GALECTIN THERAPEUTICS INC
Form 10-Q
May 11, 2015
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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, 2015

¨ **Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
For the transition period from _____ to _____

Commission File No. 001-31791

GALECTIN THERAPEUTICS INC.

Nevada	**04-3562325**
(State or other jurisdiction	**(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. x 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). x 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 x
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 x No

The number of shares outstanding of the registrant s common stock as of May 8, 2015 was 23,729,885.

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FOR THE QUARTER ENDED MARCH 31, 2015

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GALECTIN THERAPEUTICS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

	March 31, 2015	December 31, 2014
	(in thousands)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 29,349	$ 29,128
Prepaid expenses and other current assets	611	533
Total current assets	29,960	29,661
Property and equipment, net		1
Intangible assets, net	14	15
Total assets	$ 29,974	$ 29,677
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	$ 922	$ 906
Accrued expenses	369	729
Accrued dividends payable		68
Total current liabilities	1,291	1,703
Other long-term liabilities		
Total liabilities	1,291	1,703
Commitments and contingencies (Note 8)		
Series B-1 12% redeemable convertible preferred stock; 900,000 shares authorized, issued and outstanding at March 31, 2015 and December 31, 2014, redemption and liquidation value $1,800,000 at March 31, 2015	1,735	1,731
Series B-2 12% redeemable convertible preferred stock; 2,100,000 shares authorized, issued and outstanding at March 31, 2015 and December 31, 2014, redemption and liquidation value $4,200,000 at March 31, 2015	3,378	3,325
Series C super dividend convertible preferred stock; 1,000 shares authorized, 176 and 176 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively, redemption value: $5,634,000, liquidation value: $1,760,000 at March 31, 2015	1,723	1,723
Stockholders equity:		

Undesignated stock, $0.01 par value; 20,000,000 shares authorized, 8,001,000 designated at March 31, 2015 and December 31, 2014		
Series A 12% convertible preferred stock; 5,000,000 shares authorized, 1,402,500 issued and outstanding at March 31, 2015 and December 31, 2014, liquidation value $1,402,500 at March 31, 2015	567	567
Common stock, $0.001 par value; 50,000,000 shares authorized at March 31, 2015 and December 31, 2014, 23,729,885 and 22,277,283 issued and outstanding at March 31, 2015 and December 31, 2014, respectively	23	22
Additional paid-in capital	145,256	139,531
Retained deficit	(123,999)	(118,925)
Total stockholders equity	21,847	21,195
Total liabilities, redeemable convertible preferred stock and stockholders equity	$ 29,974	$ 29,667

See notes to unaudited condensed consolidated financial statements.

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GALECTIN THERAPEUTICS INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

	Three Months Ended March 31,	
	2015	2014
	(in thousands, except per share data)	
Operating expenses:		
Research and development	$ 3,136	$ 2,772
General and administrative	1,704	2,072
Total operating expenses	4,840	4,844
Total operating loss	(4,840)	(4,844)
Other income (expense):		
Interest income	14	4
Loss from equity method investment in Galectin Sciences, LLC		(270)
Total other income (expense)	14	(266)
Net loss	$ (4,826)	$ (5,110)
Preferred stock dividends	(191)	(240)
Preferred stock accretion	(57)	(58)
Net loss applicable to common stockholders	$ (5,074)	$ (5,408)
Net loss per common share basic and diluted	$ (0.22)	$ (0.27)
Weighted average common shares outstanding basic and diluted	23,062	20,270

See notes to unaudited condensed consolidated financial statements.

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GALECTIN THERAPEUTICS INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

	Three Months Ended March 31,	
	2015	2014
	(in thousands)	
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (4,826)	$ (5,110)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2	2
Stock-based compensation expense	935	1,648
Loss from equity method investment in Galectin Sciences LLC		270
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(78)	47
Accounts payable and accrued expenses	(344)	(476)
Net cash used in operating activities	(4,311)	(3,619)
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	4,532	28,178
Proceeds from exercise of common stock warrants and options		1,946
Net cash provided by financing activities	4,532	30,124
NET INCREASE IN CASH AND CASH EQUIVALENTS	221	26,105
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	29,128	10,489
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 29,349	$ 36,594
NONCASH FINANCING ACTIVITIES:		
Payment of preferred stock dividends in common stock	$ 260	$ 312

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 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, 2015 and the results of its operations for the three months ended March 31, 2015 and 2014 and its cash flows for the three months ended March 31, 2015 and 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, 2014.

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, 2015, the Company had $29.3 million of unrestricted cash and cash equivalents available to fund future operations. The Company believes that with the cash on hand at March 31, 2015, there is sufficient cash to fund currently planned operations through September 30, 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.

