# 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	s Exchange Act of 1934	
	For the quarterly period ended S	eptember 30, 2011	
	Transition report pursuant to Section 13 or 15(d) of the Securit	es Exchange Act of 1934	
	For the transition period from	to	
	Commission File No. 0	00-32877	
	GALECTIN THERA	PEUTICS, INC.	
	Nevada (State or other jurisdiction of incorporation)	04-3562325 (I.R.S. Employer Identification No.)	
	7 Wells Avenue, Newton, Massachusetts (Address of Principal Executive Offices)	02459 (Zip Code)	
	(617) 559-003. (Registrant's Telephone Number, In		
duri	cate by check mark whether the registrant (1) has filed all reports required to be filed the preceding 12 months (or for such shorter period that the registrant was requirements for the past 90 days.   Yes  No		
be si	cate by check mark whether the registrant has submitted electronically and posted abmitted and posted pursuant to Rule 405 of Regulation S-T (§232.05 of this chapstrant was required to submit and post such files).   Yes  No		
	cate by check mark whether the registrant is a large accelerated filer, an accelerate nitions of "large accelerated filer," "accelerated filer" and "smaller reporting comp		ıe
Larg	e Accelerated Filer	Accelerated Filer	
Non	-Accelerated Filer	Smaller reporting company	X
Indi	cate by check mark whether the registrant is a shell company (as defined in Rule 1	2b-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.	

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

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

(A Development-Stage Company)

# CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

	September 30, 2011		December 3 2010 aousands)	
ASSETS				
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
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)				
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
Commitments and contingencies (Note 7 and Note 9)				
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
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 Common stock, \$0.001 par value; 300,000,000 shares authorized at September 30, 2011 and		632		644
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)
Total stockholders' equity (deficit)		823		(1,694)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	\$	8,103	\$	6,300

See notes to unaudited condensed consolidated financial statements.

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

(A Development-Stage Company)

# CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

	Three Mon Septem		Nine Mon Septem		Po I (Ju	umulative eriod from (nception ly 10, 2000) eptember 30,
	2011	2010	2011	2010		2011
Operating expenses:		(in thousands,	except share and	l per share amou	nts)	
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)	<u> </u>	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.

# 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)

								Stockholders' Equity (Deficit)						
	Series B- Redeer Convertible Sto	nable Preferred	Series B-2 Redeemable C Preferred	Convertible	Dividend	C Super Convertible red Stock	Series A Convertible I Stock	Preferred	Common S	Stock		Deficit		
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Accumulated During the Development Stage	Total Stockholders' Equity (Deficit)	
Balance at December 31, 2010	900,000	\$1,664	2,100,000	\$2,474	212	\$ 2,073	1,592,500	\$ 644	63,909,155	\$ 64	\$ 54,022	\$ (56,424)	\$ (1,694)	
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 preferred stock dividend									290,303		314	(314)	_	
Series B-2 12% redeemable convertible preferred stock dividend									677,371	1	730	(731)	_	
Series C super dividend 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								, ,	<u> </u>				
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)
Balance at September 30,													
2011	900,000	\$1,677	2,100,000	\$2,634	220	\$ 2,154	1,562,500	\$ 632	76,907,440	<u>\$ 77</u>	\$65,533	<u>\$ (65,419)</u>	\$ 823

See notes to unaudited condensed consolidated financial statements

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

(A Development-Stage Company)

# CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

	Nine Mont Septem		Period from Inception (July 10, 2000) to September 30,		
	2011	2010		2011	
		(in thousand	s)		
CASH FLOWS FROM OPERATING ACTIVITIES:	<b>(7.545)</b>	0(4,001)		(50.040)	
Net loss	\$(7,547)	\$(4,901)	\$	(58,949)	
Adjustments to reconcile net loss to net cash used in operating activities:	7	1.1		5.4.4	
Depreciation and amortization Stock-based compensation expense	2.688	11 1,575		544 9,025	
Non-cash interest expense	2,000	1,373		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	
				331	
Changes in operating assets and liabilities:					
Grant receivable	234	<u> </u>		<del></del>	
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)	
CASH FLOWS FROM INVESTING ACTIVITIES:					
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)	
CASH FLOWS FROM FINANCING ACTIVITIES:					
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	
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	
	<u> </u>	<del> </del>	÷		
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	1,021	, 10		503	
Issuance of stock to acquire Pro-Pharmaceuticals-NV		_		107	
issuance of stock to acquire file-i nannaceuticals-ivv	_	_		107	

Cumulative

See notes to unaudited condensed consolidated financial statements.

# 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.

## 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 I	Months	Nine N	Months
	En	ded	En	ded
	Septem	ber 30,	Septem	iber 30,
	2011	2010	2011	2010
		(in tl	housands)	
Research and development	\$270	\$ 60	\$1,407	\$ 239
General and administrative	379	244	1,281	1,336
Total stock-based compensation expense	\$649	\$304	\$2,688	\$1,575

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:

		Weigh	ted Average
	Shares	Exer	cise 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

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		
	Nine Months	Ended	(July 10, 2000) to		
	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

# 4. Accrued Expenses

Accrued expenses consist of the following:

	ember 30, 2011		mber 31,	
	 (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:

		Weight	ed Average
	Shares	Exerc	cise 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 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.

#### 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:

		Quoted prices in	Significant other	Significant	
	Value at	active markets	observable inputs	unobservable inputs	
	Period End	(Level 1)	(Level 2)	(Level 3)	
		(i			
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 conve

Series C 6% Super Dividend Convertible Preferred Stock

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").

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 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.

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,	September 30,
	2011	2010
	(Shares)	(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 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.

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

## 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 based on current expectations, estimates and projections about the industry and markets in which Galectin Therapeutics operates, and management's beliefs and assumptions. These statements are not guarantees of future performance and involve certain known and unknown risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Such risks and uncertainties are related to, 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.

#### 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.

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 month's 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. 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.

# **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	Three Months Ended September 30,		Three Months Nine Months			2011 as Comp	ared to 2010	
	Ended Se			Ended September 30,		Three Months		Months	
	2011	2010	2011	2010	\$ Change	% Change	\$ Change	% Change	
				(In thousa	ands, except %)	)		<u> </u>	
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 I	Three Months Ended		onths
	En			ed
	Septem	September 30,		er 30,
	2011	2011 2010		2010
		(in th	ousands)	
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
	<u>\$655</u>	\$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.

General and Administrative Expense.

	Three N	Three Months Ended September 30,		Three Months Nine Months		2011 as Compared to 2010			
	Ended Sept			Ended September 30,		Months	Nine Months		
	2011	2010	2011	2010	\$ Change	% Change	\$ Change	% Change	
	<u></u>			(In thousa	nds, 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.

# **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:

		Payments due by period (in thousands)				
		Less than			More than	
Contractual Obligations	Total	1 year	1-3 years	3-5 years	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

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 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.

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 affect 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

# Item 6. Exhibits

Exhibit Number	Description of Document	Note Reference
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.

Fund 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

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

# **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

## COLLABORATION, SUPPLY, MARKETING AND DISTRIBUTION AGREEMENT

This Collaboration, Supply, Marketing and Distribution Agreement (this "<u>Agreement</u>") is made as of October 18, 2011 (the "<u>Effective Date</u>") by and between Galectin Therapeutics, Inc. (f/k/a Pro-Pharmaceuticals, Inc.), a Nevada corporation, having a principal place of business at 7 Wells Avenue, Newton, MA 02459, USA ("<u>Galectin Therapeutics</u>") and Procaps S.A., a Colombian Company, having offices at Calle 80, Bo. 78B – 201, Barranquilla, Colombia ("<u>Procaps</u>"). Galectin Therapeutics and Procaps are each a "<u>Party</u>" and are collectively referred to as the "<u>Parties</u>."

WHEREAS, Galectin Therapeutics is in the business of developing and commercializing drug therapies for cancer, as well as other diseases;

WHEREAS, Procaps is in the business of importing, seeking approval for, obtaining pricing reimbursement approval for, distributing, marketing and commercializing pharmaceutical products in the Territory (as defined below) and providing related services; and

WHEREAS, Procaps has offered to import, seek approval for, distribute, market and commercialize Galectin Therapeutics' GM-CT-01 (DAVANAT®) product in the Territory and provide related services, and Galectin Therapeutics is willing to engage Procaps, in accordance with this Agreement;

NOW THEREFORE, in consideration of the foregoing and the mutual promises and covenants contained herein, the adequacy of which each Party hereby accepts, the Parties mutually agree as follows:

## 1. **DEFINITIONS**

- 1.1. "Affiliate" means, with respect to any Person, a Person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, the first mentioned Person.
  - 1.2. "Approval Plan" has the meaning set forth in Section 4.2.
  - 1.3. "Business Day" means any day where the banks in New York, NY, USA are open.
- 1.4. "Clinical Approvals" means any approval of any applicable Regulatory Authority necessary for the marketing and sale of a pharmaceutical product in any country or regulatory jurisdiction in the Territory, excluding any separate pricing or reimbursement approvals that may be required in any country or regulatory jurisdiction in the Territory.
- 1.5. "Combination Product" means any unified dose (e.g., not a kit of two separate and distinct drug dosage forms) of pharmaceutical product which is comprised of the Product and other therapeutically active compound(s) and/or ingredient(s).
- 1.6. "Compound" means Galectin Therapeutics' oncology product GM-CT-01 (DAVANAT®) which will be renamed for distribution in Colombia and Latin America.
  - 1.7. "Confidential Information" has the meaning set forth in Section 15.1.

- 1.8. "Diligent Efforts" means, with respect to Procaps' obligations under this Agreement to Pursue Approval or Market and Distribute the Product, the carrying out of such obligations or tasks in a sustained and diligent manner consistent with the reasonable best practices of the pharmaceutical industry for the approval or marketing and distribution of a high priority pharmaceutical product at a similar stage of development or commercialization.
  - 1.9. "Excess Amount" has the meaning set forth in Section 8.1.
  - 1.10. "Field" means the treatment of cancer using a regimen containing 5-FU.
  - 1.11. "First Commercial Sale" has the meaning set forth in Section 11.2.
  - 1.12. "Formulated Dose" means the dose for the Product, which shall be a single unit, 10ml sterile vial (60mg/ml).
- 1.13. "Galectin Therapeutics Patents" means all patents and patent applications that (a) are controlled as of the Effective Date or are filed or granted during the term of the Agreement by Galectin Therapeutics or its Affiliates and that claim the composition of matter, manufacture, or use of the Compound or Product, (b) are substitutions, divisions, continuations, continuations-in-part (to the extent directed to the subject matter disclosed in a patent or patent application described in (a)) and requests for continued examination of any of the foregoing, (c) are patents arising from or claiming priority to any of the foregoing, (d) are reissues, renewals, registrations, confirmations, re-examinations, extensions, and supplementary protection certificates of any of the foregoing, and/or (e) all foreign equivalents of any of the foregoing. For the avoidance of doubt, the Galectin Therapeutics Patents shall include any patent or application claiming Product Related IP Rights to the extent that such patent or patent application claims the composition of matter, manufacture, or use of the Compound or Product.
  - 1.14. "Initial Approval Plan" has the meaning set forth in Section 4.3.
- 1.15. "Licensed Marks" means the trademarks, trade names, names, brands, logos, symbols, and other proprietary designations of Galectin Therapeutics as set forth on Exhibit A, as may be updated from time to time by Galectin Therapeutics.
- 1.16. "Market and Distribute" (and its other forms including Markets and Distributes, Marketing and Distributing, Marketing and Distribution, etc.) means to sell, market, promote and/or distribute Product and obtain remittance for said Product in the Field in the Territory.
- 1.17. "Marketing and Distribution Plan" means a written Marketing and Distribution plan setting forth anticipated Marketing and Distribution activities to be performed with respect to the Product in the Field in the Territory by Procaps or on its behalf by approved contractors (including without limitation market studies, launch plans, detailing and promotion), as well as projected timelines for such activities.
- 1.18. "Maximum Amount" means one hundred twenty percent (120%) of the amount of Compound forecasted by Procaps to be needed by it as set forth in the then current Marketing and Distribution Plan.

1.19. "Net Sales" means the gross amount invoiced by Procaps or its Affiliates for sales of the Product in the Territory to a Third Party, less: (a) financial discounts to recover receipts; (b) recalls and (c) returns; in each case actually taken and provided that any deductions for items (a), (b) and (c) above shall not exceed ten percent (10%) of the Sales Price. Net Sales shall be calculated in United States dollars pursuant to Section 11.4. A credit will be given on the subsequent order for any amounts owing for deductions due to (a), (b) or (c) above.

With respect to any sale or other disposal of any Product for any consideration other than exclusively monetary consideration on arm's length terms, for purposes of calculating the gross sales amount necessary to calculate the Net Sales under this Agreement, such Product shall be deemed to be sold exclusively for money at the average sale price charged to Third Parties for cash sales during the applicable reporting period.

