Galmed Pharmaceuticals

Galmed Pharmaceuticals Reports Fourth Quarter and Full Year 2016 Financial Results

New Independent Research is Pointing Towards Potential Direct Effect of Aramchol™ on Liver Fibrosis

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

TEL AVIV, Israel, March 23, 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 twelve months ended December 31, 2016, and announced new and exciting data from recently completed pre-clinical studies demonstrating Aramchol™'s potential direct effect on liver fibrosis. The data will be presented at the International Liver Congress™ 2017, to be held from April 19 to the 23rd in Amsterdam, the Netherlands.

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™.

"Aramchol™'s anti-steatosis effect was previously established and translated to humans in our phase IIa study. Pre-clinical studies demonstrate Aramchol™ is targeting fibrosis via two main pathways – (1) by down regulating steatosis which is the main cause of inflammation and fibrosis; and (2) by directly down regulating collagen production. The new data suggests the potential direct effect of Aramchol™ in the treatment of liver fibrosis," said Mr. Allen Baharaff, Galmed's President and CEO.

"The TAA model is the best known animal model for experimental induced liver fibrosis and cirrhosis. In this model, we investigated the effect of Aramchol™ on liver fibrosis. We found that Aramchol™ significantly reduced the amount of fibrosis in comparison to a control group which received placebo. The results are significant and quite impressive," said Prof. Shimon Reif, Gastroenterologist and Head of Pediatric Department at Hadassah Medical Center at the Hebrew University of Jerusalem. Prof. Reif continued, "The effect seen in the TAA model is due to direct effect on collagen production from stellate cells."

"As we previously reported on January 9, 2017, we have completed the enrolment of the ARREST Study, and 248 patients have been randomized. Top line Data is expected to be available during the second quarter of 2018. We believe that our cash balance will be sufficient to maintain our current operations through the first half of 2018, and allow the completion of the ARREST study as scheduled," said Mr. Baharaff.

Financial Summary – Full Year 2016 vs. Full Year 2015; 4Q16 vs. 4Q15:

- Cash and cash equivalents and marketable securities totaled approximately $15.5 million as of December 31, 2016, compared with approximately $23.0 million as of December 31, 2015. This decrease primarily resulted from approximately $12.1 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.
- The Company recorded a net loss of approximately $17.0 million, or approximately $1.49 per share, for the

twelve months ended December 31, 2016, compared with a net loss of approximately $10.6 million, or approximately $0.96 per share, for the twelve months ended December 31, 2015. During 2016, total R&D expenses increased by approximately $6.7 million, or approximately 88%, to approximately $14.3 million, and total G&A expenses decreased by approximately $168 thousand, or approximately 5%, to approximately $3.1 million. In addition, 2016's net loss included approximately $1.6 million of non-cash, stock-based compensation expense versus approximately $970 thousand of non-cash stock-based compensation expense incurred during the corresponding period in 2015.

- For the quarter ended December 31, 2016, the net loss was approximately $4.8 million, or approximately $0.40 per share, which compares with approximately $3.2 million, or approximately $0.29 per share, for the same period in 2015. During the fourth quarter of 2016, total R&D expenses increased approximately $1.4 million to approximately $4.2 million, and total G&A expenses increased approximately $273 thousand to approximately $842 thousand. This quarter's net loss included approximately $160 thousand of non-cash, stock-based compensation income versus approximately $321 thousand of non-cash stock-based compensation expense incurred during the corresponding period in 2015.
- The Company recognized approximately $0.5 million of revenue for the twelve months ended December 31, 2016, compared to no revenue for the same period in 2015. The revenue relates to the amortization of the up-front payments under the Company's license agreement with Samil Pharm Co. Ltd. The remaining unamortized up-front payment of approximately $1.6 million is reflected on the balance sheet as short-term and long-term portion of deferred revenue and will be amortized through the contractual term of the agreement.
- Research and development expenses were approximately $14.3 million for the twelve months ended December 31, 2016, compared with approximately $7.6 million for the twelve months ended December 31, 2015. The increase primarily resulted from an increase in expenses related to the ARREST Study as the trial continues to progress. The increase is also a result of an increase in 2016 of non-cash stock-based compensation expense. For the quarter ended December 31, 2016, research and development expenses totaled approximately $4.2 million, which compares with approximately $2.8 million for the same period in 2015. The increase primarily resulted from an increase in expenses related to the ARREST Study and also as a result of an increase in non-cash stock-based compensation expense.
- The Company incurred general and administrative expenses of approximately $3.1 million for the twelve months ended December 31, 2016, compared with approximately $3.2 million for the twelve months ended December 31, 2015. The decrease primarily resulted from a decrease in investor relations expenses.
- For the quarter ended December 31, 2016, general and administrative expenses totaled approximately $842 thousand, which compares with approximately $569 thousand for the same period in 2015. The increase primarily resulted from an increase in stock-based compensation expense.

