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 29, 2022

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 7.01. Regulation FD Disclosure.

On September 29, 2022, Galecto, Inc. (the "Company") issued a press release announcing results from a planned intermediate assessment of the ongoing Phase 2a trial of GB2064, a LOXL2 inhibitor product candidate, for the treatment of myelofibrosis (the "MYLOX-1 trial"). A copy of the press release is attached hereto as Exhibit 99.1.

The information in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

As noted above, the Company announced results from an intermediate assessment of the ongoing MYLOX-1 trial.

The MYLOX-1 trial is an ongoing Phase 2, open-label, single-arm study in myelofibrosis patients who are ineligible, refractory or intolerant to JAK inhibitor therapy. Patients receive 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 ongoing MYLOX-1 trial is an assessment of safety and tolerability, while secondary endpoints focus on measurements of bone marrow fibrosis and hematological parameters. Apart from evaluating the safety and tolerability of GB2064, a key objective of the MYLOX-1 trial is to evaluate the direct anti-fibrotic activity of GB2064 by blocking lysyl oxidase-like 2 (LOXL2) in an indication that allows for repeated tissue biopsies.

As part of the planned intermediate assessment of the MYLOX-1 trial, Galecto evaluated results from the first five patients who had completed at least six months of treatment with GB2064 and who had repeated bone marrow biopsies. In the intermediate assessment, four out of five evaluable myelofibrosis patients who received GB2064 monotherapy for at least six months in the MYLOX-1 trial experienced a $\geq$ 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. All four patients who experienced a > 1-grade reduction in fibrosis score also showed stable hematological parameters (hemoglobin, white blood cell count, and thrombocytes) and stable spleen volume over the six month treatment period, and none required transfusion. Two of these patients have entered the extension phase of the study due to the clinical benefit of GB2064 as evaluated by the treating physician.

GB2064 has shown a generally acceptable tolerability profile to date. Sixteen patients have been dosed with GB2064 in the MYLOX-1 trial, of which eight patients have completed or continue to receive treatment and eight patients have either discontinued treatment as a result of 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. In the five patients who completed at least six months of treatment with GB2064, there were no treatment-related serious adverse events, while in the entire trial population, the only possibly treatment-related serious adverse event was a case of fall.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release, dated September 29, 2022.
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: September 29, 2022

By: /s/ Hans T. Schambye

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

President and Chief Executive Officer

Exhibit 99.1

Galecto

GB2064 Shows Reduction in Fibrosis of the Bone Marrow in Patients with Myelofibrosis, Validating LOXL2 as a Clinical Fibrosis Target

Company to host a live conference call and webcast today, September 29, 2022, at 8:00 a.m. ET

Boston, MA, September 29, 2022 - Galecto, Inc. (NASDAQ: GLTO), a clinical stage biotechnology company focused on the development of novel treatments for fibrosis and cancer, today announced positive results from a planned intermediate assessment of its ongoing Phase 2a trial of GB2064 for the treatment of myelofibrosis ("MYLOX-1 trial", NCT04679870). Fibrosis is a key disease mechanism of myelofibrosis that destroys the bone marrow function. Reducing fibrosis is required to slow the progression of the disease. Four out of five evaluable myelofibrosis patients who received GB2064 monotherapy for at least six months in the MYLOX-1 trial 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.

Professor Srdan Verstovsek, Department of Leukemia, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center, Houston, Texas, and Principal Investigator in the MYLOX-1 trial, commented, "It is wholly unprecedented and very encouraging to observe a reduction in collagen fibrosis in this patient population. It is exciting to see the first clinical validation of LOXL2 as a fibrosis target. I very much look forward to additional developments from this ongoing study in the near future."

All four patients who experienced a ≥ 1-grade reduction in fibrosis score also showed stable hematological parameters (hemoglobin, white blood cell count, and thrombocytes) and stable spleen volume over the six month treatment period, and none required transfusion. Two of these patients have entered the extension phase of the study due to the clinical benefit of GB2064 as evaluated by the treating physician.

Professor Claire Harrison, Guy's & St Thomas NHS Foundation Trust, and Chair of the Safety Review Committee for the MYLOX-1 trial, commented, "It is exciting and encouraging to see a clear reduction in collagen fibrosis following the administration of a selective LOXL2 inhibitor in four of the five evaluable patients combined with stabilization of hematological parameters and spleen volume. Stable disease is excellent in a progressive disease such as myelofibrosis."

GB2064 has shown a generally acceptable tolerability profile to date. Sixteen patients have been dosed with GB2064 in the MYLOX-1 trial, of which eight patients have completed or continue to receive treatment and eight patients have either discontinued treatment as a result of 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. In the five patients who completed at least six months of treatment with GB2064, there were no treatment-related serious adverse events, while in the entire trial population, the only possibly treatment-related serious adverse event was a case of fall.

Dr. Hans Schambye, President and Chief Executive Officer of Galecto, commented, “We are very excited to have demonstrated proof of principle with GB2064 showing an anti-fibrotic effect in a difficult-to-treat patient population. These intermediate results strengthen our belief that GB2064 has the potential to be a disease-modifying therapy for multiple cancers and fibrotic diseases.”

