

GALECTIN THERAPEUTICS INC

Form 10-Q

November 09, 2012

[Table of Contents](#)

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

x **Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**  
For the quarterly period ended September 30, 2012

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

Commission File No. 001-31791

**GALECTIN THERAPEUTICS INC.**

Edgar Filing: GALECTIN THERAPEUTICS INC - Form 10-Q

**Nevada**  
(State or other jurisdiction)

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

of incorporation)

Identification No.)

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

**30071**  
(Zip Code)

**(678) 620-3186**

(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.  Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.05 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).  Yes  No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer

Accelerated Filer

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

Smaller reporting company

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

The number of shares outstanding of the registrant's common stock as of November 9, 2012 was 15,966,437.

**Table of Contents**

**GALECTIN THERAPEUTICS INC.**

**INDEX TO FORM 10-Q**

**FOR THE QUARTER ENDED SEPTEMBER 30, 2012**

	<b>PAGE</b>
<b>PART I FINANCIAL INFORMATION</b>	
ITEM 1. Unaudited Condensed Consolidated Financial Statements	
<u>Condensed Consolidated Balance Sheets as of September 30, 2012 and December 31, 2011 (unaudited)</u>	3
<u>Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2012 and 2011, and for the Cumulative Period From Inception (July 10, 2000) to September 30, 2012 (unaudited)</u>	4
<u>Condensed Consolidated Statement of Changes in Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit) for the Nine Months Ended September 30, 2012 (unaudited)</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2012 and 2011, and for the Cumulative Period From Inception (July 10, 2000) to September 30, 2012 (unaudited)</u>	6
<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	7
ITEM 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	12
ITEM 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	19
ITEM 4. <u>Controls and Procedures</u>	19
<b>PART II OTHER INFORMATION</b>	
ITEM 1. <u>Legal Proceedings</u>	19
ITEM 1A. <u>Risk Factors</u>	19
ITEM 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	19
ITEM 3. <u>Defaults Upon Senior Securities</u>	19
ITEM 4. <u>Mine Safety Disclosures</u>	19
ITEM 5. <u>Other Information</u>	19
ITEM 6. <u>Exhibits</u>	20
<u>SIGNATURES</u>	21

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

	September 30,	December 31,
	2012	2011
	(in thousands)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 11,059	\$ 6,397
Prepaid expenses and other current assets	89	104
<b>Total current assets</b>	<b>11,148</b>	<b>6,501</b>
Property and equipment, net	6	6
Restricted cash and other long-term assets	6	69
Intangible assets, net	33	36
<b>Total assets</b>	<b>\$ 11,193</b>	<b>\$ 6,612</b>

**LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)**

Current liabilities:		
Accounts payable	\$ 256	\$ 384
Accrued expenses	1,186	1,551
Accrued dividends payable		80
Deferred income		200
<b>Total current liabilities</b>	<b>1,442</b>	<b>2,215</b>
<b>Total liabilities</b>	<b>1,442</b>	<b>2,215</b>

## Commitments and contingencies (Note 9)

Series B-1 12% redeemable convertible preferred stock; 900,000 shares authorized, issued and outstanding at September 30, 2012 and December 31, 2011, redemption value: \$1,800,000, liquidation value: \$1,800,000 at September 30, 2012	1,694	1,681
Series B-2 12% redeemable convertible preferred stock; 2,100,000 shares authorized, issued and outstanding at September 30, 2012 and December 31, 2011, redemption value: \$4,200,000, liquidation value: \$4,200,000 at September 30, 2012	2,846	2,687
Series C super dividend convertible preferred stock; 1,000 shares authorized, 220 shares issued and outstanding at September 30, 2012 and December 31, 2011, redemption value: \$4,267,000, liquidation value: \$2,200,000 at September 30, 2012	2,154	2,154
Stockholders equity (deficit):		
Undesignated stock, \$0.01 par value; 20,000,000 shares authorized, 8,001,000 designated at September 30, 2012 and December 31, 2011		
Series A 12% convertible preferred stock; 5,000,000 shares authorized, 1,562,500 issued and outstanding at September 30, 2012 and December 31, 2011	632	632
Common stock, \$0.001 par value; 50,000,000 shares authorized at September 30, 2012 and December 31, 2011, 15,966,437 and 12,919,538 issued and outstanding at September 30, 2012 and December 31, 2011,	16	13

Edgar Filing: GALECTIN THERAPEUTICS INC - Form 10-Q

respectively		
Additional paid-in capital	79,719	66,367
Deficit accumulated during the development stage	(77,310)	(69,137)
Total stockholders' equity (deficit)	3,057	(2,125)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	\$ 11,193	\$ 6,612

See notes to unaudited condensed consolidated financial statements.

**Table of Contents****GALECTIN THERAPEUTICS INC.**

(A Development-Stage Company)

**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)**

	Three Months Ended September 30,		Nine Months Ended September 30,		Cumulative Period from Inception (July 10, 2000) to September 30, 2012
	2012	2011	2012	2011	2012
	(in thousands, except share and per share amounts)				
Operating expenses:					
Research and development	\$ 1,409	\$ 655	\$ 3,525	\$ 2,690	\$ 26,608
General and administrative	1,487	1,378	3,992	4,347	45,656
Total operating expenses	2,896	2,033	7,517	7,037	72,264
Total operating loss	(2,896)	(2,033)	(7,517)	(7,037)	(72,264)
Other income (expense):					
Interest income	7	5	18	14	812
Interest expense					(4,451)
Change in fair value of convertible debt instrument					(3,426)
Change in fair value of warrant liabilities				(524)	9,022
Other income	200		200		691
Total other income (expense)	207	5	218	(510)	2,648
Net loss	\$ (2,689)	\$ (2,028)	\$ (7,299)	\$ (7,547)	\$ (69,616)
Preferred stock dividends	(238)	(253)	(702)	(1,275)	(3,961)
Preferred stock accretion	(58)	(58)	(172)	(173)	(3,987)
Net loss applicable to common stockholders	\$ (2,985)	\$ (2,339)	\$ (8,173)	\$ (8,995)	\$ (77,564)
Net loss per common share basic and diluted	\$ (0.19)	\$ (0.19)	\$ (0.55)	\$ (0.77)	
Weighted average common shares outstanding basic and diluted	15,822	12,353	14,851	11,697	

See notes to unaudited condensed consolidated financial statements.

