

GALECTIN THERAPEUTICS INC

Form 10-Q

August 14, 2013

[Table of Contents](#)

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x **Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the quarterly period ended June 30, 2013

.. **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.

Edgar Filing: GALECTIN THERAPEUTICS INC - Form 10-Q

Nevada
(State or other jurisdiction)

04-3562325
(I.R.S. Employer

of incorporation)

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)

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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 and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer

Accelerated Filer

Non-Accelerated Filer (Do not check if a smaller reporting company)

Smaller reporting company

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

The number of shares outstanding of the registrant's common stock as of August 13, 2013 was 16,878,180.

Table of Contents

GALECTIN THERAPEUTICS INC.

INDEX TO FORM 10-Q

FOR THE QUARTER ENDED JUNE 30, 2013

| | PAGE |
|---|-------------|
| PART I FINANCIAL INFORMATION | |
| ITEM 1. Unaudited Condensed Consolidated Financial Statements | |
| <u>Condensed Consolidated Balance Sheets as of June 30, 2013 and December 31, 2012 (unaudited)</u> | 3 |
| <u>Condensed Consolidated Statements of Operations for the Three and Six Months Ended June 30, 2013 and 2012, and for the Cumulative Period From Inception (July 10, 2000) to June 30, 2013 (unaudited)</u> | 4 |
| <u>Condensed Consolidated Statement of Changes in Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit) for the Six Months Ended June 30, 2013 (unaudited)</u> | 5 |
| <u>Condensed Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2013 and 2012, and for the Cumulative Period From Inception (July 10, 2000) to June 30, 2013 (unaudited)</u> | 6 |
| <u>Notes to Unaudited Condensed Consolidated Financial Statements</u> | 7 |
| ITEM 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> | 12 |
| ITEM 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u> | 19 |
| ITEM 4. <u>Controls and Procedures</u> | 19 |
| <u>PART II OTHER INFORMATION</u> | |
| ITEM 1. <u>Legal Proceedings</u> | 19 |
| ITEM 1A. <u>Risk Factors</u> | 19 |
| ITEM 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u> | 20 |
| ITEM 3. <u>Defaults Upon Senior Securities</u> | 20 |
| ITEM 4. <u>Mine Safety Disclosures</u> | 20 |
| ITEM 5. <u>Other Information</u> | 20 |
| ITEM 6. <u>Exhibits</u> | 21 |
| <u>SIGNATURES</u> | 22 |

Table of Contents**GALECTIN THERAPEUTICS INC.**

(A Development-Stage Company)

CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

| | June 30, 2013 | December 31, 2012 |
|--|------------------|----------------------|
| | (in thousands) | |
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 5,099 | \$ 9,364 |
| Prepaid expenses and other current assets | 88 | 153 |
| Total current assets | 5,187 | 9,517 |
| Property and equipment, net | 6 | 8 |
| Other long term assets | 6 | 6 |
| Intangible assets, net | 26 | 30 |
| Total assets | \$ 5,225 | \$ 9,561 |
| LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS (DEFICIT) EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 285 | \$ 397 |
| Accrued expenses | 1,129 | 1,161 |
| Accrued dividends payable | 79 | 80 |
| Total current liabilities | 1,493 | 1,638 |
| Other long-term liabilities | 5 | 6 |
| Total liabilities | 1,498 | 1,644 |
| Commitments and contingencies (Note 8) | | |
| Series B-1 12% redeemable convertible preferred stock; 900,000 shares authorized, issued and outstanding at June 30, 2013 and December 31, 2012, redemption value: \$1,800,000, liquidation value: \$1,800,000 at June 30, 2013 | 1,706 | 1,698 |
| Series B-2 12% redeemable convertible preferred stock; 2,100,000 shares authorized, issued and outstanding at June 30, 2013 and December 31, 2012, redemption value: \$4,200,000, liquidation value: \$4,200,000 at June 30, 2013 | 3,005 | 2,900 |
| Series C super dividend convertible preferred stock; 1,000 shares authorized, 215 and 220 shares issued and outstanding at June 30, 2013 and December 31, 2012, respectively, redemption value: \$5,110,000, liquidation value: \$2,182,000 at June 30, 2013 | 2,105 | 2,154 |
| Stockholders' equity (deficit): | | |
| Undesignated stock, \$0.01 par value; 20,000,000 shares authorized, 8,001,000 designated at June 30, 2013 and December 31, 2012 | | |
| Series A 12% convertible preferred stock; 5,000,000 shares authorized, 1,562,500 issued and outstanding at June 30, 2013 and December 31, 2012 | 632 | 632 |
| Common stock, \$0.001 par value; 50,000,000 shares authorized at June 30, 2013 and December 31, 2012, 16,299,627 and 16,060,853 issued and outstanding at June 30, 2013 and December 31, 2012, respectively | 16 | 16 |

Edgar Filing: GALECTIN THERAPEUTICS INC - Form 10-Q

| | | |
|--|----------|----------|
| Additional paid-in capital | 91,394 | 80,535 |
| Deficit accumulated during the development stage | (95,131) | (80,018) |
| Total stockholders' (deficit) equity | (3,089) | 1,165 |
| Total liabilities, redeemable convertible preferred stock and stockholders' (deficit) equity | \$ 5,225 | \$ 9,561 |

See notes to unaudited condensed consolidated financial statements.

Table of Contents**GALECTIN THERAPEUTICS INC.****(A Development-Stage Company)****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)**

| | Three Months Ended June 30, | | Six Months Ended June 30, | | Cumulative Period from Inception (July 10, 2000) to June 30, 2013 |
|--|--|------------|------------------------------|------------|--|
| | 2013 | 2012 | 2013 | 2012 | |
| | (in thousands, except per share amounts) | | | | |
| Operating expenses: | | | | | |
| Research and development | \$ 1,349 | \$ 1,215 | \$ 3,101 | \$ 2,116 | \$ 30,711 |
| General and administrative | 1,198 | 1,453 | 2,654 | 2,505 | 49,690 |
| Total operating expenses | 2,547 | 2,668 | 5,755 | 4,621 | 80,401 |
| Total operating loss | (2,547) | (2,668) | (5,755) | (4,621) | (80,401) |
| Other income (expense): | | | | | |
| Interest income | 3 | 8 | 8 | 11 | 826 |
| Interest expense | | | | | (4,451) |
| Change in fair value of convertible debt instrument | | | | | (3,426) |
| Change in fair value of warrant liabilities | | | | | 9,022 |
| Other income | | | | | 691 |
| Total other income (expense) | 3 | 8 | 8 | 11 | 2,662 |
| Net loss | \$ (2,544) | \$ (2,660) | \$ (5,747) | \$ (4,610) | \$ (77,739) |
| Preferred stock dividends | (277) | (267) | (490) | (464) | (4,725) |
| Preferred stock accretion | (57) | (57) | (113) | (114) | (4,158) |
| Modification of warrants | (8,763) | | (8,763) | | (8,763) |
| Net loss applicable to common stockholders | \$ (11,641) | \$ (2,984) | \$ (15,113) | \$ (5,188) | \$ (95,385) |
| Net loss per common share basic and diluted | \$ (0.72) | \$ (0.19) | \$ (0.94) | \$ (0.36) | |
| Weighted average common shares outstanding basic and diluted | 16,236 | 15,710 | 16,158 | 14,360 | |

See notes to unaudited condensed consolidated financial statements.

