



Galecto Reports Third Quarter Operating and Financial Results

November 8, 2022

BOSTON, Nov. 08, 2022 (GLOBE NEWSWIRE) -- 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 its operating and financial results for the quarter ended September 30, 2022.

"The recent release of positive results from two clinical trials, our Phase 1b/2a GULLIVER-2 trial in decompensated liver cirrhosis and our Phase 2a MYLOX-1 trial in myelofibrosis, has created significant momentum for Galecto and our team," said Galecto CEO Hans T. Schambye, M.D., Ph.D. "Galectin-3 and LOXL2 play a central role in fueling key pathological pathways in fibrosis, and the encouraging results from both of these trials provides further evidence and strengthens our belief that the inhibition of galectin-3 and LOXL2 are crucial to reducing fibrosis and potentially modifying disease. We look forward to 2023, where we expect to announce top-line results from our Phase 2b GALACTIC-1 trial in idiopathic pulmonary fibrosis (IPF) in mid-2023 and our Phase 2a GALLANT-1 trial in non-small cell lung cancer (NSCLC) in the second half of 2023."

Recent Highlights

- Highlighted by two late-breaking presentations at the AASLD Liver Meeting® 2022, announced positive top-line results from the Phase 1b/2a GULLIVER-2 trial of GB1211, Galecto's first-in-class, oral small molecule galectin-3 inhibitor candidate, where GB1211 demonstrated a favorable tolerability profile and showed reduced signs of liver impairment in patients with decompensated cirrhosis.
- Announced positive intermediate assessment results from the ongoing Phase 2a MYLOX-1 trial of GB2064, Galecto's first-in-class, LOXL2 inhibitor candidate, for the treatment of myelofibrosis, where four out of five evaluable patients who received GB2064 for at least six months experienced a \geq 1-grade reduction in collagen fibrosis of the bone marrow, an improvement suggesting that GB2064 could impact the progression of the disease and be disease modifying.
- Poster presentation highlighting results from the intermediate assessment of the MYLOX-1 trial to be featured at the 64th American Society of Hematology (ASH) Annual Meeting and Exposition on December 10-13, 2022 in New Orleans, LA.
- Expanded Galecto's oncology reach by entering into a collaboration agreement for an investigator-initiated Phase 2 trial with Providence Cancer Institute to evaluate GB1211 in combination with pembrolizumab (Keytruda®) in patients with metastatic melanoma and head and neck squamous cell carcinoma (HNSCC).
- Published [article](#) in the September 2022 Journal of Medicinal Chemistry demonstrating that GB1211, the first orally available galectin-3 inhibitor for the treatment of fibrotic disease, is a potent inhibitor of liver and lung fibrosis in both *in vitro* and *in vivo* models.

Expected Upcoming Milestones

- Top-line results from Phase 2b GALACTIC-1 trial (IPF) in mid-2023.
- Interim safety data from Phase 2a GALLANT-1 trial (NSCLC) by Q1 2023.
- Initiation of Phase 2 investigator-initiated GB1211 oncology trial (melanoma and HNSCC) by Providence Cancer Institute in 2023.

Third Quarter 2022 Financial Highlights

Cash, cash equivalents, and investments as of September 30, 2022 were approximately \$75.9 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 \$10.5 million for the three months ended September 30, 2022, compared to \$9.7 million for the three months ended September 30, 2021. The increase of \$0.8 million was due primarily to increased clinical spending associated with four active clinical trials.

General and administrative expenses were \$3.1 million for the three months ended September 30, 2022, compared to \$3.2 million for the three months ended September 30, 2021. The decrease of \$(0.1) million was primarily related to decreased consulting expenses.

Net loss attributable to common stockholders for the three months ended September 30, 2022 was \$13.7 million or \$(0.54) per basic and diluted share, compared with \$12.7 million, or \$(0.50) per basic and diluted share, for the three months ended September 30, 2021.

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 inhibitor (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 plans for timing of initiating and planned readouts of its clinical trials; the potential of Galecto's product candidates to address significant areas of unmet need; 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 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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Financial Tables to Follow

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

	September 30, 2022	December 31, 2021
	(unaudited)	
Cash and cash equivalents	\$ 28,336	\$ 62,563
Marketable securities	40,748	37,628
Prepaid expenses and other current assets	2,115	9,911
Marketable securities, noncurrent	6,829	9,048
Operating lease right-of-use assets	852	834
Other assets, noncurrent	3,145	2,231
Total assets	\$ 82,025	\$ 122,215
Current liabilities	\$ 8,858	\$ 4,544
Operating lease liabilities, noncurrent	440	448
Total liabilities	9,298	4,992
Total stockholders' equity	72,727	117,223
Total liabilities and stockholders' equity	\$ 82,025	\$ 122,215

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	\$ 10,494	\$ 9,748	\$ 37,436	\$ 28,373
General and administrative	3,128	3,191	10,246	10,386
Total operating expenses	13,622	12,939	47,682	38,759
Loss from operations	(13,622)	(12,939)	(47,682)	(38,759)
Total other income (expense), net	(108)	243	127	416

Net loss	\$ (13,730)	\$ (12,696)	\$ (47,555)	\$ (38,343)
Net loss per common share, basic and diluted	\$ (0.54)	\$ (0.50)	\$ (1.88)	\$ (1.52)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	25,491,786	25,261,832	25,342,153	25,261,832
Other comprehensive gain (loss), net of tax	(426)	(335)	(1,605)	(763)
Total comprehensive loss	\$ (14,156)	\$ (13,031)	\$ (49,160)	\$ (39,106)



Source: Galecto, Inc.