GALECTIN THERAPEUTICS INC Form 10-Q August 14, 2018 Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

Quarterly report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 For the quarterly period ended June 30, 2018

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

Commission File No. 001-31791

GALECTIN THERAPEUTICS INC.

Nevada (State or other jurisdiction 04-3562325 (I.R.S. Employer

Table of Contents

of incorporation)

4960 Peachtree Industrial Blvd.,

Identification No.) 30071

(Zip Code)

Suite 240, Norcross, GA (Address of Principal Executive Offices)

(678) 620-3186

(Registrant s Telephone Number, Including Area Code)

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

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

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

Large Accelerated Filer		Accelerated Filer
Non-Accelerated Filer	on-Accelerated Filer (Do not check if a smaller reporting company)	
		Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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

The number of shares outstanding of the registrant s common stock as of August 8, 2018 was 40,913,855.

GALECTIN THERAPEUTICS INC.

INDEX TO FORM 10-Q

FOR THE QUARTER ENDED JUNE 30, 2018

PART I FINANCIAL INFORMATION

ITEM 1.	Unaudited Condensed Consolidated Financial Statements	
	Condensed Consolidated Balance Sheets as of June 30, 2018 and December 31, 2017	
	(unaudited)	3
	Condensed Consolidated Statements of Operations for the Three and Six Months Ended	
	June 30, 2018 and 2017 (unaudited)	4
	Condensed Consolidated Statements of Cash Flows for the Three and Six Months Ended	
	June 30, 2018 and 2017 (unaudited)	5
	Notes to Unaudited Condensed Consolidated Financial Statements	6
ITEM 2.	Management s Discussion and Analysis of Financial Condition and Results of Operations	10
ITEM 3.	Quantitative and Qualitative Disclosures about Market Risk	18
ITEM 4.	Controls and Procedures	18
	PART II OTHER INFORMATION	
ITEM 1	Legal Proceedings	19

ITEM 1.	Legal Proceedings	19
ITEM 1A.	Risk Factors	19
ITEM 2.	Unregistered Sales of Equity Securities and Use of Proceeds	19
ITEM 3.	Defaults Upon Senior Securities	19
ITEM 4.	Mine Safety Disclosures	19
ITEM 5.	Other Information	19
ITEM 6.	<u>Exhibits</u>	19
SIGNATU	RES	20

2

PAGE

GALECTIN THERAPEUTICS INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

	J	une 30, 2018		ember 31, 2017
		(in th	ousand	S)
ASSETS Current assets:				
	\$	10,497	\$	3,053
Cash and cash equivalents Prepaid expenses and other current assets	Φ	541	Φ	3,033 766
Prepaid expenses and other current assets		541		700
Total current assets		11,038		3,819
Other		172		342
Total assets	\$	11,210	\$	4,161
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS EQUITY (DEFICIT)				
Current liabilities:				
Accounts payable	\$	220	\$	608
Accrued expenses		1,148		2,292
Accrued dividends payable		67		68
Total current liabilities		1,435		2,968
Total liabilities		1,435		2,968
Commitments and contingencies (Note 9)				
Series C super dividend convertible preferred stock; 1,000 shares authorized, 176				
shares issued and outstanding at June 30, 2018 and December 31, 2017,				
redemption value: \$7,983,000, liquidation value: \$1,760,000 at June 30, 2018		1,723		1,723
Stockholders equity (deficit):				
Undesignated stock, \$0.01 par value; 20,000,000 shares authorized, 20,000,000				
designated at June 30, 2018 and December 31, 2017, respectively				
Series A 12% convertible preferred stock; 1,742,500 shares authorized, 1,352,500				
and 1,377,500 issued and outstanding at June 30, 2018 and December 31, 2017,				
respectively, liquidation value \$1,352,500 at June 30, 2018		547		557
Series B-1 12% convertible preferred stock; 900,000 shares authorized, issued and				
outstanding at June 30, 2018 and December 31, 2017, liquidation value				
\$1,800,000 at June 30, 2018		1,761		1,761
Series B-2 12% convertible preferred stock; 2,100,000 shares authorized, issued				
and outstanding at June 30, 2018 and December 31, 2017, liquidation value		2 607		2 607
\$4,200,000 at June 30, 2018		3,697		3,697
		1,224		1,224

Series B-3 8% convertible preferred stock; 2,508,000 shares authorized, 2,508,000 issued and outstanding at June 30, 2018 and December 31, 2017, liquidation value \$2,508,000 at June 30, 2018		
Common stock, \$0.001 par value; 100,000,000 and 50,000,000 shares authorized		
at June 30, 2018 and December 31, 2017, respectively, 40,628,183 and 35,789,388		
issued and outstanding at June 30, 2018 and December 31, 2017, respectively	41	36
Additional paid-in capital	190,602	173,363
Retained deficit	(189,820)	(181,168)
Total stockholders equity (deficit)	8,052	(530)
Total liabilities, redeemable convertible preferred stock and stockholders equity(deficit)	\$ 11,210	\$ 4,161

See notes to unaudited condensed consolidated financial statements.

