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): August 15, 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 7.01. Regulation FD Disclosure.

On August 15, 2023, Galecto, Inc. (the "Company," or “Galecto”) issued a press release announcing topline results from its Phase 2b GALACTIC-1 trial evaluating the safety and efficacy of inhaled GB0139 for the treatment of idiopathic pulmonary fibrosis (“IPF”). A copy of the press release is attached hereto as Exhibit 99.1.

The information in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 hereto, 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.

Topline Results of Phase 2b GALACTIC-1 Trial

As noted above, the Company announced topline results from its Phase 2b GALACTIC-1 trial evaluating the safety and efficacy of inhaled GB0139 for the treatment of IPF.

The GALACTIC-1 trial did not meet its primary endpoint of change from baseline in rate of decline in forced vital capacity (“FVC”). Based on the results of the GALACTIC-1 trial, Galecto plans to discontinue development of GB0139. Going forward, Galecto will focus on development opportunities for the treatment of severe liver diseases.

GALACTIC-1 Results

The GALACTIC-1 trial (NCT03832946) enrolled 173 patients who were not receiving pirfenidone or nintedanib, the current standard of care for IPF. The trial compared treatment with the inhaled 3 mg dose of GB0139 to placebo (randomized 2:1) over 52 weeks. The GALACTIC-1 trial did not meet its primary endpoint of change from baseline in rate of decline in FVC at week 52. Levels of galectin-3 increased from day 0 to week 52 in both the placebo and active GB0139 3 mg arms, and thus there was no confirmation of target engagement in the trial. The mean change in FVC from baseline to week 52 was -316.6 ml in the GB0139 3 mg arm compared to -127.4 ml in the placebo arm (placebo-corrected difference of -189.2 ml; 95% CI -311.28 to -67.10 ml). The observed decrease in lung function in the placebo group was lower than similar placebo groups reported in previous IPF trials with other drugs.

In the safety analysis, the Company observed a significant amount of IPF-like treatment-emergent adverse events in the active GB0139 arm commensurate with FVC development. The most common adverse events included cough, dyspnea and COVID-19. Treatment-emergent serious adverse events, which included worsening of IPF, were observed in 7.8% of patients in the GB0139 group and 1.4% of patients in the placebo group. Adverse events leading to death were similar in both groups.

Galecto intends to work in close collaboration with external experts to analyze the results observed in the placebo arm of the GALACTIC-1 trial. Additionally, Galecto plans to communicate the results of the GALACTIC-1 trial at an upcoming medical conference.

Next Steps in Severe Liver Diseases

Galecto previously announced that it had concluded a U.S. Food and Drug Administration (“FDA”) Type C meeting centered around the continued development of GB1211, Galecto’s oral galectin-3 inhibitor product candidate for the treatment of compensated and decompensated cirrhosis due to non-alcoholic steatohepatitis (“NASH”) or alcohol-associated cirrhosis. As a result of this meeting and in accordance with guidance received from the FDA, Galecto’s next step in the development of GB1211 is to initiate a long-term, randomized, placebo-controlled, Phase 2a trial in patients with decompensated NASH cirrhosis, which will evaluate efficacy and tolerability at additional dose levels. This trial, referred to as the GULLIVER-3 trial, is expected to be initiated in early 2024, subject to obtaining additional financing.

Galectin-3 and LOXL2 have been shown to be critical drivers of fibrotic disease pathogenesis and are associated with severe liver disease and poor outcomes. Galecto previously announced topline results from its Phase 1b/2a GULLIVER-2 trial of GB1211, its orally available galectin-3 inhibitor, for the treatment of decompensated cirrhosis. Topline results from the GULLIVER-2 trial showed statistically significant reductions in liver enzymes (AST, ALT and GGT) and other positive biomarker effects after 12 weeks of treatment, as well as a reduction in MELD score. GB1211 also exhibited a favorable tolerability profile in this trial.

Preliminary Cash, Cash Equivalents and Investments Balance as of July 31, 2023

As of July 31, 2023, the Company estimates that its cash, cash equivalents and investments balance was approximately $49.0 million. This estimate is preliminary and unaudited, is based on the Company's estimates, and is subject to further internal review by its management and compilation of actual results. Actual results may differ from these estimates due to the completion of the Company's closing procedures for the quarter ended September 30, 2023, including final adjustments and other developments that may arise between now and the time the financial results for the three months ended September 30, 2023 are finalized. As such, these estimates should not be viewed as a substitute for our unaudited financial statements prepared in accordance with U.S. generally accepted accounting principles. Our cash, cash equivalents and investments balance as of July 31, 2023 could change materially and is not necessarily indicative of the results to be achieved as of the quarter ended September 30, 2023 or any future period.

