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 June 30, 2023

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

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 August 8, 2023 was 59,582,253.

GALECTIN THERAPEUTICS INC.
INDEX TO FORM 10-Q
FOR THE QUARTER ENDED June 30, 2023

GALECTIN THERAPEUTICS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

	June 30, 2023	December 31, 2022
	(in thousands)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 17,966	$ 18,592
Prepaid expenses and other current assets	1,502	1,960
Total current assets	19,468	20,552
Other assets	613	733
Total assets	$ 20,081	$ 21,285
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS’ EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 1,976	$ 3,890
Accrued expenses and other	7,913	9,058
Accrued dividends payable	64	64
Total current liabilities	9,953	13,012
Convertible notes payable and accrued interest, net of discounts – related party (Note 3)	30,433	29,964
Derivative liabilities (Note 4)	852	573
Borrowing and accrued interest under convertible line of credit, net of debt discount – related party (Note 9)	29,926	9,864
Other liabilities	44	66
Total liabilities	71,208	53,479
Commitments and contingencies (Note 10)		
Series C super dividend redeemable convertible preferred stock; 1,000 shares authorized, 176 shares issued and outstanding at June 30, 2023 and December 31, 2022, redemption value: $8,282,000, liquidation value: $1,760,000 at June 30, 2023	1,723	1,723
Stockholders’ equity (deficit):		
Undesignated stock, $0.01 par value; 20,000,000 shares authorized, 20,000,000 designated at June 30, 2023 and December 31, 2022, respectively	—	—
Series A 12% convertible preferred stock; 1,742,500 shares authorized, 1,260,000 issued and outstanding at June 30, 2023 and December 31, 2022, liquidation value $1,260,000 at June 30, 2023	510	510
Common stock, $0.001 par value; 150,000,000 shares authorized at June 30, 2023 and December 31, 2022, 59,582,253 and 59,426,005 issued and outstanding at June 30, 2023 and December 31, 2022, respectively	59	59
Additional paid-in capital	276,852	275,081
Accumulated deficit	(330,271)	(309,567)
Total stockholders’ equity (deficit)	(52,850)	(33,917)
Total liabilities, redeemable convertible preferred stock and stockholders’ equity (deficit)	$ 20,081	$ 21,285

See notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
	(in thousands, except per share data)		(in thousands, except per share data)	
Operating expenses:				
Research and development	$ 7,371	$ 8,074	$ 16,170	$ 16,132
General and administrative	1,632	1,588	3,175	3,465
Total operating expenses	9,003	9,662	19,345	19,597
Total operating loss	(9,003)	(9,662)	(19,345)	(19,597)
Other income (expense):				
Interest income	50	3	93	4
Interest expense	(650)	(229)	(1,110)	(456)
Change in fair value of derivative	489	275	(279)	504
Total other income (expense)	(111)	49	(1,296)	52
Net loss	$ (9,114)	$ (9,613)	$ (20,641)	$ (19,545)
Preferred stock dividends	(63)	(64)	(63)	(48)
Net loss applicable to common stockholders	$ (9,177)	$ (9,677)	$ (20,704)	$ (19,593)
Net loss per common share — basic and diluted	$ (0.15)	$ (0.16)	$ (0.35)	$ (0.33)
Weighted average common shares outstanding — basic and diluted	59,582	59,389	59,531	59,372

See notes to unaudited condensed consolidated financial statements.

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

	Six Months Ended June 30, 2023	2022
	(in thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (20,641)	$ (19,545)
Adjustments to reconcile net loss to net cash flows from operating activities:		
Stock-based compensation expense	1,178	1,505
Amortization of right to use lease asset	16	17
Non-cash interest expense	313	158
Change in fair value of derivative liabilities	279	(504)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	458	454
Accounts payable, accrued expenses and other liabilities	(3,027)	2,147
Accrued interest on convertible debt - related party	798	298
Net cash from operating activities	(20,626)	(15,470)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from convertible line of credit – related party	20,000	—
Net cash flows from financing activities	20,000	—
NET DECREASE IN CASH AND CASH EQUIVALENTS	(626)	(15,470)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	18,592	39,648
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 17,966	$ 24,178
NONCASH FINANCING ACTIVITIES:		
Payment of preferred stock dividends in common stock	$ 62	$ 49
Reclassification of accrued bonus to additional paid in capital	210	200
Common stock purchase warrants issued in connection with related party line of credit	477	—
Noncash right to use lease asset	—	111

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, 2021	**176**	**$ 1,723**
Balance at June 30, 2022	**176**	**$ 1,723**
Balance at December 31, 2022	**176**	**$ 1,723**
Balance at June 30, 2023	**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 June 30, 2023 and 2022
(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 March 31, 2022	**1,302,500**	**$ 527**	**59,388,518**	**$ 59**	**$ 272,108**	**$ (280,610)**	**$ (7,916)**
Series A 12% convertible preferred stock dividend						(38)	(38)
Series C super dividend redeemable convertible preferred stock dividend						(26)	(26)
Issuance of common stock from conversion of Series A convertible preferred stock	(42,500)	(17)	7,289		17		
Stock-based compensation expense					647		647
Net loss						(9,613)	(9,613)
Balance at June 30, 2022	**1,260,000**	**$ 510**	**59,395,805**	**$ 59**	**$ 272,772**	**$ (290,287)**	**$ (16,946)**
Balance at March 31, 2023	**1,260,000**	**$ 510**	**59,582,253**	**$ 59**	**$ 276,156**	**$ (321,094)**	**$ (44,369)**
Series A 12% convertible preferred stock dividend						(37)	(37)
Series C super dividend redeemable convertible preferred stock dividend						(26)	(26)
Common stock purchase warrants issued in connection with related party line of credit					180		180
Stock-based compensation expense					516		516
Net loss						(9,114)	(9,114)
Balance at June 30, 2023	**1,260,000**	**$ 510**	**59,582,253**	**$ 59**	**$ 276,852**	**$ (330,271)**	**$ (52,850)**

