UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

☒ **Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the quarterly period ended September 30, 2021

☐ **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the transition period from_____ to _____

Commission File No. 001-31791

GALECTIN THERAPEUTICS INC.

Nevada **(State or other jurisdiction of incorporation)**	**04-3562325** **(I.R.S. Employer Identification No.)**
4960 Peachtree Industrial Blvd., **Suite 240, Norcross, GA** **(Address of Principal Executive Offices)**	**30071** **(Zip Code)**

(678) 620 -3186
(Registrant's Telephone Number, Including Area Code)

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	**GALT**	**The Nasdaq Stock Market LLC**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). ☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company", and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer	☐	Accelerated Filer	☐
Non-Accelerated Filer	☒	Smaller reporting company	☒
Emerging growth company	☐		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes ☒ No

The number of shares outstanding of the registrant's common stock as of November 5, 2021 was 59,341,305.

GALECTIN THERAPEUTICS INC.
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FOR THE QUARTER ENDED SEPTEMBER 30, 2021

GALECTIN THERAPEUTICS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

	September 30, 2021	December 31, 2020
	(in thousands)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 36,600	$ 27,142
Prepaid expenses and other current assets	1,398	2,323
Total current assets	37,998	29,465
Other assets	40	135
Total assets	$ 38,038	$ 29,600
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,917	$ 1,292
Accrued expenses and other	6,382	4,042
Accrued dividends payable	—	65
Total current liabilities	8,299	5,399
Convertible notes payable and accrued interest, net of debt discounts – related party (Note 4)	19,299	—
Derivative liabilities (Note 4)	1,191	—
Other liabilities	—	8
Total liabilities	28,789	5,407
Commitments and contingencies (Note 10)		
Series C super dividend redeemable convertible preferred stock; 1,000 shares authorized, 176 shares issued and outstanding at September 30, 2021 and December 31, 2020, redemption value: $8,414,000, liquidation value: $1,760,000 at September 30, 2021	1,723	1,723
Stockholders' equity:		
Undesignated stock, $0.01 par value; 20,000,000 shares authorized, 20,000,000 designated at September 30, 2021 and December 31, 2020, respectively	—	—
Series A 12% convertible preferred stock; 1,742,500 shares authorized, 1,302,500 issued and outstanding at September 30, 2021 and December 31, 2020, liquidation value $1,302,500 at September 30, 2021	527	527
Common stock, $0.001 par value; 100,000,000 shares authorized at September 30, 2021 and December 31, 2020, 59,341,305 and 57,077,055 issued and outstanding at September 30, 2021 and December 31, 2020, respectively	59	56
Additional paid-in capital	270,347	261,883
Retained deficit	(263,407)	(239,996)
Total stockholders' equity	7,526	22,470
Total liabilities, redeemable convertible preferred stock and stockholders' equity	$ 38,038	$ 29,600

See notes to unaudited condensed consolidated financial statements.

GALECTIN THERAPEUTICS INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(in thousands, except per share data)		(in thousands, except per share data)	
Operating expenses:				
Research and development	$ 6,613	$ 4,780	$ 17,962	$ 11,605
General and administrative	1,631	1,146	4,792	4,007
Total operating expenses	8,244	5,926	22,754	15,612
Total operating loss	(8,244)	(5,926)	(22,754)	(15,612)
Other income (expense):				
Interest income	1	5	3	64
Interest expense	(111)	(22)	(217)	(65)
Change in fair value of derivative	(166)	—	(338)	—
Total other income (expense)	(276)	(17)	(552)	(1)
Net loss	$ (8,520)	$ (5,943)	$ (23,306)	$ (15,613)
Preferred stock dividends	(37)	(12)	(104)	(72)
Net loss applicable to common stockholders	$ (8,557)	$ (5,955)	$ (23,410)	$ (15,685)
Net loss per common share — basic and diluted	$ (0.14)	$ (0.10)	$ (0.40)	$ (0.28)
Weighted average common shares outstanding — basic and diluted	59,290	57,047	58,253	57,013

See notes to unaudited condensed consolidated financial statements.

GALECTIN THERAPEUTICS INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

	Nine Months Ended September 30,	
	2021	2020
	(in thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (23,306)	$ (15,613)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Stock-based compensation expense	1,422	1,232
Amortization of right to use lease asset	30	27
Non-cash interest expense	217	64
Change in fair value of derivative	338	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	925	(598)
Accounts payable, accrued expenses and other liabilities	3,017	(299)
Net cash flows from operating activities	(17,357)	(15,187)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from convertible notes payable – related party	20,000	—
Net proceeds from issuance of common stock	6,815	263
Net cash flows from financing activities	26,815	263
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	9,458	(14,924)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	27,142	47,480
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 36,600	$ 32,556
NONCASH FINANCING ACTIVITIES:		
Payment of preferred stock dividends in common stock	$ 104	$ 137
Fair value of derivatives related to related party convertible notes payable	853	—
Reclassification of accrued bonus to additional paid in capital	60	—

See notes to unaudited condensed consolidated financial statements.

GALECTIN THERAPEUTICS INC.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (UNAUDITED)
(amounts in thousands except share data)

	Series C Super Dividend Redeemable Convertible Preferred Stock	
	Number of Shares	Amount
Balance at December 31, 2019	**176**	**$ 1,723**
Balance at September 30, 2020	**176**	**$ 1,723**
Balance at December 31, 2020	**176**	**$ 1,723**
Balance at September 30, 2021	**176**	**$ 1,723**

See notes to unaudited condensed consolidated financial statements.

GALECTIN THERAPEUTICS INC.
CONSOLIDATED STATEMENTS OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT) — (Continued)
For the Three Months Ended September 30, 2021 and 2020
(amounts in thousands except share data)

	Series A 12% Convertible Preferred Stock		Common Stock				
	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Retained Deficit	Total Stockholders' Equity (Deficit)
Balance at June 30, 2020	**1,327,500**	**$ 537**	**57,043,661**	**$ 56**	**$ 260,820**	**$ (226,124)**	**$ 35,289**
Series A 12% convertible preferred stock dividend			13,025		35	4	39
Series C super dividend redeemable convertible preferred stock dividend			15,816		42	(16)	26
Issuance of common stock for conversion of Series A 12% Convertible Preferred Stock	(25,000)	(10)	4,553		11	(1)	
Stock-based compensation expense					408		408
Net loss						(5,943)	(5,943)
Balance at September 30, 2020	**1,302,500**	**$ 527**	**57,077,055**	**$ 56**	**$ 261,316**	**$ (232,080)**	**$ 29,819**
Balance at June 30, 2021	**1,302,500**	**$ 527**	**59,275,031**	**$ 59**	**$ 269,657**	**$ (254,850)**	**$ 15,393**
Series A 12% convertible preferred stock dividend			13,025		50	(11)	39
Series C super dividend redeemable convertible preferred stock dividend			13,512		53	(26)	27
Issuance of common stock from exercise of warrants and options			39,737				
Stock-based compensation expense					587		587
Net loss						(8,520)	(8,520)
Balance at September 30, 2021	**1,302,500**	**$ 527**	**59,341,305**	**$ 59**	**$ 270,347**	**$ (263,407)**	**$ 7,526**

GALECTIN THERAPEUTICS INC.
CONSOLIDATED STATEMENTS OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT) — (Continued)
For the Nine Months Ended September 30, 2021 and 2020
(amounts in thousands except share data)

	Series A 12% Convertible Preferred Stock		Common Stock				
	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Retained Deficit	Total Stockholders' Equity (Deficit)
Balance at December 31, 2019	**1,327,500**	**$ 537**	**56,894,642**	**$ 56**	**$ 259,673**	**$ (216,394)**	**$ 43,872**
Series A 12% convertible preferred stock dividend			26,300		61	(22)	39
Series C super dividend redeemable convertible preferred stock dividend			33,416		76	(50)	26
Issuance of common stock for conversion of Series A 12% Convertible Preferred Stock	(25,000)	(10)	4,553		11	(1)	
Issuance of common stock			14,452		44		44
Issuance of common stock for exercise of warrants and options			84,624		219		219
Stock-based compensation expense			19,068		1,232		1,232
Net loss						(15,613)	(15,613)
Balance at September 30, 2020	**1,302,500**	**$ 527**	**57,077,055**	**$ 56**	**$ 261,316**	**$ (232,080)**	**$ 29,819**
Balance at December 31, 2020	**1,302,500**	**$ 527**	**57,077,055**	**$ 56**	**$ 261,883**	**$ (239,996)**	**$ 22,470**
Series A 12% convertible preferred stock dividend			26,050		78	(40)	38
Series C super dividend redeemable convertible preferred stock dividend			31,112		92	(65)	27
Issuance of common stock			845,214	1	3,863		3,864
Issuance of common stock for exercise of warrants and options			1,329,181	2	2,949		2,951
Stock-based compensation expense			32,693		1,482		1,482
Net loss						(23,306)	(23,306)
Balance at September 30, 2021	**1,302,500**	**$ 527**	**59,341,305**	**$ 59**	**$ 270,347**	**$ (263,407)**	**$ 7,526**

See notes to consolidated financial statements.

