



NEWS RELEASE

SELLAS Life Sciences Reports First Quarter 2022 Financial Results and Provides Business Update

5/12/2022

- Enhanced Pipeline with New Asset, GFH009, an In-licensed Next-Generation, Highly Selective CDK9 Inhibitor -
- \$25 Million of Gross Proceeds from Capital Raise in April 2022 and \$1 Million Milestone Payment Received in May 2022 Add to Cash Balance of \$14.3 Million as of March 31, 2022 -

NEW YORK, May 12, 2022 (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 its financial results for the quarter ended March 31, 2022 and provided a business update.

"SELLAS achieved several key milestones in the first four months of 2022, including expanding our development pipeline and strengthening our balance sheet," said Angelos Stergiou, M.D., Sc.D. h.c., President and Chief Executive Officer of SELLAS. "We entered into an exclusive license agreement with GenFleet Therapeutics (Shanghai), Inc. ("GenFleet") granting us exclusive rights for the development and commercialization of GFH009, a highly selective and potentially first and best in class small molecule cyclin-dependent kinase 9 ("CDK9") inhibitor, across all therapeutic and diagnostic uses worldwide outside of Greater China. We believe that GFH009 is a complementary strategic fit to our overall clinical development plans and provides us with an opportunity to further advance into the market for acute myeloid leukemia ("AML") therapeutics. GFH009 affords us the potential to treat active AML disease while our lead clinical candidate, galinpepimut-S (GPS), is potentially used in the maintenance setting in AML. The in-license of GFH009 also provides us an opportunity to address a very important pediatric market of soft tissue sarcomas as well as other cancers."

Dr. Stergiou added, "During the first quarter, we continued to advance the Phase 3 REGAL trial for our lead asset,

GPS and, in April, we also launched an expanded access program for GPS in response to multiple requests from physicians with which we hope to potentially improve clinical outcomes for patients and their families. Subsequent to the quarter, we fortified SELLAS' balance sheet with the closing of a public offering with gross proceeds of \$25 million. The funds position us to advance our clinical programs for both GPS and GFH009. We are pleased by the progress we made over the first quarter of 2022 and remain steadfast in our mission to develop innovative treatments and improve the standard of care available to patients. With GPS and GFH009, we now have two significant clinical assets in our pipeline, with several opportunities to develop and potentially commercialize, cancer drugs that can prolong the lives of patients battling cancer."

Pipeline Updates:

Galinpepimut-S (GPS)

- **Expanded Access Program:** In April 2022, the Company launched a pre-approval access/expanded access program ("EAP") with SELLAS' lead asset, GPS, for treating patients suffering from AML. For more information on the GPS EAP, please visit the PIPELINE page at www.sellaslifesciences.com.
- **Phase 3 REGAL Study:** SELLAS continued to progress enrollment of patients and activation of additional sites in the United States, Europe, and Asia in the first quarter of 2022. The Company believes that enrollment for the REGAL study will be completed in late 2022 or early in the first quarter of 2023 and the planned interim analysis will occur by the end of the first half of 2023, provided that its statistical assumptions and assumptions regarding the impact of COVID-19 on the operations of clinical sites as well as the duration of the pandemic remain unchanged.
- **Phase 1/2 GPS Study in Combination with Merck's KEYTRUDA®:** In February 2022, the Company completed enrollment in the Phase 1/2 clinical trial of GPS in combination with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in second or third line Wilms Tumor-1 (WT1+) relapsed or refractory metastatic ovarian cancer. Data from 15 patients is currently being reviewed by SELLAS and Merck, with top-line results expected by mid-2022 and a final data analysis for all evaluable patients expected by the end of 2022.
- **Phase I GPS Study in China:** In March 2022, an IND application to initiate the first clinical trial in China for GPS was approved by China's National Medical Products Administration ("NMPA"), which triggered a milestone payment of \$1 million received by the Company in May 2022. The IND, for a small Phase 1 clinical trial investigating safety, was submitted by SELLAS' partner in China, 3D Medicines Inc. ("3D Medicines"), with 3D Medicines expecting to initiate the trial by mid-2022. 3D Medicines' current clinical development plan provides for initiation of a Phase 2 clinical trial following receipt of satisfactory safety data from the Phase 1 clinical

trial; the initiation of the Phase 2 clinical trial will also trigger a milestone payment to SELLAS.