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2. Accrued Expenses

Accrued expenses consist of the following:

	March 31, 2015	December 31, 2014
	(in thousands)	
Legal and accounting fees	$ 83	$ 118
Accrued compensation	214	604
Other	72	7
Total	$ 369	$ 729

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 March 31,	
	2015	2014
Research and development	$ 317	$ 638
General and administrative	618	1,010
Total stock-based compensation expense	$ 935	$ 1,648

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, 2014 through March 31, 2015:

	Shares	Weighted Average Exercise Price
Outstanding, December 31, 2014	3,332,617	$ 5.79
Granted	304,000	3.45
Exercised	(95,574)	1.80
Options forfeited/cancelled	(121,309)	1.96
Outstanding, March 31, 2015	3,419,734	$ 5.83

As of March 31, 2015, there was $4,178,000 of unrecognized compensation related to 920,468 unvested options, which is expected to be recognized over a weighted average period of approximately 1.8 years. The weighted-average grant date fair value for options granted during the three months ended March 31, 2015 and 2014 was $2.78 and $11.28, respectively. The Company granted 304,000 stock options during the three months ended March 31, 2015, of

which 76,000 options vested upon grant with the remaining 228,000 options vesting over 3 years. Approximately $173,000 of non-cash, stock-based compensation expense was recorded during the three months ended March 31, 2015 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 Months Ended March 31, 2015	Three Months Ended March 31, 2014
Risk-free interest rate	1.64%	1.58%
Expected life of the options	6.0 years	6.0 years
Expected volatility of the underlying stock	104%	114%
Expected dividend rate	0%	0%

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The following table summarizes the restricted stock grant activity in the Company s equity incentive plans from December 31, 2014 through March 31, 2015:

	Shares
Outstanding, December 31, 2014	416,670
Granted	81,352
Exercised	
Options forfeited/cancelled	
Outstanding, March 31, 2015	498,022

On March 12, 2015, the Company granted 81,352 shares of restricted stock to non-employee directors as a component of their compensation. A total of 77,784 shares were issued to seven directors representing non-cash compensation cost of $280,000 which will be recognized on a straight-line basis from the grant date through May 20, 2016, when the restricted shares will vest in full. A total of 3,568 shares were issued to two directors, who were not nominated for reelection, representing non-cash compensation cost of $12,845 that will be recognized on a straight-line basis from the grant date through May 21, 2015, when the restricted shares will vest in full.

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, 2014 through March 31, 2015:

	Shares	Weighted Average Exercise Price
Outstanding, December 31, 2014	5,470,995	$ 3.67
Granted		
Exercised		
Forfeited/cancelled		
Outstanding, March 31, 2015	5,470,995	$ 3.67

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, 2015 or December 31, 2014.

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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:

	March 31, 2015 (shares)	March 31, 2014 (shares)
Warrants to purchase shares of common stock	5,470,995	5,505,579
Options to purchase shares of common stock	3,419,734	3,365,198
Shares of common stock issuable upon conversion of preferred stock	2,527,103	2,550,437
	11,417,832	11,421,214

7. Common Stock

2014 At Market Issuance of Common Stock

On March 30, 2014, the Company entered into an At Market Issuance Sales Agreement (the 2014 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

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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 2014 At Market Agreement. As of December 31, 2014, the Company had issued 217,622 shares of its common stock through its 2014 At Market Agreement at an average price of $5.49 per share resulting in gross proceeds of approximately $1,196,000. The Company incurred commissions of approximately $36,000 resulting in net proceeds of approximately $1,159,000 as of December 31, 2014. In three months ended March 31, 2015, the Company issued 1,279,416 shares of common stock for net proceeds of approximately $4,532,000 under the 2014 At Market Agreement.

8. Commitments and Contingencies

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 (the Nevada District Court) 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 and 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. On August 22, 2014, the Nevada District Court entered an order consolidating the three cases, relieving the defendants of any obligation to respond to the complaints currently on file, and providing that defendants may respond to a consolidated amended complaint to be filed by the lead plaintiff appointed pursuant to the Private Securities Litigation Reform Act of 1995. On January 5, 2015, the Nevada District Court granted Defendants motion to transfer the consolidated putative securities class action to the United States District Court for the Northern District of Georgia. The lead plaintiff is expected to file a consolidated amended complaint in May 2015.

