

GALECTIN THERAPEUTICS INC

Form 10-Q

November 10, 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 September 30, 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 November 7, 2014 was 22,123,583.

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**GALECTIN THERAPEUTICS INC.**

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	September 30, 2014	December 31, 2013
	(in thousands)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 31,201	\$ 10,489
Prepaid expenses and other current assets	90	198
Total current assets	31,291	10,687
Property and equipment, net	1	3
Equity method investment in Galectin Sciences, LLC	10	
Intangible assets, net	17	23
Total assets	\$ 31,319	\$ 10,713

**LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK  
AND STOCKHOLDERS EQUITY**

Current liabilities:		
Accounts payable	\$ 838	\$ 762
Accrued expenses	542	1,651
Accrued dividends payable		73
Total current liabilities	1,380	2,486
Total liabilities	1,380	2,486

**Commitments and contingencies (Note 8)**

Series B-1 12% redeemable convertible preferred stock; 900,000 shares authorized, issued and outstanding at September 30, 2014 and December 31, 2013, redemption and liquidation value \$1,800,000 at September 30, 2014	1,727	1,715
Series B-2 12% redeemable convertible preferred stock; 2,100,000 shares authorized, issued and outstanding at September 30, 2014 and December 31, 2013, redemption and liquidation value \$4,200,000 at September 30, 2014	3,272	3,112
Series C super dividend convertible preferred stock; 1,000 shares authorized, 176 and 196 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively, redemption value: \$4,806,000, liquidation value: \$1,760,000 at September 30, 2014	1,723	1,919
Stockholders equity:		

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Undesignated stock, \$0.01 par value; 20,000,000 shares authorized, 8,001,000 designated at September 30, 2014 and December 31, 2013

Series A 12% convertible preferred stock; 5,000,000 shares authorized, 1,402,500 and 1,452,500 issued and outstanding at September 30, 2014 and December 31, 2013, respectively; liquidation value \$1,402,500 at September 30, 2014

Common stock, \$0.001 par value; 50,000,000 shares authorized at September 30, 2014 and December 31, 2013, 22,123,583 and 18,386,900 issued and outstanding at September 30, 2014 and December 31, 2013, respectively	22	18
Additional paid-in capital	137,518	102,841
Accumulated deficit	(114,890)	(101,965)

Total stockholders' equity	23,217	1,481
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Total liabilities, redeemable convertible preferred stock and stockholders' equity	\$ 31,319	\$ 10,713
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See notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended September 30, 20142013		Nine Months Ended September 30, 20142013	
	(in thousands, except per share amounts)			
Operating expenses:				
Research and development	\$ 1,979	\$ 1,192	\$ 6,345	\$ 4,293
General and administrative	1,498	2,353	5,351	5,007
Total operating expenses	3,477	3,545	11,696	9,300
Total operating loss	(3,477)	(3,545)	(11,696)	(9,300)
Other income (expense):				
Interest income	12	3	29	11
Loss from equity method investment in Galectin Sciences, LLC	(53)		(390)	
Total other income (expense)	(41)	3	(361)	11
Net loss	\$ (3,518)	\$ (3,542)	\$ (12,057)	\$ (9,289)
Preferred stock dividends	(278)	(123)	(763)	(613)
Preferred stock accretion	(57)	(58)	(172)	(171)
Warrant modification				(8,763)
Net loss applicable to common stockholders	\$ (3,853)	\$ (3,723)	\$ (12,992)	\$ (18,836)
Net loss per common share basic and diluted	\$ (0.17)	\$ (0.22)	\$ (0.60)	\$ (1.15)
Weighted average common shares outstanding basic and diluted	22,051	16,988	21,732	16,438
See notes to unaudited condensed consolidated financial statements.				

See notes to unaudited condensed consolidated financial statements.

**Table of Contents****GALECTIN THERAPEUTICS INC.****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)**

	Nine Months Ended September 30, 20142013 (in thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (12,057)	\$ (9,289)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	8	9
Stock-based compensation expense	3,271	3,276
Loss from equity method investment in Galectin Sciences LLC	390	
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	108	126
Accounts payable and accrued expenses (Notes 2 and 8)	(1,033)	45
Other long-term liabilities		(5)
Net cash used in operating activities	(9,313)	(5,838)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Equity method investment in Galectin Sciences LLC	(400)	
Net cash used in investing activities	(400)	
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from issuance of common stock and warrants	28,238	3,000
Proceeds from exercise of common stock warrants and options	2,187	3,189
Net cash provided by financing activities	30,425	6,189
NET INCREASE IN CASH AND CASH EQUIVALENTS	20,712	351
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	10,489	9,364
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 31,201	\$ 9,715
NONCASH FINANCING ACTIVITIES:		
Payment of preferred stock dividends in common stock	766	694

See notes to unaudited condensed consolidated financial statements.

