



Galecto Reports First Quarter Operating and Financial Results

April 28, 2023

BOSTON, April 28, 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 March 31, 2023.

"Galecto continued to make strong progress with its clinical programs in the first quarter of 2023 and remains on target for several significant milestones this year. We reported exciting preliminary data from our clinical trials that are evaluating our oral galectin-3 inhibitor GB1211 plus atezolizumab for the first-line treatment of non-small cell lung cancer and our LOXL2 inhibitor GB2064 for the treatment of myelofibrosis, which further deepen our confidence in the potential of our pipeline," said Hans Schambye, President and Chief Executive Officer of Galecto. "The Galecto team is delivering on development plans for our novel therapies, and we continue to expect top-line results from our Phase 2b GALACTIC-1 trial of our lead product GB0139 in idiopathic pulmonary fibrosis this August."

First Quarter and Other Recent Highlights

- Reported partial response in two patients in the open-label portion (Part A) of the Phase 1b/2a GALLANT-1 trial evaluating GB1211 in combination with atezolizumab for the treatment of non-small cell lung cancer (NSCLC). A partial response is defined by RECIST criteria to be shrinkage of at least 30% of the tumor. One of these patients has been treated with GB1211 200 mg twice daily for 23 weeks, while the other has been treated with GB1211 100 mg twice daily for 14 weeks, and both patients continue to receive active treatment in the trial. Recruitment in Part A of this trial is currently ongoing.
- Reported data from three additional evaluable myelofibrosis patients in the Phase 2a MYLOX-1 trial with GB2064 for the treatment of myelofibrosis that showed one patient experienced a 1-grade reduction in reticulin fibrosis at nine months and, following an initial increase of collagen fibrosis score of 1 grade at six months, experienced a 1-grade reduction of collagen fibrosis at nine months. In the third quarter of 2022, Galecto announced that four of five evaluable myelofibrosis patients in an intermediate assessment 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 potentially be disease modifying. Because the trial has exceeded the pre-defined target of a ≥ 1 grade reduction in collagen fibrosis in at least three out of 16 evaluable patients, Galecto believes that MYLOX-1 has reached the dual goal of confirming LOXL2 as an attractive fibrosis target and demonstrating that GB2064 has clinically meaningful antifibrotic activity. Accordingly, Galecto has determined to stop enrolling additional patients in the trial and will continue following the remaining patients.
- Presented two posters at the American Association for Cancer Research (AACR) Annual Meeting 2023 showing anti-cancer activity in both our galectin-1 specific inhibitor and our dual acting galectin-1/3 inhibitor compounds, which could provide potential new cancer therapies.

Expected Upcoming Milestones

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

First Quarter 2023 Financial Highlights

Cash, cash equivalents, and investments as of March 31, 2023 were approximately \$57.2 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 \$10.4 million for the period ended March 31, 2023, compared to \$13.2 million for the period ended March 31, 2022. The decrease of \$2.8 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 March 31, 2023, compared to \$3.7 million for the period ended March 31, 2022. The decrease of \$0.6 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 March 31, 2023 was \$13.0 million or \$(0.51) 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 asset 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.

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Financial Tables to Follow

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

	March 31, 2023	December 31, 2022
	(unaudited)	
Cash and cash equivalents	\$ 25,068	\$ 32,786
Marketable securities	28,179	27,438
Prepaid expenses and other current assets	3,881	3,686
Marketable securities, noncurrent	3,964	5,832
Operating lease right-of-use assets	704	810
Other assets, noncurrent	2,834	2,636
Total assets	\$ 64,630	\$ 73,188
Current liabilities	\$ 14,063	\$ 11,107
Operating lease liabilities, noncurrent	234	328
Total liabilities	14,297	11,435
Total stockholders' equity	50,333	61,753
Total liabilities and stockholders' equity	\$ 64,630	\$ 73,188

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

	Three Months Ended March 31,	
	2023	2022
Operating expenses:		
Research and development	\$ 10,362	\$ 13,235
General and administrative	3,130	3,704
Total operating expenses	13,492	16,939
Loss from operations	(13,492)	(16,939)

Total other income, net	498	1
Net loss	\$ (12,994)	\$ (16,938)
Net loss per common share, basic and diluted	\$ (0.51)	\$ (0.67)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	<u>25,672,902</u>	<u>25,261,832</u>
Other comprehensive gain (loss), net of tax	117	(375)
Total comprehensive loss	\$ (12,877)	\$ (17,313)



Source: Galecto, Inc.