

GALECTIN THERAPEUTICS INC

Form 10-Q

May 13, 2014

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**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 March 31, 2014**

.. **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)**

**04-3562325  
(I.R.S. Employer)**

of incorporation)

Identification No.)

4960 Peachtree Industrial Blvd., Suite 240, Norcross,  
GA

30071

(Address of Principal Executive Offices)

(Zip Code)

(678) 620-3186

(Registrant's Telephone Number, Including Area Code)

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 May 9, 2014 was 21,908,265.

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**Table of Contents****GALECTIN THERAPEUTICS INC.****(A Development-Stage Company)****CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)**

|   | <b>March 31,</b>      | <b>December 31,</b> |
|---|-----------------------|---------------------|
|   | <b>2014</b>           | <b>2013</b>         |
|   | <b>(in thousands)</b> |                     |
| <b>ASSETS</b>   |                       |                     |
| Current assets:   |                       |                     |
| Cash and cash equivalents   | \$ 36,594             | \$ 10,489           |
| Prepaid expenses and other current assets   | 151                   | 198                 |
| <b>Total current assets</b>   | <b>36,745</b>         | <b>10,687</b>       |
| Property and equipment, net   | 3                     | 3                   |
| Equity method investment in Galectin Sciences, LLC  | 130                   |                     |
| Intangible assets, net  | 21                    | 23                  |
| <b>Total assets</b>   | <b>\$ 36,899</b>      | <b>\$ 10,713</b>    |
| <b>LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY</b>  |                       |                     |
| Current liabilities:  |                       |                     |
| Accounts payable  | \$ 486                | \$ 762              |
| Accrued expenses  | 1,451                 | 1,651               |
| Accrued dividends payable   |                       | 73                  |
| <b>Total current liabilities</b>  | <b>1,937</b>          | <b>2,486</b>        |
| Other long-term liabilities   |                       |                     |
| <b>Total liabilities</b>  | <b>1,937</b>          | <b>2,486</b>        |
| Commitments and contingencies (Note 8)  |                       |                     |
| Series B-1 12% redeemable convertible preferred stock; 900,000 shares authorized, issued and outstanding at March 31, 2014 and December 31, 2013, redemption and liquidation value \$1,800,000 at March 31, 2014                                | 1,719                 | 1,715               |
| Series B-2 12% redeemable convertible preferred stock; 2,100,000 shares authorized, issued and outstanding at March 31, 2014 and December 31, 2013, redemption and liquidation value \$4,200,000 at March 31, 2013                              | 3,166                 | 3,112               |
| Series C super dividend convertible preferred stock; 1,000 shares authorized, 185 and 196 shares issued and outstanding at March 31, 2014 and December 31, 2013, respectively, redemption value: \$5,130,000, liquidation value: \$1,850,000 at | 1,811                 | 1,919               |

March 31, 2014

## Stockholders' equity:

Undesignated stock, \$0.01 par value; 20,000,000 shares authorized, 8,001,000 designated at March 31, 2014 and December 31, 2013

Series A 12% convertible preferred stock; 5,000,000 shares authorized, 1,452,500 issued and outstanding at March 31, 2014 and December 31, 2013, liquidation value \$1,452,500 at March 31, 2014

587 587

Common stock, \$0.001 par value; 50,000,000 shares authorized at March 31, 2014 and December 31, 2013, 21,906,172 and 18,386,900 issued and outstanding at March 31, 2014 and December 31, 2013, respectively

22 18

Additional paid-in capital

135,030 102,841

Deficit accumulated during the development stage

(107,373) (101,965)

Total stockholders' equity

28,266 1,481

Total liabilities, redeemable convertible preferred stock and stockholders' equity

\$ 36,899 \$ 10,713

See notes to unaudited condensed consolidated financial statements.