Table of Contents**GALECTIN THERAPEUTICS INC.**

(A Development-Stage Company)

CONSOLIDATED STATEMENT OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' (DEFICIT) EQUITY SIX MONTHS ENDED JUNE 30, 2013 (UNAUDITED)

(in thousands except share data)

| | Series B-1 12% Redeemable Convertible Preferred Stock | | Series B-2 12% Redeemable Convertible Preferred Stock | | Series C Super Dividend Convertible Preferred Stock | | Series A 12% Convertible Preferred Stock | | Stockholders' Equity (Deficit) | | Additional Paid-In Capital | Deficit Accumulated During the Development Stage | Total Stockholders' Equity (Deficit) |
|--|---|-----------------|---|-----------------|---|-----------------|--|---------------|--------------------------------|--------------|----------------------------|--|--------------------------------------|
| | Number of | | Number of | | Number of | | Number of | | Common Stock | | | | |
| | Number of Shares | Amount | Shares | Amount | Shares | Amount | Shares | Amount | Shares | Amount | | | |
| Balance at December 31, 2012 | 900,000 | \$ 1,698 | 2,100,000 | \$ 2,900 | 220 | \$ 2,154 | 1,562,500 | \$ 632 | 16,060,853 | \$ 16 | \$ 80,535 | \$ (80,018) | \$ 1,165 |
| Accretion of Series B redeemable convertible preferred stock | | 8 | | 79 | | | | | | | | (87) | (87) |
| Accretion of beneficial conversion feature for Series B-2 | | | | 26 | | | | | | | | (26) | (26) |
| Series A 12% convertible preferred stock dividend | | | | | | | | | 15,625 | | 57 | (57) | |
| Series B-1 redeemable convertible preferred stock dividend | | | | | | | | | 28,490 | | 111 | (111) | |
| Series B-2 redeemable convertible preferred stock dividend | | | | | | | | | 66,476 | | 260 | (260) | |
| Series C super dividend convertible preferred stock dividend | | | | | | | | | 17,114 | | 62 | (62) | |
| Conversion of Series C to common stock | | | | | (5) | (49) | | | 8,475 | | 49 | | 49 |
| | | | | | | | | | 102,594 | | 90 | | 90 |

Edgar Filing: GALECTIN THERAPEUTICS INC - Form 10-Q

| | | | | | | | | | | | | | | |
|---|----------------|-----------------|------------------|-----------------|------------|-----------------|------------------|---------------|-------------------|--------------|------------------|--------------------|-------------------|--|
| Issuance of common stock upon exercise of options | | | | | | | | | | | | | | |
| Modification of warrants | | | | | | | | | | | 8,763 | (8,763) | | |
| Stock-based compensation expense | | | | | | | | | | | 1,467 | | 1,467 | |
| Net loss | | | | | | | | | | | | (5,747) | (5,747) | |
| Balance at June 30, 2013 | 900,000 | \$ 1,706 | 2,100,000 | \$ 3,005 | 215 | \$ 2,105 | 1,562,500 | \$ 632 | 16,299,627 | \$ 16 | \$ 91,394 | \$ (95,131) | \$ (3,089) | |

See notes to unaudited condensed consolidated financial statements.

Table of Contents**GALECTIN THERAPEUTICS INC.**

(A Development-Stage Company)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

| | Six Months Ended June 30, 2013 | | 2012 (in thousands) | Cumulative Period from Inception (July 10, 2000 to June 30, 2013) |
|---|--------------------------------------|------------|------------------------|--|
| CASH FLOWS FROM OPERATING ACTIVITIES: | | | | |
| Net loss | \$ (5,747) | \$ (4,610) | | \$ (77,739) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | | |
| Depreciation and amortization | 6 | 4 | | 561 |
| Stock-based compensation expense | 1,467 | 1,352 | | 13,841 |
| Non-cash interest expense | | | | 4,279 |
| Change in fair value of convertible debt instrument | | | | 3,426 |
| Change in fair value of warrant liabilities | | | | (9,022) |
| Write off of intangible assets | | | | 351 |
| Changes in operating assets and liabilities: | | | | |
| Prepaid expenses and other assets | 65 | 19 | | (91) |
| Accounts payable and accrued expenses | (145) | (435) | | 1,481 |
| Other long-term liabilities | (1) | | | 5 |
| Net cash used in operating activities | (4,355) | (3,670) | | (62,908) |
| CASH FLOWS FROM INVESTING ACTIVITIES: | | | | |
| Purchases of property and equipment | | | | (431) |
| Increase in patents costs and other assets | | | | (404) |
| Net cash provided by (used in) investing activities | | | | (835) |
| CASH FLOWS FROM FINANCING ACTIVITIES: | | | | |
| Net proceeds from issuance of common stock and warrants | | 10,403 | | 39,093 |
| Net proceeds from issuance of Series A preferred stock and related warrants | | | | 1,691 |
| Net proceeds from issuance of Series B-1 preferred stock and related warrants | | | | 1,548 |
| Net proceeds from issuance of Series B-2 preferred stock and related warrants | | | | 3,935 |
| Net proceeds from issuance of Series C preferred stock | | | | 2,203 |
| Net proceeds from issuance of convertible debt instruments | | | | 10,621 |
| Repayment of convertible debt instruments | | | | (1,641) |
| Proceeds from exercise of common stock warrants and options | 90 | | | 11,383 |
| Proceeds from shareholder advances | | | | 9 |
| Net cash provided by financing activities | 90 | 10,403 | | 68,842 |
| NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS | (4,265) | 6,733 | | 5,099 |
| CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD | 9,364 | 6,397 | | |
| CASH AND CASH EQUIVALENTS, END OF PERIOD | \$ 5,099 | \$ 13,130 | | \$ 5,099 |
| SUPPLEMENTAL DISCLOSURE Cash paid for interest | \$ | \$ | | \$ 114 |

Edgar Filing: GALECTIN THERAPEUTICS INC - Form 10-Q

NONCASH FINANCING ACTIVITIES:

| | | | |
|---|-----|----------|----------|
| Issuance of equity warrants in connection with equity offerings | \$ | \$ 4,445 | \$ 9,482 |
| Conversion of accrued expenses into common stock | | 16 | 329 |
| Cashless exercise of common stock options and warrants | 158 | 190 | 832 |
| Conversion and redemption of convertible notes and accrued interest into common stock | | | 12,243 |
| Conversion of extension costs related to convertible notes into common stock | | | 171 |
| Payment of preferred stock dividends in common stock | 490 | 464 | 4,645 |
| Issuance of warrants to induce conversion of notes payable | | | 503 |
| Issuance of stock to acquire Pro-Pharmaceuticals-NV | | | 107 |

See notes to unaudited condensed consolidated financial statements.

Table of Contents

GALECTIN THERAPEUTICS INC.

(A DEVELOPMENT-STAGE COMPANY)

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Basis of Presentation

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

The unaudited condensed consolidated financial statements as reported in this Quarterly Report on Form 10-Q reflect all adjustments which are, in the opinion of management, necessary to present fairly the financial position of the Company as of June 30, 2013 and the results of its operations for the three and six months ended June 30, 2013 and 2012 and the cumulative period from inception (July 10, 2000) through June 30, 2013 and its cash flows for the six months ended June 30, 2013 and 2012, and for the cumulative period from inception (July 10, 2000) to June 30, 2013. Such adjustments, other than nonrecurring adjustments that have been separately disclosed, are of a normal, recurring nature. 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 which 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, 2012.

