



NEWS RELEASE

SELLAS Life Sciences Reports 2018 Financial Results and Provides Business Update

3/22/2019

NEW YORK, March 22, 2019 (GLOBE NEWSWIRE) -- SELLAS Life Sciences Group, Inc. (Nasdaq: SLS) ("SELLAS" or the "Company"), a clinical-stage biopharmaceutical company focused on the development of novel cancer immunotherapies for a broad range of cancer indications, today reported financial results for the year ended December 31, 2018 and provided a business update.

"In February, we initiated a review of a wide range of strategic alternatives to maximize shareholder value, such as a sale of the Company, a merger, or a strategic investment or financing," stated Dr. Angelos M. Stergiou, M.D., ScD h.c., President and Chief Executive Officer of SELLAS. "We are currently actively exploring these alternatives with the goal of identifying a plan that will enhance shareholder value while advancing our novel cancer immunotherapy clinical pipeline."

2018 and Recent Business Highlights

Corporate Developments

- In February 2019, the Company announced that its Board of Directors is conducting a review of strategic options focusing on maximizing shareholder value. SELLAS has engaged Cantor Fitzgerald & Co. to act as its strategic and financial advisor for this process.
- In March 2019, the Company entered into a warrant exchange agreement with a single investor, the proceeds of which are being used by the Company to further its development programs and business operations during the strategic alternatives evaluation process.

Clinical Pipeline

Galinpepimut-S (GPS)

- In November 2018, following discussion with the U.S. Food and Drug Administration (FDA), the Company announced a streamlined clinical trial design and biostatistical plan for a Phase 3 registrational study for GPS in acute myeloid leukemia (AML). The planned Phase 3 registrational study will be a 1:1 randomized, open-label study comparing GPS in the maintenance setting to investigators' choice of best available treatment in adult AML patients who have achieved hematologic complete remission, with or without thrombocytopenia (CR2/CR2p), after second-line antileukemic therapy and who are deemed ineligible for or unable to undergo allogeneic stem-cell transplantation. The primary endpoint is overall survival and secondary endpoints include leukemia-free survival, antigen-specific T-cell immune response dynamics over time and rates of achievement of measurable residual disease negativity. The study will have a planned interim safety and futility analysis after 80 events (deaths). The Phase 3 study is expected to enroll approximately 116 patients at approximately 50 clinical sites in the United States and Europe. The Company is completing preparations for the initiation of this study which is subject to the receipt of sufficient funding. This study is being led by Drs. Hagop Kantarjian of MD Anderson Cancer Center and Gert Ossenkoppele of Amsterdam University Medical Center (VUMC) and the HOVON network.
- In December 2018, SELLAS initiated enrollment of the Phase 1/2 open-label, non-comparative, multicenter, multi-arm study of GPS in combination with Merck's anti-PD-1 therapy Keytruda® (pembrolizumab) in patients with selected WT1-positive advanced cancers, including both hematologic malignancies and solid tumors. This study, which is being conducted under a Clinical Trial Collaboration and Supply Agreement with Merck (known as MSD outside the United States and Canada), will assess the efficacy and safety of the combination, with exploratory long-term follow-up for overall survival and safety, and is expected to enroll approximately 90 patients at up to 20 sites in the United States. The initial tumor types to be treated will be AML (patients unable to attain deeper morphological response than partial on hypomethylating agents and who are not eligible for allogeneic hematopoietic stem cell transplant) and ovarian cancer (second or third line), to be followed by triple negative breast cancer (TNBC) (second line), small cell lung cancer (second line), and colorectal cancer (third or fourth line). The study is being led by Drs. Richard Maziarz of Oregon Health and Science University and Roisin O'Cearbhaill of Memorial Sloan Kettering Cancer Center.

Nelipepimut-S (NPS)

- In 2018, the Company announced positive data from a prospective, randomized, single-blinded, controlled Phase 2b independent investigator-sponsored clinical trial of the combination of NPS (NeuVax™) + trastuzumab (Herceptin®) targeting HER2 low-expressing breast cancer patient cohorts. In the study, NPS + trastuzumab demonstrated clinically and statistically significant efficacy in the cohort of patients with TNBC, with a p-value of 0.013 and a 75.2% reduction in risk of relapse or death.

- A preplanned secondary efficacy analysis across human leukocyte antigen (HLA) allele subgroups from the Phase 2b study confirmed the therapeutic potential of NPS in patients with early-stage TNBC in the adjuvant setting across HLA types A-02, -03, -24 and -26, which cover approximately 80-85% of the North American/European populations and 86-90% of Asian/Pacific basin populations. Additional positive data from the Phase 2b study showed a clinically meaningful and statistically significant decrease in the number of clinically detectable relapses in the TNBC cohort with the combination of NPS + trastuzumab (7.5%) vs. trastuzumab alone (27.3%) ($p=0.004$). In addition, four pre-defined subgroups of TNBC patients in the NPS +trastuzumab arm demonstrated an average decrease of 84.2% in relative risk of relapse or death at 24 months ($p=0.004-0.014$).
- Based on the Phase 2b data presented in 2018, as well as the unanimous recommendation of the Data Safety Monitoring Board to expeditiously seek regulatory guidance from the FDA for further development of NPS + trastuzumab in TNBC, SELLAS is currently in continuing active discussions with the FDA.

