Galmed Pharmaceuticals

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

- Conference Call and Webcast Today at 8:30 a.m. EDT / 5:30 a.m. PDT -

TEL AVIV, Israel, Aug. 3, 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 liver diseases, today reported financial results for the three and six months ended June 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™.

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

- Net loss of $4.3 million, or $0.39 per share, for the three months ended June 30, 2016, compared to a net loss of $2.4 million, or $0.21 per share, for the three months ended June 30, 2015. This period's net loss included $0.8 million of non-cash, stock-based compensation expense, versus $0.3 million of non-cash stock-based compensation expense incurred during the corresponding period in 2015.
- Research and development expenses ("R&D") of $3.4 million for the three months ended June 30, 2016, compared to $1.6 million for the three months ended June 30, 2015. The increase resulted primarily from an increase in research and development subcontractor expenses of $1.3 million which was primarily a result of the growth in patient randomization in connection with the ARREST Study, as well an increase of $0.5 million of non-cash stock-based compensation expense.
- General and administrative expenses of $0.9 million for the three months ended June 30, 2016, compared to $1.0 million for the three months ended June 30, 2015. The decrease in general and administrative expenses for the three months ended June 30, 2016 resulted primarily from our ongoing efforts to reduce non-R&D related expenses.
- Financial expense of $0.1 million for the three months ended June 30, 2016, compared to financial income of $0.2 million for the three months ended June 30, 2015. The financial expense for the three months ended June 30, 2016 resulted primarily from changes in the foreign currency exchange rate.
- Cash and cash equivalents and marketable securities totaled $16.7 million as of June 30, 2016, compared to $23.0 million at December 31, 2015. The decrease in cash resulted primarily from the costs of our ongoing clinical studies and operational activities. Galmed expect that its cash balance will be sufficient to maintain its current operations through the second half of 2017.

"Importantly, and as reflected in the significant increase in R&D activities, and associated expenses, we believe that the momentum we are currently experiencing in the ARREST Study continues to support our previously stated guidance regarding patient recruitment," stated Allen Baharaff, Galmed's President and Chief Executive Officer. "As of July 31, 2016, we had randomized 132 patients and have another 27 subjects that are eligible to be randomized. In addition, 41 subjects are currently in the screening process, which normally takes between 6-8 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 previously disclosed on July 28, 2016, we executed a license agreement (the "Agreement") with SAMIL Pharm.

Co., Ltd. ("Samil") for an exclusive, royalty-bearing license for the commercialization of Aramchol™ (with an option to manufacture) for the treatment of fatty liver indications including nonalcoholic steatohepatitis, or NASH, in the Republic of Korea (the "License"). According to the Agreement, Galmed will receive an up-front fee of $2.0 million. 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). The funds provided by this Agreement will provide additional financing for Galmed's development programs. Additionally, following the ARREST Study, Samil has an option to extend the License to Vietnam, which, if exercised, would increase the clinical- and regulatory-based milestone payments.

In addition, we also announced on August 1, 2016 that we had appointed Professor Ran Oren, M.D., as Chief Medical Officer ("CMO"), effective as of August 1, 2016. Dr. Oren currently serves as Professor of Gastroenterology & Hepatology at the Faculty of Medicine, the Hebrew University of Jerusalem, Israel, as well as the Head of the Institute of Gastroenterology and Liver Disease at Hadassah medical center, Jerusalem, Israel ("Hadassah"). Dr. Oren will serve as CMO while maintaining his ongoing commitments at Hebrew University and Hadassah.

Conference Call & Webcast:

Wednesday, August 3rd, 2016, 8:30 am Eastern Time / 5:30 am Pacific Time

Participant Dial-In Numbers:

Toll-Free:	+1-888-364-3108
Toll/International:	+1-719-457-2697
Conference ID:	3984671
Webcast:	http://galmedpharma.investorroom.com/events

Replay, available until August 17, 2016

Replay Dial-In Numbers:

