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

FORM 10-Q

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

For the quarterly period ended September 30, 2019

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

For the transition period from _____ to _____

Commission File No. 001-31791

GALECTIN THERAPEUTICS INC.

Nevada
(State or other jurisdiction
of incorporation)

04-3562325
(I.R.S. Employer
Identification No.)

**4960 Peachtree Industrial Blvd.,
Suite 240, Norcross, GA**
(Address of Principal Executive Offices)

30071
(Zip Code)

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

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

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---------------------|----------------------|--|
| Common Stock | GALT | Nasdaq |

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 (§232.05 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. 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 | <input type="checkbox"/> | Accelerated Filer | <input checked="" type="checkbox"/> |
| Non-Accelerated Filer | <input type="checkbox"/> | Smaller reporting company | <input checked="" type="checkbox"/> |
| Emerging growth company | <input type="checkbox"/> | | |

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

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

The number of shares outstanding of the registrant's common stock as of November 6, 2019 was 56,886,059.

**GALECTIN THERAPEUTICS INC.
INDEX TO FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2019**

| | <u>PAGE</u> |
|--|-------------|
| PART I — FINANCIAL INFORMATION | |
| ITEM 1. Unaudited Condensed Consolidated Financial Statements (unaudited) | |
| Condensed Consolidated Balance Sheets as of September 30, 2019 and December 31, 2018 | 3 |
| Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2019 and 2018 | 4 |
| Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2019 and 2018 | 5 |
| Condensed Consolidated Statements of Changes in Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit) for the Three Months and Nine Months ended September 30, 2019 and 2018 | 6 |
| Notes to Unaudited Condensed Consolidated Financial Statements | 9 |
| ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations | 14 |
| ITEM 3. Quantitative and Qualitative Disclosures about Market Risk | 24 |
| ITEM 4. Controls and Procedures | 24 |
| PART II — OTHER INFORMATION | |
| ITEM 1. Legal Proceedings | 25 |
| ITEM 1A. Risk Factors | 25 |
| ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds | 25 |
| ITEM 3. Defaults Upon Senior Securities | 25 |
| ITEM 4. Mine Safety Disclosures | 25 |
| ITEM 5. Other Information | 25 |
| ITEM 6. Exhibits | 25 |
| SIGNATURES | 26 |

[Table of Contents](#)
**GALECTIN THERAPEUTICS INC.
CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)**

| | September 30, 2019 | December 31, 2018 |
|---|-----------------------|----------------------|
| | (in thousands) | |
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 50,337 | \$ 8,253 |
| Prepaid expenses and other current assets | 136 | 579 |
| Total current assets | <u>50,473</u> | <u>8,832</u> |
| Other | 287 | 174 |
| Total assets | <u>\$ 50,760</u> | <u>\$ 9,006</u> |
| LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT) | | |
| Current liabilities: | | |
| Accounts payable | \$ 354 | \$ 297 |
| Accrued expenses and other | 862 | 1,512 |
| Accrued dividends payable | — | 299 |
| Total current liabilities | <u>1,216</u> | <u>2,108</u> |
| Other liabilities | 62 | — |
| Total liabilities | <u>1,278</u> | <u>2,108</u> |
| Commitments and contingencies (Note 10) | | |
| Series C super dividend redeemable convertible preferred stock; 1,000 shares authorized, 176 shares issued and outstanding at September 30, 2019 and December 31, 2018, redemption value: \$8,678,000, liquidation value: \$1,760,000 at September 30, 2019 | 1,723 | 1,723 |
| Stockholders' equity: | | |
| Undesignated stock, \$0.01 par value; 20,000,000 shares authorized, 20,000,000 designated at September 30, 2019 and December 31, 2018, respectively | — | — |
| Series A 12% convertible preferred stock; 1,742,500 shares authorized, 1,327,500 issued and outstanding at September 30, 2019 and December 31, 2018, liquidation value \$1,327,500 at September 30, 2019 | 537 | 537 |
| Series B-1 12% convertible preferred stock; 900,000 shares authorized, 0 and 900,000 issued and outstanding at September 30, 2019 and December 31, 2018 | — | 1,761 |
| Series B-2 12% convertible preferred stock; 2,100,000 shares authorized, 0 and 2,100,000 issued and outstanding at September 30, 2019 and December 31, 2018 | — | 3,697 |
| Series B-3 8% convertible preferred stock; 2,508,000 shares authorized, 0 and 2,508,000 issued and outstanding at September 30, 2019 and December 31, 2018 | — | 1,224 |
| Common stock, \$0.001 par value; 100,000,000 shares authorized at September 30, 2019 and December 31, 2018, 56,658,859 and 41,190,905 issued and outstanding at September 30, 2019 and December 31, 2018, respectively | 56 | 41 |
| Additional paid-in capital | 258,357 | 194,130 |
| Retained deficit | (211,191) | (196,215) |
| Total stockholders' equity | <u>47,759</u> | <u>5,175</u> |
| Total liabilities, redeemable convertible preferred stock and stockholders' equity | <u>\$ 50,760</u> | <u>\$ 9,006</u> |

See notes to unaudited condensed consolidated financial statements.

[Table of Contents](#)**GALECTIN THERAPEUTICS INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)**

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|--|--|------------|--|-------------|
| | 2019 | 2018 | 2019 | 2018 |
| | (in thousands, except per share data) | | (in thousands, except per share data) | |
| Operating expenses: | | | | |
| Research and development | \$ 1,503 | \$ 1,505 | \$ 3,671 | \$ 5,279 |
| General and administrative | 1,360 | 1,175 | 4,579 | 5,338 |
| Total operating expenses | 2,863 | 2,680 | 8,250 | 10,617 |
| Total operating loss | (2,863) | (2,680) | (8,250) | (10,617) |
| Other income (expense): | | | | |
| Interest income | 101 | 15 | 158 | 23 |
| Interest expense | (22) | (87) | (65) | (256) |
| Total other income (expense) | 79 | (72) | 93 | (233) |
| Net loss | \$ (2,784) | \$ (2,752) | \$ (8,157) | \$ (10,850) |
| Preferred stock dividends | (35) | (294) | (198) | (848) |
| Warrant modification (Note 9) | — | — | (6,622) | — |
| Net loss applicable to common stockholders | \$ (2,819) | \$ (3,046) | \$ (14,977) | \$ (11,698) |
| Net loss per common share — basic and diluted | \$ (0.05) | \$ (0.07) | \$ (0.27) | \$ (0.30) |
| Weighted average common shares outstanding — basic and diluted | 56,631 | 40,921 | 55,494 | 38,822 |

See notes to unaudited condensed consolidated financial statements.

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

| | Nine Months Ended | |
|--|--------------------------|------------------|
| | September 30, | |
| | 2019 | 2018 |
| | (in thousands) | |
| CASH FLOWS FROM OPERATING ACTIVITIES: | | |
| Net loss | \$ (8,157) | \$(10,850) |
| Adjustments to reconcile net loss to net cash flows from operating activities: | | |
| Stock-based compensation expense | 1,269 | 3,293 |
| Amortization of right to use lease asset | 26 | — |
| Issuance of common stock for services | — | 11 |
| Non-cash interest expense | 65 | 256 |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other assets | 239 | 372 |
| Accounts payable and accrued expenses | (531) | (1,254) |
| Net cash from operating activities | <u>(7,089)</u> | <u>(8,172)</u> |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | |
| Net proceeds from issuance of common stock and exercise of warrants | 49,567 | 15,255 |
| Payment of preferred stock dividends | (394) | — |
| Net cash flows from financing activities | <u>49,173</u> | <u>15,255</u> |
| NET INCREASE IN CASH AND CASH EQUIVALENTS | 42,084 | 7,083 |
| CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD | 8,253 | 3,053 |
| CASH AND CASH EQUIVALENTS, END OF PERIOD | <u>\$50,337</u> | <u>\$ 10,136</u> |
| NONCASH FINANCING ACTIVITIES: | | |
| Payment of preferred stock dividends in common stock | \$ 102 | \$ 915 |

See notes to unaudited condensed consolidated financial statements.