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 as it develops its therapeutic candidates. At June 30, 2013, the Company had \$5,099,000 of unrestricted cash and cash equivalents available to fund future operations. Subsequent to June 30, 2013, the Company received \$2,429,923 from the exercise of warrants for 578,553 shares of common stock. The Company believes that with the cash on hand at June 30, 2013 and the cash received subsequent to quarter end, there is sufficient cash to fund operations through the first quarter of 2014. The Company's ability to fund operations after its current cash resources are exhausted depends on its ability to obtain additional financing or achieve profitable operations, as to which no assurances can be given. The Company has developed several plans, including cost containment efforts and potential strategic alternatives in the event that such financing cannot be realized by the Company. Accordingly, based on the forecasts and estimates underlying the Company's current operating plan, the financial statements do not currently include any adjustments that might be necessary if the Company is unable to continue as a going concern.

As shown in the condensed consolidated financial statements, the Company incurred cumulative net losses applicable to common stockholders of \$95.4 million for the cumulative period from inception (July 10, 2000) through June 30, 2013. The Company's net losses have resulted principally from costs associated with (i) research and development expenses, including clinical trial costs, (ii) general and administrative activities and (iii) the Company's financing transactions including interest, dividend payments, and the costs related to fair value accounting for the Company's convertible debt instruments. As a result of planned expenditures for future research, discovery, development and commercialization activities and potential legal cost to protect its intellectual property, the Company expects to incur additional losses and use additional cash in its operations for the foreseeable future. Through June 30, 2013, the Company had raised a net total of \$68.8 million in capital through sale and issuance of common stock, common stock purchase warrants, convertible preferred stock and debt securities in public and private offerings. From inception (July 10, 2000) through June 30, 2013, the Company used cash of \$62.9 million in its operations.

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. On March 23, 2012, the Company began trading on The NASDAQ Capital Market under the symbol GALT. Immediately prior to March 23, 2012, the Company was traded on the Over-the Counter Bulletin Board (OTCBB) under the symbol GALT.OB.

The Company is subject to a number of risks similar to those of other development-stage companies, including dependence on key individuals, uncertainty of product development and generation of revenues, dependence on outside sources of capital, risks associated with clinical trials of products, dependence on third-party collaborators for research operations, need for regulatory approval of products, risks associated with protection of intellectual property, and competition with larger, better-capitalized companies. Successful completion of the Company's development program and, ultimately, the attainment of profitable operations is dependent upon future events, including obtaining adequate

Edgar Filing: GALECTIN THERAPEUTICS INC - Form 10-Q

financing to fulfill its development activities and achieving a level of revenues adequate to support the Company's cost structure. There are no assurances that the Company will be able to obtain additional financing on favorable terms, or at all, or successfully market its products.

Table of Contents**2. Accrued Expenses**

Accrued expenses consist of the following:

| | June 30, 2013 | December 31, 2012 |
|------------------------------|------------------|----------------------|
| | (in thousands) | |
| Legal and accounting fees | \$ 83 | \$ 109 |
| Accrued compensation | 36 | 42 |
| Severance agreement (Note 8) | 1,000 | 1,000 |
| Other | 10 | 10 |
| Total | \$ 1,129 | \$ 1,161 |

3. 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 June 30, | | Six Months Ended June 30, | |
|---|--------------------------------|---------------|------------------------------|-----------------|
| | 2013 | 2012 | 2013 | 2012 |
| | (in thousands) | | | |
| Research and development | \$ 211 | \$ 359 | \$ 530 | \$ 508 |
| General and administrative | 404 | 520 | 937 | 844 |
| Total stock-based compensation expense | \$ 615 | \$ 879 | \$ 1,467 | \$ 1,352 |

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, 2012 through June 30, 2013:

| | Shares | Weighted Average Exercise Price |
|-----------------------------------|------------------|------------------------------------|
| Outstanding, December 31, 2012 | 3,539,961 | \$ 5.66 |
| Granted | 225,426 | 3.42 |
| Exercised | (102,594) | 2.57 |
| Options forfeited/cancelled | (109,953) | 6.40 |
| Outstanding, June 30, 2013 | 3,552,840 | \$ 5.58 |

As of June 30, 2013, there was \$4,962,000 of unrecognized compensation related to 1,315,137 unvested options, which is expected to be recognized over a weighted average period of approximately 4.1 years. The weighted-average grant date fair value for options granted during the three and six months ended June 30, 2013 was \$3.64 and \$2.83, respectively. The weighted-average grant date fair value for options granted during the three and six months ended June 30, 2012 was \$1.72.

Table of Contents

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

| | Six Months Ended June 30, 2013 | Cumulative Period from Inception (July 10, 2000) to June 30, 2013 |
|---|--------------------------------------|--|
| Risk-free interest rate | 0.97% | 1.75% |
| Expected life of the options | 5.5 years | 5.2 years |
| Expected volatility of the underlying stock | 116% | 119% |
| Expected dividend rate | 0% | 0% |

4. Common Stock Warrants

The following table summarizes the common stock warrant activity from December 31, 2012 through June 30, 2013:

| | Shares | Weighted Average Exercise Price |
|--------------------------------|-----------|------------------------------------|
| Outstanding, December 31, 2012 | 7,424,241 | \$ 3.71 |
| Granted | 5,000 | 2.65 |
| Exercised | | |
| Forfeited/cancelled | (33,333) | 3.00 |
| Outstanding, June 30, 2013 | 7,395,908 | \$ 3.74 |

Warrants Modification

On May 6, 2013, the Company modified the terms of the Class A-2 and Class B warrants that were originally issued to the 10X Fund with the Series B Preferred Stock offering. The Class B warrants were modified to allow for the cashless exercise of all 4,000,000 outstanding Class B warrants. Previously, only half of the Class B warrants allowed for cashless exercise. The Class A-2 warrants for the purchase of 1,000,000 shares of common and all of the Class B warrants had their exercisable life extended by an additional five years. In exchange for these modifications, the 10X Fund agreed to a future amendment of the Company's Series B certificate of designation to remove the redemption provision such that the Series B Preferred Stock will no longer be redeemable, if and when the Company will no longer be required to issue Dr. Platt a promissory note as may currently be required under the separation agreement (see Note 8). Should the Company amend their Series B certificate of designation in the future as described above, the Company will be required at that time evaluate whether such amendment is to be accounted for as a modification or an extinguishment of the Company's Series B Preferred Stock. The Company has accounted for the modified terms of the Class A-2 and Class B 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. For the three and six month period ended June 30, 2013, the Company recognized a charge of \$8,763,000 related to the extension of the 5,000,000 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 0.77 to 2.01 years, volatility range of 77% to 96%, risk free interest rate range of 0.11% to 0.22% and zero dividends and; b) immediately following the modification an expected life range of 5.78 to 7.02 years, volatility range of 113% to 122%, risk free interest rate range of 0.74% to 1.19% and zero dividends.

