UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

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): September 28, 2017

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

Delaware	**001-33958**	**20-8099512**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

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

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.

On September 28, 2017, Galena Biopharma, Inc. issued a press release entitled " *Galena Biopharma Announces Completion of Enrollment in Two NeuVax™ (nelipepimut-S) Clinical Trials in Combination with Trastuzumab* ." A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

Exhibit Index

Exhibit No.	Description
99.1	Press release, dated September 28, 2017.

SIGNATURES

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: September 29, 2017

By: /s/ Stephen F. Ghiglieri
Stephen F. Ghiglieri
Interim Chief Executive Officer & Chief Financial Officer

Exhibit 99.1

Galena Biopharma Announces Completion of Enrollment in Two NeuVax™ (nelipepimut-S) Clinical Trials in Combination with Trastuzumab

Interim efficacy analysis expected in Q1, 2018 for Phase 2b in HER2 1+/2+ patients

San Ramon, California, September 28, 2017 — Galena Biopharma, Inc. (NASDAQ: GALE), a biopharmaceutical company developing hematology and oncology therapeutics that address unmet medical needs, today announced that two clinical trials evaluating NeuVax™ (nelipepimut-S) in combination with trastuzumab (Herceptin ® ; Genentech/Roche) for the prevention of recurrence in breast cancer patients have enrolled the protocol-defined number of patients to complete enrollment. The milestones were reported by the clinical research organization conducting both trials – a Phase 2b clinical trial in HER2 1+/2+ patients and a Phase 2 clinical trial in HER2 3+ patients.

"Completing enrollment in both of these trials represents a major milestone for NeuVax development," said Bijan Nejadnik, M.D., Executive Vice President and Chief Medical Officer of Galena. "The combination of trastuzumab and NeuVax has been shown to be synergistic in preclinical investigation, and we believe could be an effective treatment to prevent breast cancer recurrence in patients with no other treatment options. We would like to thank our investigators and patients who are participating in these trials as we look forward to the interim results next year for the Phase 2b trial and the primary endpoints for both trials in 2019."

Phase 2b Clinical Trial in HER2 1+/2+ Patients

The Phase 2b clinical trial has enrolled the necessary 300 patients to complete enrollment. The clinical trial is a randomized, multicenter, investigator-sponsored, study enrolling HER2 1+ and 2+, HLA A2+, A3+, A24 and/or A26, node positive, and high-risk node negative breast cancer patients. Eligible patients are randomized to receive NeuVax + GM-CSF + trastuzumab or trastuzumab + GM-CSF alone. Once enrolled, all patients receive the standard trastuzumab dosing for 12 months. One cohort also receives six doses of NeuVax given as a primary vaccine series starting with the third dose of trastuzumab and then goes on to receive a NeuVax booster inoculation once every six months for up to 36 months. The next milestone for the trial will be the interim efficacy analysis that is scheduled to be performed by the Data Safety Monitoring Board (DSMB) in the first quarter of 2018. The primary endpoint of the study is disease-free survival after 24 months, with results expected from that milestone in the fourth quarter of 2019. Genentech/Roche is providing the trastuzumab and partial funding for this trial.

Data presented in October 2016 demonstrated that this novel combination of trastuzumab and NeuVax with HER2 low-expressing patients is well tolerated and the cardiac effects of trastuzumab are not impacted by the addition of NeuVax. In February 2017, the DSMB reported that there were no safety concerns with the trial and the trial is not futile. The recommendation from the DSMB was to continue the trial with one revision to the statistical analysis plan regarding the timing of the pre-specified interim analysis. Given the lengthy duration of enrollment for the trial, the DSMB determined that the pre-specified interim efficacy analysis be moved up from 12 months to 6 months after the last patient is enrolled. Therefore, the DSMB expects to perform the interim efficacy analysis in the first quarter of 2018.

Phase 2 Clinical Trial in HER2 3+ Patients

The Phase 2 clinical trial has enrolled the necessary 100 patients to complete enrollment. This multi-center, prospective, randomized, single-blinded trial enrolled patients with a diagnosis of HER2 3+ breast cancer who are HLA A2+ or HLA A3+ and are determined to be at high-risk for recurrence. High-risk is defined as having received neoadjuvant therapy with an approved regimen that includes trastuzumab but not obtaining a pathological complete response at surgery, or underwent surgery as a first intervention and was found to be pathologically node-positive (≥ 4 positive lymph nodes, or having 1-3 positive lymph nodes (pN1) if hormone receptor negative). These high-risk patients are known to have higher recurrence rates than other HER2 3+ breast cancer patients. Eligible patients are randomized to receive NeuVax + GM-CSF + trastuzumab or trastuzumab + GM-CSF alone. Once enrolled, all patients receive the standard trastuzumab dosing for 12 months. One cohort also receives six doses of NeuVax given as a primary vaccine series starting with the third dose of trastuzumab and then goes on to receive a NeuVax booster inoculation once every six months for up to 36 months. The primary endpoint of the study is disease-free survival after 24 months, with results expected from that milestone in the fourth quarter of 2019. Partial funding for this trial was awarded through the Congressionally Directed Medical Research Program funded through the Department of Defense, via a Breast Cancer Research Program Breakthrough Award.