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

| | Series C Super Dividend Redeemable Convertible Preferred Stock | |
|--------------------------------------|---|-----------------|
| | Number of Shares | Amount |
| Balance at December 31, 2017 | 176 | \$ 1,723 |
| Balance at September 30, 2018 | 176 | \$ 1,723 |
| Balance at December 31, 2018 | 176 | \$ 1,723 |
| Balance at September 30, 2019 | 176 | \$ 1,723 |

GALECTIN THERAPEUTICS INC.
CONSOLIDATED STATEMENTS OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS'
EQUITY (DEFICIT) — (Continued)

For the Three Months Ended September 30, 2019 and 2018
(amounts in thousands except share data)

| | Series A 12% Convertible Preferred Stock | | Series B-1 12% Convertible Preferred Stock | | Series B-2 12% Convertible Preferred Stock | | Series B-3 8% Convertible Preferred Stock | | Common Stock | | Additional Paid-In Capital | Retained Deficit | Total Stockholders' Equity (Deficit) |
|---|--|---------------|--|-----------------|--|-----------------|---|-----------------|------------------------|--------------|----------------------------------|---------------------|---|
| | Number of Shares | Amount | Number of Shares | Amount | Number of Shares | Amount | Number of Shares | Amount | Number of Shares | Amount | | | |
| Balance at June 30, 2018 | 1,352,500 | \$ 547 | 900,000 | \$ 1,761 | 2,100,000 | \$ 3,697 | 2,508,000 | \$ 1,224 | 40,628,183 | \$ 41 | \$ 190,602 | \$(189,820) | \$ 8,052 |
| Series A 12% convertible preferred stock dividend | | | | | | | | | 13,351 | | 81 | (40) | (41) |
| Series B-1 12% convertible preferred stock dividend | | | | | | | | | 8,956 | | 54 | (54) | |
| Series B-2 12% convertible preferred stock dividend | | | | | | | | | 20,897 | | 126 | (126) | |
| Series B-3 8% convertible preferred stock dividend | | | | | | | | | 8,291 | | 50 | (50) | |
| Series C super dividend redeemable convertible preferred stock dividend | | | | | | | | | 8,495 | | 51 | (26) | (26) |
| Issuance of common stock | | | | | | | | | 51,100 | | 361 | | 5,242 |
| Issuance of common stock from exercise of warrants and options | | | | | | | | | 397,237 | | 854 | | 854 |
| Issuance of common stock for services | | | | | | | | | 228 | | 1 | | 1 |
| Stock-based compensation expense | | | | | | | | | | | 663 | | 663 |
| Net loss | | | | | | | | | | | | (2,752) | (2,752) |
| Balance at September 30, 2018 | 1,352,500 | \$ 547 | 900,000 | \$ 1,761 | 2,100,000 | \$ 3,697 | 2,508,000 | \$ 1,224 | 41,136,738 | \$ 41 | \$ 192,843 | \$(192,868) | \$ 7,245 |
| Balance at June 30, 2019 | 1,327,500 | \$ 537 | — | \$ — | — | \$ — | — | \$ — | 56,591,278 | \$ 56 | \$ 257,678 | \$(208,373) | \$ 49,898 |
| Series A 12% convertible preferred stock dividend | | | | | | | | | 13,275 | | 49 | (9) | 40 |
| Series C super dividend redeemable convertible preferred stock dividend | | | | | | | | | 14,280 | | 53 | (25) | 28 |
| Issuance of common stock | | | | | | | | | 40,026 | | 163 | | 163 |
| Stock-based compensation expense | | | | | | | | | | | 414 | | 414 |
| Net loss | | | | | | | | | | | | (2,784) | (2,784) |
| Balance at September 30, 2019 | 1,327,500 | \$ 537 | — | \$ — | — | \$ — | — | \$ — | 56,658,859 | \$ 56 | \$ 258,357 | \$(211,191) | \$ 47,759 |

See notes to consolidated financial statements.

[Table of Contents](#)

GALECTIN THERAPEUTICS INC.
CONSOLIDATED STATEMENTS OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS'
EQUITY (DEFICIT) — (Continued)

For the Nine Months Ended September 30, 2019 and 2018

(amounts in thousands except share data)

| | Series A 12% Convertible Preferred Stock | | Series B-1 12% Convertible Preferred Stock | | Series B-2 12% Convertible Preferred Stock | | Series B-3 8% Convertible Preferred Stock | | Common Stock | | Additional Paid-In Capital | Retained Deficit | Total Stockholders' Equity (Deficit) |
|---|--|---------------|--|-----------------|--|-----------------|---|-----------------|------------------------|--------------|----------------------------------|---------------------|---|
| | Number of Shares | Amount | Number of Shares | Amount | Number of Shares | Amount | Number of Shares | Amount | Number of Shares | Amount | | | |
| Balance at | | | | | | | | | | | | | |
| December 31, 2017 | 1,377,500 | \$ 557 | 900,000 | \$ 1,761 | 2,100,000 | \$ 3,697 | 2,508,000 | \$ 1,224 | 35,789,388 | \$ 36 | \$ 173,363 | \$(181,168) | \$ (530) |
| Series A 12% convertible preferred stock dividend | | | | | | | | | 27,126 | | 147 | (106) | 41 |
| Series B-1 12% convertible preferred stock dividend | | | | | | | | | 27,835 | | 155 | (155) | |
| Series B-2 12% convertible preferred stock dividend | | | | | | | | | 64,948 | | 363 | (363) | |
| Series B-3 8% convertible preferred stock dividend | | | | | | | | | 25,769 | | 144 | (144) | |
| Series C super dividend redeemable convertible preferred stock dividend | | | | | | | | | 20,394 | | 107 | (82) | 25 |
| Issuance of common stock | | | | | | | | | 669,714 | 1 | 5,602 | | 5,603 |
| Issuance of common stock from exercise of warrants and options | | | | | | | | | 4,504,424 | 4 | 9,647 | | 9,651 |
| Issuance of common stock for services | | | | | | | | | 2,883 | | 12 | | 12 |
| Issuance of common stock from Series A conversion | (25,000) | (10) | | | | | | | 4,257 | | 10 | | |
| Stock-based compensation expense | | | | | | | | | | | 3,293 | | 3,293 |
| Net loss | | | | | | | | | | | | (10,850) | (10,850) |
| Balance at | | | | | | | | | | | | | |
| September 30, 2018 | <u>1,352,500</u> | <u>\$ 547</u> | <u>900,000</u> | <u>\$ 1,761</u> | <u>2,100,000</u> | <u>\$ 3,697</u> | <u>2,508,000</u> | <u>\$ 1,224</u> | <u>41,136,738</u> | <u>\$ 41</u> | <u>\$ 192,843</u> | <u>\$(192,868)</u> | <u>\$ 7,245</u> |
| Balance at | | | | | | | | | | | | | |
| December 31, 2018 | 1,327,500 | \$ 537 | 900,000 | \$ 1,761 | 2,100,000 | \$ 3,697 | 2,508,000 | \$ 1,224 | 41,190,905 | \$ 41 | \$ 194,130 | \$(196,215) | \$ 5,175 |
| Series A 12% convertible preferred stock dividend | | | | | | | | | 13,275 | | 49 | (89) | (40) |
| Series B-1 12% convertible preferred stock dividend | | | | | | | | | | | | (6) | (6) |
| Series B-2 12% convertible preferred stock dividend | | | | | | | | | | | | (15) | (15) |
| Series B-3 8% convertible preferred stock dividend | | | | | | | | | | | | (9) | (9) |
| Series C super dividend redeemable convertible preferred stock dividend | | | | | | | | | 14,280 | | 53 | (78) | (25) |
| Issuance of common stock | | | | | | | | | 10,923,420 | 10 | 46,907 | | 46,917 |
| Conversion of Series B Convertible Preferred to common | | | (900,000) | (1,761) | (2,100,000) | (3,697) | (2,508,000) | (1,224) | 3,789,346 | 4 | 6,678 | | |
| Issuance of common stock for exercise of warrants and options | | | | | | | | | 727,633 | 1 | 2,649 | | 2,650 |
| Warrant modification (Note 9) | | | | | | | | | | | 6,622 | (6,622) | |
| Stock-based compensation expense | | | | | | | | | | | 1,269 | | 1,269 |
| Net loss | | | | | | | | | | | | (8,157) | (8,157) |
| Balance at | | | | | | | | | | | | | |
| September 30, 2019 | <u>1,327,500</u> | <u>\$ 537</u> | <u>—</u> | <u>\$ —</u> | <u>—</u> | <u>\$ —</u> | <u>—</u> | <u>\$ —</u> | <u>56,658,859</u> | <u>\$ 56</u> | <u>\$ 258,357</u> | <u>\$(211,191)</u> | <u>\$ 47,759</u> |

**GALECTIN THERAPEUTICS INC.
NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

1. Basis of Presentation

Galectin Therapeutics Inc. (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, skin diseases and cancer. These candidates are based on the Company’s targeting of galectin proteins which are key mediators of biologic and pathologic function. These compounds also may have application for drugs to treat other diseases and chronic health conditions.