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**GALECTIN THERAPEUTICS INC.**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**1. Basis of Presentation**

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

The unaudited condensed consolidated financial statements as reported in this Quarterly Report on Form 10-Q reflect all adjustments which are, in the opinion of management, necessary to present fairly the financial position of the Company as of September 30, 2014 and the results of its operations for the three and nine months ended September 30, 2014 and 2013 and its cash flows for the nine months ended September 30, 2014 and 2013. All adjustments made to the interim financial statements are 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 as of and 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 September 30, 2014, the Company had \$31.2 million of unrestricted cash and cash equivalents available to fund future operations. The Company believes that with the cash on hand at September 30, 2014, there is sufficient cash to fund currently planned operations through mid-2016. 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.

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, risks associated with litigation, 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.

The Company adopted Financial Accounting Standards Board, Accounting Standards Update No. 2014-10

Development Stage Entities (Topic 915) as of June 30, 2014. This new standard modifies financial statement presentation to eliminate the requirement to include inception-to-date information in the statements of operations and cash flows, among other provisions.

## 2. Accrued Expenses

Accrued expenses consist of the following:

	September 30, 2014	December 31, 2013
	(in thousands)	
Legal and accounting fees	\$ 96	\$ 103
Accrued compensation	444	526
Severance agreement (Note 8)		1,000
Other	2	22
<b>Total</b>	<b>\$ 542</b>	<b>\$ 1,651</b>

**Table of Contents****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 September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
	(in thousands)			
Research and development	\$ 224	\$ 335	\$ 1,083	\$ 865
General and administrative	653	1,473	2,188	2,411
<b>Total stock-based compensation expense</b>	<b>\$ 877</b>	<b>\$ 1,808</b>	<b>\$ 3,271</b>	<b>\$ 3,276</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 September 30, 2014:

	Shares	Weighted Average Exercise Price
Outstanding, December 31, 2013	3,348,705	\$ 4.70
Granted	354,823	12.72
Exercised	(350,728)	1.91
Options forfeited/cancelled	(24,283)	3.85
<b>Outstanding, September 30, 2014</b>	<b>3,328,517</b>	<b>\$ 4.82</b>

As of September 30, 2014, there was \$5,063,000 of unrecognized compensation related to 1,103,474 unvested options, which is expected to be recognized over a weighted average period of approximately 2 years. The weighted-average grant date fair value for options granted during the nine months ended September 30, 2014 and 2013 was \$10.75 and \$3.17, respectively.

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

	Nine Months Ended September 30,	
	2014	2013
Risk-free interest rate	1.58%	1.17%
Expected life of the options	6.0 years	5.3 years
Expected volatility of the underlying stock	114%	115%
Expected dividend rate	0%	0%

In January 2014, the Company entered into an agreement with a consultant that provided for the grant of common stock as part of the compensation to the consultant. During the three months ended September 30, 2014, the Company

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issued 3,873 shares of its common stock valued at \$50,000 under the agreement. During the nine months ended September 30, 2014, the Company issued 8,966 shares of its common stock valued at \$100,000 under the agreement. This agreement ended in October 2014.

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The following table summarizes the common stock warrant activity from December 31, 2013 through September 30, 2014:

	Shares	Weighted Average Exercise Price
Outstanding, December 31, 2013	6,035,229	\$ 3.63
Granted		
Exercised	576,734	3.11
Forfeited/cancelled	(7,500)	15.00
Outstanding, September 30, 2014	5,450,995	\$ 3.66

*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 at the time of grant as they were vested upon issuance.

*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 to 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. The Company recognized a charge of \$8,763,000 related to the extension of the 5,000,000 warrants in the quarter ended June 30, 2013. 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.

**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 and 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 September 30, 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.

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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:

	September 30, 2014 (shares)	September 30, 2013 (shares)
Warrants to purchase shares of common stock	5,450,995	6,548,029
Options to purchase shares of common stock	3,328,517	3,507,005
Shares of common stock issuable upon conversion of preferred stock	2,527,103	2,618,772
	11,306,615	12,673,806

**7. Common Stock***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. During the nine months ended September 30, 2014, the Company issued 2,674,500 shares of common stock for net proceeds of approximately \$28,238,000.