Net Sales shall be determined in accordance with generally accepted accounting principles in the United States.

- 1.20. "Person" means an individual, corporation, partnership, association, trust, unincorporated organization or other entity.
- 1.21. "Procaps" has the meaning set forth in the first paragraph of this Agreement.
- 1.22. "Product" means the final formulation of the Compound, including fill and finish, for which Regulatory Approval has been received, and any accompanying instructions for use and any other documentation and materials provided by Galectin Therapeutics as a package with, or for use with, such product, as may be modified by Galectin Therapeutics.
  - 1.23. "Product Order" has the meaning set forth in Section 10.1.
  - 1.24. "Product Related IP Rights" has the meaning set forth in Section 14.1
  - 1.25. "Purchaser" shall mean a doctor, hospital, clinic or any other entity purchasing the Product from Procaps for administration to patients.
- 1.26. "Pursue Approval" (and its other forms including Pursues Approval, Pursuing Approval, Approval Pursuit, etc.) means all activities that relate to (a) obtaining, maintaining or expanding Regulatory Approval of the Product or (b) developing the ability to formulate, fill and finish commercial quantities of the Product. This includes, without limitation, (i) formulation and manufacturing-related technology development; (ii) preparation, submission, review, and development of data or information for the purpose of submission to a governmental authority to obtain, maintain and/or expand Regulatory Approval of the Product, including pricing approval, and outside regulatory services related thereto; (iii) fill/finish work associated with the supply of Product for Regulatory Approval and commercial supplies, and related quality assurance technical support activities; (iv) stability studies; (v) clinical trials, (vi) post-Regulatory Approval product support for the Product (including manufacturing and quality assurance technical support, efforts directed toward the further understanding of the safety and efficacy of Product and clinical trials); and (vii) Product-related medical affairs (including regulatory support necessary for product maintenance).
- 1.27. "Regulatory Approvals" means any approval of any applicable Regulatory Authority necessary for the marketing and sale of a pharmaceutical product in any country or regulatory jurisdiction in the Territory, including any separate pricing or reimbursement approvals that may be required in any country or regulatory jurisdiction in the Territory.

- 1.28. "Regulatory Authority" means any federal, national, multi-national, state, provincial or local regulatory agency, department, bureau or other governmental entity with authority over the marketing or sale of pharmaceutical products.
- 1.29. "Regulatory Materials" means regulatory applications, submissions, notifications, registrations, Regulatory Approvals and/or other filings made to or with a Regulatory Authority that are necessary or reasonably desirable in order to Pursue Approval, manufacture, or Market and Distribute the Product in a particular country or regulatory jurisdiction.
- 1.30. "<u>RFN Eligible Countries</u>" shall mean the countries in South and Central America other than Columbia. For the avoidance of doubt, Mexico and the Caribbean are not RFN Eligible Countries.
  - 1.31. "RFN Notice" has the meaning set forth in Section 2.3.
  - 1.32. "RFN Term" has the meaning set forth in Section 2.3.
  - 1.33. "Sales Price" shall initially be \$[\*\*\*\*] USD per Formulated Dose, subject to change pursuant to Sections 2.1 and 9.1.
- 1.34. "Specifications" means the applicable release specifications for Compound agreed to by the Parties and set out in Exhibit B attached hereto and incorporated herein, as may be amended from time to time by mutual agreement of the Parties.
  - 1.35. "Term" has the meaning set forth in Section 18.
- 1.36. "Territory" means Columbia and such RFN Eligible Countries, if any, to which Galectin Therapeutics grants Procaps exclusive distribution rights to the Product pursuant to Section 2.3.
  - 1.37. "Third Party" means any Person not a Party to this Agreement, excluding any Affiliate of either Party.
- 1.38. "Transfer Price" means the total price at which Galectin Therapeutics will sell the Compound to Procaps, which shall be [\*\*\*\*] percent ([\*\*\*\*]%) of the Sales Price. The Sales Price shall be \$[\*\*\*\*] for Colombia and can only be changed by mutual agreement. The Transfer Price may be different for each RFN Eligible Country, if any, for which Galectin Therapeutics grants Procaps exclusive distributions rights to the Product pursuant to Section 2.3, as determined by mutual agreement of the Parties. Under no circumstances will the Transfer Price be less than \$[\*\*\*\*] in any country. If it is determined that a country(ies) to which Procaps has exclusive distribution rights to the Product will not support a final sales price of \$[\*\*\*\*], the Parties may mutually decide not to pursue approval in such country(ies). The transfer price for all RFN Eligible Countries will be a maximum of \$[\*\*\*\*].

## 2. APPOINTMENT OF PROCAPS

2.1. <u>Scope of Arrangement</u>. Subject to the terms and conditions of this Agreement, Galectin Therapeutics hereby grants Procaps exclusive rights during the term of this Agreement, and Procaps

accepts such appointment, to Market and Distribute Product solely in the Territory in the Field to Purchasers. However, Galectin Therapeutics may render this arrangement non-exclusive upon written notice to Procaps in accordance with the provisions of Sections 19.1. Procaps shall purchase Compound exclusively from Galectin Therapeutics and Market and Distribute the Product for its own account and this Agreement does not make Procaps an agent of Galectin Therapeutics for any purpose. Procaps shall not purchase or make Product other than through the purchase of Compound from Galectin Therapeutics pursuant to the terms of this Agreement. Procaps shall not sell Product as a Combination Product without the prior written consent of Galectin Therapeutics. If Galectin Therapeutics consents to the sale by Procaps of a Combination Product, the parties shall mutually agree upon changes, if any, to the definitions of Formulated Dose, Transfer Price and Sales Price for purposes of the Combination Product only to reflect any difference in the quantity of Compound in a dose of the Combination Product. In addition, and subject to the terms and conditions of this Agreement, Procaps shall perform the additional responsibilities set forth in this Agreement. Procaps shall not outsource or otherwise delegate any of its rights or obligations under this Agreement to any Third Party unless preapproved in writing by Galectin Therapeutics.

- 2.2. <u>Reservation of Rights</u>. All rights not expressly granted to Procaps are reserved to Galectin Therapeutics, including, without limitation the right to Market and Distribute the Compound or Product outside the Territory itself or through one or more other Persons.
- 2.3 Right of First Negotiation. Following the Regulatory Approval and for a period ending [\*\*\*\*] months after the First Commercial Sale of the Product in Columbia (the "RFN Term") and provided that Procaps is not in breach of this Agreement, Procaps may provide Galectin Therapeutics written notice (the "RFN Notice") that it wishes to exercise its right of first negotiation to procure distribution rights to the Product in the Field for those RFN Eligible Countries specified in the RFN Notice; provided however, with respect to Argentina and Brazil only, the RFN Term shall end [\*\*\*\*] months after Regulatory Approval of the Product in Colombia, unless the RFN Term and Procaps' right of first negotiation is terminated earlier pursuant to this Agreement. Thereafter, Procaps shall not have a right of first negotiation for any other country or jurisdiction not specified in the RFN Notice. Galectin Therapeutics and Procaps shall negotiate in good faith an amendment to this Agreement or a separate commercial agreement (such amendment or new agreement, the "RFN Agreement") which will include an upfront license payment, Transfer Price for the Compound, royalties on Net Sales and other business terms and conditions typically found in similar commercial agreements, under which Procaps shall be granted the exclusive distribution rights to the Product in the Field in the RFN Eligible Countries specified in the RFN Notice. The rights granted to Procaps to the Compound and the Product in the RFN Agreement shall be non-exclusive and Galectin Therapeutics have the right to terminate the RFN Agreement upon ten (10) days prior notice until Galectin Therapeutics receives all upfront license payments provided for in the RFN Agreement, at which point the exclusivity and termination rights shall revert to those set forth in the RFN Agreement.

The upfront license payment for each RFN Eligible Country in the RFN Notice shall be determined using the following model:

Based on the assumption that the license fee for Colombia [\*\*\*\*] USD ([\*\*\*\*]), then the maximum upfront license fee for each RFN Eligible Country in the RFN Notice will be a ratio of the population of that country to the population of Colombia. Population estimates will be from a source agreed to by both parties. The license fee may be adjusted for the specific economic situation of each RFN Eligible Country in the RFN Notice. For example, if the population of Colombia is estimated to be 49,000,000 (August

2011), and the population of Venezuela is estimated to be 29,000,000 (August 2011 - Source True Knowledge), then the upfront license fee due for Venezuela would be \$[\*\*\*\*]. The upfront license fee for each country added pursuant to the RFN Agreement will be paid according to the following schedule; [\*\*\*\*]% is due within ten (10) days of signing of the RFN Agreement for that country, and [\*\*\*\*]% is due within ten (10) days of Regulatory Approval of the Product in such country. If Regulatory Approval is not received in a country, the [\*\*\*\*]% of the upfront license fee for such country will not be due; provided, however, that the [\*\*\*\*]% of the upfront license fee paid to Galectin Therapeutics for each country added pursuant to the RFN Agreement is non-refundable and non-creditable. The parties understand and agree that agreement on the upfront license fee to be paid for one or more RFN Eligible Country(ies) shall not obligate either party to enter an RFN Agreement for such country and that additional terms including, without limitation, the Transfer Price for the Compound, the Sales Price, royalties and/or milestones on Net Sales and other business terms and conditions must be negotiated and agreed upon.

Procaps shall provide Galectin Therapeutics within thirty (30) days of Procaps' issuance of the RFN Notice an approval plan for the Product in the RFN Eligible Countries in the RFN Notice describing the proposed overall program of Approval Pursuit, including stability studies, fill and finish production, process development, regulatory plans and other elements of obtaining Regulatory Approval(s), as well as timelines for key regulatory authority meetings, drug approval applications and Regulatory Approvals. If the Parties are unable to reach an agreement with respect to one or more of the countries within ninety (90) days of Galectin Therapeutics' receipt of the RFN Notice, Procaps shall have no further contractual rights to negotiation with respect to such countries. If, during the RFN Term, and after Procaps has send the RFN notice, Galectin Therapeutics' desires to distribute or commercialize the Compound or Product in one or more RFN Eligible Countries for which Procaps has not sent a RFN Notice, Galectin Therapeutics shall provide written notice to Procaps identifying such countries and Procaps shall have ten (10) Business Days in which to send an RFN Notice with respect to such countries. If Procaps does not send an RFN Notice with respect to such RFN Eligible Countries identified by Galectin Therapeutics within ten (10) Business Days, its right of first negotiation and the RFN Term for such RFN Eligible Countries shall immediately expire.

# 3. GOVERNANCE

- 3.1. <u>Joint Steering Committee</u>. Within thirty (30) days after the Effective Date, Galectin Therapeutics and Procaps shall form a joint steering committee ("<u>JSC</u>") consisting of three (3) representatives from Galectin Therapeutics or one of its Affiliates and three (3) representatives from Procaps. Each Party may replace its JSC representatives at any time upon prior written notice to the other Party. JSC membership shall evolve over time as the Agreement progresses so that each Party's combined membership represents the key functions (such as Approval Pursuit, manufacturing or Marketing and Distribution) that are the current focus of work on the Product.
- 3.2. Meetings of the JSC. The JSC shall meet at least four (4) times every calendar year unless a particular meeting is waived by mutual consent, on such dates and at such times as agreed to by the Parties, alternating between Galectin Therapeutics' and Procaps' places of business, or such other mutually agreeable locations. Each Party may permit visitors to attend meetings of the JSC; provided that (i) such Party provides the other Party at least twenty (20) days notice of its intent to bring such visitor(s) to the JSC meeting, providing a reasonable description of such visitor(s) and the purpose of their attendance; (ii) the other Party does not object in writing to such visitor(s) attendance within five (5) days of receipt of such notice, and (iii) each such visitor has executed prior to attendance a confidentiality

agreement with each Party containing restrictions on disclosure and use substantially similar to Section 15 of this Agreement. Each Party shall be responsible for its own expenses for participating in the JSC. Meetings of the JSC shall be effective only if at least one representative of each Party is present and participating.

- 3.3. Responsibilities of the JSC. The JSC shall have the responsibility and authority to:
- (a) Oversee the Approval Pursuit, Regulatory Approval, and Marketing and Distribution of the Product in the Field in the Territory in support of such activities;
  - (b) Review and approve the overall strategy for Approval Pursuit in the Field in the Territory;
  - (c) Review and approve any proposed amendments or updates to the Approval Plan;
  - (d) Monitor the Approval Pursuit of the Product in the Field in the Territory against the Approval Plan;
- (e) Discuss the requirements for Regulatory Approval in applicable countries in the Territory and oversee regulatory matters with respect to the Product in the Territory;
  - (f) Review the Marketing and Distribution Plan and any proposed amendments or updates thereto;
  - (g) Monitor the Marketing and Distribution of the Product in the Territory against the Marketing and Distribution Plan;
- (h) Monitor, review and oversee safety issues that may arise from use of the Product in Colombia including, but not limited to, potential recalls, market withdrawals and regulatory issues and responses;
- (i) Establish subcommittees pursuant to Section 3.6 on an as-needed basis, oversee the activities of all subcommittees so established, and address disputes or disagreements arising in all such subcommittees; and
  - (j) Perform such other functions as the Parties may agree in writing.
- 3.4. <u>Areas Outside the JSC's Authority</u>. Neither the JSC nor the Chief Executive Officer of Galectin Therapeutics acting through the authority provided in Section 3.5(b) herein shall have any authority other than that expressly set forth in Section 3.3 and, specifically, shall have no authority (a) to amend or interpret this Agreement, (b) to determine whether or not a Party has met its diligence or other obligations under the Agreement, or (c) to determine whether or not a breach of this Agreement has occurred.