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

|  | <b>Cumulative</b>                           |             |                     |
|--|---|-------------|---------------------|
|  | <b>Period from</b>                          |             |                     |
|  | <b>Inception</b>                            |             |                     |
|  | <b>(July 10, 2000)</b>                      |             |                     |
|  | <b>Three Months Ended</b>                   |             | <b>to March 31,</b> |
|  | <b>March 31,</b>                            | <b>2013</b> | <b>2014</b>         |
|  | <b>2014</b>                                 | <b>2013</b> | <b>2014</b>         |
|  | <b>(in thousands except per share data)</b> |             |                     |
| Operating expenses:  |   |             |                     |
| Research and development                                     | \$ 2,772                                    | \$ 1,752    | \$ 36,070           |
| General and administrative                                   | 2,072                                       | 1,456       | 55,524              |
| Total operating expenses                                     | 4,844                                       | 3,208       | 91,594              |
| Total operating loss   | (4,844)                                     | (3,208)     | (91,594)            |
| Other income (expense):                                      |   |             |                     |
| Interest income  | 4   | 5           | 838                 |
| Interest expense   |   |             | (4,451)             |
| Loss from equity method investment in Galectin Sciences, LLC | (270)                                       |             | (270)               |
| 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)                                 | (266)                                       | 5           | 2,404               |
| Net loss   | \$ (5,110)                                  | \$ (3,203)  | \$ (89,190)         |
| Preferred stock dividends                                    | (240)                                       | (213)       | (5,344)             |
| Preferred stock accretion                                    | (58)  | (56)        | (4,332)             |
| Warrant modification   |   |             | (8,763)             |
| Net loss applicable to common stockholders                   | \$ (5,408)                                  | \$ (3,472)  | \$ (107,629)        |
| Net loss per common share basic and diluted                  | \$ (0.27)                                   | \$ (0.22)   |                     |
| Weighted average common shares outstanding basic and diluted | 20,270                                      | 16,079      |                     |

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)**

|   | <b>Three Months Ended</b> |             | <b>Cumulative</b>      |
|---|---------------------------|-------------|------------------------|
|   | <b>March 31,</b>          | <b>2013</b> | <b>Period from</b>     |
|   | <b>2014</b>               | <b>2013</b> | <b>Inception</b>       |
|   | <b>(in thousands)</b>     |             | <b>(July 10, 2000)</b> |
|   |                           |             | <b>to March 31,</b>    |
|   |                           |             | <b>2014</b>            |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>                                |                           |             |                        |
| Net loss  | \$ (5,110)                | \$ (3,203)  | \$ (89,190)            |
| Adjustments to reconcile net loss to net cash used in operating activities: |                           |             |                        |
| Depreciation and amortization   | 2                         | 3           | 569                    |
| Stock-based compensation expense  | 1,648                     | 852         | 17,811                 |
| Loss from equity method investment in Galectin Sciences LLC                 | 270                       |             | 270                    |
| 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   | 47                        | 16          | (148)                  |
| Accounts payable and accrued expenses                                       | (476)                     | (90)        | 1,998                  |
| Other long-term liabilities   |                           | (1)         |                        |
| Net cash used in operating activities                                       | (3,619)                   | (2,423)     | (69,656)               |
| <b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>                                |                           |             |                        |
| Purchases of property and equipment   |                           |             | (431)                  |
| Equity method investment in Galectin Sciences LLC                           | (400)                     |             | (400)                  |
| Increase in patents costs and other assets                                  |                           |             | (404)                  |
| Net cash provided by (used in) investing activities                         | (400)                     |             | (1,235)                |
| <b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>                                |                           |             |                        |
| Net proceeds from issuance of common stock and warrants                     | 28,178                    |             | 71,104                 |
| Net proceeds from issuance of Series A preferred stock and related warrants |                           |             | 1,691                  |
|   |                           |             | 1,548                  |