*2013 Private Placement of Common Stock*

On August 16, 2013, the Company issued 500,000 unregistered shares of its common stock for proceeds of \$3,000,000 to a single investor pursuant to a private placement. There were no warrants or placement fees associated with this transaction.

*Other Issuances of Common Stock*

For the nine-month periods ended September 30, 2014 and 2013 the Company issued shares of common stock in exchange for cash proceeds of \$2,187,000 and \$3,189,000, respectively, related to the exercise of stock options and warrants.

## 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 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 which was included in accrued expenses at December 31, 2013.

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

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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. 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 claimed 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 sought repayment of all separation benefits paid to Dr. Platt to date.

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 delayed payment pending the outcome of this arbitration. In June 2014, the arbitrator issued a judgment in favor of Dr. Platt. In July 2014, the Company paid the \$1 million severance obligation.

*Shareholder Class Actions and Derivative Lawsuits*

Between July 30, 2014, and August 6, 2014, three putative class action complaints were filed in the United States District Court for the District of Nevada against the Company and certain of its officers and directors on behalf of all persons who purchased or otherwise acquired the Company's stock between January 6, 2014 and July 28, 2014. The complaints allege that the defendants made false or misleading statements in certain press releases and other public statements in violation of the federal securities laws. The complaints seek class certification, unspecified monetary damages, costs, and attorneys' fees. The Company disputes the allegations in the complaints and intends to vigorously defend against the claims. By order entered August 22, 2014, the Court consolidated the three putative class actions. The Court's consolidation order relieves the defendants of any obligation to respond to the complaints currently on file and provides that defendants may respond to a consolidated amended complaint once it is filed by the lead plaintiff(s) to be appointed by the Court. Defendants' motion to transfer the consolidated putative securities class action to the United States District Court for the Northern District of Georgia is currently fully briefed and pending.

On August 1 and 25, 2014, persons claiming to be Galectin shareholders filed putative shareholder derivative complaints in the United States District Court for the District of Nevada, seeking recovery on behalf of the Company against certain of the Company's directors and officers. The putative derivative complaints allege that the defendants breached their fiduciary duties to the Company's shareholders by causing or permitting the Company to make allegedly false and misleading public statements concerning the Company's financial results, prospects, and internal controls over financial reporting, and by allegedly failing to ensure that the Company had adequate internal controls over financial reporting. Collectively, the complaints also allege that defendants were unjustly enriched, aided and abetted breaches of fiduciary duties, abused their control of and grossly mismanaged the Company, and violated the federal securities laws by allegedly making false or misleading statements of material fact in the Company's proxy filings. One of the complaints also alleges that certain defendants breached their fiduciary duties through allegedly improper sales of Galectin stock. The complaints seek unspecified monetary damages on behalf of the Company, corporate governance reforms, disgorgement of profits, benefits and compensation by the defendants, costs, and attorneys' and experts' fees. By order entered September 10, 2014, the Court consolidated the putative derivative actions. The Court's consolidation order relieves the defendants of any obligation to respond to the complaints currently on file and provides that defendants may respond to a consolidated amended complaint once it is filed by the



plaintiffs. Defendants' motion to transfer the consolidated putative derivative litigation to the United States District Court for the Northern District of Georgia is currently fully briefed and pending.

On August 29, 2014, another alleged Galectin shareholder filed a putative shareholder derivative complaint in state court in Las Vegas, Nevada, seeking recovery on behalf of the Company against the same directors and officers who are named as defendants in the derivative litigation pending in the United States District Court for the District of Nevada. The state court derivative complaint alleges claims for breach of fiduciary duties, unjust enrichment, and waste of corporate assets, based on allegations that are substantially similar to those in the derivative complaints pending in the United States District Court for the District of Nevada, and seeks unspecified monetary damages on behalf of the Company, corporate governance reforms, disgorgement of profits, benefits and compensation by the defendants, costs, and attorneys' and experts' fees. The defendants in the state court derivative litigation have not yet been required to respond to the allegations of the complaint and therefore have not yet done so.

#### *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 nine month period ending September 30, 2014 was \$390,000, 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 September 30, 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; expectations regarding any litigation; potential strategic partnerships; expectations regarding the effectiveness of our products; plans for research and development and related costs; statements about accounting assumptions and estimates; expectations regarding liquidity and the sufficiency of cash to fund currently planned operations through mid-2016; 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,

uncertainties related to any litigation, including a shareholder class actions and derivative lawsuits filed,

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.

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### **Overview**

We are a clinical stage biopharmaceutical 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.