The unaudited condensed consolidated financial statements as reported in this Quarterly Report on Form 10-Q reflect all adjustments which are, in the opinion of management, necessary to present fairly the financial position of the Company as of September 30, 2019 and the results of its operations for the three and nine months ended September 30, 2019 and 2018 and its cash flows for the nine months ended September 30, 2019 and 2018. 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, 2018 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, 2018.

The Company has operated at a loss since its inception and has had no significant revenues. The Company anticipates that losses will continue for the foreseeable future. At September 30, 2019, the Company had \$50.3 million of unrestricted cash and cash equivalents available to fund future operations. The Company believes there is sufficient cash, including availability of the line of credit (see Note 3), to fund currently planned operations at least through December 31, 2020. We expect that we will require more cash to fund our operations after December 31, 2020 and believe we will be able to obtain additional financing. The currently planned operations include estimated costs related to a planned clinical trial, through December 31, 2020.

The costs of the trial and general overhead during its next planned clinical trial are estimated to be approximately \$100 to \$115 million; however, the costs and timing of such trial are not yet completely finalized. These costs will require additional funding. There can be no assurance that we will be successful in obtaining financing to support our operations beyond December 31, 2020 or, if available, that any such financing will be on terms acceptable to us. Accordingly, based on the forecasts and estimates underlying our current operating plan, the financial statements do not currently include any adjustments that might be necessary if we are unable to continue as a going concern.

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

Recently Adopted Accounting Standards

The Financial Accounting Standards Board (the “FASB”) issued Accounting Standards Update (“ASU”) No. 2016-02, *Leases (Topic 842)*, amended by ASU 2018-11, *Leases (Topic 842): Targeted Improvements*. The new guidance requires a lessee to recognize assets and liabilities for all leases with lease terms of more than 12 months and provide additional disclosures. The ASU requires adoption using a modified retrospective transition approach with either 1) periods prior to the adoption date being recast or 2) a cumulative-effect adjustment recognized to the opening balance of retained earnings on the adoption date with prior periods not recast. We adopted this standard using a modified retrospective transition approach on January 1, 2019 however we only have one lease related to our office space and it was amended effective January 1, 2019. Therefore, no cumulative-effect adjustment approach was required. See Note 11 for the financial position impact and additional disclosures.

2. Accrued Expenses and Other

Accrued expenses consist of the following:

| | September 30, 2019 | December 31, 2018 |
|--|-----------------------|----------------------|
| | (in thousands) | |
| Legal and accounting fees | \$ 194 | \$ 45 |
| Accrued compensation | 630 | 1,294 |
| Lease liability | 37 | — |
| Accrued research and development costs and other | 1 | 173 |
| Total | \$ 862 | \$ 1,512 |

3. Line of Credit

On December 19, 2017, the Company entered into a \$10 million Line of Credit arrangement with Richard E. Uihlein, a director and shareholder who had an approximate 7% ownership interest in the Company on a fully-diluted basis at December 31, 2017. Originally, borrowings may be made by the Company through December 31, 2018. Borrowings bear interest at the Applicable Federal Rate for short term loans published by the Internal Revenue Service (2.7% in January 2019). All borrowings and interest were originally due on December 31, 2019 but could be prepaid without penalty. In connection with the Line of Credit agreement, the Company issued to Mr. Uihlein warrants to purchase 1 million shares of the Company's common stock for \$5 per share. Half of the warrants vested at closing of the Line of Credit and the other half vest ratably with borrowings under the agreement. There have been no borrowings under the Line of Credit to date.

On December 20, 2018, the Line of Credit arrangement was extended for one year for both borrowings and maturity. At the time of the conversion of the Series B Convertible Preferred stock into common stock (See Note 9), on January 11, 2019, the Line of Credit arrangement was extended for an additional two years for both borrowings and maturity. After the second amendment to the Line of Credit arrangement, borrowings may be made through December 31, 2021 with repayment due on December 31, 2022. There was no additional consideration or benefits provided to Mr. Uihlein for any of the extensions of the Line of Credit.

The fair value of the 500,000 warrants vested at closing in December 2017 was \$696,000 at the date of issuance based on the following assumptions: an expected life of 7 years, volatility of 98%, risk free interest rate of 2.05% and zero dividends. The fair value of the vested warrants was recorded in other current assets and other assets (non-current) as a deferred financing cost and were to be amortized on a straight-line basis from December 19, 2017 through December 31, 2019. The remaining unamortized balance of the deferred financing cost on January 11, 2019 was adjusted to be recorded as expense on a straight-line basis through December 31, 2022. Amortization for the nine months ended June 30, 2019 and 2018 of \$65,000 and \$256,000, respectively, was recorded as interest expense. In May 2019, Mr. Uihlein exercised the 500,000 vested warrants and the Company received the proceeds of \$2,500,000.

The fair value of warrants that vest in the future based on borrowings will be computed when those borrowings occur and amortized over the remaining period through December 31, 2022 reflecting the second extension.

4. Stock-Based Compensation

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|-------------------------------------|---------------|------------------------------------|-----------------|
| | 2019 | 2018 | 2019 | 2018 |
| Research and development | \$ 74 | \$ 252 | \$ 244 | \$ 1,413 |
| General and administrative | 340 | 411 | 1,025 | 1,880 |
| Total stock-based compensation expense | \$ 414 | \$ 663 | \$ 1,269 | \$ 3,293 |

[Table of Contents](#)

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, 2018 through September 30, 2019:

| | Shares | Weighted Average Exercise Price |
|---------------------------------|------------------|---------------------------------|
| Outstanding, December 31, 2018 | 2,713,979 | \$ 4.67 |
| Granted | 530,000 | 4.72 |
| Exercised | (142,543) | 1.79 |
| Options forfeited/cancelled | (39,098) | 2.09 |
| Outstanding, September 30, 2019 | <u>3,062,338</u> | <u>\$ 4.85</u> |

As of September 30, 2019, there was \$909,000 of unrecognized compensation related to 468,750 unvested options, which is expected to be recognized over a weighted-average period of approximately 0.9 years. The weighted-average grant date fair value for options granted during the nine months ended September 30, 2019 was \$3.83. The Company granted 530,000 stock options in January 2019.

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

| | Nine Months Ended September 30, 2019 | Nine Months Ended September 30, 2018 |
|---|--------------------------------------|--------------------------------------|
| Risk-free interest rate | 2.68% | 2.47% |
| Expected life of the options | 6 years | 5.7 years |
| Expected volatility of the underlying stock | 104% | 104% |
| Expected dividend rate | 0% | 0% |

5. Common Stock Warrants

The following table summarizes the common stock warrant activity from December 31, 2018 through September 30, 2019:

| | Shares | Weighted Average Exercise Price |
|---------------------------------|-------------------|---------------------------------|
| Outstanding, December 31, 2018 | 10,647,026 | \$ 3.48 |
| Granted | 2,622,154 | 7.00 |
| Exercised | (585,090) | 4.71 |
| Forfeited/cancelled | (143,411) | 3.00 |
| Outstanding, September 30, 2019 | <u>12,540,679</u> | <u>\$ 4.22</u> |

6. Fair Value of Financial Instruments

The Company has certain financial assets and liabilities recorded at fair value. Fair values determined by Level 1 inputs utilize observable data such as quoted prices in active markets. Fair values determined by Level 2 inputs utilize data points other than quoted prices in active markets that are observable either directly or indirectly. Fair values determined by Level 3 inputs utilize unobservable data points in which there is little or no market data, which require the reporting entity to develop its own assumptions. The carrying amounts reflected in the consolidated balance sheets for cash equivalents, accounts payable and accrued expenses approximate their carrying value due to their short-term nature. There were no level 2 or level 3 assets or liabilities at September 30, 2019 or December 31, 2018.

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.

