Galmed Pharmaceuticals

Galmed Pharmaceuticals Reports Third Quarter 2016 Financial Results and Provides Business Update

- Conference Call and Webcast Today at 8:30 a.m. EST / 5:30 a.m. PST -

TEL AVIV, Israel, Nov. 7, 2016 /PRNewswire/ -- Galmed Pharmaceuticals Ltd. (Nasdaq: GLMD) ("Galmed" or the "Company"), a clinical-stage biopharmaceutical company focused on the development of a once-daily, oral therapy for the treatment of nonalcoholic steatohepatitis, or NASH, and liver diseases, today reported financial results for the three and nine months ended September 30, 2016. The Company will host a conference call and webcast today to discuss the financial results and to provide an update on current developments with respect to its clinical programs for Aramchol™.

"Recruitment for the ARREST Study continues to trend according to our expectations," stated Allen Baharaff, Galmed's President and Chief Executive Officer." As of November 6, 2016, we had randomized 182 patients and have another 11 subjects that are eligible to be randomized. In addition, 130 subjects are currently in the screening process, which normally takes between 4-6 weeks. Based on this, we continue to expect to complete the full recruitment of 240 patients by the end of the fourth quarter, 2016."

As we previously reported on March 30, 2016, we have data demonstrating significant anti-fibrotic activity of Aramchol™ in MCD diet in mice suggesting potential effect of Aramchol in NASH induced fibrosis. We have also received additional data showing similar results in our other pre-clinical models which will be submitted for presentation at EASL.

During the quarter, we continued to bolster our medical and scientific leadership. Specifically, we announced the appointment of Professor Ran Oren, M.D., as Chief Medical Officer, as well as the appointment of Dr. Liat Hayardeny, Ph.D. MBA, as Chief Scientific Officer. Dr. Oren was a scientific collaborator of the Company's Co-Founder, the late Professor Tuvia Gilat, and has served as a member of Galmed's Scientific Advisory Board since 2014, as well as previously serving as the principal investigator of Aramchol's Phase IIa study. Dr. Oren currently serves as Professor of Gastroenterology & Hepatology at the Faculty of Medicine, the Hebrew University of Jerusalem, as well as the Head of the Institute of Gastroenterology and Liver Disease at Hadassah Medical Center. Dr. Hayardeny joins Galmed with 16 years of experience in drug development in the global R&D division at Teva Pharmaceuticals, where she served as Senior Director, Head of Research Scientific Affairs. In that capacity, Dr. Hayardeny established the scientific positioning of Teva's major innovative compounds. In addition, Dr. Hayardeny managed Teva's global research collaborations, as well as publications.

Josh Blacher, the Company's Chief Financial Officer, has notified the Company of his wish to leave the Company to pursue other opportunities, effective January 31, 2017.

The Company accepted Mr. Blacher's decision and intends to appoint a new CFO in due course. In the meantime, CPA Yohai Stenzler, the Company's director of finance, will act as interim CFO. Mr. Stenzler joined the Company in June 2014 with about 6 years' experience as an auditor at Ernst & Young LLP. With his accounting and finance expertise and extensive experience in his current role as director of finance, Mr. Stenzler is well-positioned to lead the Finance function through this transition period.

"I would like to personally thank Josh for his contribution to the Company since he joined two years ago. Josh has been a strong leader and valuable colleague, and was instrumental in many of Galmed's accomplishments during his tenure with the Company. We wish Josh well in his future endeavors," commented Mr. Baharaff, Galmed's President and Chief Executive Officer.

As previously disclosed during the quarter, we executed a license agreement (the "Agreement") with SAMIL Pharm. Co., Ltd. ("Samil") for an exclusive, royalty-bearing license for the commercialization of Aramchol™ for the treatment of fatty liver indications including nonalcoholic steatohepatitis, or NASH, in the Republic of Korea (the "License"). According to the Agreement, Galmed received a gross up-front fee of $2.1 million, which is reflected in this quarter's financial statements. Samil has also agreed to pay additional clinical- and regulatory-based milestone payments, which may aggregate up to an additional $6.0 million, as well as tiered, double-digit royalties payable on sales (under certain limitations).

