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): January 27, 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 8.01. Other Events.

On January 27, 2022, Galecto, Inc. (the "Company") issued a press release announcing the publication of the full results of an investigator-initiated open and randomized trial to evaluate the Company's inhaled galectin-3 inhibitor, GB0139, in hospitalized patients with COVID-19 infection. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release, dated January 27, 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: January 27, 2022

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

Exhibit 99.1

Galecto Publishes Results Showing Safety and Efficacy of the GB0139 Inhaled Galectin-3 Inhibitor in Hospitalized COVID-19 Patients on Standard of Care

Results Support Favorable Safety and Tolerability Profile and Target Engagement of GB0139 and Potential for GB0139 in Severe Lung Disease

Company Provides Update on GALACTIC-1 Trial

Boston, MA, January 27, 2022 - Galecto, Inc. (NASDAQ: GLTO), a clinical stage biotechnology company focused on the development of novel treatments for fibrosis and cancer, today announced the publication of the full results of an investigator-initiated open and randomized trial to evaluate Galecto's inhaled galectin-3 inhibitor, GB0139, in hospitalized patients with COVID-19 infection who required oxygen but not mechanical ventilation, compared to patients only on standard of care.

Galectin-3 plays a key role in COVID-19-related acute lung injury, cytokine storm, T-cell exhaustion and organ micro-thrombosis, and the results from this trial suggest that GB0139 has the potential for treatment of viral induced acute respiratory distress syndrome (ARDS) and acute lung injury (ALI).

The study met its primary endpoint of safety as there were no observed treatment-related adverse events. Despite patients having a mean age of 65 years, mean BMI of 32, multiple comorbidities, and being breathless, all patients were able to effectively inhale GB0139 and achieve pharmacologically relevant plasma levels. Target engagement was confirmed with a statistically significant reduction ($p<0.01$) in serum galectin-3 levels.

The study showed that GB0139 on top of standard of care (which included treatments such as steroids, heparin, remdesivir and tocilizumab) may rapidly decrease markers of inflammation linked to the cytokine storm, inflammation-associated micro-thrombosis and those of short or long-term fibrosis. Patients treated with GB0139 had a significantly greater rate of decline in oxygen requirement versus standard of care alone and showed other signs of reduced organ damage. These effects were further accentuated in a subgroup of patients with moderate-to-severe disease who were at higher clinical risk. These patients showed multiple signs of improved immune-mediated viral responses as well as decreased lymphocyte exhaustion and decreased level of profibrotic macrophages. A 21% reduction of mortality was observed in this subgroup of patients at high clinical risk.

Professor Bertil Lindmark, Chief Medical Officer of Galecto, stated, "We are excited that the results of this study showed that GB0139 was biologically active and safely administered at high doses (20mg and 10mg) to patients with severe lung disease and difficulties breathing. Galectin-3 inhibition prevents key escalation steps of the viral-induced inflammatory response, including inflammation related thrombosis, and the processes of acute and chronic fibrosis. These novel findings enhance our conviction for the potentially wide medical applicability of our expanding portfolio of galectin-3 inhibitors."

Dr. Hans Schambye, President and Chief Executive Officer of Galecto, commented, “The published results further demonstrate the positive impact of galectin-3 inhibition in patients with severe lung disease. The safety and tolerability profile of GB0139 in patients with compromised lung function is encouraging, and we believe suggests additional potential in virus-induced acute lung injury. Given these exciting data, we plan to explore co-development opportunities with GB0139 for the treatment of COVID-19 and other severe viral lung diseases. Furthermore, the data from this study aligns with our findings in our IPF clinical trials completed to date and reaffirms the potential efficacy of GB0139 in our ongoing GALACTIC-1 trial.”

The GALACTIC-1 trial is a Phase 2b, 52-week randomized, double-blind, multicenter, parallel, placebo-controlled trial investigating the safety and efficacy of GB0139 (3mg) in patients with IPF, with the rate of decline of forced vital capacity (FVC) as the primary endpoint. Based on blinded FVC (lung function) data from patients in this trial, the Company has determined that it may be possible to demonstrate a meaningful effect with fewer than the planned target of up to 210 randomized patients. As a result of this statistical analysis, the Company plans to seek regulatory approval of a protocol amendment to reduce the target patient population for the GALACTIC-1 trial, which would enable Galecto to maintain the cost structure of the trial and report topline results in mid-2023, as previously reported.

The research article is titled “*GB0139, an inhaled small molecule inhibitor of galectin-3, in COVID-19 pneumonitis: A randomised, controlled, open-label, Phase 2a experimental medicine trial of the safety, pharmacokinetics, and potential therapeutic value*.” It is available through the medRxiv preprint server and has not yet been peer-reviewed. Galecto has submitted the article to a peer-reviewed publication and has had an abstract of the trial results accepted for presentation at the 2022 American Thoracic Society (ATS) Conference in San Francisco, CA from May 13-18, 2022.

COVID-19 Trial
In this open-label trial (https://clinicaltrials.gov/ct2/show/NCT04473053), 41 patients were randomized to receive either standard of care, which included treatments such as steroids, heparin, remdesivir and tocilizumab (n=21), or inhaled GB0139 (dosed at 10 mg twice a day for 2 days and subsequently once a day for up to 14 days) plus standard of care (n=20), to evaluate the safety and tolerability of GB0139, pharmacokinetics, and its effects on clinical outcomes and biomarkers. Patients had a mean age of 65 years, mean BMI of 32, multiple comorbidities, and were hospitalized and needed oxygen therapy, but did not require mechanical ventilation.

About Galecto
Galecto is a clinical stage company incorporated in the U.S. that is developing small molecule-based inhibitors of galectin-3 (and the galectin family generally) and LOXL2. Galecto has multiple 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 a separate phase 2 trial for the treatment of 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 GB0139 in COVID-19 lung inflammation; that GB0139 may reduce lung fibrosis seen in COVID-19 patients; that GB0139 has the potential to counter the cytokine storm, inflammation-associated thrombosis, short and long-term fibrosis and multi-organ damage; the GALACTIC-1 trial, including plans for continuing to enroll patients and working with regulatory authorities to amend the protocol for the trial; that Galecto intends to submit the research article to a peer reviewed publication; 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 March 29, 2021. 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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