[Table of Contents](#)

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

| | September 30, 2019 (shares) | September 30, 2018 (shares) |
|--|--------------------------------|--------------------------------|
| Warrants to purchase shares of common stock | 12,540,679 | 10,697,026 |
| Options to purchase shares of common stock | 3,062,338 | 3,764,648 |
| Shares of common stock issuable upon conversion of preferred stock | 514,602 | 4,308,115 |
| | <u>16,117,619</u> | <u>18,769,789</u> |

8. Common Stock

2017 At Market Issuance of Common Stock

On May 19, 2017, the Company entered into an At Market Issuance Sales Agreement (the “2017 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 \$30.0 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 2017 At Market Agreement. During the nine months ended September 30, 2019, the Company issued 435,259 shares of its common stock under the 2017 At Market Agreement for net proceeds of approximately \$2,028,000.

For the nine months ended September 30, 2019, the Company has issued a total of 27,555 shares of common stock for dividends on Series A and Series C Preferred Stock. For the nine months ended September 30, 2018, the Company has issued a total of 166,072 shares of common stock for dividends on Series A, Series B and Series C Preferred Stock.

Rights Offering

On May 23, 2019, the Company completed an offering of common stock and warrants to its shareholders of record as of April 29, 2019. In the offering, the Company received approximately \$44.9 million for the issuance of 10,488,161 shares of common stock and warrants which may be exercised for 2,622,154 shares of common stock. The warrants may be exercised at \$7.00 per share of common stock and expire on May 23, 2026. The warrants were valued at approximately \$8.2 million as of the issuance, using the closing price of \$4.01, a life of 7 years, a volatility of 101% and a risk-free interest rate of 2.33%. Based upon the Company’s analysis of the criteria contained in ASC Topic 815-40, “Derivatives and Hedging — Contracts in Entity’s Own Equity” the Company has determined that warrants issued in connection with this financing transaction were not derivative liabilities and therefore, were recorded as additional paid-in capital.

9. Preferred Stock Conversion into Common Stock

On January 11, 2019, 10X Fund L.P. (“10X Fund”), converted all of its Series B Convertible Preferred Stock into Common Stock of Galectin Therapeutics. Pursuant to the terms of the conversion, as of January 11, 2019, 10X Fund converted 5,508,000 shares of its Series B-1, B-2 and B-3 Convertible Preferred Stock into 3,789,346 shares of Common Stock of Galectin Therapeutics. All special voting rights and protective provisions that previously benefited the Series B Preferred Stock were extinguished by the conversion to Common Stock.

In connection with the conversion of the Series B Preferred Stock, the Company extended by five years the exercise date of warrants for 3,579,642 shares of Common Stock issued by the Company in connection with sale of the Series B-1 and Series B-2 Preferred Stock. Before the extension, the warrants had various expiration dates in 2019 and 2020. The warrant amendments give 10X Fund the right to nominate one director to the Company’s board of directors. Previously, under the now extinguished voting rights of the Series B Preferred, 10X Fund had the right to name two directors and nominate an additional three directors.

The Company has accounted for the modified terms of the warrants pursuant to ASC 718, Stock Compensation, whereby the Company has recognized a charge for the change in fair value of the warrants immediately before and immediately after the modification. In January 2019, the Company recognized a one-time non-cash charge of \$6,622,000 related to the extension of the 3,579,642 warrants. The following assumptions were used to value the extension of the warrants immediately before and immediately after the modification: a) immediately before the modification — an expected life range of 0.09 to 1.33 years, volatility of 98%, risk free interest rate range of 2.4% to 2.59% and zero dividends and; b) immediately following the modification — an expected life range of 5.09 to 6.33 years, volatility range of 106%, risk free interest rate range of 2.56% to 2.6% and zero dividends.

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.

11. Leases

The Company has one operating lease for its office space which was amended effective January 1, 2019 for a term of 38 months with no residual value guarantees or material restrictive covenants. The amended lease provided for free rent for the first two months of the lease and continues the security deposit of \$6,000. In addition to base rental payments included in the contractual obligations table below, the Company is responsible for our pro-rata share of the operating expenses for the building. Our lease cost for the nine-month period ended September 30, 2019 was \$33,000 and is included in general and administrative expenses. As of September 30, 2019, the right to use lease asset consisted of \$92,000 and is included in other assets. Also, at September 30, 2019, current lease liability of \$37,000 is included in accrued expenses and other and noncurrent lease liability of \$62,000 is in other liabilities.

Maturity of operating lease as of September 30, 2019 in thousands:

| | |
|----------------------------------|--------------|
| 2019 | \$ 12 |
| 2020 | 47 |
| 2021 | 48 |
| 2022 | 8 |
| Total | 115 |
| Less imputed interest | 16 |
| Present value of lease liability | <u>\$ 99</u> |

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

12. Galectin Sciences LLC

In January 2014, we created Galectin Sciences, LLC (the "LLC" or "Investee"), a collaborative joint venture co-owned by SBH Sciences, Inc. ("SBH"), to research and develop small organic molecule inhibitors of galectin-3 for oral administration. The LLC was initially capitalized with a \$400,000 cash investment to fund future research and development activities, which was provided by the Company, and specific in-process research and development ("IPR&D") contributed by SBH. The estimated fair value of the IPR&D contributed by SBH, on the date of contribution, was \$400,000. Initially, the Company and SBH each had a 50% equity ownership interest in the LLC, with neither party having control over the LLC. Accordingly, from inception through the fourth quarter of 2014, the Company accounted for its investment in the LLC using the equity method of accounting. Under the equity method of accounting, the Company's investment was initially recorded at cost with subsequent adjustments to the carrying value to recognize additional investments in or distributions from the Investee, as well as the Company's share of the Investee's earnings, losses and/or changes in capital. The estimated fair value of the IPR&D contributed to the LLC was immediately expensed upon contribution as there was no alternative future use available at the point of contribution. The operating agreement provides that if either party does not desire to contribute its equal share of funding required after the initial capitalization, then the other party, providing all of the funding, will have its ownership share increased in proportion to the total amount contributed from inception. In the fourth quarter of 2014, after the LLC had expended the \$400,000 in cash, SBH decided not to contribute its share of the funding required. Since then, the Company has contributed a total of \$1,908,000, including \$105,000 for the nine months ended September 30, 2019, for expenses of the LLC. Since the end of 2014, SBH has contributed \$158,000 for expenses in the LLC. As of September 30, 2019, the Company's ownership percentage in the LLC was 80.5%. 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, 2020; 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, including manufacturing of drug product, 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, and
- 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 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, severe skin disease, and cancer. 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 galectins have a demonstrated role in the pathogenesis of a given disease. We focus on diseases with serious, life-threatening consequences to patients and those where current treatment options are limited. 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 a program becomes advanced and requires significant additional resources.

Our lead galectin-3 inhibitor is GR-MD-02, which has been demonstrated in preclinical models to reverse liver fibrosis and cirrhosis. GR-MD-02 has the potential to treat many diseases due to galectin-3's involvement in multiple key biological pathways such as fibrosis, immune cell function and immunity, cell differentiation, cell growth, and apoptosis (cell death). The importance of galectin-3 in the fibrotic process is supported by experimental evidence. Animals with the gene responsible for galectin-3 "knocked-out" can no longer develop fibrosis in response to experimental stimuli compared to animals with an intact galectin-3 gene. Galectin Therapeutics Inc. is using its galectin-3 inhibitor to treat advanced liver fibrosis and liver cirrhosis in NASH (non-alcoholic steatohepatitis) patients. We have completed two Phase 1 clinical studies, a Phase 2 clinical study in NASH patients with advanced fibrosis (NASH-FX) and a second Phase 2B clinical trial in NASH patients with well compensated cirrhosis. We announced, in December 2017 top line results from our Phase 2b study in NASH patients with cirrhosis (NASH-CX) and results of an End of Phase 2 meeting with the FDA in May 2018 that provided direction on potentially acceptable end points for a Phase 3 trial. The latter was confirmed in a Type C meeting with FDA in February 2019. Thereafter, the Company with its external NASH consultants designed a Phase 3 study that was sent to various contract research organizations (CROs) for their input on feasibility, timing costs and other important considerations. At the request of United States Food and Drug Administration (FDA), the trial protocol and answers to questions raised by FDA at the February meeting was submitted as a Type C (Written Response Only) request to FDA on July 17, 2019; this response sought FDA feedback and agreement with regards to the proposed clinical program.