GALECTIN THERAPEUTICS INC.
CONSOLIDATED STATEMENTS OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT) — (Continued)
For the Six Months Ended June 30, 2023 and 2022
(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, 2021	**1,302,500**	**$ 527**	**59,341,305**	**$ 59**	**$ 271,001**	**$ (270,694)**	**$ 893**
Series A 12% convertible preferred stock dividend			13,025		20	(20)	
Series C super dividend redeemable convertible preferred stock dividend			17,600		29	(28)	1
Issuance of common stock from conversion of Series A convertible preferred stock	(42,500)	(17)	7,287		17		
Stock-based compensation expense			16,588		1,705		1,705
Net loss						(19,545)	(19,545)
Balance at June 30, 2022	**1,260,000**	**$ 510**	**59,395,805**	**$ 59**	**$ 272,772**	**$ (290,287)**	**$ (16,946)**
Balance at December 31, 2022	**1,260,000**	**$ 510**	**59,426,005**	**$ 59**	**$ 275,081**	**$ (309,567)**	**$ (33,917)**
Series A 12% convertible preferred stock dividend			12,600		26	(26)	
Series C super dividend redeemable convertible preferred stock dividend			17,600		36	(37)	(1)
Common stock purchase warrants issued in connection with related party line of credit					477		477
Stock-based compensation expense			126,048		1,232		1,232
Net loss						(20,641)	(20,641)
Balance at June 30, 2023	**1,260,000**	**$ 510**	**59,582,253**	**$ 59**	**$ 276,852**	**$ (330,271)**	**$ (52,850)**

See notes to consolidated financial statements.

GALECTIN THERAPEUTICS INC.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Basis of Presentation and Liquidity

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 June 30, 2023 and the results of its operations for the three and six months ended June 30, 2023 and 2022 and its cash flows for the three and six months ended June 30, 2023 and 2022. 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, 2022 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, 2022.

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 June 30, 2023, the company had $17,966,000 of unrestricted cash and cash equivalents available to fund future operations. In July 2022, the Company entered into a $60 million unsecured line of credit financing with its chairman, Richard E. Uihlein (See Note 12). The Company believes there is sufficient cash, including availability of the line of credit, to fund currently planned operations at least through December 31, 2024. To meet its future capital needs, the Company intends to raise additional capital through debt or equity financings, collaborations, partnerships or other strategic transactions. However, there can be no assurance that the Company will be able to complete any such transactions on acceptable terms or otherwise. The inability of the Company to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company's business, results of operations and financial condition. The Company has the ability to delay certain research activities and related clinical expenses if necessary due to liquidity concerns until a date when those concerns are relieved.

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:

	June 30, 2023	December 31, 2022
	(in thousands)	
Legal and accounting fees	$ 100	$ 65
Accrued compensation	641	973
Lease liability	43	40
Accrued research and development costs and other	7,129	7,980
Total	$ 7,913	$ 9,058

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. 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 2021 Note") in the principal amount of ten million dollars.

The April 2021 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 2021 Note bears interest at the rate of two percent (2%) per annum, compounded annually with an effective interest rate of approximately 3%. For the three months ended June 30, 2023 and 2022, approximately $52,000 and $51,000, respectively, of interest expense was accrued and included with the principal in the financial statements. For the six months ended June 30, 2023 and 2022, approximately $102,000 and $101,000, respectively, of interest expense was accrued and included with the principal in the financial statements.

The April 2021 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 2021 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 2021 Note at its inception. The fair value of the contingent interest derivative liability was $420,000 at note inception (April 16, 2021). The fair value of the contingent interest derivative liability was $366,000 and $249,000 at June 30, 2023 and December 31, 2022, respectively, and is recognized as a derivative liability in the consolidated balance sheet. The change in the fair value of the derivative liability for the three months ended June 30, 2023 and 2022 of $(221,000) and $(114,000), respectively, was charged to other expense/(income) for the three months ended June 30, 2023 and 2022. The change in the fair value of the derivative liability for the six months ended June 30, 2023 and 2022 of $117,000 and $(219,000), respectively, was charged to other expense/(income) for the six months ended June 30, 2023 and 2022. The amortization of the original $420,000 debt discount of $26,000 and $26,000 was recorded as additional interest expense for the three months ended June 30, 2023 and 2022, respectively. The amortization of the original $420,000 debt discount of $52,000 and $52,000 was recorded as additional interest expense for the six months ended June 30, 2023 and 2022, respectively.