**Table of Contents****GALECTIN THERAPEUTICS INC.**

(A Development-Stage Company)

**CONSOLIDATED STATEMENT OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)**

NINE MONTHS ENDED SEPTEMBER 30, 2012 (UNAUDITED)

(in thousands except share data)

	Series B-1 12% Redeemable Convertible Preferred Stock		Series B-2 12% Redeemable Convertible Preferred Stock		Series C Super Dividend Convertible Preferred Stock		Series A 12% Convertible Preferred Stock		Stockholders Equity (Deficit)		Additional Paid-In Capital	Deficit Accumulated During the Development Stage	Total Stockholders Equity (Deficit)
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount			
<b>Balance at December 31, 2011</b>	<b>900,000</b>	<b>\$ 1,681</b>	<b>2,100,000</b>	<b>\$ 2,687</b>	<b>220</b>	<b>\$ 2,154</b>	<b>1,562,500</b>	<b>\$ 632</b>	<b>12,919,538</b>	<b>\$ 13</b>	<b>\$ 66,367</b>	<b>\$ (69,137)</b>	<b>\$ (2,125)</b>
Accretion of Series B redeemable convertible preferred stock		13		117								(130)	(130)
Accretion of beneficial conversion feature for Series B-2				42								(42)	(42)
Issuance of common stock and warrants, net of issuance costs of \$1,597,000									2,666,722	3	10,400		10,403
Issuance of shares related to reverse split of common stock									3,324				
Series A 12% convertible preferred stock dividend									31,250		103	(56)	47
Series B-1 redeemable convertible preferred stock dividend									67,259		166	(166)	

Edgar Filing: GALECTIN THERAPEUTICS INC - Form 10-Q

Series B-2 redeemable convertible preferred stock dividend										156,936	386	(386)	
Series C super dividend convertible preferred stock dividend										46,053	127	(94)	33
Issuance of common stock to a consultant										11,348	26		26
Issuance of common stock upon exercise of warrants										12,177			
Issuance of common stock upon exercise of options										51,830			
Stock-based compensation expense											2,144		2,144
Net loss												(7,299)	(7,299)
<b>Balance at September 30, 2012</b>	<b>900,000</b>	<b>\$ 1,694</b>	<b>2,100,000</b>	<b>\$ 2,846</b>	<b>220</b>	<b>\$ 2,154</b>	<b>1,562,500</b>	<b>\$ 632</b>	<b>15,966,437</b>	<b>\$ 16</b>	<b>\$ 79,719</b>	<b>\$ (77,310)</b>	<b>\$ 3,057</b>

See notes to unaudited condensed consolidated financial statements.



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

	Nine Months Ended September 30,		Cumulative Period from Inception (July 10, 2000) to September 30,
	2012	2011	2012
	(in thousands)		
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	\$ (7,299)	\$ (7,547)	\$ (69,616)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	5	7	551
Stock-based compensation expense	2,170	2,688	11,752
Non-cash interest expense			4,279
Change in fair value of convertible debt instrument			3,426
Change in fair value of warrant liabilities		524	(9,022)
Write off of intangible assets			351
Changes in operating assets and liabilities:			
Grant receivable		234	
Prepaid expenses and other assets	68	19	(33)
Accounts payable and accrued expenses	(693)	(47)	1,510
Other long-term liabilities		(12)	
<b>Net cash used in operating activities</b>	<b>(5,749)</b>	<b>(4,134)</b>	<b>(56,802)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchases of property and equipment	(2)	(5)	(428)
Change in restricted cash	10	(5)	(59)
Increase in patents costs and other assets			(404)
<b>Net cash provided by (used in) investing activities</b>	<b>8</b>	<b>(10)</b>	<b>(891)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Net proceeds from issuance of common stock and warrants	10,403		39,093
Net proceeds from issuance of Series A preferred stock and related warrants			1,691
Net proceeds from issuance of Series B-1 preferred stock and related warrants			1,548
Net proceeds from issuance of Series B-2 preferred stock and related warrants			3,935
Net proceeds from issuance of Series C preferred stock		130	2,203
Net proceeds from issuance of convertible debt instruments			10,621
Repayment of convertible debt instruments			(1,641)
Proceeds from exercise of common stock warrants and options		6,067	11,293
Proceeds from shareholder advances			9
<b>Net cash provided by financing activities</b>	<b>10,403</b>	<b>6,197</b>	<b>68,752</b>
<b>NET INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>4,662</b>	<b>2,053</b>	<b>11,059</b>
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD</b>	<b>6,397</b>	<b>5,891</b>	

Edgar Filing: GALECTIN THERAPEUTICS INC - Form 10-Q

CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 11,059	\$ 7,944	\$ 11,059
SUPPLEMENTAL DISCLOSURE Cash paid for interest	\$	\$	\$ 114
NONCASH FINANCING ACTIVITIES:			
Issuance of equity warrants in connection with equity offerings	\$ 4,445	\$	\$ 9,482
Conversion of accrued expenses into common stock	26		329
Cashless exercise of common stock options and warrants	190		629
Conversion and redemption of convertible notes and accrued interest into common stock			12,243
Conversion of extension costs related to convertible notes into common stock			171
Payment of preferred stock dividends in common stock	782	1,321	3,961
Issuance of warrants to induce conversion of notes payable			503
Issuance of stock to acquire Pro-Pharmaceuticals-NV			107

See notes to unaudited condensed consolidated financial statements.

---

**Table of Contents**

**GALECTIN THERAPEUTICS INC.**

**(A DEVELOPMENT-STAGE COMPANY)**

**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

**1. Basis of Presentation**

Galectin Therapeutics Inc. (the Company) is a development-stage company that is applying its leadership in galectin science and drug development to create new therapies for fibrotic disease and cancer. These 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, 2012 and the results of its operations for the three and nine months ended September 30, 2012 and 2011 and the cumulative period from inception (July 10, 2000) through September 30, 2012 and its cash flows for the nine months ended September 30, 2012 and 2011, and for the cumulative period from inception (July 10, 2000) to September 30, 2012. 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, 2011.

On March 23, 2012, the Company effected a one-for-six reverse stock split. All common share and per share amounts in these financial statements have been retroactively adjusted to reflect the effect of the reverse split. On March 28, 2012, the Company sold 2,666,722 shares of common stock and related warrants to purchase 1,333,361 shares of common stock for gross proceeds of \$12.0 million (net cash proceeds \$10.4 million). See Note 6 for further discussion of the transaction.

At September 30, 2012, the Company had \$11,059,000 of unrestricted cash and cash equivalents available to fund future operations. The Company believes that with the cash and cash equivalents on hand at September 30, 2012, there is sufficient cash to fund operations through 2013. If the Company is unsuccessful in raising additional capital or is unsuccessful in bringing its products to market before the end of 2013, the Company may be required to cease operations or seek bankruptcy protection.