Comments from FDA were received in late October 2019 and are being evaluated for incorporation into the final version of the clinical trial protocol by the Company in conjunction with its hepatology consultants and medical and other experts at Covance, its chosen CRO. Further information is described below under "NASH-RX Trial".

NASH cirrhosis is a progressive disease, currently not treatable and ultimately may result in liver failure that has poor prognosis and no effective, approved medical therapies other than liver transplant. Galectin-3 expression is highly increased in the liver of patients with liver fibrosis and liver cirrhosis. We believe that our galectin-3 inhibitor, by reducing galectin-3 at the cellular level, ultimately showing a strong anti-fibrotic potential may provide a novel treatment for various forms of liver fibrosis.

We endeavor to leverage our scientific and product development expertise as well as established relationships with outside sources to achieve cost-effective and efficient drug development. These outside sources, amongst others, provide us with expertise in preclinical models, pharmaceutical development, toxicology, clinical trial operations, pharmaceutical manufacturing, sophisticated physical and chemical characterization, and commercial development. We also have established several collaborative scientific discovery programs with leading experts in carbohydrate chemistry and characterization. These discovery programs are generally aimed at the targeted development of new carbohydrate molecules that bind galectin proteins and offer alternative options to larger market segments in our primary disease indications. We also have established through Galectin Sciences LLC, a discovery program aimed at the targeted development of small molecules (generally, non-carbohydrate) that bind galectin proteins and may afford options for alternative means of drug delivery (e.g., oral) and as a result expand the potential uses of our galectin-3 inhibitor compounds. We are also pursuing a development pathway to clinical enhancement and commercialization for our lead compounds in immuno-oncology for cancer therapy. However, our clinical development efforts are focused on both liver fibrosis and fatty liver disease as represented by a Phase 2 clinical trial in NASH-cirrhosis which reported top line data in December 2017 and on planning for subsequent clinical studies. All of our proposed products are presently in development, including pre-clinical and clinical trials.

Our Drug Development Programs

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

We have one new proprietary chemical entity (NCE) in development, GR-MD-02, which has shown promise in preclinical and early clinical studies in treatment of fibrosis, severe skin disease, and in cancer therapy. Currently we are focusing on development of GR-MD-02, belapectin, intended to be used in the treatment of liver fibrosis associated with fatty liver disease (NASH) and more specifically in NASH cirrhosis. We have also leveraged our relationships with well-known investigators to demonstrate clinical effects of GR-MD-02 in treating moderate to severe plaque psoriasis, severe atopic dermatitis, and in cancer therapy in combination with immune-system modifying agent(s). GR-MD-02 is a proprietary, patented compound derived from natural, readily available, plant-based starting materials, which, following chemical processing, exhibits the properties of binding to and inhibiting galectin-3 proteins.

Table of Contents

A second NCE, GM-CT-01 is a proprietary, patented compound that is made from a completely different starting source plant material and also binds and inhibits galectin proteins. Previously in clinical development for cancer indications, GM-CT-01 compound has been explored in limited other preclinical studies.

Our product pipeline is shown below:

| Indication | Drug | Status |
|--|-----------------------|--|
| Fibrosis NASH with Advanced Fibrosis: NASH-CX trial and NASH-FX trial | GR-MD-02 | IND submitted January 2013. Results from the Phase 1 clinical trial were reported in 2014, with final results reported in January 2015. End of Phase 1 meeting held with FDA in 2014. Two Phase 2 clinical trials were designed. The NASH FX trial was designed for patients with advanced fibrosis but not cirrhosis. The NASH FX trial top line data was reported in September 2016 The NASH CX trial, was designed for patients with well compensated cirrhosis. The NASH CX trial top line data was reported in December 2017. End of Phase 2 (EOP2) meeting held with FDA in May 2018. |
| NASH – RX | | Based on recent FDA feedback, the NASH-RX trial is being designed as an adaptive Phase 3 trial for NASH patients with well compensated cirrhosis. An interim analysis will be incorporated to confirm previous Phase 2 data, and end of study endpoints will include a composite clinical endpoint including progression to varices requiring treatment (large varices or varices with a red wale). Comments from FDA were received in late October 2019 and are still being evaluated by the Company in conjunction with its hepatology consultants and medical and other experts at Covance, its chosen CRO. Further information is described under “NASH-RX Trial” below. |
| Lung Fibrosis | GR-MD-02 | In pre-clinical development |
| Kidney Fibrosis | GR-MD-02 | In pre-clinical development |
| Cardiac and Vascular Fibrosis | GR-MD-02 and GM-CT-01 | In pre-clinical development |
| Cancer Immunotherapy Melanoma, Head, Neck Squamous Cell Carcinoma (HNSCC) | GR-MD-02 | Investigator IND submitted in December 2013. Phase 1B study in process. A second Phase 1B study began in Q-1 2016. Investigator IND for that study submitted in September 2015. Early data was reported in February 2017 and studies with the 3 rd cohort were reported in September 2018. Continuation of trial is ongoing to expand the dataset of melanoma and HNSCC patients at the 4 mg/Kg dose. |

[Table of Contents](#)

| Psoriasis | | Drug | Status |
|--|--|-------------|--|
| Indication Moderate to Severe Plaque Psoriasis Severe Atopic Dermatitis | | GR-MD-02 | IND submitted March 2015. A phase 2a trial in moderate to severe plaque psoriasis patients began in January 2016. Interim data on the first four patients were positive and were reported in May 2016. Further positive data was reported in September 2016. Investigator initiated IND submitted for treatment of three patients with severe atopic dermatitis, with positive preliminary data presented in February 2017. Further studies are dependent on finding a suitable strategic partner. |

Fibrosis. GR-MD-02 is our lead product candidate for treatment of fibrotic disease. Our preclinical data show that GR-MD-02 has a significant therapeutic effect on liver fibrosis as shown in several relevant animal models. In addition, in NASH animal models, GR-MD-02 has been shown to reduce liver fat, inflammation, and ballooning degeneration or death of liver cells. Therefore, we chose GR-MD-02 as the lead candidate in a development program targeted initially at fibrotic liver disease associated with non-alcoholic steatohepatitis (NASH, or fatty liver disease). In January 2013, an Investigational New Drug (“IND”) was submitted to the FDA with the goal of initiating a Phase 1 study in patients with NASH and advanced liver fibrosis to evaluate the human safety of GR-MD-02 and pharmacodynamics biomarkers of disease. On March 1, 2013, the FDA indicated we could proceed with a US Phase 1 clinical trial for GR-MD-02 with a development program aimed at obtaining support for a proposed indication of GR-MD-02 for treatment of NASH with advanced fibrosis. The Phase 1 trial was completed and demonstrated that GR-MD-02 up to 8 mg/kg, i.v. was safe and well tolerated. The human pharmacokinetic data defined a drug dose for use in the planned Phase 2 trials based on extrapolation from efficacy data in NASH animal models of liver fibrosis and/or cirrhosis. Additionally, there was evidence of a pharmacodynamic effect of GR-MD-02 at the 8 mg/kg dose with a decrease in alpha 2 macroglobulin, a serum marker of fibrotic activity, and a reduction in liver stiffness as determined by FibroScan®. An “End of Phase 1 Meeting” was held with FDA which, amongst other items, provided guidance on the primary endpoint for the Phase 2 clinical trial, the NASH-CX trial.

Additionally, an open label drug-drug interaction study was completed in healthy volunteers during the second quarter of 2015 with GR-MD-02 and it showed that with 8 mg/kg dose of GR-MD-02 and 2 mg/kg dose of midazolam there was no drug-drug interaction and no serious adverse events or drug-related adverse events were observed. This study was required by the U.S. Food and Drug Administration (FDA) and the primary objective was to determine if single or multiple intravenous (IV) doses of GR-MD-02 affect the pharmacokinetics (PK) of midazolam. The secondary objective was to assess the safety and tolerability of GR-MD-02 when administered concomitantly with midazolam. The lack of a drug interaction in this study enabled the Company to expand the number of patients eligible for its Phase 2 clinical trial. In addition, should GR-MD-02 be approved for marketing, the success of this study supports a broader patient population for the drug label.

