

Galmed Pharmaceuticals Reports First 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, May 16, 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 months ended March 31, 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 - First Quarter 2016 vs. First Quarter 2015:

- Net loss of \$4.0 million, or \$0.36 per share, for the three months ended March 31, 2016, compared to a net loss of \$2.5 million, or \$0.22 per share, for the three months ended March 31, 2015. This period's net loss included \$0.3 million of non-cash, stock-based compensation expense, versus \$0.6 million of non-cash stock-based compensation expense incurred during the corresponding period in 2015. The increase in net loss was due primarily to increased research and development expenses.
- Research and development expenses of \$3.4 million for the three months ended March 31, 2016, compared to \$1.4 million for the three months ended March 31, 2015. The increase resulted primarily from an increase in research and development subcontractor expenses of \$1.6 million in connection with significant growth in subject screening and patient recruitment, as well as initiating additional clinical testing sites for the ARREST Study.
- General and administrative expenses of \$0.7 million for the three months ended March 31, 2016, compared to \$1.1 million for the three months ended March 31, 2015. The decrease in 2016 resulted primarily from lower non-cash stock-based compensation.
- Financial income of \$0.1 million for the three months ended March 31, 2016, compared to a financial income of \$0.04 million for the three months ended March 31, 2015. The increase in 2016 financial income resulted primarily from movement in foreign currency exchange rates.
- Cash and cash equivalents and marketable securities, or current assets, totaled \$20.0 million as of March 31, 2016, compared to \$23.0 million at December 31, 2015. The decrease in the first quarter of 2016 resulted primarily from our ongoing clinical studies and operational activities. Galmed continues to expect that its cash balance will be sufficient to maintain its current operations into the second half of 2017.

"The significant increase in R&D activities and the momentum we are seeing in the ARREST Study patient recruitment pace continues to support our previously stated timelines concerning the ARREST Study," stated Allen Baharaff, Galmed's President and Chief Executive Officer. "Specifically, as previously disclosed, we are currently on track to have 120 patients enrolled by the end of the second quarter of

2016 and 240 patients by the end of the fourth quarter of 2016."

Mr. Baharaff continued, "Worldwide, we have now screened over 575 subjects for the ARREST Study, a 37% increase since our last public disclosure on March 22, 2016, less than 2 months ago. As of yesterday, May 15, 2016, we had randomized 107 patients (+43% since March 22, 2016) and have another 6 subjects who are eligible to be randomized. In addition, 81 subjects are currently within the screening process, which, again, normally takes between 6-8 weeks."

Josh Blacher, Galmed's Chief Financial Officer, commented, "During the first quarter 2016, our G&A expense decreased by a total of 8% quarter-over-quarter, excluding the effect of non-cash based compensation. Additionally, the expenses associated with R&D and G&A improved from 68% R&D / 32% G&A in the fourth quarter of 2015, to 85% R&D / 15% G&A in the first quarter of 2016. We will continue to remain vigilant about our G&A spend."

Mr. Baharaff continued, "We recently announced an investigator initiated clinical trial agreement with the Icahn School of Medicine at Mount Sinai for a study testing the effect of a combination of Aramchol™ with Vitamin D. Combination therapy has been widely accepted by the scientific community as the future direction of treating NASH. Aramchol™, with its strong safety profile and promising efficacy, together with Vitamin D, which is emerging as an anti-fibrotic agent, is the first NASH combo treatment to enter a Phase IIa study. This innovative dual therapy is a natural expansion of our pipeline in addition to the ongoing ARREST and ARRIVE studies."

Mr. Baharaff concluded, "We are encouraged by the recent preclinical data announced in March demonstrating Aramchol™'s direct anti-fibrotic effect, which, together with its clinically-demonstrated effect on steatosis, provides a strong foundation for Aramchol™ development to address the full spectrum of NAFLD and NASH through a comprehensive portfolio approach, rather than a single 'shot-on-goal.'"