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|   |                  |                 |                  |
|---|------------------|-----------------|------------------|
| Net proceeds from issuance of Series B-1 preferred stock and related warrants         |                  |                 |                  |
| 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                           | 1,946            | 77              | 18,015           |
| Proceeds from shareholder advances  |                  |                 | 9                |
| <b>Net cash provided by financing activities</b>                                      | <b>30,124</b>    | <b>77</b>       | <b>107,485</b>   |
| <b>NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS</b>                           | <b>26,105</b>    | <b>(2,346)</b>  | <b>36,594</b>    |
| <b>CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD</b>                                 | <b>10,489</b>    | <b>9,364</b>    |                  |
| <b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>                                       | <b>\$ 36,594</b> | <b>\$ 7,018</b> | <b>\$ 36,594</b> |
| <b>SUPPLEMENTAL DISCLOSURE</b> Cash paid for interest                                 | \$               | \$              | \$ 114           |
| <b>NONCASH FINANCING ACTIVITIES:</b>  |                  |                 |                  |
| Issuance of equity warrants in connection with equity offerings                       | \$               | \$              | \$ 9,482         |
| Conversion of accrued expenses into common stock                                      |                  |                 | 329              |
| 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                                  | 312              | 293             | 5,334            |
| 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.

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**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 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 March 31, 2014 and the results of its operations for the three months ended March 31, 2014 and 2013 and the cumulative period from inception (July 10, 2000) through March 31, 2014 and its cash flows for the three months ended March 31, 2014 and 2013, and for the cumulative period from inception (July 10, 2000) to March 31, 2014. All adjustments made to the interim financial statements include all those of a normal and 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, 2013.

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 March 31, 2014, the Company had \$36.6 million of unrestricted cash and cash equivalents available to fund future operations. The Company believes that with the cash on hand at March 31, 2014, there is sufficient cash to fund operations through 2015. 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. 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 \$107.6 million for the cumulative period from inception (July 10, 2000) through March 31, 2014. 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 March 31, 2014, the Company had raised a net total of \$107.5 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 March 31, 2014, the Company used cash of \$69.7 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 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.

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Accrued expenses consist of the following:

|                              | March 31,<br>2014 | December 31,<br>2013 |
|------------------------------|-------------------|----------------------|
|                              | (in thousands)    |                      |
| Legal and accounting fees    | \$ 173            | \$ 103               |
| Accrued compensation         | 180               | 526                  |
| Severance agreement (Note 8) | 1,000             | 1,000                |
| Other                        | 98                | 22                   |
| <b>Total</b>                 | <b>\$ 1,451</b>   | <b>\$ 1,651</b>      |

**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:

|   | <b>Three Months Ended<br/>March 31,</b> |               |
|---|---|---------------|
|   | <b>2014</b>                             | <b>2013</b>   |
| Research and development                      | \$ 638                                  | \$ 319        |
| General and administrative                    | 1,010                                   | 533           |
| <b>Total stock-based compensation expense</b> | <b>\$ 1,648</b>                         | <b>\$ 852</b> |

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, 2013 through March 31, 2014:

|                                    | Shares           | Weighted Average<br>Exercise Price |
|------------------------------------|------------------|------------------------------------|
| Outstanding, December 31, 2013     | 3,348,705        | \$ 4.70                            |
| Granted                            | 326,500          | 13.38                              |
| Exercised                          | (288,749)        | 2.07                               |
| Options forfeited/cancelled        | (21,258)         | 3.59                               |
| <b>Outstanding, March 31, 2014</b> | <b>3,365,198</b> | <b>\$ 5.78</b>                     |

As of March 31, 2014, there was \$6,491,000 of unrecognized compensation related to 1,360,476 unvested options, which is expected to be recognized over a weighted average period of approximately 2.6 years. The weighted-average grant date fair value for options granted during the three months ended March 31, 2014 and 2013 was \$11.28 and

\$2.73, respectively. The Company granted 326,500 stock options during the three months ended March 31, 2014, of which 81,625 options vested upon grant with the remaining 244,875 options vesting over 3 years. Approximately \$921,000 of non-cash, stock-based compensation expense was recorded during the three months ended March 31, 2014 related to the options granted during the quarter that were vested upon the grant date.

