Galmed Pharmaceuticals

Galmed Pharmaceuticals Reports Second Quarter 2017 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, July 31, 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 and six months ended June 30, 2017. 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 2017 vs. Second Quarter 2016:

- Net loss of $2.7 million, or $0.22 per share, for the three months ended June 30, 2017, compared to a net loss of $4.3 million, or $0.39 per share, for the three months ended June 30, 2016. This period's net loss included $0.3 million of non-cash, stock-based compensation expense, versus $0.8 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 June 30, 2017, compared to no revenue for the three months ended June 30, 2016. The revenue in this quarter relates to the amortization of the up-front payments under the license agreement with Samil pharm.
- Research and development ("R&D") expenses amounted to approximately $2.3 million for the three months ended June 30, 2017, compared to approximately $3.4 million for the three months ended June 30, 2016. The decrease resulted primarily from a decrease in expenses in connection with the ARREST Study, as well as a decrease of non-cash stock-based compensation expenses.
- General and administrative expenses amounted to approximately $0.6 million for the three months ended June 30, 2017, compared to approximately $0.9 million for the three months ended June 30, 2016. The decrease in general and administrative expenses for the three months ended June 30, 2017 resulted primarily from a decrease in professional fees, as well as a decrease in salaries and benefits expenses.
- Financial income of $0.01 million for the three months ended June 30, 2017, compared to financial income of $0.1 million for the three months ended June 30, 2016. The decrease in financial income for the three months ended June 30, 2017 resulted primarily from changes in the foreign currency exchange rate.
- Cash and cash equivalents and marketable securities totaled $9.1 million as of June 30, 2017, compared to $15.5 million at December 31, 2016. The decrease in cash resulted primarily from the costs of 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, July 31, 2017, 8:30 am Eastern Time / 5:30 am Pacific Time

Participant Dial-In Numbers:	
Toll-Free:	+1-888-287-5563
Toll/International:	+1-719-325-4878
Conference ID:	8068047
Webcast:	http://galmedpharma.investorroom.com/events

Replay, available until August 14, 2017

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

Passcode:

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 an estimated 3% to 5% of the U.S. population and an estimated 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. Many factors could cause Galmed's actual activities or results to differ materially from the activities and results anticipated in forward-looking statements, including, but not limited to, the following: the timing and cost of Galmed's ongoing Phase IIb ARREST Study, and planned Phase III trials for Aramchol™, or whether Phase III trials will be conducted at all; completion and receiving favorable results of these Phase IIb ARREST Study and Phase III trials for Aramchol™; regulatory action with respect to Aramchol™ by the FDA or the EMA; the commercial launch and future sales of Aramchol™ or any other future products or product candidates; Galmed's ability to comply with all applicable post-market regulatory requirements for Aramchol™ in the countries in which it seeks to market the product; Galmed's ability to achieve favorable pricing for Aramchol™; Galmed's expectations regarding the commercial market for NASH in patients who are overweight or obese and have pre diabetes or type II diabetes mellitus; third-party payor reimbursement for Aramchol™; Galmed's estimates regarding anticipated capital requirements and Galmed's needs for additional financing; market adoption of Aramchol™ by physicians and patients; the timing, cost or other aspects of the

commercial launch of Aramchol™; the development and approval of the use of Aramchol™ for additional indications or in combination therapy; and Galmed's expectations regarding licensing, acquisitions and strategic operations. More detailed information about the risks and uncertainties affecting Galmed is contained under the heading "Risk Factors" included in Galmed's most recent Annual Report on Form 20-F filed with 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 June 30, 2017	As of December 31, 2016
	Unaudited	**Audited**
Assets		
Current assets		
Cash and cash equivalents	$ 1,747	$ 3,097
Marketable securities	7,408	12,351
Other accounts receivable	266	284
Total current assets	9,421	15,732
Property and equipment, net	606	718
Total assets	$ 10,027	$ 16,450
Liabilities and stockholders' equity		
Current liabilities		
Trade payables	$ 2,365	$ 3,122
Other accounts payable	185	363
Short-term portion of deferred revenue	1,085	1,094
Total current liabilities	3,635	4,579
Long-term liabilities		
Related parties	150	267
Long-term portion of deferred revenue	-	529
Total long-term liabilities	150	796
Stockholders' equity:		
Ordinary shares par value NIS 0.01 per share; Authorized 50,000,000; Issued and outstanding: 12,219,186 shares as of June 30, 2017; 12,149,226 shares as of December 31, 2016	34	34
Additional paid-in capital	76,402	75,446

Accumulated other comprehensive loss	(20)	(85)
Accumulated deficit	(70,174)	(64,320)
Total stockholders' equity	6,242	11,075
Total liabilities and stockholders' equity	$ 10,027	$ 16,450

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,	
	2017	**2016**	**2017**	**2016**
Revenue	$ 270	$ -	$ 538	$ -
Research and development expenses	2,347	3,360	5,090	6,744
General and administrative expenses	624	861	1,413	1,580
Total operating expenses	2,701	4,221	5,965	8,324
Financial expenses (income), net	(9)	89	(111)	(30)
Loss before income taxes	2,692	4,310	5,854	8,294
Taxes on Income	-	1	-	1
Net loss	$ 2,692	$ 4,311	$ 5,854	$ 8,295
Basic and diluted net loss per share	$ 0.22	$ 0.39	$ 0.48	$ 0.75
Weighted-average number of shares outstanding used in computing basic and diluted net loss per share	12,175,147	11,100,853	12,171,668	11,100,655

GALMED PHARMACEUTICALS LTD.

Consolidated Statements of Cash Flows (Unaudited)

U.S. Dollars in thousands

	Six months ended June 30,	
	2017	**2016**
Cash flow from operating activities		
Net loss	$ (5,854)	$ (8,295)
Adjustments required to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	120	66
Stock-based compensation expense	709	1,063

Amortization of discount/premium on marketable securities	(207)	35
Loss from Realization of marketable securities	115	138
Changes in operating assets and liabilities:		
Decrease (Increase) in other accounts receivable	18	43
Increase (decrease) in trade payables	(757)	706
Increase (decrease) in other accounts payable	(178)	106
Increase (decrease) in related party	(117)	45
Decrease in deferred revenue	(538)	-
Net cash used in operating activities	(6,689)	(6,093)
Cash flow from investing activities		
Purchase of property and equipment	(8)	(23)
Investment in securities, available for sale	-	(1,212)
Consideration of securities, available for sale	5,100	6,250
Net cash provided in (used in) investing activities	5,092	5,015
Cash flow from financing activities		
Issuance of ordinary shares (*)	247	11
Deferred issuance costs	-	(143)
Net cash used in financing activities	247	(132)
Increase (decrease) in cash and cash equivalents	(1,350)	(1,210)
Cash and cash equivalents at the beginning of the year	3,097	4,156
Cash and cash equivalents at the end of the period	$ 1,747	$ 2,946
Supplemental disclosure of cash flow information:		
Cash received from interest	$ 136	223

SOURCE Galmed Pharmaceuticals Ltd.

For further information: Galmed Investor & Media Contact:Guy Nehemya, VP Operations, Galmed Pharmaceuticals Ltd., guy@galmedpharma.com