Financial Summary - Third Quarter 2016 vs. Third Quarter 2015:

- Net loss of $3.8 million, or $0.34 per share, for the three months ended September 30, 2016, compared to a net loss of $2.6 million, or $0.23 per share, for the three months ended September 30, 2015. This period's net loss included $0.2 million of non-cash, stock-based compensation expense, versus $0.2 million of non-cash stock-based compensation expense incurred during the corresponding period in 2015.
- The Company recognized $0.2 million of revenue for the three months ended September 30, 2016, compared to no revenue for the three months ended September 30, 2015. The revenue in this quarter relates to the amortization of the up-front payments under the Agreement with Samil. The remaining unamortized up-front payment of $1.9 million is reflected on the balance sheet as short-term and long-term portion of deferred revenue and will be amortized on a straight-line method.
- Research and development expenses of $3.3 million for the three months ended September 30, 2016, compared to $1.9 million for the three months ended September 30, 2015. The increase primarily resulted from an increase in research and development subcontractor expenses of $1.3 million resulting from the substantial growth in screening and randomization in connection with the ARREST Study.
- General and administrative expenses of $0.7 million for the three months ended September 30, 2016, compared to $0.6 million for the three months ended September 30, 2015.
- Financial income of $0.1 million for the three months ended September 30, 2016, compared to a financial expense of $0.1 million for the three months ended September 30, 2015. The increase primarily resulted from foreign currency exchange rate movements.
- Cash and cash equivalents and marketable securities totaled $18.3 million as of September 30, 2016, compared to $23.0 million at December 31, 2015. This decrease primarily resulted from $9.3 million used in operating activities, mainly due to our ongoing clinical studies and operational activities, which was partially offset by net proceeds of approximately $4.5 million raised through our ATM offering.

Conference Call & Webcast

Monday, November 7th, 2016, 8:30 am Eastern Time / 5:30 am Pacific Time

Participant Dial-In Numbers:

Toll-Free:	+1-888-259-8885
Toll/International:	+1-913-312-1521
Conference ID:	2611728
Webcast:	http://galmedpharma.investorroom.com/events

Replay, available until November 21, 2016

Replay Dial-In Numbers:

Toll-Free:	+1-877-870-5176

Toll/International:	+1-858-384-5517
Passcode:	2611728

About Nonalcoholic Fatty Liver Disease and Nonalcoholic Steatohepatitis:

Nonalcoholic fatty liver disease (NAFLD) is the most common cause of chronic liver disease inthe United States and it affects almost 30% of adults in Western countries. With climbing obesity rates and more sedentary patient populations, the prevalence of NAFLD is increasing worldwide and is becoming the predominant cause of chronic liver disease in parts of the world. NAFLD represents a spectrum of diseases ranging from simple excess liver fat, or steatosis, to nonalcoholic steatohepatitis (NASH). NASH is the progressive form of fatty liver disease that can lead to cardiovascular disease, cirrhosis and liver-related mortality in persons who drink little or no alcohol. NASH represents the more severe end of this spectrum and is characterized by steatosis, ballooning degeneration and lobular inflammation with or without fibrosis. Long-term risks of NASH include cardiovascular disease, cirrhosis, hepatocellular carcinoma and end stage liver disease requiring liver transplantation.

About Galmed Pharmaceuticals Ltd.:

Galmed is a clinical-stage biopharmaceutical company focused on the development of a novel, once-daily, oral therapy for the treatment of nonalcoholic steatohepatitis, or NASH and liver diseases utilizing its proprietary first-in-class family of synthetic fatty-acid/bile-acid conjugates, or FABACs. Galmed believes that its product candidate, Aramchol^{TM}, has the potential to be a disease modifying treatment for fatty liver disorders, including NASH, which is a chronic disease that Galmed believes constitutes a large unmet medical need. Galmed is currently conducting the ARREST Study, a multicenter, randomized, double blind, placebo-controlled Phase IIb clinical study designed to evaluate the efficacy and safety of Aramchol^{TM} in subjects with NASH, who are overweight or obese, and who are pre-diabetic or type-II-diabetic. More information about the ARREST Study may be found on ClinicalTrials.gov identifier: NCT02279524.

Forward-Looking Statements:

This press release may include forward-looking statements. Forward-looking statements may include, but are not limited to, statements relating to Galmed's objectives, plans and strategies, as well as statements, other than historical facts, that address activities, events or developments that Galmed intends, expects, projects, believes or anticipates will or may occur in the future. These statements are often characterized by terminology such as "believes," "hopes," "may," "anticipates," "should," "intends," "plans," "will," "expects," "estimates," "projects," "positioned," "strategy" and similar expressions and are based on assumptions and assessments made in light of management's experience and perception of historical trends, current conditions, expected future developments and other factors believed to be appropriate. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statements. Applicable risks and uncertainties include risks and uncertainties associated with the initiation, timing, progress and results of the Company's research, preclinical studies and clinical trials as well as risks and uncertainties identified under the heading "Risk Factors" included in Galmed's most recent Annual Report on Form 20-F filed with the Securities and Exchange Commission, or the SEC, on March 22, 2016, and in other filings that Galmed has made and may make with the SEC in the future. The forward-looking statements contained in this press release are made as of the date of this press release and reflect Galmed's current views with respect to future events, and Galmed does not undertake and specifically disclaims any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

GALMED PHARMACEUTICALS LTD.