GALECTIN THERAPEUTICS INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)

		Three Months Ended June 30,			Six Months Endo June 30,				
		2018		2017		2018		2017	
	(in thou	isands, exce	ept pe	r share d in	atho	usands, exc	ept p	er share data	
Operating expenses:									
Research and development	\$	1,476	\$	3,444	\$	3,774	\$	7,216	
General and administrative		2,283		1,070		4,163		2,244	
Total operating expenses		3,759		4,514		7,937		9,460	
Total operating loss		(3,759)		(4,514)		(7,937)		(9,460)	
Other income (expense):									
Interest income		4		6		8		15	
Interest expense		(85)				(169)			
Total other income (expense)		(81)		6		(161)		15	
Net loss	\$	(3,840)	\$	(4,508)	\$	(8,098)	\$	(9,445)	
Preferred stock dividends		(268)		(301)		(553)		(573)	
Net loss applicable to common stockholders	\$	(4,108)	\$	(4,809)	\$	(8,651)	\$	(10,018)	
Net loss per common share basic and diluted	l \$	(0.11)	\$	(0.14)	\$	(0.23)	\$	(0.29)	
Weighted average common shares outstanding basic		· · · ·		· · · ·					
and diluted		38,227		34,692		37,755		34,312	
See notes to unaudite	d conder	nsed consolid	See notes to unaudited condensed consolidated financial statements.						

GALECTIN THERAPEUTICS INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

	Six Montl June 2018 (in thou	e 30, 2017
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (8,098)	\$ (9,445)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization		1
Stock-based compensation expense	2,630	599
Issuance of common stock for services	10	18
Non-cash interest expense	169	
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	226	230
Accounts payable and accrued expenses	(1,532)	(268)
Net cash used in operating activities	(6,595)	(8,865)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from issuance of common stock and warrants	14,039	2,630
	- ,,,	_,
Net cash provided by financing activities	14,039	2,630
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	7,444	(6,235)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	3,053	15,362
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 10,497	\$ 9,127
NONCASH FINANCING ACTIVITIES:		
Payment of preferred stock dividends in common stock	\$ 553	\$ 573
See notes to unaudited condensed consolidated financial statements.		

GALECTIN THERAPEUTICS INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Basis of Presentation

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

The unaudited condensed consolidated financial statements as reported in this Quarterly Report on Form 10-Q reflect all adjustments which are, in the opinion of management, necessary to present fairly the financial position of the Company as of June 30, 2018 and the results of its operations for the three and six months ended June 30, 2018 and 2017 and its cash flows for the six months ended June 30, 2018 and 2017. All adjustments made to the interim financial statements include all those of a normal and recurring nature. Amounts presented in the condensed consolidated balance sheet as of December 31, 2017 are derived from the Company s audited consolidated financial statements as of that date, but do not include all of the information and footnotes required by accounting principles generally accepted in the United States of America for complete 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 that 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, 2017.

The Company has operated at a loss since its inception and has had no significant revenues. The Company anticipates that losses will continue for the foreseeable future. At June 30, 2018, the Company had \$10.5 million of unrestricted cash and cash equivalents available to fund future operations. The Company believes there is sufficient cash, including availability of the line of credit (discussed in Note 3 below), to fund currently planned operations at least through June 30, 2019. The Company s ability to fund operations after its current cash resources are exhausted depends on its ability to obtain additional financing or achieve profitable operations, as to which no assurances can be given. Accordingly, based on the forecasts and estimates underlying the Company s current operating plan, the financial statements do not currently include any adjustments that might be necessary if the Company is unable to continue as a going concern.

The Company was founded in July 2000, was incorporated in the State of Nevada in January 2001 under the name Pro-Pharmaceuticals, Inc., and changed its name to Galectin Therapeutics Inc. on May 26, 2011.

2. Accrued Expenses

Accrued expenses consist of the following:

June 30, December 31, 2018 2017

		(in thousands)		
Legal and accounting fees	\$	77	\$	74
Accrued compensation		692		790
Accrued research and development costs and other		379		1,428
Total	\$ 1	,148	\$	2,292

3. Line of Credit

On December 19, 2017, the Company entered into a \$10 million Line of Credit arrangement with Richard E. Uihlein, a director and shareholder who has an approximate 7% ownership interest in the Company on a fully-diluted basis at December 31, 2017. Borrowings may be made by the Company through December 31, 2018. Borrowings bear interest at the Applicable Federal Rate for short term loans published by the Internal Revenue Service (1.51% on December 19, 2017). All borrowings and interest are due on December 31, 2019 but may be prepaid without penalty. In connection with the Line of Credit agreement, the Company issued to Mr. Uihlein warrants to purchase 1 million shares of the Company s common stock for \$5 per share. Half of the warrants vested at closing of the Line of Credit and the other half vest ratably with borrowings under the agreement. There have been no borrowings under the Line of Credit through June 30, 2018.