## 3.5. JSC Decisions.

(a) <u>Consensus; Good Faith; Action Without Meeting</u>. The JSC shall decide all matters by consensus, with the Chairperson acting as the facilitator, except in the case of safety issues, such as the disposition of adverse events or recalls, which shall be decided by the Joint Safety

Management Committee pursuant to Section 3.6. Consistent with Section 3.7, the members of the JSC shall act in good faith to cooperate with one another and to reach agreement with respect to issues to be decided by the JSC. Action that may be taken at a meeting of the JSC also may be taken without a meeting if a written consent setting forth the action so taken is signed by all members of the JSC.

(b) Failure to Reach Consensus. Except as set forth in Section 3.6, in the event that the members of the JSC cannot come to consensus within fifteen (15) days with respect to any matter over which the JSC has authority and responsibility, the JSC shall submit the respective positions of the Parties with respect to such matter for discussion in good faith by the Parties' respective Chief Executive Officers or their respective designees. If such individuals are not able to mutually agree upon the resolution to such matter within fifteen (15) days after the JSC's submission to them, then the Chief Executive Officer of Galectin Therapeutics shall have the right to decide such matter, taking into account and seeking reasonably to accommodate (i) Procaps' legitimate interest under the Agreement and (ii) the operating principals in Section 3.7; provided, that in no event can the Chief Executive Officer of Galectin Therapeutics unilaterally decide such matter in a manner that would violate the limitations set forth in Section 3.4 or increase Procaps' costs to Pursue Approval or Market and Distribute the Product greater than ten percent (10%) of the amount set forth in the then current Approval Plan or Marketing and Distribution Plan, as applicable, unless such increase is necessitated by the requirement, order or request of a Regulatory Authority. Notwithstanding the foregoing, consensus of the JSC or mutual agreement of the Chief Executive Officers shall be necessary with respect to any decision that materially impairs or is reasonably likely to impair any rights or assets of either Party or any of their respective Affiliates, and unless and until the JSC reaches consensus or the Chief Executive Officers reach mutual agreement on any such matter, the Parties shall continue to operate under the status quo with respect to such matter and neither Party shall have the right, without the prior written consent of the other Party, to take any action that departs from the status quo with respect to such matter.

## 3.6. Subcommittees.

- (a) The JSC shall establish the Joint Safety Management Committee ("JSMC") as a subcommittee to the JSC, the primary purpose of which shall be to monitor, review, oversee and authorize such actions as necessary to address safety issues that may arise from use of the Product in the Territory including, but not limited to, potential recalls, market withdrawals and regulatory issues and responses. The JSMC shall take into account the requirements, regulations and guidance of Regulatory Authorities in the Territory as well as the United States, Europe and Japan in fulfilling its duties. The JSMC shall consist of the Chief Medical Officer of each Party and up to one additional member designated by each Party. Each Party shall have one vote on the JSMC. In the event the representatives of the Parties on the JSMC are unable to reach agreement on a matter, the Chief Medical Officer of Galectin Therapeutics shall have responsibility for the final decision.
- (b) The JSC shall have the right to establish subcommittees and to delegate certain of its powers and responsibilities thereto. Except as mutually agreed by the Parties, such subcommittees shall decide all matters by consensus, with each Party having one collective vote, and any disputes that cannot be resolved by a subcommittee in a reasonable time period shall be submitted to the JSC for resolution in accordance with Section 3.5.
- 3.7. Operating Principles. The Parties hereby acknowledge and agree that the deliberations and decision-making of the JSC and any subcommittee established by the JSC shall be in accordance with the following operating principle:
- (a) The Parties' mutual objective is to maximize the commercial success of the Product in the Field in the Territory, consistent with sound and ethical business and scientific practices.

3.8. <u>Termination of JSC</u>. The JSC shall continue to exist until the first to occur of: (a) the Parties mutually agreeing to disband the committee; or (b) Galectin Therapeutics providing to Procaps written notice of its intention to disband and no longer participate in the JSC. Thereafter, the JSC shall have no further obligations under this Agreement, and Procaps shall continue to provide to Galectin Therapeutics the reports, summaries, correspondences, notices, minutes, etc. and take such actions and provide such rights to Galectin Therapeutics as required by this Agreement.

# 4. APPROVAL PURSUIT

4.1. <u>Overview</u>. Subject to the oversight of the JSC, Procaps shall be responsible for Approval Pursuit of the Product in the Field in the Territory. Procaps shall perform all Approval Pursuit activities in accordance with the Approval Plan. The costs of Approval Pursuit shall be borne by Procaps.

# 4.2. Approval Project Plan.

- (a) <u>Scope</u>. The Approval Pursuit of the Product under this Agreement shall be governed by an Approval Pursuit Project plan for the Field in the Territory (the "<u>Approval Plan</u>"). The Approval Plan shall be developed in good faith with the overall objective of optimizing the commercial potential of the Product in the Field in the Territory. The Approval Plan shall describe the proposed overall program of Approval Pursuit for the Product in the field in Colombia, including stability studies, fill and finish production, process development, regulatory plans, clinical trials required for Regulatory Approval and other elements of obtaining Regulatory Approval(s) in Colombia as well as timelines for key regulatory authority meetings, drug approval applications and Regulatory Approvals. In the event of any inconsistency between the Approval Plan and this Agreement, the terms of this Agreement shall prevail.
- (b) <u>Initial Approval Plan</u>. Within ten (10) days after the Effective Date, Procaps shall provide Galectin Therapeutics with a draft Approval Plan for Galectin Therapeutics' review. The Parties shall use commercially reasonable efforts to reach agreement on the initial Approval Plan within thirty (30) days after the Effective Date (the "<u>Initial Approval Plan</u>"). The Parties may agree to extend the period in which to reach mutual agreement on the Initial Approval Plan, but no later than forty-five (45) days after the Effective Date.
- 4.3. <u>Updates to the Approval Plans</u>. As early as necessary in each calendar year, Procaps shall update and prepare the Approval Plan for the following calendar year to take into account completion, commencement or cessation of Approval Pursuit activities not contemplated by the then-current Approval Plan, and submit such proposed Approval Plan to the JSC no later than February 15th of such year for review and approval. Procaps may, at its election, update the Approval Plan between annual updates subject to review and approval by the JSC. If additional countries are added to the Territory, Procaps shall present a revised Approval Plan to the JSC with thirty (30) days of the addition of such countries to the Territory for review and approval. Notwithstanding the above, the JSC will review the Approval Plan, progress to the Approval Plan and updates at each JSC meeting.
- 4.4. <u>Diligent Approval Pursuit</u>. Procaps shall use Diligent Efforts to Pursue Approval of the Product in the Field in the Territory. Without limiting the generality of the foregoing, Procaps shall,

among other things, receive Regulatory Approval of the Product in Colombia by June 15, 2012. Any failure by Procaps to comply with the obligations set forth in this Section 4.4 shall be deemed to be a material breach of this Agreement, for which Galectin Therapeutics may exercise its rights under Section 19 to terminate this Agreement.

- 4.5. <u>Approval Reports.</u> Procaps shall maintain complete and accurate records (in the form of technical notebooks and/or electronic files where appropriate) of all work conducted by it under the Approval Plan and all information and data resulting from such work. Such records, including any electronic files, shall fully and properly reflect all work done and results achieved in the performance of the Approval Plan in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes. Galectin Therapeutics shall have the right to review such records maintained by Procaps at reasonable times upon reasonable notice. Procaps shall provide Galectin Therapeutics:
  - (a) with regular reports detailing its Approval Pursuit activities under the Approval Plan and the results of such activities;
- (b) on or before January 31 and July 31 of each calendar year during the term of this Agreement, with a written report that summarizes, in reasonable detail, all Approval Pursuit activities performed by Procaps, its Affiliates, and approved contractors during the preceding six (6) month period, and compares such performance with the goals and timelines set forth in the Approval Plan; and
  - (c) with any additional information regarding its Approval Pursuit of the Product reasonably requested thereby.
- 4.6. <u>Standards of Conduct</u>. Procaps shall perform, and shall ensure that its Affiliates, and approved contractors perform, the Approval Pursuit activities for which it is responsible under the Approval Plan in good scientific and regulatory manner and in material compliance with applicable laws, rules and regulations.

# 5. REGULATORY

# 5.1. Regulatory Filings

(a) Procaps shall be responsible for preparing and filing all Regulatory Materials, including without limitation furnishing timely notice of all side effects, drug interactions and other adverse effects identified or suspected with respect to the Product, and seeking all Regulatory Approvals in the Territory. All Regulatory Materials for the Product in the Territory shall be filed in the name of Galectin Therapeutics, and Procaps alone shall be responsible for all communications and other dealings with the Regulatory Authorities relating to the Product in the Territory, except as required by a Regulatory Authority; provided that such communications and dealings have been agreed upon by the JSC or its applicable subcommittees and/or Galectin Therapeutics. To the maximum extent permitted by law, Galectin Therapeutics shall be the legal and beneficial owner of all Regulatory Approvals and Regulatory Materials in the Territory or in the event such Regulatory Approvals and/or Regulatory Materials may not be owned by Galectin Therapeutics, they shall be held for the benefit of Galectin Therapeutics and shall be transferable as directed by Galectin Therapeutics. In the event that any such Regulatory Approvals and/or Regulatory Materials are not transferable to Galectin Therapeutics, then upon expiration or termination of this Agreement or earlier upon request of Galectin Therapeutics,

Procaps shall use its best efforts to assist Galectin Therapeutics in obtaining Regulatory Approvals and/or Regulatory Materials substantially similar to the non-transferable Regulatory Approvals and/or Regulatory Materials.

- (b) The JSC shall develop and implement procedures for drafting and review of Regulatory Materials for the Product in the Territory, which shall provide sufficient time for Galectin Therapeutics to provide substantive comments. Procaps shall consider Galectin Therapeutics comments on such Regulatory Materials in good faith.
- (c) Procaps shall promptly notify Galectin Therapeutics of all Regulatory Materials that it submits, and, at Galectin Therapeutics' request, shall promptly provide Galectin Therapeutics with a copy (which may be wholly or partly in electronic form) of such Regulatory Materials. Procaps will provide Galectin Therapeutics with reasonable advance notice of any scheduled meeting with any regulatory agency relating to Approval Pursuit and/or any Regulatory Approval in Colombia, and Galectin Therapeutics shall have the right to participate in any such meeting, to the extent permitted by law. Procaps also shall promptly furnish Galectin Therapeutics with summaries of all material correspondence or material meetings with any Regulatory Authority relating to Approval Pursuit, Regulatory Materials and/or a Regulatory Approval in the Territory, and Procaps shall, at Galectin Therapeutics' request, promptly furnish Galectin Therapeutics with copies of such correspondence or copies of minutes of such meetings in both Spanish and English, if requested.
- 5.2. Product Withdrawals and Recalls. In the event that any Regulatory Authority (a) threatens or initiates any action to remove the Product from the market in any country in the Territory or (b) requires Procaps or its Affiliates to distribute a "Dear Doctor" letter or its equivalent regarding use of the Product in the Field, Procaps shall notify Galectin Therapeutics and the JSMC of such event within one (1) business day after Procaps becomes aware of the action, threat, or requirement (as applicable). The JSMC shall immediately evaluate the request of such Regulatory Authority prior to initiating a recall or withdrawal of the Product in Colombia; provided, however, the JSMC shall review the recall information and medical data within five (5) business days. If the JMSC does not reach and agreement within five (5) business days the final decision as to whether to recall or withdraw the Product or take other remedial action in Colombia pursuant to Section 3.6, will be the responsibility of the CMO of Galectin Therapeutics. Galectin Therapeutics will be responsible, at its sole expense, for conducting any recalls or taking such other necessary remedial action if the recall is related to the Compound. If the recall or remedial action is the result of Procaps process, quality, fill and finish or marketing or violation of any laws, regulations, rules or guidelines or the breach of this Agreement, Procaps shall be responsible for the expense of such recall or remedial action. Procaps shall maintain complete distribution records by Purchaser, and by unique patient code and batch number for all Product Marketed and Distributed within the Territory in accordance with Galectin Therapeutics' procedures and instructions. If either Party becomes aware of information about the Product indicating that it may not conform to the specifications for the Product, or that there are potential adulteration, misbranding and/or other issues regarding safety or effectiveness, it shall promptly so notify the other Party. The Parties sha

# 6. MARKETING AND DISTRIBUTION

6.1. General. Procaps shall have sole responsibility and decision-making authority for Marketing and Distribution activities, all of which shall be carried out in accordance with the Marketing and Distribution Plan. Procaps shall be responsible for all costs and expenses associated with the Marketing and Distribution activities.