As shown in the condensed consolidated financial statements, the Company incurred cumulative net losses applicable to common stockholders of \$77.6 million for the cumulative period from inception (July 10, 2000) through September 30, 2012. The Company's net losses have resulted principally from costs associated with (i) research and development expenses, including clinical trial costs, (ii) general and administrative activities and (iii) the Company's financing transactions including interest, dividend payments, and the costs related to fair value accounting for the Company's convertible debt instruments. As a result of planned expenditures for future research, discovery, development and commercialization activities and potential legal cost to protect its intellectual property, the Company expects to incur additional losses and use additional cash in its operations for the foreseeable future. Through September 30, 2012, the Company had raised a net total of \$68.8 million in capital through sale and issuance of common stock, common stock purchase warrants, convertible preferred stock and debt securities in public and private offerings. From inception (July 10, 2000) through September 30, 2012, the Company used cash of \$56.8 million in its operations.

The Company was founded in July 2000, was incorporated in the State of Nevada in January 2001 under the name Pro-Pharmaceuticals, Inc., and changed its name to Galectin Therapeutics Inc. on May 26, 2011. On March 23, 2012, the Company began trading on The NASDAQ Capital Market under the symbol GALT. Immediately prior to March 23, 2012, the Company was traded on the Over-the Counter Bulletin Board (OTCBB) under the symbol GALT.OB.

The Company is subject to a number of risks similar to those of other development-stage companies, including dependence on key individuals, uncertainty of product development and generation of revenues, dependence on outside sources of capital, risks associated with clinical trials of products, dependence on third-party collaborators for research operations, need for regulatory approval of products, risks associated with protection of intellectual property, and competition with larger, better-capitalized companies. Successful completion of the Company's development program and, ultimately, the attainment of profitable operations is dependent upon future events, including obtaining adequate financing to fulfill its development activities and achieving a level of revenues adequate to support the Company's cost structure. There are no

assurances that the Company will be able to obtain additional financing on favorable terms, or at all, or successfully market its products.

**Table of Contents****2. Agreement with PROCAPS S.A.**

On March 25, 2010, the Company granted PROCAPS S.A. ( PROCAPS ) (in the form of a definitive term sheet) exclusive rights to market and sell GM-CT-01 (formerly DAVANAT®) to treat cancer in Colombia, South America. PROCAPS is an international, privately held pharmaceutical company based in Barranquilla, Colombia. In October 2010, the Company received a payment of \$200,000 and shipped GM-CT-01 to PROCAPS to be used by PROCAPS to qualify its vial filling process and to replicate the Company's stability study. The \$200,000 payment from PROCAPS was included as deferred income on the condensed consolidated balance sheets as of December 31, 2011.

On October 18, 2011, the Company entered into a Collaboration, Supply, Marketing and Distribution Agreement (the Agreement) with PROCAPS. The Agreement granted PROCAPS first negotiation rights to enter into similar agreements in other Central and South American countries. The Company was to be the sole manufacturer and supplier of GM-CT-01 to PROCAPS. The Agreement obligated PROCAPS to procure regulatory approvals necessary for the marketing and sale of GM-CT-01 naming the Company as the owner of such approvals to the extent permitted by law, or alternatively hold the approvals for the Company's benefit. PROCAPS was to pay the Company a stated fee for each dose it purchased and royalties at an incremental rate determined by annual net sales of GM-CT-01. The Company retains all intellectual property rights to GM-CT-01 and related products and PROCAPS may not produce, modify, reverse engineer, or otherwise interfere with the GM-CT-01 compound. PROCAPS was not able to manufacture or sell products that compete with GM-CT-01 during the term of the Agreement and for five years thereafter.

PROCAPS had not obtained approval to sell GM-CT-01 in Columbia as required by the Agreement and, as they were in material breach of the Agreement, the Company terminated the Agreement, effective September 29, 2012. With no further obligations, the Company recognized the \$200,000 payment as Other Income in the Statements of Operations during the three and nine month periods ended September 30, 2012.

**3. Accrued Expenses**

Accrued expenses consist of the following:

	September 30, 2012	December 31, 2011
	(in thousands)	
Legal and accounting fees	\$ 90	\$ 69
Accrued compensation	50	385
Severance agreement (Note 9)	1,000	1,000
Other	46	97
<b>Total</b>	<b>\$ 1,186</b>	<b>\$ 1,551</b>

**4. Stock-Based Compensation**

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

	Three Months Ended September 30, 2012		Nine Months Ended September 30, 2011	
	2012	2011	2012	2011
	(in thousands)			
Research and development	\$ 248	\$ 270	\$ 756	\$ 1,407
General and administrative	571	379	1,414	1,281
<b>Total stock-based compensation expense</b>	<b>\$ 819</b>	<b>\$ 649</b>	<b>\$ 2,170</b>	<b>\$ 2,688</b>



**Table of Contents**

The following table summarizes the stock option activity in the Company's equity incentive plans, including non-plan grants to Company executives, from December 31, 2011 through September 30, 2012:

	Shares	Weighted Average Exercise Price
Outstanding, December 31, 2011	3,091,474	\$ 6.83
Granted	730,000	2.16
Exercised	(51,830)	2.31
Options forfeited/cancelled	(228,014)	7.65
Outstanding, September 30, 2012	3,541,630	\$ 5.88

As of September 30, 2012, there was \$6,125,000 of unrecognized compensation related to 1,514,863 unvested options, which is expected to be recognized over a weighted average period of approximately 3.7 years. The weighted-average grant date fair value for options granted during the three and nine months ended September 30, 2012 was \$1.89 and \$1.78, respectively. The weighted-average grant date fair value for options granted during the three and nine months ended September 30, 2011 was \$1.00 and \$1.02, respectively.

Of the options granted during the nine months ended September 30, 2011, 166,668 vest only upon the achievement of certain market conditions (83,334 and 83,334 upon the Company achieving a market capitalization of \$5 billion and \$10 billion, respectively). These market condition stock option awards were valued at \$1,006,000 using a Monte Carlo model and will be recognized over a weighted average period of 5.5 years. Assumptions used to value these options included the following: annualized volatility of 110%, annualized drift/risk-free interest rate of 3.5% and a forecast horizon/life of 10 years.