In February 2017, the DSMB reported that there were no safety concerns with the trial and the trial is not futile. The pre-specified interim safety analysis was completed on n=50 patients and demonstrated that the agent is well tolerated with no increased cardiotoxicity associated with giving NeuVax in combination with trastuzumab. The recommendation from the DSMB was to continue the HER2 3+ trial unmodified.

About NeuVax™ (nelipepimut-S)

NeuVax™ (nelipepimut-S) is a first-in-class, HER2-directed cancer immunotherapy under evaluation to prevent breast cancer recurrence after standard of care treatment in the adjuvant setting. It is the immunodominant peptide derived from the extracellular domain of the HER2 protein, a well-established target for therapeutic intervention in breast carcinoma. The nelipepimut-S sequence stimulates specific CD8+ cytotoxic T lymphocytes (CTLs) following binding to specific HLA molecules on antigen presenting cells (APC). These activated specific CTLs recognize, neutralize and destroy, through cell lysis, HER2 expressing cancer cells, including occult cancer cells and micrometastatic foci. The nelipepimut-S immune response can also generate CTLs to other immunogenic peptides through inter- and intra-antigenic epitope spreading. In clinical studies, NeuVax is combined with recombinant granulocyte macrophage-colony stimulating factor (GM-CSF).

NeuVax is currently in two breast cancer studies in combination with trastuzumab (Herceptin ® ; Genentech/Roche): a Phase 2b trial in node positive and triple negative HER2 IHC 1+/2+ (clinicaltrials.gov identifier: NCT01570036); and, a Phase 2 trial in high risk, node positive or negative HER2 IHC 3+ patients (clinicaltrials.gov identifier: NCT02297698). A Phase 2 clinical trial is also ongoing with NeuVax in patients with ductal carcinoma in situ (DCIS) (clinicaltrials.gov identifier: NCT02636582), and a Phase 2 trial is planned in patients with gastric cancer.

About Breast Cancer

New cases of breast cancer occur at an annual rate of 125 per 100,000 women in the U.S., with over 250,000 new cases and 40,000 deaths expected in 2017. Approximately 89.7% of breast cancer patients are expected to survive five years after diagnosis. Approximately 12.4% of women will be diagnosed with breast cancer at some point during their lifetime (2011 – 2013 data). The prevalence data from 2013 showed an estimated 3,053,450 women living with breast cancer in the United States.

According to the National Cancer Institute (NCI), only about 25% of breast cancers diagnosed are HER2 positive (IHC 3+). NeuVax targets approximately 50%-60% of these women who are HER2 low to intermediate (IHC 1+/2+ or FISH < 2.0) and achieve remission with current standard of care, but have no available HER2-targeted adjuvant treatment options to maintain their disease-free status.

Sources: National Cancer Institute and NCI Surveillance, Epidemiology, and End Results Program

About Galena Biopharma

Galena Biopharma, Inc. is a biopharmaceutical company developing hematology and oncology therapeutics that address unmet medical needs. Galena's pipeline consists of multiple mid-to-late-stage clinical assets led by its hematology asset, GALE-401, and its novel cancer immunotherapy programs including NeuVax™ (nelipepimut-S) and GALE-301/GALE-302. For more information, visit www.galenabiopharma.com .

Forward Looking Statements

This Press Release contains statements that include the words "expect," "intend," "plan," "believe," "project," "estimate," "may," "should," "anticipate," "will" and similar statements of a future or forward looking nature identify forward-looking statements for purposes of the federal securities laws and otherwise. Forward-looking statements are neither historical facts nor assurances of future performance. All statements, other than statements of historical facts, included in this press release regarding strategy, future operations, future financial position, prospects, plans and objectives of management are forward-looking statements. Examples of such statements include, but are not limited to, statements relating to the efficacy of the combination of trastuzumab and NeuVax in the treatment of breast cancer, the timing of the interim efficacy analysis for the Phase 2b clinical trial, the timing of the primary endpoints for both the Phase 2b and the Phase 2 trial, and the planned Phase 2 trial in patients with gastric cancer. *Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors, including, without limitation, risks and uncertainties associated the conduct of clinical trials and the risks and uncertainties relating to Galena and its business that can be found under the caption "Risk Factors" and elsewhere in the Company's SEC filings and reports, including in Galena's Annual Report on Form 10-K, filed with the SEC on March 15, 2017 and Galena's Quarterly Report on Form 10-Q, filed with the SEC on August 14, 2017 and in subsequently filed Form 10-Qs. Galena disclaims any intent or obligation to update these forward-looking statements to reflect events or circumstances that exist after the date on which they were made.*

Additional Information about the Proposed Merger involving Galena Biopharma, Inc. and SELLAS Life Sciences Group Ltd. and Where to Find It

In connection with the previously disclosed proposed merger involving Galena and SELLAS Life Sciences Group Ltd., SELLAS, 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/consent solicitation 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 merger. Information regarding the special interests of these directors and executive officers in the proposed merger are included in the proxy statement/prospectus/consent solicitation statement referred to above.

Contact:

Remy Bernarda
SVP, Investor Relations & Corporate Communications
(925) 498-7709
ir@galenabiopharma.com

Source: Galena Biopharma, Inc.