Consultant Warrants

In January 2013, the Company entered into an agreement with a consultant that provided for the grant of warrants for the purchase of 5,000 shares of common stock at an exercise price of \$2.65 per share. The following assumptions were used to value the warrants: an expected life of 3 years, volatility of 87%, risk free interest rate of 0.42% and zero dividends. The Company recognized an expense of \$7,000 related to these warrants during the six months ended June 30, 2013.

5. 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

Table of Contents

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 approximates their carrying value due to their short-term nature. Included in cash and cash equivalents, as of June 30, 2013 and December 31, 2012, the Company had \$2,000 and \$583,000, respectively invested in money market funds which had calculated net asset values and were therefore classified as Level 2. There were no level 3 assets held at fair value at June 30, 2013 or December 31, 2012.

6. 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. The computation of diluted net loss per share does not assume the issuance of common shares that have an anti-dilutive effect on net loss per share. Dilutive shares which could exist pursuant to the exercise of outstanding stock instruments and which were not included in the calculation because their affect would have been anti-dilutive are as follows:

| | June 30, 2013 (shares) | June 30, 2012 (shares) |
|--|---------------------------|---------------------------|
| Warrants to purchase shares of common stock | 7,395,908 | 7,424,241 |
| Options to purchase shares of common stock | 3,552,840 | 3,291,630 |
| Shares of common stock issuable upon conversion of preferred stock | 2,618,772 | 2,627,110 |
| | 13,567,520 | 13,342,981 |

7. Common Stock and Warrant Offering and Reverse Split

On March 22, 2012, the Company entered into an underwriting agreement relating to the offer and sale of 1,159,445 units (the Units) of the Company. Each unit consisted of two shares of Common Stock and one warrant to purchase one share of Common Stock. Pursuant to the underwriting agreement, the Company granted the underwriters a 45-day option to purchase up to an additional 173,916 Units to cover over-allotments, which they exercised on March 26, 2012. The public offering price for each Unit was \$9.00. Each warrant has an initial exercise price of \$5.63 per share, is exercisable upon separation of the Units and expires on March 28, 2017.

On March 28, 2012, the Company sold and issued 1,333,361 Units (2,666,722 shares of common stock and related \$5.63 warrants to purchase 1,333,361 shares of common stock) for gross proceeds of \$12.0 million (net cash proceeds of \$10,403,000 after the underwriting discount and offering costs). The warrants were valued at \$4,445,000 as of the issuance date of March 28, 2012, using the closing price of \$4.20, a life of 5 years, a volatility of 119% and a risk free interest rate of 1.05%. 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.

On March 28, 2012, in connection with this underwritten financing as per the underwriting agreement, the Company issued a total of 46,378 common stock purchase warrants to the underwriters. These warrants expire May 2, 2016, have an exercise price of \$5.63 per share, and are exercisable beginning 1 year from March 22, 2012 (the date of the underwriting agreement). These warrants were valued at \$143,000 as of the date of issuance (March 28, 2012), using the closing price of \$4.20, life of 4.1 years, volatility of 117% and risk free interest rate of 0.78. 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 these warrants issued in connection with this financing transaction were not derivative liabilities and therefore, were recorded as additional paid-in capital.

Effective as of March 23, 2012, and in connection with the pricing of the offering of Units, the Company effected a one-for-six reverse split of its Common Stock. Per the terms of the reverse split, all fractional shares were rounded up.

Table of Contents**8. Commitments, Contingencies and Legal Proceedings***Agreement with CTI for Phase I Clinical Trial*

On February 1, 2013, the Company entered into an Amended and Restated Master Services Agreement (the *Agreement*) with CTI Clinical Trial Services, Inc. and CTI Clinical Consulting Services, Inc. (individually and collectively, *CTI*), whereby CTI is assisting the Company in the design, development and conduct of one or more clinical research studies from time to time. All work performed by CTI for the Company is being conducted pursuant to the terms of work orders that describe the specific obligations undertaken by CTI with respect to any particular clinical research study sponsored or conducted by the Company. Unless otherwise terminated sooner in accordance with the terms of the Agreement, the Agreement will be effective until January 31, 2018.

On February 1, 2013, the Company entered into a work order (the *Work Order*) with CTI in accordance with the terms of the Agreement. The Work Order provides that CTI will provide services with respect to the Company's Phase I Clinical Trial to evaluate the safety of the Company's drug GR-MD-02 in subjects with Non-Alcoholic Steatohepatitis (*NASH*) with advanced hepatic fibrosis. CTI is providing the following services, amongst others, with respect to the Work Order: reviewing and providing notices regarding IND safety reports, selecting investigators and monitors for the study, informing investigators of new observations, monitoring the progress of the study and reviewing ongoing investigations, keeping certain records, inspecting the Company's records and reports, and disposing of any unused supply of the investigational drug.

The Work Order provides for CTI's anticipated involvement in the study from February 1, 2013 until March 31, 2014. The estimated budget for the Work Order is \$2,155,000, which is subject to change as necessary, with payments made throughout the term of the project as the work is performed. During the three and six months ended June 30, 2013, the Company recognized \$361,000 and \$1,090,000, respectively, of expenses related to this agreement for services performed.

The Agreement or any work order may be terminated for any reason by any party upon ninety (90) days prior written notice to the other party. In addition, the Agreement may be terminated by either party immediately if the other party becomes insolvent, is dissolved or liquidated, makes a general assignment for the benefit of its creditors, files or has filed against it (and does not obtain a dismissal within ninety (90) days) a petition of bankruptcy, or has a receiver appointed for it or a substantial part of its assets, among other reasons. Further, the Agreement or any relevant work order may be terminated immediately by written notice from the Company, in the following circumstances: (1) the FDA withdraws authorization and approval to conduct a study; or (2) the Company reasonably determines that for medical, clinical or patient safety reasons, a study should terminate immediately. In addition, either party may terminate the Agreement or any work order for material breach upon thirty (30) days' written notice specifying the nature of the breach, if such breach has not been substantially cured within the thirty (30) day period.

Drug Discovery Program with the University of Georgia

In February 2013, the Company established a collaborative drug discovery program at the Complex Carbohydrate Research Center at the University of Georgia. This program is focused on the discovery of new carbohydrate molecules that can be used in the therapy of diseases where galectin proteins play a major role, including cancer and inflammatory and fibrotic disorders. The term of the agreement is effective through December 31, 2013, for which the Company will provide funding of \$154,000 during the period as work is performed. The Company has paid \$135,000 related to this program through June 30, 2013. This agreement may be terminated by either party upon 90 days notice.

