



Galecto Reports Second Quarter Operating and Financial Results

July 31, 2023

BOSTON, July 31, 2023 (GLOBE NEWSWIRE) -- 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 its operating and financial results for the quarter ended June 30, 2023.

"Galecto has made strong clinical progress in the first half of the year, setting the stage for several important milestones during the rest of 2023. We completed dosing in our Phase 2b GALACTIC-1 trial of GB0139 in idiopathic pulmonary fibrosis in May and topline results are expected in August. In our oral galectin-3 program, GB1211, we are pleased to have completed dose-range finding in our Phase 1b/2a GALLANT-1 study in non-small cell lung cancer (NSCLC) patients. This allowed us to identify the GB1211 100 mg dose of this promising compound to be examined in combination with checkpoint inhibitors in future oncology trials," said Hans Schambye, President and Chief Executive Officer of Galecto. "We are also looking forward to later this year reporting topline results from the Phase 2a MYLOX-1 trial of GB2064 and potential initiation of the Phase 2 NIH-sponsored and investigator-initiated GB1211 oncology trial."

Second Quarter and Other Recent Highlights

- Announced completion of dosing in the Company's 52-week Phase 2b GALACTIC-1 study of GB0139 for the treatment of idiopathic pulmonary fibrosis (IPF). GB0139 is an investigational inhaled small molecule inhibitor of galectin-3 that is administered as a once-daily inhalation via a generic dry powder inhaler. GB0139 is designed to specifically target galectin-3, a main regulator of the fibrosis cascade. The overexpression of galectin-3 is ubiquitous in fibrotic tissue, including fibrotic lung tissue, and is linked to both disease severity and disease progression, as well as acute exacerbations of IPF. The Company expects to announce topline data from the GALACTIC-1 trial in August 2023, which will represent the third data readout from Galecto's anti-fibrotic clinical pipeline in the last year.
- Completed Part A of the Phase 2a GALLANT-1 trial evaluating GB1211 in combination with atezolizumab for the treatment of non-small cell lung cancer (NSCLC). The GALLANT-1 trial is an open-label study to select the dose of GB1211, Galecto's selective oral small molecule inhibitor of galectin-3, to be used in future trials to evaluate the safety and tumor shrinkage of the combination of GB1211 and checkpoint inhibitors. In connection with completing Part A of the GALLANT-1 trial we conducted an interim safety analysis from Part A of the trial where GB1211 exhibited a favorable safety and tolerability profile. The Safety Review Committee for the trial reviewed the results from Part A and recommended that we continue at the 100 mg twice daily dose of GB1211 in Part B and in combination with checkpoint inhibitors in future trials.
- Concluded FDA Type C meeting focused on the continued development of GB1211 for the treatment of compensated and decompensated cirrhosis due to non-alcoholic steatohepatitis (NASH) or alcohol-associated cirrhosis. As a result of this recent FDA Type C meeting, Galecto is planning a Phase 2 trial in patients with decompensated NASH cirrhosis. This trial is expected to be initiated in early 2024, subject to obtaining additional financing or collaborating with a third party.
- Presented a poster at the ATS 2023 International Conference in May highlighting new data on GB0139 in IPF patient-derived lung samples. The poster, entitled: "*The Anti-Fibrotic Effect of GB0139, a Small Molecule Galectin-3 Inhibitor, in Precision Cut Lung Slices from Idiopathic Pulmonary Fibrosis Tissue,*" showed GB0139 effected a concentration-dependent reduction in markers of fibrosis in comparison to currently approved IPF therapies, perfinidone and nintedanib.

Expected Upcoming Milestones

- Topline results from Phase 2b GALACTIC-1 trial (IPF) with GB0139 in August 2023
- Topline results from Phase 2a MYLOX-1 trial (myelofibrosis) with GB2064 in 2H 2023
- Initiation of Phase 2 investigator-sponsored GB1211 oncology trial (melanoma and HNSCC) by Providence Cancer Institute in 2H 2023

Second Quarter 2023 Financial Highlights

Cash, cash equivalents, and investments as of June 30, 2023 were approximately \$52.1 million. The company anticipates that its cash, cash equivalents and investments will be sufficient to fund operating expenses and capital requirements into the second half of 2024.

Research and development expenses were \$8.1 million for the period ended June 30, 2023, compared to \$13.7 million for the period ended June 30, 2022. The decrease of \$5.6 million was due primarily to lower clinical spending based on timing of clinical trial activities.

General and administrative expenses were \$3.1 million for the period ended June 30, 2023, compared to \$3.4 million for the period ended June 30, 2022. The decrease of \$0.3 million was primarily related to decreased insurance costs and other various general and administrative costs.

Net loss attributable to common stockholders for the period ended June 30, 2023 was \$10.7 million or \$(0.41) per basic and diluted share, compared with \$16.9 million, or \$(0.67) per basic and diluted share, for the prior year period.

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 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 2a trial for the treatment of myelofibrosis; (iii) an orally active galectin-3 inhibitor (GB1211) in a recently completed Phase 1b/2a trial in liver cirrhosis; and (iv) 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, Galecto's anticipated timelines for its clinical trials investigating GB0139, GB1211 and GB2064, and Galecto's expectation that its cash, cash equivalents and marketable securities will be sufficient to fund its operating expenses and capital requirements into the second half 2024. 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 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.

For more information, contact:

Galecto, Inc.

Hans Schambye, CEO
Jon Freve, CFO
+45 70 70 52 10

Investors/US

Ashley R. Robinson
arr@lifesciadvisors.com
+1 617 430 7577

Media/EU

Sandya von der Weid
svonderweid@lifesciadvisors.com
+41 78 680 0538

Financial Tables to Follow

GALECTO, INC. Condensed Consolidated Balance Sheets (in thousands)

	June 30, 2023	December 31, 2022
	(unaudited)	
Cash and cash equivalents	\$ 22,956	\$ 32,786
Marketable securities	29,168	27,438
Prepaid expenses and other current assets	3,238	3,686
Marketable securities, noncurrent	0	5,832
Operating lease right-of-use assets	633	810
Other assets, noncurrent	2,808	2,636
Total assets	\$ 58,803	\$ 73,188
Current liabilities	\$ 14,897	\$ 11,107
Operating lease liabilities, noncurrent	206	328
Total liabilities	15,103	11,435
Total stockholders' equity	43,700	61,753
Total liabilities and stockholders' equity	\$ 58,803	\$ 73,188

GALECTO, INC. Condensed Consolidated Statements of Operations and Comprehensive Loss (in thousands, except share and per share amounts) (unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	\$ 8,089	\$ 13,707	\$ 18,451	\$ 26,942
General and administrative	3,070	3,414	6,200	7,118
Total operating expenses	11,159	17,121	24,651	34,060
Loss from operations	(11,159)	(17,121)	(24,651)	(34,060)
Total other income, net	415	234	913	235
Net loss	\$ (10,744)	\$ (16,887)	\$ (23,738)	\$ (33,825)
Net loss per common share, basic and diluted	\$ (0.41)	\$ (0.67)	\$ (0.91)	\$ (1.34)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	26,375,076	25,270,314	26,025,929	25,266,096
Other comprehensive gain (loss), net of tax	(10)	(804)	107	(1,179)
Total comprehensive loss	\$ (10,754)	\$ (17,691)	\$ (23,631)	\$ (35,004)



Source: Galecto, Inc.