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. We are also pursuing additional preclinical studies related to further characterizing the potential mechanisms of actions of our galectin inhibitors including further studies in cancer immunotherapy at the Earl A. Childs Research Institute of the Providence Portland Medical Center and in fibrosis cellular mechanisms of action studies at Mt. Sinai School of Medicine. 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, 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 and second cohorts of the Phase 1 clinical trial were presented on March 31, 2014 and July 28, 2014, respectively. Enrollment of the third cohort of the Phase 1 clinical trial began in July 2014. Interim results from the third cohort of the Phase 1 clinical trial were presented in November 2014 with the final report of cohort 3 expected in January 2015.
Lung Fibrosis	GR-MD-02	In pre-clinical development
Kidney Fibrosis	GR-MD-02	In pre-clinical development
Cardiac Fibrosis	GM-CT-01 &	
	GR-MD-02	In pre-clinical development
<b>Cancer Immunotherapy</b>		
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 intravenous 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 exploratory 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.

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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 three 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 is capable of binding to multiple galectin proteins, we believe that it has the greatest affinity for galectin-3, the most prominent galectin implicated in pathological processes. Blocking galectin in cancer and liver fibrosis has specific salutary effects on the disease process.

**Results of Operations****Three and Nine Months Ended September 30, 2014 Compared to Three and Nine Months Ended September 30, 2013***Research and Development Expense.*

	Three Months Ended		Nine Months Ended		2014 as Compared to 2013			
	September 30,		September 30,		Three Months		Nine Months	
	2014	2013	2014	2013	\$ Change	% Change	\$ Change	% Change
	(In thousands, except %)							

Research and development	\$ 1,979	\$ 1,192	\$ 6,345	\$ 4,293	\$ 787	66%	\$ 2,052	48%
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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



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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 from the first cohort of patients on June 30, 2014. The second cohort of this Phase 1 trial began and enrollment was completed in April 2014. In July 2014, we reported the results from the second cohort of patients. Enrollment of the third cohort of Phase 1 began in July 2014 with interim results presented in November 2014 with the final report on cohort 3 expected in January 2015. Depending on the results of the Phase 1 study, we expect to initiate a Phase 2 clinical trial in the first half of 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 which has not been finalized. 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.

Our research and development expenses were as follows:

	Three Months Ended September 30, 2014		Nine Months Ended September 30, 2014	
	2013		2013	
	(in thousands)			
Direct external expenses:				
Clinical programs	\$ 649	\$ 480	\$ 2,462	\$ 1,734
Pre-clinical activities	804	243	2,056	1,287
All other research and development expenses	526	469	1,827	1,272
	\$ 1,979	\$ 1,192	\$ 6,345	\$ 4,293

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 and nine months ended September 30, 2014 over 2013. As we continue 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 to its expected completion in the fourth quarter of 2014. Pre-clinical activities increased primarily due to pre-clinical work related preparation for our anticipated Phase 2 clinical trial program including, amongst other items, toxicology studies, manufacturing of active pharmaceutical ingredient and finished product and additional supporting studies. Other research and development expense increased in the nine months ended September 30, 2014 over 2013 primarily due to increased stock-based compensation of \$218,000.

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		Nine Months		2014 as Compared to 2013			
	Ended September 30,		Ended September 30,		Three Months		Nine Months	
	2014	2013	2014	2013	\$ Change	% Change	\$ Change	% Change
	(In thousands, except %)							

General and administrative	\$ 1,498	\$ 2,353	\$ 5,351	\$ 5,007	\$ (945)	(36)%	\$ 344	7%
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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 decrease for the three months ended September 30, 2014 as compared to the same period in 2013 is due to decreased stock-based compensation (\$817,000) primarily due to a modification in September 2013 of certain vested options held by a former board member to extend the contractual exercise period through the original expiration dates as opposed to 90 days after service on the board ended. The primary reason for the increase for the nine months ended September 30, 2014 as compared to the same period in 2013 was increased legal expenses (\$280,000) primarily related to litigation with Dr. Platt which was settled in the third quarter of 2014.

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### **Liquidity and Capital Resources**

As described above in the Overview and elsewhere in this Quarterly Report on Form 10-Q, we are a clinical development stage company 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 September 30, 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 September 30, 2014, we had \$31.2 million of unrestricted cash and cash equivalents available to fund future operations. We believe that with the cash on hand at September 30, 2014, there is sufficient cash to fund currently planned operations through mid-2016. 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.