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,		Cumulative Period from Inception (July 10, 2000) to September 30, 2012
	2012	2011	
Risk-free interest rate	0.84%	1.91%	1.87%
Expected life of the options	5.4 years	5.1 years	5.1 years
Expected volatility of the underlying stock	117%	121%	119%
Expected dividend rate	0%	0%	0%

During the three and nine months ended September 30, 2012, the Company modified the terms of certain option grants for four employees to extend the exercisable period from ninety days post-employment to the remaining legal life of the option grant. During the nine months ended September 30, 2012, the Company modified certain cashless exercise terms for one employee. The modification of these options resulted in additional stock-based compensation expense of \$172,000 and \$271,000 during the three and nine month periods ended September 30, 2012, respectively. During the nine months ended September 30, 2011, the Company similarly modified the options of one employee to extend the exercisable period post-employment, resulting in additional stock-based compensation expense of \$63,000.

In May 2012, the Company granted 7,000 shares of common stock to a consultant for payment of past services. These shares of common stock were valued at \$16,000, based on the market value of the shares at the date of grant and are included in stock based compensation expense for the nine months ended September 30, 2012.

In August 2012, the Company granted 4,348 shares of common stock to a consultant for payment of services. These shares of common stock were valued at \$10,000, based on the market value of the shares at the date of grant and are included in stock based compensation expense for the three and nine months ended September 30, 2012.





**Table of Contents****5. Common Stock Warrants**

The following table summarizes the common stock warrant activity from December 31, 2011 through September 30, 2012:

	Shares	Weighted Average Exercise Price
Outstanding, December 31, 2011	6,673,405	\$ 3.95
Granted	1,379,739	5.63
Exercised	(12,177)	3.18
Forfeited/cancelled	(616,726)	10.62
Outstanding, September 30, 2012	7,424,241	\$ 3.71

*Consultant Warrants*

In April 2009, the Company entered into agreements with consultants that provided for the grant of warrants for the purchase of 33,333 shares of common stock at an exercise price of \$3.00 per share which will vest upon the achievement of certain milestones. At September 30, 2012, these warrants are no longer expected to vest. The Company recognized a reversal of previously recognized expense related to these warrants of \$10,000 and \$98,000 for the three and nine months ended September 30, 2012, respectively, and a reversal of expense of \$36,000 and \$16,000 for the three and nine months ended September 30, 2011, respectively.

In May 2010, the Company entered into an agreement with a consultant that provided for the grant of warrants for the purchase of 12,000 shares of common stock at an exercise price of \$15.00 per share, of which 7,500 vested and 4,500 were forfeited in 2011. The following assumptions were used to value the warrants for the nine months ended September 30, 2011: an expected life of 2.99 to 3.32 years, volatility of 128% to 130%, risk free interest rate of 0.79% to 1.29% and zero dividends. The company recognized an expense of \$12,000 related to these warrants during the nine months ended September 30, 2011.

In August 2010, the Company entered into an agreement with a consultant, who was also a board member, which provided for the grant of warrants for 100,000 shares of common stock at an exercise price of \$4.26 per share. Of the 100,000 warrants, 25,000 vested immediately on signing of the agreement, 25,000 were to vest at the end of one year and the remaining 50,000 warrants were to vest based on the achievement of certain milestones. The following assumptions were used to value the warrants on March 7, 2011 at the date the consultant effectively became an employee of the Company: an expected life of 4.28 years, volatility of 135%, risk free interest rate of 1.705% and zero dividends. Pursuant to an employment agreement entered into in May 2011, all remaining unvested warrants were immediately vested. The Company recognized the total remaining expense of \$340,000 related to these warrants during the nine months ended September 30, 2011.

**6. Common Stock and Warrant Offering and Reverse Split**

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

On March 28, 2012, the Company sold and issued 1,333,361 Units (2,666,722 shares of common stock and related \$5.63 warrants to purchase 1,333,361 shares of common stock) for gross proceeds of \$12.0 million (net cash proceeds of \$10,403,000 after the underwriting discount and offering costs). The warrants were valued at \$4,445,000 as of the issuance date of March 28, 2012, using the closing price of \$4.20, a life of 5 years, a volatility of 119% and a risk free interest rate of 1.05%. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, Derivatives and Hedging Contracts in Entity's Own Equity the Company has determined that warrants issued in connection with this financing transaction were not derivative liabilities and therefore, were recorded as additional paid-in capital.

On March 28, 2012, in connection with this underwritten financing as per the underwriting agreement, the Company issued a total of 46,378 common stock purchase warrants to the underwriters. These warrants expire May 2, 2016, have an exercise price of \$5.63 per share, and are

## Edgar Filing: GALECTIN THERAPEUTICS INC - Form 10-Q

exercisable beginning one year from March 22, 2012 (the date of the underwriting agreement). These warrants were valued at \$143,000 as of the date of issuance (March 28, 2012), using the closing price of \$4.20, life of 4.1 years, volatility of 117% and risk free interest rate of 0.78%. Based upon the Company's analysis of the criteria contained in ASC Topic 815-40, Derivatives and Hedging - Contracts in Entity's Own Equity, the Company has determined that these warrants issued in connection with this financing transaction were not derivative liabilities and therefore, were recorded as additional paid-in capital.

**Table of Contents**

Effective as of March 23, 2012, and in connection with the pricing of the offering of Units, the Company effected a one-for-six reverse split of its Common Stock. Per the terms of the reverse split, all fractional shares were rounded up. Based on the effective split date of March 23, 2012, the Company issued 3,324 shares of common stock to cover fractional shares.

**7. Fair Value of Financial Instruments**

In general, fair values determined by Level 1 inputs utilize identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are observable, such as quoted prices, interest rates and yield curves. Fair values determined by Level 3 inputs utilize unobservable data points for the asset or liability. The Company had no financial instruments carried at fair value as of September 30, 2012 or December 31, 2011.

The Company's financial instruments consist of cash equivalents, accounts payable and accrued expenses. The estimated fair value of these financial instruments approximates their carrying value due to their short-term nature using level 3 inputs as defined above.

