

GALECTIN THERAPEUTICS INC

Form 10-Q

November 10, 2011

[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, 2011

.. **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. 000-32877

**GALECTIN THERAPEUTICS, INC.**

Edgar Filing: GALECTIN THERAPEUTICS INC - Form 10-Q

<b>Nevada</b> (State or other jurisdiction of incorporation)	<b>04-3562325</b> (I.R.S. Employer Identification No.)
<b>7 Wells Avenue, Newton, Massachusetts</b> (Address of Principal Executive Offices)	<b>02459</b> (Zip Code)
<b>(617) 559-0033</b> (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 <input type="checkbox"/>	Accelerated Filer <input type="checkbox"/>
Non-Accelerated Filer <input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company <input checked="" type="checkbox"/>

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 1, 2011 was 77,060,181.

**Table of Contents**

**GALECTIN THERAPEUTICS, INC.  
(FORMERLY PRO-PHARMACEUTICALS, INC.)**

**INDEX TO FORM 10-Q**

**FOR THE QUARTER ENDED September 30, 2011**

	<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, 2011 and December 31, 2010 (unaudited)</u>	3
<u>Condensed Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2011 and 2010, and for the Cumulative Period From Inception (July 10, 2000) to September 30, 2011 (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, 2011 (unaudited)</u>	5
<u>Condensed Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2011 and 2010, and for the Cumulative Period From Inception (July 10, 2000) to September 30, 2011 (unaudited)</u>	6
<u>Notes to Unaudited Condensed Consolidated Financial Statements (unaudited)</u>	7
ITEM 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	14
ITEM 3. <u>Quantitative and Qualitative Disclosures about Market Risk</u>	20
ITEM 4. <u>Controls and Procedures</u>	20
<b>PART II OTHER INFORMATION</b>	
ITEM 1. <u>Legal Proceedings</u>	20
ITEM 1A. <u>Risk Factors</u>	20
ITEM 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	20
ITEM 3. <u>Defaults Upon Senior Securities</u>	20
ITEM 4. <u>(removed and reserved)</u>	20
ITEM 5. <u>Other Information</u>	20
ITEM 6. <u>Exhibits</u>	21
<u>SIGNATURES</u>	22

**Table of Contents**

GALECTIN THERAPEUTICS, INC.

(FORMERLY PRO-PHARMACEUTICALS, INC.)

(A Development-Stage Company)

**CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)**

	September 30, 2011	December 31, 2010
	(in thousands)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 7,944	\$ 5,891
Grant receivable		234
Prepaid expenses and other current assets	51	70
Total current assets	7,995	6,195
Property and equipment, net	7	7
Restricted cash	64	59
Intangible assets, net	37	39
Total assets	\$ 8,103	\$ 6,300
<b>LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Current liabilities:		
Accounts payable	\$ 198	\$ 125
Accrued expenses	417	537
Accrued dividends payable		48
Deferred revenue	200	200
Warrant liabilities		861
Total current liabilities	815	1,771
Other long-term liabilities		12
Total liabilities	815	1,783
<b>Commitments and contingencies (Note 7 and Note 9)</b>		
Series B-1 12% redeemable convertible preferred stock; 900,000 shares authorized, issued and outstanding at September 30, 2011 and December 31, 2010, redemption value: \$1,800,000, liquidation value: \$1,800,000 at September 30, 2011	1,677	1,664
Series B-2 12% redeemable convertible preferred stock; 2,100,000 shares authorized at September 30, 2011 and December 31, 2010, 2,100,000 issued and outstanding at September 30, 2011 and December 31, 2010, redemption value: \$4,200,000, liquidation value of \$4,200,000 at September 30, 2011	2,634	2,474
Series C super dividend redeemable convertible preferred stock; 1,000 shares authorized, 220 and 212 issued and outstanding at September 30, 2011 and December 31, 2010, respectively, redemption value: \$4,202,000, liquidation value: \$2,200,000 at September 30, 2011	2,154	2,073

Edgar Filing: GALECTIN THERAPEUTICS INC - Form 10-Q

Stockholders' equity (deficit):		
Undesignated stock, \$0.01 par value; 20,000,000 shares authorized at September 30, 2011 and December 31, 2010, 8,001,000 designated at September 30, 2011 and December 31, 2010		
Series A 12% convertible preferred stock; 5,000,000 shares authorized, 1,562,500 and 1,592,500 issued and outstanding at September 30, 2011 and December 31, 2010, respectively	632	644
Common stock, \$0.001 par value; 300,000,000 shares authorized at September 30, 2011 and December 31, 2010, 76,907,440 and 63,909,155 issued and outstanding at September 30, 2011 and December 31, 2010, respectively	77	64
Additional paid-in capital	65,533	54,022
Deficit accumulated during the development stage	(65,419)	(56,424)
<b>Total stockholders' equity (deficit)</b>	<b>823</b>	<b>(1,694)</b>
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	\$ 8,103	\$ 6,300

See notes to unaudited condensed consolidated financial statements.

**Table of Contents**

GALECTIN THERAPEUTICS, INC.

(FORMERLY PRO-PHARMACEUTICALS, INC.)

(A Development-Stage Company)

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

	Three Months Ended		Nine Months Ended		Cumulative
	September 30,		September 30,		Period from
	2011	2010	2011	2010	Inception
	(July 10, 2000)				
	to September 30,				
	2011				
	(in thousands, except share and per share amounts)				
Operating expenses:					
Research and development	\$ 655	\$ 313	\$ 2,690	\$ 676	\$ 22,221
General and administrative	1,378	899	4,347	2,918	39,154
Total operating expenses	2,033	1,212	7,037	3,594	61,375
Total operating loss	(2,033)	(1,212)	(7,037)	(3,594)	(61,375)
Other income (expense):					
Interest income	5	3	14	4	790
Interest expense					(4,451)
Change in fair value of convertible debt instrument					(3,426)
Change in fair value of warrant liabilities		100	(524)	(1,311)	9,022
Other income					491
Total other income (expense)	5	103	(510)	(1,307)	2,426
Net loss	\$ (2,028)	\$ (1,109)	\$ (7,547)	\$ (4,901)	\$ (58,949)
Preferred stock dividends	(253)	(239)	(1,275)	(664)	(2,966)
Preferred stock accretion	(58)	(551)	(173)	(1,626)	(3,758)
Net loss applicable to common stockholders	\$ (2,339)	\$ (1,899)	\$ (8,995)	\$ (7,191)	\$ (65,673)
Net loss per common share basic and diluted	\$ (0.03)	\$ (0.03)	\$ (0.13)	\$ (0.13)	
Weighted average common shares outstanding basic and diluted	74,118	58,764	70,181	54,268	

See notes to unaudited condensed consolidated financial statements.