GALECTIN THERAPEUTICS INC.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Basis of Presentation

Galectin Therapeutics Inc. and subsidiaries (the "Company") is a clinical stage biopharmaceutical company that is applying its leadership in galectin science and drug development to create new therapies for fibrotic disease and cancer. These candidates are based on the Company's targeting of galectin proteins which are key mediators of biologic and pathologic function. These compounds also may have application for drugs to treat other diseases and chronic health conditions.

The unaudited condensed consolidated financial statements as reported in this Quarterly Report on Form 10-Q reflect all adjustments which are, in the opinion of management, necessary to present fairly the financial position of the Company as of September 30, 2021 and the results of its operations for the three and nine months ended September 30, 2021 and 2020 and its cash flows for the three and nine months ended September 30, 2021 and 2020. All adjustments made to the interim financial statements include all those of a normal and recurring nature. Amounts presented in the condensed consolidated balance sheet as of December 31, 2020 are derived from the Company's audited consolidated financial statements as of that date, but do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete financial statements. The Company considers events or transactions that occur after the balance sheet date but before the financial statements are issued to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. Subsequent events have been evaluated through the date these financial statements are available to be issued. The results for interim periods are not necessarily indicative of results that may be expected for any other interim period or for the full year. The unaudited condensed consolidated financial statements of the Company should be read in conjunction with its Annual Report on Form 10-K for the year ended December 31, 2020.

The Company has operated at a loss since its inception and has had no revenues. The Company anticipates that losses will continue for the foreseeable future. At September 30, 2021, the Company had $36,600,000 of unrestricted cash and cash equivalents available to fund future operations. The Company believes there is sufficient cash, including a $10,000,000 convertible note payable that will close in December 2021 (see Note 4), to fund currently planned operations at least through March 31, 2023. We will require more cash to fund our operations after March 31, 2023 and believe we will be able to obtain additional financing. The currently planned operations include costs related to our adaptively designed NAVIGATE Phase 2b/3 clinical trial. Currently, we expect to require an additional approximately $30-$35 million to cover costs of the trial to reach the planned interim analysis estimated to occur around the end of the first quarter of 2024 along with drug manufacturing and other scientific support activities and general and administrative costs. However, there can be no assurance that we will be successful in obtaining such new financing or, if available, that such financing will be on terms favorable to us. If we are unsuccessful in raising additional capital to fund operations before March 31, 2023, we may be required to cease operations. Accordingly, based on the forecasts and estimates underlying our current operating plan, the financial statements do not currently include any adjustments that might be necessary if we are unable to continue as a going concern.

The Company was founded in July 2000, was incorporated in the State of Nevada in January 2001 under the name "Pro-Pharmaceuticals, Inc.," and changed its name to "Galectin Therapeutics Inc." on May 26, 2011.

2. Accrued Expenses and Other

Accrued expenses consist of the following:

	September 30, 2021	December 31, 2020
	(in thousands)	
Legal and accounting fees	$ 127	$ 122
Accrued compensation	520	789
Lease liability	19	44
Accrued research and development costs and other	5,716	3,087
Total	$ 6,382	$ 4,042

Research and development expenses, including personnel costs, allocated facility costs, lab supplies, outside services, contract laboratory costs related to manufacturing drug product, clinical trials and preclinical studies are charged to research and development expense as incurred. The Company accounts for nonrefundable advance payments for goods and services that will be used in future research and development activities as expense when the service has been performed or when the goods have been received. Our current NAVIGATE clinical trial is being supported by third-party contract research organizations, or CROs, and other vendors. We accrue expenses for clinical trial activities performed by CROs based upon the estimated amount of work completed on each trial. For clinical trial expenses and related expenses associated with the conduct of clinical trials, the significant factors used in estimating accruals include the number of patients enrolled, the number of active clinical sites, and the duration for which the patients have been enrolled in the trial. We monitor patient enrollment levels and related activities to the extent possible through internal reviews, review of contractual terms and correspondence with CROs. We base our estimates on the best information available at the time. We monitor patient enrollment levels and related activities to the extent possible through discussions with CRO personnel and based our estimates of clinical trial costs on the best information available at the time. However, additional information may become available to us which will allow us to make a more accurate estimate in future periods. In that event, we may be required to record adjustments to research and development expenses in future periods when the actual level of activity becomes more certain.

3. Line of Credit – Related Party

The Company has a $10 million Line of Credit arrangement with Richard E. Uihlein, Chairman of Board of Directors and a shareholder pursuant to an agreement established in December, 2017 and amended in December, 2018 and January, 2019. Under the arrangement the Company may borrow up to $10 million from Mr. Uihlein on an unsecured basis and with any borrowings bearing interest at the Applicable Federal Rate for short terms loans published by the Internal Revenue Service (0.17% in September 2021). Borrowings may be made through December 31, 2021 with repayment due on December 31, 2022. In connection with the Line of Credit agreement, the Company issued to Mr. Uihlein warrants to purchase 1 million shares of the Company's common stock for $5 per share. Half of the warrants vested at closing of the Line of Credit and the other half vest ratably with borrowings under the agreement. The 500,000 warrants that vested at closing were exercised in May 2019 for cash proceeds to the Company of $2.5 million. As of the date of this Quarterly Report, there have been no borrowings under the Line of Credit.

The fair value of the 500,000 warrants vested at closing in December 2017 was $696,000 at the date of issuance based on the following assumptions: an expected life of 7 years, volatility of 98%, risk free interest rate of 2.05% and zero dividends. The fair value of the vested warrants was recorded in other current assets and other assets (non-current) as a deferred financing cost and were to be amortized on a straight-line basis from December 19, 2017 through December 31, 2019. The remaining unamortized balance of the deferred financing cost on January 11, 2019 was adjusted to be recorded as expense on a straight-line basis through December 31, 2022. Amortization for the nine months ended September 30, 2021 and 2020 of $65,000 and $65,000, respectively, was recorded as interest expense. The fair value of warrants that vest in the future based on borrowings will be computed when those borrowings occur and amortized over the remaining period through December 31, 2022 reflecting the second extension.

4. Convertible Notes Payable – Related Party

On April 16, 2021, the Company and Richard E. Uihlein entered into a debt financing arrangement whereby Mr. Uihlein loaned $10,000,000 to Company. In consideration for the loan, the Company issued a convertible promissory note (the "April Note") in the principal amount of ten million dollars.

The April Note has a maturity date of April 16, 2025, is prepayable at the option of the Company in whole or in part at any time and is convertible into the Company's common stock at a conversion price equal to $5.00 per share at the option of the noteholder. The April Note bears interest at the rate of two percent (2%) per annum, compounded annually. From April 16, 2021 through September 30, 2021, approximately $92,000 of interest expense was accrued and included with the principal in the financial statements.

The April Note also includes a contingent interest component that requires the Company to pay additional interest at a rate of two and one-half percent (2.5%) per quarter (10% per annum) (the "Additional Interest") beginning on the date of issuance of this Note and ending on the maturity date, provided however, that such payment is only required if and only if the noteholder elects to convert the entire balance of the April Note into the Company's common stock on or prior to maturity. As the contingent event is not based on creditworthiness, such feature is not clearly and closely related to the host instrument and accordingly must be bifurcated and recognized as a derivative liability and a debt discount on the April Note at its inception. The fair value of the contingent interest derivative liability was $420,000 and $776,000 at note inception (April 16, 2021) and September 30, 2021, respectively, and is recognized as a derivative liability in the consolidated balance sheet. The change in the fair value of the derivative liability from April 16, 2021 to September 30, 2021 of $356,000 was charged to other expense for the period ended September 30, 2021. The amortization of the debt discount of $420,000 recorded initially upon note inception of $48,000 was recorded as additional interest expense from April 16, 2021 through September 30, 2021.

On September 17, 2021, the Company and Mr. Uihlein entered into a loan agreement in the aggregate of $20,000,000 (the "Loan Agreement") to be funded in two closings and evidenced by two separate unsecured convertible promissory notes. The first of the two promissory notes was also executed and delivered on September 17, 2021, (the "September Note") to evidence the first loan in the principal amount of $10,000,000. The second closing under the Loan Agreement for the remaining $10,000,000 will occur on or before December 17, 2021.

The September Note has a maturity date of September 17, 2025, is prepayable at the option of the Company in whole or in part at any time and is convertible into the Company's common stock at a conversion price equal to $8.64 per share at the option of the noteholder. The September Note bears interest at the rate of two percent (2%) per annum, compounded annually. From September 17, 2021 through September 30, 2021, approximately $7,000 of interest expense was accrued and included with the principal in the financial statements.