**8. Loss Per Share**

Basic net loss per common share is computed by dividing the net loss available to common stockholders by the weighted average number of common shares outstanding during the period. Diluted net loss per common share is computed by dividing the net loss available to common stockholders by the weighted average number of common shares and other potential common shares then outstanding. Potential common shares consist of common shares issuable upon the assumed exercise of in-the-money stock options and warrants and potential common shares related to the conversion of the preferred stock. The computation of diluted net loss per share does not assume the issuance of common shares that have an anti-dilutive effect on net loss per share.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
	(in thousands, except share and per share amounts)			
Basic and diluted net loss per common share:				
Net loss applicable to common stockholders	\$ (2,985)	\$ (2,339)	\$ (8,173)	\$ (8,995)
Weighted average common shares outstanding basic and diluted	15,822	12,353	14,851	11,697
Net loss per common share basic and diluted	\$ (0.19)	\$ (0.19)	\$ (0.55)	\$ (0.77)

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 during the three and nine month periods ended September 30, 2012 and 2011 are as follows:

	September 30, 2012 (shares)	September 30, 2011 (shares)
Warrants to purchase shares of common stock	7,424,241	6,673,400
Options to purchase shares of common stock	3,541,630	3,205,582
Restricted shares subject to vesting		3,473
Shares of common stock issuable upon conversion of preferred stock	2,627,110	2,627,110
	13,592,981	12,509,565

**9. Commitments, Contingencies and Legal Proceedings**

*Separation Agreement*

## Edgar Filing: GALECTIN THERAPEUTICS INC - Form 10-Q

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

**Table of Contents**

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 September 30, 2012 and December 31, 2011.

On May 2, 2012, Dr. Platt instituted arbitration before the American Arbitration Association, seeking a \$1.0 million separation payment based on a claim that a milestone event in the Separation Agreement has occurred (see clause (iii) above). On March 22, 2012, the Company's common stock was listed on the NASDAQ Capital Markets, but since that date, the stock has not achieved the required market capitalization. Therefore, it is the Company's position that a milestone event has not yet occurred. The arbitration hearing was held on October 16-17, 2012 and on November 1, 2012, the arbitrator denied Dr. Platt's demand in all respects. Insofar as the Company does not dispute its obligations under the Separation Agreement to pay Dr. Platt upon the occurrence of a milestone event, it has recorded the payment as an accrued expense payable if and when the milestone event occurs.

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

*Series C Post Conversion Dividend Rights*

In July 2011, 5 shares of the Company's Series C Super Dividend Convertible Preferred Stock (Series C) were converted into 8,334 shares of common stock which also resulted in the issuance of 5 Series C post-conversion dividend rights (Dividend Rights). Under the terms of the Series C, the Dividend Rights entitle the holder only to dividend payments based on actual sales of GM-CT-01 but not, following a conversion to common stock, the 6% dividend payable on outstanding shares of Series C. At September 30, 2012, the outstanding Dividend Rights were determined to have a de minimis value, because payment of a dividend for the Dividend Rights is considered improbable at this time and the Company has not recorded a liability related to the Dividend Rights. The Company will continue to evaluate and assess the Dividend Rights for each reporting period.

*Other Legal Proceedings*

The Company records accruals for such contingencies to the extent that the Company concludes that their occurrence is probable and the related damages are estimable, except as noted above. There has been no change in the matters reported in our Annual Report on Form 10-K for the year ended December 31, 2011.

**Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations**

In addition to historical information, the following Management's Discussion and Analysis of Financial Condition and Results of Operations contains forward-looking statements as defined under Section 21E of the Securities Exchange Act of 1934, as amended, and is subject to the safe harbor created therein for forward-looking statements. Such statements include, but are not limited to, statements concerning our anticipated operating results, research and development, clinical trials, regulatory proceedings, and financial resources, and can be identified by use of words such as, for example, anticipate, estimate, expect, project, intend, plan, believe and would, should, could or may. All statements, other than statements of historical facts, included herein that address activities, events, or developments that the Company expects or anticipates will or may occur in the future, are forward-looking statements, including statements regarding: plans and expectations regarding clinical trials; plans and expectations regarding regulatory approvals; our strategy and expectations for clinical development and commercialization of our products; potential strategic partnerships; expectations regarding the effectiveness of our products; plans for research and development and related costs; statements about accounting assumptions and estimates; expectations regarding liquidity and the sufficiency of cash to fund operations through 2013; 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

## Edgar Filing: GALECTIN THERAPEUTICS INC - Form 10-Q

actual results to differ materially from those expressed or implied by such statements. Such risks and uncertainties are related to, without limitation, our early stage of development; our

---

## **Table of Contents**

dependence on outside capital; uncertainties related to our technology and clinical trials, intellectual property protection, uncertainties of regulatory approval requirements for our products; competition and stock price volatility in the biotechnology industry, limited trading volume for our stock, concentration of ownership of our stock, and other risks detailed herein and from time to time in our SEC reports, including our Form 10-K for the year ended December 31, 2011. The following discussion should be read in conjunction with the accompanying consolidated financial statements and notes thereto of Galectin Therapeutics appearing elsewhere herein.

### **Overview**

We are a development-stage company engaged in drug development to create new therapies for cancer and fibrotic disease. Our drug candidates are based on our method of targeting galectin proteins, which are key mediators of biologic and pathologic function. We use naturally occurring plant materials to create complex carbohydrates with specific molecular weights and pharmaceutical properties. Using these unique carbohydrate-based candidate compounds that bind and inhibit galectin proteins, we are undertaking the 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 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 attempt to leverage our scientific and development expertise as well as established relationships with outside sources to achieve cost-effective and efficient development. 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.

### **2012 Common Stock and Warrant Offering and Reverse Split**

On March 22, 2012, in anticipation of completing a public offering of securities, we effected a one-for-six reverse stock split of our common stock. All common share and per unit amounts in this report, including the financial statements, have been retroactively adjusted to reflect the reverse split. Our common stock began trading on The NASDAQ Capital Market under the symbol GALT on March 23, 2012, and the units and warrants that we sold in the offering began trading on that exchange under the symbols GALTU and GALTW, respectively, on March 28, 2012.

On March 28, 2012, we completed the public offering in which we issued 2,666,722 shares of common stock and related warrants exercisable until March 28, 2017, at \$5.63 per share to purchase 1,333,361 shares of common stock for gross proceeds of \$12.0 million (net cash proceeds of 10.4 million).

### **Our Drug Development Programs**

We have two compounds in development, one intended to be used in cancer therapy and the other intended to be used in the treatment of liver fibrosis and fatty liver disease. These two compounds are produced from completely different natural starting materials, both possessing the property which lends itself to binding to and inhibiting galectin proteins. GM-CT-01, our lead product candidate for cancer therapy, is a proprietary linear polysaccharide polymer comprised of mannose and galactose that has a precisely defined chemical structure and is derived from a plant source. GR-MD-02, our lead product for treatment of liver fibrosis and fatty liver disease with inflammation and fibrosis, is a proprietary complex polysaccharide polymer possessing both linear and globular structures, which also is derived from a plant source.