**Table of Contents**

GALECTIN THERAPEUTICS, INC.

(FORMERLY PRO-PHARMACEUTICALS, INC.)

(A Development-Stage Company)

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

NINE MONTHS ENDED SEPTEMBER 30, 2011 (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)		Total Stockholders Equity (Deficit)		
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Common Stock	Additional Paid-In Capital	Deficit	Accumulated	
<b>Balance at December 31, 2010</b>	<b>900,000</b>	<b>\$ 1,664</b>	<b>2,100,000</b>	<b>\$ 2,474</b>	<b>212</b>	<b>\$ 2,073</b>	<b>1,592,500</b>	<b>\$ 644</b>	<b>63,909,155</b>	<b>\$ 64</b>	<b>\$ 54,022</b>	<b>\$ (56,424)</b>	<b>\$ (1,694)</b>
Accretion of Series B redeemable convertible preferred stock		13		119								(132)	(132)
Accretion of beneficial conversion feature for Series B-2				41								(41)	(41)
Issuance of Series C super dividend convertible preferred stock					13	130							
Series A 12% convertible preferred stock dividend									181,925	180		(133)	47
Series B-1 12% redeemable convertible									290,303	314		(314)	

Edgar Filing: GALECTIN THERAPEUTICS INC - Form 10-Q

preferred stock dividend														
Series B-2 12% redeemable convertible preferred stock dividend								677,371	1	730		(731)		
Series C super convertible preferred stock dividend								102,392		97		(97)		
Issuance of restricted common stock								125,000						
Issuance of common stock upon exercise of warrants								10,628,294	11	7,208				7,219
Issuance of common stock upon exercise of options								913,000	1	233				234
Conversion of Series A to common stock							(30,000)	(12)		30,000		12		
Conversion of Series C to common stock									(5)	(49)		50,000	49	49
Stock-based compensation expense												2,688		2,688
Net loss													(7,547)	(7,547)
<b>Balance at September 30, 2011</b>	<b>900,000</b>	<b>\$ 1,677</b>	<b>2,100,000</b>	<b>\$ 2,634</b>	<b>220</b>	<b>\$ 2,154</b>	<b>1,562,500</b>	<b>\$ 632</b>	<b>76,907,440</b>	<b>\$ 77</b>	<b>\$ 65,533</b>	<b>\$ (65,419)</b>	<b>\$ 823</b>	

See notes to unaudited condensed consolidated financial statements



**Table of Contents**

GALECTIN THERAPEUTICS, INC.

(FORMERLY PRO-PHARMACEUTICALS, INC.)

(A Development-Stage Company)

**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)**

	Nine Months Ended		Cumulative
	September 30,	September 30,	Period from
	2011	2010	Inception
	(in thousands)		(July 10, 2000)
	2011	2010	to September 30,
			2011
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net loss	\$ (7,547)	\$ (4,901)	\$ (58,949)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	7	11	544
Stock-based compensation expense	2,688	1,575	9,025
Non-cash interest expense			4,279
Change in fair value of convertible debt instrument			3,426
Change in fair value of warrant liabilities	524	1,311	(9,022)
Write off of intangible assets			351
Changes in operating assets and liabilities:			
Grant receivable	234		
Prepaid expenses and other current assets	19	3	(48)
Accounts payable and accrued expenses	(47)	(228)	883
Other long-term liabilities	(12)	(290)	
Net cash used in operating activities	(4,134)	(2,519)	(49,511)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchases of property and equipment	(5)		(426)
Change in restricted cash	(5)		(64)
Increase in patents costs and other assets			(404)
Net cash used in investing activities	(10)		(894)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Net proceeds from issuance of common stock and warrants			28,690
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		1,463	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	3,619	11,293
Proceeds from shareholder advances			9

Edgar Filing: GALECTIN THERAPEUTICS INC - Form 10-Q

Net cash provided by financing activities	6,197	5,082	58,349
NET INCREASE IN CASH AND CASH EQUIVALENTS	2,053	2,563	7,944
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	5,891	251	
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 7,944	\$ 2,814	\$ 7,944
SUPPLEMENTAL DISCLOSURE Cash paid for interest	\$	\$	\$ 114
NONCASH FINANCING ACTIVITIES:			
Issuance of equity warrants in connection with equity offerings	\$	\$ 1,029	\$ 5,037
Conversion of accrued expenses into common stock			303
Cashless exercise of stock options			98
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	1,321	716	3,012
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.**

**(FORMERLY PRO-PHARMACEUTICALS, 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 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. The condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Pro-Pharmaceuticals Securities Corp., which was incorporated in Delaware on December 23, 2003, and Medi-Pharmaceuticals, Inc., which was incorporated in Nevada on August 17, 2010. All intercompany transactions have been eliminated.

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, 2011 and the results of its operations for the three and nine months ended September 30, 2011 and 2010 and the cumulative period from inception (July 10, 2000) through September 30, 2011 and its cash flows for the nine months ended September 30, 2011 and 2010, and for the cumulative period from inception (July 10, 2000) to September 30, 2011. 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, 2010.

As shown in the unaudited condensed consolidated financial statements, the Company incurred cumulative net losses applicable to common stockholders of approximately \$65.7 million for the cumulative period from inception (July 10, 2000) through September 30, 2011. 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 and the costs related to fair value accounting for the Company's convertible debt instrument and warrant liabilities. 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. From inception (July 10, 2000) through September 30, 2011, the Company has raised a net total of approximately \$58.3 million in capital through sale and issuance of common stock, common stock warrants, convertible preferred stock, redeemable convertible preferred stock, convertible debt securities in public and private offerings and the exercise of common stock options and warrants. From inception (July 10, 2000) through September 30, 2011, the Company has used approximately \$49.5 million of cash in its operations.

At September 30, 2011, the Company had \$7,944,000 of unrestricted cash and cash equivalents available to fund future operations. The Company believes that with the funds on hand at September 30, 2011, there is sufficient cash to fund core operations through the first quarter of 2013. The Company is actively seeking to raise additional capital. If the Company is unsuccessful in raising additional capital before the end of the first quarter of 2013, the Company may be required to cease operations or seek bankruptcy protection.

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. and Research Grants***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 Company recorded the \$200,000 payment from PROCAPS as deferred revenue on the condensed consolidated balance sheets as of September 30, 2011 and December 31, 2010 and will recognize the revenue when the remaining deliverables of the collaboration agreement have been completed.

