Galectin Therapeutics Reports Financial Results for the Quarter Ended June 30, 2024 and Provides Business Update

08/13/24

- *NAVIGATE trial on track for interim top-line analysis in December 2024*

NORCROSS, Ga., Aug. 13, 2024 (GLOBE NEWSWIRE) -- Galectin Therapeutics, Inc. (NASDAQ: GALT), the leading developer of therapeutics that target galectin proteins, today reported financial results and provided a business update for the quarter ended June 30, 2024.

Joel Lewis, Chief Executive Officer and President of Galectin Therapeutics, said, “We continued to advance the NAVIGATE Phase 2b/3 trial of belapectin in the first half of 2024. We believe that belapectin can potentially offer a new medical treatment option for the increasing number of patients affected with MASH associated liver cirrhosis and portal hypertension that represents a significant unmet medical need, and we are excited for the planned upcoming interim analysis in December 2024.”

Khurram Jamil, M.D., Chief Medical Officer, added, “We were pleased to share the important data from our belapectin program demonstrating that collagen content in liver biopsies of MASH cirrhotic patients does not correlate with portal pressure, which is a key marker of disease progression at the EASL 2024 congress. These insights underscore the importance of truly understanding the overall health of the liver and highlights the effectiveness of endoscopies in determining that.”

Belapectin Program Q2 2024 and Recent Highlights

Belapectin is a complex carbohydrate drug that targets galectin-3, a critical protein in the pathogenesis of MASH and fibrosis.

MASH Cirrhosis

- The NAVIGATE Phase 2b/3 trial (NCT04365868) evaluating the efficacy and safety of belapectin for the prevention of esophageal varices in MASH in 357 patients across 14 countries on five continents is progressing as planned. Interim top-line data readout from the Phase 2b portion of the trial is anticipated late in December 2024.
- Presented a poster at the European Association for the Study of the Liver (EASL) 2024 Congress. The poster highlighted data from an evaluation of the correlation between portal pressure, collagen proportional area, and α-smooth muscle actin in patients with portal hypertension due to MASH cirrhosis. The data showed that collagen content in liver biopsies of MASH cirrhotic patients fails to correlate with measures of portal pressure, a main marker of disease progression and underscores the importance of endoscopies to assess the development of esophageal varices, a direct consequence of increased portal pressure.

Q2 2024 Financial Highlights

- As of June 30, 2024, the Company had $25.6 million of cash and cash equivalents. Additionally, the Company has $10 million remaining available under a line of credit provided by its chairman of the board to fund operations. The Company believes it has sufficient cash to fund currently planned operations and research and development activities through approximately May 15, 2025.
- Research and development expenses for the quarter ended June 30, 2024 were $9.8 million compared with $7.4 million for the same period in 2023. The increase was primarily due to timing of incurrence of expenditures related to our NAVIGATE clinical trial.
- General and administrative expenses for the quarter ended June 30, 2024 were $1.5 million, compared to $1.6 million for the quarter ended June 30, 2023.
- For the quarter ended June 30, 2024, the Company reported a net loss applicable to common stockholders of $12.4 million, or ($0.20) per share, compared to a net loss applicable to common stockholders of $9.2 million, or ($0.15) per share for the quarter ended June 30, 2023.
- These results are included in the Company's Quarterly Report on Form 10-Q as of and for the period ended June 30, 2024, which has been filed with the U.S. Securities and Exchange Commission and is available at **www.sec.gov**.