Separation Agreement

In February 2009, the Company entered into a Separation Agreement in connection with the resignation of David Platt, Ph.D., the Company's former Chief Executive Officer and Chairman of the Board of Directors. The Separation Agreement provides for the deferral of a \$1.0 million separation payment due to Dr. Platt upon the earlier occurrence of any of the following milestone events: (i) the approval by the Food and Drug Administration for a new drug application (*NDA*) for any drug candidate or drug delivery candidate based on the Company's GM-CT-01 technology (whether or not such technology is patented), in which case Dr. Platt is also entitled to a fully vested 10-year cashless-exercise stock option to purchase at least 83,334 shares of common stock at an exercise price not less than the fair market value of the common stock determined as of the date of grant; (ii) consummation of a transaction with a pharmaceutical company expected to result in at least \$10.0 million of equity investment or \$50 million of royalty revenue to the Company, in which case Dr. Platt is also entitled to stock options on the same terms to purchase at least 50,000 shares of common stock; or (iii) the renewed listing of the Company's securities on a national securities exchange and the achievement of a market capitalization of \$100 million. Payment upon the events (i) and (iii) may be deferred up to six months, and if the Company has insufficient cash at the time of any of such events, it may issue Dr. Platt a secured promissory note for such amount. If the Company files a voluntary or involuntary petition for bankruptcy, whether or not a milestone event has occurred, such event shall trigger the obligation to pay the \$1.0 million with the result that Dr. Platt may assert a claim for such obligation against the bankruptcy estate. During 2011, when it became probable that the Company could be relisted on a national securities exchange and eventually reach a market capitalization of \$100 million, the Company recognized the \$1.0 million severance payment due to Dr. Platt and it is included in accrued expenses at June 30,

Edgar Filing: GALECTIN THERAPEUTICS INC - Form 10-Q

2013 and December 31, 2012.

On May 2, 2012, Dr. Platt instituted an arbitration with the American Arbitration Association seeking the \$1 million payment based on a claim that the milestone event in the Separation Agreement described in clause (iii) above had occurred. Although the

Table of Contents

Company had listed its common stock on the Nasdaq Capital Markets as of March 22, 2012, the market capitalization since the listing had not reached \$100 million when the arbitration was heard in October 2012. On November 1, 2012, the arbitrator denied Dr. Platt's demand in all respects.

On October 12, 2012, Dr. Platt commenced a lawsuit under the Massachusetts Wage Act against Dr. Traber and Mr. McGauley who in their capacities as the Company's Chief Executive Officer and Chief Financial Officer respectively can be held individually liable under the Wage Act for non-payment of wages. The lawsuit is based on the facts and issues raised in the arbitration regarding the payment of the \$1.0 million separation payment under the Separation Agreement, and other unspecified wages. The statute provides that a successful claimant may be entitled to multiple damages, interest and attorney's fees. Although the Company is not a party to the lawsuit, it plans to indemnify Dr. Traber and Mr. McGauley consistent with its obligations under the by-laws and applicable law, believes the lawsuit is without merit, and intends a vigorous defense on their behalf. On April 29, 2013, the Court allowed Dr. Traber's and Mr. McGauley's motion to dismiss. Dr. Platt filed a Notice of Appeal to appeal the Court's order allowing the defendants' motion to dismiss.

On March 29, 2013, the Company instituted arbitration before the American Arbitration Association, seeking to rescind or reform the Separation Agreement discussed above. The Company claims that Dr. Platt fraudulently induced the Company to enter into the Separation Agreement, breached his fiduciary duty to the Company, and was unduly enriched from his conduct. Along with removal of the \$1.0 million milestone payment under the Separation Agreement, the Company is seeking repayment of all separation benefits paid to Dr. Platt to date. Depending on the outcome of the arbitration, the previously accrued \$1.0 million could be reversed. The timing and ultimate outcome of this arbitration, though, is uncertain and there is no guarantee that the Company will be successful in this demand.

On August 1, 2013, the market capitalization of the Company's common stock exceeded \$100 million. As described in the preceding paragraph, the Company had previously instituted an arbitration against Dr. Platt seeking to rescind the Separation Agreement, including the milestone payment provision.

Series C Post Conversion Dividend Rights

In January 2013, 5 shares of the Company's Series C Super Dividend Convertible Preferred Stock (Series C) were converted into 8,475 shares of common stock (consisting of 8,334 shares of common stock for principal and 141 shares for accrued interest at the time of the conversion) which also resulted in the issuance of 5 Series C post-conversion dividend rights (Dividend Rights). Under the terms of the Series C, the Dividend Rights entitle the holder only to dividend payments based on actual sales of GM-CT-01 and will not participate in the 6% dividend payable on outstanding shares of Series C following a conversion to common stock. At June 30, 2013, there are a total of 10 outstanding Dividend Rights which were determined to have a de minimis value, because payment of a dividend for the Dividend Rights is considered improbable at this time and the Company has not recorded a liability related to the Dividend Rights. The Company will continue to evaluate and assess the Dividend Rights for each reporting period. At June 30, 2013, the Dividend Rights had a redemption value of \$241,000.

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, except as noted above. There has been no change in the matters reported in our Annual Report on Form 10-K for the year ended December 31, 2012.

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;

plans regarding lawsuits, arbitration, and any related indemnification of Company employees;

Table of Contents

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 operations through the first quarter of 2014;

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, without limitation: our early stage of development; our dependence on outside capital; uncertainties related to our technology and clinical trials, intellectual property protection, uncertainties of regulatory approval requirements for our products; competition and stock price volatility in the biotechnology industry, limited trading volume for our stock, concentration of ownership of our stock, and other risks detailed herein and from time to time in our SEC reports, including our Annual Report on Form 10-K filed with the SEC for the fiscal year ended December 31, 2012, and our subsequent SEC filings. The following discussion should be read in conjunction with the accompanying consolidated financial statements and notes thereto of Galectin Therapeutics appearing elsewhere herein.

Overview

We are a development-stage company engaged in drug research and development to create new therapies for fibrotic disease and cancer. Galectins are a class of proteins that are made by many cells in the body. As a group, these proteins are able to bind to sugar molecules that are part of other proteins in and on the cells of our body. Galectin proteins act as a kind of glue, bringing together molecules that have sugars on them. Galectin proteins are known to be markedly increased in a number of important diseases including 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.

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 materials as starting material in manufacturing processes to create proprietary 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 bind and inhibit galectin proteins, 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 additional resources.

We endeavor to leverage our scientific and product development expertise as well as established relationships with outside sources to achieve cost-effective and efficient development. These outside sources, amongst others, provide us with expertise in preclinical models, pharmaceutical development, toxicology, clinical development, pharmaceutical manufacturing, sophisticated physical and chemical characterization, and commercial development. We also have established a collaborative scientific discovery program with leading experts in carbohydrate chemistry and characterization. This discovery program is aimed at the targeted development of new molecules which bind galectin proteins and offer

alternative options to larger market segments in our primary disease targets. We are pursuing a development pathway to clinical enhancement and commercialization for our lead compounds in liver fibrosis and fatty liver disease as well as in immune enhancement for cancer therapy. All of our proposed products are presently in development, including pre-clinical and clinical trials.

Our Drug Development Programs

We have two compounds in development, one intended to be used in the treatment of liver fibrosis and fatty liver disease and the other intended to be used in cancer therapy. These two compounds are produced from completely different, natural, readily available, starting materials, which, following chemical processing, both exhibit the property of binding to and inhibiting galectin proteins.

Table of Contents

Our product pipeline is shown below:

| Indication | Drug | Status |
|--|----------|--|
| Fibrosis NASH with Advanced Fibrosis | GR-MD-02 | Phase I clinical trial started July 2013 |
| Cancer Immunotherapy Melanoma | GM-CT-01 | Phase I/II study in process in Europe |

We believe the mechanism of action for GR-MD-02 and GM-CT-01 is based upon interaction with, and inhibition of, galectin proteins, which are expressed at high levels in certain pathological states including inflammation, fibrosis and cancer. While GR-MD-02 and GM-CT-01 are capable of binding to multiple galectin proteins, we believe that they have 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.

