant modifications	—	—	—	(78)
Net loss attributable to common stockholders	<u>\$ (7,085)</u>	<u>\$ (4,473)</u>	<u>\$ (14,101)</u>	<u>\$ (13,119)</u>
Per share information:				
Net loss per common share attributable to common stockholders, basic and diluted	<u>\$ (0.45)</u>	<u>\$ (0.53)</u>	<u>\$ (0.92)</u>	<u>\$ (1.83)</u>
Weighted average common shares outstanding, basic and diluted	15,874,076	8,418,038	15,344,210	7,174,859

SELLAS LIFE SCIENCES GROUP, INC.
CONSOLIDATED BALANCE SHEETS
(Amounts in thousands, except share and per share data)
(Unaudited)

		September 30, 2021	December 31, 2020
ASSETS			
Current assets:			
Cash and cash equivalents		\$ 26,281	\$ 35,302

Restricted cash and cash equivalents	100	100
Contract asset	—	1,128
Prepaid expenses and other current assets	2,593	395
Total current assets	28,974	36,925
Operating lease right-of-use asset	767	896
In-process research and development	5,700	5,700
Goodwill	1,914	1,914
Deposits and other assets	597	614
Total assets	<u>\$ 37,952</u>	<u>\$ 46,049</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 2,545	\$ 4,657
Accrued expense and other current liabilities	2,584	1,913
Operating lease liability	190	166
Deferred revenue	—	5,600
Total current liabilities	5,319	12,336
Operating lease liability, non-current	667	825
Deferred tax liability	239	239
Warrant liability	84	55
Contingent consideration	5,036	4,633
Total liabilities	11,345	18,088
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 5,000,000 shares authorized; Series A convertible preferred stock, 17,500 shares designated; no shares issued and outstanding at September 30, 2021 and December 31, 2020	—	—
Common stock, \$0.0001 par value; 350,000,000 shares authorized, 15,874,131 and 14,254,554 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	2	1
Additional paid-in capital	158,610	145,864
Accumulated deficit	(132,005)	(117,904)
Total stockholders' equity	26,607	27,961
Total liabilities and stockholders' equity	<u>\$ 37,952</u>	<u>\$ 46,049</u>

Source: SELLAS Life Sciences Group, Inc.