About Galectin Therapeutics
Galectin Therapeutics is dedicated to developing novel therapies to improve the lives of patients with chronic liver disease and cancer. Galectin’s lead drug belapectin is a carbohydrate-based drug that inhibits the galectin-3 protein, which is directly involved in multiple inflammatory, fibrotic, and malignant diseases, for which it has Fast Track designation by the U.S. Food and Drug Administration. The lead development program is in metabolic dysfunction-associated steatohepatitis (MASH, formerly known as nonalcoholic steatohepatitis, or NASH) with cirrhosis, the most advanced form of MASH-related fibrosis. Liver cirrhosis is one of the most pressing medical needs and a significant drug development opportunity. Additional development programs are in treatment of combination immunotherapy for advanced head and neck cancers and other malignancies. Advancement of these additional clinical programs is largely dependent on finding a suitable partner. Galectin seeks to leverage extensive scientific and

development expertise as well as established relationships with external sources to achieve cost-effective and efficient development. Additional information is available at **www.galectintherapeutics.com**.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements relate to future events or future financial performance, and use words such as "may," "estimate," "could," "expect," "look forward," "believe," "hope" and others. They are based on management's current expectations and are subject to factors and uncertainties that could cause actual results to differ materially from those described in the statements. These statements include those regarding the hope that Galectin's development program for belapectin will lead to the first therapy for the treatment of MASH, formerly known as NASH, with cirrhosis and those regarding the hope that our lead compounds will be successful in cancer immunotherapy and in other therapeutic indications. Factors that could cause actual performance to differ materially from those discussed in the forward-looking statements include, among others, that trial endpoints required by the FDA may not be achieved; Galectin may not be successful in developing effective treatments and/or obtaining the requisite approvals for the use of belapectin or any of its other drugs in development; the Company may not be successful in scaling up manufacturing and meeting requirements related to chemistry, manufacturing and control matters; the Company's current clinical trial and any future clinical studies may not produce positive results in a timely fashion, if at all, and could require larger and longer trials, which would be time consuming and costly; plans regarding development, approval and marketing of any of Galectin's drugs are subject to change at any time based on the changing needs of the Company as determined by management and regulatory agencies; regardless of the results of any of its development programs, Galectin may be unsuccessful in developing partnerships with other companies or raising additional capital that would allow it to further develop and/or fund any studies or trials. Galectin has incurred operating losses since inception, and its ability to successfully develop and market drugs may be impacted by its ability to manage costs and finance continuing operations. For a discussion of additional factors impacting Galectin's business, see the Company's Annual Report on Form 10-K for the year ended December 31, 2023, and subsequent filings with the SEC. You should not place undue reliance on forward-looking statements. Although subsequent events may cause its views to change, management disclaims any obligation to update forward-looking statements.

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Condensed Consolidated Statements of Operations

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
	(in thousands, except per share data)			
Operating expenses:				
Research and development	$ 9,813	$ 7,371	$ 17,867	$ 16,170
General and administrative	1,478	1,632	3,072	3,175
Total operating expenses	11,291	9,003	20,939	19,345
Total operating loss	(11,291)	(9,003)	(20,939)	(19,345)
Other income (expense):				
Interest income	80	50	160	93
Interest expense	(1,269)	(650)	(2,321)	(1,110)
Change in fair value of derivative	109	489	(760)	(279)
Total other income	(1,080)	(111)	(2,921)	(1,296)
Net loss	$ (12,371)	$ (9,114)	$ (23,860)	$ (20,641)
Preferred stock dividends	(64)	(63)	(72)	(63)
Warrant modification				
Net loss applicable to common stock	$ (12,435)	$ (9,177)	$ (23,932)	$ (20,704)
Basic and diluted net loss per share	$ (0.20)	$ (0.15)	$ (0.38)	$ (0.35)
Shares used in computing basic and diluted net loss per share	62,233	59,582	62,192	59,531

Condensed Consolidated Balance Sheet Data

	December 31,
	June 30, 2024

				2023
		(in thousands)		
Cash and cash equivalents	$	25,598	$	25,660
Total assets		27,655		28,200
Total current liabilities		14,617		15,676
Total liabilities		109,802		88,441
Total redeemable, convertible preferred stock		1,723		1,723
Total stockholders’ equity (deficit)	$	(83,870)	$	(61,964)