Our Phase 2 program in fibrotic disease consisted of two separate human clinical trials. The primary clinical trial was the Phase 2b NASH-CX study for one year for patients with NASH with well compensated cirrhosis, which began enrolling in June, 2015. This study was the primary focus of our program and is a randomized, placebo-controlled, double-blind, parallel-group Phase 2b trial to evaluate the safety and efficacy of GR-MD-02 for treatment of liver fibrosis and resultant portal hypertension in NASH patients with well 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, a Phase 2a pilot trial NASH-FX for patients with NASH advanced fibrosis that explored use of three non-invasive imaging technologies, is now complete. It was a short, single site, four-month trial in 30 NASH patients with advanced fibrosis, but not cirrhosis, randomized 1:1 to either 9 bi-weekly doses of 8 mg/kg of GR-MD-02 or placebo. The trial did not meet its primary biomarker endpoint as measured using multi-parametric magnetic resonance imaging (LiverMultiScan[®], Perspectum Diagnostics). The trial also did not meet secondary endpoints that measure liver stiffness as a surrogate for fibrosis using, magnetic resonance-elastography and FibroScan[®] score. We, and many experts in the field, now believe that a four-month treatment period may not be sufficient to show efficacy results in established liver fibrosis. This small study was not powered for the secondary endpoints and thus, not surprisingly, did not meet the secondary endpoints. In the trial, GR-MD-02 was found to be safe and well tolerated among the patient population with no serious adverse events. Although there was no apparent improvement in the three non-invasive tests for assessment of liver fibrosis in the four-month NASH-FX trial, the principal investigator of the NASH-FX trial has stated that the inhibition of galectin-3 with GR-MD-02 remains promising for the treatment of NASH fibrosis. Of note is that GR-MD-02 has demonstrated an improved clinical effect in moderate-to-severe psoriasis, suggesting the compound has activity in humans in an

immune-mediated inflammatory human disease that can occur in association with NASH. We believe our drug candidate provides a promising new approach for the therapy of fibrotic diseases, and liver fibrosis in particular. Fibrosis is the formation of excess connective tissue (collagen and other proteins plus cellular elements such as myofibroblasts) in response to damage, inflammation or repair. When the fibrotic tissue becomes confluent, it obliterates the cellular architecture, leading to scarring and dysfunction of the underlying organ. Given galectin-3's broad biological functionality, it has been demonstrated to be involved in cancer, inflammation and fibrosis, heart disease, and renal disease. We have further demonstrated the broad applicability of the actions of our galectin-3 inhibitor's biological effect in ameliorating fibrosis involving lung, kidney, blood vessels, and cardiac tissues in a wide variety of animal models.

NASH-CX Trial: The NASH-CX trial was a larger well-designed multi-center clinical trial that explored use of GR-MD-02 for the treatment of liver fibrosis and resultant portal hypertension in patients with well-compensated NASH cirrhosis. Enrollment in this trial was completed in September 2016, and a total of 162 patients at 36 sites in the United States were randomized to receive either 2 mg/kg of GR-MD-02, 8 mg/kg of GR-MD-02 or placebo, with approximately 54 patients in each group. The primary endpoint was a reduction in change in hepatic venous pressure gradient (HVPG). Patients received an infusion every other week for one year, total of 26 infusions, and were evaluated to determine the change in HVPG as compared with placebo. HVPG was also correlated with secondary endpoints of fibrosis on liver biopsy as well as with measurement of liver stiffness (FibroScan[®]) and assessment of liver metabolism (¹³C-methacetin breath test, Exalenz), which are non-invasive measures of the liver that may be used in future studies. Top line data readout was reported in December 2017 demonstrating positive efficacy data and safety and clinically meaningful results in the NASH patients with well compensated cirrhosis without esophageal varices (stage 1 cirrhosis).

In the total patient population, the primary endpoint HVPG showed a trend toward benefit with GR-MD-02 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 dose and 8 mg/kg dose of GR-MD-02, respectively.

Further analysis showed that the drug effect was significantly dependent on dose "varices" in the total group of patients ($p < 0.02$). In those NASH cirrhosis patients without varices at baseline (about 50% of the total population), there was a statistically significant effect of the 2 mg/kg dose of GR-MD-02 on the absolute change in HVPG (-1.08 mm Hg, $p < 0.01$). The effect of the 8 mg/kg dose of GR-MD-02 on absolute or percent change in HVPG from baseline to week 54 was not significant. The population of patients without varices at baseline were further subdivided into those with mild portal hypertension (HVPG greater than or equal to 6 mm Hg and less than 10 mm Hg). In patients with mild portal hypertension (MPH), both doses of GR-MD-02 demonstrated a statistically significant effect on change in HVPG. The mean change in HVPG in the MPH group were +1.8 mm Hg for placebo and -0.3 and -0.4 mm Hg in the 2 mg/kg and 8 mg/kg dose groups, respectively. In patients with clinically significant portal hypertension (HVPG greater than 10 mm Hg) with no varices at baseline, there was a statistically significant effect of 2 mg/kg of GR-MD-02 on the change in HVPG.

A responder analysis was performed on those patients without varices at baseline. Analysis was performed looking at two groups: those with an equal to or greater than 2 mm Hg decrease in HVPG from baseline or those with an equal to or greater than 2 mm Hg and a greater than or equal to 20% decrease in HVPG from baseline. In both cases, the change observed in the GR-MD-02 2 mg/kg group was statistically significant ($p < 0.01$) while that of the 8 mg/kg group was not.

In terms of cirrhosis complications over the 54-week treatment period, in patients without varices there were statistically significantly fewer new varices that developed in the treatment groups vs placebo. We believe this may represent a useful measure of clinical outcome.

The major conclusions, to date from the NASH-CX trial results are that: i) GR-MD-02 had a statistically significant and clinically meaningful effect in improving HVPG vs placebo in patients with NASH cirrhosis who did not have esophageal varices at baseline. This effect was seen regardless of the patient's baseline portal hypertension. Furthermore, we believe that patients with esophageal varices may have masked benefits in the total patient population. ii) There was an important drug effect of GR-MD-02 in the total patient population on liver biopsy with a statistically significant improvement in hepatocyte ballooning (ie cell death), (iii) There was a statistically significant reduction ($p = 0.02$) in the development of new esophageal varices in drug-treated patients compared to placebo. We believe that this is a clinically relevant endpoint related to patient outcomes, (iv) While there was a drug effect in both the 2 mg/kg and 8 mg/kg dosage groups on liver biopsy and in the mild portal hypertension group, there was a consistently greater and statistically significant effect of the 2 mg/kg dose of GR-MD-02, (v) GR-MD-02 appears to be safe and well tolerated in this one year clinical trial and (vi) We believe this is the first large, randomized clinical trial of any drug to demonstrate a clinically meaningful improvement in portal hypertension or liver biopsy in patients with compensated NASH cirrhosis without esophageal varices.

[Table of Contents](#)

Further information and details on the NASH-CX results summarized above is available in public presentations posted to our website and filed with the SEC.

NASH-RX Trial: The NASH-RX Trial was initially designed as a Phase 3 trial of GR-MD-02 in NASH cirrhosis patients based on FDA feedback from a February 2019 meeting between the Company and the FDA. The trial design is being refined as a result of further input received from the FDA in late October 2019 and ongoing input from the FDA.

The late October 2019 FDA comments are being evaluated by the Company in conjunction with its external hepatology experts and medical and other experts at Covance. In its comments, the FDA seemingly is departing from its earlier implied potential support of the use of progression to varices as a surrogate endpoint for accelerated approval. A follow up call with the FDA is scheduled for later in November to clarify aspects of its communication. The FDA also made additional constructive comments and suggestions mostly of an operational nature. Based on updated feedback, the Company is redesigning the trial protocol. We will continue to seek approval in a manner consistent with the data derived from the results of the trial. The pathway pursued will be based on the assessment of that data.

Currently, as a result of the Agency's feedback and after consultation with external experts, the Company plans to conduct an adaptive-designed trial that confirms dose selection and data observed in the NASH-CX trial and where, in a seamless fashion with pre-planned adaptations, an interim analysis informs the larger Phase 3 trial component. The adaptive design being considered allows pre-planned adjustments of the trial which may include, amongst other factors, optimization of dose selection, confirmation of efficacy and proof of concept, optimized sizing and statistical powering of the Phase 3 component, and possible inclusion of more advanced cirrhotic patients. We believe that these adaptations taken together should optimize conduct of the NASH-RX trial giving GR-MD-02 the best opportunity to show a positive therapeutic effect. Existing patients in the first component of the trial are expected to be seamlessly transitioned to the Phase 3 trial component. An important aspect of the adaptive design is potential early termination of the study for futility after evaluation of the results from the first part of the trial, thereby saving the company resources that it could expend on other trials. Conversely, if the final results of the NASH-RX trial are compelling there could be the potential for FDA approval and/or partnership opportunity with a large pharmaceutical company.

