Galmed Pharmaceuticals

Galmed Pharmaceuticals Reports First Quarter 2017 Financial Results

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

TEL AVIV, Israel, May 15, 2017 /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 other liver diseases, today reported financial results for the three months ended March 31, 2017. The Company will host a conference call and webcast today to discuss the financial results.

Financial Summary – First Quarter 2017 vs. First Quarter 2016:

- Net loss of $3.2 million, or $0.26 per share, for the three months ended March 31, 2017, compared to a net loss of $4.0 million, or $0.36 per share, for the three months ended March 31, 2016. This period's net loss included $0.4 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 2016.
- The Company recognized $0.3 million of revenue for the three months ended March 31, 2017, compared to no revenue for the three months ended March 31, 2015. The revenue in this quarter relates to the amortization of the up-front payments under the Agreement with Samil.
- Research and development expenses of $2.7 million for the three months ended March 31, 2017, compared to $3.4 million for the three months ended March 31, 2016. The decrease primarily resulted from a decrease in CMC related expenses.
- General and administrative expenses of $0.8 million for the three months ended March 31, 2017, compared to $0.7 million for the three months ended March 31, 2016. The Increase primarily resulted from an increase in salaries and benefits expenses, including non-cash stock-based compensation expenses.
- Cash and cash equivalents and marketable securities totaled $11.7 million as of March 31, 2017, compared to $15.5 million at December 31, 2016. This decrease primarily resulted from $3.9 million used in operating activities, mainly due to our ongoing clinical studies and operational activities. Galmed continues to believe that its cash balance will be sufficient to maintain its current operations through the first half of 2018, and allow the Company to complete the ARREST study as scheduled.

Conference Call & Webcast:

Monday, May 15th, 2017, 8:30 am Eastern Time / 5:30 am Pacific Time

Participant Dial-In Numbers:

Toll-Free:	+1-888-587-0613
Toll/International:	+1-719-457-2082

Toll/International:	+1-719-457-2083
Conference ID:	6659068
Webcast:	http://galmedpharma.investorroom.com/events

Replay, available until May 29, 2017

Replay Dial-In Numbers:	
Toll-Free:	+1-844-512-2921
Toll/International:	+1-412-317-6671
Passcode:	6659068

About Aramchol™ and Non-alcoholic Steatohepatitis (NASH)

Aramchol™ (arachidyl amido cholanoic acid) is a novel fatty acid bile acid conjugate, inducing beneficial modulation of intra-hepatic lipid metabolism. Aramchol™'s ability to modulate hepatic lipid metabolism was discovered and validated in animal models, demonstrating down regulation of the three key pathologies of NASH; steatosis, inflammation and fibrosis. The effect of Aramchol™ on fibrosis is mediated by down regulation of steatosis and directly on human collagen producing cells. Aramchol™ has been granted by the FDA Fast Track designation status for the treatment of NASH.

NASH is an emerging world crisis impacting 3% to 5% of the U.S. population and 2% to 4% globally. It is the fastest growing cause of liver cancer and liver transplant in the U.S. due to the rise in obesity. NASH is the progressive form of non alcoholic fatty liver disease that can lead to cardiovascular disease, cirrhosis and liver-related mortality.

About Galmed Pharmaceuticals Ltd.:

Galmed is a clinical-stage biopharmaceutical company focused on the development of Aramchol™, a first in class, novel, once-daily, oral therapy for the treatment of NASH for variable populations, as well as other liver associated disorders. 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. Galmed also sponsors the ARRIVE Study, a proof-of-concept Phase IIa clinical trial designed to evaluate the safety and efficacy of Aramchol™ in up to 50 patients with HIV-associated NAFLD and lipodystrophy. The ARRIVE Study is an investigator-initiated trial, conducted at the University of California San Diego by Professor Rohit Loomba. More information about the ARREST Study and the ARRIVE Study may be found on ClinicalTrials.gov identifiers: NCT02279524 and NCT02684591, respectively.

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 23, 2017, 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 March 31, 2017	As of December 31, 2016
	Unaudited	Audited
Assets		
Current assets		
Cash and cash equivalents	$ 1,660	$ 3,097
Marketable securities	9,993	12,351
Other accounts receivable	336	284
Total current assets	11,989	15,732
Property and equipment, net	665	718
Total assets	$ 12,654	$ 16,450

Liabilities and stockholders' equity		
Current liabilities		
Trade payables	$ 2,538	$ 3,122
Other accounts payable	196	363
Short-term portion of deferred revenue	1,085	1,094
Total current liabilities	3,819	4,579
Long-term liabilities		
Related parties	267	267
Long-term portion of deferred revenue	270	529
Total long-term liabilities	537	796
Stockholders' equity:		
Ordinary shares par value NIS 0.01 per share; Authorized 50,000,000; Issued and outstanding: 12,164,983 shares as of March 31, 2017; 12,149,226 shares as of December 31, 2016	34	34
Additional paid-in capital	75,807	75,446
Accumulated other comprehensive loss	(61)	(85)
Accumulated deficit	(67,482)	(64,320)
Total stockholders' equity	8,298	11,075
Total liabilities and stockholders' equity	$ 12,654	$ 16,450

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Consolidated Statements of Operations

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

	Three months ended March 31,	
	2017	**2016**
Revenue	$ 268	$ -
Research and development expenses	2,743	3,384
General and administrative expenses	789	719
Total operating expenses	3,264	4,103

Financial income, net	(102)	(119)
Net loss	$ 3,162	$ 3,984
Basic and diluted net loss per share	$ 0.26	$ 0.36
Weighted-average number of shares outstanding used in computing basic and diluted net loss per share	12,164,983	11,100,453

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Consolidated Statements of Cash Flows (audited)

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

	Three months ended March 31,	
	2017	**2016**
Cash flow from operating activities		
Net loss	$ (3,162)	$ (3,984)
Adjustments required to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	60	32
Stock-based compensation expense	361	273
Amortization of discount/premium on marketable securities	(140)	(62)
Loss from Realization of marketable securities	78	55
Changes in operating assets and liabilities:		
Decrease (increase) in other accounts receivable	(52)	123
Increase (decrease) in trade payables	(584)	692
Decrease in other accounts payable	(167)	(209)
Decrease in deferred revenue	(268)	-
Net cash used in operating activities	(3,874)	(3,080)
Cash flow from investing activities		
Purchase of property and equipment	(7)	(8)
Consideration of securities, available for sale	2.444	2,016
Net cash provided in investing activities	2,437	2,008
Decrease in cash and cash equivalents	(1,437)	(1,072)

Cash and cash equivalents at the beginning of the year	3,097	4,156
Cash and cash equivalents at the end of the period	$ 1,660	$ 3,084
Supplemental disclosure of cash flow information:		
Cash received from interest	$ 88	140

SOURCE Galmed Pharmaceuticals Ltd.

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https://galmedpharma.investorroom.com/2017-05-15-Galmed-Pharmaceuticals-Reports-First-Quarter-2017-Financial-Results