The September 2021 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 2021 Note bears interest at the rate of two percent (2%) per annum, compounded annually with an effective interest rate of approximately 3%. For the three months ended June 30, 2023 and 2022, approximately $51,000 and $50,000, respectively, of interest expense was accrued and included with the principal in the financial statements. For the six months ended June 30, 2023 and 2022, approximately $101,000 and $99,000, respectively, of interest expense was accrued and included with the principal in the financial statements.

The September 2021 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 2021 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 at note inception (September 17, 2021). The fair value of the contingent interest derivative liability was $159,000 and $109,000 and June 30, 2023 and December 31, 2022, respectively, and is recognized as a derivative liability in the consolidated balance sheet. The change in the fair value of the derivative liability for three months ended June 30, 2023 and 2022 of $(116,000) and ($57,000), respectively, was recorded to other expense/(income) for three months ended June 30, 2023 and 2022. The change in the fair value of the derivative liability for six months ended June 30, 2023 and 2022 of $50,000 and ($119,000), respectively, was recorded to other expense/(income) for six months ended June 30, 2023 and 2022. The amortization of the original $433,000 debt discount of $27,000 and $27,000 was recorded as additional interest expense for the three months ended June 30, 2023 and 2022. The amortization of the original $433,000 debt discount of $54,000 and $54,000 was recorded as additional interest expense for the six months ended June 30, 2023 and 2022.

On December 20, 2021, the second of the two promissory notes under the Loan Agreement was executed and delivered, (the "December 2021 Note") to evidence the second loan in the principal amount of $10,000,000. The December 2021 Note has a maturity date of December 20, 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 $5.43 per share at the option of the noteholder. The December Note bears interest at the rate of two percent (2%) per annum, compounded annually with an effective interest rate of approximately 3%. For three months ended June 30, 2023 and 2022, approximately $51,000 and $50,000, respectively, of interest expense was accrued and included with the principal in the financial statements. For six months ended June 30, 2023 and 2022, approximately $101,000 and $99,000, respectively, of interest expense was accrued and included with the principal in the financial statements.

The December 2021 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 December 2021 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 December Note at its inception. The fair value of the contingent interest derivative liability was $415,000 at note inception (December 20, 2021). The fair value of the contingent interest derivative liability was $327,000 and $215,000 at June 30, 2023 and December 31, 2022, respectively, and is recognized as a derivative liability in the consolidated balance sheet. The change in the fair value of the derivative liability for three months ended June 30, 2023 and 2022.of $(152,000) and ($103,000), respectively was recorded to other expense/(income) for three months ended June 30, 2023 and 2022. The change in the fair value of the derivative liability for six months ended June 30, 2023 and 2022.of $112,000 and ($166,000), respectively was recorded to other expense/(income) for six months ended June 30, 2023 and 2022. The amortization of the original $415,000 debt discount of $26,000 and $26,000 was recorded as additional interest expense for three months ended June 30, 2023 and 2022, respectively. The amortization of the original $415,000 debt discount of $52,000 and $52,000 was recorded as additional interest expense for six months ended June 30, 2023 and 2022, respectively.

The Company's contractual cash obligations related to the outstanding convertible notes payable is a repayment of the April 2021 Note of the $10,000,000 plus accrued interest on April 16, 2025 and a repayment of the September 2021 Note of the $10,000,000 plus accrued interest on September 17, 2025 and a repayment of the December 2021 Note of the $10,000,000 plus accrued interest on December 30, 2025, unless converted at the option of the noteholder.

4. 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 1 or 2 assets or liabilities at June 30, 2023 or December 31, 2022. See below for Fair Value of Derivatives related to Convertible Notes Payable at June 30, 2023 and December 31, 2022, which are level 3 liabilities.

Level 3 assets and liabilities measured and recorded at fair value on a recurring basis at June 30, 2023 and December 31, 2022 were as follows:

	June 30, 2023	December 31, 2022
Derivative Liability – Contingent Interest April Note	$ 366,000	$ 249,000
Derivative Liability – Contingent Interest September Note	$ 159,000	$ 109,000
Derivative Liability – Contingent Interest December Note	$ 327,000	$ 215,000

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 June 30, 2023 and December 31, 2022 are as follows:

	June 30, 2023	December 31, 2022
Stock Price	$ 1.44	$ 1.13
Conversion Price of conversion feature	$ 5.00	$ 5.00
Term	1.8 years	2.29 years
Risk Free Interest Rate	4.87%	4.41%
Credit Adjusted Discount Rate	12.8%	14.76%
Volatility	72%	81%
Dividend Rate	0%	0%

The roll forward of the April Note derivative liability – contingent interest is as follows for the six months ended June 30, 2023 and 2022:

Balance – December 31, 2022	$ 249,000
Fair Value Adjustment	117,000
Balance – June 30, 2023	$ 366,000
Balance – December 31, 2021	$ 495,000
Fair Value Adjustment	(219,000)
Balance – June 30, 2022	$ 276,000

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 June 30, 2023 and December 31, 2022 are as follows:

	June 30, 2023	December 31, 2022
Stock Price	$ 1.44	$ 1.13
Conversion Price of conversion feature	$ 8.64	$ 8.64
Term	2.22 years	2.72 years
Risk Free Interest Rate	4.87%	4.22%
Credit Adjusted Discount Rate	12.8%	14.76%
Volatility	79%	81%
Dividend Rate	0%	0%