# 6.2. Marketing and Distribution Plan.

- (a) Procaps shall deliver to the JSC upon the formation of the JSC for its review and comment the draft Marketing and Distribution Plan which shall at such time be set forth in <a href="Exhibit C">Exhibit C</a>. Procaps shall implement all such reasonable comments received from the JSC and shall submit such revised document to the JSC for review. The JSC shall approve the final initial Marketing and Distribution Plan within forty-five (45) days after the Regulatory Approval for the Product in Colombia.
- (b) Procaps shall thereafter update the Marketing and Distribution Plan on a semi-annual basis as follows: Procaps shall provide the JSC with a draft update to the Marketing and Distribution Plan within forty-five (45) days of the anniversary of the Effective Date and within forty-five (45) days of the sixth (6th) month after such anniversary. Procaps shall implement all such comments received from the JSC and shall submit such revised document to the JSC for review. Procaps may, at its election, update the Marketing and Distribution Plan between annual updates by following this same procedure. If additional countries are added to the Territory, Procaps shall present a revised Marketing and Distribution Plan to the JSC with thirty (30) days of the addition of such countries to the Territory for review and approval.
- (c) The Marketing and Distribution Plan shall include, without limitation: (i) a description of Procaps' anticipated marketing activities (both preand post-launch), including the plans to use key opinion leaders and focus groups; (ii) four (4) year sales projections, broken down by calendar quarter; (iii) any requirements for additional marketing studies, including without limitation clinical trials appropriate to meet the objectives set forth in Section 3.7; (iv) competitive analysis including specific actions to mitigate competitive threats; (v) planned promotional material and sales/detailing protocols and (vi) a forecast of the amount of Compound to be purchased from Galectin Therapeutics in each of the next four (4) calendar quarters. Each annual Marketing and Distribution Plan shall have the minimum annual sales targets set forth in Exhibit D. The minimum annual sales targets after the first year of this Agreement may be updated, but not reduced for the first four (4) years of this Agreement, upon the mutual agreement of the Parties. The failure of Procaps to meet a minimum annual sales target shall be deemed a material breach of this Agreement.
  - (d) In the event of any inconsistency between the Marketing and Distribution Plan and this Agreement, the terms of this Agreement shall prevail.
- 6.3. <u>Diligent Commercialization</u>. Procaps shall use Diligent Efforts to Market and Distribute the Product in the Field in the Territory in each country for which a Regulatory Approval has been received. Without limiting the generality of the foregoing, Procaps shall satisfy each of the following requirements:
- (a) commence commercial sales of the Product to end users in a country, in commercially significant quantities, promptly after, and in any case not later than three (3) months after, the date upon which Regulatory Approval and any necessary pricing approval for the Product is granted with respect to such country.

- (b) undertake a sales effort commensurate with optimizing the gross sales of the Product in the Territory taking full advantage of the resources of Procaps and its Affiliates, which shall include a competent marketing and sales organization.
  - (c) assist Galectin Therapeutics, at and to the extent of its request, in designing and constructing a Spanish language website for the Product.
  - (d) develop a market for the Product, and enhance Galectin Therapeutics' image in the marketplace as a provider of quality pharmaceuticals.

Any failure by Procaps to comply with the obligations set forth in this Section 6.3 shall be deemed to be a material breach of this Agreement for which Galectin Therapeutics may exercise its rights under Section 19 to terminate this Agreement or any other available remedies at law or in equity.

- 6.4. Marketing and Distribution Reports. Procaps shall:
- (a) Keep the JSC fully informed regarding the progress and results of its Marketing and Distribution activities and those of its Affiliates and approved contractors, agents, etc.
- (b) Within thirty (30) days after the end of each calendar quarter, provide the JSC with a written report that (i) summarizes, in reasonable detail, all Marketing and Distribution activities performed during such quarter, (ii) compares such performance with the goals and timelines set forth in the Marketing and Distribution Plan, (iii) describes the sales, market share, business trends and key marketing issues of or related to the Product, (iv) contains (A) a list of all Product Distributed per Purchaser and patient code, (B) an action plan to resolve and issues and sales discrepancies, and (C) any other information as Galectin Therapeutics may reasonably request.
- (c) Also promptly provide the JSC or Galectin Therapeutics with any additional information or data regarding the Marketing and Distribution of the Product reasonably requested thereby.
- 6.5. <u>Safety and Product Reports</u>. Within ten (10) Business Days following the end of every calendar quarter, Procaps shall provide Galectin Therapeutics with a report related to pharmacovigelence during the calendar quarter, which shall contain: (a) all Product safety information reported to Procaps during such calendar quarter, (b) any other comments or information reported to Procaps regarding the Product, and (c) any other information as Galectin Therapeutics may reasonably request. In addition, Procaps will maintain safety information, including information contained in the safety reports, in an organized and up to date manner at all times so that it can be provided to Galectin Therapeutics upon request. Procaps shall notify Galectin Therapeutics in writing of any serious adverse events potentially relating to the Product within twenty four (24) hours of such event, including, but not limited to, an unexpected event, injury, toxicity or sensitivity reaction or any unexpected incidents of which Procaps becomes aware, in accordance with all applicable laws and regulations including without limitation the International Committee of Harmonization guidelines (hereinafter the "ICH Guidelines") to the extent that such ICH Guidelines comport with U.S. FDA guidelines.

6.6. Marketing and Distribution Standards of Conduct. Procaps shall in all respects comply with all applicable laws, regulations and guidelines in Marketing and Distributing the Product in the Territory under this Agreement, including without limitation, all United States Food and Drug Administration and ICH pharmacovigilence requirements and guidelines, the pharmacovigilence guidelines of each country in the Territory for which the Product has received Regulatory Approval, and the Foreign Corrupt Practices Act of 1977, as amended ("FCPA"). Distributor shall not make any false or misleading representations to Purchasers or others regarding Galectin Therapeutics or the Compound or Product. Distributor shall not make any representations, warranties or guarantees with respect to the specifications, features or capabilities of the Compound or Product that are not consistent with Galectin Therapeutics documentation accompanying the Compound or Galectin Therapeutics' literature describing the Compound or Product, including the limited warranty and disclaimers. Distributor shall not make any commitments on behalf of Galectin Therapeutics except as specifically defined in this Agreement or as agreed to in writing by Galectin Therapeutics.

#### 7. ADDITIONAL DUTIES, RESPONSIBILITIES, AND WARRANTIES OF PROCAPS

- 7.1. General Compliance. Procaps and its employees and agents shall: (i) comply with all applicable laws and regulations of each country in the Territory and the U.S. FDA rules and regulations. Procaps shall collect, monitor, research and evaluate information from healthcare providers and patients in the Territory on the adverse effects of the cancer treatments which include the Product. This information shall be provided to the JSMC as required in Sections 3.5 and 3.6. Procaps shall also follow Galectin Therapeutics' standards, policies, instructions and procedures relating to the Product and its activities under this Agreement, and (ii) not engage in any false, misleading or deceptive practices with respect to Galectin Therapeutics or the Product.
- 7.2. <u>Procaps Licenses and Permits</u>. Procaps represents, warrants and covenants to Galectin Therapeutics that Procaps shall possess during the term of this Agreement all licenses, permits and other authorizations required by any Regulatory Authority or other each governmental body within the Territory to import and Market and Distribute the Product, and fulfill its other obligations in accordance with the terms of this Agreement.
- 7.3. <u>Product Importation</u>. Procaps shall apply to necessary Regulatory Authority to import Product into the Territory and will be responsible for completing all necessary paperwork to enable importation of Product into the Territory at its expense.
- (a) <u>Product Licenses and Documentation</u>. Procaps shall be responsible for the satisfaction of all relevant licenses and requirements for Product in the Territory that apply to this Agreement, including without limitation, import and pharmaceutical licenses and providing guidance on all documents necessary for the importation of Product into the Territory. Each Party shall cooperate with the other in executing any other documents or licenses necessary for each Party to comply with any export or import or other similar applicable laws of the Territory.
- (b) <u>Batch Certifications and Customs Clearance</u>. Procaps shall provide for Product batch certification to be performed by customs inspectors or others, as applicable. In addition, Procaps shall ensure the integrity of the Product is maintained at all times prior to successful delivery to the Purchaser, including following all procedures and instructions of Galectin Therapeutics.

7.4. Notice Upon Change of Control. Procaps shall promptly provide Galectin Therapeutics with written notice in the event that Procaps undergoes a change in its principal place of business or name, identity, or corporate structure, or any merger, consolidation, sale or transfer of all or substantially all of the assets, or other similar transaction to which Procaps is a party.

#### 7.5. U.S. Foreign Corrupt Practices Act Compliance.

- (a) Procaps acknowledges that it understands that Galectin Therapeutics is an issuer of securities in the United States and is subject to the provisions of the FCPA. This law prohibits making, promising or offering to make corrupt payments to foreign officials, political parties or candidates, or making payments to other persons who will offer or make payments to any of the aforementioned parties in order to obtain business, retain business or gain an improper advantage. Procaps represents and warrants to Galectin Therapeutics that it is familiar with and understands the FCPA.
- (b) Procaps represents, warrants, and covenants to Galectin Therapeutics that throughout the term of this Agreement, neither Procaps, nor any Person performing activities on behalf of Procaps will engage in any activity that could cause a violation of any provision of the FCPA. Procaps represents and warrants that it has not made, promised to make, or arranged for any Third Party to make any payments or gifts to foreign officials in connection with its engagement by Galectin Therapeutics. Further, Procaps represents and warrants to Galectin Therapeutics that it has not violated any anti-corruption law, including any law applicable within the Territory, and further that Procaps is not involved in, or the subject of, any investigation involving bribery, corruption or improper payments to foreign government officials, as defined in the FCPA. Procaps agrees to update these representations and warranties on a periodic basis as required by Galectin Therapeutics in a format prescribed by Galectin Therapeutics.
- (c) Procaps agrees to notify Galectin Therapeutics immediately in writing if Procaps or any Person who is performing activities hereunder on behalf of Procaps is suspected of violating any anti-corruption law or becomes involved in, or a subject of, an investigation or law enforcement inquiry into possible improper payments to foreign officials or possible violations of anti-corruption laws. Procaps further agrees to provide such notification if Procaps or any Person performing activities on behalf of Procaps becomes involved in any action, suit, claim, investigation or proceeding that is pending, or to the knowledge of Procaps threatened, relating to a potential violation of any anti-corruption laws, including the FCPA.
- (d) Procaps shall maintain all records related to the import and Marketing and Distribution of the Product as required by any applicable laws, rules, regulations and guidelines. Procaps agrees to grant Galectin Therapeutics the right to audit Procaps' books and records regarding the receipt and disposition of any payments made to or by Procaps relating to the Product. Procaps further agrees to cooperate with Galectin Therapeutics in connection with such audits.
- (e) It is agreed between Procaps and Galectin Therapeutics that this Section 7.5 is deemed by the Parties to be a material provision of this Agreement.

## 8. ADDITIONAL RIGHTS, DUTIES, RESPONSIBILITIES, AND WARRANTIES OF GALECTIN THERAPEUTICS

8.1. Compound Manufacture. Galectin Therapeutics itself or through its Third-Party manufacturer will be responsible for manufacturing and supplying the Compound, in bulk form, to

Procaps in such amounts consistent with the then current Marketing and Distribution Plan; provided that if Procaps requests more than the Maximum Amount, Galectin Therapeutics shall have six (6) months in which to supply any amount of the Compound requested by Procaps over the Maximum Amount ("Excess Amount"). On any Product Order for, in whole or part, an Excess Amount, Procaps shall provide Galectin Therapeutics a deposit equal to fifty percent (50%) of the product of the Excess Amount times the Transfer Price. The second payment of 50% shall be due in 60 days from shipment. Galectin Therapeutics shall have no obligation to initiate the manufacture of any Excess Amount prior to receipt of the full deposit for such Excess Amount. Galectin Therapeutics or its Third Party manufacturer shall comply with all regulatory requirements and obtain any necessary regulatory approvals to manufacture the Compound.