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

|   | Three<br>Months Ended<br>March 31,<br>2014 | Three<br>Months Ended<br>March 31,<br>2013 |
|---|--|--|
| Risk-free interest rate                     | 1.58%                                      | 0.80%                                      |
| Expected life of the options                | 6.0 years                                  | 5.0 years                                  |
| Expected volatility of the underlying stock | 114%                                       | 117%                                       |
| Expected dividend rate                      | 0%   | 0%   |

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In January 2014, the Company entered into an agreement with a consultant that provided for the grant of 3,000 shares of common stock. The Company recognized an expense of \$25,000, representing the market value of the common stock, during the three months ended March 31, 2014.

**4. Common Stock Warrants**

The following table summarizes the common stock warrant activity from December 31, 2013 through March 31, 2014:

|                                | Shares    | Weighted Average<br>Exercise Price |
|--------------------------------|-----------|------------------------------------|
| Outstanding, December 31, 2013 | 6,035,229 | \$ 3.63                            |
| Granted                        |           |                                    |
| Exercised                      | 529,650   | 3.12                               |
| Forfeited/cancelled            |           |                                    |
| Outstanding, March 31, 2014    | 5,505,579 | \$ 3.67                            |

*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 three months ended March 31, 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 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. There were no level 2 or level 3 assets held at fair value at March 31, 2014 or December 31, 2013.

**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. 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.

|  | Three Months Ended<br>March 31,                       |            |
|--|---|------------|
|  | 2014  | 2013       |
|  | (in thousands, except share<br>and per share amounts) |            |
| Basic and diluted net loss per common share:                 |   |            |
| Net loss applicable to common stockholders                   | \$ (5,408)  | \$ (3,472) |
| Weighted average common shares outstanding basic and diluted | 20,270  | 16,079     |
| Net loss per common share basic and diluted                  | \$ (0.27)   | \$ (0.22)  |

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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:

|  | March 31, 2014 | March 31, 2013 |
|--|----------------|----------------|
|  | (shares)       | (shares)       |
| Warrants to purchase shares of common stock                        | 5,505,579      | 7,429,241      |
| Options to purchase shares of common stock                         | 3,365,198      | 3,656,217      |
| Shares of common stock issuable upon conversion of preferred stock | 2,550,437      | 2,618,772      |
|  | 11,421,214     | 13,704,230     |

**7. Common Stock***March 2012 Offering and Reverse Stock 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.

*At Market Issuance of Common Stock*



On October 25, 2013, the Company entered into an At Market Issuance Sales Agreement (the "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 At Market Agreement. As of December 31, 2013, the Company had issued 99,942 shares of its common stock through its At Market issuance program at an average price of \$9.02 per share resulting in gross proceeds of approximately \$944,000. The Company incurred one time, initial legal and accounting costs of approximately \$82,000 and commissions of \$29,000 resulting in net proceeds of \$833,000 as of December 31, 2013. In January and February 2014, the Company issued 2,663,647 shares of common stock for net proceeds of approximately \$28,178,000 which completed the At Market Agreement.

## **8. Commitments and Contingencies**

### *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

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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 December 31, 2013 and 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 the Company's former 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, and intends a vigorous defense on their behalf. On April 29, 2013, the Superior Court allowed Dr. Traber's and Mr. McGauley's motion to dismiss. On May 28, 2013, Dr. Platt filed a Notice of Appeal to appeal the Superior Court's order allowing the defendants' motion to dismiss. On April 14, 2014, the Appeals Court denied Dr. Platt's appeal of the dismissal in full.

