FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 2, 2017

Galena Biopharma, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-33958
(Commission
File Number)

20-8099512
(IRS Employer
Identification No.)

2000 Crow Canyon Place, Suite 380
San Ramon, CA 94583
(Address of principal executive offices)

Registrant's telephone number, including area code: (855) 855-4253

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

☒ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐
Item 8.01. Other Events.


Item 9.01. Financial Statements and Exhibits.

Exhibit Index

<table>
<thead>
<tr>
<th>Exhibit No.</th>
<th>Description</th>
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Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Galena Biopharma, Inc.

Dated: October 2, 2017

By: /s/ Stephen F. Ghiglieri
   Stephen F. Ghiglieri
   Interim Chief Executive Officer & Chief Financial Officer
SELLAS Enters into a Clinical Trial Collaboration and Supply Agreement with Merck & Co., Inc., Kenilworth, N.J., USA

Initiation of a Phase 1/2 Combination Clinical Trial with
Galinpepimut-S and KEYTRUDA ® (pembrolizumab) Across Various Indications
Expected in 1H, 2018

Hamilton, Bermuda and New York, NY (October 2, 2017) – SELLAS Life Sciences Group, Ltd. (SELLAS), a development-stage biopharmaceutical company focused on novel cancer immunotherapies for a broad range of cancer indications, today announced entry into a Clinical Trial Collaboration and Supply Agreement for the conduct of a combination clinical trial targeting multiple cancer types with Merck & Co., Inc., Kenilworth, N.J., USA (known as MSD outside the United States and Canada). SELLAS’ Wilms tumor-1 (WT1)-targeting peptide immunotherapeutic agent, galinpepimut-S, will be administered in combination with MSD’s anti-PD-1 therapy KEYTRUDA ® (pembrolizumab) in a Phase 1/2 trial enrolling patients in five cancer indications, including both hematologic malignancies and solid tumors.

The purpose of the trials is to determine if the administration of galinpepimut-S in combination with KEYTRUDA has the potential to demonstrate clinical activity in the presence of macroscopic disease, where monotherapy with either agent would have a more limited effect. The rationale for the study is based upon the presumed immunobiologic and pharmacodynamic synergy between the two agents, whereby the negative influence of tumor microenvironment factors on the immune response is mitigated by PD-1 inhibition (by KEYTRUDA) thus allowing the patients’ own immune cells to invade and destroy cancerous growth deposits specifically sensitized against WT1 (by galinpepimut-S).

Angelos Stergiou, MD, ScD h.c., Vice Chairman and Chief Executive Officer of SELLAS, stated, “SELLAS is enthused to embark upon this trial with MSD as we look to expand the utility of galinpepimut-S in combination with other agents. The KEYTRUDA/galinpepimut-S active immunotherapy combination is positioned to exploit the unique features of each of these two agents through potential synergistic immune-based mechanisms of antitumor action. If positive, this clinical effort will allow us to evaluate indications whereby galinpepimut-S and KEYTRUDA could be further studied in combination, providing the basis for a potentially promising cancer immunotherapy approach in the future.”

The Phase 1/2 trial will utilize a combination of galinpepimut-S plus KEYTRUDA in patients with WT1-positive relapsed or refractory tumors. Specifically, the study is expected to explore the following cancer indications: colorectal (arm enriched in but not exclusive to patients with microsatellite instability-low [MSI-L]), ovarian, small cell lung, triple-negative breast, and AML. This study will assess the efficacy and safety of the combination, comparing overall response rates (ORRs) and immune response markers achieved with the combination versus prespecified rates based on those seen with KEYTRUDA alone in comparable patient populations. The trial is anticipated to begin in the first half of 2018.

Galinpepimut-S is currently expected to enter a pivotal, Phase 3 clinical trial in patients with acute myeloid leukemia (AML) and is also in various development phases in multiple myeloma (MM) and ovarian cancer, while additional indications are expected as a monotherapy or in combination with other immuno-oncology agents. Galinpepimut-S demonstrated positive Phase 2 clinical results as well as induction of strong and sustained immune responses (both CD4+ and CD8+) against the WT1 antigen in AML and malignant pleural mesothelioma in 2016 and MM in 2017, while being able to access a broad range of human leukocyte antigen (HLA) types; tolerability has been good across indications to date.
The Clinical Trial and Collaboration Supply Agreement is between Sellas Life Sciences Group Ltd. and MSD through a subsidiary. Additional details of the collaboration were not disclosed.