On October 18, 2011, the Company entered into a Collaboration, Supply, Marketing and Distribution Agreement (the Agreement) with PROCAPS. The Agreement grants PROCAPS first negotiation rights to enter into similar agreements in other Central and South American countries. The Company is the sole manufacturer and supplier of GM-CT-01 to PROCAPS. The Agreement obligates 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 must pay the Company a stated fee for each dose it purchases 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 may not manufacture or sell products that compete with GM-CT-01 during the term of the Agreement and for five years thereafter.

*Qualifying Therapeutic Discovery Project*

In October 2010, the Company was awarded \$489,000 total in two federal grants under the Qualifying Therapeutic Discovery Project ( QTDP ) Program for its GM-CT-01 anti-cancer compound and for its GR/GM-Series of anti-fibrotic, cirrhosis compounds for work performed during 2010 and 2009. The Company recognized this grant in other income in the statement of operations for the year ended December 31, 2010. The Company received \$255,000 of the grant in 2010 and the remaining \$234,000 was received in 2011 and was included in grants receivable on the consolidated balance sheet at December 31, 2010.

**3. Stock-Based Compensation**

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

	Three Months Ended September 30, 2011		Nine Months Ended September 30, 2010	
	2011	2010	2011	2010
	(in thousands)			
Research and development	\$ 270	\$ 60	\$ 1,407	\$ 239
General and administrative	379	244	1,281	1,336
<b>Total stock-based compensation expense</b>	<b>\$ 649</b>	<b>\$ 304</b>	<b>\$ 2,688</b>	<b>\$ 1,575</b>

Included in stock-based compensation for the three and nine months ended September 30, 2011 was \$119,000 of research and development expenses accrued for at June 30, 2011. Included in stock-based compensation for the nine months ended September 30, 2010 was \$70,000 of research and development expenses and \$295,000 of general and administrative expenses which were accrued for as bonuses as of December 31, 2009 and which were paid with the issuance of options in 2010.

*Common Stock Options*

The following table summarizes the stock option activity in the Company's equity incentive plans from December 31, 2010 through September 30, 2011:

Edgar Filing: GALECTIN THERAPEUTICS INC - Form 10-Q

	Shares	Weighted Average Exercise Price
Outstanding, December 31, 2010	11,794,250	\$ 1.07
Granted	9,961,242	1.17
Exercised	(913,000)	0.20
Options forfeited/cancelled	(1,609,000)	1.32
Outstanding, September 30, 2011	19,233,492	\$ 1.14

**Table of Contents**

As of September 30, 2011, there was \$7,567,000 of unrecognized compensation related to 8,164,263 unvested options, which is expected to be recognized over a weighted average period of approximately 3.2 years. 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. The weighted-average grant date fair value for options granted during the nine months ended September 30, 2010 was \$0.26; there were no options granted during the three months ended September 30, 2010.

Of the options granted during the nine months ended September 30, 2011, 1,000,000 vest only upon the achievement of certain market conditions (500,000 and 500,000 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 the options granted, other than as noted, is determined using the Black-Scholes option-pricing model. The following weighted average assumptions were used:

	Cumulative Period from Inception (July 10, 2000) to		
	Nine Months Ended September 30,		September 30,
	2011	2010	2011
Risk-free interest rate	1.93%	2.38%	2.24%
Expected life of the options	5.1 years	5 years	5.1 years
Expected volatility of the underlying stock	121%	126%	116%
Expected dividend rate	0%	0%	0%

*Restricted Stock.*

During the year ended December 31, 2009, the Company granted 2,500,000 shares of restricted common stock to members of its Board of Directors. Of the 2,500,000 shares, 2,343,750 were vested as of December 31, 2010 and the remaining 156,250 vested during the nine months ended September 30, 2011. The restricted shares were valued at \$450,000 (\$0.18 per share) at the date of grant, which was recognized over the vesting period.

During the nine months ended September 30, 2011, the Company issued 125,000 shares of restricted common stock to a consultant. These shares are restricted until November 15, 2011 and any unvested shares are subject to forfeiture upon termination and would revert back to the Company. At September 30, 2011 there were 125,000 restricted shares remaining. The restricted shares were valued at \$108,000 (\$0.86 per share) at September 30, 2011 and will be adjusted for unvested shares and will be recognized over the vesting period. During the three and nine months ended September 30, 2011, the Company recognized \$16,000 and \$96,000 of stock-based compensation, respectively.

The following table summarizes restricted stock activity from December 31, 2010 through September 30, 2011:

	Shares
Restricted, December 31, 2010	156,250
Granted	125,000
Vested	(156,250)
Restricted, September 30, 2011	125,000





**Table of Contents****4. Accrued Expenses**

Accrued expenses consist of the following:

	September 30, 2011	December 31, 2010
	(in thousands)	
Legal and accounting fees	\$ 86	\$ 94
Accrued compensation	58	87
Severance agreement (Note 9)		293
Legal settlement	175	13
Other	98	50
 Total	 \$ 417	 \$ 537

**5. Common Stock Warrants**

The following table summarizes the common stock warrant activity from December 31, 2010 through September 30, 2011:

	Shares	Weighted Average Exercise Price
Outstanding, December 31, 2010	51,515,194	\$ 0.63
Granted		0.00
Exercised	(10,628,294)	0.55
Forfeited/cancelled	(846,500)	0.89
 Outstanding, September 30, 2011	 40,040,400	 \$ 0.66

*Consultant Warrants*

In April 2009, the Company entered into agreements with consultants that provided for the grant of warrants for 330,000 shares of common stock at an exercise price of \$0.50 per share. Of the 330,000 warrants, 200,000 remained unvested as of September 30, 2011. The Company valued the unvested warrants at \$95,000 as of September 30, 2011 using the following assumptions: expected life of 1.54 years, volatility of 80%, risk free interest rate of 0.25% and zero dividends. The Company recognized a reversal of expense related to the 200,000 warrants of \$36,000 and \$16,000 for the three and nine months ended September 30, 2011, respectively. The Company recognized expense of \$23,000 and \$79,000 for the three and nine months ended September 30, 2010.

In May 2010, the Company entered into an agreement with a consultant that provided for the grant of warrants for 72,000 shares of common stock at an exercise price of \$2.50 per share. The warrants vested at a rate of 3,000 per month and the unvested warrants were revalued as they vested. 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. At September 30, 2011, 45,000 warrants were vested and 27,000 were forfeited upon cancellation of the agreement. The company recognized an expense of \$12,000 related to these warrants during the nine months ended September 30, 2011. The company recognized an expense of \$4,000 and \$15,000 related to these warrants during the three and nine months ended September 30, 2010.