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. This arbitration has been scheduled for April 28, 2014; however, the ultimate outcome 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 and the Company received a letter dated October 1, 2013, demanding payment of the \$1 million. As described in the preceding paragraph, the Company had previously instituted an arbitration proceeding against Dr. Platt seeking to rescind the Separation Agreement, including the milestone payment provision, and the Company is currently delaying payment pending the outcome of this arbitration.

*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 are no other pending legal proceedings except as noted above.

#### **9. 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. Both the Company and SBH have a 50% equity ownership interest in the LLC, with neither party having control over the LLC. Accordingly, the Company has 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 Company's portion of the LLC's net loss for the 3 month period ending March 31, 2014 was \$270,000, which includes the Company's proportionate share of the non-cash charge associated with the contributed IPR&D of \$200,000.

#### **10. Subsequent Events**

The Company has evaluated all events or transactions that occurred through the date on which the financial statements were issued, with no items noted for disclosure or recording in the consolidated financial statements as of March 31, 2014.

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**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, 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 operations through 2015; 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 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 our technology and clinical trials,

we may be unable to demonstrate the efficacy and safety of our developmental product candidates in human trials, intellectual property protection, and we may be unable to improve upon, protect and/or enforce our intellectual property,

we are subject to extensive and costly regulation by the U.S. Food and Drug Administration (FDA) and by foreign regulatory authorities, which must approve our product candidates in development and could restrict the sales and marketing and pricing of such products,

competition and stock price volatility in the biotechnology industry,

limited trading volume for our stock, concentration of ownership of our stock, and other risks detailed herein and from time to time in our SEC reports.

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, 2013, 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. 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 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 additional resources.

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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 synthetic carbohydrate molecules which bind galectin proteins and offer alternative options to larger market segments in our primary disease targets. This effort is conducted with the Center for Complex Carbohydrate Research at the University of Georgia. Several synthetic compounds have been made and attached to various scaffolds and tested for galectin binding activity. We also have established through Galectin Sciences, LLC, a joint venture created in January 2014, a discovery program aimed at the targeted development of small molecules (non-carbohydrate) which bind galectin proteins and may afford options for alternative means of drug delivery including oral and as a result expand the potential uses of our compounds. This effort involves in silico modeling using a proprietary molecular model built based on existing crystal structures of galectin, especially galectin-3. Chemical libraries have been screened for compounds with oral drugability and hits evaluated for galectin-3 binding. Pharmacophores for hit compounds are then synthesized and optimized via medicinal chemistry approaches. In addition to these efforts we are also pursuing derivatives of GR-MD-02, our lead compound, for subcutaneous administration which is focused on reductions in molecular weight and other potential modifications. We are pursuing a development pathway to clinical enhancement and commercialization for our lead compounds in immune enhancement for cancer therapy as well as in both liver fibrosis and fatty liver disease. 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. 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 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 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.

We have two compounds in development, GR-MD-02 and GM-CT-01, both of which have shown promise in preclinical studies in treatment of fibrosis and in cancer therapy. However, we are currently focusing on development of GR-MD-02 intended to be used in the treatment of liver fibrosis and fatty liver disease and in cancer therapy in combination with immune-system modifying agent(s). Both of our proprietary 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.

Our product pipeline is shown below:

| <b>Indication</b>           | <b>Drug</b> | <b>Status</b>  |
|-----------------------------|-------------|--|
| <b>Fibrosis</b>             |             |  |
| NASH with Advanced Fibrosis | GR-MD-02    | IND submitted January 2013, FDA indicated on March 1, 2013 that we could proceed with a Phase 1 US clinical trial. Phase 1 clinical trial started Q2-2013. Results from the first cohort of the Phase 1 clinical trial presented on March 31, 2014. Enrollment of the second |

cohort of the Phase 1 clinical trial was completed in April 2014. Results from the second cohort of the Phase 1 clinical trial are expected around the end of July 2014.

|                  |                        |                             |
|------------------|------------------------|-----------------------------|
| Lung Fibrosis    | GR-MD-02               | In pre-clinical development |
| Kidney Fibrosis  | GR-MD-02               | In pre-clinical development |
| Cardiac Fibrosis | GM-CT-01 &<br>GR-MD-02 | In pre-clinical development |

**Cancer Immunotherapy**

Melanoma GR-MD-02 Investigator IND filed in December 2013. Phase 1B study in process.