On August 1 and 25, 2014, persons claiming to be Galectin shareholders filed putative shareholder derivative complaints in the Nevada District Court, seeking recovery on behalf of the Company against certain of the Company s directors and officers. On September 10, 2014, the Nevada District Court entered an order consolidating the two cases, relieving the defendants of any obligation to respond to the initial complaints, and providing that defendants may respond to a consolidated amended complaint to be filed by the plaintiffs. On January 5, 2015, the Nevada District Court granted Defendants motion to transfer the consolidated putative derivative litigation to the United States District Court for the Northern District of Georgia. The plaintiffs filed a consolidated amended complaint on February 27, 2015. The consolidated amended complaint alleges 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 and business prospects. The consolidated amended complaint also alleges that the defendants violated the federal securities laws by allegedly making false or misleading statements of material fact in the Company s proxy filings, committed waste of corporate assets, were unjustly enriched, aided and abetted breaches of fiduciary duties, and 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. Defendants filed a timely motion to dismiss the consolidated amended complaint on April 6, 2015. That motion to dismiss currently remains 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 plaintiff filed an amended complaint on December 1, 2014, and filed a second amended complaint on March 27, 2015. The second amended complaint alleges that the defendants breached their fiduciary duties to the Company s shareholders by causing or permitting the Company and third parties to make allegedly false and misleading public statements and/or omissions of material fact concerning the Company s financial and business prospects. The second amended complaint also alleges claims for unjust enrichment and waste of corporate assets and alleges insider trading claims against certain of the Company s directors and officers. The second amended complaint 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. Defendant filed motions to dismiss the second amended complaint on April 22, 2015.

Estimating an amount or range of possible losses resulting from litigation proceedings is inherently difficult and requires an extensive degree of judgment, particularly where the matters involve indeterminate claims for monetary damages, are in the early stages of the proceedings, and are subject to appeal. In addition, because most legal proceedings are resolved over extended periods of time, potential losses are subject to change due to, among other things, new developments, changes in legal strategy, the outcome of intermediate procedural and substantive rulings and other parties settlement posture and their evaluation of the strength or weakness of their case against us. For these reasons, we are currently unable to predict the ultimate timing or outcome of, or reasonably estimate the possible losses or a range of possible losses resulting from, the matters described above. Based on information currently available, the Company does not believe that any reasonably possible losses arising from currently pending legal matters will be material to the Company s results of operations or financial condition. However, in light of the inherent uncertainties involved in such matters, an adverse outcome in one or more of these matters could materially and adversely affect the Company s financial condition, results of operations or cash flows in any particular reporting period.

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Other Legal Proceedings

The Company records accruals for such contingencies to the extent that the Company concludes that their occurrence is probable and the related damages are estimable. There are no 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. Initially, the Company and SBH have a 50% equity ownership interest in the LLC, with neither party having control over the LLC. Accordingly from inception through the fourth quarter of 2014, the Company accounted for its investment in the LLC using the equity method of accounting. Under the equity method of accounting, the Company s investment was initially recorded at cost with subsequent adjustments to the carrying value to recognize additional investments in or distributions from the Investee, as wells the Company s share of the Investee s earnings, losses and/or changes in capital. The estimated fair value of the IPR&D contributed to the LLC was immediately expensed upon contribution as there was no alternative future use available at the point of contribution. The operating agreement provides that if either party does not desire to contribute its equal share of funding required after the initial capitalization, then the other party, providing all of the funding, will have its ownership share increased in proportion to the total amount contributed from inception. In the fourth quarter of 2014, after the LLC had expended the $400,000 in cash, SBH decided not to contribute its share of the funding required. As a result, the Company contributed the $73,000 and $159,000 needed for the fourth quarter of 2014 and first quarter of 2015 expenses of the LLC, respectively. As a result, the Company s ownership percentage in the LLC is 61.3% at March 31, 2015. The Company accounts for the interest in the LLC as a consolidated, less than wholly owned subsidiary. The Company s portion of the LLC s net loss for the year ended December 31, 2014, prior to the change in accounting discussed previously, was $400,000, 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, 2015.

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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 currently planned operations through September 30, 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 any litigation, including shareholder class actions and derivative lawsuits filed,

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, 2014, 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 several collaborative scientific discovery programs with leading experts in carbohydrate chemistry and characterization. These discovery programs are generally aimed at the targeted development of new carbohydrate molecules which bind galectin proteins and offer alternative options to larger market segments in our primary disease indications, such as subcutaneous or oral administration. We also have established 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 (e.g., oral) and as a result expand the potential uses of our compounds. 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. Published data show that mice lacking the galectin-3 gene, and thus unable to produce galectin-3, are incapable of developing liver fibrosis in response to toxic insult to the liver and in fatty liver disease.