- 8.2. Delayed Shipments. Except as provided in Section 8.1, Galectin Therapeutics shall ship all Compound within ninety (90) days of receipt of a Product Order compliant with this Agreement. If the Compound is not shipped within ninety (90) days of receipt of the applicable Product Order, Galectin Therapeutics will have thirty (30) days to initiate shipment of the Compound for such Product Order. If the Compound is not shipped by the end of such additional thirty (30) day period, Procaps will receive a xx discount to the invoice price of such Product Order. If the Compound shipment is (i) delayed beyond one-hundred and twenty (120) days and (ii) Procaps inventory of Product and Compound is fully depleted due to the delayed shipment, Procaps will receive a [\*\*\*\*]% discount to the invoice price of such Product Order. Galectin Therapeutics' shipment obligations end upon transfer of the shipment to the Carrier. Such delayed shipment discounts shall be Procaps' sole remedy in the event of Galectin Therapeutics' failure to ship Compound within the time required under this Agreement. The above delayed shipment discounts shall not apply if due to an Act of God or a Force Majeure. Galectin Therapeutics and Procaps agree to maintain levels of inventory as provided in Sections 10.3 and 10.6, respectively.
- 8.3. <u>Technology Transfer and Compound Supply</u>. Galectin Therapeutics shall cooperate with Procaps to transfer to Procaps for use solely with the fulfillment of Procaps' obligations under this Agreement, such formulation and fill and finish technology and processes as reasonably requested by Procaps. Procaps shall have no right to use such transferred technology and processes other than to fulfill its obligations under this Agreement or after the termination or expiration of this Agreement. Galectin Therapeutics shall be free to use, license or transfer such transferred technology and processes in any manner it sees fit.
- 8.4. <u>Supply of Compound for Approval Pursuit Purposes</u>. Galectin Therapeutics has supplied Procaps [\*\*\*\*] mg of Compound for use by Procaps to define the vial filling process and stability testing for the Product as required by Regulatory Authorities. Such Compound shall not be sold commercially by Procaps and shall be used only for such vial filling and stability testing.
- 8.5. Compound for Increasing Capacity of Production Process. If Regulatory Approval of the Product is received in Colombia by December 31, 2011, Galectin Therapeutics will provide Procaps within ninety (90) days of notice of such Regulatory Approval, [\*\*\*\*] of Compound free of charge to be used for the qualification and approval of the increased capacity production process for the Product in Columbia. Compound provided pursuant to this Section 8.5, or any Product produced from such Compound, shall not be sold commercially by Procaps and shall be used only for the qualification and approval of the increased capacity production process for the Product in Columbia.
- 8.6. <u>Training for Procaps' Personnel</u>. Galectin Therapeutics or its Third Party designee(s) shall provide training to Procaps' personnel at periodic intervals mutually agreed upon, as Galectin Therapeutics and Procaps deem necessary. The cost for such training shall be shared equally.

8.7. <u>U.S. Export Controls</u>. Galectin Therapeutics or its Third Party designee(s) shall be responsible for satisfaction of United States export and import licenses and requirements that apply to this Agreement. Each Party shall cooperate with the other in executing any other documents or licenses necessary for each Party to comply with any export or import or other similar laws of the United States applicable in this connection.

#### 9. PRICING AND PAYMENT PROCESSES

- 9.1. Product Pricing. Unless otherwise agreed between the Parties and reflected in the applicable Product Order, Procaps shall purchase, and Galectin Therapeutics shall sell to Procaps, the Compound at the Transfer Price. The Transfer Price shall be subject to annual increases based upon the increase Producer Price Index, Pharmaceutical Preparation Mfg-pcu325412325412 PCU, as reported by the Bureau of Labor Statistics, U.S. Department of Labor. The Transfer Price is inclusive of packaging but exclusive of any applicable value added or any other sales tax and customs duties for which Procaps shall be responsible. Distributor shall be responsible for costs for insurance during shipment. Unless otherwise agreed between the Parties, Procaps shall sell Formulated Doses at the Sales Price. The difference between the Transfer Price and the Sales Price shall be Procaps' sole remuneration for the Approval Pursuit and Marketing and Distribution of the Product and for all other obligations of Procaps under this Agreement. In the event that the Procaps sells Product at a price above the Sales Price, Procaps shall provide Galectin Therapeutics a written statement within thirty (30) days of the end of each calendar quarter detailing the number of Formulated Doses sold above the Sales Price, if any, during such quarter and pay Galectin Therapeutics at such time pursuant to Section 9.3 an amount equal to fifty percent (50%) of product of (i) the number of Formulated Doses sold above the Sales Price and (ii) the difference between the price such Formulated Doses were sold at and the Sales Price. Procaps shall have the right to decide appropriate credit terms for Purchasers, including requiring pre-payment.
- 9.2. Payments to Galectin Therapeutics. Galectin Therapeutics shall invoice Procaps for each Product Order by Procaps under this Agreement. Invoices may be sent by Galectin Therapeutics via email to (or such other email address as provided by Procaps) or in hard copy. Invoices for the Transfer Price shall be sent to Procaps after Galectin Therapeutics' receipt of the Product Order for such Compound. Unless otherwise elected by Galectin Therapeutics, Procaps shall make all payments required under this Agreement in U.S. Dollars by wire transfer to an account specified by Galectin Therapeutics. Procaps shall be responsible for the banking charges associated with any wire transfers under this Section 9.3. Galectin Therapeutics reserves the right to withhold delivery of Compound during any period in which Procaps has any amounts outstanding and past due. Such withholding of delivery will not constitute a breach of Galectin Therapeutics' obligations under this Agreement.
- 9.3. <u>Payment Terms</u>. Except as provided in Sections 8.1 and 19.3, Procaps shall pay the first [\*\*\*\*] in advance of shipment and thereafter, unless otherwise agreed, Procaps shall pay {\*\*\*\*]% of the amount of each invoice within thirty (30) days of the date of Galectin Therapeutics' invoice and the remaining [\*\*\*\*]% within 60 days of the date of invoice.

#### 10. PRODUCT ORDERING

10.1. <u>Product Orders.</u> Procaps may order Compound from Galectin Therapeutics in accordance with this Agreement and the following procedures. Compound may be ordered by use of the

order form in a form and substance satisfactory to Galectin Therapeutics (the "<u>Product Order</u>"). Each Product Order shall be for at least one (1) kilogram of Compound and shall be sent by Procaps to Galectin Therapeutics at the address sent forth in Section 21.13 to the attention of Maureen Foley with copies to Theodore Zucconi and Lillian DePasquale. Notwithstanding Section 9.3, Galectin Therapeutics shall have no obligation to ship any Compound to Procaps for a Product Order compliant with this Agreement while unpaid amounts are outstanding for prior Product Orders or if any royalty, upfront, license or milestone payments due to Galectin Therapeutics are overdue.

- 10.2. <u>Commitment to Purchase</u>. Procaps shall purchase all Compound that Galectin Therapeutics produces based on Product Orders submitted by Procaps under this Agreement.
- 10.3. <u>Compound Inventory</u>. Galectin Therapeutics will use its reasonable commercial efforts to maintain an inventory of Compound sufficient to supply Procaps needs as set forth in the then current Marketing and Distribution Plan such that Compound will be shipped to Procaps within ninety (90) days of receipt by Galectin Therapeutics of a Product Order.
- 10.4. Shipment. Galectin Therapeutics agrees to deliver the Compound using a carrier selected by Procaps for shipment to Procaps (the "Carrier"). Title to and risk for loss or damage shall pass to Procaps upon delivery to the Carrier. Procaps shall be responsible for selecting and making all arrangements for a Carrier to ship the Compound from Galectin Therapeutics' manufacturing facility. Procaps shall not make any modifications to the Compound or its packaging or labeling other than as required in connection with the production of Formulated Doses. Unless otherwise agreed, delivery of the Compound to the Carrier shall take place at Galectin Therapeutics' manufacturer's premises ex works (ICC Incoterms 2000). Risk of loss and damage shall pass to Procaps upon shipment in accordance with this Section 10.4.
- 10.5. Testing and Acceptance. Procaps shall have thirty (30) days after the delivery to Procaps of an order of Compound supplied hereunder to determine whether Compound conforms to the Specifications (using the same validated test methods as Galectin Therapeutics) and order quantity. Procaps will be deemed to have acknowledged that an order of Compound conforms to the Specifications and order quantity and is accepted, unless Procaps rejects such Compound order by giving written notice of non-conformity to Galectin Therapeutics within such thirty (30) day period. If Procaps determines that a Compound order fails to meet the Specifications, or that there is a shortage in the quantity delivered, it shall promptly so notify Galectin Therapeutics in writing within such thirty (30) day period. Any such notice shall specify the reason, with supporting documentation, for the non-conformity or the details of any quantity shortage, as the case may be. In the event that Galectin Therapeutics agrees that an order of Compound is non-conforming with the Specifications or that there was a shortage in quantity delivered, Galectin Therapeutics shall, at its own cost (including shipping) use commercially reasonable efforts to replace the non-conforming quantities of Compound or make up the shortage, as soon as reasonably possible. If Galectin Therapeutics does not agree that the particular order of Compound fails to meet the Specifications or that it delivered a shortage of Compound, it shall notify Procaps and the Parties (through the JSC) shall try to negotiate a mutually satisfactory resolution of their differences. Should a dispute over the conformity of a Compound order persist beyond thirty (30) days after Galectin Therapeutics' notice to Procaps of disagreement, a representative sample of the Compound at issue shall be submitted to an independent testing laboratory designated by Galectin Therapeutics and reasonably agreeable to Procaps for testing against the Specifications using the same validated test methods in use by

final and binding on the Parties. The cost of such test shall be borne by the Party whose results disagree with those of the independent laboratory. Where the test results demonstrate that the Compound order fails to meet any of the Specifications, Galectin Therapeutics shall replace the non-conforming quantities of Compound at no additional cost to Procaps as soon as reasonably possible after receipt of such results. The provisions of this Section shall not apply to any Compound damaged or lost in transit after delivery by Galectin Therapeutics to the Carrier, which shall be the responsibility of Procaps.

10.6. <u>Product Inventory</u>. During the term of this Agreement, (i) Procaps shall maintain reasonable inventory levels of the Product at a level equal to at least the amount of Product forecasted to be needed for the following two calendar quarters as set forth in the then current Marketing and Distribution Plan and (ii) Galectin Therapeutics shall maintain reasonable inventory levels of the Compound at a level equal to at least the amount of Compound forecasted to be needed for the following calendar quarter as set forth in the then current Marketing and Distribution Plan.

#### 11. ROYALTIES

11.1 <u>Royalties</u>. For the term specified in Section 11.2, Procaps shall pay to Galectin Therapeutics royalties on Net Sales in Columbia, at an incremental royalty rate determined by annual Net Sales of all Product in aggregate in each calendar year as follows:

Annual Net Sales of Product	Royalty Rate
Portion less than or equal to USD \$[****] million	[****]%
Portion greater than USD $\{****\}$ million and less than or equal to USD $\{****\}$ million	[****]%
Portion greater than USD \$[****] million and less than or equal to USD \$[****] million	[****]%
Portion greater than USD \$[****] million	[****]%

For example, if the calendar year Net Sales to which the royalty obligations in this Section 11.1 apply, were \$[\*\*\*\*], there would be [\*\*\*\*] royalty on the first \$[\*\*\*\*] million of such Net Sales, the [\*\*\*\*]% royalty rate would apply to the next \$[\*\*\*\*] of such Net Sales, the [\*\*\*\*]% royalty rate would apply to the final \$[\*\*\*\*] of such Net Sales. For the avoidance of doubt, royalty rates for countries other than Columbia in the Territory will be separately negotiated at the time the Parties agree, if at all, to add additional RFN Eligible Countries pursuant to Section 2.3; provided, that the maximum royalty rate in such countries shall be [\*\*\*\*]% of Net Sales. Minimum annual sales requirements for each RFN Eligible Country included in the RFN Agreement will be proportional to the minimum annual sales requirements for Columbia set forth in <a href="Exhibit D">Exhibit D</a> taking into account for each such country the factors set forth in Section 2.3 to determine upfront license fees. Royalties in each RFN Eligible Country included in the RFN Agreement will commence upon the First Commercial Sale in such country (i.e., royalties shall be due upon the first dollar of Net Sales in such country), except for Colombia which royalty schedule is set forth above.

