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 31, 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 October 31, 2022, Galecto, Inc. (the "Company") issued a press release announcing certain topline results from its Phase 1b/2a GULLIVER-2 trial that will be presented at the American Association for the Study of Liver Diseases' (AASLD) The Liver Meeting 2022 being held from November 4-8, 2022. 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 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release, dated October 31, 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: October 31, 2022

By: /s/ Hans T. Schambye

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

President and Chief Executive Officer

Galecto to Present Topline Data from GULLIVER-2 Clinical Trial Showing GB1211 Reduced Signs of Liver Impairment at AASLD's The Liver Meeting® 2022

- *Late-breaking oral and poster presentations include clinical and preclinical data related to GULLIVER-2 clinical trial*
- *Galecto to host a webinar at 8:00 a.m. ET on Tuesday, November 8, 2022 to discuss expanded topline data and analysis*

Boston, Mass., October 31, 2022 - Galecto, Inc. (NASDAQ: GLTO), a clinical-stage biotechnology company and a world leader in galectin biology focused on the development of novel treatments for fibrosis and cancer, today announced it will present data from its recently completed Phase 1b/2a GULLIVER-2 trial at the American Association for the Study of Liver Diseases' (AASLD) The Liver Meeting 2022 being held in Washington, D.C. on November 4-8, 2022. GULLIVER-2 is a clinical trial designed to assess GB1211, an orally available and high-affinity small molecule carbohydrate-based galectin-3 inhibitor, for the treatment of severe liver diseases. Galectin-3 is a pro-fibrotic β-galactoside binding protein highly expressed in fibrotic livers and implicated in severe liver diseases.

In a late-breaking oral presentation, which was selected as Best of the Liver Meeting in the NASH/NAFLD category, Galecto will present topline data from Part 2 of its GULLIVER-2 trial (NCT05009680), an innovative, hybrid-design 3-part study investigating the safety, pharmacokinetics (PK), and exploratory efficacy of GB1211 in patients with decompensated cirrhosis. In this study, GB1211 was well-tolerated, had a predictable PK profile and showed encouraging signs of clinical efficacy (liver laboratory tests and FibroScan®). The observed reductions of liver enzyme values and measurements of liver fat indicate a decrease of liver inflammation and underlying steatosis, respectively. Overall, the data suggests a positive therapeutic effect in severe cirrhosis. This trial offers strong support for further development of GB1211 in severe liver diseases.

Additional information and further analysis of these data relating to the GULLIVER-2 Part 2 trial findings will also be discussed in a webinar hosted by Galecto on Monday, November 8th at 8 a.m. ET.

In a separate poster presentation, Galecto will highlight findings from Parts 1 and 3 of the GULLIVER-2 trial, where preliminary data indicates that liver impairment had moderate effects on the GB1211 PK profile compared to healthy participants. In patients with decompensated cirrhosis, GB1211 was observed to be well-tolerated with no treatment-related adverse events, supporting that it can be orally administered to patients with moderate and severe liver impairment in future trials.

In support of the clinical data to be presented at The Liver Meeting 2022, Galecto will also present a late-breaking preclinical poster demonstrating GB1211's ability to inhibit galectin-3 in severe liver diseases. In this study, the efficacy of GB1211 was investigated in a high fat diet rabbit model of non-alcoholic steatohepatitis (NASH)/fibrosis. GB1211 significantly reduced all measures of inflammation, fibrosis and fat compared to the control group. There were also trends for reduction in fibrotic and galectin-3 mechanistic genes (COL1A1, COL3A1, SNAI2, LGALS3, PAI-1), indicating positive effects of galectin-3 inhibition.

"With no approved disease-modifying treatments for decompensated cirrhosis, overall survival rates are poor with a median survival of approximately two years," said Bertil Lindmark, M.D., Ph.D., Galecto's Chief Medical Officer. "There is a critical need for new treatment options for severe liver diseases and related

complications, including liver cancer. Our presentations at The Liver Meeting demonstrate GB1211's potential to provide hope to patients living with severe liver diseases."

Presentation Details:

Oral Presentation Title: Preliminary safety, pharmacokinetics, and efficacy of GB1211 in cirrhotic patients: initial findings from the GULLIVER-2 trial with focus on the randomized, placebo controlled, 12-week part 2
Abstract Number: 5014
Publication Number: 39068
Date: Tuesday, November 8, 2022
Time: 10:30 a.m. ET
Location: Poster Hall

Poster Presentation Title: The novel GALECTIN-3 inhibitor GB1211 reduces inflammation & fibrosis in a rabbit high fat diet model of NASH & fibrosis
Abstract Number: 38895
Poster Number: 5042
Date: Monday, November 7, 2022
Time: 1:00 – 2:00 p.m. ET
Location: Poster Hall

Poster Presentation Title: GULLIVER-2 is an innovative, hybrid, hepatic impairment trial of the oral GALECTIN-3 inhibitor GB1211
Abstract Number: 3627
Poster Number: 3627
Date: Sunday, November 6, 2022
Time: 1:00 p.m. ET
Location: Poster Hall

The abstracts for each of these presentations may be accessed here.

GULLIVER-2 Topline Data Webcast Information:

Galecto will host a live conference call and webcast at 8:00 am ET on Tuesday, November 8, 2022. **Below please find updated dial-in and webcast information.**

U.S. Dial-in Number: 1-877-300-8521
Int'l Dial-in Number: 1-412-317-6026
Conference ID: 10172584
Webcast: Click HERE

The presentation and poster materials along with a replay of the call will be available on Galecto's investor relations website at https://ir.galecto.com.

About Liver Disease
Liver diseases, including liver fibrosis or cirrhosis, are a global health burden. Cirrhosis – primarily caused by non-alcoholic steatohepatitis, alcoholic liver disease and hepatitis – is the end stage of progressive liver fibrosis and the leading cause of liver-related death globally.

About the GULLIVER-2 Trial
The GULLIVER-2 trial (NCT05009680) is a Phase 1b/2a trial designed to assess the safety, tolerability, pharmacokinetics and potential activity of GB1211 in up to 54 participants. This study includes patients with decompensated cirrhosis (**Child-Pugh Classes B and C**). The study consists of three separate parts.

Parts 1 and 3 of the GULLIVER-2 trial are open-label, single dose study parts designed to evaluate the safety

and pharmacokinetics of GB1211 in patients with moderate to severe hepatic impairment (**Child-Pugh B and C, respectively**) and compare with matched healthy subjects.

Part 2 of the GULLIVER-2 trial is a Phase 2, randomized, double-blind, placebo-controlled trial in 30 patients that is designed to assess the effect of 12-week repeated dosing of oral GB1211 in patients with decompensated cirrhosis (**Child-Pugh B**). Patients are randomized 1:1 to receive oral GB1211 100mg or placebo twice daily for 12 weeks.

About GB1211
Galecto is developing GB1211, an orally available and potent small molecule galectin-3 inhibitor. Galecto's initial target indications for GB1211 are liver cirrhosis, a severe, progressive disease that ultimately leads to liver failure, and non-small cell lung cancer, a cancer indication with a high unmet medical need.

GB1211 demonstrated antifibrotic activity and anti-cancer effects in multiple preclinical models and has successfully completed a Phase 1 trial in 78 healthy volunteers. In the Phase 1 trial, GB1211 had a favorable tolerability profile and exhibited dose-dependent pharmacokinetics.

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
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 tolerability and efficacy of GB1211, that the GULLIVER-2 trial will provide a holistic view of the safety, pharmacokinetics, liver function and liver-related parameters of GB1211, as well as Galecto's general 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 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 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.

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