# Galectin Therapeutics Provides Business Update And Reports Financial Results for the Quarter Ended September 30, 2020

November 9, 2020

**Innovative Phase 2b/3 NASH-RX Trial in NASH Cirrhosis Initiated**

**Board Member Joel Lewis Assumes CEO Role –**
**Board Adds Two New Highly Accomplished Professionals**

NORCROSS, Ga., Nov. 09, 2020 (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 September 30, 2020. These results are included in the Company's Quarterly Report on Form 10-Q, which has been filed with the U.S. Securities and Exchange Commission and is available at **www.sec.gov**.

Joel Lewis, Chief Executive Officer and President of Galectin Therapeutics, said, “With the June launch of our innovative NASH-RX clinical trial, we now have one of the very few, if not only, active late stage trial of patients with compensated NASH-cirrhosis, where the medical need is greatest. Continuing our progress, the first patient was randomized in August and we are enrolling patients and adding sites to this global clinical trial of belapectin, our proprietary galectin-3 inhibiting compound. We believe our innovative trial design, experienced medical and clinical teams and clear primary endpoint provide a strong foundation for success. A positive result will be very clinically relevant. If the trial shows that belapectin is effective and safe, it will be a medical breakthrough for patients with NASH cirrhosis.”

“As I close out my first quarter as the head of Galectin Therapeutics, I want to reiterate how excited I am to be leading this team,” concluded Lewis. “I also want to thank the investigators and patients who will participate in our NASH-RX trial. Without your commitment, there is no way the company would be where we are today nor would we have a future.”

Richard E. Uihlein, Chairman of the Board, added, “Galectin Therapeutics is competitively well-positioned in the industry, and we are fortunate to have Joel leading these efforts. I am also glad to welcome Mr. Richard Zordani and Dr. Elissa Schwartz to our Board of Directors, both seasoned professionals that will strengthen our financial and clinical capabilities, respectively.”

“Success in NASH cirrhosis potentially opens new treatment possibilities for belapectin's use in other types of liver cirrhosis and in other forms of organ fibrosis affecting kidney, lung, as well as other organs. More research is warranted to expand our understanding of galectins and the role that a galectin-3 inhibitor like belapectin may play in preventing and treating disease. Thus, our NASH-RX trial will set the stage for realizing the full potential of our proprietary compound, belapectin.”

**Summary of Key Development Programs and Updates**

- On June 30 announced that we had enrolled our first patients in the NASH-RX trial. NASH-RX is an international, seamless, adaptively-designed Phase 2b/3 trial of our galectin-3 inhibitor belapectin (GR-MD-02), the company's lead compound, in nonalcoholic steatohepatitis (NASH) cirrhosis patients who have clinical signs of portal hypertension and are at risk of developing esophageal varices. Belapectin had previously been shown that it could prevent the development of new varices in this patient population in the Phase 2 NASH-CX clinical trial (Gastroenterology 2020;158:1334–1345 or https://doi.org/10.1053/j.gastro.2019.11.296).

- Announced the appointment of current board member, Joel Lewis, to the position of Chief Executive Officer (CEO) and President. In this position, Mr. Lewis will set corporate strategy and oversee operations, most importantly the Company’s global NASH-RX adaptively-designed trial for the prevention of varices in NASH cirrhosis patients using its proprietary galectin-3 inhibiting compound, belapectin (GR-MD-02).

- Engaged Dr. Harold Shlevin, who retired from the CEO position, to a consulting agreement through which he has agreed to devote significant effort to advancing the NASH-RX trial and will remain a member of the Board of Directors.

- Enhanced its Board of Directors with the addition of two additional directors, Mr. Richard Zordani and Dr. Elissa Schwartz. Mr. Zordani is a seasoned financial executive with extensive public accounting and Family Office experience and has assumed the role of Audit Committee Chairman. Dr. Schwartz has extensive experience in epidemiology and clinical research, biomathematics, and biostatistics, which complements the Company's clinical development capabilities.

- Hosted a virtual conference call and webinar with the investment community on September 29th that provided a comprehensive description and update on the status of the NASH-RX trial and introduced our new CEO, Joel Lewis. **A replay of the Investor Call can be accessed at this link: https://edge.media-server.com/mmc/p/hmudntyg**

**About the NASH-RX Trial**

- The NASH-RX trial will use a seamless, adaptive design to confirm dose selection and reaffirm the observed efficacy of belapectin to prevent the development of esophageal varices in the NASH-CX trial. Pre-planned adaptations will inform the larger Phase 3 trial component. NASH-RX is expected to enroll approximately 315 NASH cirrhotic patients in the Phase 2b part of the trial at approximately 130 sites in 12 countries in North America, Europe, Asia and Australia.

**Financial Results**

For the three months ended September 30, 2020, the Company reported a net loss applicable to common stockholders of $5.955 million, or ($0.10) per share, compared to a net loss applicable to common stockholders of $2.819 million, or ($0.05) per share for the three months ended September 30, 2019. The increase is due to 2020 research and development expense related to the Company's NASH-RX trial.