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

Balance – December 31, 2022	$ 109,000
Fair Value Adjustment	50,000
Balance – June 30, 2023	$ 159,000
Balance – December 31, 2021	250,000
Fair Value Adjustment	(119,000)
Balance – June 30, 2022	$ 131,000

The December Note derivative liability – contingent interest was valued using a Monte Carlo Geometric Brownian Stock Path Model. The key assumptions used in the model at June 30, 2023 and December 31, 2022 are as follows:

	June 30, 2023	December 31, 2022
Stock Price	$ 1.44	$ 1.13
Conversion Price of conversion feature	$ 5.43	$ 5.43
Term	2.48 years	2.97 years
Risk Free Interest Rate	4.68%	4.22%
Credit Adjusted Discount Rate	12.8%	14.76%
Volatility	80%	83%
Dividend Rate	0%	0%

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

Balance – December 31, 2022	$ 215,000
Fair Value Adjustment	112,000
Balance – June 30, 2023	$ 327,000
Balance – December 31, 2021	$ 385,000
Fair Value Adjustment	(166,000)
Balance – June 30, 2022	$ 219,000

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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
		in thousands		
Research and development	$ 134	$ 154	$ 403	$ 379
General and administrative	382	493	775	1,126
Total stock-based compensation expense	$ 516	$ 647	$ 1,178	$ 1,505

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, 2022 through June 30, 2023:

	Shares	Weighted Average Exercise Price
Outstanding, December 31, 2022	5,745,561	$ 2.90
Granted	800,000	1.11
Exercised	—	—
Options forfeited/cancelled	(258,804)	2.45
Outstanding, June 30, 2023	6,286,757	$ 2.69

As of June 30, 2023, there was $1,488,000 of unrecognized compensation related to 2,331,247 unvested options, which is expected to be recognized over a weighted–average period of approximately 1.1 years. The weighted-average grant date fair value for options granted during the six months ended June 30, 2023 was $0.80. The Company granted 800,000 stock options during the six months ended June 30, 2023.

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

	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022
Risk-free interest rate	3.76%	1.56%
Expected life of the options	5.5 years	5.6 years
Expected volatility of the underlying stock	86%	94%
Expected dividend rate	0%	0%

In January 2023, the Company's board chairman elected to take restricted stock grants in lieu of cash retainers for 2023. A total of 36,036 shares of restricted stock valued at approximately $40,000 is being amortized to expense on a straight-line basis until December 31, 2023 when the stock vests in full. In January 2022, the Company's board chairman elected to take restricted stock grants in lieu of cash retainers for 2022. A total of 17,677 shares of restricted stock valued at approximately $35,000 were amortized to expense on a straight-line basis until December 31, 2022 when the stock vested 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. Pursuant to an amendment to the DSU Agreement in July 2022, 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, fifty percent shall be issued on March 1, 2024 and twenty five percent shall be issued on September 1, 2028. On March 1, 2023, twenty five percent of the DSU's were issued to Mr. Lewis in accordance with the DSU Agreement. A total of 183,900 shares were due to be issued; however, 75,529 shares were withheld to cover income tax withholding of $156,345 resulting in 108,371 shares actually issued.

For the six months ended June 30, 2023, approximately $228,000 of his compensation was recorded as stock compensation expense representing 143,568 shares of common stock to be issued under the DSU agreement with a weighted average grant date fair value of $1.59 per share. For the six months ended June 30, 2022, approximately $208,000 of his compensation was recorded as stock compensation expense representing 130,546 shares of common stock to be issued under the DSU agreement with a weighted average grant date fair value of $1.65 per share.

Also, Mr. Lewis' bonus for the year ended December 31, 2022 of $210,000 (which was included in accrued compensation at December 31, 2022) was approved in January 2023 and represents 143,836 shares of common stock to be issued under the DSU agreement with a grant date fair value of $1.46 per share. The $210,000 was reclassified from accrued compensation to additional paid in capital in January 2023. 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, 2022 through June 30, 2023:

	Shares	Weighted Average Exercise Price
Outstanding, December 31, 2022	11,557,964	$ 4.37
Granted	400,000	3.13
Exercised	—	—
Forfeited/cancelled	—	—
Outstanding, June 30, 2023	11,957,964	$ 4.33

The weighted average expiration of the warrants outstanding as of June 30, 2023 is 1.7 years.

7. 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:

	June 30, 2023 (shares)	June 30, 2022 (shares)
Warrants to purchase shares of common stock	11,957,964	10,857,964
Options to purchase shares of common stock	6,286,757	5,645,561
Shares of common stock issuable upon conversion of convertible notes payable – related party	6,117,006	5,515,161
Shares of common stock issuable upon conversion of convertible line of credit – related party	10,170,002	—
Shares of common stock issuable upon conversion of preferred stock	503,340	503,340
	35,035,069	22,522,026

8. 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 six months ended June 30, 2023, there were no issuances of shares of common stock under the 2020 At Market Agreement.

For each of the six months ended June 30, 2023 and 2022, the Company issued a total of 30,200 and 30,625 shares of common stock, respectively, for dividends on Series A and Series C Preferred Stock.

9. Convertible Line of Credit – Related Party

On July 25, 2022, the Company and Richard E. Uihlein (the "Lender") entered into a Line of Credit Letter Agreement (the "Credit Agreement"), pursuant to which the Lender shall provide the Company a line of credit of up to $60.0 million (the "Line of Credit") to finance the Company's working capital needs. The Company may draw upon the Line of Credit through July 31, 2024.