Conference Call & Webcast:

Monday, May 16, 2016, 8:30 am EDT / 5:30 am PDT

Participant Dial-In Numbers:

Toll-Free: +1-888-587-0615

Toll/International: +1-719-325-2323

Conference ID: 2502914

Webcast: <http://galmedpharma.investorroom.com/events>

Replay, available until May 30, 2016

Replay Dial-In Numbers:

Toll-Free: +1-877-870-5176

Toll/International: +1-858-384-5517

Passcode: 2502914

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](https://clinicaltrials.gov/ct2/show/study/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 those 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 March 31, 2016 <u>Unaudited</u>	As of December 31, 2015 <u>Audited</u>
Assets		
Current assets		
Cash and cash equivalents	\$ 3,084	\$ 4,156
Marketable securities	16,882	18,845
Other accounts receivable	256	379
Total current assets	<u>20,222</u>	<u>23,380</u>
Property and equipment, net	859	883
Total assets	<u>\$ 21,081</u>	<u>\$ 24,263</u>
Liabilities and stockholders' equity		
Current liabilities		
Trade payables	\$ 2,951	\$ 2,259
Other accounts payable	73	282
Total current liabilities	<u>3,024</u>	<u>2,541</u>
Long-term liabilities		
Related parties	177	177
Total long-term liabilities	<u>177</u>	<u>177</u>
Stockholders' equity:		
Ordinary shares par value NIS 0.01 per share;		
Authorized 50,000,000; Issued and outstanding: 11,100,453 shares	32	32
Additional paid-in capital	69,359	69,086
Accumulated other comprehensive loss	(160)	(206)
Accumulated deficit	(51,351)	(47,367)
Total stockholders' equity	<u>17,880</u>	<u>21,545</u>
Total liabilities and stockholders' equity	<u>\$ 21,081</u>	<u>\$ 24,263</u>

GALMED PHARMACEUTICALS LTD.**Consolidated Statements of Operations (Unaudited)****U.S. Dollars in thousands, except share data and per share data**

	Three months ended	
	March 31,	
	2016	2015
Research and development expenses	\$ 3,384	\$ 1,431
General and administrative expenses	719	1,073
Total operating expenses		
	4,103	2,504
Financial income, net	(119)	(41)
Net loss		
	\$ 3,984	\$ 2,463
Basic and diluted net loss per share from continuing operations	\$ 0.36	\$ 0.22
Weighted-average number of shares outstanding used in computing basic and diluted net loss per share	11,100,453	11,100,453

GALMED PHARMACEUTICALS LTD.**Consolidated Statements of Cash Flows (Unaudited)****U.S. Dollars in thousands**

	Three months	
	ended March 31,	
	2016	2015
Cash flow from operating activities		
Net loss	\$ (3,984)	\$ (2,463)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	32	3
Stock-based compensation expense	273	558
Amortization of discount/premium on marketable securities	(62)	(185)

Loss from realization of marketable securities	55	11
Changes in operating assets and liabilities:		
Increase (decrease) in other accounts receivable	123	(223)
Increase in trade payables	692	272
Decrease in other accounts payable	(209)	(34)
Decrease in related party	-	(195)
Net cash used in operating activities		
	(3,080)	(2,256)
Cash flow from investing activities		
Purchase of property and equipment	(8)	(2)
Investment in securities, available for sale	-	(19,445)
Realization of securities, available for sale	2,016	307
Net cash provided by (used in) investing activities		
	2,008	(19,140)
Decrease in cash and cash equivalents	(1,072)	(21,396)
Cash and cash equivalents at the beginning of the year	4,156	23,736
Cash and cash equivalents at the end of the period	\$ 3,084	\$ 2,340
Supplemental disclosure of cash flow information:		
Cash received from interest	\$ 140	\$ 65

GALMED PHARMACEUTICALS LTD.

Notes to Consolidated Statements of Operations (unaudited)

U.S. Dollars in thousands

Research and Development Expenses:

	Three months ended	
	March 31,	
	2016	2015
	(in thousands)	
Chemistry and formulation studies	\$ 877	\$ 387
Salaries and benefits	142	93
Stock-based compensation	115	121
Research and preclinical studies	352	448
Clinical studies	1,745	158
Regulatory and other expenses	153	224

\$ 3,384 \$ 1,431

General and Administrative Expenses:

	Three months ended	
	March 31,	
	2016	2015
	(in thousands)	
Stock-based compensation	\$ 159	\$ 466
Professional fees	178	236
Salaries and benefits	178	168
Traveling and conference costs	29	24
Rent and office-maintenance fees	85	61
Investor relations and business	88	113
Development		
Other	2	5
	\$ 719	\$ 1,073

Logo - <http://photos.prnewswire.com/prnh/20150720/238362LOGO>

SOURCE Galmed Pharmaceuticals Ltd.

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Additional assets available online: [Photos \(1\)](#)

<https://galmedpharma.investorroom.com/2016-05-16-Galmed-Pharmaceuticals-Reports-First-Quarter-2016-Financial-Results-and-Provides-Business-Update>