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 600,000 shares of common stock at an exercise price of \$0.71 per share. Of the 600,000 warrants, 150,000 vested immediately on signing of the agreement, 150,000 vest at the end of one year and the remaining 300,000 warrants were to vest based on the achievement of certain milestones. The following assumptions were used to value the remaining unvested 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 with the consultant, all remaining unvested warrants were

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

immediately vested. The Company recognized expense of \$340,000 related to these warrants during the nine months ended September 30, 2011. The Company recognized an expense of \$60,000 and \$160,000 related to these warrants during the three and nine months ended September 30, 2010.

**Table of Contents****6. Fair Value of Financial Instruments**

In general, fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for 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's financial liabilities were classified as Level 2. These Level 2 liabilities consisted of warrant liabilities at December 31, 2010 and have been valued using the Black-Scholes pricing model. The Company did not have any warrant liabilities at September 30, 2011.

The Company uses the Black-Scholes pricing model to calculate fair value of its warrant liabilities. Key assumptions used to apply these models are as follows:

	December 31, 2010
Risk free interest rate	0.19%
Expected life	0.62 years
Expected volatility of common share price	70%
Common share price	\$ 0.90

Below is a summary of our fair value measurements at December 31, 2010:

	Value at Period End	Quoted prices in active markets (Level 1)	Significant other observable inputs (Level 2) (in thousands)	Significant unobservable inputs (Level 3)
Warrant liabilities	\$ 861	\$	\$ 861	\$

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.

**7. Preferred Stock***Series B Convertible Preferred Stock*

Through a series of closings from February 2009 through May 2010, the Company issued and sold a total of (i) 900,000 shares of Series B-1 convertible preferred stock ( Series B-1 redeemable convertible preferred stock or Series B-1 ) and related common stock warrants for 10,800,000 shares of common stock and (ii) 2,100,000 shares of Series B-2 convertible preferred stock ( Series B-2 redeemable convertible preferred stock or Series B-2 ) and together with the Series B-1, the Series B ) and related warrants for 25,200,000 shares of common stock. During the nine months ended September 30, 2010, the Company issued 770,000 shares of Series B-2 and related warrants, for net proceeds of \$1,463,000. Pursuant to an agreement with the holder of all shares of Series B, on January 26, 2011, the Company amended and restated the Certificate of Designation of Preferences, Rights and Limitations for the Series B-1 Convertible Preferred Stock and Series B-2 Convertible Preferred Stock, as previously amended, to (i) delete Section 5(c) (entitled Mandatory Conversion ) in order to remove the Company's right to compel conversion of the Series B Preferred Stock to shares of its Common Stock, (ii) amend the definitions in Section 1 (entitled Definitions ) of the terms Series B-1 Redemption Date and the Series B-2 Redemption Date in order to extend such redemption dates to be the earlier of February 12, 2019, or the date of a promissory note issued to David Platt, Ph.D. pursuant to a separation agreement between him and the Company, (iii) amend Section 3 (entitled Dividends ) such that dividends are payable in cash or shares of Common Stock valued at 100% of the volume weighted average price of the Common Stock for the 20 consecutive trading days prior to the dividend payment date on and after September 30, 2011, and (iv) insert new Section 5(d) (entitled Automatic Conversion Upon Transfer ) to require that any request for transfer of shares of Series B Preferred Stock to another holder shall result in an automatic conversion to shares of Common Stock.

*Series C 6% Super Dividend Convertible Preferred Stock*

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

On December 29, 2010, the Company designated and authorized the sale and issuance of up to 1,000 shares of Series C Super Dividend Convertible Preferred Stock ( Series C ) with a par value of \$0.01 and a stated value equal to \$10,000 (the Stated Value ).

**Table of Contents**

On December 30, 2010, the Company sold and issued 212 shares of Series C at a price of \$10,000 per share for gross proceeds of \$2,120,000. The Company incurred \$47,000 of cash transaction costs resulting in net cash proceeds of \$2,073,000. In addition, the Company issued 3,000 warrants exercisable at \$1.20 to a placement agent which had a de minimis value.

During January 2011, the Company sold and issued 13 shares of Series C at a price of \$10,000 per share for gross proceeds of \$130,000.

The terms of the Series C are as follows:

*Conversion Rights.* Each holder of Series C may convert all, but not less than all, of his Series C shares plus accrued and unpaid dividends into Common Stock at the price of \$1.00 per share of Common Stock ( Conversion Price ), such that 10,000 shares of Common Stock will be issued per each converted share of Series C (accrued and unpaid dividends will be issued as additional shares).

Subject to the continuing obligation to pay post conversion dividends, the Company may convert all, but not less than all, of the Series C (plus all accrued and unpaid dividends) into Common Stock, at the Conversion Price, upon such time that the closing price of the Common Stock is no less than \$3.00 per share for 15 consecutive trading days.

*Dividends.* Holders of Series C shall be entitled to receive cumulative non-compounding dividends at the rate per share of Series C equal to the greater of (i) 6% per annum of the Stated Value (also defined as the Floor ) or (ii) 2.5% of net sales until the total dividends paid is equal to the initial investment and 1.25% of net sales thereafter. The maximum amount each Series C shareholder will receive in dividend payments is equal to \$100,000 (the Maximum Payout ). For purposes of this dividend calculation, net sales shall mean gross revenues actually received by the Company, from the sale or licensing of the product DAVANAT®, less chargebacks, returns, expenses attributable to product recalls, duties, customs, sales tax, freight, insurance, shipping expenses, allowances and other customary deductions.

The dividend shall be payable in arrears semi annually on March 31 and September 30, beginning with the first such date after the original issue date; provided, however, that all dividends and all other distributions shall cease, and no further dividends or other distributions shall be paid, in respect of each share of Series C from and after such time that the Maximum Payout has been paid in respect of such share of Series C. Such dividends shall be payable at the Company's option either in cash or in duly authorized, fully paid and non-assessable shares of Common Stock valued at the higher of (i) \$0.50 per share or (ii) the average of the Common Stock trading price for the ten (10) consecutive trading days ending on the trading day that is immediately prior to the dividend payment date.