GR-MD-02. The main initiative in our development strategy is the application of galectin inhibition in connection with liver fibrosis, a condition that leads to cirrhosis. We believe that GR-MD-02 has the potential to treat nonalcoholic steatohepatitis (NASH) and other forms of liver fibrosis. The driving factor for our commitment to galectin inhibition for fibrosis is scientific evidence that strongly suggests that galectin-3 is essential for the development of liver fibrosis in animals. Published data show that mice lacking the galectin-3 gene are incapable of developing liver fibrosis in response to toxin insult to the liver and in fatty liver disease. Moreover, mice that do not have the galectin-3 gene are resistant to lung and kidney fibrosis. Our preclinical data show that GR-MD-02 has a powerful therapeutic effect on liver fibrosis as shown in several relevant animal models. 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). Pre-clinical studies also show promise for the combination of GR-MD-02 with other approved immunotherapies and this additional use will be explored for possible advancement into clinical trials.

In January 2013, an Investigational New Drug (IND) was submitted to the FDA with the goal of initiating a Phase I study in patients with NASH and advanced liver fibrosis to primarily evaluate the human safety of GR-MD-02 and pharmacodynamics biomarkers of disease are also included in the trial design. On March 1, 2013, the FDA indicated we could proceed with a U.S. 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. In February 2013 we entered into an agreement with Clinical Trial Services Inc. (CTI) to conduct a Phase I clinical trial of GR-MD-02 to assess safety and preliminary evidence of efficacy in humans. In June 2013, we submitted a Fast Track application to the FDA to help expedite its clinical development program of GR-MD-02 in the treatment of NASH with advanced fibrosis. FDA grants Fast Track designation to help expedite review and approval of drugs in development that treat serious or life threatening diseases and fill an unmet medical need. On August 7, 2013, FDA concluded that the development program for GR-MD-02 meets the criteria for Fast Track designation, and FDA has designated the investigation of GR-MD-02 for non-alcoholic steatohepatitis with hepatic fibrosis as a Fast Track development program. We began enrolling patients in this trial in July 2013 and we expect top line of the first cohort of patients (total of 8 patients) by late 2013 or early 2014. Results of cohort 2 and cohort 3, if needed, will be available by mid-2014. In Q3 of 2014, depending on the results of the Phase I study and available funding, we may initiate a Phase II clinical trial to assess the efficacy of GR-MD-02 in patients with NASH and advanced liver fibrosis and based on that timing we would expect top-line clinical results by late 2015 or early 2016, depending on the final design of the phase 2 study.

GM-CT-01. We believe the potential exists for galectin inhibition to play an important role in cancer therapy. Galectin proteins, particularly galectin-1 and galectin-3, have been shown to be highly expressed in the majority of cancers and have multiple roles in promoting cancer progression, including tumor cell invasion, metastasis, angiogenesis, and tumor evasion of the immune system. GM-CT-01 has progressed in development for the therapy of colorectal cancer and is currently in a Phase I/II clinical trial in Europe as a combination therapy with a tumor vaccine in patients with advanced melanoma. The current developmental approach for GM-CT-01 is to enhance the activity of the immune system against the cancer.

In May 2012, we initiated a Phase I/II clinical trial of GM-CT-01 in Belgium in combination with a tumor vaccine in patients with advanced melanoma, a deadly skin cancer. The Belgian Federal Agency of Medicine and Health Products, or FAMHP, granted approval for this clinical trial, which is being conducted at three centers in Belgium and one in Luxembourg. There are two primary cohorts of patients in this study, one where GM-CT-01 is given intravenously (Cohort 1) and a second cohort where GM-CT-01 is given both intravenously and directly injected into a cutaneous metastasis (Cohort 2). As of now, 6 patients total have been enrolled and two patients have completed treatment in Cohort 1 and one patient has completed treatment in Cohort 2. The three completed patients have tolerated the therapy well with no stage 3/4 adverse events. None of the three patients had a partial or complete response to therapy based on RECIST criteria, but two patients had a mixed response with some tumors receding in size. Enrollment

Table of Contents

in the study is continuing, but we do not have an estimate of completion of the first stage of the cohorts because enrollment is under the control of the site conducting the trial. For each cohort, 6 patients will be enrolled in stage one of the study, and if at least one out of six patients has a response (PR or CR by RECIST criteria), the remaining patients will be enrolled up to a total of 23 per cohort. Depending on the results of Stage 1, which is defined as a partial or complete response by RECIST criteria in at least one out of six patients, the study could continue enrollment to complete Stage 2 (46 total patients), initiate a new Phase II trial based on positive results or be halted because of lack of efficacy. Stage 1 of the trial is being funded by the Cancer Centre at the Cliniques Universitaires Saint-Luc and Stage 2 may require funding from the Company, beyond the provision of material, however, we have no commitment to fund Stage 2 of the trial. We do not control this Phase I/II clinical trial in Belgium which is being conducted under an EMA-approved IMPD. We are the sponsor of an open IND application under the FDA for GM-CT-01; no trials are currently being conducted in the U.S.

Results of Operations**Three and Six Months Ended June 30, 2013 Compared to Three and Six Months Ended June 30, 2012***Research and Development Expense.*

| | Three Months Ended | | Six Months Ended | | 2013 as Compared to 2012 | | | |
|--|--------------------|------------------|------------------|------------------|--------------------------|----------|------------|----------|
| | June 30, 2013 | June 30, 2012 | June 30, 2013 | June 30, 2012 | Three Months | | Six Months | |
| | | | | | \$ Change | % Change | \$ Change | % Change |

| | | | | | | | | |
|--------------------------|----------|----------|----------|----------|--------|-----|--------|-----|
| Research and development | \$ 1,349 | \$ 1,215 | \$ 3,101 | \$ 2,116 | \$ 134 | 11% | \$ 985 | 47% |
|--------------------------|----------|----------|----------|----------|--------|-----|--------|-----|

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.

We have two product candidates, GR-MD-02 and GM-CT-01. We filed for an IND for GR-MD-02 in January 2013 and in February 2013 we entered into an agreement with CTI to conduct a Phase I clinical trial of GR-MD-02 which we began enrolling patients in July 2013. GM-CT-01 is in a Phase I/II clinical trial in Europe at this time, which is being conducted in collaboration with the Cancer Centre at the Cliniques Universitaires Saint-Luc and the Ludwig Institute for Cancer Research in Belgium.

Our research and development expenses were as follows:

| | Three Months Ended | | Six Months Ended | |
|---|--------------------|------------------|------------------|------------------|
| | June 30, 2013 | June 30, 2012 | June 30, 2013 | June 30, 2012 |
| | (in thousands) | | | |
| Direct external expenses: | | | | |
| Clinical programs | \$ 511 | \$ 275 | \$ 1,254 | \$ 523 |
| Pre-clinical activities | 491 | 434 | 1,044 | 754 |
| All other research and development expenses | 347 | 506 | 803 | 839 |
| | \$ 1,349 | \$ 1,215 | \$ 3,101 | \$ 2,116 |

Clinical programs expenses increased primarily due to the startup costs related to our Phase I clinical trial agreement with CTI during the three and six months ended June 30, 2013 versus primarily compound manufacturing, toxicology testing and other preparation costs during the three and six months ended June 30, 2012 for GM-CT-01. As we continue enrolling patients in the Phase I trial we expect our clinical activities costs

Edgar Filing: GALECTIN THERAPEUTICS INC - Form 10-Q

will increase and may fluctuate from quarter to quarter as the trial progresses. Pre-clinical activities increased primarily due to pre-clinical work related to fibrosis prior to the IND approval as well as our agreement with the University of Georgia. Other research and development expenses decreased during the three months ended June 30, 2013 primarily due to decreased stock-based compensation (\$148,000). Other research and development expenses decreased during the six months ended June 30, 2013 primarily due to decreased rent and overhead expenses (\$57,000), offset by increased stock-based compensation (\$22,000).

