



NEWS RELEASE

# SELLAS Life Sciences Reports Full Year 2022 Financial Results and Provides Business Update

3/16/2023

Phase 3 REGAL GPS AML Study on Track for Interim Analysis by Late 2023/Early 2024

Ongoing Phase 1 Study of CDK9 Inhibitor Suggests Broad Therapeutic Window and High Potential for Both Monotherapy and Combination Treatment

\$20 Million of Gross Proceeds from Capital Raise in February 2023 Adds to Cash Position of \$17.1 Million as of December 31, 2022; Additional \$13 Million Milestone Payment Expected in 1H 2023

NEW YORK, March 16, 2023 (GLOBE NEWSWIRE) -- SELLAS Life Sciences Group, Inc. (NASDAQ: SLS) ("SELLAS" or the "Company"), a late-stage clinical biopharmaceutical company focused on the development of novel therapies for a broad range of cancer indications, today reported financial results for the full year ended December 31, 2022 and provided a business update.

"Broad success defines the past year, with positive efficacy signals reported across our clinical programs and expansion of our development pipeline," said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. "Early this year we took proactive steps to considerably strengthen our balance sheet and prepare us for the coming year, raising an additional \$20 million in gross proceeds from institutional investors, which lays the groundwork for continued advancement of both our GPS and GFH009 programs and carries us through key value-driving milestones in the upcoming year."

Pipeline Program Summary for 2022:

Galinpepimut-S (GPS): Wilms Tumor-1 (WT1) targeting immunotherapeutic

Phase 3 REGAL study in acute myeloid leukemia (AML): Enrollment continued in the global Phase 3 REGAL registrational clinical trial in patients with AML who have achieved complete remission following second-line salvage therapy (CR2 patients). SELLAS announced in November that the REGAL clinical trial protocol and statistical analysis plan were revised to adjust for higher-than-expected overall survival observed in blinded pooled patient data, with interim analysis currently expected to occur in late 2023 or early 2024. SELLAS also announced that 3D Medicines, its development and commercialization partner for Greater China, informed SELLAS that it will participate in the REGAL study with the inclusion of patients from the Greater China territory. This participation will trigger milestone payments totaling \$13 million to SELLAS, which are expected during the first half of 2023.

3D Medicines phase 1 clinical trial in China: An investigational new drug (IND) application was approved by China's National Medical Products Administration for the first clinical trial for GPS in China, which triggered a milestone payment of \$1 million to SELLAS. 3D Medicines initiated the open-label, single-arm, multi-center Phase 1 clinical trial in patients with AML, multiple myeloma, non-Hodgkin's lymphoma, or higher-risk myelodysplastic syndrome.

Phase 1/2 Study in combination with pembrolizumab (Keytruda®) in ovarian cancer: SELLAS released top-line data in November showing clinical benefit of GPS in combination with pembrolizumab anti-PD-1 therapy in WT1 positive relapsed or refractory platinum resistant advanced metastatic ovarian cancer patients. The study was conducted under a Clinical Trial Collaboration and Supply Agreement with Merck & Co., Inc., Rahway, N.J., USA (known as MSD outside the United States and Canada), and SELLAS plans to present final data from this study at a medical conference in the first half of 2023.

Phase 1 Study in combination with nivolumab (Opdivo®) for malignant pleural mesothelioma (MPM): Updated positive data were announced in June from an investigator sponsored open-label Phase 1 trial for GPS combination therapy with checkpoint inhibitor nivolumab for treatment of MPM in patients who were either refractory to or relapsed after at least one line of the standard of care therapy. Patient enrollment was completed at the end of 2022 and SELLAS expects to report topline data during the first half of 2023.

Manufacturing: Completed and ongoing stability studies confirmed stability of GPS for at least 42 months at -20C and for at least 12 months at 2-8C and room temperatures.

GFH009: highly selective CDK9 inhibitor

License agreement with GenFleet Therapeutics (Shanghai), Inc.: In March, SELLAS entered into a license agreement with GenFleet Therapeutics (Shanghai), Inc. ("GenFleet") for an in-license of global rights outside of Greater China for the highly-selective small molecule cyclin-dependent kinase 9 (CDK9) inhibitor, GFH009.

Phase 1 clinical trial in hematological malignancies: Positive interim data from the ongoing Phase 1 dose-escalating clinical trial showed no dose limiting toxicities; anticancer effects were observed across multiple dose levels in both AML and lymphoma patients, suggesting a broad therapeutic window and high potential for both monotherapy as well as combination treatment. One patient in the AML cohort achieved a confirmed complete response, which SELLAS believes represents the first reported in AML for any CDK9 monotherapy. Initial pharmacodynamics (PD) studies showed clear reductions of CDK9 activity in the two biomarkers, MCL-1 and MYC.

Following completion of the Phase 1 clinical trial and determination of the recommended Phase 2 dose, SELLAS intends to commence a Phase 2a clinical trial of GFH009 in combination with venetoclax and azacitidine in AML patients who failed or did not respond to treatment with venetoclax and azacitidine. The primary endpoint of the Phase 2a clinical trial, which SELLAS expects to initiate during the second quarter of 2023, will likely be complete remission (CR) rate and secondary endpoints will likely include progression free survival, overall survival and proportion of patients proceeding to transplant. The topline data for this study are expected in the fourth quarter of 2023. SELLAS is also planning to potentially commence a Phase 2 clinical trial of GFH009 in certain solid tumors and/or lymphoma in the third quarter of 2023.