*Series C Post Conversion Dividend Right.* In the event that any share of Series C is converted into Common Stock before the Maximum Payout is paid in respect of such converted share of Series C, then the holder shall have the right to continue to receive dividends in respect of such converted share of Series C equal to the remaining payout (the Series C Preferred Stock Post Conversion Dividend Right ) which shall be equal to the Maximum Payout less the cumulative dividends received through the conversion date. One share of Series C Preferred Stock Post Conversion Dividend Right shall be issued for each such converted share of Series C. The holder of each Series C Preferred Stock Post Conversion Dividend Right shall receive the remaining payout on an equal basis and in conjunction with the then outstanding shares of Series C and all the other then outstanding Series C Post Conversion Dividend Rights, in the same manner and subject to the same terms and conditions as applicable to the payment of dividends on each share of Series C, except that for purposes of calculating the dividend the Floor shall not apply. The Series C Preferred Stock Post Conversion Dividend Right shall have no stated value, liquidation preference or right to any dividends or distributions other than the remaining payout. The Series C Preferred Stock Post Conversion Right is subject to redemption in the same manner as outstanding Series C shares.

At the date of issuance, the Series C have an embedded dividend right to continue to receive dividend payments after conversion to common stock (the Series C Post Conversion Dividend Right) which requires bifurcation. The value of this post conversion dividend right on the date of issuance was determined to be de minimis due to the payment of a dividend stream other than the 6% dividend and conversion of Series C prior to the Company achieving sales of GM-CT-01 was deemed improbable at that time. Upon a conversion of the Series C, the Company will be required to record a liability and the related expense during the period of conversion. The Company will continue to evaluate and assess the Series C Post Conversion Dividend Right for each reporting period.

In July 2011, 5 shares of Series C were converted into 50,000 shares of common stock and 5 Series C Post Conversion Dividend Rights (Dividend Rights) were issued. Per the terms of the Series C, these Dividend Rights shall continue to participate in dividends, however the Floor shall not apply. At September 30, 2011, these Dividend Rights were determined to have a de minimis value, as the payment of a dividend is considered improbable at this time. At September 30, 2011, these five Dividend Rights have a redemption value of \$97,000.

*Liquidation Rights.* In the event of any liquidation, dissolution or winding up of the Company, either voluntarily or involuntarily, the holders of Series C will receive \$10,000 per share plus accrued and unpaid dividends, payable prior and in preference to any distributions to the holders of

Edgar Filing: GALECTIN THERAPEUTICS INC - Form 10-Q

Common Stock but after and subordinate to the Series A 12% Convertible Preferred Stock ( Series A ), Series B-1 and Series B-2, subject to the Maximum Payout.

**Table of Contents**

*Redemption.* Upon a sale of the Company, the Company shall redeem all of the then outstanding shares of Series C and Series C Preferred Stock Post Conversion Rights within thirty (30) days after the transaction constituting the sale of the Company is closed and such closing is fully funded. The price to redeem a share of Series C and each redeemed Series C Preferred Stock Post Conversion Redemption Right shall be equal to (i) (A) the applicable return on investment ( ROI ) percentage, multiplied by (B) \$10,000, minus (ii) the cumulative dividends received through the redemption date. The redemption price shall be payable at our option either in cash or in shares of common stock valued at the higher of (i) \$0.50 per share or (ii) the average market price for the ten consecutive trading days ending immediately prior to the date of redemption. The ROI Percentage shall mean the percentage that applies as of the redemption date, as follows:

## ROI Percentage

200%	before the second anniversary of the date of issuance;
250%	on or after the second anniversary of the date of issuance, but before the third anniversary of the date of issuance;
300%	on or after the third anniversary of the date of issuance, but before the fourth anniversary of the date of issuance;
350%	on or after the fourth anniversary of the date of issuance, but before the fifth anniversary of the date of issuance;
400%	on or after the fifth anniversary of the date of issuance, but before the sixth anniversary of the date of issuance;
450%	on or after the sixth anniversary of the date of issuance, but before the seventh anniversary of the date of issuance;
500%	on or after the seventh anniversary of the date of issuance, but before the eighth anniversary of the date of issuance;
	and
550%	on or after the eighth anniversary of the date of issuance, but before the ninth anniversary of the date of issuance.

Due to the redemption feature, the Company has presented the Series C outside of permanent equity, in the mezzanine of the consolidated balance sheet at September 30, 2011 and December 31, 2010.

*Voting Rights.* The Series C shares have no voting rights.

**8. Loss Per Share**

Basic loss per share is based on the weighted-average number of common shares outstanding during each period. Diluted loss per share is based on basic shares as determined above plus the incremental shares that would be issued upon the assumed exercise of in-the-money stock options and warrants using the treasury stock method. 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. For the three and nine month periods ended September 30, 2011 and 2010, all stock options, warrants and potential shares related to conversion of the Series A, the Series B and the Series C were excluded from the computation of diluted net loss per share. Dilutive shares which could exist pursuant to the exercise of outstanding stock instruments and which were not included in the calculation because their affect would have been anti-dilutive are as follows:

	September 30, 2011 (Shares)	September 30, 2010 (Shares)
Warrants to purchase shares of common stock	40,040,400	54,144,344
Options to purchase shares of common stock	19,233,492	11,829,250
Restricted shares subject to vesting	125,000	412,500
Shares of common stock issuable upon conversion of preferred stock	15,762,500	13,592,500
	75,161,392	79,978,594

**9. Commitments and Contingencies***Separation Agreement Former Chief Executive Officer and Chairman of the Board of Directors*

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 that the Company shall continue to

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

pay Dr. Platt his salary at a monthly rate of \$21,667 for 24 months as well as health and dental benefits. The Company recognized the full amount of the salary, health insurance and automobile during the first quarter of 2009. The remaining liability related to this severance was reflected in accrued expenses (\$293,000) on the condensed consolidated balance sheet at December 31, 2010 and was paid to Dr. Platt on February 12, 2011.



**Table of Contents**

The Separation Agreement also provides for the deferral of a \$1.0 million severance payment due to Dr. Platt under his employment agreement until the occurrence of any of the following milestone events: (i) the approval by the Food and Drug Administration for a new drug application ( NDA ) for any drug candidate or drug delivery candidate based on the GM-CT-01 technology (whether or not such technology is patented), in which case Dr. Platt is also entitled to a fully vested 10-year cashless-exercise stock option to purchase at least 500,000 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 300,000 shares of common stock; or (iii) the renewed listing of our securities on a national securities exchange. Payment upon the events (i) and (iii) may be deferred up to nine 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 Company's obligation to pay the \$1.0 million with the result that Dr. Platt may assert a claim for such obligation against the bankruptcy estate. Due to the uncertainties regarding the achievement of any of the milestones as described, the Company has not accrued for the \$1.0 million severance nor has it recognized the value of the unissued stock options as of September 30, 2011. When it is deemed probable that one or more of the milestone events will be achieved, the Company will then recognize the \$1.0 million severance and the expense related to the issuance of the stock option at that time based on the then current fair value.