Table of Contents

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

General and Administrative Expense.

| | Three Months | | Six Months | | 2013 as Compared to 2012 | | | |
|----------------------------|--------------------------|----------|----------------|----------|--------------------------|----------|------------|----------|
| | Ended June 30, | | Ended June 30, | | Three Months | | Six Months | |
| | 2013 | 2012 | 2013 | 2012 | \$ Change | % Change | \$ Change | % Change |
| | (In thousands, except %) | | | | | | | |
| General and administrative | \$ 1,198 | \$ 1,453 | \$ 2,654 | \$ 2,505 | \$ (255) | (18)% | \$ 149 | 6% |

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 reason for the decrease for the three months ended June 30, 2013 as compared to the same period in 2012 is due to decreased stock-based compensation (\$116,000) and decreased rent (\$58,000) due to our relocation in October 2012, offset by increased legal expenses (\$42,000) related to ongoing litigation with the Company's former CEO, Dr. Platt. The primary reason for the increase for the six months ended June 30, 2013 as compared to the same period in 2012 is due to increased legal expenses (\$166,000) related to our ongoing litigation with Dr. Platt and increased investor relations (\$39,000), offset by decreased rent expense (\$119,000).

Liquidity and Capital Resources

As described above in the Overview and elsewhere in this Quarterly Report on Form 10-Q, we are in the development stage and have not generated any revenues.

Since our inception on July 10, 2000, we have financed our operations from proceeds of public and private offerings of debt and equity. As of June 30, 2013, we raised a net total of \$68.8 million from these offerings. We have operated at a loss since our inception and have had no significant revenues. We anticipate that losses will continue for the foreseeable future. At June 30, 2013, we had \$5.1 million of unrestricted cash and cash equivalents available to fund future operations. Subsequent to June 30, 2013, we received \$2,429,923 from the exercise of warrants for 578,553 shares of common stock. We believe that with the cash on hand at June 30, 2013 and the cash received subsequent to year end, there is sufficient cash to fund operations through the first quarter of 2014. Our ability to fund operations after our current cash resources are exhausted depends on our ability to obtain additional financing or achieve profitable operations, as to which no assurances can be given. We have developed several plans, including cost containment efforts and potential strategic alternatives in the event that such financing cannot be realized by 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.

Net cash used in operations increased by \$685,000 to \$4,355,000 for the six months ended June 30, 2013, as compared to \$3,670,000 for the six months ended June 30, 2012. Cash operating expenses increased principally due to increased research and development activities related to our clinical trial activity with GR-MD-02.

Net cash provided by financing activities was \$90,000 during the six months ended June 30, 2013 from cash paid for option exercises as compared to \$10,403,000 during the six months ended June 30, 2012, due to a public offering we completed in the first quarter of 2012.

Table of Contents**Payments Due Under Contractual Obligations**

The following table summarizes the payments due under our contractual obligations at June 30, 2013, and the effect such obligations are expected to have on liquidity and cash flow in future periods:

| Contractual Obligations | Total | Payments due by period (in thousands) | | | |
|--|-------|---------------------------------------|-----------|-----------|----------------------|
| | | Less than 1 year | 1-3 years | 3-5 years | More than 5 years |
| Operating leases | \$ 59 | \$ 43 | \$ 16 | \$ | \$ |
| Total payments due under contractual obligations | \$ 59 | \$ 43 | \$ 16 | \$ | \$ |

Operating leases.

In September 2012, we entered into an operating lease for office space in Norcross, GA for a term of twenty-six months, beginning on October 1, 2012 and ending November 30, 2014 at a rate of \$3,000 per month. The lease provided for free rent for the first two months of the lease and required a security deposit of \$6,000. In addition to base rental payments included in the contractual obligations table above, we are responsible for our pro-rata share of increases in the operating expenses for the building.

In October 2012, we entered into an operating lease for office space collocated with lab space for research and development activities. The lease is for a period of one year, beginning on October 1, 2012, for a rate of \$15,000 for the term, payable in monthly increments.

Agreement with CTI for Phase I Clinical Trial

On February 1, 2013, the Company entered into an Amended and Restated Master Services Agreement (the *Agreement*) with CTI Clinical Trial Services, Inc. and CTI Clinical Consulting Services, Inc. (individually and collectively, *CTI*), whereby CTI will assist the Company in the design, development and conduct of one or more clinical research studies from time to time. All work performed by CTI for the Company will be conducted pursuant to the terms of work orders that describe the specific obligations undertaken by CTI with respect to any particular clinical research study sponsored or conducted by the Company. Unless otherwise terminated sooner in accordance with the terms of the Agreement, the Agreement will be effective until January 31, 2018.

On February 1, 2013, the Company entered into a work order (the *Work Order*) with CTI in accordance with the terms of the Agreement. The Work Order provides that CTI will provide services with respect to the Company's Phase I Clinical Trial to evaluate the safety of the Company's drug GR-MD-02 in subjects with Non-Alcoholic Steatohepatitis (*NASH*) with advanced hepatic fibrosis. CTI will provide the following services, amongst others, with respect to the Work Order: reviewing and providing notices regarding IND safety reports, selecting investigators and monitors for the study, informing investigators of new observations, monitoring the progress of the study and reviewing ongoing investigations, keeping certain records, inspecting the Company's records and reports, and disposing of any unused supply of the investigational drug.

The Work Order provides for CTI's anticipated involvement in the study from February 1, 2013 until March 31, 2014. The estimated budget for the Work Order is \$2,155,000, which is subject to change as necessary, with payments made throughout the term of the project as the work is performed. During the three and six months ended June 30, 2013, the Company recognized \$361,000 and \$1,090,000 of expenses related to this agreement for services performed.

The Agreement or any work order may be terminated for any reason by any party upon ninety (90) days prior written notice to the other party. In addition, the Agreement may be terminated by either party immediately if the other party becomes insolvent, is dissolved or liquidated, makes a general assignment for the benefit of its creditors, files or has filed against it (and does not obtain a dismissal within ninety (90) days) a petition of bankruptcy, or has a receiver appointed for it or a substantial part of its assets, among other reasons. Further, the Agreement or any relevant work order may be terminated immediately by written notice from the Company, in the following circumstances: (1) the FDA withdraws authorization and approval to conduct a study; or (2) the Company reasonably determines that for medical, clinical or patient safety reasons, a study should terminate immediately. In addition, either party may terminate the Agreement or any work order for material breach upon thirty (30) days' written notice specifying the nature of the breach, if such breach has not been substantially cured within the thirty (30) day period.