- 11.2 <u>Royalty Term</u>. Royalties due under Section 11.1 with respect to the Product will commence upon the first commercial sale of the Product to a Third Party after Regulatory Approval ("<u>First Commercial Sale</u>") in any RFN country or jurisdiction and will be payable until the later of (i) the Term and (ii) any post-termination sales pursuant to Section 19.3.
- 11.3 Royalty Payments and Net Sales Reports. All amounts payable to Galectin Therapeutics pursuant to Section 11.1 shall be paid in United States dollars within thirty (30) days after the end of each calendar quarter with respect to Net Sales in such calendar quarter. Within thirty (30) days after the end of each calendar quarter, following Regulatory Approval of the Product in Colombia, Procaps shall provide Galectin Therapeutics a report setting forth (i) the amount of gross sales of Product during the applicable calendar quarter, (ii) an itemized calculation of Net Sales showing deductions provided for in the definition of Net Sales during such calendar quarter, (iii) the Net Sales Price for such calendar quarter, and (iv) a calculation of the amount of royalty payment due on such Net Sales for such calendar quarter.
- 11.4 <u>Foreign Exchange</u>. The rate of exchange to be used in computing the amount of currency equivalent in United States dollars of Net Sales invoiced in other currencies shall be made at the period-end rate of exchange quoted on the last business day of the applicable calendar quarter by Citibank in New York City or, to the extent mutually agreed by the Parties, any other widely accepted source of published exchange rates.
- 11.5 <u>Late Payments</u>. If Galectin Therapeutics does not receive payment of any sum due to it on or before the due date, simple interest shall thereafter accrue on the sum due to Galectin Therapeutics from the due date until the date of payment at the prime rate (as stated in the Wall Street Journal on the date such payment was due) plus four percent (4%) or the maximum rate allowable by applicable law, whichever is less.
- 11.6 Financial Records; Audits. Procaps shall maintain complete and accurate records in sufficient detail to permit Galectin Therapeutics to confirm the accuracy of the Net Sales generated by Procaps and the calculation of royalty payments and the Net Sales Price. Upon reasonable prior notice of at least five (5) Business Days, such records shall be open during regular business hours for a period of three (3) years from the creation of individual records for examination at Galectin Therapeutics' expense, and not more often than twice each calendar year, by an independent certified public accountant selected by Galectin Therapeutics for the sole purpose of verifying for Galectin Therapeutics the accuracy of the financial reports, royalty payment or Net Sales and Net Sales Price calculations or of any payments made by Procaps to Galectin Therapeutics pursuant to this Agreement. Any such auditor shall not disclose Procaps' Confidential Information to Galectin Therapeutics, except to the extent such disclosure is necessary to verify the accuracy of the financial reports, royalty payment or Net Sales and Net Sales Price calculation furnished by Procaps or the amount of payments due by Procaps under this Agreement. Any amounts shown to be owed but unpaid or overpaid and in need of reimbursement shall be paid or refunded (as the case may be) within thirty (30) days after the accountant's report, plus interest (as set forth in Section 11.5) from the original due date. Galectin Therapeutics shall bear the full cost of such audit unless such audit discloses that Procaps paid too little because of a discrepancy in a report that Procaps provided to the JSC or Galectin Therapeutics during the applicable audit period, which underpayment was equal to more than five percent (5%) of the amount set forth in such report, in which case Procaps shall bear the full cost of such audit.

### 12. REPRESENTATIONS AND WARRANTIES

- 12.1 <u>Mutual Representations and Warranties</u>. Each Party hereby represents, warrants, and covenants (as applicable) to the other Party as follows, as of the Effective Date:
- (a) <u>Corporate Existence and Power</u>. It is a company or corporation duly organized, validly existing, and in good standing under the laws of the jurisdiction in which it is incorporated, and has full corporate power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being conducted and as contemplated in this Agreement.
- (b) <u>Authority and Binding Agreement</u>. It has the corporate or organizational power and authority and the legal right to enter into this Agreement and perform its obligations hereunder; it has taken all necessary corporate or organizational action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder; and this Agreement has been duly executed and delivered on its behalf, and constitutes a legal, valid, and binding obligation of such Party that is enforceable against it in accordance with its terms and this Agreement will not violate (a) such Party's certificate of incorporation or bylaws, (b) any agreement, instrument or contractual obligation to which such Party is bound in any material respect, (c) any requirement of any applicable laws or regulation, or (d) any order, writ, judgment, injunction, decree, determination or award of any court or governmental agency presently in effect applicable to such Party.
- (c) No Conflict. It is not a party to and will not enter into any agreement that would materially prevent it from granting the rights granted to the other Party under this Agreement or performing its obligations under this Agreement.
- (d) No Debarment. To the best of such Party's knowledge, such Party has not used prior to the Effective Date and shall not use, during the term of the Agreement, any employee, agent or independent contractor who has been debarred by any Regulatory Authority, or is the subject of debarment proceedings by a Regulatory Authority.
- 12.2. <u>Disclaimer</u>. Procaps understands that the Compound and Product are the subject of ongoing clinical research and development and that the safety or efficacy profile of the Compound and Product are not fully defined.

### 13. PRODUCT WARRANTY AND CONDITIONS

13.1. Warranty. Galectin Therapeutics warrants to Procaps that the Product delivered by Galectin Therapeutics to Procaps pursuant to this Agreement: (a) shall be free from defects in material or workmanship or design, and (b) shall conform to the Product specifications, any technical conditions or standards provided by the certificate of analysis, and all applicable laws. The warranties in this Section 13.1 are exclusive and in lieu of all other warranties, whether oral or in writing, express or implied or statutory. In the event that Galectin Therapeutics delivers Product in non-conformance with these warranties, Procaps shall have the right to return the Product, at the cost and expense of Galectin Therapeutics, and Galectin Therapeutics shall reimburse Procaps any Transfer Price paid for such non-conforming Product. The above warranties shall only apply to the extent the Product is handled, stored, transported and used by or on behalf of Procaps, and Purchasers in accordance with this Agreement, Galectin Therapeutics' instructions, and applicable laws, rules and regulations. Any disputes between the Parties regarding whether Product delivered to Procaps meets the warranty provided in this Section shall be resolved pursuant to Section 20.

- 13.2. No Modification of Product Warranty. Procaps shall provide in each product order with a Purchaser, a written notice containing the Product warranty provisions of Section 13.1. Procaps shall not modify or supplement such warranty or disclaimer without the express prior written consent of an authorized representative of Galectin Therapeutics, or provide any additional warranty. Procaps shall indemnify and hold Galectin Therapeutics harmless from all liabilities, claims, damages and expenses, including attorneys' fees that may be incurred by Galectin Therapeutics during or after the term of this Agreement that result from or arise out of the failure of Procaps to comply with the terms of this Section 13.
- 13.3. <u>WARRANTY DISCLAIMER</u>. THE EXPRESS REPRESENTATIONS AND WARRANTIES OF GALECTIN THERAPEUTICS STATED IN THIS AGREEMENT ARE IN LIEU OF ALL OTHER REPRESENTATIONS AND WARRANTIES, EXPRESS, IMPLIED, OR STATUTORY, INCLUDING WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NON-INFRINGEMENT OR NON-MISAPPROPRIATION OF THIRD PARTY INTELLECTUAL PROPERTY RIGHTS. NO REPRESENTATION OR WARRANTY MADE BY EMPLOYEES OF GALECTIN THERAPEUTICS, PROCAPS OR ANY OTHER PARTY SHALL BE CONSIDERED A WARRANTY BY GALECTIN THERAPEUTICS FOR ANY PURPOSE OR CREATE ANY LIABILITY OF GALECTIN THERAPEUTICS.

#### 14. INTELLECTUAL PROPERTY

14.1. Intellectual Property. Procaps acknowledges that all current and future patents, patent applications, trade marks, trade names, service marks, internet domain names, copyrights, design rights, trade secrets, and other intellectual property rights in or related to the Compound and/or Product or any materials used in connection with the manufacture, Approval Pursuit, use or Marketing and Distribution of the Compound and/or Product (the "Product Related IP Rights") are and shall remain the exclusive property of Galectin Therapeutics. Galectin Therapeutics shall be solely responsible for prosecution, maintenance and enforcement of the Galectin Therapeutics Patents, Product Related IP Rights and Licensed Marks. Except as explicitly provided under this Agreement, Procaps has no right to, and shall not, make, use, modify, reproduce, disassemble, reverse engineer, translate, reconstruct, or improve the Compound and/or Product, the Confidential Information, or any other materials used in connection with the manufacture, Approval Pursuit, use or Marketing and Distribution of the Compound and/or Product, or practice any of Galectin Therapeutics' current or future intellectual property rights, except upon the prior written consent of Galectin Therapeutics. Procaps hereby assigns, or in jurisdictions that do not allow present assignment of future rights, agrees to assign, to Galectin Therapeutics, without additional consideration, all of Procaps' rights in any Product Related IP Rights that now exists or hereafter arises including the right to claim priority from the relevant patent application(s). Procaps shall execute such documents and take such actions as Galectin Therapeutics may reasonably request in connection with the documentation of any Product Related IP Right or the assignment of such right to Galectin Therapeutics and to the maximum extent possible under applicable law. Procaps shall promptly notify Galectin Therapeutics of any action by any Person that comes to Procaps' attention that constitutes or may

- 14.2. <u>Cooperation of Procaps</u>. Procaps shall provide Galectin Therapeutics all reasonable assistance and cooperation in Galectin Therapeutics' patent prosecution efforts with respect to Product Related IP Rights, including providing any necessary powers of attorney and executing any other required documents or instruments for such prosecution. In addition, Procaps shall provide to Galectin Therapeutics reasonable assistance in enforcement of patents or patent applications claiming Product Related IP Rights, at Galectin Therapeutics' request and expense, including joining such action as a party plaintiff if required by applicable law to pursue such action.
- 14.3. Licensed Marks. The Licensed Marks, and any reputation and goodwill in them, are, and will remain, the exclusive property of Galectin Therapeutics, and Procaps does not have and shall not have any right to use any such Licensed Mark other than in connection with the Marketing and Distribution of the Product under the terms and conditions of this Agreement. All use of the Licensed Marks shall inure solely to the benefit of Galectin Therapeutics. Procaps shall not: (a) use any Licensed Mark, or any word, symbol, or design confusingly similar to any Licensed Mark or other Galectin Therapeutics mark, as part of its corporate or legal name or in connection with any product sold by Procaps; (b) do or suffer to be done any act or thing which would in any way impair the rights of Galectin Therapeutics in and to any Licensed Mark; (c) apply for any registration of any trademark or other designation which includes in whole or in part any Licensed Mark or which otherwise would affect the ownership of any Licensed Mark, no file any document with any governmental authority to take any action that would affect the ownership of any Licensed Mark or assist any other Person or entity to undertake any such action; or (d) acquire or claim any title to any Licensed Mark adverse to Galectin Therapeutics by virtue of the rights granted to Procaps under this Agreement or through Procaps' use of such Licensed Mark. If any Licensed Marks are to be used in conjunction with another trademark on or in relation to the Product, then the Licensed Mark(s) shall be presented equally legibly, equally prominently, and of greater size than the other, but nevertheless separated from the other, so that each appears to be a mark in its own right, distinct from the other mark.
- 14.4. <u>Patent Marking</u>. Procaps shall, and shall require its Affiliates, to mark the Product sold by it hereunder with appropriate patent numbers or indicia to the extent permitted by applicable law and regulations, in those countries in which such markings or such notices impact recoveries of damages or equitable remedies available with respect to infringements of patents.
- 14.5. Employee Obligations. Prior to the Effective Date, each employee, agent or independent contractor of Procaps or its Affiliates that may be involved at any time during the Term in the Approval Pursuit or Distribution of the Product or other obligations under this Agreement shall sign, to the extent it has not already signed, a non-disclosure and invention assignment agreement pursuant to which such person agrees to comply with all of the obligations of Procaps, as appropriate, in this Section 14, including without limitation: (a) promptly reporting any invention, discovery, process or other intellectual property right; (b) assigning to Procaps all of his or her right, title and interest in and to any invention, discovery, process or other intellectual property right; (c) cooperating in the preparation, filing, prosecution, maintenance and enforcement of any patent and patent application; (d) performing all acts and signing, executing, acknowledging and delivering any and all documents required for effecting the obligations and purposes of this Agreement; and (e) abiding by the obligations of confidentiality and non-use set forth in Section 15. It is understood and agreed that such non-disclosure and invention assignment agreement need not reference or be specific to this Agreement. New employees shall sign such an agreement before receiving or being exposed to Galectin Confidential information.