Dr. Schambye continued, “With respect to our other ongoing clinical programs, we anticipate announcing top-line results from our Phase 1b/2a GULLIVER-2 trial for liver cirrhosis in the coming weeks.”

Company to Host Webcast
Galecto will host a webcast event today, **September 29, 2022, at 8:00 a.m. Eastern Time**, to discuss the results from the intermediate assessment of the MYLOX-1 trial. Full details for the webcast are as follows:

Date: September 29, 2002
Time: 8:00 am Eastern Time
U.S. Dial-in Number: 1-877-704-4453
Int’l Dial-in Number: 1-201-389-0920
Conference ID: 13733039
Webcast: Click HERE

A replay will be available on the Events portion of the Company’s investor relation’s website.

About MYLOX-1 Trial
The MYLOX-1 clinical trial is an ongoing Phase 2, open-label, single-arm study in myelofibrosis patients who are ineligible, refractory or intolerant to JAK inhibitor therapy. These patients have a progressive disease with poor quality of life, high mortality rates, and very limited treatment options. Patients receive 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 ongoing MYLOX-1 trial is an assessment of safety and tolerability, while secondary endpoints focus on measurements of bone marrow fibrosis and hematological parameters. Apart from evaluating the safety and tolerability of GB2064, a key objective of the MYLOX-1 trial is to evaluate the direct anti-fibrotic activity of GB2064 by blocking lysyl oxidase-like 2 (LOXL2) in an indication that allows for repeated tissue biopsies.

As part of the planned intermediate assessment, Galecto evaluated results from the first five patients who had completed at least six months of treatment with GB2064 and who had repeated bone marrow biopsies. In the intermediate assessment, GB2064 demonstrated target engagement and penetration into the fibrotic bone marrow.

As with many ongoing clinical trials in myelofibrosis, Galecto has experienced both COVID-19-related and non-COVID-19 related challenges recruiting patients in the MYLOX-1 trial, which will delay the expected timing of data readouts. Galecto continues to evaluate whether adjustments will need to be made to the protocol for the MYLOX-1 trial to further facilitate patient recruitment. The company intends to provide an update later this year on the expected timing for full data readout of the MYLOX-1 trial.

About Myelofibrosis

Myelofibrosis is a hematological cancer that causes fibrosis of the bone marrow and disrupts the body's normal production of blood cells, which can lead to multiple negative impacts and a significantly reduced quality of life and mortality. The bone marrow is destroyed by fibrosis, forcing out the production of blood components and aggravating symptoms, including anemia, thrombocytopenia, leukocytosis, and spleen enlargement. JAK inhibition is the current standard of care for patients with myelofibrosis; however, these therapies do not address the core of the underlying disease biology and have not shown a consistent effect on fibrosis, biomarkers of disease modification, or overall survival.

About LOXL2 and GB2064
GB2064, a potentially first-in-class, LOXL2 inhibitor candidate, is in development for the treatment of fibrotic diseases and cancer. LOXL2 is an enzyme that plays a key role in myelofibrosis and contributes to the fibrotic progression of the disease. LOXL2 catalyzes cross-linking of collagen, forming the backbone of fibrosis. The molecular target for GB2064 is LOXL2, an enzyme that plays a central role in the crosslinking of collagen in tissue fibrosis and is involved in multiple types of fibrotic diseases, including myelofibrosis. In contrast to previous attempts to inhibit LOXL2 with a monoclonal antibody, GB2064 is specifically designed to completely inhibit the LOXL2 enzymatic activity.

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 four ongoing Phase 2 clinical programs in fibrosis and cancer, including (i) an inhaled galectin-3 modulator (GB0139) in a Phase 2b trial for the treatment of idiopathic pulmonary fibrosis (IPF); (ii) an orally active LOXL2 inhibitor (GB2064) in a Phase 2 trial for the treatment of myelofibrosis; (iii) an orally active galectin-3 inhibitor (GB1211) in a Phase 1b/2a trial in liver cirrhosis; and (iv) an orally active galectin-3 inhibitor (GB1211) in a separate Phase 2 trial for the treatment of non-small cell lung cancer (NSCLC) in combination with atezolizumab (Tecentriq®).

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
This press release contains forward-looking statements that involve a number of risks and uncertainties. Such forward-looking statements include statements about the enrollment and timing of availability of clinical trial data for the MYLOX-1 trial, including as a result of COVID-19; the safety and efficacy of GB2064; and Galecto's plans, strategies and prospects for clinical development of its product candidates and pipeline. Such forward-looking statements include statements about Galecto's focus, plans for clinical development, 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 whether preliminary data that is reported herein changes following a more comprehensive review of the data related to the clinical trial and as more patient data become available or as additional analyses are conducted, the impact of any protocol changes on the clinical development of GB2064, the ongoing development of Galecto's product candidates and evaluation of their therapeutic potential, including emerging data on the

safety profile of such candidates and their potential for disease-modifying activity, 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 February 17, 2022. 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.

For more information, contact:

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