Edgar Filing: GALECTIN THERAPEUTICS INC - Form 10-Q

Drug Discovery Program with the University of Georgia

In February 2013, the Company established a collaborative drug discovery program at the Complex Carbohydrate Research Center at the University of Georgia. This program is focused on the discovery of new carbohydrate molecules that can be used in the therapy of diseases where galectin proteins play a major role, including cancer and inflammatory and fibrotic disorders. The term of the agreement is effective through December 31, 2013, for which the Company will provide funding of \$154,000 during the period as work is performed. The Company has paid \$135,000 related to this program through June 30, 2013. This agreement may be terminated by either party upon 90 days notice.

Table of Contents*Separation agreement.*

In February 2009, we entered into a Separation Agreement in connection with the resignation of David Platt, Ph.D., the Company's former Chief Executive Officer and Chairman of the Board of Directors. The Separation Agreement provides for the deferral of a \$1.0 million separation payment due to Dr. Platt upon the earlier occurrence of any of the following milestone events: (i) the approval by the Food and Drug Administration for a new drug application (NDA) for any drug candidate or drug delivery candidate based on the GM-CT-01 technology (whether or not such technology is patented), in which case Dr. Platt is also entitled to a fully vested 10-year cashless-exercise stock option to purchase at least 83,334 shares of common stock at an exercise price not less than the fair market value of the common stock determined as of the date of grant; (ii) consummation of a transaction with a pharmaceutical company expected to result in at least \$10.0 million of equity investment or \$50 million of royalty revenue to the Company, in which case Dr. Platt is also entitled to stock options on the same terms to purchase at least 50,000 shares of common stock; or (iii) the renewed listing of our securities on a national securities exchange and the achievement of a market capitalization of \$100 million. Payment upon the events (i) and (iii) may be deferred up to six months, and if we have insufficient cash at the time of any of such events, we may issue Dr. Platt a secured promissory note for such amount. If we file a voluntary or involuntary petition for bankruptcy, whether or not a milestone event has occurred, such event shall trigger our obligation to pay the \$1.0 million with the result that Dr. Platt may assert a claim for such obligation against the bankruptcy estate. During 2011, when it became probable that our common stock could be relisted on a national securities exchange and eventually reach a market capitalization of \$100 million, we recognized the \$1.0 million severance payment due to Dr. Platt and it is included in accrued expenses at June 30, 2013 and December 31, 2012.

On May 2, 2012, Dr. Platt instituted an arbitration with the American Arbitration Association seeking the \$1 million payment based on a claim that the milestone event in the Separation Agreement described in clause (iii) above had occurred. Although the Company had listed its common stock on the Nasdaq Capital Markets as of March 22, 2012, the market capitalization since the listing had not reached \$100 million when the arbitration was heard in October 2012. On November 1, 2012, the arbitrator denied Dr. Platt's demand in all respects.

On October 12, 2012, Dr. Platt commenced a lawsuit under the Massachusetts Wage Act against Dr. Traber and Mr. McGauley who in their capacities as the Company's Chief Executive Officer and Chief Financial Officer respectively can be held individually liable under the Wage Act for non-payment of wages. The lawsuit is based on the facts and issues raised in the arbitration regarding the payment of the \$1.0 million separation payment under the Separation Agreement, and other unspecified wages. The statute provides that a successful claimant may be entitled to multiple damages, interest and attorney's fees. Although the Company is not a party to the lawsuit, it plans to indemnify Dr. Traber and Mr. McGauley consistent with its obligations under the by-laws and applicable law, believes the lawsuit is without merit, and intends a vigorous defense on their behalf. On April 29, 2013, the Court allowed Dr. Traber's and Mr. McGauley's motion to dismiss. Dr. Platt filed a Notice of Appeal to appeal the Court's order allowing the defendants' motion to dismiss.

On March 29, 2013, the Company instituted arbitration before the American Arbitration Association, seeking to rescind or reform the Separation Agreement discussed above. The Company claims that Dr. Platt fraudulently induced the Company to enter into the Separation Agreement, breached his fiduciary duty to the Company, and was unduly enriched from his conduct. Along with removal of the \$1.0 million milestone payment under the Separation Agreement, the Company is seeking repayment of all separation benefits paid to Dr. Platt to date. Depending on the outcome of the arbitration, the previously accrued \$1.0 million could be reversed. The timing and ultimate outcome of this arbitration, though, is uncertain and there is no guarantee that the Company will be successful in this demand.

On August 1, 2013, the market capitalization of the Company's common stock exceeded \$100 million. As described in the preceding paragraph, the Company had previously instituted an arbitration against Dr. Platt seeking to rescind the Separation Agreement, including the milestone payment provision.

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.

Table of Contents

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 2012 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

Our management, with the participation of the Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934) and concluded that, as of June 30, 2013, our disclosure controls and procedures were effective at a reasonable assurance level. During the quarter ended June 30, 2013, 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

As previously disclosed in the Company's Form 10-K for the year ended December 31, 2012, David Platt, Ph.D., the Company's former Chief Executive Officer and Chairman of the Board of Directors, commenced a lawsuit on October 12, 2012, under the Massachusetts Wage Act against Peter G. Traber, M.D. and Mr. Thomas A. McGauley, who in their capacities as the Company's Chief Executive Officer and Chief Financial Officer respectively can be held individually liable under the Wage Act for non-payment of wages.

On April 29, 2013, the Court allowed Dr. Traber's and Mr. McGauley's motion to dismiss. Dr. Platt filed a Notice of Appeal dated May, 28, 2013 to appeal the Court's order allowing the defendants' motion to dismiss.

On March 29, 2013, the Company instituted arbitration before the American Arbitration Association, seeking to rescind or reform Dr. Platt's Separation Agreement with the Company. The Company claims that Dr. Platt fraudulently induced the Company to enter into the Separation Agreement, breached his fiduciary duty to the Company, and was unduly enriched from his conduct. Along with removal of the \$1.0 million milestone payment provided for under the Separation Agreement, the Company is seeking repayment of all separation benefits paid to Dr. Platt to date.

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, 2012, which could materially impact our business, financial condition or future results.

Table of Contents

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
None

Table of Contents**Item 6. Exhibits**

| Exhibit Number | Description of Document | Note Reference |
|---------------------------|---|---------------------------|
| 3.1 | Amended and Restated Bylaws of Galectin Therapeutics Inc. | 1 |
| 3.2 | Restated Articles of Incorporation of Galectin Therapeutics Inc. | 1 |
| 10.1* | Amended Form of Class A-2 Common Stock Purchase Warrant | |
| 10.2* | Amended Form of Class B Common Stock Purchase Warrant | |
| 10.3* | Employment Agreement dated June 20, 2013 between Jack W. Callicutt and Galectin Therapeutics Inc. | |
| 10.4* | Amendment to Independent Consulting Agreement dated June 19, 2013 between Thomas A. McGauley and Galectin Therapeutics Inc. | |
| 10.5* | Stock Option Agreement with Thomas A. McGauley dated June 19, 2013 | |
| 23.1* | Consent of McGladrey LLP, an independent registered public accounting firm. | |
| 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.

1. Incorporated by reference to the Company's Current Report on Form 8-K filed with the Commission on May 30, 2012.

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on August 14, 2013.

GALECTIN THERAPEUTICS INC.

By: /s/ Peter G. Traber
Name: Peter G. Traber, M.D.
Title: Chief Executive Officer and President

/s/ Jack W. Callicutt
Name: Jack W. Callicutt
Title: Chief Financial Officer