Conference Call & Webcast:

Thursday, March 23, 2017, 8:30 am Eastern Time / 5:30 am Pacific Time

Participant Dial-In Numbers:

Toll-Free:	+1-888-663-2242
Toll/International:	+1-913-312-0380
Conference ID:	3745268
Webcast:	http://galmedpharma.investorroom.com/events

Replay, available until April 6, 2017

Replay Dial-In Numbers:

Toll-Free:	+1-844-512-2921
Toll/International:	+1-412-317-6671
Passcode:	3745268

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 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 December 31,	
	2016	**2015**
Assets		
Current assets		
Cash and cash equivalents	$ 3,097	$ 4,156
Marketable securities	12,351	18,845
Other accounts receivable	284	379
Total current assets	15,732	23,380
Property and equipment, net	718	883
Total assets	$ 16,450	$ 24,263
Liabilities and stockholders' equity		
Current liabilities		
Trade payables	3,122	2,259
Other accounts payable	363	282
Short-term portion of deferred revenue	1,094	-
Total current liabilities	4,579	2,541
Long-term liabilities		
Related parties	267	177
Long-term portion of deferred revenue	529	-
Total long-term liabilities	796	177
Stockholders' equity		
Ordinary shares, par value NIS 0.01 per share; Authorized 50,000,000 shares; Issued and outstanding: 12,149,226 shares as of December 31, 2016; 11,100,453 shares as of December 31, 2015	34	32
Additional paid-in capital	75,446	69,086

Accumulated other comprehensive loss	(85)	(206)
Accumulated deficit	(64,320)	(47,367)
Total stockholders' equity	11,075	21,545
Total liabilities and stockholders' equity	$ 16,450	$ 24,263

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Consolidated Statements of Operations (Audited)

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

	Three months ended December 31,		Twelve months ended December 31,	
	2016	**2015**	**2016**	**2015**
Revenue	$ 274	$ -	$ 467	$ -
Research and development expenses	4,185	2,776	14,271	7,629
General and administrative expenses	842	569	3,078	3,246
Total operating expenses	4,753	3,345	16,882	10,875
Financial expenses (income), net	73	(140)	(35)	(253)
Loss before income taxes	4,826	3,205	16,847	10,622
Taxes on Income	-	-	106	-
Net loss	$ 4,826	$ 3,205	$ 16,953	$ 10,622
Basic and diluted net loss per share	$ 0.40	$ 0.29	$ 1.49	$ 0.96
Weighted-average number of shares outstanding used in computing basic and diluted net loss per share	12,149,226	11,100,453	11,374,653	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

Year ended December 31,

	2016	2015
Cash flow from operating activities		
Net loss for the year	$ (16,953)	$ (10,622)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	169	50
Amortization of discount/premium on marketable securities	44	92
Loss from realization of marketable securities	231	50
Stock-based compensation expense	1,628	970
Changes in operating assets and liabilities:		
Increase in deferred revenue from collaboration agreement	1,623	–
Decrease (increase) in other accounts receivable	95	(214)
Increase (decrease) in trade payables	863	1,384
Increase (decrease) in other accounts payable	81	39
Increase (decrease) in related party	90	(223)
Net cash used in operating activities	(12,129)	(8,474)
Cash flow from investing activities		
Purchase of property and equipment	(17)	(159)
Proceeds from sale of property and equipment	13	–
Investment in securities, available for sale	(7,615)	(26,541)
Proceeds from sale of securities, available for sale	13,955	9,594
Disposal of (Investment in) short-term deposit	–	6,000
Net cash provided by (used in) investing activities	6,336	(11,106)
Cash flow from financing activities		
Issuance of stock offerings, net of issuance costs (**)	4,479	–
Proceeds from exercise of options	255	–
Net cash provided by financing activities	4,734	–
Increase (decrease) in cash and cash equivalents	(1,059)	(19,580)
Cash and cash equivalents at the beginning of the year	4,156	23,736
Cash and cash equivalents at the end of the year	$ 3,097	$ 4,156
Cash received from interest	$ 382	$ 473
Cash paid for taxes	$ 106	$ -

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Notes to Consolidated Statements of Operations (audited)

U.S. Dollars in thousands

Research and Development Expenses:

	Three months ended December 31,		Year ended December 31,	
	2016	2015	2016	2015
	(in thousands)		(in thousands)	
Chemistry and formulation studies	$ 267	$ 818	$ 1,802	$ 1,902
Salaries and benefits	405	251	1,004	808
Stock-based compensation	24	(105)	757	111
Research and preclinical studies	288	233	924	637
Clinical studies	3,103	1,412	9,263	3,671
Regulatory and other expenses	98	167	521	500
	$ 4,185	$ 2,776	$ 14,271	$ 7,629

General and Administrative Expenses:

	Three months ended December 31,		Year ended December 31,	
	2016	2015	2016	2015
	(in thousands)		(in thousands)	
Stock-based compensation	$ 297	$ (55)	$ 871	$ 858
Professional fees	144	130	683	741
Salaries and benefits	262	262	849	747
Traveling and conference costs	14	17	106	65
Rent and office-maintenance fees	55	129	303	359
Investor relations and business development	66	78	248	457
Other	4	8	18	19
	$ 842	$ 569	$ 3,078	$ 3,246

SOURCE Galmed Pharmaceuticals Ltd.

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https://galmedpharma.investorroom.com/2017-03-23-Galmed-Pharmaceuticals-Reports-Fourth-Quarter-and-Full-Year-2016-Financial-Results