*Fibrosis.* GR-MD-02 is our lead product candidate for treatment of fibrotic disease. 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). 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

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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.

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.

*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 two recent approvals of drugs that enhance a patient's immune system to fight cancer. With many additional vaccines and immune stimulatory agents in development, industry analysts forecast that this market could generate over \$35 billion in sales over the next 10 years. It is our goal to use a galectin inhibitor to enhance the immune system function to fight cancer in a way that complements other approaches to this type of therapy. 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 and more specifically 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. These preclinical data have led to the filing of an Investigator-sponsored IND and the initiation of a study of GR-MD-02 in combination with Yervoy® (ipilimumab) in a Phase 1B study of patients with metastatic melanoma. This study is being conducted under the sponsorship of Providence Portland Medical Center's Earle A. Chiles Research Institute (EACRI) and is being supported by the Company.

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 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.

**Results of Operations****Three Months Ended March 31, 2014 Compared to Three Months Ended March 31, 2013***Research and Development Expense.*

|                          | Three Months<br>Ended March 31, |          | 2014 as Compared to 2013<br>Three Months |          |
|--------------------------|---------------------------------|----------|--|----------|
|                          | 2014                            | 2013     | \$ Change                                | % Change |
|                          | (In thousands, except %)        |          |  |          |
| Research and development | \$ 2,772                        | \$ 1,752 | \$ 1,020                                 | 58%      |

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 1 clinical trial of GR-MD-02. In March 2013, the FDA indicated we could proceed with a Phase 1 human clinical trial of GR-MD-02, and we began enrolling patients in the third quarter of 2013. In January 2014, we completed the enrollment of the first cohort of patients in the Phase 1 trial with no serious adverse events being reported. We reported initial safety and tolerability results, as well as encouraging changes in various biomarkers of fibrosis to evaluate for potential disease effect, from the first cohort of patients on March 31, 2014. The second cohort of this Phase 1 trial began and enrollment was completed in April 2014 with results expected around the end of July 2014. Depending on the results of the Phase 1 study, we expect to initiate a Phase 2 clinical trial in late 2014 to early 2015 to assess the efficacy of GR-MD-02 in patients with NASH and advanced liver fibrosis. The timing of initial results from the Phase 2 trial are dependent upon the trial design but currently are planned to be available in the first half of 2016. Our Phase 2 clinical program is likely to include additional clinical trials to fully characterize human response to GR-MD-02 and to better position the Company for a successful Phase 3 clinical trial program.

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Our research and development expenses were as follows:

|   | Three Months<br>Ended<br>March 31,<br>2014      2013<br>(in thousands) |          |
|---|--|----------|
| Direct external expenses:                   |  |          |
| Clinical activities                         | \$ 1,162   | \$ 743   |
| Pre-clinical activities                     | 774  | 553      |
| All other research and development expenses | 836  | 456      |
|   | \$ 2,772   | \$ 1,752 |

Clinical programs expenses increased primarily due to costs related to our Phase 1 clinical trial and compound manufacturing costs in anticipation of a Phase 2 clinical trial during the three months ended March 31, 2014 over 2013. As we begin enrolling patients in the Phase I trial we expect our clinical activities costs will increase and may fluctuate from quarter to quarter as the trial progresses. Pre-clinical activities increased primarily due to pre-clinical work related preparation for our anticipated Phase 2 clinical trial program. Other research and development expense increased primarily due to increased stock-based compensation (\$318,000).

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.

