
**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): October 23, 2023

GALECTO, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39655
(Commission
File Number)

37-1957007
(I.R.S. Employer
Identification No.)

75 State Street, Suite 100
Boston, MA 02109
(Address of principal executive offices, including zip code)

(+45) 70 70 52 10
(Registrant's telephone number, including area code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trade Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.00001 par value per share	GLTO	The Nasdaq Global Select Market

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 October 23, 2023, Galecto, Inc. (the “Company,” or “Galecto”) issued a press release announcing updated clinical data from its Phase 1b/2a GALLANT-1 trial evaluating the combination of atezolizumab (Tecentriq®) and GB1211, Galecto’s first-in-class, oral small-molecule galectin-3 inhibitor candidate, in the first-line treatment of patients with metastatic/advanced non-small cell lung cancer. As part of Galecto’s recently announced strategic alternative process, Galecto also announced that it will not initiate Part B of the GALLANT-1 trial. The information in the press release attached as Exhibit 99.1 to this report is incorporated by reference into this Item 8.01 of this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release, dated October 23, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURE

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.

Galecto, Inc.

Date: October 23, 2023

By: /s/ Hans T. Schambye
Hans T. Schambye, M.D., Ph.D.
President and Chief Executive Officer



Galecto Presents Updated Clinical Data at ESMO Congress 2023 and Provides Update on Phase 1b/2a GALLANT-1 Trial

Partial response seen in three of five patients with advanced non-small cell lung cancer who received GB1211 100 mg plus atezolizumab for at least three weeks

Boston, MA, October 23, 2023 - Galecto, Inc. (NASDAQ: GLTO), a clinical-stage biotechnology company focused on the development of novel treatments for fibrosis and cancer, today presented a poster with new and encouraging clinical data, including two additional partial responders, from the dose-finding Part A of its Phase 1b/2a trial ([NCT05240131](#)) (the GALLANT-1 trial) at the European Society of Medical Oncology (ESMO) Congress 2023 in Madrid, Spain. The GALLANT-1 trial is designed to study the combination of atezolizumab (Tecentriq®) and GB1211, Galecto's first-in-class, oral small-molecule galectin-3 inhibitor candidate, in the first-line treatment of patients with metastatic/advanced non-small cell lung cancer (NSCLC).

At the recommended Phase 2 dose level of 100 mg GB1211 twice daily, investigator-assessed objective tumor responses (defined as partial responses per RECIST criteria 1.1) were observed in three of five patients (60%) who received GB1211 for at least three weeks. Response rates of only 22–38% have been observed with atezolizumab monotherapy in the first-line treatment of advanced NSCLC, suggesting a potential benefit of adding GB1211 to atezolizumab. The Company believes that GALLANT-1 is the first clinical trial to show that combining an oral galectin-3 inhibitor with a checkpoint inhibitor may enhance the effect of checkpoint inhibitors.

In addition, insights from early biomarker analyses revealed a trend showing that responders had increased levels of galectin-3 at baseline, and stable or decreasing galectin-3 levels during treatment. In contrast, patients with progressive disease demonstrated increasing levels of galectin-3 during treatment. This correlation suggests that the detection of galectin-3 levels could potentially be used to select and monitor patient populations.

Overall, the combination of GB1211 100 mg and atezolizumab appeared to be well-tolerated, with predominantly Grade 1 and Grade 2 treatment emergent adverse effects observed. At the 200 mg twice daily dose-level, two severe dose-limiting skin reactions were observed that may indicate lymphocyte activation in line with the GB1211 mode of action, which resulted in a reduction to the 100 mg GB1211 dose level. Importantly, these skin rashes were not observed at the recommended Phase 2 dose level of 100 mg GB1211 twice daily.

As part of Galecto's recently announced strategic alternative process, Galecto has determined that it will not initiate Part B of the GALLANT-1 trial and will instead reallocate its resources to focus on the treatment of severe liver diseases. Galecto will continue to supply GB1211 100 mg for the upcoming investigator-initiated Phase 2 trial at Providence Portland Medical Center's Earle A. Chiles Research Institute (EACRI). This trial, which is expected to be initiated in early 2024, will evaluate the safety and efficacy of GB1211 in combination with pembrolizumab (Keytruda®). Galecto plans to explore external options for partnering and/or funding additional oncology-focused activities for GB1211 as part of its strategic alternative process.

Following the poster presentation at the ESMO Congress, the poster will be available on the Scientific Conferences page of Galecto's investor relations website at <https://ir.galecto.com/news-and-events/scientific-events>.

About GB1211 and Galectin-3 Mechanisms in Cancer

Increased galectin-3 expression in tumors is linked to tumor growth, invasiveness and metastatic potential. In the tumor tissue, galectin-3 supports the creation of fibrosis, tumor proliferation, metastasis, and immune avoidance. Galectin-3 uses a host of mechanisms to increase tumor growth and metastasis. Furthermore, increased levels of galectin-3 in the tumor microenvironment facilitates tumor escape from the immune response by suppressing essential T-cell functions and activating tumor-protecting macrophages.

Evidence suggests that galectin-3 can enhance PD-1 and PD-L1 binding and avert the interference of anti-PD-1/anti-PD-L1 therapies by blocking the binding of the antibodies to their respective targets. GB1211 is designed to counter these effects.

About the GALLANT-1 trial

The Phase 1b/2a trial of GB1211 in combination with atezolizumab (Tecentriq®) was designed to be a randomized, double-blind, placebo-controlled trial in patients with NSCLC in the first-line setting. Part A of the GALLANT-1 trial was an open-label trial that determined the 100 mg dose of GB1211 to be the recommended dose in future oncology trials. Part B of the GALLANT-1 trial had been designed to evaluate safety and tumor shrinkage in NSCLC patients and explore tumor response rate based on RECIST criteria (version 1.1), clinical activity, and immune biomarkers.

About Galecto

Galecto is a clinical stage company incorporated in the U.S. that is developing small molecule-based inhibitors of galectin-3 and LOXL2. Galecto has multiple Phase 2 clinical programs in fibrosis and cancer, including (i) an orally active LOXL2 inhibitor (GB2064) in a Phase 2a trial for the treatment of myelofibrosis; (ii) an orally active galectin-3 inhibitor (GB1211) in a recently completed Phase 1b/2a trial in liver cirrhosis; and (iii) an orally active galectin-3 inhibitor (GB1211) in combination with atezolizumab (Tecentriq®) in a separate Phase 2a trial for the treatment of NSCLC.

Galecto intends to use its website as a means of disclosing material non-public information. For regular updates about Galecto, visit www.galecto.com.

Forward-Looking Statements

Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements include statements about the potential safety and efficacy of GB1211; the timing of initiating clinical trials not being conducted by Galecto; and Galecto's focus and plans for clinical development of its product candidates and pipeline. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. For such statements, Galecto claims the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from Galecto's expectations. Factors that could cause actual results to differ materially from the forward-looking statements include risks and uncertainties related to the development of Galecto's product candidates and their therapeutic potential, having adequate funds and their use, and those disclosed in Galecto's filings with the Securities and Exchange Commission (SEC), including, but not limited to, Galecto's Annual Report on Form 10-K, as filed with the SEC on March 9, 2023. These forward-looking statements represent Galecto's judgment as of the time of this release. Galecto disclaims any intent or

obligation to update these forward-looking statements, other than as may be required under applicable law.

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