The September Note also includes a contingent interest component that requires the Company to pay additional interest at a rate of two and one-half percent (2.5%) per quarter (10% per annum) (the "Additional Interest") beginning on the date of issuance of this Note and ending on the maturity date, provided however, that such payment is only required if and only if the noteholder elects to convert the entire balance of the September Note into the Company's common stock on or prior to maturity. As the contingent event is not based on creditworthiness, such feature is not clearly and closely related to the host instrument and accordingly must be bifurcated and recognized as a derivative liability and a debt discount on the September Note at its inception. The fair value of the contingent interest derivative liability was $433,000 and $415,000 at note inception (September 17, 2021) and September 30, 2021, respectively, and is recognized as a derivative liability in the consolidated balance sheet. The change in the fair value of the derivative liability from September 17, 2021 to September 30, 2021 of ($18,000) was recorded to other expense for the three month period ended September 30, 2021. The amortization of the debt discount of $433,000 recorded initially upon note inception of $5,000 was recorded as additional interest expense for the for the three month period ended September 30, 2021.

Under the terms of the Loan Agreement, the Line of Credit for $10 million between the Company and Mr. Uihlein, (See Note 3) will be terminated upon closing of the second $10 million unsecured convertible loan in December 2021. Currently there are no borrowings under the Line of Credit.

The Company's contractual cash obligations related to the outstanding convertible notes payable is a repayment of the April Note of the $10,000,000 plus accrued interest on April 16, 2025 and a repayment of the September Note of the $10,000,000 plus accrued interest on September 17, 2025, unless converted at the option of the noteholder.

5. Stock-Based Compensation

Following is the stock-based compensation expense related to common stock options, restricted common stock, common stock warrants and deferred stock units:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	in thousands			
Research and development	$ 91	$ 138	$ 247	$ 378
General and administrative	496	270	1,175	854
Total stock-based compensation expense	$ 587	$ 408	$ 1,422	$ 1,232

The following table summarizes the stock option activity in the Company's equity incentive plans, including non-plan grants to Company executives, from December 31, 2020 through September 30, 2021:

	Shares	Weighted Average Exercise Price
Outstanding, December 31, 2020	3,987,575	$ 4.29
Granted	2,260,000	2.31
Exercised	(396,664)	2.35
Options forfeited/cancelled	(1,190,350)	5.18
Outstanding, September 30, 2021	4,660,561	$ 3.27

As of September 30, 2021, there was $3,346,200 of unrecognized compensation related to 2,401,668 unvested options, which is expected to be recognized over a weighted–average period of approximately 2 years. The weighted-average grant date fair value for options granted during the nine months ended September 30, 2021 was $1.71. The Company granted 2,260,000 stock options during the nine months ended September 30, 2021. During the nine months ended September 30, 2021, 396,664 stock options were exercised on a net basis resulting in the issuance of 148,938 shares of common stock.

The fair value of all other options granted is determined using the Black-Scholes option-pricing model. The following weighted average assumptions were used:

	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Risk-free interest rate	0.58%	1.26%
Expected life of the options	6 years	6 years
Expected volatility of the underlying stock	91%	98%
Expected dividend rate	0%	0%

In January 2020, two directors elected to take restricted stock grants in lieu of cash retainers for 2020. A total of 32,693 shares of restricted stock valued at approximately $93,500 was amortized to expense on a straight-line basis until January 9, 2021 when the stock vested in full.

In March 2021, one director elected to take a restricted stock grant in lieu of cash retainers for 2021. A total of 16,588 shares of restricted stock valued at approximately $35,000 is being amortized to expense on a straight-line basis until December 31, 2021 when the stock vests in full.

In September 2020, the Company entered into an employment agreement with its new Chief Executive Officer whereby 20% of his base salary and performance bonuses will be paid in cash, and 80% will be paid in the form of deferred stock units ("DSUs") in accordance with the terms and subject to the provisions set forth in the DSU Agreement. DSUs credited to Mr. Lewis as of any date shall be fully vested and nonforfeitable at all times. The Company shall issue the shares underlying the outstanding whole number of DSUs credited to Mr. Lewis as follows: twenty five percent shall be issued on March 1, 2023, twenty five percent shall be issued on September 1, 2023 and fifty percent shall be issued on March 1, 2024. For the nine months ended September 30, 2021, $300,000 of his compensation was recorded as stock compensation expense representing 104,378 shares of common stock to be issued under the DSU agreement with a weighted average grant date fair value of $2.87 per share. Also, Mr. Lewis' bonus for the year ended December 31, 2020 of $60,000 (which was included in accrued compensation at December 31, 2020) was approved in March 2021 and represents 27,027 shares of common stock to be issued under the DSU agreement with a grant date fair value of $2.22 per share. The $60,000 was reclassified from accrued compensation to additional paid in capital in March 2021. There is no unrecognized compensation expense related to the DSUs.

6. Common Stock Warrants

The following table summarizes the common stock warrant activity from December 31, 2020 through September 30, 2021:

	Shares	Weighted Average Exercise Price
Outstanding, December 31, 2020	12,538,204	$ 4.22
Granted	—	—
Exercised	(1,180,240)	2.50
Forfeited/cancelled	—	—
Outstanding, September 30, 2021	11,357,964	$ 4.40

The weighted average expiration of the warrants outstanding as of September 30, 2021 is 3.0 years.

7. Fair Value of Financial Instruments

The Company has certain financial assets and liabilities recorded at fair value. Fair values determined by Level 1 inputs utilize observable data such as quoted prices in active markets. Fair values determined by Level 2 inputs utilize data points other than quoted prices in active markets that are observable either directly or indirectly. Fair values determined by Level 3 inputs utilize unobservable data points in which there is little or no market data, which require the reporting entity to develop its own assumptions. The carrying amounts reflected in the consolidated balance sheets for cash equivalents, accounts payable and accrued expenses approximate their carrying value due to their short-term nature. There were no level 2 or level 3 assets or liabilities at December 31, 2020.

Assets and liabilities measured and recorded at fair value on a recurring basis at the end of September 30, 2021 were as follows:

	Level 1	Level 2	Level 3	Total
Derivative Liability – Contingent Interest April Note	$ —	$ —	$ 776,000	$ 776,000
Derivative Liability – Contingent Interest September Note	$ —	$ —	$ 415,000	$ 415,000

The April Note derivative liability – contingent interest was valued using a Monte Carlo Geometric Brownian Stock Path Model. The key assumptions used in the model at inception, and at September 30, 2021 are as follows:

	Inception	September 30, 2021
Stock Price	$ 2.19	$ 3.88
Conversion Price of conversion feature	$ 5.00	$ 5.00
Term	4 years	3.54 years
Risk Free Interest Rate	0.59%	0.76%
Credit Adjusted Discount Rate	7.60%	7.95%
Volatility	88%	85%
Dividend Rate	0%	0%

The roll forward of the April Note derivative liability – contingent interest is as follows:

Balance – December 31, 2020	$ —
Issuance of April convertible note payable – related party	420,000
Fair Value Adjustment	356,000
Balance – September 30, 2021	$ 776,000

The September Note derivative liability – contingent interest was valued using a Monte Carlo Geometric Brownian Stock Path Model. The key assumptions used in the model at inception, and at September 30, 2021 are as follows:

	Inception	September 30, 2021
Stock Price	$ 4.06	$ 3.88
Conversion Price of conversion feature	$ 8.64	$ 8.64
Term	4 years	3.97 years
Risk Free Interest Rate	0.68%	0.76%
Credit Adjusted Discount Rate	7.59%	7.94%
Volatility	91%	91%
Dividend Rate	0%	0%

The roll forward of the September Note derivative liability – contingent interest is as follows:

Balance – December 31, 2020	$ —
Issuance of September convertible note payable – related party	433,000
Fair Value Adjustment	(18,000)
Balance – September 30, 2021	$ 415,000

8. Loss Per Share

Basic net loss per common share is computed by dividing the net loss available to common stockholders by the weighted average number of common shares outstanding during the period. Diluted net loss per common share is computed by dividing the net loss available to common stockholders by the weighted average number of common shares and other potential common shares then outstanding. Potential common shares consist of common shares issuable upon the assumed exercise of in-the-money stock options and warrants and potential common shares related to the conversion of the preferred stock. The computation of diluted net loss per share does not assume the issuance of common shares that have an anti-dilutive effect on net loss per share.

Dilutive shares which could exist pursuant to the exercise of outstanding stock instruments and which were not included in the calculation because their affect would have been anti-dilutive are as follows:

	September 30, 2021 (shares)	September 30, 2020 (shares)
Warrants to purchase shares of common stock	11,357,964	12,538,204
Options to purchase shares of common stock	4,660,561	3,987,575
Shares of common stock issuable upon conversion of convertible notes payable	3,271,876	—
Shares of common stock issuable upon conversion of preferred stock	510,424	510,424
	19,800,825	17,036,203

9. Common Stock

2020 At Market Issuance of Common Stock

On May 11, 2020, the Company entered into an At Market Issuance Sales Agreement (the "2020 At Market Agreement") with a sales agent under which the Company may issue and sell shares of its common stock having an aggregate offering price of up to $40.0 million from time to time through the sales agent. Sales of the Company's common stock through the sales agent, if any, will be made by any method that is deemed an "at the market" offering as defined by the U.S. Securities and Exchange Commission. The Company will pay to the sales agent a commission rate equal to 3.0% of the gross proceeds from the sale of any shares of common stock sold through the sales agent under the 2020 At Market Agreement. During the nine months ended September 30, 2021, the Company issued 845,214 shares of common stock under the 2020 At Market Agreement for net proceeds of $3,864,000.