*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. Other than claims and legal proceedings that arise from time to time in the ordinary course of business which are not material, the Company has no pending legal proceedings except as follows:

In January 2003, Custom Equity Research, Incorporated (d/b/a Summer Street Research Partners) filed a lawsuit against the Company alleging breach of contract, among other claims, based on an engagement letter in which Summer Street agreed to provide investment services to us. We denied the claims and believed they were without merit. In January 2011, the Company learned that Maxim Group, which the Company had previously engaged as a placement agent, had been named respondent in an arbitration matter with the Financial Industry Regulatory Authority (FINRA) initiated by Summer Street, for which the Company was obligated to indemnify Maxim Group. After consideration of the continued costs of litigation, the Company settled both matters for an amount that is not material to our balance sheet or our cash position. Subsequent to the execution of the settlement agreement, but before the settlement proceeds were paid, a dispute arose with Summer Street regarding the scope of a release of unrelated claims that Summer Street has requested be provided by Maxim Group. Motions for the enforcement of the settlement agreement are currently pending in the litigation and in the arbitration. In the event the motions are not granted, the litigation and/or arbitration may resume.

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.

**10. Subsequent Events**

The Company has evaluated all events or transactions that occurred through the date on which the financial statements were issued, noting the following:

As described in Note 2, on October 18, 2011, the Company entered into a Collaboration, Supply, Marketing and Distribution Agreement with PROCAPS.

As described in Note 9, on October 21, 2011, the Company entered into a settlement agreement with Summer Street.

**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 federal securities laws 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, legal 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. Forward-looking statements are expectations, estimates and projections about the industry and markets in which Galectin Therapeutics operates, and management's beliefs and

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

assumptions. These statements are not guarantees of future performance and involve certain known and unknown risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Such risks and uncertainties are related to, without limitation, our early stage of development, our dependence on outside capital, uncertainties of our technology and clinical trials, 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. The following discussion should be read in conjunction with the accompanying condensed consolidated financial statements and notes thereto of Galectin Therapeutics appearing elsewhere herein.

## **Table of Contents**

### **Overview**

Galectin Therapeutics 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 our unique targeting of galectin proteins which are key mediators of biologic and pathologic function. Galectin Therapeutics uses naturally occurring carbohydrate polymers with galactose residues to create complex carbohydrates with specific molecular weights. Using these unique carbohydrate-based candidate compounds that bind and inhibit galectin proteins, we are pursuing therapies for indications where galectins have a demonstrated role in the pathogenesis of a particular 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 approaches that add value to the Company in the shortest time possible, and to seek partners when the program becomes advanced and requires much greater resources.

Galectin Therapeutics leverages extensive 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 liver fibrosis, tumor vaccine enhancement, and colorectal cancer. All of our products are presently in development, including pre-clinical and clinical trials.

Since our inception on July 10, 2000, our focus has been the development of a new generation of polysaccharide polymers which are designed to increase survival and improve the quality of life for liver fibrosis and cancer patients. We adopted our new corporate name, Galectin Therapeutics, Inc., on May 26, 2011. Our lead product candidate is GM-CT-01 (formerly DAVANAT®). We hold the patent on GM-CT-01 without any licensing or royalty obligations.

At September 30, 2011, we had \$7,944,000 of unrestricted cash to fund our operations. We believe that with the cash on hand at September 30, 2011, there is sufficient cash to fund core operations through the first quarter of 2013. 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.

### *Development of GM and GR Series to Treat Fibrosis*

We are developing therapeutic compounds for treatment of serious disease, such as liver fibrosis. The GM and GR series of compounds are first-in-class, novel carbohydrate compounds that significantly reduced collagen expression and reversed fibrosis in animal models.

Uncontrolled collagen expression is a pathological process that occurs during the fibrotic process, affecting various organs leading to scar tissue. Chemical toxicity, viral infection or physical injury cause liver, renal and other types of fibrosis. According to the American Liver Foundation, more than 25 million Americans are or have been afflicted with liver and biliary diseases. The disease is even more of a problem outside the U.S. because of the prevalence of chronic hepatitis B and C that often results in fibrosis, and ultimately cirrhosis, of the liver. The area of anti-fibrotics is generating great interest based on their potential to impact chronic liver disease. The need for an effective therapeutic solution for liver fibrosis is acute, and this innovative project would significantly advance treatment in this critical area. The only current treatment for late stage fibrosis or cirrhosis is a liver transplant. Therefore, carbohydrate polymers were created and screened to inhibit collagen production in *in-vivo* and *in-vitro* fibrosis models.

In December 2010, we announced an extension of our research collaboration with Mount Sinai School of Medicine which began in 2006 to evaluate, in pre-clinical models, the anti-fibrotic effects of several of our novel, Galectin-targeting compounds. Mount Sinai has one of the world's largest, most productive and well-respected liver disease investigation programs.

Dr. Scott Friedman, Chief of Liver Diseases, Division of Medicine at Mount Sinai, has performed pioneering research into the underlying causes of scarring, or fibrosis associated with chronic liver disease, which affects millions worldwide. Dr. Friedman was among the first to isolate and characterize the hepatic stellate cell, which is the key cell type responsible for scar production in liver.

In initial experiments in Dr. Friedman's laboratory, our polysaccharide compounds that target galectin receptors markedly reduced the markers of fibrosis in cultured stellate cells and reversed the formation of fibrotic tissue in diseased rat livers. In the extension of our research collaboration, he and his team will be testing several of our galactomannans and rhamnogalacturonans as galectin blockers in liver anti-fibrotic therapies. Specifically Dr. Friedman will complete the *in vitro* and *in vivo* analysis of several of our compounds for anti-fibrotic efficacy and mechanism of action using state-of-the-art molecular methods to assess fibrosis, fibrogenic gene expression and liver function. Additionally, we are testing our compounds in three different models of liver fibrosis with commercial laboratories. We expect this work will lead to an IND to begin clinical investigations.



## **Table of Contents**

Peter G. Traber, M.D., became our President and Chief Executive Officer on March 17, 2011. He formerly had been our interim Chief Medical Officer and has been a member of our Board of Directors since February 2009. Dr. Traber was President Emeritus and former Chief Executive Officer of Baylor School of Medicine. His previous positions include Senior Vice President of Clinical Development and Medical Affairs and Chief Medical Officer of GlaxoSmithKline, and Chief Executive Officer of the University of Pennsylvania Health System.