Toll-Free:	+1-877-870-5176
Toll/International:	+1-858-384-5517
Passcode:	3984671

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 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™, 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™ 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 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 June 30, 2016	As of December 31, 2015
	Unaudited	Audited
Assets		
Current assets		
Cash and cash equivalents	$ 2,946	$ 4,156
Marketable securities	13,736	18,845
Other accounts receivable	479	379
Total current assets	17,161	23,380
Property and equipment, net	840	883
Total assets	$ 18,001	$ 24,263
Liabilities and stockholders' equity		
Current liabilities		
Trade payables	$ 2,965	$ 2,259
Other accounts payable	388	282
Total current liabilities	3,353	2,541

Long-term liabilities		
Related parties	222	177
Total long-term liabilities	222	177
Stockholders' equity:		
Ordinary shares par value NIS 0.01 per share; Authorized 50,000,000; Issued and outstanding: 11,102,753 shares as of June 30, 2016; 11,100,453 shares as of December 31, 2015	32	32
Additional paid-in capital	70,160	69,086
Accumulated other comprehensive loss	(104)	(206)
Accumulated deficit	(55,662)	(47,367)
Total stockholders' equity	14,426	21,545
Total liabilities and stockholders' equity	$ 18,001	$ 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 June 30,		Six months ended June 30,	
	2016	**2015**	**2016**	**2015**
Research and development expenses	$ 3,360	$ 1,562	$ 6,744	$ 2,993
General and administrative expenses	861	967	1,580	2,040
Total operating expenses	4,221	2,529	8,324	5,033
Financial expenses (income), net	89	(175)	(30)	(216)
Loss before income taxes	4,310	2,354	8,294	4,817
Taxes on Income	1	-	1	-
Net loss	$ 4,311	$ 2,354	$ 8,295	$ 4,817
Basic and diluted net loss per share	$ 0.39	$ 0.21	$ 0.75	$ 0.43
Weighted-average number of shares outstanding used in computing basic and diluted net loss per share	11,100,853	11,100,453	11,100,655	11,100,453

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Consolidated Statements of Cash Flows (Unaudited)

U.S. Dollars in thousands

	Six months ended June 30,	
	2016	**2015**
Cash flow from operating activities		
Net loss	$ (8,295)	$ (4,817)
Adjustments required to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	66	13
Stock-based compensation expense	1,063	890
Amortization of discount/premium on marketable securities	35	(27)
Loss from Realization of marketable securities	138	-
Changes in operating assets and liabilities:		
Decrease (Increase) in other accounts receivable	43	(220)
Increase (decrease) in trade payables	706	354
Increase in other accounts payable	106	29
Increase (decrease) in related party	45	(206)
Net cash used in operating activities	(6,093)	(3,984)
Cash flow from investing activities		
Purchase of property and equipment	(23)	(154)
Maturity of short term deposit	-	6,000
Investment in securities, available for sale	(1,212)	(21,839)
Maturity of securities, available for sale	6,250	3,565
Net cash provided in (used in) investing activities	5,015	(12,428)
Cash flow from financing activities		
Issuance of ordinary shares	11	-
Deferred Issuance costs	(143)	-
Net cash used in financing activities	(132)	-
Increase (decrease) in cash and cash equivalents	1,210	(16,412)
Cash and cash equivalents at the beginning of the year	4,156	23,736
Cash and cash equivalents at the end of the period	$ 2,946	$ 7,324

Supplemental disclosure of cash flow information:

Cash received from interest	$ 223	245

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Notes to Consolidated Statements of Operations (unaudited)

U.S. Dollars in thousands

Research and Development Expenses:

	Three months ended June 30,	
	2016	**2015**
	(in thousands)	
Chemistry and formulation studies	$ 210	$ 325
Salaries and benefits	240	203
Stock-based compensation	523	35
Research and preclinical studies	162	144
Clinical studies	2,043	783
Regulatory and other expenses	183	72
	$ 3,360	$ 1,562

General and Administrative Expenses:

	Three months ended June 30,	
	2016	**2015**
	(in thousands)	
Stock-based compensation	$ 267	$ 296
Professional fees	225	222
Salaries and benefits	212	188
Rent and office-maintenance fees	71	110
	83	148
Investor relations and business Development	3	3
Other	$ 861	$ 967

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SOURCE Galmed Pharmaceuticals Ltd.

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Additional assets available online: Photos (1)

https://galmedpharma.investorroom.com/2016-08-03-Galmed-Pharmaceuticals-Reports-Second-Quarter-2016-Financial-Results-and-Provides-Business-Update