Galmed Pharmaceuticals

Galmed Pharmaceuticals Reports Third Quarter 2017 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. 9, 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 nine months ended September 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™.

Business Update

- Galmed announced the publication of a paper entitled "Role of Aramchol™ in steatohepatitis and fibrosis in mice" in *Hepatology Communications*, a peer-reviewed, online journal. This paper summarizes the work conducted by a collaboration of key international basic and clinical scientists, who are well known NASH experts. The data help to understand the mechanism by which Aramchol exerts its effect on steatosis and steato-fibrosis and identify its potential direct anti-fibrotic effect. A poster of the data was presented at the American Association for the Study of Liver Diseases (AASLD) Liver Meeting on October 20-24, 2017 in Washington, D.C.
- During the third quarter, the Company raised net proceeds of approximately$2.7 million in a registered direct offering to existing investors and a concurrent private placement to Galmed's Chairman of the Board and an additional board member. Both offerings were completed at $7.10 per share.
- As of the beginning of November, 2017, all patients have been randomized in the ARRIVE study. ARRIVE is a proof-of-concept clinical trial that is evaluating the safety and efficacy of Aramchol in 50 patients with HIV-associated lipodystrophy and nonalcoholic fatty liver disease, or NAFLD. ARRIVE is a randomized, double-blinded, placebo-controlled, proof-of-concept Phase IIa clinical trial, comparing Aramchol at 600 mg versus placebo over 12 weeks. It is an investigator-initiated study being conducted by Professor Rohit Loomba at the NAFLD Research Center, at the University of California San Diego. The primary end point is improvement in hepatic steatosis as measured by MRI. Secondary endpoints measure improvements in total body fat, metabolic profile, and liver biochemistry. Release of topline data is expected in the first quarter of 2018.

"We are pleased with our continued progress on both our ARRIVE and ARREST clinical trials, which we anticipate will report our topline data in the first and second quarters of 2018, respectively," said Allen Baharaff, President and Chief Executive Officer of Galmed. Mr. Baharaff continued, "Moreover, we strengthened our balance sheet with the support of institutional investors, along with two members of our board."

Financial Summary - Third Quarter 2017 vs. Third Quarter 2016:

- Net loss of $2.8 million, or $0.23 per share, for the three months ended September 30, 2017, compared to a net loss of $3.8 million, or $0.34 per share, for the three months ended September 30, 2016. This period's net loss included $0.4 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 2016.
- The Company recognized $0.3 million of revenue for the three months ended September 30, 2017, compared to $0.2 million revenue for the three months ended September 30, 2016. The revenue 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 September 30, 2017, compared to approximately $3.3 million for the three months ended September 30, 2016. The decrease resulted primarily from a decrease in expenses in connection with the ARREST study.
- General and administrative expenses amounted to approximately $0.70 million for the three months ended September 30, 2017, compared to approximately $0.66 million for the three months ended September 30, 2016. The slight increase in general and administrative expenses for the three months ended September 30, 2017 resulted primarily from an increase in professional fees.
- Financial expenses amounted to $0.05 million for the three months ended September 30, 2017, compared to financial income of $0.08 million for the three months ended September 30, 2016. The decrease in financial income for the three months ended September 30, 2017 resulted primarily from changes in the foreign currency exchange rate.
- Cash and cash equivalents and marketable securities totaled $9.0 million as of September 30, 2017, compared to $15.5 million at December 31, 2016. Subsequent to the balance sheet date, the Company raised net proceeds of approximately $1.1 million in its "at-the-market" equity offering program. Galmed believes that its cash balance will be sufficient to maintain its current operations through 2018.