### *Development of GM-CT-01 to Treat Cancer*

Cancer Immunotherapy: The Ludwig Institute of Cancer Research in Brussels, Belgium indicated that GM-CT-01 reactivates T-cell-dependent tumor cell killing that had been turned off by galectins secreted by cancer cells. The Ludwig Institute is planning to initiate a Phase 1/2 trial of GM-CT-01 for patients with advanced metastatic melanoma. Patients will receive a tumor-specific peptide vaccination combined with multiple systemic and intra-tumor doses of GM-CT-01 following the second month and subsequent months vaccine administration.

In 2002, the Food and Drug Administration ( FDA ) granted an Investigational New Drug ( IND ) application for us to administer GM-CT-01 in combination with 5-FU to treat late-stage cancer patients with solid tumors. 5-FU is FDA-approved, and one of the most widely used chemotherapies for treatment of various types of cancer, including colorectal, breast and gastrointestinal. We believe that using GM-CT-01 in combination with 5-FU enables greater absorption of the chemotherapy in cancer cells while reducing its toxic side effects.

The FDA also has granted us an IND for GM-CT-01 to be administered with Avastin®, 5-FU and leucovorin in a combination therapy to treat early-stage colorectal cancer patients and an IND for GM-CT-01 to be administered with 5-FU to treat early stage bile duct cancer patients. In addition, the FDA also has granted us, on a case-by-case basis, the ability to treat patients with breast cancer in response to physicians' requests for so-called compassionate use.

To date, GM-CT-01 has been administered to approximately 100 cancer patients. Data from a Phase II trial for end-stage colorectal cancer patients showed that GM-CT-01 in combination with 5-FU extended median survival to 6.7 months with significantly reduced side effects, as compared to 4.6 months for best standard of care as determined by the patients' physicians. These clinical trials also showed that patients experienced fewer adverse side effects of the chemotherapy and required less hospitalization.

Our pre-clinical and clinical trial data also show that GM-CT-01 is well tolerated, safe and non-toxic.

On December 17, 2010, we met with officials from the FDA to present our Phase III clinical development program for GM-CT-01. Agreement was reached on the design of pivotal, randomized, controlled, and blinded Phase III clinical trials of GM-CT-01 co-administered with standard chemotherapy for second line treatment of patients with metastatic colorectal cancer. At the present time, we will not be initiating Phase III clinical trials as we await more experience from the Ludwig clinical trial on the immunologic effects of GM-CT-01.

### *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 sheets as of September 30, 2011 and December 31, 2010 and will recognize the revenue when the remaining deliverables of the agreement have been completed.

On October 18, 2011, we entered into a Collaboration, Supply, Marketing and Distribution Agreement (the Agreement) with PROCAPS. The Agreement grants PROCAPS first negotiation rights to enter into similar agreements in other Central and South American countries. We are the sole manufacturer and supplier of GM-CT-01 to PROCAPS. The Agreement obligates 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.

### *Qualifying Therapeutic Discovery Project*

In October 2010, we were awarded \$489,000 total in two federal grants under the Qualifying Therapeutic Discovery Project ( QTDP ) Program for our GM-CT-01 anti-cancer compound and GR/GM-Series of anti-fibrotic, cirrhosis compounds for work performed during 2010 and 2009.

Edgar Filing: GALECTIN THERAPEUTICS INC - Form 10-Q

We received \$255,000 of the grant in 2010 and the remaining \$234,000 was received in 2011 and was included in grants receivable on the consolidated balance sheet at December 31, 2010.

**Table of Contents****Results of Operations****Three and Nine Months Ended September 30, 2011 Compared to Three and Nine Months Ended September 30, 2010***Research and Development Expense.*

	Three Months		Nine Months		2011 as Compared to 2010			
	Ended September 30, 2011	2010	Ended September 30, 2011	2010	\$ Change	% Change	\$ Change	% Change
	(In thousands, except %)							
Research and development	\$ 655	\$ 313	\$ 2,690	\$ 676	\$ 342	109%	\$ 2,014	298%

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. We have one product candidate GM-CT-01 in clinical trials at this time. 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.

Our research and development expenses for the three and nine months ended September 30, 2011, as compared to the three and nine months ended September 30, 2010, were as follows:

	Three Months		Nine Months	
	Ended September 30, 2011	2010	Ended September 30, 2011	2010
	(in thousands)			
Direct external expenses:				
Clinical programs	\$ 110	\$ 196	\$ 332	\$ 338
Pre-clinical activities	209	14	583	24
All other research and development expenses	336	103	1,775	314
	\$ 655	\$ 313	\$ 2,690	\$ 676

Clinical program and pre-clinical expenses for the three and nine months ended September 30, 2011, increased compared to the same periods in 2010, due primarily to increased pre-clinical activity on our fibrosis program and clinical program activity related to GM and GR compounds. Other research and development expense increased primarily due to increased employee stock-based compensation (\$210,000 and \$1,288,000 increase for the three and nine months, respectively) and payroll expenses (\$79,000 and \$173,000 increase for the three and nine month periods, respectively) as employee salaries returned to more normal levels and our research and development headcount increased.

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.





**Table of Contents***General and Administrative Expense.*

	Three Months		Nine Months		2011 as Compared to 2010			
	Ended September 30, 2011	2010	Ended September 30, 2011	2010	\$ Change	% Change	\$ Change	% Change
	(In thousands, except %)							
General and administrative	\$ 1,378	\$ 899	\$ 4,347	\$ 2,918	\$ 479	53%	\$ 1,429	49%

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 increase for the three and nine months ended September 30, 2011 as compared to the same periods in 2010 is due to increased payroll (\$112,000 and \$255,000 increase for the three and nine month periods, respectively) as employee salaries returned to more normal levels from the reductions during the prior periods and an additional employee starting in Q2 2011, increased legal costs (\$58,000 and \$454,000 increase for the three and nine month periods, respectively) related primarily to our re-branding and name change, employee stock-based compensation costs (\$207,000 and \$531,000 increase for the three and nine month periods, respectively), offset by decreased business development expenses (\$119,000 and \$180,000 decrease for the three and nine month periods, respectively). Additionally, we settled litigation in October 2011 and recognized \$162,000 of related expense during the three and nine months ended September 30, 2011.

*Other Income and Expense.* Other income and expense for the three and nine months ended September 30, 2011 was income of \$5,000 and expense of \$510,000, respectively, and during the three and nine months ended September 30, 2010 was income of \$103,000 and expense of \$1,307,000, respectively, related primarily to the change in fair value of warrant liabilities. At September 30, 2011 the Company has no further liabilities related to warrants.