For the nine months ended September 30, 2021 and 2020, the Company issued a total of 57,162 and 59,716 shares of common stock, respectively, for dividends on Series A and Series C Preferred Stock.

10. Commitments and Contingencies

Other Legal Proceedings

The Company records accruals for such contingencies to the extent that the Company concludes that their occurrence is probable, and the related damages are estimable. There are no significant pending legal proceedings.

Clinical Trial and Research Commitments

The Company has entered into agreements with contractors for research and development activities to further its product candidates. The contracts generally may be canceled at any time by providing thirty days' notice.

11. Leases

The Company has one operating lease for its office space which was amended effective January 1, 2019 for a term of 38 months with no residual value guarantees or material restrictive covenants. The amended lease provided for free rent for the first two months of the lease and continues the security deposit of $6,000. In addition to base rental payments included in the contractual obligations table above, the Company is responsible for our pro-rata share of the operating expenses for the building. Our lease cost for the nine-month periods ended September 30, 2021 and 2020 was $33,000 for each period and is included in general and administrative expenses. As of September 30, 2021, the right to use lease asset consisted of $18,000 and is included in other assets. Also, as of September 30, 2021, current lease liability of $19,000 is included in accrued expenses.

Maturity of operating lease as of September 30, 2021 in thousands:

2021	12
2022	8
Total	20
Less imputed interest	(1)
Present value of lease liability	$ 19

The discount rate used in calculating the present value of the lease payments was 11.04%

12. Galectin Sciences LLC

In January 2014, we created Galectin Sciences, LLC (the “LLC” or “Investee”), a collaborative joint venture co-owned by SBH Sciences, Inc. (“SBH”), to research and develop small organic molecule inhibitors of galectin-3 for oral administration. The LLC was initially capitalized with a $400,000 cash investment to fund future research and development activities, which was provided by the Company, and specific in-process research and development (“IPR&D”) contributed by SBH. The estimated fair value of the IPR&D contributed by SBH, on the date of contribution, was $400,000. Initially, the Company and SBH each had a 50% equity ownership interest in the LLC, with neither party having control over the LLC. Accordingly, from inception through the fourth quarter of 2014, the Company accounted for its investment in the LLC using the equity method of accounting. Under the equity method of accounting, the Company’s investment was initially recorded at cost with subsequent adjustments to the carrying value to recognize additional investments in or distributions from the Investee, as well as the Company’s share of the Investee’s earnings, losses and/or changes in capital. The estimated fair value of the IPR&D contributed to the LLC was immediately expensed upon contribution as there was no alternative future use available at the point of contribution. The operating agreement provides that if either party does not desire to contribute its equal share of funding required after the initial capitalization, then the other party, providing all of the funding, will have its ownership share increased in proportion to the total amount contributed from inception. In the fourth quarter of 2014, after the LLC had expended the $400,000 in cash, SBH decided not to contribute its share of the funding required. Since then, the Company has contributed a total of $2,585,000, including $56,000 for the three months ended September 30, 2021, for expenses of the LLC. Since the end of 2014, SBH has contributed $158,000 for expenses in the LLC. As of September 30, 2021, the Company’s ownership percentage in the LLC was 84.2%. The Company accounts for the interest in the LLC as a consolidated, less than wholly owned subsidiary. Because the LLC’s equity is immaterial, the value of the non-controlling interest is also deemed to be immaterial.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

In addition to historical information, the following Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements as defined under Section 21E of the Securities Exchange Act of 1934, as amended, and is subject to the safe harbor created therein for forward-looking statements. Such statements include, but are not limited to, statements concerning our anticipated operating results, research and development, clinical trials, regulatory proceedings, and financial resources, and can be identified by use of words such as, for example, "anticipate," "estimate," "expect," "project," "intend," "plan," "believe" and "would," "should," "could" or "may." All statements, other than statements of historical facts, included herein that address activities, events, or developments that the Company expects or anticipates will or may occur in the future, are forward-looking statements, including statements regarding: plans and expectations regarding clinical trials; plans and expectations regarding regulatory approvals; our strategy and expectations for clinical development and commercialization of our products; potential strategic partnerships; expectations regarding the effectiveness of our products; plans for research and development and related costs; statements about accounting assumptions and estimates; expectations regarding liquidity and the sufficiency of cash to fund currently planned operations through at least September 30, 2022; our commitments and contingencies; and our market risk exposure. Forward-looking statements are based on current expectations, estimates and projections about the industry and markets in which Galectin Therapeutics operates, and management's beliefs and assumptions. These statements are not guarantees of future performance and involve certain known and unknown risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Such risks and uncertainties are related to and include, without limitation,

- our early stage of development,
- we have incurred significant operating losses since our inception and cannot assure you that we will generate revenue or profit,
- our dependence on additional outside capital,
- we may be unable to enter into strategic partnerships for the development, commercialization, manufacturing and distribution of our proposed product candidates,
- uncertainties related to any litigation, including shareholder class actions and derivative lawsuits filed,
- uncertainties related to our technology and clinical trials, including expected dates of availability of clinical data,
- we may be unable to demonstrate the efficacy and safety of our developmental product candidates in human trials,
- we may be unable to improve upon, protect and/or enforce our intellectual property,
- we are subject to extensive and costly regulation by the U.S. Food and Drug Administration (FDA) and by foreign regulatory authorities, which must approve our product candidates in development and could restrict the sales and marketing and pricing of such products,
- competition and stock price volatility in the biotechnology industry,
- limited trading volume for our stock, concentration of ownership of our stock, and other risks detailed herein and from time to time in our SEC reports,
- the impact resulting from the outbreak of COVID-19, which has delayed and may continue to delay our clinical trial and development efforts, as well as the impact that COVID-19 has on the volatility of the capital market and our ability to access the capital market and,
- other risks detailed herein and from time to time in our SEC reports, including our Annual Report on Form 10-K filed with the SEC for the fiscal year ended December 31, 2020, and our subsequent SEC filings.

The following discussion should be read in conjunction with the accompanying consolidated financial statements and notes thereto of Galectin Therapeutics appearing elsewhere herein. Furthermore, in this Quarterly Report on Form 10-Q, we refer to other sources of information, such as the information posted on our website or peer reviewed publications. The information from these sources are not incorporated by reference to this Quarterly Report on Form 10-Q.

Overview

We are a clinical stage biopharmaceutical company engaged in drug research and development to create new therapies for fibrotic disease, cancer and selected other diseases. Our drug candidates are based on our method of targeting galectin proteins, which are key mediators of biologic and pathologic functions. We use naturally occurring, readily-available plant products as starting material in manufacturing processes to create proprietary, patented complex carbohydrates with specific molecular weights and other pharmaceutical properties. These complex carbohydrate molecules are appropriately formulated into acceptable pharmaceutical formulations. Using these unique carbohydrate-based candidate compounds that largely bind and inhibit galectin proteins, particularly galectin-3, we are undertaking the focused pursuit of therapies for indications where galectin proteins have a demonstrated role in the pathogenesis of a given disease. We focus on diseases with serious, life-threatening consequences and those where current treatment options, are limited specifically in NASH (non-alcoholic steatohepatitis) with cirrhosis and certain cancer indications. Our strategy is to establish and implement clinical development programs that add value to our business in the shortest period of time possible and to seek strategic partners when one of our programs becomes advanced and requires significant additional resources.

Our lead galectin-3 inhibitor is belapectin (GR-MD-02), which has been demonstrated in preclinical models to reverse liver fibrosis and cirrhosis. Belapectin has the potential to treat many diseases due to galectin-3's involvement in multiple key biological pathways such as fibrosis, immune cell function and immunity, cell differentiation, cell growth, and apoptosis (cell death). The importance of galectin-3 in the fibrotic process is supported by experimental evidence. Animals with the gene responsible for galectin-3 "knocked-out" can no longer develop fibrosis in response to experimental stimuli compared to animals with an intact galectin-3 gene. We are using our galectin-3 inhibitor to treat advanced liver fibrosis and liver cirrhosis in NASH patients. We have completed two Phase 1 clinical studies, a Phase 2 clinical study in NASH patients with advanced fibrosis (NASH-FX) and a second Phase 2b clinical trial in NASH patients with well compensated cirrhosis (NASH-CX) meaning the liver is scarred but still able to perform most of its basic functions.