About SELLAS Life Sciences Group
SELLAS Life Sciences Group Ltd. is a development-stage biopharmaceutical company focused on novel cancer immunotherapeutics for a broad range of cancer indications. SELLAS’ product candidate, galinpepimut-S, is a cancer immunotherapeutic agent licensed from Memorial Sloan Kettering Cancer Center that targets the WT1 protein, which is present in a large number of different tumor types. Galinpepimut-S has potential as a monotherapy or in combination to address a broad spectrum of hematologic, or blood, cancers and solid tumor indications. Galinpepimut-S is Phase 3-ready for two indications, AML and malignant pleural mesothelioma (MPM), and is also in development as a potential treatment for multiple myeloma and ovarian cancer. SELLAS plans to study galinpepimut-S in up to four additional indications. SELLAS recently received Orphan Drug designations from the U.S. Food & Drug Administration (FDA), as well as the European Medicines Agency, for galinpepimut-S in AML and MPM; as well as Fast Track designation for AML and MPM from the FDA. SELLAS was founded in 2012 and is currently headquartered in Hamilton, Bermuda, with additional offices in New York City, NY. For more information on SELLAS, please visit www.sellaslifesciences.com.

Forward-Looking Statement of SELLAS
This press release contains forward-looking statements, including, but not limited to, statements related to the potential of galinpepimut-S as a treatment for multiple myeloma, acute myeloid leukemia, mesothelioma and other cancers, as well as statements regarding SELLAS’ planned Phase 1/2 trial studying galinpepimut-S in combination with KEYTRUDA. These forward-looking statements are based on SELLAS’ 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 immune-oncology product development and clinical success thereof, the uncertainty of regulatory approval, and other risks and uncertainties affecting SELLAS and its development programs. 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 or as of the dates indicated in the forward-looking statements, even if they are subsequently made available by SELLAS on its website or otherwise. 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.

Keytruda® is a registered trademark of Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, N.J., USA.
Additional Information about the Proposed Merger involving Galena Biopharma, Inc. (NASDAQ: GALE) and SELLAS Life Sciences Group Ltd. and Where to Find It

In connection with the previously disclosed proposed merger involving Galena Biopharma, Inc. (Galena) and SELLAS Life Sciences Group Ltd., Galena and SELLAS intend to file relevant materials with the Securities and Exchange Commission, or the SEC. On September 22, 2017, Galena filed a registration statement on Form S-4 with the SEC that contains a preliminary proxy statement/prospectus/consent solicitation statement. **Galena and SELLAS will mail the final proxy statement/prospectus/consent solicitation statement to their respective stockholders when it becomes available. Investors and stockholders of Galena and SELLAS are urged to read the materials Galena and SELLAS file with the SEC, including the final proxy statement/prospectus/consent solicitation statement, when they become available because they will contain important information about Galena, SELLAS and the proposed merger.** The proxy statement /prospectus /information statement and other relevant materials (when they become available), and any other documents filed by Galena with the SEC, may be obtained free of charge at the SEC web site at www.sec.gov. In addition, copies of the documents filed with the SEC by Galena will be available free of charge on the Company’s website at www.galenabiopharma.com (under “Investors” – “Financials” – “SEC Filings”) or by directing a written request to: Galena Biopharma, Inc., 2000 Crow Canyon Place, Suite 380, San Ramon, CA 94583, Attention: Investor Relations or by email to: ir@galenabiopharma.com.

This communication shall not constitute an offer to sell or the solicitation of an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities in connection with the proposed merger shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended.

Participants in the Solicitation

Galena and its directors and executive officers and Sellas and its directors and executive officers may be deemed to be participants in the solicitation of proxies from the stockholders of Galena in connection with the proposed transaction. Information regarding the special interests of these directors and executive officers in the proposed merger are included in the proxy statement /prospectus /information statement referred to above.

Contact:

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