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 associated with fatty liver disease (NASH) and in cancer therapy in combination with immune-system modifying agent(s). Both of our proprietary, patented compounds are derived from completely different, natural, readily available, starting materials, which, following chemical processing, both exhibit the property of binding to and inhibiting galectin proteins.

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Our product pipeline is shown below:

Indication	Drug	Status
Fibrosis		
NASH with Advanced Fibrosis and NASH cirrhosis	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 three cohorts of the Phase 1 clinical trial were reported in 2014, with final results reported in January 2015. End of Phase 1 meeting held with FDA in 2014 and Phase 2 clinical program expected to begin in Q2 2015.
Lung Fibrosis	GR-MD-02	In pre-clinical development
Kidney Fibrosis	GR-MD-02	In pre-clinical development
Cardiac Fibrosis	GR-MD-02 and GM-CT-01	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. In addition, in NASH animal models GR-MD-02 is able to reduce liver fat, inflammation, and ballooning degeneration or death of liver cells. Therefore, we chose GR-MD-02 as the lead candidate in a development program targeted initially at fibrotic liver disease associated with non-alcoholic steatohepatitis (NASH, or fatty liver disease). In January 2013, an Investigational New Drug (IND) was submitted to the FDA with the goal of initiating a Phase 1 study in patients with NASH and advanced liver fibrosis to evaluate the human safety of GR-MD-02 and pharmacodynamics biomarkers of disease. On March 1, 2013, the FDA indicated we could proceed with a US Phase 1 clinical trial for GR-MD-02 with a development program aimed at obtaining support for a proposed indication of GR-MD-02 for treatment of NASH with advanced fibrosis. The Phase 1 trial was completed and demonstrated that GR-MD-02 up to 8 mg/Kg, i.v. was safe and well tolerated and the human pharmacokinetic data defined a drug dose for use in the planned Phase 2 trials. Additionally, there was evidence of a pharmacodynamic effect of GR-MD-02 at the 8 mg/kg dose with a decrease in alpha 2 macroglobulin, a serum marker of fibrotic activity, and a reduction in liver stiffness. An End of Phase 1 Meeting was held with FDA which, amongst other items, provided guidance on the primary endpoint for the Phase 2 clinical trial. We are progressing in our Phase 2 program and expect to begin clinical trials in the summer of 2015.

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. The goal of the therapeutic program is to stop the progression of and reverse the fibrosis in the liver and, thereby improve liver function and prevent the development of complications of fibrosis/cirrhosis and liver-related mortality.

Cancer Immunotherapy. We believe there is potential for galectin inhibition to play a key role in the burgeoning area of cancer immunotherapy. For example, there have been several recent approvals of drugs that enhance a patient s immune system to fight cancer. 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).

We believe the mechanism of action for GM-CT-01 and 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 GM-CT-01 and 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.

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Results of Operations

Three Months Ended March 31, 2015 Compared to Three Months Ended March 31, 2014

Research and Development Expense.

	Three Months Ended March 31,		2015 as Compared to 2014 Three Months	
	2015	2014	$ Change	% Change
	(In thousands, except %)			
Research and development	$ 3,136	$ 2,772	$ 364	13%

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; however only GR-MD-02 is in active development. 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 March 31, 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 presented in January 2015. The results of the Phase 1 study demonstrate that (i) GR-MD-02 was safe and well tolerated by patients with advanced NASH liver fibrosis after IV administration of four doses of 2 mg/kg, 4 mg/kg and 8mg/kg lean body weight, (ii) Pharmacokinetics revealed drug exposure in humans at the 8 mg/kg dose that was equivalent to the upper range of the targeted therapeutic dose determined from effective doses in NASH animal models, (iii) Disease Serum Marker Effect showed there was a statistically significant, dose-dependent reduction in FibroTest® scores due to a statistically significant reduction in alpha-2 macroglobulin serum levels, and (iv) Liver Stiffness Effect, as measured by FibroScan® showed that there was a signal of reduced liver stiffness in patients receiving GR-MD-02. The reduction seen in A2M does *not* necessarily mean fibrosis got better in this short study, but does suggest changes in the fibrogenic process that might lead to an improvement in fibrosis with longer-term therapy. These Phase 1 results in NASH patients with advanced fibrosis provide a firm foundation for entry into a Phase 2 development program.