Conference Call & Webcast:

Thursday, November 9th @ 8:30am Eastern Time

Toll-Free: 800-479-9001
Toll/International: 719-457-2639
Conference ID: 9813581
Webcast: http://public.viavid.com/index.php?id=126942

Replays, available through November 23, 2017
Toll-Free: 844-512-2921
Toll/International: 412-317-6671

Replay PIN: 9813581

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 downregulation of the three key pathologies of NASH: steatosis, inflammation and fibrosis. The effect of Aramchol™ on fibrosis is mediated by downregulation of steatosis and directly on human collagen producing cells. Aramchol™ has been granted Fast Track designation status by the FDA 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 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 September 30, 2017	As of December 31, 2016
	Unaudited	Audited
Assets		
Current assets		
Cash and cash equivalents	$ 2,614	$ 3,097
Marketable securities	6,344	12,351
Other accounts receivable	171	284
Total current assets	9,129	15,732
Property and equipment, net	548	718
Total assets	$ 9,677	$ 16,450

Liabilities and stockholders' equity		
Current liabilities		
Trade payables	$ 1,965	$ 3,122
Other accounts payable	219	363
Short-term portion of deferred revenue	811	1,094
Total current liabilities	2,995	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: 12,733,512 shares as of September 30, 2017; 12,149,226 shares as of December 31, 2016	36	34
Additional paid-in capital	79,479	75,446
Accumulated other comprehensive loss	(8)	(85)
Accumulated deficit	(72,975)	(64,320)
Total stockholders' equity	6,532	11,075
Total liabilities and stockholders' equity	$ 9,677	$ 16,450

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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,	
	2017	**2016**	**2017**	**2016**
Revenue	$ 273	$ 193	$ 811	$ 193

Research and development expenses	2,331	3,342	7,421	10,086
General and administrative expenses	697	656	2,110	2,236
Total operating expenses	2,755	3,805	8,720	12,129
Financial expenses (income), net	46	(78)	(65)	(108)
Loss before income taxes	2,801	3,727	8,655	12,021
Taxes on Income	-	105	-	106
Net loss	$ 2,801	$ 3,832	$ 8,655	$ 12,127
Basic and diluted net loss per share	$ 0.23	$ 0.34	$ 0.71	$ 1.09
Weighted-average number of shares outstanding used in computing basic and diluted net loss per share	12,364,249	11,150,023	12,274,536	11,101,360

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Consolidated Statements of Cash Flows (Unaudited)

U.S. Dollars in thousands

	Nine months ended September 30,	
	2017	**2016**
Cash flow from operating activities		
Net loss	$ (8,655)	$ (12,127)
Adjustments required to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	180	118
Stock-based compensation expense	1,066	1,307
Amortization of discount/premium on marketable securities	(187)	18
Loss from Realization of marketable securities	130	150

Changes in operating assets and liabilities:		
Decrease in other accounts receivable	113	13
Decrease in trade payables	(1,157)	(556)
Decrease in other accounts payable	(144)	(173)
Increase (decrease) in related party	(117)	45
Increase (decrease) in deferred revenue	(812)	1,897
Net cash used in operating activities	(9,583)	(9,305)
Cash flow from investing activities		
Purchase of property and equipment	(10)	(26)
Investment in securities, available for sale	(1,447)	(2,480)
Maturity of securities, available for sale	7,589	9,956
Net cash provided in (used in) investing activities	6,132	7,450
Cash flow from financing activities		
Proceeds from issuance of stock offerings, net of issuance costs	2,655	4,479
Proceeds from exercise of options	313	255
Net cash used in financing activities	2,968	4,734
Increase (decrease) in cash and cash equivalents	(483)	2,879
Cash and cash equivalents at the beginning of the year	3,097	4,156
Cash and cash equivalents at the end of the period	$ 2,614	$ 7,035
Supplemental disclosure of cash flow information:		
Cash received from interest	$ 169	$ 319

SOURCE Galmed Pharmaceuticals Ltd.

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https://galmedpharma.investorroom.com/2017-11-09-Galmed-Pharmaceuticals-Reports-Third-Quarter-2017-Financial-Results-and-Provides-Business-Update