We believe the mechanism of action for GM-CT-01 and GR-MD-02 is based upon interaction with, and inhibition of, galectin proteins, which are expressed at high levels in certain pathological states including inflammation, fibrosis and cancer. While 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, as discussed below.

#### ***GM-CT-01 Galectin Inhibition in Cancer Therapy***

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





**Table of Contents**

In May 2012, we initiated a Phase I/II clinical trial of GM-CT-01 in Belgium in combination with a tumor vaccine in patients with advanced melanoma, a deadly skin cancer. The Belgian Federal Agency of Medicine and Health Products, or FAMHP, granted approval for this clinical trial, which is being conducted at three centers in Belgium and one in Luxembourg. There are two primary cohorts of patients in this study, one where GM-CT-01 is given intravenously (Cohort 1) and a second cohort where GM-CT-01 is given both intravenously and directly injected into a cutaneous metastasis (Cohort 2). Because of patient availability, Cohort 1 is expected to be enrolled faster than Cohort 2. For each cohort, 6 patients will be enrolled in stage one of the study, and if at least one out of six patients has a response (PR or CR by RECIST criteria), the remaining patients will be enrolled up to a total of 23 per cohort. We expect the first stage of Cohort 1 of this trial (involving 6 evaluable patients) to be completed in the second quarter of 2013 and that it will provide data that could deliver an indication of efficacy. Depending on the results of Stage 1, which is defined as a partial or complete response by RECIST criteria in at least one out of six patients, the study could continue enrollment to complete Stage 2 (46 total patients), initiate a new Phase II trial based on positive results or be halted because of lack of efficacy. Stage 1 of the trial is being funded by the Cancer Centre at the Cliniques Universitaires Saint-Luc and Stage 2 will require funding from the Company, currently estimated at approximately \$1.0 million. The Phase I/II clinical trial in Belgium is being conducted under an EMA-approved IMPD, but there is an open IND under the FDA for GM-CT-01 and this trial has been reported to the FDA under that IND.

There are potentially additional pathways for the development of GM-CT-01 for use in treatment of cancer. GM-CT-01 was found to be generally safe when studied in a Phase I clinical trial in end-stage cancer patients with multiple tumor types alone and in combination with 5-Fluorouracil (5-FU), which is an FDA-approved chemotherapy used for treatment of various types of cancer. Three Phase II studies were conducted, but were only partially completed due to financing issues at the time. DAVFU-003 was terminated in 2007. Although only partially completed, when compared to historical controls, the data collected for DAVFU-003 suggested a favorable effect of the therapy, since the controls had an overall survival of 4.6 months. DAVFU-006 was a Phase II, open-label clinical trial in line 1 patients with locally advanced and unresectable or metastatic colorectal cancer (who were unable to tolerate intensive chemotherapy), who were treated with a regimen of GM-CT-01, 5-FU, leucovorin and Avastin®. Ten patients were enrolled in this study. DAVFU-006 was terminated in March 2010. Finally, DAVFU-007 was a Phase II, multi-center, open-label clinical trial to evaluate the efficacy and safety of GM-CT-01 in combination with 5-FU when administered as first line chemotherapy in patients with advanced biliary cancer. Seventeen patients were enrolled in this study. This study was stopped in March 2010. Based on these completed Phase I and partially completed Phase II clinical trials, we are exploring additional potential indications for the use of GM-CT-01 in combination with cancer chemotherapy. We are seeking potential strategic partners to assist in researching the use of GM-CT-01 in the amelioration of 5-FU related side effects. Such a partnership would permit additional clinical trials in the U.S., which would not be started until a partnership was consummated.

We attempted to gain regulatory approval of GM-CT-01 for use in combination with 5-FU containing chemotherapy regimens for metastatic colorectal cancer in Colombia. This approach had been recommended to the Company by key oncology opinion leaders in Colombia and by PROCAPS S.A. ( PROCAPS ), a Colombia-based pharmaceutical company. There has been no approval of GM-CT-01 in a major region such as the U.S. or Europe and it was determined that approval from the regulatory authority in Columbia (INVIMA) would require additional clinical trial data. Although the Company worked with PROCAPS to design a Phase III clinical trial, a satisfactory plan could not be agreed upon and we terminated the Agreement with PROCAPS (as described below), effective September 29, 2012, and have no current plans to continue attempts to gain approval of GM-CT-01 in Columbia. We had not taken into account projections for any potential revenues from this agreement in our financing plans.

***GR-MD-02 Liver Fibrosis***

The second main initiative in our development strategy is the application of galectin inhibition in connection with liver fibrosis, a condition that leads to cirrhosis. We believe that GR-MD-02 has the potential to treat nonalcoholic steatohepatitis (NASH) and other forms of liver fibrosis. The driving factor for our commitment to galectin inhibition for fibrosis is scientific evidence that strongly suggests that galectin-3 is essential for the development of liver fibrosis in animals. Published data show that mice lacking the galectin-3 gene are incapable of developing liver fibrosis in response to toxin insult to the liver and in fatty liver disease. Moreover, mice that do not have the galectin-3 gene are resistant to lung and kidney fibrosis.

We have evaluated the ability of GR-MD-02 to block galectin-3 in animal models of liver fibrosis, the conclusions of which yielded positive results. Our pre-clinical data show that GR-MD-02 may have a 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 NASH. GR-MD-02 is currently being evaluated in pre-clinical toxicology and pharmacology studies with the aim of filing an IND with the FDA by January 2013 for initiating human studies in patients with NASH. In early 2013, upon filing an IND, we plan to start a Phase I clinical trial with GR-MD-02 in patients with NASH to assess safety and preliminary evidence of efficacy in humans. By the end of 2013 or early 2014, depending on the results of the Phase I study, we plan on initiating a Phase II clinical trial to assess the efficacy of GR-MD-02 in patients with NASH and advanced liver fibrosis with expected top-line clinical results by the end of 2014 or early 2015.



**Table of Contents**

In July 2012, we received a notice of issuance from the U.S. Patent and Trademark Office for the patent Galactose-prolonged polysaccharides in a formulation for antifibrotic therapies . This patent covers key methods of derivation and use for our carbohydrate-based galectin inhibitor compound for use in patients with chronic liver disease associated with the development of fibrosis, established liver fibrosis or end-stage scarring, or cirrhosis. The major claim is for a method of obtaining the galectin inhibitor compound, obtaining a composition for parenteral administration in an acceptable pharmaceutical carrier and administering to a subject having at least one of the following: chronic liver disease associated with the development of fibrosis, established liver fibrosis or cirrhosis. The use covers inhibiting or slowing the progression of fibrosis or the reversal of fibrosis. GR-MD-02, is covered by this patent and it provides opportunities for development of additional compounds in the class.