#### 15. CONFIDENTIALITY

- 15.1. <u>Definition</u>. "Confidential Information" shall mean any technical, scientific, clinical, financial, commercial or business information furnished by one Party to the other Party in connection with this Agreement or developed by Procaps in the course of fulfilling its obligations under this Agreement, regardless of whether such Confidential Information is in oral, electronic or written form. Such Confidential Information includes, without limitation, all trade secrets, know-how, inventions, developments, technical data or specifications, formulations, formulae, testing methods, research and development activities, product and marketing plans, customer and supplier information, materials, compositions of matter, manuals, processes, procedures, reports, instructions, databases, information, marketing reports, expertise, technology, test data including pharmacological, biological, chemical, biochemical, toxicological, and clinical test data, analytical and quality control data, stability data, studies and procedures relating to Galectin Therapeutics, Procaps, the Compound or the Product. All Confidential Information is and shall remain the exclusive property of the disclosing Party; provided that Confidential Information developed by Procaps in the course of fulfilling its obligations under this Agreement shall be Confidential Information of Galectin Therapeutics.
  - 15.2. Obligations. The receiving Party shall:
    - (a) maintain all Confidential Information of disclosing Party in strict confidence;
    - (b) use all Confidential Information of disclosing Party solely for the purpose of fulfilling its obligations under this Agreement; and
- (c) reproduce the Confidential Information of disclosing Party only to the extent necessary for fulfilling its obligations under this Agreement, with all such reproductions being considered Confidential Information.
  - 15.3. Exceptions. Information shall not be deemed Confidential Information if the receiving Party can demonstrate that such information:
    - (a) was in the public domain prior to the disclosure of such information by the disclosing Party;
- (b) entered the public domain after receipt from the disclosing Party through means other than an unauthorized disclosure resulting from an act or omission by the receiving Party in violation of this Agreement; or
- (c) was already known to the receiving Party or its Affiliate, other than under an obligation of confidentiality, at the time of disclosure by the disclosing Party.
- 15.4. <u>Authorized Disclosure</u>. Each Party may disclose Confidential Information belonging to the other Party to the extent such disclosure is reasonably necessary in the following situations:
  - (a) regulatory filings and other filings with Governmental Authorities, including filings with the SEC, with respect to the Compound or Product;

- (b) complying with applicable laws and regulations, including regulations promulgated by securities exchanges;
- (c) disclosure to its Affiliates, employees, agents, and approved independent contractors, only on a need-to-know basis and solely as necessary in connection with the performance of this Agreement, provided that each disclosee must be bound by similar obligations of confidentiality and non-use at least as equivalent in scope as those set forth in this Section 15 prior to any such disclosure; and
- (d) solely with respect to the material terms of this Agreement, disclosure to any bona fide potential or actual investor, investment banker, acquirer, merger partner, or other potential or actual financial partner; provided that in connection with such disclosure, the disclosing Party shall use all reasonable efforts to inform each disclosee of the confidential nature of such Confidential Information and cause each disclosee to treat such Confidential Information as confidential.

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to this Section 15.4, it will, except where impracticable, give reasonable advance notice to the other Party of such disclosure and use reasonable efforts to limit the scope of such disclosure, as well as any subsequent use or disclosure of the information so disclosed, by seeking confidential treatment, a protective order, or the like and reasonably assist the other Party in its efforts to seek such confidential treatment, protective order or the like. In any event, the Parties agree to take all reasonable action to avoid disclosure of Confidential Information hereunder.

- 15.5. <u>Return of Confidential Information</u>. Upon the expiration or termination of this Agreement, the receiving Party shall return to the disclosing Party or destroy all originals, copies, and summaries of documents, materials, and other tangible manifestations of Confidential Information in the possession or control of the receiving Party; except that one copy may be retained by the other Party's legal counsel to ascertain compliance with this Agreement.
- 15.6. <u>Survival of Obligations</u>. The obligations set forth in this Section 15 shall remain in effect for a period of ten (10) years after expiration or termination of this Agreement, except that the obligations of the receiving Party to return Confidential Information shall survive until fulfilled.

#### 16. INDEMNIFICATION; INSURANCE; LIMITATION OF LIABILITY

- 16.1. Scope of Indemnification. Each Party (the "Indemnitor") hereby agrees to indemnify and hold the other Party and its Affiliates and their respective shareholders, officers, directors, employees, consultants and agents (the "Indemnitees") harmless for any loss, claim, damage, cost, expense (including reasonable attorney's fees), or liability by or to a Third Party (a "Claim") arising out of: (a) the negligence or willful misconduct of the Indemnitor, its Affiliates or any of their respective officers, directors, employees, consultants or agents; (b) a breach by the Indemnitor of any of its representations, warranties or obligations under this Agreement or any breach of applicable law; or (c) the Indemnitor's Approval Pursuit and Marketing and Distribution of the Product.
- 16.2. <u>Process</u>. If any claim is asserted against an Indemnitee by any Third Party, which claim is subject to indemnity under this Section 16, the Indemnitee shall notify the Indemnitor thereof promptly after its receipt of such claim, but any delay in giving such notice shall not affect the Indemnitee's rights under this Section 16 except to the extent the Indemnitor is actually prejudiced thereby. The Indemnitor

shall have the right to take charge of the defense of such claim by giving notice to the Indemnitee within ten (10) days after Indemnitee's notice. If the Indemnitor so assumes the defense, (i) the defending counsel shall be selected by the Indemnitor and shall be free of material conflicts with the Indemnitee's interests and otherwise reasonably satisfactory to the Indemnitee, (ii) all costs and expenses of defense, including without limitation all attorney, witness, investigation, and court fees and expenses, (collectively, "Defense Costs") shall be borne and promptly paid by the Indemnitor, and (iii) any engagement of separate counsel by Indemnitee shall be solely at the Indemnitee's expense. If the Indemnitor does not so assume the defense, or if the Indemnitor fails to diligently pursue such defense or timely pay any Defense Costs, then the Indemnitee may take charge of the defense of such claim, including the designation of defense counsel, and all Defense Costs, including without limitation the reasonable fees and expenses of counsel designated by the Indemnitee, shall be borne and promptly paid by the Indemnitor. No settlement of a claim for which indemnification will be sought under this Section 16 shall be made without the consent of the Indemnitor, which shall not unreasonably be withheld. No settlement of a claim shall be entered into without the consent of the Indemnitee unless it fully and finally releases the Indemnitee from all obligations and liability relating to or arising out of the subject matter of the claim and imposes no restrictions or burdens on the Indemnitee.

- 16.3. <u>Insurance</u>. Each Party shall secure and maintain in full force and effect throughout the term of this Agreement policies of insurance, including general commercial liability and product liability, with limits, deductibles and other terms appropriate to the conduct of their business. Each Party shall furnish certificates evidencing such insurance upon the other Party's request.
- 16.4. <u>LIMITATION OF LIABILITY</u>. EXCEPT TO THE EXTENT GALECTIN THERAPEUTICS MAY BE REQUIRED TO INDEMNIFY PROCAPS UNDER SECTION 16, NEITHER GALECTIN THERAPEUTICS NOR ITS AFFILIATES OR AGENTS SHALL BE LIABLE FOR SPECIAL, EXEMPLARY, CONSEQUENTIAL OR PUNITIVE DAMAGES, WHETHER IN CONTRACT, WARRANTY, TORT, STRICT LIABILITY OR OTHERWISE. ANY LIABILITY OF GALECTIN THERAPEUTICS FOR DAMAGES RELATING TO THE PRODUCT SHALL NOT EXCEED THE PRICE PAID BY PROCAPS FOR THE PRODUCT.
- 16.5. No Goodwill. Procaps shall not be entitled to compensation for any goodwill which may have accrued due to the Approval Pursuit and Marketing and Distribution of the Product by Procaps. Procaps shall have no claim against Galectin Therapeutics based on, arising out of, or in connection with, the alleged value of any particular customer account or group of accounts located within the Territory. Upon termination or expiration of this Agreement, Galectin Therapeutics shall be free, at its sole discretion, to make whatever other arrangements for Pursuing Approval and Marketing and Distributing the Product in the Territory as Galectin Therapeutics may deem appropriate, with whatever party and under whatever terms and pricing as Galectin Therapeutics shall determine.

#### 17. NON-COMPETE

Procaps hereby covenants and agrees that during the term of this Agreement and for a period of five (5) years thereafter it will not, and will cause its Affiliates, not to, directly or indirectly, other than as provided in this Agreement, import, develop, manufacture, market, sell or distribute any products that can be substituted for the Compound or Product or enter into a collaboration or license agreement with any Third Party to do the same. A product that can be substituted for the Product shall be any oncology

therapeutic that can be used instead of a regime containing 5-FU (whether alone or in combination with other therapeutics) for an oncology indication in which a 5-FU containing regime is used or any oncology therapeutics that can be used to replace 5-FU in a regime otherwise containing 5-FU. Notwithstanding the prior sentence, Procaps may import, develop, manufacture, market, sell or distribute products used solely to diagnose cancer or treat side effects associated with cancer treatments or those products which it currently imports, develops, manufactures, markets, sells or distributes or for which it has the right to do so that are identified on Exhibit E. Procaps agrees that any breach or threatened breach by it of this Section 17 shall entitle Galectin Therapeutics, in addition to all other legal remedies available to them, to a temporary or permanent injunction to enjoin such breach or threatened breach without having to post bond, together with an award of its attorneys' fees incurred in connection with same.

#### 18. TERM

This Agreement shall begin on the Effective Date and shall continue until the [\*\*\*\*] anniversary of the Effective Date unless terminated earlier in accordance with the terms of Section 19 or another provision of this Agreement, or unless extended by written agreement of both Parties for one or more countries in the Territory upon mutually agreeable terms within sixty (60) days of the then current termination date (the "Term").

#### 19. TERMINATION

19.1. <u>Termination by Either Party</u>. Except as otherwise provided in this Agreement, either Party may terminate this Agreement or, in the case of Galectin Therapeutics, render Procaps' rights under this Agreement non-exclusive: (a) for cause upon the material breach of any obligation or responsibility by the other Party which breach remains uncured for thirty (30) days after written notice thereof; (b) for cause upon the non-material breach of any obligation or responsibility by the other Party which breach remains uncured for sixty (60) days after written notice thereof; (c) upon thirty (30) days written notice upon the revocation, termination of a Regulatory Approval or the suspension of sales of the Product for a period of greater than one hundred and eighty days (180) days by a Regulatory Authority in the Territory. For the avoidance of doubt, subject to Section 21.6, this Agreement shall survive a merger, consolidation or sale of all or substantially all of a Party's assets.

19.2. <u>Post-Termination Obligations</u>. In the event of Termination of this Agreement, (i) Galectin Therapeutics shall, in its sole discretion, process in the ordinary course of business all Product Orders confirmed by Galectin Therapeutics prior to the written notice of termination, or prior to the expiration date of this Agreement; provided, however, that Procaps shall pay the invoice for all such Product Orders in advance of shipment, (ii) Procaps may sell any existing Product in its inventory during the period ending one hundred eighty (180) days following receipt of notice of termination, provided Regulatory Approval has not been revoked, terminated or suspended, (iii) Galectin Therapeutics shall have the option to purchase all or part of Compound in Procaps' inventory as of the date notice of termination is received at the price paid by Procaps for such Compound, and (iv) at the end of the period ending one hundred eighty (180) days following receipt of notice of termination, Procaps shall destroy any remaining Compound not purchased by Galectin Therapeutics and any remaining Product and provide Galectin Therapeutics with written certification thereof. Termination or expiration of this Agreement shall not prevent or excuse Procaps from settling accounts, collecting funds, or engaging in any activity necessary to bring successfully to completion any transaction outstanding at the time of the termination or expiration of this Agreement. In the event of termination for breach by Procaps or a termination pursuant to Section 19.1(d), (A) all outstanding Product Orders shall be immediately terminated, (B) Procaps shall immediately cease all Marketing and Distribution of the Product, (C) Galectin Therapeutics shall have the option to purchase all or part of Compound in Procaps inventory as of the date notice of termination is

received at the price paid by Procaps for such Compound, and (D) Procaps shall destroy any remaining Compound not purchased by Galectin Therapeutics and any remaining Product and provide Galectin Therapeutics with written certification thereof. Immediately after termination or expiration, Procaps shall provide all cooperation and assistance reasonably requested by Galectin Therapeutics to enable Galectin Therapeutics to assume and/or continue, with as little disruption as reasonably possible, the continued Approval Pursuit and Marketing and Distribution of the Product in the Territory, including, without limitation, (a) as directed by Galectin Therapeutics, terminate all agreements between Procaps and any Third Parties relating to the Approval Pursuit or Marketing and Distribution of the Product, or assign them to Galectin Therapeutics or a Third Party designated by Galectin Therapeutics, (b) at Galectin Therapeutics' request, transfer to Galectin Therapeutics or its designee all inventory of the Compound and the Product (c) at the direction of Galectin Therapeutics, remove from any literature or other media of Procaps any and all references to Galectin Therapeutics and the Product, (d) cease to use any trademarks or trade names of Galectin Therapeutics, the Compound or the Product and assign to Galectin Therapeutics all right, title and interest in any such trademarks or trade names to the extent necessary, (e) transfer or assign to Galectin Therapeutics all Regulatory Materials, Regulatory Approvals, Product Related IP Rights, licenses, permits, authorizations or similar documents for the Product that Procaps holds as of the time of any such termination, (f) return to Galectin Therapeutics all Confidential Information of Galectin Therapeutics, (g) pay Galectin Therapeutics any outstanding invoices and royalty amounts, and (h) provide Galectin Therapeutics with a final Marketing and Distribution report containing data through the effective date of the termination or expiration of the Agreement, including without limitation, customer account information and market data and intelligence. The provisions of Sections 5.1, 5.2, 6.5, 7.5, 13.2, 13.3, 14, 15, 16, 17, 20 and this Section 19.3 shall survive expiration or termination of this Agreement. In addition, the following provisions shall survive expiration or termination of this Agreement with respect to sales made prior to such expiration or termination, or in accordance with this Section 19.3: 4.4, 4.6, 5.2, 6.3, 6.5, 6.6, 7.5, 9.1, 9.2, 9.3, 11 and 13.