Consolidated Balance Sheets

U.S. Dollars in thousands, except share data and per share data

	As of September 30, 2016	As of December 31, 2015
	Unaudited	Audited
Assets		
Current assets		
Cash and cash equivalents	$ 7,035	$ 4,156
Marketable securities	11,272	18,845
Other accounts receivable	366	379
Total current assets	18,673	23,380
Property and equipment, net	791	883
Total assets	$ 19,464	$ 24,263
Liabilities and stockholders' equity		
Current liabilities		
Trade payables	$ 1,703	$ 2,259
Other accounts payable	112	282
Short-term portion of deferred revenue	1,045	-
Total current liabilities	2,860	2,541
Long-term liabilities		
Related parties	222	177
Long-term portion of deferred revenue	852	-
Total long-term liabilities	1,074	177
Stockholders' equity:		
Ordinary shares par value NIS 0.01 per share; Authorized 50,000,000; Issued and outstanding: 12,149,226 shares as of September 30, 2016; 11,100,453 shares as of December 31, 2015	34	32
Additional paid-in capital	75,125	69,086
Accumulated other comprehensive loss	(135)	(206)
Accumulated deficit	(59,494)	(47,367)
Total stockholders' equity	15,530	21,545
Total liabilities and stockholders' equity	$ 19,464	$ 24,263

GALMED PHARMACEUTICALS LTD.

Consolidated Statements of Operations (Unaudited)

U.S. Dollars in thousands, except share data and per share data

	Three months ended September 30,		Nine months ended September 30,	
	2016	**2015**	**2016**	**2015**
Revenue	$ 193	$ -	$ 193	$ -
Research and development expenses	3,342	1,860	10,086	4,853
General and administrative expenses	656	637	2,236	2,677
Total operating expenses	3,805	2,497	12,129	7,530
Financial expenses (income), net	(78)	103	(108)	(113)
Loss before income taxes	3,727	2,600	12,021	7,417
Taxes on Income	105	-	106	-
Net loss	$ 3,832	$ 2,600	$ 12,127	$ 7,417
Basic and diluted net loss per share	$ 0.34	$ 0.23	$ 1.09	$ 0.67
Weighted-average number of shares outstanding used in computing basic and diluted net loss per share	11,150,023	11,100,453	11,101,360	11,100,453

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Consolidated Statements of Cash Flows (Unaudited)

U.S. Dollars in thousands

	Nine months ended September 30,	
	2016	**2015**
Cash flow from operating activities		
Net loss	$ (12,127)	$ (7,417)
Adjustments required to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	118	32
Stock-based compensation expense	1,307	1,130
Amortization of discount/premium on marketable securities	18	195
Loss from Realization of marketable securities	150	-
Changes in operating assets and liabilities:		
Decrease (increase) in other accounts receivable	13	(181)

Increase (decrease) in trade payables	(556)	251
Decrease in other accounts payable	(173)	(43)
Increase in deferred revenue from collaboration agreement	1,897	-
Increase (decrease) in related party	45	(213)
Net cash used in operating activities	(9,305)	(6,246)
Cash flow from investing activities		
Purchase of property and equipment	(26)	(160)
Maturity of short term deposit	-	6,000
Investment in securities, available for sale	(2,480)	(25,132)
Maturity of securities, available for sale	9.956	6,265
Net cash provided in (used in) investing activities	7,450	(13,027)
Cash flow from financing activities		
Proceeds from issuance of stock offerings, net of issuance costs	4,479	-
Proceeds from exercise of options	255	-
Net cash used in financing activities	4,734	-
Increase (decrease) in cash and cash equivalents	2,879	(19,273)
Cash and cash equivalents at the beginning of the year	4,156	23,736
Cash and cash equivalents at the end of the period	$ 7,035	$ 4,463
Supplemental disclosure of cash flow information:		
Cash received from interest	$ 319	370

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Notes to Consolidated Statements of Operations (unaudited)

U.S. Dollars in thousands

Research and Development Expenses:

	Three months ended September 30,	
	2016	**2015**
	(in thousands)	
Chemistry and formulation studies	$ 448	$ 372
Salaries and benefits	217	196
Stock-based compensation	95	88
Research and preclinical studies	122	139
Clinical studies	2,373	1,028

Regulatory and other expenses	87	37
	$ 3,342	$ 1,860

General and Administrative Expenses:

	Three months ended September 30,	
	2016	**2015**
	(in thousands)	
Stock-based compensation	$ 148	$ 151
Professional fees	136	153
Salaries and benefits	197	129
Rent and office-maintenance fees	92	59
Investor relations and business development	74	142
Other	9	3
	$ 656	$ 637

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SOURCE Galmed Pharmaceuticals Ltd.

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Additional assets available online: Photos (1)

https://galmedpharma.investorroom.com/2016-11-07-Galmed-Pharmaceuticals-Reports-Third-Quarter-2016-Financial-Results-and-Provides-Business-Update