We are now engaged in a Phase 2b/3 clinical trial. Our study protocol was filed with the FDA on April 30, 2020 for a seamless adaptively-designed Phase 2b/3 clinical study, the NAVIGATE trial (formerly called NASH-RX), evaluating the safety and efficacy of its galectin-3 inhibitor, belapectin (GR-MD-02), for the prevention of esophageal varices in patients with non-alcoholic steatohepatitis (NASH) cirrhosis (Further details are available at www.clinicaltrials.gov under study NCT04365868); this study began enrolling patients in Q2-2020. In September 2020, the Company received a letter from the FDA providing comments, asking questions and providing guidance on various aspects of the ongoing NAVIGATE trial.

Additionally, a study protocol entitled "A Single-dose, Open-label, Pharmacokinetic Study of Belapectin (GR-MD-02) in Subjects With Normal Hepatic Function and Subjects With Varying Degrees of Hepatic Impairment" has been filed with the FDA to examine the effects of the drug in subjects with normal hepatic function and subjects with varying degrees of hepatic impairment (study details are listed under study NCT04332432 on www.clinicaltrials.gov); this study is enrolling patients.

We endeavor to leverage our scientific and product development expertise as well as established relationships with outside sources to achieve cost-effective and efficient drug development. These outside sources, amongst others, provide us with expertise in preclinical models, pharmaceutical development, toxicology, clinical trial operations, pharmaceutical manufacturing, sophisticated physical and chemical characterization, and commercial development. We also have established through our majority-owned joint venture subsidiary, Galectin Sciences LLC, a discovery program aimed at the targeted development of small molecules (generally, non-carbohydrate) that bind galectin proteins and may afford options for alternative means of drug delivery (e.g., oral) and as a result expand the potential uses of our galectin-3 inhibitor compounds. Three series of composition of matter patents covering discoveries at Galectin Sciences have been filed.

We are also pursuing a development pathway to clinical enhancement and commercialization for our lead compounds in immuno-oncology for cancer therapy in collaboration with Providence Portland Cancer Center. However, our clinical development efforts are primarily focused on liver fibrosis and NASH. All of our proposed products are presently in development, including pre-clinical and clinical trials.

Our Drug Development Programs

Galectins are a class of proteins that are made by many cells in the body, but predominantly in cells of the immune system. As a group, these proteins are able to bind to sugar molecules that are part of other proteins, glycoproteins, in and on the cells of our body. Galectin proteins act as a kind of molecular glue, bringing together molecules that have sugars on them. Galectin proteins, in particular galectin-3, are known to be markedly increased in a number of important diseases including inflammatory diseases, scarring of organs (e.g. liver, lung, kidney, and heart) and cancers of many kinds. The increase in galectin protein promotes the disease and is detrimental to the patient. Published data substantiating the importance of galectin-3 in the fibrotic process arises from gene knockout experiments in animal studies. Mice genetically altered to eliminate the galectin-3 gene, and thus unable to produce galectin-3, are incapable of developing liver fibrosis in response to toxic insult to the liver and in fatty liver disease as well as development of fibrosis in other tissues.

We have one new proprietary chemical entity (NCE) in development, belapectin, which has shown promise in preclinical and early clinical studies in treatment of fibrosis, severe skin disease, and in cancer therapy. Currently we are focusing on development of belapectin intended to be used in the treatment of liver fibrosis associated with fatty liver disease (NASH) and more specifically in NASH cirrhosis. We have also leveraged our relationships with well-known investigators to demonstrate clinical effects of belapectin in treating moderate to severe plaque psoriasis, severe atopic dermatitis, and in cancer therapy in combination with immune-system modifying agent(s). Belapectin is a proprietary, patented compound derived from natural, readily available, plant-based starting materials, which, following chemical processing, exhibits the properties of binding to and inhibiting galectin-3 proteins. A second NCE, GM-CT-01 is a proprietary, patented compound that is made from a completely different starting source plant material and also binds and inhibits galectin proteins. Previously in clinical development for cancer indications, GM-CT-01 compound has been explored in limited other preclinical studies.

Our product pipeline is shown below:

Indication Fibrosis	Drug	Status
NASH with Advanced Fibrosis: NASH-CX trial and NASH-FX trial	belapectin	IND submitted January 2013. Results from the Phase 1 clinical trial were reported in 2014, with final results reported in January 2015. The Phase 2 NASH FX trial was designed for patients with advanced fibrosis but not cirrhosis. Its principal purpose was to evaluate various imaging modalities. The NASH FX trial top line data was reported in September 2016 The Phase 2 NASH CX trial, was designed for patients with well compensated cirrhosis. The NASH CX trial top line data was reported in December 2017 and was published in *Gastroenterology* in 2020.
NASH NAVIGATE		Based on FDA feedback, the NAVIGATE trial is an adaptive Phase 2b/3 trial for the prevention of esophageal varices in NASH patients with compensated cirrhosis. A Phase 2b interim efficacy analysis will be incorporated to confirm previous Phase 2 data, select an optimal dose and reaffirm the risk/benefit of belapectin. The Phase 3 end of study analysis will evaluate the development of esophageal varices as the primary outcome of efficacy and a composite clinical endpoint including progression to varices requiring treatment as a key secondary outcome of efficacy. See www.clinicaltrials.gov NCT04365868. The first patient was randomized in the third quarter of 2020. A hepatic impairment is being conducted in subjects with normal hepatic function and subjects with varying degrees of hepatic impairment (CF: www.clinicaltrials.gov NCT04332432) and began enrolling patients in the second quarter of 2020.
Lung Fibrosis	belapectin	In pre-clinical development
Kidney Fibrosis	belapectin	In pre-clinical development
Indication	**Drug**	**Status**
Cardiac and Vascular Fibrosis	belapectin and GM-CT-01	In pre-clinical development
Cancer Immunotherapy		
Melanoma, Head, Neck Squamous Cell Carcinoma (HNSCC)	belapectin	Investigator IND study in process. A Phase 1B study began in Q-1 2016. Early data was reported in February 2017 and additional data were reported in September 2018. A further expansion cohort of patients with melanoma and HNSCC was reported in July 2021.
Psoriasis		
Moderate to Severe Plaque Psoriasis Severe Atopic Dermatitis	belapectin	IND submitted March 2015. A Phase 2a trial in moderate to severe plaque psoriasis patients began in January 2016. Interim data on the first four patients were positive and were reported in May 2016. Further positive data was reported in September 2016. Investigator initiated IND submitted for treatment of three patients with severe atopic dermatitis, with positive preliminary data presented in February 2017. Further studies are dependent on finding a suitable strategic partner which is unlikely.

Fibrosis. Belapectin is our lead product candidate for treatment of fibrotic disease. Our preclinical data show that belapectin has a significant therapeutic effect on liver fibrosis as shown in several relevant animal models. In addition, in NASH animal models, belapectin has been shown to reduce liver fat, inflammation, and ballooning degeneration (death of liver cells). Therefore, we chose belapectin as the lead candidate in a development program targeted initially at fibrotic liver disease associated with non-alcoholic steatohepatitis (NASH). In January 2013, an Investigational New Drug ("IND") was submitted to the FDA with the goal of initiating a Phase 1 study in patients with NASH and advanced liver fibrosis to evaluate the human safety of belapectin and pharmacodynamics biomarkers of disease. On March 1, 2013, the FDA indicated we could proceed with a US Phase 1 clinical trial for belapectin with a development program aimed at obtaining support for a proposed indication of belapectin for treatment of NASH with advanced fibrosis. The Phase 1 trial was completed and demonstrated that belapectin up to 8 mg/kg Lean Body Mass (LBM), i.v. was safe and well tolerated.

Additionally, an open label drug-drug interaction study was completed in healthy volunteers during the second quarter of 2015 with belapectin and it showed that with 8 mg/kg LBM dose of belapectin and 2 mg/kg LBM dose of midazolam there was no drug-drug interaction and no serious adverse events or drug-related adverse events were observed. The secondary objective was to assess the safety and tolerability of belapectin when administered concomitantly with midazolam.

Our Phase 2 program in fibrotic disease consisted of two separate human clinical trials. The primary clinical trial was the Phase 2b NASH-CX study for one year for patients with NASH with compensated cirrhosis, which began enrolling in June 2015. This study was the primary focus of our program and was a randomized, placebo-controlled, double-blind, parallel-group Phase 2b trial to evaluate the safety and efficacy of belapectin for treatment of liver fibrosis and resultant portal hypertension in NASH patients with compensated cirrhosis. A smaller, exploratory NASH-FX trial was conducted to explore potential use of various non-invasive imaging techniques in NASH patients with advanced fibrosis but not cirrhosis.