*General and Administrative Expense.*

|                            | Three Months<br>Ended March 31,<br>2014      2013 |          | 2014 as Compared to 2013<br>Three Months |          |
|----------------------------|---|----------|--|----------|
|                            |   |          | \$ Change                                | % Change |
|                            | (In thousands, except %)                          |          |  |          |
| General and administrative | \$ 2,072  | \$ 1,456 | \$ 616                                   | 42%      |

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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 for the three-months ended March 31, 2014 as compared to the same period in 2013 is due to increased stock-based compensation (\$478,000) and increased legal expenses (\$56,000) related to ongoing litigation with the Company's former CEO, Dr. Platt.

## **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 March 31, 2014, we raised a net total of \$107.5 million from these offerings. We have operated at a loss since our inception and have had no significant revenues. We anticipate that losses will continue for the foreseeable future. At March 31, 2014, we had \$36.6 million of unrestricted cash and cash equivalents available to fund future operations. We believe that with the cash on hand at March 31, 2014, there is sufficient cash to fund operations through 2015. 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. 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 March 21, 2014, the Company filed a new shelf registration statement on Form S-3 to replace its previous shelf registration. The new shelf registration statement allows the Company to offer up to \$100 million in additional common stock. Along with the filing of the new shelf registration statement, the Company filed a prospectus supplement to allow it to issue up to \$30 million in common stock under the new shelf registration statement pursuant to its At Market Agreement. The Company believes the ability to sell the common stock under its new registration statement provides flexibility and an additional source of liquidity, although there can be no assurance that market conditions will allow it to do so at any given time.

Net cash used in operations increased by \$2,133,000 to \$3,619,000 for the three months ended March 31, 2014, as compared to \$1,486,000 for the three months ended March 31, 2013. 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 \$30,124,000 for the three months ending March 31, 2014, consisting of \$28,178,000 from sale of common stock and \$1,946,000 from the proceeds from the exercise of stock options and warrants. During the three months ended March 31, 2013, \$77,000 was received for option exercises.

### *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 December 31, 2013 and 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.

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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. This arbitration has been scheduled for April 28, 2014; however, the ultimate outcome 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 and the Company received a letter dated October 1, 2013, demanding payment of the \$1 million. As described in the preceding paragraph, the Company had previously instituted an arbitration proceeding against Dr. Platt seeking to rescind the Separation Agreement, including the milestone payment provision, and the Company is currently delaying payment pending the outcome of this arbitration.

### *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 2013 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 March 31, 2014, our disclosure controls and procedures were effective at a reasonable assurance level. During the quarter ended March 31, 2014, 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.

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**PART II OTHER INFORMATION**

**Item 1. Legal Proceedings**

None except as disclosed above.

**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, 2013, which could materially impact our business, financial condition or future results.

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

In January 2014, the Company (i) issued 3,000 shares of common stock to Acorn Management Partners, LLC in connection with a consulting agreement, at a price of \$8.36 per share, and (ii) issued 8,331 shares of common stock to David Donabedian upon the exercise of warrants, at a price of \$3.00 per share. In issuing the shares the Company relied on an exemption from registration under the Securities Act of 1933 provided by Section 4(a)(2) and Regulation D promulgated thereunder.

**Item 3. Defaults Upon Senior Securities**

None

**Item 4. Mine Safety Disclosures**

Not Applicable

**Item 5. Other Information**

Not Applicable

**Table of Contents****Item 6. Exhibits**

| <b>Exhibit</b> |  | <b>Note</b>      |
|----------------|--|------------------|
| <b>Number</b>  | <b>Description of Document</b>   | <b>Reference</b> |
| 3.1            | Amended and Restated Bylaws of Galectin Therapeutics Inc.  | 1                |
| 3.2            | Restated Articles of Incorporation of Galectin Therapeutics Inc.   | 1                |
| 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.

**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 May 13, 2014.

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