All of the data presented above has been prepared by and is the responsibility of the Company's management. The Company's independent registered public accounting firm has not audited, reviewed or performed any procedures with respect to the preliminary financial data presented in this Current Report on Form 8-K. Accordingly, the Company's independent registered public accounting firm does not express an opinion or any other form of assurance with respect to the preliminary financial data presented in this Current Report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release, dated August 15, 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: August 15, 2023

By: /s/ Hans T. Schambye

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

President and Chief Executive Officer

Exhibit 99.1

Galecto Announces Topline Results from Phase 2b GALACTIC-1 Trial of GB0139 for the Treatment of Idiopathic Pulmonary Fibrosis

Announces next steps for clinical development plan in severe liver diseases

Boston, MA, August 15, 2023 - Galecto, Inc. (NASDAQ: GLTO), a clinical-stage biotechnology company and world leader in galectin biology, focused on the development of novel treatments for fibrosis and cancer, today announced topline results from its Phase 2b GALACTIC-1 trial evaluating the safety and efficacy of inhaled GB0139 for the treatment of idiopathic pulmonary fibrosis (IPF).

The GALACTIC-1 trial did not meet its primary endpoint of change from baseline in rate of decline in forced vital capacity (FVC). Based on the results of the GALACTIC-1 trial, Galecto plans to discontinue development of GB0139. Going forward, Galecto will focus on development opportunities for the treatment of severe liver diseases.

“We are very disappointed that the GALACTIC-1 results do not support the continued development of GB0139 as a new treatment for IPF,” said Hans Schambye, President and Chief Executive Officer of Galecto. “Galecto expresses its sincere thanks to the patients and clinical trial investigators for their participation in this study.”

Dr. Schambye continued, “As of July 31, 2023, Galecto had approximately $49.0 million in cash, cash equivalents and investments. Given the impact of the results from the GALACTIC-1 trial on our future plans, we are currently evaluating resource allocation with the goal of extending our cash runway into 2025. Going forward, we are eager to expand our focus on advancing our pipeline of our orally administered compounds, GB1211 and GB2064. We believe that the previously reported promising clinical results with these compounds represent significant and meaningful opportunities in severe liver diseases, including decompensated cirrhosis and hepatocellular carcinoma. We plan to provide greater detail and next steps before the end of October.”

GALACTIC-1 Results

The GALACTIC-1 trial (NCT03832946) enrolled 173 patients who were not receiving pirfenidone or nintedanib, the current standard of care for IPF. The trial compared treatment with the inhaled 3 mg dose of GB0139 to placebo (randomized 2:1) over 52 weeks. The GALACTIC-1 trial did not meet its primary endpoint of change from baseline in rate of decline in forced vital capacity (FVC) at week 52. Levels of galectin-3 increased from day 0 to week 52 in both the placebo and active GB0139 3 mg arms, and thus there was no confirmation of target engagement in the trial. The mean change in FVC from baseline to week 52 was -316.6 ml in the GB0139 3 mg arm compared to -127.4 ml in the placebo arm (placebo-corrected difference of -189.2 ml; 95% CI -311.28 to -67.10 ml). The observed decrease in lung function in the placebo group was lower than similar placebo groups reported in previous IPF trials with other drugs.

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Galecto previously announced that it had concluded a U.S. Food and Drug Administration (FDA) Type C meeting centered around the continued development of GB1211, Galecto's oral galectin-3 inhibitor product candidate for the treatment of compensated and decompensated cirrhosis. As a result of this meeting and in accordance with guidance received from the FDA, Galecto's next step in the development of GB1211 is to initiate a long-term, randomized, placebo-controlled, Phase 2a trial in patients with decompensated NASH cirrhosis, which will evaluate efficacy and tolerability at additional dose levels. This trial, referred to as the GULLIVER-3 trial, is expected to be initiated in early 2024, subject to obtaining additional financing.

Dr. Michael Charlton, Professor of Medicine and Chief of Hepatology at the University of Chicago, commented, "The Galecto program is forging a new path in liver disease with its focus on patients with decompensated cirrhosis, a very serious condition with high mortality. I am hopeful that this new program can translate into meaningful improvements for patients. As we progress, it is vital that we keep refining our approach to drug development for severe liver disease and apply practical and meaningful variables, like Model for End-stage Liver Disease (MELD) score, a highly validated model used throughout the world for predicting mortality in liver disease and to prioritize patients for liver transplantation."

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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 ongoing 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 Galecto's ability to make progress across its clinical pipeline of assets and Galecto's expectation that it will evaluate resource allocation to extend its cash runway into 2025. 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, the risk that results of earlier-stage clinical trials may not reflect the results of later-stage clinical trials, 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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