Net cash used in operations increased by \$3,475,000 to \$9,313,000 for the nine months ended September 30, 2014, as compared to \$5,838,000 for the nine months ended September 30, 2013. Cash operating expenses increased principally due to increased research and development activities related to our clinical activity with GR-MD-02 and the payment of the severance obligation to Dr. Platt.

Net cash provided by financing activities was \$30,425,000 for the nine months ending September 30, 2014, consisting of \$28,238,000 from sale of common stock and \$2,187,000 from the proceeds from the exercise of stock options and warrants. During the nine months ended September 30, 2013, \$3,189,000 was received from the exercise of stock options and warrants and \$3,000,000 from a private placement of common stock.

### *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.

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. 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.

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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 claimed 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 sought repayment of all separation benefits paid to Dr. Platt to date.

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 delayed payment pending the outcome of this arbitration. In June 2014, the arbitrator issued a judgment in favor of Dr. Platt. In July 2014, the Company paid the \$1 million severance obligation.

### *Shareholder Class Actions and Derivative Lawsuits*

Between July 30, 2014, and August 6, 2014, three putative class action complaints were filed in the United States District Court for the District of Nevada against the Company and certain of its officers and directors on behalf of all persons who purchased or otherwise acquired the Company's stock between January 6, 2014 and July 28, 2014. The complaints allege that the defendants made false or misleading statements in certain press releases and other public statements in violation of the federal securities laws. The complaints seek class certification, unspecified monetary damages, costs, and attorneys' fees. The Company disputes the allegations in the complaints and intends to vigorously defend against the claims. By order entered August 22, 2014, the Court consolidated the three putative class actions. The Court's consolidation order relieves the defendants of any obligation to respond to the complaints currently on file and provides that defendants may respond to a consolidated amended complaint once it is filed by the lead plaintiff(s) to be appointed by the Court. Defendants' motion to transfer the consolidated putative securities class action to the United States District Court for the Northern District of Georgia is currently fully briefed and pending.

On August 1 and 25, 2014, persons claiming to be Galectin shareholders filed putative shareholder derivative complaints in the United States District Court for the District of Nevada, seeking recovery on behalf of the Company against certain of the Company's directors and officers. The putative derivative complaints allege that the defendants breached their fiduciary duties to the Company's shareholders by causing or permitting the Company to make allegedly false and misleading public statements concerning the Company's financial results, prospects, and internal controls over financial reporting, and by allegedly failing to ensure that the Company had adequate internal controls over financial reporting. Collectively, the complaints also allege that defendants were unjustly enriched, aided and abetted breaches of fiduciary duties, abused their control of and grossly mismanaged the Company, and violated the federal securities laws by allegedly making false or misleading statements of material fact in the Company's proxy filings. One of the complaints also alleges that certain defendants breached their fiduciary duties through allegedly improper sales of Galectin stock. The complaints seek unspecified monetary damages on behalf of the Company, corporate governance reforms, disgorgement of profits, benefits and compensation by the defendants, costs, and attorneys' and experts' fees. By order entered September 10, 2014, the Court consolidated the putative derivative actions. The Court's consolidation order relieves the defendants of any obligation to respond to the complaints currently on file and provides that defendants may respond to a consolidated amended complaint once it is filed by the plaintiffs. Defendants' motion to transfer the consolidated putative derivative litigation to the United States District Court for the Northern District of Georgia is currently fully briefed and pending.

On August 29, 2014, another alleged Galectin shareholder filed a putative shareholder derivative complaint in state court in Las Vegas, Nevada, seeking recovery on behalf of the Company against the same directors and officers who are named as defendants in the derivative litigation pending in the United States District Court for the District of

Nevada. The state court derivative complaint alleges claims for breach of fiduciary duties, unjust enrichment, and waste of corporate assets, based on allegations that are substantially similar to those in the derivative complaints pending in the United States District Court for the District of Nevada, and seeks unspecified monetary damages on behalf of the Company, corporate governance reforms, disgorgement of profits, benefits and compensation by the defendants, costs, and attorneys' and experts' fees. The defendants in the state court derivative litigation have not yet been required to respond to the allegations of the complaint and therefore have not yet done so.

*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.

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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 September 30, 2014, our disclosure controls and procedures were effective at a reasonable assurance level. During the quarter ended September 30, 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 July 2014, the Company issued 3,873 shares of common stock to Acorn Management Partners, LLC in connection with a consulting agreement, at a price of \$12.91 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
10.1	Galectin Therapeutics Inc. Amended and Restated 2009 Incentive Compensation Plan	2
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.
2. Incorporated by reference to Exhibit A of the Company's Definitive Proxy Statement filed on March 21, 2014.



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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on November 10, 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