Each advance made pursuant to the Credit Agreement shall be evidenced by an unsecured, convertible promissory note (individually, a "Promissory Note," and collectively, the "Promissory Notes"), and bear interest at the Applicable Federal Rate for short term loans, plus two (2%) percent. Principal and interest on the Promissory Notes are due on or before January 31, 2026. Only with the consent of the Lender, may the Promissory Notes be prepaid, in whole or in part, at any time without premium or penalty, but with interest on the amount or amounts prepaid.

At the election of Lender, the principal and accrued interest on Promissory Note(s) may be converted into the number of shares of the Company's Common Stock equal to the amount of principal and accrued interest on such Promissory Note divided by the price equal to the closing price of the Common Stock on the date of such Promissory Note, but in no event less than $3.00 per share.

In connection with the Credit Agreement, the Company agreed to issue the Lender warrants to purchase up to an aggregate of 1,700,000 shares of the Company's common stock, par value $0.001 per share (collectively, the "Warrants"). Upon execution of the Credit Agreement, the Company issued the Lender a Warrant to purchase up to 500,000 shares of Company's Common Stock at an exercise price of $5.00 per share, which Warrant is exercisable upon issuance. Further, pursuant to the Credit Agreement, the Company shall issue to the Lender additional Warrants to purchase up to the remaining 1,200,000 shares of the Company's common stock, ratably, upon borrowings under the Credit Agreement, with exercise prices equal to 150% of the closing price of the Company's common Stock on the date of the Promissory Note evidencing such draw, but in no event more than $10.00 per share nor less than $3.00 per share. The Warrants expire on July 31, 2029.

The fair value of the 500,000 warrants vested at closing on July 25, 2022 was $738,000 at the date of issuance based on the following assumptions: an expected life of 7 years, volatility of 92%, risk free interest rate of 3.19% and zero dividends. The fair value of the vested warrants was recorded in other assets (non-current) as a deferred financing cost and will be amortized on a straight-line basis from July 25, 2022 through January 31, 2026. Amortization for the six months ended June 30, 2023 of $104,000 was recorded as interest expense.

On December 19, 2022, the Company executed a $10 million Promissory Note under the Line of Credit. The interest rate on this draw is 6.46% (Applicable Federal Rate for short term loans on date of draw of 4.46% plus 2%). The effective interest rate is approximately 7.1%. Accrued interest on this draw was $23,000 at December 31, 2022. The principal and accrued interest is convertible at the option of the Lender at $3.00 per share. In accordance with the Credit Agreement, the Company issued the Lender a Warrant to purchase up to 200,000 shares of Company's Common Stock at an exercise price of $3.00 per share, which Warrant is exercisable upon issuance.

The fair value of the 200,000 warrants vested at closing on December 19, 2022 was $160,780 at the date of issuance based on the following assumptions: an expected life of 7 years, volatility of 91%, risk free interest rate of 4.06% and zero dividends. The proceeds were allocated between the Promissory Note and the warrants issued, and the amount allocated to the warrants was recorded as a debt discount netted against principal to be amortized on a straight-line basis, which is not materially different than the effective interest method, from December 19, 2022 through January 31, 2026. Amortization for the six months ended June 30, 2023 of $26,000 was recorded as interest expense.

On March 31, 2023, the Company executed an additional $10 million Promissory Note under the Line of Credit. The interest rate on this draw is 6.41% (Applicable Federal Rate for short term loans on date of draw of 4.41% plus 2%). The effective interest rate is approximately 7.1%. The principal and accrued interest is convertible at the option of the Lender at $3.00 per share. In accordance with the Credit Agreement, the Company issued the Lender a Warrant to purchase up to 200,000 shares of Company's Common Stock at an exercise price of $3.26 per share, which Warrant is exercisable upon issuance.

The fair value of the 200,000 warrants vested at closing on March 31, 2023 was $296,680 at the date of issuance based on the following assumptions: an expected life of 6.33 years, volatility of 88%, risk free interest rate of 3.94% and zero dividends. The proceeds were allocated between the Promissory Note and the warrants issued, and the amount allocated to the warrants was recorded as a debt discount netted against principal amortized on a straight-line basis, which is not materially different than the effective interest method, from March 31, 2023 through January 31, 2026. Amortization for the six months ended June 30, 2023 of $26,000 was recorded as interest expense.

On June 30, 2023, the Company executed an additional $10 million Promissory Note under the Line of Credit. The interest rate on this draw is 6.34% (Applicable Federal Rate for short term loans on date of draw of 4.34% plus 2%). The effective interest rate is approximately 7.1%. The principal and accrued interest is convertible at the option of the Lender at $3.00 per share. In accordance with the Credit Agreement, the Company issued the Lender a Warrant to purchase up to 200,000 shares of Company's Common Stock at an exercise price of $3.00 per share, which Warrant is exercisable upon issuance.

The fair value of the 200,000 warrants vested at closing on June 30, 2023 was $179,920 at the date of issuance based on the following assumptions: an expected life of 6.08 years, volatility of 85%, risk free interest rate of 3.59% and zero dividends. The proceeds were allocated between the Promissory Note and the warrants issued, and the amount allocated to the warrants was recorded as a debt discount netted against principal amortized on a straight-line basis, which is not materially different than the effective interest method, from June 30, 2023 through January 31, 2026.