In the Phase 3 component of this trial, the primary endpoint would likely be a composite clinical outcomes endpoint, including varices requiring treatment (development of large varices or varices with a red wale), decompensated events, all-cause mortality, MELD score increase as defined earlier and liver transplant. Patient selection would be based on clinical criteria indicative of clinically significant portal hypertension, amongst others, including presence or absence of varices, platelet count, spleen size and evidence of collaterals by imaging. In addition, in parallel, a hepatic impairment study in patients with Child-Turcotte-Pugh (CTP) classes A, B, and C would be conducted to potentially allow inclusion of patients with CTP Class B and/or C who are at increased risk of decompensating. Subject to additional assessments to assure appropriate study sizing and other operational considerations, these changes are believed to be relatively straight-forward modifications of the protocols submitted to the Agency in July 2019, and we believe the changes will increase the likelihood of success of the Phase 3 component of the study. These current plans are subject to modification after discussion with FDA. The final study design will be announced when available.

The focus and goal of the therapeutic program is to stop the progression of and reverse the fibrosis and/or portal hypertension in the liver and thereby improve liver function and prevent the development of varices and clinical complications of fibrosis/cirrhosis and liver-related mortality in patients. 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 portal hypertension.

The key milestones and associated target dates for the NASH-RX trial will be announced as elements of design of the trial are finalized based on the recent FDA feedback. However, we currently expect the first patient to be enrolled in the first quarter of 2020. The study likely will involve at least 500 patients at up to approximately 130 sites in 11 countries in North America, Europe, Asia, and Australia and will continue for at least two years of dosing.

Covance has already begun extensive work on site and vendor startup activities. We are also including a NASH-specific site network to accelerate site startup and patient enrollment for this trial. A startup agreement has been executed with Covance which allowed them to start work on protocol development, statistical analysis plans, support us in addressing some of FDA's questions, and to engage vendors for various activities in support of the NASH-RX Trial.

[Table of Contents](#)

Covance has also identified more than 125 clinical trial sites in 11 countries interested in the trial, and many sites have been qualified by pre-study visits. Various procedural manuals related to conduct and evaluation EGDs have been compiled, charters for various oversight committees such as the adjudication committee, and data safety monitoring board, amongst others, have been drafted, and key members of these committees have been identified. Additional activities include defining the initial structure of the electronic data capture systems and its initial build and the contracting for key patient questionnaires, organizing vendors for product labeling and distribution globally, and preparing submissions to foreign regulatory agencies.

Cancer Immunotherapy. We believe there is potential for galectin inhibition to play a key role in the burgeoning area of cancer immunotherapy. For example, there have been several recent approvals of drugs that enhance a patient's immune system to fight cancer. It is our goal to use a galectin inhibitor to further enhance the immune system function to fight cancer in a way that complements other approaches to this type of therapy. This hypothesis is supported by the fact that galectin-3 is expressed at high levels in multiple types of tumors, adds to the malignant nature of the tumors, and protects the tumors from immune system attack. Our drug candidates provide a promising new therapeutic approach to enhance the activity of the immune system against cancer cells. Preclinical studies have indicated that GR-MD-02 enhances the immune response to cancer cells, increased tumor shrinkage and enhanced survival in immune competent mice with prostate, breast, melanoma and sarcoma cancers when combined with one of the immune checkpoint inhibitors, anti-CTLA-4 or anti-PD-1, or with the immune cell activator anti-OX40. These preclinical data led to the filing of two Investigator-sponsored INDs and the initiation of studies of GR-MD-02 in combination with Yervoy® (ipilimumab) and KEYTRUDA (pembrolizumab) in Phase 1B studies of patients with metastatic melanoma. The KEYTRUDA trial has also been expanded to include patients with non-small cell lung cancer and head and neck squamous cell carcinoma. These studies are being conducted under the sponsorship of Providence Portland Medical Center's Earle A. Chiles Research Institute (EACRI).

Data on this combination immunotherapy program was initially presented on February 7, 2017 at the 9th GTCBio Immunotherapeutics & Immunomonitoring Conference in San Diego, CA by Dr. William L. Redmond, Providence Cancer Center. Preclinical results in mouse models of multiple types of cancers showed important anti-tumor activity and increased survival effects of combining GR-MD-02 with different types of immune modulators, providing a case for progressing studies into human patients with cancer. Seven patients were treated in the GR-MD-02 in combination with Yervoy trial, with no safety concerns in these low dose cohorts. Due to changes in the standard of care for metastatic melanoma (i.e., approval of anti-PD-1), recruitment has been slowed significantly in this trial. Promising results were reported in the Phase 1b trial combining GR-MD-02 with pembrolizumab (KEYTRUDA). Cohort 1 was completed (n=6, 5 with melanoma, one head and neck) with one partial response and one mixed response in 5 melanoma patients. There was a rapid and marked tumor response after 3 doses of combined GR-MD-02 and pembrolizumab in the one partial response patient who had failed high-dose IL-2 and oncolytic virus + ipilimumab. The study is ongoing and progression to further development will be based on response rate as compared to historical response rates to pembrolizumab alone. In September 2018 we announced additional preliminary clinical data from cohort 3 of this investigator-initiated trial. When aggregated with cohorts previously reported, the data shows a 50% objective response rate in advanced melanoma with GR-MD-02 in combination with KEYTRUDA, and a significant decrease in the frequency of suppressive myeloid-derived suppressor cells following treatment in the responding patients (on day 85 post-treatment). Fourteen advanced melanoma patients across three dose cohorts now have Objective Response Rate (ORR) and Disease Control Rate (DCR) data. Six patients completed in cohort 3 (8 mg/Kg) have now been added to the three patients completed in cohort 2 (4 mg/Kg) and five patients completed in cohort 1 (2 mg/Kg). Cohorts 1 and 3 each had two patients with an objective response. All three patients in cohort 2 had an objective

response. In addition to the fourteen advanced melanoma patients, six patients with head and neck cancer were enrolled in this trial with a 33% ORR and 67% DCR. These data, taken together with the observed favorable safety and tolerability of the combination, in the view of the principal investigator, provide compelling rationale to move forward. Given that all three melanoma patients were responders at the 4 mg/Kg dose, the investigators plan to continue the trial with the expansion of the 4 mg/Kg cohort to include additional advanced melanoma patients and additional head and neck cancer patients. The expansion cohort will target to include 15 patients and is planned to have continued GR-MD-02 dosing as long as pembrolizumab is administered. Assuming these additional data are positive, the next logical step could be a Phase II trial.

Severe skin diseases. During our Phase 1 NASH fibrosis trial with GR-MD-02, a clinical effect on plaque psoriasis was observed in a NASH patient who also had this disease. This patient had marked improvement in her psoriasis, with improvement beginning after the third infusion. She reported that her psoriasis was “completely gone” and her skin was “normal” after the fourth infusion. Her skin remained normal for 17 months after the final infusion of study drug. The patient is convinced that the improvement in her psoriasis is related to the study drug.

This serendipitous finding, combined with galectin-3 protein being markedly upregulated in the capillary epithelia (small blood vessels) of the psoriatic dermis (plaque lesions), led to a phase 2a trial in patients with moderate to severe plaque psoriasis. GR-MD-02 inhibition of galectin-3 may attenuate capillary changes in the psoriatic dermis and inflammatory recruitment, perhaps explaining the improvements observed in the NASH fibrosis trial patient. In this open-label, unblinded trial (no placebo, all patients knowingly receive active drug), 5 patients with moderate to severe plaque psoriasis were administered GR-MD-02 every two weeks for 24 weeks. In May 2016, we reported positive results on the first four patients after 12 weeks of therapy. Based on these results, we modified the trial to include 24 weeks of therapy. In August 2016, we reported on four patients after 24 weeks of therapy and one patient after 12 weeks of therapy. The four patients who received 24 weeks of therapy experienced an average of 48% improvement in their plaque psoriasis. At this time, the average response in all five patients remains at 50% with one patient having an 82% improvement. However, there are existing drugs on the market in this disease that produce 75% and higher improvements in 60-90% of patients. While we are encouraged that this study has demonstrated clinically meaningful results in a human disease with GR-MD-02, the next steps would entail a controlled, does-ranging clinical trial which we do not expect to conduct absent a strategic partnership.