- **New Patent Allowance:** In February 2022, the U.S. Patent and Trademark Office issued a Notice of Allowance for a patent application covering certain WT1-targeting peptides, in combination with other molecules such as other peptides and immunomodulating compounds, useful for treatment of WT1-expressing cancers. The patent application covers WT1-targeting peptides linked to other molecules and is expected to be granted later this year. The patent will have a term extending to at least 2026. This patent complements the Company's existing composition of matter patents covering GPS peptides which expire in 2033 not including any potential extensions.

GFH009

- **In-License:** On March 31, 2022 the Company announced it had entered into an exclusive license agreement with GenFleet Therapeutics (Shanghai), Inc. ("GenFleet"), that grants rights to SELLAS for the development and commercialization of GFH009, a highly selective small molecule CDK9 inhibitor, across all therapeutic and diagnostic uses worldwide outside of Greater China (mainland China, Hong Kong, Macau and Taiwan). CDK9 activity has shown a negative correlation with overall survival in a number of cancer types, including hematologic cancers, such as AML and lymphomas, as well as solid cancers, such as osteosarcoma, pediatric soft tissue sarcomas, and melanoma, and endometrial, lung, prostate, breast and ovarian cancer.
- **Ongoing Phase 1 Clinical Trial:** In April 2022, SELLAS announced that initial data from the first four dose levels of the ongoing Phase 1 dose-escalating clinical trial of GFH009 show a significant anti-leukemic effect at the 9mg and 15mg dose levels given twice a week in AML patients resistant to standard-of-care treatments, with two patients refractory to, or relapsed after, venetoclax treatment experiencing greater or equal to a 50 percent decrease in bone marrow blasts following GFH009 monotherapy. There have been no dose-limiting toxicities, including no grade 3/4 neutropenia (an abnormally low count of a type of white blood cells), in the first four dose levels (2.5mg, 4.5mg, 9mg and 15 mg) with the twice-weekly GFH009 dosing. The first AML patient has been enrolled in the fifth dose level (22.5mg twice a week) cohort. The last planned dose level in this clinical trial is 30mg.

Corporate Highlights:

- **Underwritten Public Offering:** On April 5, 2022, the Company consummated an underwritten public offering providing gross proceeds to the Company of \$25.0 million, before deducting underwriting discounts and commissions and offering expenses.
- **Bolstered Leadership Team:** In March 2022, SELLAS appointed Robert Francomano as Chief Commercial

Officer. In January 2022, the Company promoted John Burns to Senior Vice President, Finance, and Chief Accounting Officer.

- Settlement of Legacy Galena Litigations: In February 2022, SELLAS received the final court approval of the settlement of securities litigation relating to the Company's predecessor, Galena. This marked the end to all litigation related to activities of Galena.

Financial Results for the First Quarter 2022:

Licensing revenue: Licensing revenue for the first quarter of 2022 was \$1.0 million, as compared to \$5.7 million for the same period in 2021. Licensing revenue in the first quarter of 2022 was related to China's NMPA approval of an IND application by 3D Medicines and licensing revenue during the first quarter of 2021 was related to the initial transaction price of the license agreement with 3D Medicines, which was recognized over a period of time.

R&D Expenses: Research and development expenses for the first quarter of 2022 were \$4.6 million, as compared to \$4.3 million for the same period in 2021. The increase was primarily due to an increase in clinical trial expenses for the ongoing Phase 3 clinical trial of GPS in AML and personnel related expenses due to increased headcount, partially offset by a decrease in manufacturing expenses due to the timing of the manufacture of registration batches of GPS in the prior year.

Acquired In-Process Research and Development: Acquired in-process research and development for the first quarter 2022 was \$10.0 million, related to the in-licensing of GFH009. There was no acquired in-process research and development during the first quarter of 2021.

