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): December 21, 2023

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

Delaware	**001-39655**	**37-1957007**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(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.

Topline Results from the MYLOX-1 Trial

On December 21, 2023, Galecto, Inc. (the "Company," or "Galecto") announced positive topline results from its Phase 2a MYLOX-1 trial of GB2064 for the treatment of myelofibrosis. The MYLOX-1 trial dosed a total of 18 myelofibrosis patients, of which 11 (61%) patients had previously received janus kinase inhibitor ("JAKi") therapy with ruxolitinib, with eight of those patients being refractory and three being intolerant to JAKi therapy. Six out of ten evaluable myelofibrosis patients who received GB2064 monotherapy for at least six months experienced a ≥ 1-grade reduction in collagen fibrosis of the bone marrow, an improvement suggesting that GB2064 could impact the progression of the disease and be disease-modifying.

Fibrosis is a key disease mechanism of myelofibrosis that destroys bone marrow function. Reducing fibrosis is required to slow the progression of the disease. Bone marrow biopsies taken during the study showed that GB2064 penetrated the bone marrow and could exert its anti-fibrotic effect directly in the disease compartment. Furthermore, GB2064 demonstrated target engagement systemically by binding to lysyl oxidase-like 2 (LOXL2) in plasma.

All six patients who experienced a > 1-grade reduction in bone marrow fibrosis score also showed stable hematological parameters, including hemoglobin, white blood cell count and platelets. At six months of treatment, one patient obtained a ≥35% reduction in spleen volume, two patients reduced their Total Symptom Score (TSS) by more than 50% and one patient had an anemia response. Four of these patients have entered the extension phase of the study due to the clinical benefit derived from GB2064 as evaluated by the treating physician, with one patient receiving treatment for more than 30 months.

GB2064 showed a generally acceptable tolerability profile in the MYLOX-1 trial. Eighteen patients were dosed with GB2064 monotherapy in the MYLOX-1 trial. Eight patients completed treatment in the core phase of the MYLOX-1 trial and ten patients discontinued treatment due to an adverse event or disease progression. The most commonly observed treatment-related adverse events were gastrointestinal in nature and were manageable in most patients with standard therapy. The only treatment-related serious adverse event was a case of fall, which was assessed as possibly related to GB2064 by the investigator.

Galecto will not make any decisions relating to funding additional trials with GB2064 until it completes its previously announced strategic alternative process.

About the MYLOX-1 Trial

The MYLOX-1 trial was a Phase 2, open-label, single-arm study in myelofibrosis patients who were ineligible, refractory, or intolerant to JAKi therapy. These patients have a progressive disease with poor quality of life, high mortality rates and very limited treatment options. Patients received GB2064 orally at a dose of 1000mg twice daily for nine months and undergo bone marrow biopsies at the beginning of the trial and again at months 3, 6 and 9. The primary endpoint of the MYLOX-1 trial was to assess the safety and tolerability of GB2064.

Apart from evaluating the safety and tolerability of GB2064, key secondary objectives of the MYLOX-1 trial were to evaluate hematological parameters as well as the direct anti-fibrotic activity of GB2064 by blocking LOXL2 in an indication that allows for repeated tissue biopsies.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
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: December 21, 2023

By: /s/ Hans T. Schambye

Hans T. Schambye, M.D., Ph.D.

President and Chief Executive Officer