The company held an End of Phase 1 meeting with FDA and, amongst other things, received guidance on the primary endpoints for a Phase 2 trials. In Phase 2 we plan to explore two indications, NASH cirrhosis and NASH with advanced fibrosis. The NASH-CX trial is designed to target a patient population with cirrhosis due to NASH. The study endpoints will include those that are closely associated with outcomes in patients with cirrhosis with the primary

endpoint: chosen as hepatic venous pressure gradient (HVPG). HVPG is reflective of portal pressure and portal hypertension is responsible for most of the complications resulting from cirrhosis; a reduction in HVPG is associated with a reduction in complications of cirrhosis and reduced mortality. Planned secondary endpoints include: morphometric analysis of collagen on liver biopsies, a change in histopathological stage, and other secondary endpoints will include non-invasive tests to evaluate for correlation with HVPG and liver collagen. We have awarded the contract for the NASH-CX trial to a CRO and expect to initiate the clinical trial in the first half of 2015 to assess the efficacy of GR-MD-02 in patients with NASH cirrhosis. The timing of initial results from the NASH-CX are dependent upon the trial design, and, amongst other factors, the rate of patient enrollment, but we anticipate top line results by the end of 2017. In the indication of NASH with advanced fibrosis, we are initiating a single site, placebo controlled, randomized clinical trial (NASH-FX) to evaluate 4 months of treatment on patients with stage 3 bridging fibrosis. We anticipate this trial to initiate by the end of Q2 2015 with top line results available by the end of 2016. Our Phase 2 clinical program is designed to position the Company for a strong Phase 3 clinical trial program.

Additionally, during the Phase 1 clinical trial, there appeared to be a potential beneficial effect on at least one patient s moderate to severe psoriasis. As a result, we are planning a single site, 10 patient, open label clinical trial with GR-MD-02 to determine whether more extensive studies in this indication are warranted.

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Our research and development expenses were as follows:

	Three Months Ended March 31,	
	2015	2014
	(in thousands)	
Direct external expenses:		
Clinical activities	$ 2,073	$ 1,162
Pre-clinical activities	442	774
All other research and development expenses	621	836
	$ 3,136	$ 2,772

Clinical programs expenses increased primarily due to costs related to completion of our Phase 1 clinical trial, expenses related to planning for our Phase 2 clinical trial and compound manufacturing costs in anticipation of a Phase 2 clinical trial during the three months ended March 31, 2015 as compared to the same period in 2014. As we begin enrolling patients in the Phase 2 trial we expect our clinical activities costs will increase and may fluctuate from quarter to quarter as the trial progresses. Pre-clinical activities decreased primarily because we are nearing completion of pre-clinical work directly related preparation for our anticipated Phase 2 clinical trial program. Other research and development expense decreased primarily due to decreased stock-based compensation expense.

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

General and Administrative Expense.

	Three Months Ended March 31,		2015 as Compared to 2014 Three Months	
	2015	2014	$ Change	% Change
	(In thousands, except %)			
General and administrative	$ 1,704	$ 2,072	$ (368)	(18)%

General and administrative expenses consist primarily of salaries including stock based compensation, legal and accounting fees, insurance, investor relations, business development and other office related expenses. The primary reason for the decrease in general and administrative expenses for the three-months ended March 31, 2015 as

compared to the same period in 2014 is due to a decrease in stock-based compensation expense of $394,000.

Liquidity and Capital Resources

Since our inception on July 10, 2000, we have financed our operations from proceeds of public and private offerings of debt and equity. As of March 31, 2015, we raised a net total of $112 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, 2015, we had $29.3 million of unrestricted cash and cash equivalents available to fund future operations. We believe that with the cash on hand at March 31, 2015, there is sufficient cash to fund currently planned operations through September 30, 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.

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Net cash used in operations increased by $692,000 to $4,311,000 for the three months ended March 31, 2015, as compared to $3,619,000 for the three months ended March 31, 2014. 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 the three months ended March 31, 2015, of $4,532,000 represents net proceeds from the sale of common stock. Net cash provided by financing activities was $30,124,000 for the three months ending March 31, 2014, consisting of $28,178,000 in net proceeds from sale of common stock and $1,946,000 from the proceeds from the exercise of stock options and warrants.

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 2014 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, 2015, our disclosure controls and procedures were effective at a reasonable assurance level. During the quarter ended March 31, 2015, 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 discussed in Note 8 to our condensed consolidated financial statements included in this report.

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, 2014, which could materially impact our business, financial condition or future results.

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

None

Item 3. Defaults Upon Senior Securities

None

Item 4. Mine Safety Disclosures

Not Applicable

Item 5. Other Information

Not Applicable

Item 6. Exhibits

Exhibit Number	Description of Document	Note Reference
31.1*	Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934	
31.2*	Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934	
32.1**	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	
32.2**	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	
101.INS	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.

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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 May 11, 2015.

GALECTIN THERAPEUTICS INC.

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

(principal executive officer)

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

(principal financial and accounting officer)