G&A Expenses: General and administrative expenses for the first quarter of 2022 were \$3.0 million, as compared to \$3.6 million for the same period in 2022. The decrease was primarily due to a decrease in amortization expense associated with the capitalized contract acquisition costs of the 3D Medicines license agreement and a decrease in professional service fees, partially offset by an increase in personnel related expenses due to increased headcount.

Net Loss: Net loss was \$16.7 million for the first quarter of 2022, or a basic and diluted loss per share of \$1.05, as compared to a net loss of \$2.4 million for the same period in 2021, or a basic and diluted loss per share of \$0.16.

Cash Position: As of March 31, 2022, cash and cash equivalents totaled approximately \$14.3 million. Subsequent to March 31, 2022, the Company consummated an underwritten public offering providing gross proceeds to the Company of \$25.0 million, before deducting underwriting discounts and commissions and offering expenses, and received a \$1.0 million milestone payment from 3D Medicines.

About SELLAS Life Sciences Group, Inc.

SELLAS Life Sciences Group, Inc. (NASDAQ: SLS) 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 or in 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.

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 and GFH009 for various cancer indications, including the timing of commencement and completion of clinical trials therefor, the potential for GPS and GFH009 as drug development candidates for various cancer indications, alone and in combination with other therapeutic agents, the timing for the completion of enrollment for the GPS REGAL Phase 3 clinical trial, the timing for analyses and reporting of data for GPS, the potential for regulatory approval and commercialization of GPS, and the potential for additional milestone payments under the license agreement with 3D Medicines. 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 31, 2022 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 March 31,	
	2022	2021
Licensing revenue	\$ 1,000	\$ 5,700
Operating expenses:		
Cost of licensing revenue	100	100
Research and development	4,611	4,284
Acquired in-process research and development	10,000	—
General and administrative	3,024	3,561
Total operating expenses	17,735	7,945
Operating loss	(16,735)	(2,245)
Non-operating income (expense):		
Change in fair value of warrant liability	(11)	(31)
Change in fair value of contingent consideration	—	(129)
Interest income	2	2
Total non-operating expense	(9)	(158)
Net loss	\$ (16,744)	\$ (2,403)
Per share information:		
Net loss per share, basic and diluted	\$ (1.05)	\$ (0.16)
Weighted average shares outstanding, basic and diluted	15,897,479	14,877,317

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

	ASSETS	March 31, 2022	December 31, 2021
Current assets:			
Cash and cash equivalents		\$ 14,252	\$ 21,355
Restricted cash and cash equivalents		100	100
Accounts receivable		1,000	—
Prepaid expenses and other current assets		2,487	1,589
Total current assets		<u>17,839</u>	<u>23,044</u>
Operating lease right-of-use assets		1,127	723
Goodwill		1,914	1,914
Deposits and other assets		554	594
Total assets		<u>\$ 21,434</u>	<u>\$ 26,275</u>
	LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:			
Accounts payable		\$ 2,842	\$ 2,144
Accrued expense and other current liabilities		3,012	2,640
Operating lease liabilities		325	198
Acquired in-process research and development payable		4,500	—
Total current liabilities		<u>10,679</u>	<u>4,982</u>
Acquired in-process research and development payable, non-current		5,500	—
Operating lease liabilities, non-current		883	610
Warrant liability		51	40
Contingent consideration		296	296
Total liabilities		<u>17,409</u>	<u>5,928</u>
Commitments and contingencies (Note 7)			
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 March 31, 2022 and December 31, 2021		—	—
Common stock, \$0.0001 par value; 350,000,000 shares authorized, 15,905,999 and 15,895,637 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively		2	2
Additional paid-in capital		159,370	158,948
Accumulated deficit		(155,347)	(138,603)
Total stockholders' equity		<u>4,025</u>	<u>20,347</u>
Total liabilities and stockholders' equity		<u>\$ 21,434</u>	<u>\$ 26,275</u>

Source: SELLAS Life Sciences Group, Inc.