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 January 31, 2026.

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 March 1, 2022 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 six and a half 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 six-month periods ended June 30, 2023 and 2022 was approximately $22,000 for each period and is included in general and administrative expenses. As of June 30, 2023, the right to use lease asset consisted of $70,000 and is included in other assets. Also, at June 30, 2023, current lease liability of $43,000 is included in accrued expenses and long term lease liability was $43,000 and included in other liabilities.

Maturity of operating lease as of June 30, 2023 in thousands:

2023		25
2024		51
2025		18
Total		94
Less imputed interest		8
Present value of lease liability	$	86

The discount rate used in calculating the present value of the lease payments was 11%.

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. Cumulatively, the Company has contributed a total of $3,514,000, including $150,000 for the three months ended June 30, 2023, for expenses of the LLC. Since the end of 2014, SBH has contributed $311,000 for expenses in the LLC. As of June 30, 2023, the Company's ownership percentage in the LLC was 83.2%. 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 December 31, 2024; 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,
- 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, 2022, 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.

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 and in clinical studies to decrease portal hypertension and prevent its complication: the development of esophageal varices. 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 galectin-3 gene "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 compensated cirrhosis and portal hypertension (NASH-CX).

In February 2023, we completed randomizations totaling 357 patients in a large, global 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, evaluating the safety and efficacy of our galectin-3 inhibitor, belapectin, 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. These comments were addressed, and the study proceeded accordingly.

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 became fully enrolled in February 2022 and results will be presented in an upcoming scientific congress.

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, including physical and chemical drug characterization, and commercial development. We also have established through our majority-owned joint venture subsidiary, Galectin Sciences LLC, a discovery program developing small molecules that inhibit galectin-3 and may afford alternative drug delivery (e.g., oral) and as a result expand the potential uses of galectin-3 inhibitor beyond belapectin. Three chemical series of composition of matter patents have been filed.

We are also pursuing a development pathway to clinical enhancement and commercialization for our lead compounds in immuno-oncology following our previous successful collaboration with Providence Portland Cancer Center. In 2022, we filed a new IND with FDA for advanced or metastatic head and neck cancer using belapectin in combination with a checkpoint (PD-1) inhibitor and received a Study May Proceed letter. The proposed phase 2 trial commencement is dependent on timing of financing.

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 attached to other proteins, called glycoproteins that are responsible for various functions within the body, most notably inflammation and fibrosis. Galectins, in particular galectin-3,act as a molecular glue, bringing together molecules that have sugars on them. Galectin-3, is known to be markedly increased in a number of significant diseases including inflammatory diseases leading to organs scarring (e.g. liver, lung, kidney, and heart) and cancers. The increase in galectin-3, by creating the so-called galectin-3 fibrosome, promotes the progression of multiple diseases. Published data substantiating the importance of galectin-3 in the fibrotic process arises from gene knockout experiments in animal studies. For instance, mice genetically altered to eliminate the galectin-3 gene, and thus unable to produce galectin-3, do not develop liver fibrosis in response to toxic insult to the liver.

We have one new proprietary chemical entity (NCE) in development, belapectin, which has shown promise in preclinical and clinical studies for the treatment of liver fibrosis, severe skin disease, and cancer (melanoma and head and neck squamous cell carcinoma). Currently, we are focusing on development of belapectin for the treatment of NASH cirrhosis and head and neck cancer. Belapectin is a proprietary, patented compound derived from natural, plant-based, starting materials, which following chemical processing, exhibits the properties of binding to and inhibiting galectin.

Our product pipeline is shown below:

Indication	**Drug**	**Status**
Prevention of esophageal varices in NASH cirrhosis		
Phase 1 interaction trial: NASH-CX trial and NASH-FX trial	belapectin	IND submitted January 2013. Results from the Phase 1 interaction trial were reported in 2014, with final results reported in January 2015. The Phase 2 NASH FX trial was conducted in 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 and published in Alimentary Pharmacology and Therapeutics in 2016. The Phase 2 NASH CX trial was conducted in patients with compensated cirrhosis and portal hypertension. The NASH CX trial top line data was reported in December 2017 and was published in *Gastroenterology* in 2020.
NASH NAVIGATE		Following FDA feedback, the NAVIGATE trial is an adaptive Phase 2b/3 trial for the prevention of esophageal varices in NASH patients with compensated cirrhosis and clinical signs of portal hypertension. 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 same primary outcome of efficacy and a composite clinical endpoint including progression to varices requiring treatment as a key secondary outcome of efficacy (www.clinicaltrials.gov NCT04365868). The final patient was randomized in February 2023.
Phase 1 study: hepatic insufficiency		A hepatic impairment study has been completed in subjects with normal hepatic function and subjects with varying degrees of hepatic impairment (www.clinicaltrials.gov NCT04332432) and began enrolling patients in the second quarter of 2020. The study completed enrollment in February 2022.
Cancer Immunotherapy		
Melanoma, Head, Neck Squamous Cell Carcinoma (HNSCC)	belapectin	Investigator IND study was completed. A Phase 1B study began in Q-1 2016. Early data was reported in February 2017 and additional data were reported in September 2018. Data from an extension trial was reported in July 2021 for additional melanoma and HNSCC patients which provided a rational basis for additional trials which the Company is exploring. In the third quarter of 2022, the Company announced its IND application for belapectin in combination with a checkpoint inhibitor for the treatment of HNSCC was filed and a Study May Proceed letter was received from FDA. The Company is reviewing options for financing this trial which will determine when such trial could commence.

