



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

11/14/24

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

NORCROSS, Ga., Nov. 14, 2024 (GLOBE NEWSWIRE) -- [Galectin Therapeutics, Inc.](https://www.galectin.com) (NASDAQ: GALT), the leading developer of therapeutics that target galectin proteins, today reported financial results and provided a business update for the quarter ended September 30, 2024.

Joel Lewis, Chief Executive Officer and President of Galectin Therapeutics, said "This past quarter, we remained laser-focus on advancing the NAVIGATE trial of belapectin in patients with MASH cirrhosis. As we eagerly await the topline results next month, we remain hopeful that belapectin may be a potential new treatment for the large number of patients in the U.S. with compensated cirrhosis, portal hypertension, and which have not developed esophageal varices. These patients represent a large unmet medical need."

Khurram Jamil, M.D., Chief Medical Officer, added, "We are pleased to share that Galectin will present three posters highlighting important data from our belapectin program at the upcoming American Association for the Study of Liver Disease (AASLD) 2024 meeting. Our presentations will discuss the central evaluation process of upper endoscopies for our novel primary endpoint, as well as the unique characteristics of the patient population enrolled in the NAVIGATE trial utilizing the latest clinical guidelines for portal hypertension."

Belapectin Program Q3 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 trial \(NCT04365868\)](https://clinicaltrials.gov/ct2/show/study/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. Based on feedback from the U.S. Food and Drug Administration (FDA), the Company has decided to analyze stage 1 of the NAVIGATE clinical trial results as a stand-alone trial. Therefore, full top-line efficacy and safety results, following last patient last visit and database lock which both have occurred recently, are expected to be presented in December 2024. At this point, the Company remains blinded to any data until after the Data Safety Monitoring Board meeting, which is expected in December 2024.
- Three abstracts on clinical data from the NAVIGATE trial in patients with MASH cirrhosis and portal hypertension have been accepted for poster presentation at the American Association for the Study of Liver Diseases (AASLD)'s 2024 annual Liver Meeting, being held November 15-19, 2024, in San Diego, California. These posters cover the primary endpoint evaluation and patient population of the NAVIGATE trial.

2024 Annual Meeting of Stockholders

As previously announced, due to the expected top-line results of the NAVIGATE trial in December 2024, the Board of Directors established January 23, 2025, as the date of the 2024 Annual Meeting of Stockholders.

Q3 2024 Financial Highlights

- As of September 30, 2024, the Company had \$27.1 million of cash and cash equivalents. Additionally, the Company has \$6 million available under a new 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 May 2025.
- Research and development expenses for the quarter ended June 30, 2024 were \$7.6 million compared with \$7.7 million for the same period in 2023. Overall, there was a moderate increase in expenditures related to our NAVIGATE clinical trial offset by lower preclinical and nonclinical costs.
- General and administrative expenses for the quarter ended September 30, 2024 were \$1.5 million, compared to \$1.4 million for the quarter ended September 30, 2023.
- For the quarter ended September 30, 2024, the Company reported a net loss applicable to common stockholders of \$11.2 million, or (\$0.18) per share, compared to a net loss applicable to common stockholders of \$14.0 million, or (\$0.24) per share for the quarter ended September 30, 2023.
- These results are included in the Company's Quarterly Report on Form 10-Q as of and for the period ended September

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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Galectin Therapeutics and its associated logo is a registered trademark of Galectin Therapeutics Inc. Belapectin is the USAN assigned name for Galectin Therapeutics' galectin-3 inhibitor belapectin.

Condensed Consolidated Statements of Operations

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2024	2023	2024	2023
	(in thousands, except per share data)			
Operating expenses:				
Research and development	\$7,595	\$7,732	\$25,462	\$23,902
General and administrative	1,471	1,434	4,543	4,609
Total operating expenses	<u>9,066</u>	<u>9,166</u>	<u>30,005</u>	<u>28,511</u>
Total operating loss	<u>(9,066)</u>	<u>(9,166)</u>	<u>(30,005)</u>	<u>(28,511)</u>
Other income (expense):				
Interest income	93	62	253	156
Interest expense	(1,494)	(835)	(3,815)	(1,945)
Change in fair value of derivative	(753)	(489)	(1,513)	(769)
Total other income	<u>(2,154)</u>	<u>(1,262)</u>	<u>(5,075)</u>	<u>(2,558)</u>
Net loss	<u>\$(11,220)</u>	<u>\$(10,428)</u>	<u>\$(35,080)</u>	<u>\$(31,069)</u>
Preferred stock dividends	(18)	6	(90)	(57)

Warrant modification		(3,619)		(3,619)
Net loss applicable to common stock	\$ (11,238)	\$ (14,041)	\$ (15,170)	\$ (34,745)
Basic and diluted net loss per share	\$ (0.18)	\$ (0.24)	\$ (0.57)	\$ (0.58)
Shares used in computing basic and diluted net loss per share	62,278	59,704	62,163	59,590

Condensed Consolidated Balance Sheet Data

	September 30, 2024	December 31, 2023
	(in thousands)	
Cash and cash equivalents	\$ 27,060	\$ 25,660
Total assets	28,972	28,200
Total current liabilities	25,258	15,676
Total liabilities	121,453	88,441
Total redeemable, convertible preferred stock....	1,723	1,723
Total stockholders' equity (deficit)	\$ (94,204)	\$ (61,964)