We believe the mechanism of action for GR-MD-02 is based upon interaction with, and inhibition of, galectin proteins, particularly galectin-3, which are expressed at high levels in certain pathological states including inflammation, fibrosis and cancer. While GR-MD-02 is capable of binding to multiple galectin proteins, we believe that it has the greatest affinity for galectin-3, the most prominent galectin implicated in pathological processes. Blocking galectin in cancer and liver fibrosis has specific salutary effects on the disease process, as discussed previously.

Results of Operations

Three and Nine Months Ended September 30, 2019 Compared to Three and Nine Months Ended September 30, 2018

Research and Development Expense.

| | Three Months Ended | | Nine Months Ended | | 2019 as Compared to 2018 | | | |
|--------------------------|--------------------------|----------|-------------------|----------|--------------------------|----------|-------------|----------|
| | September 30, | | September 30, | | Three Months | | Nine Months | |
| | 2019 | 2018 | 2019 | 2018 | \$ Change | % Change | \$ Change | % Change |
| | (In thousands, except %) | | | | | | | |
| Research and development | \$ 1,503 | \$ 1,505 | \$ 3,671 | \$ 5,279 | \$ (2) | 0% | \$ (1,608) | (30%) |

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 | | Nine Months Ended | |
|---|--------------------|-----------------|-------------------|-----------------|
| | September 30, | | September 30, | |
| | 2019 | 2018 | 2019 | 2018 |
| | (in thousands) | | | |
| Direct external expenses: | | | | |
| Clinical programs | \$ 718 | \$ 539 | \$ 1,648 | \$ 2,156 |
| Pre-clinical activities | 232 | 52 | 333 | 169 |
| All other research and development expenses | 553 | 914 | 1,690 | 2,954 |
| | <u>\$ 1,503</u> | <u>\$ 1,505</u> | <u>\$ 3,671</u> | <u>\$ 5,279</u> |

Clinical programs expenses increased in the three months ended September 30, 2019 over the three months ended September 30, 2018 primarily due to costs related to our the NASH RX clinical trial planning and site start-up and qualification processes globally and preparations and some preclinical activities incurred in support of the planned clinical program such as development and reproductive toxicity studies, clinical supplies and other supportive activities. Other research and development expense decreased in the three months ended September 30, 2019 over the three months ended September 30, 2018 primarily due to a decrease in non-cash stock-based compensation expense of approximately \$177,000. For the nine months ended September 30, 2019 compared to the previous year, clinical program expenses are lower due to the close out costs in 2018 of the Phase 2 clinical trials in that period being higher than the startup costs and activities related to the NASH-RX Trial through the first nine months of 2019. Other research and development expense decreased in the nine months ended September 30, 2019 over the nine months ended September 30, 2018 primarily due to a decrease in non-cash stock-based compensation expense of approximately \$1,169,000.

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.

[Table of Contents](#)

General and Administrative Expense.

| | Three Months | | Nine Months | | 2019 as Compared to 2018 | | | |
|----------------------------|---------------------|----------|---------------------|----------|--------------------------|----------|-------------|--------------------------|
| | Ended September 30, | | Ended September 30, | | Three Months | | Nine Months | |
| | 2019 | 2018 | 2019 | 2018 | \$ Change | % Change | \$ Change | % Change |
| | | | | | | | | |
| | | | | | | | | (In thousands, except %) |
| General and administrative | \$ 1,360 | \$ 1,176 | \$ 4,579 | \$ 5,338 | \$ 184 | 16% | \$ (759) | (14)% |

General and administrative expenses consist primarily of salaries including stock-based compensation, legal and accounting fees, insurance, investor relations, business development and other office related expenses. The primary reasons for the increase in general and administrative expenses for the three months ended September 30, 2019 as compared to the same period in 2018 are increases in legal and business development expenses. The primary reasons for the decrease in general and administrative expenses for the nine months ended September 30, 2019 as compared to the same period in 2018 is due to a decrease in non-cash, stock-based compensation expense of \$855,000.

Liquidity and Capital Resources

Since our inception on July 10, 2000, we have financed our operations from proceeds of public and private offerings of debt and equity. The Company has operated at a loss since its inception and has had no significant revenues. The Company anticipates that losses will continue for the foreseeable future. At September 30, 2019, the Company had \$50.3 million of unrestricted cash and cash equivalents available to fund future operations. The Company believes there is sufficient cash, including availability of the line of credit (see Note 3), to fund currently planned operations at least through December 31, 2020. We expect that we will require more cash to fund our operations after December 31, 2020 and believe we will be able to obtain additional financing. The currently planned operations include estimated costs related to our NASH-RX clinical trial through December 31, 2020. While the costs of the trial and general overhead during the trial are expected to be approximately \$100 to \$115 million, the costs and timing of such trial is not yet completely finalized. These costs will require additional funding. There can be no assurance that we will be successful in obtaining financing to support our operations beyond December 31, 2020 or, if available, that any such financing will be on terms acceptable to us. Accordingly, based on the forecasts and estimates underlying our current operating plan, the financial statements do not currently include any adjustments that might be necessary if we are unable to continue as a going concern.

On May 23, 2019, we completed an offering of common stock and warrants to its shareholders of record as of April 29, 2019. In the offering, we received approximately \$44.9 million for the issuance of 10,488,161 shares of common stock and warrants which may be exercised for 2,622,154 shares of common stock. The warrants may be exercised at \$7.00 per share of common stock and expire on May 23, 2026.

Net cash used in operations decreased by \$689,000 to \$7,483,000 for the nine months ended September 30, 2019, as compared to \$8,172,000 for the nine months ended September 30, 2018. Cash operating expenses decreased principally due to the winding down in 2018 of Phase 2 clinical trial somewhat offset by startup activities related to the planned NASH-RX clinical trial in 2019.

Net cash provided by financing activities for the nine months ended September 30, 2019, of \$49,567,000 represents proceeds from the issuance of common stock from the stockholder rights offering of \$44,889,000, from the ATM of \$2,028,000 and \$2,650,000 from the exercise of common stock options and warrants. Net cash provided by financing activities for the nine months ended September 30, 2018, of \$15,255,000 represents proceeds from the exercise of common stock warrants and options and issuances of common stock from the ATM.

Other

We have engaged outside vendors for certain services associated with our clinical trials. These services are generally available from several providers and, accordingly, our arrangements are typically cancellable on 30 days notice.

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 intangible assets, 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 2018 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

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), is recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer to allow timely decisions regarding required disclosure. Our management, with the participation of the Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934) and concluded that, as of September 30, 2019, our disclosure controls and procedures were effective at a reasonable assurance level. In designing and evaluating our disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

Changes in Internal Control over Financial Reporting

During the quarter ended September 30, 2019, 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, 2018, 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

| <u>Exhibit Number</u> | <u>Description of Document</u> | <u>Note Reference</u> |
|-----------------------|--|-----------------------|
| 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 | XBRL Instance Document* | |
| 101.SCH | XBRL Taxonomy Extension Schema Document* | |
| 101.CAL | XBRL Taxonomy Calculation Linkbase Document* | |
| 101.DEF | XBRL Taxonomy Extension Definition Linkbase Document* | |
| 101.LAB | XBRL Taxonomy Label Linkbase Document* | |
| 101.PRE | XBRL Taxonomy Presentation Linkbase Document* | |

* 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 November 12, 2019.

GALECTIN THERAPEUTICS INC.

By: /s/ Harold H. Shlevin

Name: Harold H. Shlevin, Ph.D.

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)

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

I, Harold H. Shlevin, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Galectin Therapeutics Inc;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2019

/s/ Harold H. Shlevin

Name: Harold H. Shlevin, Ph.D.
Title: Chief Executive Officer and President
(principal executive officer)

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

I, Jack W. Callicutt, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Galectin Therapeutics Inc;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2019

/s/ Jack W. Callicutt

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

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

In connection with the Quarterly Report of Galectin Therapeutics Inc. (the "Company") on Form 10-Q for the period ended September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Harold H. Shlevin, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12, 2019

/s/ Harold H. Shlevin

Name: Harold H. Shlevin, Ph.D.
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.

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

In connection with the Quarterly Report of Galectin Therapeutics Inc. (the "Company") on Form 10-Q for the period ended September 30, 2019 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Jack W. Callicutt, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 12, 2019

/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.