#### 20. DISPUTE RESOLUTION

20.1. <u>Disputes</u>. Any contractual dispute arising under this Agreement (the "<u>Dispute</u>") shall be discussed first by the respective chief executive officers of each Party or his/her designee for attempted resolution by good faith discussions within sixty (60) days. In the event that the chief executive officers or his/her designee are not able to resolve such Dispute within such sixty (60) day period, and do not agree to extend the time period for resolving the Dispute, unless the Parties otherwise agree to extend the time period for resolving the Dispute, then such Dispute shall be resolved pursuant to the provisions of Section 20.2.

20.2. Arbitration. If the Dispute is not resolved pursuant to Section 20.1, such Dispute must be referred to and finally resolved by arbitration, to which the Parties hereto expressly agree and submit. The arbitration will be submitted to the International Centre for Dispute Resolution of the American Arbitration Association ("AAA") and conducted in accordance with the Commercial Arbitration Rules of the AAA ("Rules"). Pre-hearing information exchange shall be limited to the reasonable production of relevant, nonprivileged documents and carried out expeditiously. There will be one arbitrator selected by mutual agreement of the Parties. It is the intent of the Parties that, barring extraordinary circumstances, arbitration proceedings will be concluded within ninety (90) days from the date the arbitrator is appointed. The arbitral tribunal may extend this time limit in the interests of justice. Failure to adhere to this time limit shall not constitute a basis for challenging the award. The arbitration will be conducted in English and the place of arbitration will be in New York City, New York, USA. Either Party may, without waiving any remedy under this Agreement, apply to the arbitral tribunal and/or any court having

jurisdiction any interim, provisional, injunctive or conservatory relief that is necessary to protect the rights or property of that Party until the arbitration award is rendered or the Dispute is otherwise resolved. Any decision rendered by the arbitral tribunal will be final and binding on the Parties, and judgment thereon may be entered by any court of competent jurisdiction, including, but not limited to, any court that has jurisdiction over either of the Parties or any of their assets. The Parties expressly agree that the arbitral tribunal will be empowered to award and order equitable or injunctive relief with respect to matters brought before it, provided however, that such remedy or relief is consistent with the remedies and limitations set forth in this Agreement. The Parties agree that all arbitral proceedings conducted pursuant to this Section, including the existence of any arbitral proceedings, information disclosed in the course of such arbitral proceedings, and any settlements, negotiations, discussions, proposals, and awards related thereto shall be considered Confidential Information. The Parties may, however, disclose such information to an appropriate court, as is necessary to seek enforcement of any award rendered by the arbitral tribunal.

20.3. Governing law; Venue. This Agreement shall be governed by and construed under the substantive laws of the United States of America and the Commonwealth of Massachusetts, without regard to conflicts of law rules. Each Party (a) hereby irrevocably submits itself to and consents to the exclusive jurisdiction of the Commonwealth of Massachusetts for the purposes of any action, claim, suit or proceeding in connection with any controversy, claim or dispute arising out of or relating to this Agreement for which Section 20.2 permits access to the courts, and (b) hereby waives, and agrees not to assert, by way of motion, as a defense or otherwise, in any such action, claim, suit or proceeding, any claim that it is not personally subject to the jurisdiction of such court(s), that the action, claim, suit or proceeding is brought in an inconvenient forum or that the venue of the action, claim, suit or proceeding is improper. The Parties agree that the 1980 United Nations Convention on Contracts for the International Sale of Goods shall not apply to or affect any term of this Agreement.

#### 21. GENERAL PROVISIONS

- 21.1. <u>Relationship of the Parties</u>. The Parties are and shall remain independent contractors. Procaps shall conduct all of its business in its own name and shall pay all expenses of its office and activities and be solely responsible for the acts and expenses of its employees. Procaps shall purchase and resell the Product for its own account and at its own risk. This Agreement does not constitute a partnership or joint venture and does not establish either Party as the agent, franchisee, or legal representative of the other for any purpose, and neither Party has the authority to act for, bind, or make commitments on behalf of the other, except as specifically provided for in this Agreement.
- 21.2. Force Majeure. Neither Procaps nor Galectin Therapeutics shall be liable for any delay or failure to perform its obligations under this Agreement because of events beyond its reasonable control and which were not reasonably foreseeable at the time of signing this Agreement, including but not limited to strikes, riots, war, fire, acts of God, acts of government, supplier delays, and breakdown or general unavailability of materials or transportation facilities. In the event that a Party's non-performance extends for a period greater than one hundred eighty (180) days as permitted by this Section 21.2, the other Party may terminate the Agreement upon written notice to the non-performing Party.

#### 21.3. Publicity.

(a) If Galectin Therapeutics desires to make public announcements related to this Agreement concerning (i) completion of clinical studies in the Territory and top line results thereof, (ii)

filings for Regulatory Approvals in the Territory; iii) Regulatory Approvals in the Territory; and (iv) milestone achievements and/or payments, Galectin Therapeutics shall give reasonable prior advance notice of the proposed text of such announcement to Procaps for its prior review and approval (except as otherwise provided herein), such approval not to be unreasonably withheld. Procaps shall provide its comments, if any, within three (3) business days after receiving the announcement for review. Neither Party shall be required to seek the permission of the other Party to repeat any information regarding the terms of this Agreement that have already been publicly disclosed by such Party, or by the other Party, in accordance with this Section 21.3.

- (b) Procaps acknowledges that Galectin Therapeutics may be obligated to file a copy of this Agreement with the U.S. Securities and Exchange Commission. Galectin Therapeutics shall be entitled to make such a required filing, provided that it requests confidential treatment of at least the commercial terms and sensitive technical terms hereof to the extent such confidential treatment is reasonably available to Galectin Therapeutics. In the event of any such filing, Galectin Therapeutics will provide Procaps with a copy of the Agreement a reasonable time in advance of filing marked to show provisions for which Galectin Therapeutics intends to seek confidential treatment and shall reasonably consider and incorporate Procaps' comments thereon (which shall be provided to Galectin Therapeutics a reasonable time in advance of filing) to the extent consistent with the legal requirements governing redaction of information from material agreements that must be publicly filed.
- 21.4. Entire Agreement and Amendment. This Agreement, including its exhibits, schedules and attachments constitutes the entire agreement between the Parties with respect to its subject matter and cancels and supersedes all prior agreements, understandings, and arrangements, whether written or oral, between the Parties with respect to such subject matter. No amendment, modification, or waiver of the terms of this Agreement, or any of its exhibits, schedules, or attachments will be binding on either Party unless reduced to writing and signed by an authorized representative of the Party to be bound.
- 21.5. <u>Performance by Galectin Therapeutics</u>. Any of Galectin Therapeutics' obligations to be performed under this Agreement may be performed by any subsidiary or Affiliate or Third party designee of Galectin Therapeutics.
- 21.6. <u>Assignment.</u> Procaps may not assign, delegate, or subcontract its rights or obligations under this Agreement or otherwise engage agents to perform or assist in performing its duties and obligations under this Agreement without the prior written consent of Galectin Therapeutics. For purposes of this Agreement, a merger, consolidation or sale of all or substantially all of a Party's assets shall not be deemed an assignment; *provided* that such Party's rights and obligations under this Agreement shall be assumed by its successor in interest in any such transaction and shall not be transferred separate from all or substantially all of its other business assets, including those business assets that are the subject of this Agreement. Any successor in interest to a Party may terminate this Agreement only pursuant to the terms hereof or pursuant to mutual written agreement with the other Party.
  - 21.7. Language of the Agreement. This Agreement is written in the English language and the English language shall govern its interpretation.
- 21.8. Severability. If any provision of this Agreement is held by a court of competent jurisdiction to be unenforceable or inoperative, either in whole or in part, the remaining provisions shall

be severable and continue in full force and effect, and the Parties shall negotiate in good faith enforceable, operative replacement provisions for the unenforceable or inoperative ones that meets the original intention of the Parties as much as possible.

- 21.9. No Waiver. The failure of either Party to this Agreement to insist upon the performance of any of its terms and conditions, or the waiver of any breach of any of the terms and conditions of this Agreement, shall not be construed as later waiving any terms and conditions, but they shall continue and remain in full force and effect as if no forbearance or waiver had occurred.
- 21.10. <u>Headings</u>. The headings of this Agreement have been included solely for reference and are to have no force or effect in interpreting its provisions.
- 21.11. <u>Gender and Number</u>. Words used in this Agreement, regardless of the number and gender specifically used, will be deemed and construed to include such other number, singular or plural, and such other gender, masculine, feminine, or neuter, as the context requires and the term "including" or "includes" means including, without limiting the generality of any description preceding such term.
- 21.12. Counterparts. This Agreement may be executed in one (1) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.
- 21.13. <u>Notices</u>. Any notice or other communication required or permitted by this Agreement shall be in writing in the English language and sent to the following addresses (or such other addresses as provided in writing by the applicable Party):

If to Galectin Therapeutics:

Galectin Therapeutics Inc. 7 Wells Avenue Newton, MA 02459 Attn: CEO Fax No.: 617-928-3450 Telephone No.: 617-559-0033

If to Procaps:

## [PROCAPS TO COMPLETE]

Any such notice or other communication shall be deemed given (a) when delivered personally, (b) three (3) Business Days after having been sent by registered or certified mail, return receipt requested, postage prepaid; (c) one (1) day after deposit with a commercial express courier specifying next day delivery, with written verification or receipt, or (d) when acknowledged or confirmed after being faxed.

Notwithstanding the foregoing, notices to be sent pursuant to Section 9.2 shall be sent via email to by Procaps) followed by a hard copy sent by fax.

(or such other email address as provided

(Remainder of page intentionally left blank.)

Π	IN WITNESS WHEREOF, the Parties by their duly authorized representatives have executed this Agreement as of the Effective Date.					
GALEC	TIN THERAPEUTICS, INC.					
By:						
Name:	Dr. Peter G. Traber	<u>.</u>				
Title:	CEO and President	<u>.</u>				
PROCA	PS S.A.					
By:		<u>.</u>				
Name:	Ruben Minski					
Title:	President	<u>.</u>				

### Exhibit A LICENSED MARKS

 $Trademarks, trade \ names, brands, logos\ and\ symbols\ for\ GM-CT-01\ (DAVANAT \circledR)\ in\ Latin\ America\ to\ be\ agreed\ upon\ by\ Procaps\ and\ by\ Galectin\ The rapeutics.$ 

# Exhibit B SPECIFICATIONS

The specifications shall be those specifications for the Compound set forth in the Technical Dossier to be submitted to INVIMA.

## Exhibit C MARKETING AND DISTRIBUTION PLAN

To be provided by Procaps pursuant to Section 6.2

## Exhibit D MINIMUM ANNUAL SALES TARGETS (In U.S. Dollars)

YEAR One	SALES	PATIENTS	DOSES			
One	\$ [****] million	[****]	[****]			
Two	\$ [****] million	[****]	[****]			
Three	\$ [****] million	[****]	[****]			
Four	\$ [****] million	[****]	[****]			
[****]	[****]	[****]	[****]			
Metric for Contract						
	Minimums	example	example			

# Exhibit E CURRENT AND FUTURE PROCAPS ONCOLOGY PRODUCTS

To be provided by Procaps before Regulatory Approval

#### Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934

#### I, Peter G. Traber, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Galectin Therapeutics, Inc;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or cause such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2011 /s/ Peter G. Traber

Name: Peter G. Traber, M.D.

Title: Chief Executive Officer and President

(principal executive officer)

#### Certification Pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934

#### I, Anthony D. Squeglia, certify that:

- 1. I have reviewed this quarterly report on Form 10-Q of Galectin Therapeutics, Inc;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or cause such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2011 /s/ Anthony D. Squeglia

Name: Anthony D. Squeglia Title: Chief Financial Officer

(principal financial and accounting officer)

## CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Galectin Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2011 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Peter G. Traber, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 10, 2011 /s/ Peter G. Traber

Name: Peter G. Traber, M.D.

Title: Chief Executive Officer and President

(principal executive officer)

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Galectin Therapeutics, Inc. and will be retained by Galectin Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

## CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Galectin Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2011 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Anthony D. Squeglia, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 10, 2011 /s/ Anthony D. Squeglia

Name: Anthony D. Squeglia Title: Chief Financial Officer

(principal financial and accounting officer)

A signed original of this written statement required by Section 906, or other document authenticating, acknowledging, or otherwise adopting the signature that appears in typed form within the electronic version of this written statement required by Section 906, has been provided to Galectin Therapeutics, Inc. and will be retained by Galectin Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.