Research and development expense for the three months ended September 30, 2020 was $4.780 million compared with $1.503 million for the three months ended September 30, 2019. The increase was primarily due to costs related to our NASH-RX clinical trial, along with preparations and some preclinical activities incurred in support of the clinical program, such as development and reproductive toxicity studies, clinical supplies and other supportive activities. General and administrative expenses for the three months ended September 30, 2020, were $1.146 million, down from $1.360 million for the three months ended September 30, 2019, primarily due to a decrease in stock-based compensation expenses.

As of September 30, 2020, the Company had $32.6 million of cash and cash equivalents. The Company also has a $10 million unsecured line of credit, under which no borrowings have been made to date. The Company believes it has sufficient cash, including availability under the line of credit, to fund currently planned operations and research and development activities through at least December 31, 2021.

The Company expects that it will require more cash to fund operations after December 31, 2021 and believes it will be able to obtain additional financing as needed. Currently, we expect to require an additional approximately $40 million to cover costs of the trial to reach the planned interim analysis estimated to occur in the second quarter of 2023 along with drug manufacturing and other scientific support activities and general and administrative costs. These costs will require additional funding. There can be no assurance that we will be successful in obtaining financing to support our operations beyond December 31, 2021, or, if available, that any such financing will be on terms acceptable to us.

**About Belapectin (GR-MD-02)**

Belapectin (GR-MD-02) is a complex carbohydrate drug that targets galectin-3, a critical protein in the pathogenesis of NASH and fibrosis. Galectin-3 plays a major role in diseases that involve scarring of organs including fibrotic disorders of the liver, lung, kidney, heart and vascular system. Belapectin binds to galectin-3 and disrupts its function. Preclinical data in animals have shown that belapectin has robust treatment effects in reversing liver fibrosis and cirrhosis. Galectin-3 has a significant role in cancer and the Company is supporting a Phase 1 study in combined immunotherapy of belapectin and Keytruda in treatment of advanced melanoma and in head and neck cancer.

**About Non-alcoholic steatohepatitis (NASH) with Advanced Fibrosis and Cirrhosis**
NASH has become a common disease of the liver with the rise in obesity and other metabolic diseases. NASH is estimated to affect up to 28 million people in the U.S. It is characterized by the presence of excess fat in the liver along with inflammation and hepatocyte damage (ballooning) in people who consume little or no alcohol. Over time, patients with NASH can develop excessive fibrosis, or scarring of the liver, and ultimately liver cirrhosis. It is estimated that as many as 1 to 2 million individuals in the U.S. will develop cirrhosis as a result of NASH, for which liver transplantation is currently the only curative treatment available. There are no drug therapies approved for the treatment of liver fibrosis or cirrhosis.

**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 (formerly known as GR-MD-02) 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 for NASH cirrhosis by the U.S. Food and Drug Administration. The lead development program is in non-alcoholic steatohepatitis (NASH) with cirrhosis, the most advanced form of NASH-related fibrosis. This is the most common liver disease and one of the largest drug development opportunities available today. Additional development programs are in treatment of combination immunotherapy for advanced melanoma 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" 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 fatty liver disease 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 currently planned clinical trial and any future clinical studies as modified to meet the requirements of the FDA 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. Global factors such as coronavirus may limit access to NASH patient populations around the globe and slow trial enrollment and prolong the duration of the trial and significantly impact associated costs. 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, 2019, 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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2020 | 2019 | 2020 | 2019 |
| | (in thousands, except per share data) | | | |
| Operating expenses: | | | | |
| Research and development | $ 4,780 | $ 1,503 | $ 11,605 | $ 3,671 |
| General and administrative | 1,146 | 1,360 | 4,007 | 4,579 |
| Total operating expenses | 5,926 | 2,863 | 15,612 | 8,250 |
| Total operating loss | (5,926) | (2,863) | (15,612) | (8,250) |
| Other income (expense): | | | | |
| Interest income | 5 | 101 | 64 | 158 |
| Interest expense | (22) | (22) | (65) | (65) |
| Total other income | (17) | 79 | (1) | 93 |
| Net loss | $ (5,943) | $ (2,784) | $ (15,613) | $ (8,157) |
| Preferred stock dividends | (12) | (35) | (72) | (198) |
| Warrant modification | | | | (6,622) |
| Net loss applicable to common stock | $ (5,955) | $ (2,819) | $ (15,685) | $ (14,977) |
| Basic and diluted net loss per share | $ (0.10) | $ (0.05) | $ (0.28) | $ (0.27) |
| Shares used in computing basic and diluted net loss per share | 57,047 | 56,631 | 57,013 | 55,494 |

**Condensed Consolidated Balance Sheet Data**

| | September 30, 2020 | December 31, 2019 |
|---|---|---|
| | (in thousands) | |
| Cash and cash equivalents | $ 32,556 | $ 47,480 |
| Total assets | 34,049 | 48,467 |
| Total current liabilities | 2,488 | 2,820 |
| Total liabilities | 2,507 | 2,872 |
| Total redeemable, convertible preferred stock | 1,723 | 1,723 |
| Total stockholders' equity | $ 29,819 | $ 43,872 |