NASH-FX Trial: The NASH-FX trial was a Phase 2a pilot trial for patients with NASH and advanced fibrosis that explored use of three non-invasive imaging technologies. It was a short, single site, four-month trial in 30 NASH patients with advanced fibrosis (F3), but not cirrhosis (F4), randomized 1:1 to either 9 bi-weekly doses of 8 mg/kg LBM of belapectin or placebo. The trial did not meet its primary biomarker endpoint as measured using multi-parametric magnetic resonance imaging (LiverMultiScan$^{(R)}$, Perspectum Diagnostics). The trial also did not meet secondary endpoints that measure liver stiffness as a surrogate for fibrosis using, magnetic resonance-elastography and FibroScan® score. We, and many experts in the field, now believe that a four-month treatment period was not sufficient to show efficacy results in established advanced liver fibrosis. This small study was also not adequately powered for the secondary endpoints. In the trial, belapectin was found to be safe and well tolerated with no serious adverse events and evidence of a pharmacodynamic effect. These results provided support for further development in NASH.

NASH-CX Trial: The NASH-CX trial was a larger multi-center clinical trial that explored the use of belapectin for the treatment of liver fibrosis and resultant portal hypertension in patients with well-compensated NASH cirrhosis. Enrollment in this trial was completed in September 2016, and a total of 162 patients at 36 sites in the United States were randomized to receive either 2 mg/kg LBM of belapectin, 8 mg/kg LBM of belapectin or placebo, with 54 patients in each group. Approximately 50% of patients at baseline had esophageal varices (a complication of portal hypertension). The primary endpoint was a reduction in hepatic venous pressure gradient (HVPG). Patients received an infusion of belapectin or placebo every other week for one year, a total of 26 infusions, and were evaluated to determine the change in HVPG as compared with placebo. Secondary or exploratory endpoints included fibrosis on liver biopsy, measurement of liver stiffness (FibroScan$^{(R)}$) and assessment of liver metabolism (^{13}C-methacetin breath test, Exalenz). Top line data readout was reported in December 2017. The study demonstrated a favorable safety profile and clinically meaningful efficacy results in patients without esophageal varices at baseline demonstrated by a prevention of development of varices when compared to placebo.

In the total patient population, the primary endpoint HVPG showed a trend toward benefit with belapectin treatment, but the difference from placebo was not statistically significant. The mean change in HVPG of placebo from baseline to week 54 was 0.3 mm Hg. The mean change in HVPG from baseline was -0.37 and -0.42 for the 2 mg/kg LBM dose and 8 mg/kg LBM dose of belapectin, respectively.

In those NASH cirrhosis patients without varices at baseline (about 50% of the total population), there was a statistically significant effect of the 2 mg/kg LBM dose of belapectin on the absolute change in HVPG (-1.08 mm Hg, $p<0.01$). The effect of the 8 mg/Kg LBM dose of belapectin on absolute or percent change in HVPG from baseline to week 54 was not significant.

Also because of the clinical relevance of this population, a responder analysis was performed on those patients without varices at baseline. Analysis was performed looking at two groups: those with an equal to or greater than 2 mm Hg decrease in HVPG from baseline or those with an equal to or greater than 2 mm Hg and a greater than or equal to 20% decrease in HVPG from baseline. In both cases, the change observed in the belapectin 2 mg/kg LBM group was statistically significant ($p<0.01$) while that of the 8 mg/kg LBM group was not.

Over the 54-week treatment period, in patients without varices there were statistically significantly fewer new varices that developed in the belapectin treatment groups (0% and 4% in the 2 mg/kg LBM and the 8 mg/kg LBM, respectively) vs placebo (18%). As esophageal varices can lead to hemorrhagic complication, which can be fatal, we believe the prevention of esophageal varices may represent a clinically relevant measure of clinical efficacy in patients with NASH cirrhosis.

The major conclusions from the NASH-CX trial results were that: i) belapectin had a statistically significant and clinically meaningful effect in improving HVPG vs placebo in patients with NASH cirrhosis who did not have esophageal varices at baseline. This effect was seen regardless of the patient's baseline portal hypertension. ii) There was an important drug effect of belapectin in the total patient population on liver biopsy with a statistically significant improvement in hepatocyte ballooning (ie cell death), (iii) There was a statistically significant reduction (p=0.02) in the development of new esophageal varices in drug-treated patients compared to placebo. We believe that this is a clinically relevant endpoint related to patient outcomes, (iv) While there was a drug effect in both the 2 mg/kg LBM and 8 mg/kg LBM groups on the development of varices and liver biopsy there was a consistently greater and statistically significant effect of the 2 mg/kg LBM dose of belapectin, (v) belapectin appears to be safe and well tolerated in this one year clinical trial, a feature that is of prime importance for a cirrhotic population and (vi) We believe this is the first large, randomized clinical trial to demonstrate a clinically meaningful improvement in portal hypertension or liver biopsy in patients with compensated NASH cirrhosis who have not yet developed esophageal varices.

Further information and details on the NASH-CX results summarized above is available in public presentations posted to our website and filed with the SEC and in a peer reviewed publication in *Gastroenterology* (Gastroenterology 2020;158:1334–1345).

NASH NAVIGATE Trial: Building on the experience of the NASH-CX trial, the NAVIGATE Trial is a seamless adaptively-designed Phase 2b/3 clinical study evaluating the safety and efficacy of our galectin-3 inhibitor, belapectin (GR-MD-02), for the prevention of esophageal varices in patient with non-alcoholic steatohepatitis (NASH) cirrhosis. The major features of this innovative Phase 2b/3 study design are: i) In patients with NASH cirrhosis and clinical signs of portal hypertension but without esophageal varices at baseline, this trial will assess the effect of belapectin on the incidence of new varices (the primary endpoint) – as well as assessing effect on the incidence of long-term, clinically significant cirrhosis-related outcomes (a key secondary efficacy endpoint), (ii) The study targets NASH patients with a clearly identified unmet medical need: patients with compensated cirrhosis who are at risk of developing esophageal varices, a potentially life-threatening complication of cirrhosis (bleeding varices are a cause of death in about one-third of cirrhotic patients). There is no approved treatment for preventing varices in these patients. In addition, the development of esophageal varices reflects the progression of hepatic cirrhosis and thus portends the development of other cirrhosis complications such as ascites, hepatic encephalopathy, and liver failure, and (iii) During the first 18 months, two belapectin dose levels (2 mg/kg LBM and 4 mg/kg LBM) will be compared to placebo (phase 2b). Then, at the interim analysis (IA), one belapectin dose will be selected based on efficacy and safety, for continued evaluation (Phase 3). The belapectin dose selected for the phase 2b/3 are based on the analysis of the NASH-CX trial, including a dose response pharmacokinetic analysis of the hepatic venous gradient pressure (HVPG, a reflection of portal hypertension). Prior belapectin clinical studies have also indicated the good tolerance and safety profile of belapectin with doses of up to 8 mg/kg LBM for 52 weeks (Phase 2b Study NASH-CX), an important feature of the future risk benefit analysis in patients with NASH cirrhosis.

The study design provides for a pre-specified interim analysis (IA). The IA of efficacy and safety data will be conducted after all planned subjects in Phase 2b component have completed at least 78 weeks (18 months) of treatment and an esophago-gastro-duodeno endoscopic assessment. The purpose of the IA is to allow potential seamless adaptive modifications of the study, including: (1) the selection of the optimal dose of belapectin for Phase 3, (2) the re-estimation of the study sample size for the Phase 3 portion of the trial, (3) the re-evaluation of the randomization ratio for the Phase 3 portion of the trial, (4) the refinement of the inclusion and exclusion criteria for the Phase 3 portion of the trial, including the cirrhosis status and, (5) possible termination of the study for overwhelming efficacy or for futility.

The trial design also includes a blinded sample size re-estimation ("SSR") during the Phase 2b, prior to the IA, to allow for potential sample size readjustment. The SSR will be conducted when 50% of the patients have completed 18 months of therapy. This will allow us to confirm the underlying assumption regarding the rate of varices development, currently estimated from our prior Phase 2b trial (NASH-CX). The study design also minimizes invasive testing requirements, such as the measurement of HVPG or repeated liver biopsies, which we believe will facilitate enrollment and retention of patients. It also provides for a seamless transition of patients from the Phase 2b component into the phase 3 stage, including the potential addition of new patients. The trial design preserves the surrogate end-point concepts (development of new varices versus variceal hemorrhage) previously discussed with FDA.

We believe that these adaptations taken together are innovative and optimize conduct of the NAVIGATE trial with a clinically relevant primary outcome giving belapectin the best opportunity to show a positive therapeutic effect to address an unmet medical need. If the IA results of the NAVIGATE trial are compelling, there could be the potential for accelerated FDA approval and/or partnership opportunity with a pharmaceutical company.

In the Phase 3 component of this trial, as proposed in the protocol, the primary endpoint remain the development of varices. Secondary endpoints include a composite clinical outcomes endpoint, including varices requiring treatment (development of large varices or varices with a red wale), decompensating events, all-cause mortality, MELD score increase, liver transplant. Also, NASH non-invasive biomarkers will be evaluated. To target a population at risk of developing esophageal varices, patient selection will be based on clinical signs of portal hypertension, including, a low platelet count, an increased spleen size and/or evidence of collaterals circulation.