**Agreement with PROCAPS S.A.**

On March 25, 2010, we granted PROCAPS S.A. (in the form of a definitive term sheet) exclusive rights to market and sell GM-CT-01 to treat cancer in Colombia, South America. PROCAPS is an international, privately held pharmaceutical company based in Barranquilla, Colombia. In October 2010, we received a payment of \$200,000 and shipped GM-CT-01 to PROCAPS to be used by PROCAPS to undertake initial steps contemplated by the term sheet. We recorded the \$200,000 payment from PROCAPS as deferred revenue on the condensed consolidated balance sheet as of December 31, 2011, to be recognized when the remaining deliverables of the agreement were completed.

On October 18, 2011, we entered into a Collaboration, Supply, Marketing and Distribution Agreement (the Agreement ) with PROCAPS. The Agreement granted PROCAPS first negotiation rights to enter into similar agreements in other Central and South American countries. We were to be the sole manufacturer and supplier of GM-CT-01 to PROCAPS. The Agreement obligated PROCAPS to procure regulatory approvals necessary for the marketing and sale of GM-CT-01 naming us as the owner of such approvals to the extent permitted by law, or alternatively hold the approvals for our benefit. PROCAPS must pay us a stated fee for each dose it purchases and royalties at an incremental rate determined by annual net sales of GM-CT-01. We retain all intellectual property rights to GM-CT-01 and related products and PROCAPS may not produce, modify, reverse engineer, or otherwise interfere with the GM-CT-01 compound. PROCAPS may not manufacture or sell products that compete with GM-CT-01 during the term of the Agreement and for five years thereafter.

PROCAPS had not obtained approval to sell GM-CT-01 in Columbia as required by the Agreement and, as they were in material breach of the Agreement, we terminated the Agreement, effective September 29, 2012. With no further obligations under the Agreement, we recognized the \$200,000 payment as Other Income in the Statements of Operations during the three and nine month periods ended September 30, 2012.

**Results of Operations****Three and Nine Months Ended September 30, 2012 Compared to Three and Nine Months Ended September 30, 2011***Research and Development Expense.*

	Three Months Ended		Nine Months Ended		2012 as Compared to 2011			
	September 30, 2012	September 30, 2011	September 30, 2012	September 30, 2011	\$ Change	% Change	\$ Change	% Change
Research and development	\$ 1,409	\$ 655	\$ 3,525	\$ 2,690	\$ 754	115%	\$ 835	31%

(In thousands, except %)

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 subdivide external expenses between clinical programs and pre-clinical activities. 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, GM-CT-01 and GR-MD-02. GM-CT-01 is in a Phase I/II clinical trial at this time, which is being conducted in collaboration with the Cancer Centre at the Cliniques Universitaires Saint-Luc and the Ludwig Institute for Cancer Research in Belgium. GR-MD-02 is currently being evaluated in pre-clinical toxicology and pharmacology studies with the aim of obtaining an IND from the FDA by

January 2013. We will then seek to gain FDA approval for Phase I and Phase II studies of GR-MD-02.

**Table of Contents**

Our research and development expenses for the three and nine months ended September 30, 2012, as compared to the three and nine months ended September 30, 2011, were as follows:

	Three Months		Nine Months	
	Ended September 30,		Ended September 30,	
	2012	2011	2012	2011
	(in thousands)			
Direct external expenses:				
Clinical programs	\$ 94	\$ 110	\$ 617	\$ 332
Pre-clinical activities	885	209	1,639	583
All other research and development expenses	430	336	1,269	1,775
	\$ 1,409	\$ 655	\$ 3,525	\$ 2,690

Pre-clinical expenses for the three and nine months ended September 30, 2012, increased compared to the same periods in 2011, due primarily to increased pre-clinical activity on our fibrosis program as we prepare to file an IND with the FDA by January 2013. Clinical programs remained relatively unchanged for the three months ended September 30, 2012 as compared to the same period in 2011 and increased during the nine months ended September 30, 2012 as compared to the same period in 2011 primarily due to drug manufacturing. The overall decrease in other research and development expenses during the nine months ended September 30, 2012 as compared to the same period in 2011 is due to decreased stock-based compensation (\$651,000) partially offset by increased salary and overhead costs (\$55,000).

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. However, we expect to continue to have substantial research and development expenses for the foreseeable future as we continue to develop our products.

*General and Administrative Expense.*

	Three Months		Nine Months Ended		2012 as Compared to 2011			
	Ended September 30,		September 30,		Three Months		Nine Months	
	2012	2011	2012	2011	\$ Change	% Change	\$ Change	% Change
	(In thousands, except %)							
General and administrative	\$ 1,487	\$ 1,378	\$ 3,992	\$ 4,347	\$ 109	8%	\$ (355)	(8)%

General and administrative expenses consist primarily of salaries including stock-based compensation, legal and accounting fees, insurance, investor relations, business development and other office related expenses. The primary reasons for the increase for the three months ended September 30, 2012 as compared to the same period in 2011 is due to increased stock-based compensation (\$192,000) and investor relations and business development costs (\$40,000), partially offset by decreased legal expense (\$144,000) due primarily to a litigation settlement during the three months ended September 30, 2011. The primary reasons for the decrease during the nine months ended September 30, 2012 as compared to the same period in 2011 is due to decreased legal expenses (\$427,000) due to our rebranding and litigation settlement during the nine months ended September 30, 2011, decreased business development (\$263,000) related to our attempts to gain approval for GM-CT-01 in Columbia, partially offset by increased stock-based compensation (\$134,000) and public company and other overhead costs (\$166,000).

As of October 1, 2012, the Company relocated its headquarters from Massachusetts to Georgia. On a going forward basis we expect this move will decrease our operating lease expenses by approximately \$226,000 annually.



**Table of Contents***Other Income and Expense.*

During the three and nine months ended September 30, 2012, other income and expense consisted primarily of the \$200,000 payment from PROCAPS which was previously accounted for as deferred revenue and recognized upon the termination of the PROCAPS Agreement, as previously described.

Other income and expense for the nine months ended September 30, 2011 included an expense of \$515,000, respectively, primarily related to the change in fair value of warrant liabilities. The Company had no warrant liabilities as of September 30, 2012 or during the three and nine months then ended.