Liver cirrhosis. Belapectin is our lead product candidate for treatment of compensated NASH cirrhosis in patients with portal hypertension. 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, portal pressure, 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 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 phase 1 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 main clinical trial was the Phase 2b NASH-CX study for one year for patients with NASH with compensated cirrhosis and portal hypertension, which began enrolling patients in June 2015. This study 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) 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 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. With a four-month treatment period and a small number of patients per arm the study was not powered to demonstrate efficacy results in established advanced liver fibrosis. In the trial however, belapectin was found to be safe and well tolerated with no serious adverse events and showing 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 patients with well-compensated NASH cirrhosis and portal hypertension. Enrollment 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. 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), a hemodynamic measure that estimates portal hypertension. Patients received an infusion of belapectin or placebo every other week for one year and were evaluated to determine the change in HVPG as compared with placebo. Secondary or exploratory endpoints included evaluation of fibrosis on liver biopsy, measurement of liver stiffness (FibroScan) and assessment of liver metabolism (^{13}C-methacetin breath test). 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 as demonstrated by a decrease in portal pressure associated with the 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 with portal hypertension who have not yet developed esophageal 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 esophageal 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 at baseline there were also a 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%). This meant that the decrease seen in portal pressure was associated with a decreased incidence of esophageal varices. The results were noticeable in the belapectin 2 mg/Kg LBM group as statistical significance against placebo was achieved for both parameters. As esophageal varices can lead to hemorrhagic complication, which can be fatal, and are a severe complication of liver cirrhosis, 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, (ii) Belapectin in the total patient population was associated 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 the prevention of esophageal varices 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) This is the first large, randomized clinical trial to demonstrate a clinically meaningful improvement in portal hypertension in patients with compensated NASH cirrhosis who have not yet developed esophageal varices.

Further information and details on the NASH-CX results is available in public presentations posted to our website and filed with the SEC and in a peer reviewed publication in *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, 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 the effect of belapectin on the incidence of additional 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 have clinical signs of portal hypertension and, thus, 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 currently 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), the best belapectin dose will be selected, based on efficacy and safety, for continued evaluation (Phase 3). The belapectin dose selected for the phase 2b/3 were based on the analysis of the NASH-CX trial. 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 up to 52 weeks, an important feature to inform 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 a second 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 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, (5) and/or 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 are particularly risky in patients with portal hypertension and 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. As a testimony of this innovation, the NAVIGATE trial design was presented to the hepatology community and featured during the last meeting of the American Association for the Study of Liver Diseases, in November 2021. 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 remains 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, but not limited to, a low platelet count, an increased spleen size and/or evidence of abdominal 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 complications 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 for whom, currently no specific, liver targeted, treatment are available.

The COVID-19 pandemic has delayed and may continue to delay our regulatory and ethics approvals, recruitment of sites, and enrollment of patients for our Phase 2b/3 NAVIGATE trial despite a recent uptick in screening activities. Many investigational centers in the United States and Europe have experienced shut-downs, and while some have loosened or removed restrictions, there may be a risk of experiencing new shut-downs and restrictions. In some countries, shutdown orders have also affected the regulatory process to authorize study starts. Governments and medical facilities focused their resources for battling the COVID-19 pandemic. For several reasons, the pandemic made 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. It is also important to consider the safety of our candidate participants first, as cirrhotic patients with portal hypertension are immune compromised. As we emerged from the COVID-19 pandemic, site recruitment and patient enrollment accelerated and we experienced increases in enrollment, particularly in the United States. However, we did not see the enrollment in Europe that we anticipated, and conditions there remain uncertain. Consequently, we activated multiple sites in Latin America. The final patient was randomized in February 2023, and we expect topline results from the IA in Fall of 2024.

We have activated more than 150 clinical trial sites in 14 countries for the NAVIGATE trial.

Further details on the NAVIGATE trial can be found on www.clinicaltrials.gov under study NCT04365868 and on our NAVIGATE website (navigatenash.com).

The Company also has completed a Hepatic Impairment Study, as part of the development program. The Hepatic Impairment Study was conducted at four sites and involved 38 subjects 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 received a single infusion of belapectin (4 mg/kg LBM) and their serum belapectin levels were monitored for up to approximately two weeks to define the effects of various stages of cirrhosis on serum belapectin pharmacokinetics. Enrollment in this study was completed in February 2022, and results will be presented at an upcoming scientific congress. In this study, Belapectin at 4 mg/kg LBM, the highest dose evaluated in the ongoing Phase 2b/3 NAVIGATE study, appeared safe and was well tolerated. Hepatic function had minimal impact on key PK parameters of belapectin suggesting that no dose adjustment of belapectin will be required for patients with increasing severity of hepatic impairment. 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 innovative 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 ourgalectin-3 inhibitor to further enhance the immune system function to help the body 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 and their micro-environment, where it fosters the malignant nature of the tumors, and protects the tumors from immune attack by the patient's own defense mechanism. 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 Phase 1B studies of belapectin in combination with Yervoy® (ipilimumab) in metastatic melanoma and another phase 1B study in combination with KEYTRUDA (pembrolizumab) in patients with metastatic melanoma and head and neck squamous cell carcinoma. These studies were conducted under the sponsorship of Providence Portland Medical Center's Earle A. Chiles Research Institute (EACRI).