The focus and goal of the therapeutic program is to stop the progression of and/or reverse portal hypertension and thereby prevent the development of varices, potentially one of the most immediately life-threatening complication of cirrhosis. Based on the results of the NASH-CX trial and subject to confirmation in later stage clinical trials, we believe that this goal is achievable in a significant portion of the NASH cirrhosis patient population i.e. those NASH cirrhosis patients with clinical signs of portal hypertension.

The COVID-19 pandemic has delayed and may continue to delay our recruitment of sites and enrollment of patients for our Phase 2b/3 NAVIGATE trial. While there has been a large decline in cases and hospitalizations in the United States because of vaccinations, the decline in the rate of vaccinations and the emergence of variants has extended the pandemic within the United States and has caused continued concern particularly in medical and hospital settings. While many cities in the United States and Europe had loosened restrictions, many of those restrictions are being re-imposed. In some countries, shutdown orders have also affected the regulatory process to authorize study starts. Governments and medical facilities continue to focus their resources for battling the COVID-19 pandemic. For several reasons, the pandemic makes enrolling patients for the NAVIGATE trial more challenging, including because patients eligible for the NAVIGATE trial have liver cirrhosis and, as such, are at a greater health risk of complications from COVID-19. Even with vaccinations being more readily available, we continue to be impacted by COVID-19. We have experienced increases in the rate of enrollment in the United States but not in Europe, Latin America, and South Korea. We believe that as more people get vaccinated for COVID-19 in the United States and in other countries, site recruitment and patient enrollment will accelerate. At this time, we estimate that enrollment completion will occur around June 30, 2022.

We have identified more than 130 clinical trial sites in 11 countries for the NAVIGATE trial.

Further details on the NAVIGATE trial can be found on www.clinicaltrials.gov under study NCT04365868.

The Company also has commenced a Hepatic Impairment Study, which will run in parallel with the phase 2b/3 trial as part of the development program. The Hepatic Impairment Study is being conducted at three sites and will involve approximately 40 patients (divided amongst normal healthy volunteers, and patients with hepatic impairment categorized as Child-Turcotte-Pugh (CTP) classes A (mild), B (moderate), and C (severe)). Each subject will receive a single infusion of belapectin (4 mg/kg LBM) and their serum belapectin levels will be monitored for up to approximately two weeks to define the effects of various stages of cirrhosis on serum belapectin levels. The tolerance and safety of belapectin will be evaluated. Based on the results from this hepatic impairment study, the Company may consider including patients with more advanced cirrhosis in the Phase 3 portion of its NAVIGATE trial. Until dosing and safety profile is further informed in CTP Class B and/or Class C patients, the NAVIGATE trial will enroll only CTP Class A patients. Further details on this hepatic impairment study can be found on www.clinicaltrials.gov study NCT04332432.

Cancer Immunotherapy. We believe there is potential for galectin inhibition to play a key role in the burgeoning area of cancer immunotherapy. For example, there have been several recent approvals of drugs that enhance a patient's immune system to fight cancer. It is our goal to use a galectin inhibitor to further enhance the immune system function to fight cancer in a way that complements other approaches to this type of therapy. This hypothesis is supported by the fact that galectin-3 is expressed at high levels in multiple types of tumors, adds to the malignant nature of the tumors, and protects the tumors from immune system attack. Our drug candidates provide a promising new therapeutic approach to enhance the activity of the immune system against cancer cells. Preclinical studies have indicated that belapectin enhances the immune response to cancer cells, increased tumor shrinkage and enhanced survival in immune competent mice with prostate, breast, melanoma and sarcoma cancers when combined with one of the immune checkpoint inhibitors, anti-CTLA-4 or anti-PD-1, or with the immune cell activator anti-OX40. These preclinical data led to the filing of two Investigator-sponsored INDs and the initiation of studies of belapectin in combination with Yervoy® (ipilimumab) and KEYTRUDA (pembrolizumab) in Phase 1B studies of patients with metastatic melanoma. The KEYTRUDA trial has also been expanded to include patients with non-small cell lung cancer and head and neck squamous cell carcinoma. These studies are being conducted under the sponsorship of Providence Portland Medical Center's Earle A. Chiles Research Institute (EACRI).

Promising results were reported in the Phase 1b trial combining belapectin with pembrolizumab (KEYTRUDA®). Cohort 1 was completed (n=6, 5 with melanoma, one with head and neck cancer) with one partial response and one mixed response in the melanoma patients. There was a rapid and marked tumor response after 3 doses of combined belapectin and pembrolizumab in the one partial response patient who had failed high-dose IL-2 and oncolytic virus + ipilimumab. The study is ongoing and progression to further development will be based on response rate as compared to historical response rates to pembrolizumab alone. In September 2018 we announced additional preliminary clinical data from cohort 3 of this investigator-initiated trial. When aggregated with cohorts previously reported, the data shows a 50% objective response rate in advanced melanoma with belapectin in combination with KEYTRUDA, and a significant decrease in the frequency of suppressive myeloid-derived suppressor cells following treatment in the responding patients (on day 85 post-treatment). Fourteen advanced melanoma patients across three dose cohorts now have Objective Response Rate (ORR) and Disease Control Rate (DCR) data. Six patients completed in cohort 3 (8 mg/kg LBM) have now been added to the three patients completed in cohort 2 (4 mg/kg LBM) and five patients completed in cohort 1 (2 mg/kg LBM). Cohorts 1 and 3 each had two patients with an objective response. All three patients in cohort 2 had an objective response. In addition to the fourteen advanced melanoma patients, six patients with head and neck cancer were enrolled in this trial with a 33% ORR and 67% DCR. These data, taken together with the observed favorable safety and tolerability of the combination, in the view of the principal investigator, provide compelling rationale to move forward. Given that all three melanoma patients were responders at the 4 mg/kg dose, the investigators continued the trial with the expansion of the 4 mg/Kg cohort to include additional advanced melanoma patients and additional head and neck cancer patients.

The expansion cohort enrolled nine melanoma patients and five head and neck squamous cell carcinoma cancer patients. Compared to the initial phase 1b patients, reported earlier, the cohort in this extension study was heavily pretreated with systemic therapy, including chemotherapy, immunotherapy with checkpoint inhibitors and cytokines, melanoma mutation-directed therapies (BRAF inhibitors and MEK inhibitors), as well as surgery and radiation therapies (external and radio-labeled). Patients also had a high burden of metastasis, with the lungs, soft tissues, and the liver being the most frequently involved organs. Four of the nine melanoma patients had a choroidal (ocular) tumor as a primary site of their cancer and had also developed liver metastasis. The treatment consisted of Belapectin 4 mg/Kg of lean body mass administered every three weeks by infusion, after the infusion of pembrolizumab. Pembrolizumab was administered according to its label. Patients' response was evaluated at day 85, according to the Response Evaluation Criteria in Solid Tumors (RECIST) criteria. The median number of treatment cycles was four (range 3-15) for melanoma patients and five (range 4-8) for head and neck cancer patients. Melanoma patient results included one partial response, four stable disease, and four progressive disease, providing a disease control rate of 56% (five out of nine patients). Head and neck cancer patients observed included two stable disease and three progressive disease, providing a disease control rate of 40% (two out of five patients). The combination of Belapectin and pembrolizumab was well tolerated and appeared safe. The most frequent adverse event related to pembrolizumab, in six patients, was grade 1 (mild) pruritus (itching), a known and labeled side-effect of pembrolizumab. The second most frequent adverse event related to pembrolizumab was grade 2 fatigue in three patients. All other adverse events were mild (grade 1). There were no grade 3 or above adverse events. Similar to the initial phase 1 study results, the frequency and severity of toxicities related to pembrolizumab, notably immune-mediated adverse events, was less than anticipated. No adverse event was deemed related to belapectin.

Discussions are ongoing about the planning and feasibility of a multicenter Phase 2 study.

Results of Operations

Three and Nine Months Ended September 30, 2021 Compared to Three and Nine Months Ended September 30, 2020

Research and Development Expense.

	Three Months Ended September 30,		Nine Months Ended September 30,		2021 as Compared to 2020			
					Three Months		Nine Months	
	2021	2020	2021	2020	$ Change	% Change	$ Change	% Change
	(In thousands, except %)							
Research and development	$ 6,613	$ 4,780	$ 17,962	$ 11,605	$ 1,833	38%	$ 6,357	55%

We generally categorize research and development expenses as either direct external expenses, comprised of amounts paid to third party vendors for services, or all other research and development expenses, comprised of employee payroll and general overhead allocable to research and development. We consider a clinical program to have begun upon acceptance by the FDA, or similar agency outside of the United States, to commence a clinical trial in humans, at which time we begin tracking expenditures by the product candidate. Clinical program expenses comprise payments to vendors related to preparation for, and conduct of, all phases of the clinical trial, including costs for drug manufacture, patient dosing and monitoring, data collection and management, oversight of the trials and reports of results. Pre-clinical expenses comprise all research and development amounts incurred before human trials begin, including payments to vendors for services related to product experiments and discovery, toxicology, pharmacology, metabolism and efficacy studies, as well as manufacturing process development for a drug candidate.