**Liquidity and Capital Resources**

As described above in the Overview and elsewhere in this Quarterly Report on Form 10-Q, we are in the development stage and have not generated any revenues. Since our inception on July 10, 2000, we have financed our operations from proceeds of public and private offerings of debt and equity. As of September 30, 2012, we raised a net total of \$68.8 million from these offerings. At September 30, 2012, we had \$11.1 million of unrestricted cash and cash equivalents available to fund future operations. We will require more cash to fund our operations and believe we will be able to obtain additional financing. However, there can be no assurance that we will be successful in obtaining such new financing or, if available, that such financing will be on terms favorable to us. If we are unsuccessful in raising additional capital before the end of 2013, we may be required to cease operations or seek bankruptcy protection.

Net cash used in operations increased by \$1,615,000 to \$5,749,000 for the nine months ended September 30, 2012, as compared to \$4,134,000 for the nine months ended September 30, 2011. Cash operating expenses increased principally due to increased research and development activities related our ongoing clinical and preclinical activities with GM-CT-01 and GR-MD-02, partially offset by decreased general and administrative expenses.

Cash provided by investing activities during the nine months ended September 30, 2012 consisted of \$10,000 related to a decrease in restricted cash as compared to a \$5,000 increase in restricted cash and equipment purchases of \$5,000 during the nine months ended September 30, 2011.

Net cash provided by financing activities was \$10,403,000 during the nine months ended September 30, 2012 as compared to \$6,197,000 during the nine months ended September 30, 2011, due to a public offering we completed in the first quarter of 2012. On March 28, 2012, we sold 2,666,722 shares of common stock and related warrants to purchase 1,333,361 shares of common stock for gross proceeds of \$12.0 million (net proceeds \$10.4 million).

**Payments Due Under Contractual Obligations**

The following table summarizes the payments due under our contractual obligations at September 30, 2012, and the effect such obligations are expected to have on liquidity and cash flow in future periods:

	Total	Payments due by period (in thousands)			More than 5 years
		Less than 1 year	1-3 years	3-5 years	
<b>Contractual Obligations</b>					
Operating leases	\$ 92	\$ 47	\$ 45	\$	\$
Total payments due under contractual obligations	\$ 92	\$ 47	\$ 45	\$	\$

*Operating leases.*

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

## Edgar Filing: GALECTIN THERAPEUTICS INC - Form 10-Q

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

In July 2011, we entered into an agreement to amend our lease for our offices in Newton, MA to extend the term for a period of one year, expiring on September 30, 2012, at a base rent of \$235,000 for the period. In addition to base rental payments, we were responsible for our pro-rata share of increases in the operating expenses for the building. In connection with this lease, a commercial bank issued a letter of credit collateralized by cash, which we had on deposit with the bank of \$59,000 at September 30, 2012,.



**Table of Contents***Separation agreement.*

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

On May 2, 2012, Dr. Platt instituted arbitration before the American Arbitration Association, seeking a \$1.0 million separation payment based on a claim that a milestone event in the Separation Agreement has occurred (see clause (iii) above). On March 22, 2012, the Company's common stock was listed on the NASDAQ Capital Markets, but since that date, the stock has not achieved the required market capitalization. Therefore, it is the Company's position that a milestone event has not yet occurred. The arbitration hearing was held on October 16-17, 2012 and on November 1, 2012, the arbitrator denied Dr. Platt's demand in all respects. Insofar as the Company does not dispute its obligations under the Separation Agreement to pay Dr. Platt upon the occurrence of a milestone event, it has recorded the payment as an accrued expense payable if and when the milestone event occurs.

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

*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.

## Edgar Filing: GALECTIN THERAPEUTICS INC - Form 10-Q

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 2011 Annual Report on Form 10-K.

## **Table of Contents**

### **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, 2012, our disclosure controls and procedures were effective at a reasonable assurance level. During the quarter ended September 30, 2012, no change in our internal control over financial reporting has materially affected, or is likely to materially affect, our internal control over financial reporting.

## **PART II OTHER INFORMATION**

### **Item 1. Legal Proceedings**

From time to time, the Company is exposed to litigation relating to its operations. The Company is not currently engaged in any legal proceedings that are expected, individually or in the aggregate, to have a material, adverse affect on its financial condition or results of operations, except as noted below:

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

On May 2, 2012, Dr. Platt instituted arbitration before the American Arbitration Association, seeking a \$1.0 million separation payment based on a claim that a milestone event in the Separation Agreement has occurred (see clause (iii) above). On March 22, 2012, the Company's common stock was listed on the NASDAQ Capital Markets, but since that date, the stock has not achieved the required market capitalization. Therefore, it is the Company's position that a milestone event has not yet occurred. The arbitration hearing was held on October 16-17, 2012 and on November 1, 2012, the arbitrator denied Dr. Platt's demand in all respects. Insofar as the Company does not dispute its obligations under the Separation Agreement to pay Dr. Platt upon the occurrence of a milestone event, it has recorded the payment as an accrued expense payable if and when the milestone event occurs.

### **Item 1A. Risk Factors**

The risks we face, as set forth Item 1A, Risk Factors, of Part I of our Annual Report on Form 10-K for the year ended December 31, 2011, have not changed materially during the three months ended September 30, 2012.

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

None

### **Item 3. Defaults Upon Senior Securities**

None

**Item 4. Mine Safety Disclosures**

Not Applicable

**Item 5. Other Information**

None

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

<b>Exhibit Number</b>	<b>Description of Document</b>	<b>Note 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	Independent Consulting Agreement dated April 30, 2012, between Scott L. Friedman, M.D. and Galectin Therapeutics Inc.	2
10.2	Amended Employment Agreement dated July 19, 2012 between Maureen Foley and Galectin Therapeutics Inc.	3
10.3*	Employment Agreement dated August 27, 2012, 2012 between Harold H. Shlevin and Galectin Therapeutics Inc.	
10.4	Independent Consulting Agreement dated September 19, 2012 between Thomas A. McGauley and Galectin Therapeutics Inc.	4
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 the Company's Current Report on Form 8-K filed with the Commission on May 1, 2012.
3. Incorporated by reference to the Company's Current Report on Form 8-K filed with the Commission on July 25, 2012.
4. Incorporated by reference to the Company's Current Report on Form 8-K filed with the Commission on September 21, 2012.

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on November 9, 2012.

GALECTIN THERAPEUTICS INC.

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

/s/ Thomas A. McGauley  
Name: Thomas A. McGauley  
Title: Chief Financial Officer