Year End 2018 Financial Results

Cash Position: As of December 31, 2018, cash and cash equivalents were \$5.3 million, compared to \$2.3 million as of December 31, 2017. Net cash used in operating activities was \$30.4 million for the year ended December 31, 2018, compared to \$11.0 million for the year ended December 31, 2017. Net cash provided by financing activities was \$23.1 million for the year ended December 31, 2018, primarily attributable to \$31.5 million in net proceeds from the sale of equity securities, partially offset by \$7.6 million in principal payments on previously outstanding debt. Net cash provided by financing activities for the year ended December 31, 2017 was \$5.5 million, primarily attributable to \$6 million in net proceeds from the sale of equity securities, partially offset by \$0.5 million on previously outstanding long-term debt.

R&D Expenses: Research and development expenses were \$8.8 million for the year ended December 31, 2018, as compared to \$6.1 million for the year ended December 31, 2017. The \$2.7 million increase was primarily due to increases in clinical and regulatory consulting and other clinical expenses related to startup costs for the Phase 1/2 basket trial of GPS in combination with pembrolizumab (Keytruda®) in multiple tumor types during 2018, and ongoing costs incurred related to the Phase 2b trial of NPS in combination with trastuzumab (Herceptin®). These increases were partially offset by decreases in compensation and benefits, including stock-based compensation, and manufacturing expenses.

G&A Expenses: General and administrative expenses were \$12.8 million for the year ended December 31, 2018, as compared to \$15.1 million for the year ended December 31, 2017. The \$2.3 million decrease was primarily driven by a decrease in compensation and employee benefits, including stock-based compensation, and in banking and advisory fees partially offset by increases in outside services and public company costs, rebates and returns of former commercial products, and insurance premiums.

Net Loss: Net loss for the year ended December 31, 2018 was \$27.7 million and loss attributable to common stockholders was \$41.3 million, or a basic and diluted loss per share to common stockholders of \$3.15, as compared to a net loss of \$23.8 million and loss attributable to common stockholders of \$24.4 million for the year ended December 31, 2017, or a basic and diluted loss per share to common stockholders of \$10.44. Net loss and loss attributable to common stockholders for the year ended December 31, 2018 includes a \$9.6 million one-time non-cash impairment charge of in-process research and development associated with the termination of a license agreement for anagrelide CR formulation (GALE-401).

Keytruda® and Herceptin® are registered trademarks of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, N.J., USA, and Genentech, Inc., respectively, and are not trademarks 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 clinical-stage biopharmaceutical company focused on novel cancer immunotherapeutics for a broad range of cancer indications. SELLAS' lead product candidate, GPS, is licensed from Memorial Sloan Kettering Cancer Center and targets the Wilms Tumor 1 (WT1) protein, which is present in an array of tumor types. GPS has potential as a monotherapy or in combination to address a broad spectrum of hematologic malignancies and solid tumor indications. SELLAS has a Phase 3 clinical trial planned (pending funding availability) for GPS in AML and is also studying GPS in combination with pembrolizumab (Keytruda®) in multiple indications. SELLAS has received Orphan Drug designations for GPS from the FDA and the European Medicines Agency for AML, malignant pleural mesothelioma (MPM), and multiple myeloma (MM); GPS has also received Fast Track designation for AML, MPM and MM from the FDA. SELLAS' second product candidate, NPS, is a HER2-directed cancer immunotherapy being investigated for the prevention of the recurrence of breast cancer after standard of care treatment in the adjuvant setting. NPS has received Fast Track status designation by FDA for the treatment of patients with early stage breast cancer with low to intermediate HER2 expression, otherwise known as HER2 1+ or 2+, which includes TNBC patients, following 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 Company's plans to explore strategic alternatives, the potential outcome and benefits of a strategic transaction or a financing, the further development of GPS and NPS, including the timing of clinical results, the potential time to market for GPS and NPS, the potential results from a clinical trial and interactions with the U.S. Food and Drug Administration. 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 Company's ability to identify potential strategic and financial transactions and to complete any transactions it pursues, whether SELLAS will be able to realize the expected benefits from a strategic review or a strategic transaction, immune-oncology product development and clinical success thereof, the uncertainty of regulatory approval, the uncertainty of finding potential partners for product candidate development, 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 22, 2019 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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