Our research and development expenses were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(in thousands)			
Direct external expenses:				
Clinical programs	$ 5,768	$ 3,768	$ 15,928	$ 8,566
Pre-clinical activities	237	64	418	427
All other research and development expenses	608	948	1,616	2,612
	$ 6,613	$ 4,780	$ 17,962	$ 11,605

Clinical programs expenses increased primarily due to costs related to our NAVIGATE trial during the three and nine months ended September 30, 2021.

Both the time required and costs we may incur in order to commercialize a drug candidate that would result in material net cash inflow are subject to numerous variables, and therefore we are unable at this stage of our development to forecast useful estimates. Variables that make estimates difficult include the number of clinical trials we may undertake, the number of patients needed to participate in the clinical trial, patient recruitment uncertainties, trial results as to the safety and efficacy of our product, and uncertainties as to the regulatory agency response to our trial data prior to receipt of marketing approval. Moreover, the FDA or other regulatory agencies may suspend clinical trials if we or an agency believes patients in the trial are subject to unacceptable risks or find deficiencies in the conduct of the clinical trial. Delays or rejections may also occur if governmental regulation or policy changes during our clinical trials or in the course of review of our clinical data. Due to these uncertainties, accurate and meaningful estimates of the ultimate cost to bring a product to market, the timing of costs and completion of our program and the period during which material net cash inflows will commence are unavailable at this time.

General and Administrative Expense.

	Three Months Ended September 30,		Nine Months Ended September 30,		2021 as Compared to 2020			
					Three Months		Nine Months	
	2021	2020	2021	2020	$ Change	% Change	$ Change	% Change
	(In thousands, except %)							
General and administrative	$ 1,631	$ 1,146	$ 4,792	$ 4,007	$ 485	42%	$ 785	20%

General and administrative expenses consist primarily of salaries including stock-based compensation, legal and accounting fees, insurance, investor relations, business development and other office related expenses. The primary reasons for the increase in general and administrative expenses for the three months ended September 30, 2021 as compared to the same period in 2020 are due to increases in insurance expense of $131,000, and non-cash stock-based compensation expense of $226,000. The primary reasons for the increase in general and administrative expenses for the nine months ended September 30, 2021 as compared to the same period in 2020 are due to increases in insurance expense of $385,000, investor relations/business development expense of $103,000 and non-cash stock-based compensation expense of $322,000, partially offset by decrease in legal fees expense of $206,000.

Liquidity and Capital Resources

Since our inception on July 10, 2000, we have financed our operations from proceeds of public and private offerings of debt and equity. As of September 30, 2021, we raised a net total of $214.5 million from these offerings. We have operated at a loss since our inception and have had no significant revenues. We anticipate that losses will continue for the foreseeable future. At September 30, 2021, the Company had $36,600,000 of unrestricted cash and cash equivalents available to fund future operations. The Company believes there is sufficient cash, including a $10,000,000 convertible note payable that will close in December 2021 (see Note 4), to fund currently planned operations at least through March 31, 2023. We will require more cash to fund our operations after March 31, 2023 and believe we will be able to obtain additional financing. The currently planned operations include costs related to our adaptively designed NAVIGATE Phase 2b/3 clinical trial. Currently, we expect to require an additional approximately $30-$35 million to cover costs of the trial to reach the planned interim analysis estimated to occur around the end of the first quarter of 2024 along with drug manufacturing and other scientific support activities and general and administrative costs. However, there can be no assurance that we will be successful in obtaining such new financing or, if available, that such financing will be on terms favorable to us. If we are unsuccessful in raising additional capital to fund operations before March 31, 2023, we may be required to cease operations. Accordingly, based on the forecasts and estimates underlying our current operating plan, the financial statements do not currently include any adjustments that might be necessary if we are unable to continue as a going concern.

Net cash used in operations increased by $2,170,000 to $17,357,000 for the nine months ended September 30, 2021, as compared to $15,187,000 for the nine months ended September 30, 2020. Cash operating expenses increased principally due to the preparations and expenses related to our NAVIGATE clinical trial with belapectin.

Net cash provided by financing activities for the nine months ended September 30, 2021, of $26,815,000 represents proceeds of $20,000,000 from two convertible notes payable, $2,951,000 from the exercise of common stock warrants and $3,864,000 in net proceeds from issuance of common shares under our ATM. Net cash provided by financing activities for the nine months ended September 30, 2020, of $263,000 represents proceeds of $219,000 from the exercise of common stock options and $44,000 in net proceeds from issuance of common shares under our ATM.

Off-Balance Sheet Arrangements

We have not created, and are not a party to, any special-purpose or off-balance sheet entities for the purpose of raising capital, incurring debt or operating parts of our business that are not consolidated into our financial statements. We do not have any arrangements or relationships with entities that are not consolidated into our financial statements that are reasonably likely to materially affect our liquidity or the availability of capital resources.

Application of Critical Accounting Policies and Estimates

The preparation of condensed consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, expenses, and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to accrued expenses, stock-based compensation, contingencies and litigation. We base our estimates on historical experience, terms of existing contracts, our observance of trends in the industry, information available from other outside sources and on various other factors that we believe to be appropriate under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

Critical accounting policies are those policies that affect our more significant judgments and estimates used in preparation of our consolidated financial statements. We believe our critical accounting policies include our policies regarding stock-based compensation, accrued expenses, derivatives and income taxes. For a more detailed discussion of our critical accounting policies, please refer to our 2020 Annual Report on Form 10-K.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Market risk represents the risk of loss that may impact our financial position, operating results or cash flows due to changes in the U.S. interest rates. The primary objective of our investment activities is to preserve cash until it is required to fund operations. To minimize risk, we maintain our portfolio of cash and cash equivalents in operating bank accounts and money market funds. Since our investments are short-term in duration, we believe that we are not subject to any material market risk exposure.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of the Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934) and concluded that, as of September 30, 2021, our disclosure controls and procedures were effective.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected.

Changes in Internal Control Over Financial Reporting

During the quarter ended September 30, 2021, no change in our internal control over financial reporting has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

The information set forth in this report should be read in conjunction with the risk factors set forth in Item 1A, “Risk Factors,” of Part I of our Annual Report on Form 10-K for the year ended December 31, 2020, which could materially impact our business, financial condition or future results.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None

Item 3. Defaults Upon Senior Securities

None

Item 4. Mine Safety Disclosures

Not Applicable

Item 5. Other Information

Not Applicable

Item 6. Exhibits

Exhibit Number	Description of Document	Note Reference
31.1*	Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934	
31.2*	Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934	
32.1**	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	
32.2**	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	
	The following financial statements and footnotes from the Registrant's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2021 formatted in Inline Extensible Business Reporting Language (Inline XBRL):	
101.INS	Inline XBRL Instance Document**	
101.SCH	Inline XBRL Taxonomy Extension Schema Document*	
101.CAL	Inline XBRL Taxonomy Calculation Linkbase Document*	
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document*	
101.LAB	Inline XBRL Taxonomy Label Linkbase Document*	
101.PRE	Inline XBRL Taxonomy Presentation Linkbase Document*	
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded in the Inline XBRL document and included in Exhibit 101)*	

* Filed herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on November 15, 2021.

GALECTIN THERAPEUTICS INC.

By: /s/ Joel Lewis
Name: Joel Lewis
Title: Chief Executive Officer and President
(principal executive officer)

By: /s/ Jack W. Callicutt
Name: Jack W. Callicutt
Title: Chief Financial Officer
(principal financial and accounting officer)

Exhibit 31.1

Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934

I, Joel Lewis, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Galectin Therapeutics Inc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 15, 2021

/s/ Joel Lewis

Name: Joel Lewis
Title: Chief Executive Officer and President
(principal executive officer)

Exhibit 31.2

Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934

I, Jack W. Callicutt, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Galectin Therapeutics Inc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 15, 2021

/s/ Jack W. Callicutt

Name: Jack W. Callicutt
Title: Chief Financial Officer
(principal financial and accounting officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Galectin Therapeutics Inc. (the "Company") on Form 10-Q for the period ended September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joel Lewis, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 15, 2021

/s/ Joel Lewis

Name: Joel Lewis
Title: Chief Executive Officer and President
(principal executive officer)

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Galectin Therapeutics Inc. and will be retained by Galectin Therapeutics Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Galectin Therapeutics Inc. (the "Company") on Form 10-Q for the period ended September 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jack W. Callicutt, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 15, 2021

/s/ Jack W. Callicutt

Name: Jack W. Callicutt
Title: Chief Financial Officer
(principal financial and accounting officer)

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Galectin Therapeutics Inc. and will be retained by Galectin Therapeutics Inc. and furnished to the Securities and Exchange Commission or its staff upon request.