**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, 2011, we raised a net total of \$58.3 million from these offerings. At September 30, 2011, we had \$7,944,000 of unrestricted cash and cash equivalents available to fund future operations.

We believe that with the cash on hand at September 30, 2011, there is sufficient cash to fund core operations through the first quarter of 2013. 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 the first quarter of 2013, we may be required to cease operations or seek bankruptcy protection.

Net cash used in operations increased by \$1,615,000 to \$4,134,000 for the nine months ended September 30, 2011, as compared to \$2,519,000 for the nine months ended September 30, 2010. Cash operating expenses increased principally due to increased research and development activities and increased general and administrative expenses.

Cash used in investing activities during the nine months ended September 30, 2011 consisted of an increase in restricted cash by \$5,000 and equipment purchases of \$5,000 as compared to no cash used in or provided by investing activities during the same period in 2010.

Net cash provided by financing activities was \$6,197,000 during the nine months ended September 30, 2011 as compared to \$5,082,000 during the nine months ended September 30, 2010, due primarily to the transactions described below.

In January 2011, we issued and sold 13 shares of Series C Preferred Stock for net proceeds of \$130,000.

During the nine months ended September 30, 2011, we issued 10,628,294 shares of common stock for the exercise of common stock warrants and 913,000 shares of common stock for the exercise of common stock options, resulting in net proceeds of \$5,833,000 and \$234,000, respectively.

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

The following table summarizes the payments due under our contractual obligations at September 30, 2011, and the effect such obligations are expected to have on liquidity and cash flow in future periods:

Contractual Obligations	Total	Payments due by period (in thousands)			
		Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating leases	\$ 269	\$ 269	\$	\$	\$
Total payments due under contractual obligations	\$ 269	\$ 269	\$	\$	\$

*Operating leases.* On May 1, 2006, we entered into an operating lease for office space. The lease commenced on August 11, 2006 and terminated on September 30, 2011. The lease provided for annual base rental payments of \$235,000 in the first year, increasing in each subsequent lease year to \$244,000, \$253,000, \$263,000 and \$273,000, respectively. 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 after calendar year 2006 and taxes for the building after fiscal year 2007. We have the option to extend the term of the lease for an additional five year period at the prevailing market rate at the time of exercise. In connection with this lease, a commercial bank has issued a letter of credit collateralized by cash we have on deposit with the bank of \$59,000. In July 2011, we entered into an agreement to amend this lease 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 July 2011, we entered into an operating lease for an apartment for Company executive use for a one-year term, ending July 2012, at a rate of \$41,000 for the term.

*Separation agreement.* In February 2009, the Company entered into a Separation Agreement in connection with the resignation of David Platt, Ph.D., the Company's former Chief Executive Officer and Chairman of the Board of Directors. The Separation Agreement provides that the Company shall continue to pay Dr. Platt his current salary at a monthly rate of \$21,667 for 24 months as well as medical and dental benefits. The Company recognized the full amount of the salary, health insurance and automobile during the first quarter of 2009. The remaining liability related to this severance is reflected in accrued expenses (\$293,000) on the condensed consolidated balance sheet at December 31, 2010 and was paid to Dr. Platt on February 12, 2011.

The Separation Agreement also provides for the deferral of a \$1.0 million severance payment due to Dr. Platt under his employment agreement until the 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 500,000 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 300,000 shares of common stock; or (iii) the renewed listing of our securities on a national securities exchange. Payment upon the events (i) and (iii) may be deferred up to nine 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 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. Due to the uncertainties regarding the achievement of any of the milestones as described, the Company has not accrued for the \$1.0 million severance nor has it recognized the value of the unissued stock options as of September 30, 2011. When it is deemed probable that one or more of the milestone events will be achieved, the Company will then recognize the \$1.0 million severance and the expense related to the issuance of the stock option at that time based on the then current fair value.

*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 cancelable on 30 days notice.

**Off-Balance Sheet Arrangements**

We have not created, and are not 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

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

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 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, convertible debt instrument and warrant liabilities, 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.

## **Table of Contents**

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, income taxes and convertible debt instrument and warrant liabilities. For a more detailed discussion of our critical accounting policies, please refer to our 2010 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 and internal control over financial reporting (as defined in the SEC rules promulgated under the Securities Exchange Act of 1934) and concluded that, as of September 30, 2011, our disclosure controls and procedures were effective. During the quarter ended September 30, 2011, 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 effect on its financial condition or results of operations. Other than claims and legal proceedings that arise from time to time in the ordinary course of business which are not material, we have no pending legal proceedings except as follows:

In January 2003, Custom Equity Research, Incorporated (d/b/a Summer Street Research Partners) filed a lawsuit against us alleging breach of contract, among other claims, based on an engagement letter in which Summer Street agreed to provide investment services to us. We denied the claims and believed they were without merit. In January 2011, we learned that Maxim Group, which we had previously engaged as a placement agent, had been named respondent in an arbitration matter with the Financial Industry Regulatory Authority (FINRA) initiated by Summer Street, for which we were obligated to indemnify Maxim Group. After consideration of the continued costs of litigation, we settled both matters for an amount that is not material to our balance sheet or our cash position. Subsequent to the execution of the settlement agreement, but before the settlement proceeds were paid, a dispute arose with Summer Street regarding the scope of a release of unrelated claims that Summer Street has requested be provided by Maxim Group. Motions for the enforcement of the settlement agreement are currently pending in the litigation and in the arbitration. In the event the motions are not granted, the litigation and/or arbitration may resume.

### **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, 2010, have not changed materially during the three months ended September 30, 2011.

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

None

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

None

**Item 4. (removed and reserved)**

**Item 5. Other Information**

None

**Table of Contents**

**Item 6. Exhibits**

<b>Exhibit Number</b>	<b>Description of Document</b>	<b>Note Reference</b>
10.1	Employment Agreement dated June 28, 2011 between James C. Czirr, and Galectin Therapeutics, Inc.	1
10.2*	Collaboration, Supply, Marketing and Distribution Agreement dated October 18, 2011 between PROCAPS S.A. and Galectin Therapeutics, Inc.***	
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	

\* Filed herewith.

\*\* Furnished herewith and not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

\*\*\* Filed herewith redacted and subject to a Confidential Treatment Request submitted to the Commission pursuant to Rule 12b-24 under the Exchange Act

1. Incorporated by reference to the Company's Current Report on Form 8-K filed with the Commission on July 5, 2011.

**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 10, 2011.

GALECTIN THERAPEUTICS, INC.

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

/s/ Anthony D. Squeglia  
Name: Anthony D. Squeglia  
Title: Chief Financial Officer