# Galecto

# **Galecto Reports Second Quarter Operating and Financial Results**

August 5, 2021

BOSTON, Aug. 05, 2021 (GLOBE NEWSWIRE) -- Galecto, Inc. (NASDAQ: GLTO), a clinical stage biotechnology company focused on the development of novel treatments for fibrosis and cancer, today announced its operating and financial results for the quarter ended June 30, 2021.

Hans Schambye, CEO of Galecto, said, "During the second quarter we continued to focus on the execution of our fibrosis and cancer pipeline. Our clinical team was able to effectively work with regulatory authorities on a revised protocol for our Phase 2b GALACTIC-1 trial with GB0139, which allowed us to re-initiate recruitment. GB0139, our most advanced product candidate, is an inhaled small molecule inhibitor of galectin-3 for the treatment of idiopathic pulmonary fibrosis (IPF). We were also encouraged by the results from a study of GB0139 in COVID-19 patients with compromised lung function. This study confirmed that GB0139 was generally well-tolerated, showed target engagement by reducing plasma galectin-3, had a positive trend on acute lung injury related to COVID-19 with signs of improved lung function and decreased levels of plasma biomarkers similar to those observed in our prior IPF trials. We believe this second data set of biomarkers in patients with compromised lung function strengthens the notion that inhaled GB0139 can rapidly and strongly affect key biological processes such as inflammation, coagulation and fibrosis."

Dr. Schambye continued, "Beyond our fibrosis programs, we are excited about the advancement of our compounds for the treatment of cancer, beginning with GB1211, a potent small molecule selective oral galectin-3 inhibitor that we are developing for cancer (initially in NSCLC), as well as fibrosis (initially in liver cirrhosis). We believe that both our galectin-3 inhibitors and our collagen-cross linking enzyme, LOXL2, inhibitor could prove to be important tools in the treatment of cancer, as these compounds are designed to enhance the aggressiveness of the immune system on cancer tissue through changing the tumor microenvironment, and also provide direct anti-growth effects on cancer cells. We are on track to have our fibrosis and cancer product candidates in four separate Phase 2 clinical trials by early 2022."

# **Recent Highlights & Developments**

- Announced that Galecto has resumed recruiting IPF patients in its GALACTIC-1 Phase 2b trial under a revised protocol that was submitted to the U.S. Food and Drug Administration and other regulatory bodies. Galecto believes that GB0139 is well positioned to address a significant unmet need for a safer and more efficacious treatment.
- Announced the results of GB0139 in COVID-19 patients with compromised lung function, which confirmed that the compound was well-tolerated and showed target engagement and highly relevant biological effects.

# **Expected Upcoming Milestones**

- Completion of enrollment in GALACTIC-1 Phase 2b clinical trial in IPF patients in 1H 2022
- Initiation of enrollment in three Phase 2 trials:
  - MYLOX-1 trial (myelofibrosis) in Q3 2021
  - o GULLIVER-2 trial (liver cirrhosis) by Q4 2021
  - GALLANT-1 trial (NSCLC) by Q2 2022

## Second Quarter 2021 Financial Highlights

Cash, cash equivalents, and marketable securities as of June 30, 2021 were approximately \$138 million. We currently expect that our cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital requirements into the second half of 2024.

Research and development expenses were \$8.6 million for the three months ended June 30, 2021, compared to \$4.5 million for the three months ended June 30, 2020. The increase of \$4.1 million was due primarily to increased clinical spending associated with the GALACTIC-1 study.

General and administrative expenses were \$3.6 million for the three months ended June 30, 2021, compared to \$1.8 million for the three months ended June 30, 2020. The increase of \$1.8 million was primarily related to public company costs and non-cash stock-based compensation.

Net loss attributable to common stockholders for the three months ended June 30, 2021 was \$12.3 million, or \$(0.49) per basic and diluted share, compared with \$5.9 million, or \$(22.83) per basic and diluted share, for the prior year period.

## **About Galecto**

Galecto is a clinical stage biotechnology company incorporated in the U.S. that is developing small molecule-based galectin inhibitors and the collagen cross-linking enzyme, LOXL2, inhibitors. Galecto has multiple clinical programs in fibrosis and cancer focused on galectin-3 and LOXL2, including an inhaled galectin-3 modulator (GB0139) currently in a phase 2b trial for the potential treatment of idiopathic pulmonary fibrosis. The company's pipeline also includes an orally active galectin-3 inhibitor (GB1211) that is expected to be part of (i) a phase 2 trial for the potential treatment of NSCLC in combination with an anti-PD1/-L1 product and (ii) a phase 1b/2a trial in liver cirrhosis, as well as an orally active LOXL2 inhibitor (GB2064) that is expected to part of a phase 2 trial for the potential treatment of myelofibrosis.

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 company's observations from its COVID-19 study and the relation of such observations to the treatment of patients with compromised lung function or IPF; GB0139 being well positioned to address a significant unmet need for a safer and more efficacious treatment; the potential role of galectin-3 and LOXL2 inhibitors in the treatment of cancer; Galecto's ability to complete of enrollment in GALACTIC-1 Phase 2b clinical trial in IPF patients in 1H 2022; Galecto's initiation of enrollment in three Phase 2 trials: MYLOX-1 trial (myelofibrosis) in Q3 2021,

GALLANT-1 trial (NSCLC) by Q2 2022 and GULLIVER-2 trial (liver cirrhosis) by Q4 2021; and Galecto's expectation that it cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital requirements into the second half of 2024. Such forward-looking statements include statements about Galecto's 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 fliings 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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Financial Tables to Follow

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

	June 30, 2021			December 31, 2020				
	(unaudited)							
Cash and cash equivalents	\$	68,638	\$	163,582				
Marketable securities		33,176		—				
Prepaid expenses and other current assets		5,895		5,713				
Marketable securities, long-term		35,860		—				
Operating lease right-of-use assets		1,075		885				
Other assets		2,178		1,416				
Total assets	\$	146,822	\$	171,596				
Current liabilities	\$	4,755	\$	5,566				
Operating lease liabilities, noncurrent		635		541				
Total liabilities		5,390		6,107				
Total stockholders' equity		141,432		165,489				
Total liabilities and stockholders' equity	\$	146,822	\$	171,596				

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

	For the Three Months Ended June 30,			For the Six Months Ended June 30,				
		2021		2020		2021		2020
Operating expenses:								
Research and development	\$	8,635	\$	4,515	\$	18,625	\$	9,222
General and administrative		3,633		1,823		7,195		2,946
Total operating expenses		12,268		6,338		25,820		12,168
Loss from operations		(12,268)		(6,338)		(25,820)		(12,168)
Total other income (expense), net		(34)		403		173		559

Net loss	(12,302)		(5,935)	(25,647)	(11,609)
Net loss per common share, basic and diluted	\$ (0.49)	\$	(22.83)	\$ (1.02)	\$ (44.66)
Weighted-average number of shares used in computing net loss per common share, basic and diluted	25.261.832		259.966	25.261.832	259.966
loss per common share, basic and diluted	 23,201,032	-	233,300	 23,201,032	 233,300
Other comprehensive gain (loss), net of tax	 176		15	 (428)	 (195)
Total comprehensive loss	\$ (12,126)	\$	(5,920)	\$ (26,075)	\$ (11,804)



Source: Galecto, Inc.