The phase IB study in combination with Yervoy was rapidly discontinued after the first patients were recruited because of the availability of new treatment in the selected population.

Promising results were reported in the Phase 1b trial combining belapectin with pembrolizumab (KEYTRUDA®). When aggregated cohorts are combined, in advanced melanoma, a 50% objective response rate with belapectin in combination with KEYTRUDA, was documented. In addition, a 33% response rate was documented in patients with head and neck cancer. The results have been published in 2021 in a highly rated peer reviewed journal (Curti et al. Journal of Immunotherapy of cancer 2021;9:e002371). There was also a suggestion that the combination of belapectin with pembrolizumab could decrease the auto-immune side-effect induced by pembrolizumab. These side-effects, which are directly linked to the mechanism of action of pembrolizumab, can be poorly tolerated and even severe enough to lead to treatment interruption, even if the effect on the cancer was encouraging. This is, a very frustrating situation for patients who have to discontinue an active treatment but have no other options available to them. We believe these data, taken together with the observed favorable safety and tolerability of the combination, provide a rationale to move the belapectin program in oncology forward.

Late in 2021, we engaged three noted physicians – Dr. Chetan Bettegowda, from Johns Hopkins, and Dr. Nishant Agrawal and Dr. Ari Rosenberg, both from University of Chicago Medical Center – as consultants to help define the path forward in oncology. In consultation with our oncology experts, we have now selected the treatment of recurrent or metastatic head and neck cancer as the lead indication to pursue for belapectin in combination with an immune checkpoint inhibitor. The decision is notably based on the lack of available treatments for these patients, the limited number of therapies in development, and the resulting very high medical need. We filed an IND with FDA and are planning a phase 2 trial to be filed with the FDA oncology division.

Results of Operations

Three and Six Months Ended June 30, 2023 Compared to Three and Six Months Ended June 30, 2022

Research and Development Expense.

	Three Months Ended June 30,		Six Months Ended June 30,		2023 as Compared to 2022			
					Three Months		Six Months	
	2023	2022	2023	2022	$ Change	% Change	$ Change	% Change
	(In thousands, except %)							
Research and development	$ 7,371	$ 8,074	$ 16,170	$ 16,132	$ (703)	(9)%	$ 38	0.2%

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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
	(in thousands)			
Direct external expenses:				
Clinical programs	$ 5,494	$ 6,791	$ 12,314	$ 13,660
Pre-clinical activities	776	368	1,548	727
All other research and development expenses	1,101	915	2,308	1,745
	$ 7,371	$ 8,074	$ 16,170	$ 16,132

Clinical programs expenses decreased primarily due to timing of activities associated with the NAVIGATE clinical trial. Pre-clinical activities increased primarily due to non-clinical activities associated with the NASH cirrhosis program. Other research and development expenses increased primarily due to additional employees hired after the first quarter of 2022.

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 June 30,		Six Months Ended June 30,		2023 as Compared to 2022			
					Three Months		Six Months	
	2023	2022	2023	2022	$ Change	% Change	$ Change	% Change
	(In thousands, except %)							
General and administrative	$ 1,632	$ 1,588	$ 3,175	$ 3,465	$ 44	3%	$ (290)	(8)%

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 decrease in general and administrative expenses for the six-months ended June 30, 2023 as compared to the same period in 2022 is due to a decrease non-cash stock based compensation expenses of approximately $351,000.

Other Income and Expense

During the three and six months ended June 30, 2023 and 2022, other income and expense consisted of interest income, interest expense and amortization of debt discounts on convertible notes payable and convertible line of credit and the change in fair value of derivatives related to the convertible notes payable. Interest income increased in 2023 due to higher interest rates and cash on deposit. Interest expense and amortization of debt discounts increased due to borrowings on the convertible line of credit. The fair value of derivatives vary based on variables including the Company's stock price.

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 June 30, 2023, we raised a net total of $264.5 million from these offerings. At June 30, 2023, the Company had $18.0 million of unrestricted cash and cash equivalents in addition to $30 million remaining available under a line of credit provided by our chairman available to fund future operations. The Company believes there is sufficient cash to fund currently planned operations at least through December 31, 2024. We will require more cash to fund our operations after December 31, 2024 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. 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.

Net cash used in operations increased by $5,156,000 to $20,626,000 for the six months ended June 30, 2023, as compared to $15,470,000 for the six months ended June 30, 2022. Cash operating expenses increased principally due to the preparations and expenses related to our NAVIGATE clinical trial with belapectin and the hiring of additional employees.

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 and income taxes. For a more detailed discussion of our critical accounting policies, please refer to our 2022 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 June 30, 2023, 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 June 30, 2023, 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, 2022, 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	
101.INS	Inline XBRL Instance Document** (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document).	

Exhibit Number	Description of Document	Note Reference
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.
** Furnished herewith and not “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

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 August 14, 2023.

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: August 14, 2023

/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: August 14, 2023

/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 June 30, 2023 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: August 14, 2023

/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 June 30, 2023 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: August 14, 2023

/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.