The fair value of the 500,000 warrants vested at closing was \$696,000 at the date of issuance based on the following assumptions: an expected life of 7 years, volatility of 98%, risk free interest rate of 2.05% and zero dividends. The fair value of the vested warrants was recorded in other current assets and other assets (non-current) as a deferred financing cost and will be amortized

on a straight-line basis from December 19, 2017 through December 31, 2019. Amortization for the three and six months ended June 30, 2018 of \$85,000 and \$169,000, respectively, was recorded as interest expense. The fair value of warrants that vest in the future based on borrowings will be computed when those borrowings occur and amortized over the remaining period through December 31, 2019.

4. Stock-Based Compensation

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

	Three Months Ended June 30,			Six Months Ende June 30,			
		2018	2	017		2018	2017
Research and development	\$	627	\$	132	\$	1,161	\$ 301
General and administrative		816		137		1,469	298
Total stock-based compensation expense	\$	1,443	\$	269	\$	2,630	\$ 599

The following table summarizes the stock option activity in the Company s equity incentive plans, including non-plan grants to Company executives, from December 31, 2017 through June 30, 2018:

		Weight	ed Average
	Shares	Exerc	cise Price
Outstanding, December 31, 2017	5,155,263	\$	4.11
Granted	1,001,875		5.02
Exercised	(1,829,525)		1.79
Options forfeited/cancelled	(33,334)		6.24
Outstanding, June 30, 2018	4,294,279	\$	5.30

As of June 30, 2018, there was \$1,819,000 of unrecognized compensation related to 1,140,318 unvested options, which is expected to be recognized over a weighted average period of approximately 0.5 years. The weighted-average grant date fair value for options granted during the three months ended June 30, 2018 was \$3.98. The Company granted 460,000 stock options In January 2018, of which 115,000 options vested upon grant with the remaining 345,000 options vesting over the remainder of 2018. Approximately \$526,000 of non-cash, stock-based compensation expense was recorded during the three months ended March 31, 2018 related to the options granted in January 2018 that vested upon the grant date. Additionally, Company granted 506,875 stock options during May 2018, of which 115,000 options vesting over the remaining 391,875 options vesting over the remainder of 2018. Approximately \$433,000 of non-cash, stock-based compensation expense was recorded during the three months ended merch 30, 2018 related to the remainder of 2018. Approximately \$433,000 of non-cash, stock-based compensation expense was recorded during the three months ended stock options vesting over the remainder of 2018. Approximately \$433,000 of non-cash, stock-based compensation expense was recorded during the three months ended June 30, 2018 related to the options granted in May 2018 that vested upon the grant date.

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

	Six	Six
	Months Ended	Months Ended
	June 30,	June 30,
	2018	2017
Risk-free interest rate	2.47%	
Expected life of the options	5.7 years	
Expected volatility of the underlying stock	104%	
Expected dividend rate	0%	

5. Common Stock Warrants

The following table summarizes the common stock warrant activity from December 31, 2017 through June 30, 2018:

	Shares	•	ed Average ise Price
Outstanding, December 31, 2017	13,229,778	\$	3.35
Granted	267		5.15
Exercised	(2,414,709)		2.50
Forfeited/cancelled			
Outstanding, June 30, 2018	10,815,336	\$	3.53

6. Fair Value of Financial Instruments

At times, the Company has certain financial assets and liabilities recorded at fair value. Fair values determined by Level 1 inputs utilize observable data such as quoted prices in active markets. Fair values determined by Level 2 inputs utilize data points other than quoted prices in active markets that are observable either directly or indirectly. Fair values determined by Level 3 inputs utilize unobservable data points in which there is little or no market data, which require the reporting entity to develop its own assumptions. The carrying amounts reflected in the consolidated balance sheets for cash equivalents, accounts payable and accrued expenses approximate their carrying value due to their short-term nature. There were no level 2 or level 3 assets or liabilities at June 30, 2018 or December 31, 2017.

7. Loss Per Share

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

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:

	June 30, 2018	June 30, 2017
	(shares)	(shares)
Warrants to purchase shares of common stock	10,815,336	12,249,189
Options to purchase shares of common stock	4,294,279	4,656,888
Shares of common stock issuable upon conversion of		
preferred stock	4,308,115	4,312,282