Preclinical Pediatric Testing and Results: GFH009 was selected for the National Cancer Institute (NCI) Pediatric Preclinical in Vivo Testing (PIVOT) Program, which involves a two-phase research plan for pharmacokinetics (PK) and efficacy in pediatric tumors. As part of the program, PIVOT principal investigators at eight participating research institutions evaluate GFH009 against pediatric solid tumors and leukemia models, and these studies are supported by NCI cooperative agreement grants. SELLAS also announced results from preclinical in vitro studies of GFH009 in solid tumor and AML cell lines demonstrating significant anti-tumor effects and cancer cell growth inhibition in all selected cell lines.

Financial Results for the Full Year 2022:

Licensing revenue: Licensing revenue for the year ended December 31, 2022 was \$1.0 million which related to approval by Chinese regulatory authorities of an IND application by 3D Medicines. This compares to \$7.6 million for the year ended December 31, 2021.

R&D Expenses: Research and development expenses for the year ended December 31, 2022 were \$20.3 million, as compared to \$15.7 million for the year ended December 31, 2021. The increase was primarily due to an increase in clinical trial expenses related to the REGAL clinical trial and personnel related expenses due to increased headcount.

Acquired In-Process Research and Development: Acquired in-process research and development was \$10.0 million for the year ended December 31, 2022, resulting from the in-licensing of GFH009. There was no acquired in-process

research and development during the year ended December 31, 2021.

G&A Expenses: General and administrative expenses for the year ended December 31, 2022 were \$12.6 million, as compared to \$11.3 million for the year ended December 31, 2021. The increase was primarily due to personnel related expenses due to increased headcount, which was partially offset by a decrease in amortization expense associated with the capitalized contract acquisition costs of the 3D Medicines license agreement.

Net Loss: Net loss was \$41.3 million for the year ended December 31, 2022, or a basic and diluted loss per share of \$2.13, as compared to a net loss of \$20.7 million for the year ended December 31, 2021, or a basic and diluted loss per share of \$1.34.

Cash Position: As of December 31, 2022, cash and cash equivalents totaled approximately \$17.1 million.

Subsequent to December 31, 2022, the Company consummated an underwritten public offering providing gross proceeds to the Company of \$20 million, before deducting underwriting discounts and commissions and offering expenses. An additional \$13 million milestone payment from 3D Medicines is expected in the first half of 2023.

Keytruda® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA and is not a trademark of SELLAS. Opdivo® is a registered trademark of Bristol-Myers Squibb Company, New York, NY, USA and is not a trademark of SELLAS. The manufacturers of these brands are not affiliated with and do not endorse SELLAS or its products.

About SELLAS Life Sciences Group, Inc. SELLAS is a late-stage clinical biopharmaceutical company focused on the development of novel therapeutics for a broad range of cancer 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 as a monotherapy and combination with other therapies to address a broad spectrum of hematologic malignancies and solid tumor indications. The Company is also developing GFH009, a small molecule, highly selective CDK9 inhibitor, which is licensed from GenFleet Therapeutics (Shanghai), Inc., for all therapeutic and diagnostic uses in the world outside of Greater China. For more information on SELLAS, please visit [www.sellaslifesciences.com](http://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 GPS and GFH-009 clinical development programs, clinical data of GPS and GFH009, the pre-clinical development of GFH009, plans for further clinical development of GFH009 and the potential for GPS and GFH009 as drug development candidates.

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 with 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 16, 2023 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)

	Year Ended December 31,	
	2022	2021
Licensing revenue	\$ 1,000	\$ 7,600
Operating expenses:		
Cost of revenue	100	200
Research and development	20,268	15,674
General and administrative	12,582	11,320
Acquired in-process research and development	10,000	—
In-process research and development impairment charge	—	5,700
Total operating expenses	<u>42,950</u>	<u>32,894</u>
Loss from operations	(41,950)	(25,294)
Non-operating income:		
Change in fair value of warrant liability	36	15
Change in fair value of contingent consideration	296	4,337
Interest income	317	6
Total non-operating income	<u>649</u>	<u>4,358</u>
Loss before income taxes	(41,301)	(20,936)
Income tax benefit	—	237
Net loss	<u>\$ (41,301)</u>	<u>\$ (20,699)</u>
Per share information:		
Net loss per common share, basic and diluted	<u>\$ (2.13)</u>	<u>\$ (1.34)</u>
Weighted average common shares outstanding, basic and diluted	19,395,709	15,481,113

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

ASSETS	December 31, 2022	December 31, 2021
Current assets:		
Cash and cash equivalents	\$ 17,125	\$ 21,355
Restricted cash and cash equivalents	100	100
Prepaid expenses and other current assets	531	1,589
Total current assets	<u>17,756</u>	<u>23,044</u>
Operating lease right-of-use assets	874	723
Goodwill	1,914	1,914
Deposits and other assets	399	594
Total assets	<u>\$ 20,943</u>	<u>\$ 26,275</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 3,357	\$ 2,144
Accrued expenses and other current liabilities	6,286	2,640
Operating lease liabilities	372	198
Acquired in-process research and development payable	5,500	—
Total current liabilities	<u>15,515</u>	<u>4,982</u>
Operating lease liabilities, non-current	573	610
Warrant liability	4	40
Contingent consideration	—	296
Total liabilities	<u>16,092</u>	<u>5,928</u>
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; 0 shares issued and outstanding at December 31, 2022 and 2021	—	—
Common stock, \$0.0001 par value; 350,000,000 shares authorized, 21,005,405 and 15,895,637 shares issued and outstanding at December 31, 2022 and 2021, respectively	2	2
Additional paid-in capital	184,753	158,948
Accumulated deficit	(179,904)	(138,603)
Total stockholders' equity	<u>4,851</u>	<u>20,347</u>
Total liabilities and stockholders' equity	<u>\$ 20,943</u>	<u>\$ 26,275</u>

Source: SELLAS Life Sciences Group, Inc.