

## **Galmed Pharmaceuticals Reports Full Year 2015 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, March 22, 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 and twelve months ended December 31, 2015. 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 - Full Year 2015 vs. Full Year 2014; 4Q15 vs. 4Q14:**

- Net loss of \$10.6 million, or \$0.96 per share, for the twelve months ended December 31, 2015, compared with a net loss of \$9.1 million, or \$0.88 per share, for the twelve months ended December 31, 2014. During 2015, total R&D expenses increased \$965 thousand, or 14% to \$7.6 million, and total G&A expenses increased \$768 thousand, or 31% to \$3.2 million. In addition, 2015's net loss included \$970 thousand of non-cash, stock-based compensation expense versus \$601 thousand of non-cash stock-based compensation expense incurred during the corresponding period in 2014.
- For the quarter ended December 31, 2015, the net loss was \$3.2 million, or \$0.29 per share, which compares with \$2.0 million, or \$0.17 per share, for the same period in 2014. During the fourth quarter of 2015, total R&D expenses increased \$1.7 million to \$2.8 million, and total G&A expenses decreased \$359 thousand to \$569 thousand. This quarter's net loss included \$160 thousand of non-cash, stock-based compensation income versus \$131 thousand of non-cash stock-based compensation expense incurred during the corresponding period in 2014.
- Research and development expenses of \$7.6 million for the twelve months ended December 31, 2015, compared with \$6.7 million for the twelve months ended December 31, 2014. The increase primarily resulted from an increase in expenses related to the ARREST Study as the trial continues to progress, offset by a decrease in chemistry and formulation studies, due to the fact that, during 2014, the Company manufactured sufficient quantities of Aramchol™ for the ARREST Study.
- For the quarter ended December 31, 2015, research and development expenses totaled \$2.8 million, which compares with \$1.1 million for the same period in 2014. The increase primarily resulted from an increase in expenses related to the ARREST Study as the trial continues to progress.
- General and administrative expenses of \$3.2 million for the twelve months ended December 31, 2015, compared with \$2.5 million for the twelve months ended December 31, 2014. The increase primarily resulted from an increase in stock-based compensation expenses, salaries, benefits as well as an increase in professional services and investor relations and business development expenses.
- For the quarter ended December 31, 2015, general and administrative expenses totaled \$569 thousand, which compares with \$928 thousand for the same period in 2014. The decrease primarily

resulted from a decrease in stock-based compensation expenses and a decrease in investor relations and business development expenses.

- Total current assets totaled \$23.4 million as of December 31, 2015, compared with \$32.2 million as of December 31, 2014. The decrease in 2015 primarily resulted from our spend on ongoing clinical studies and operating activities. Galmed continues to expect that its cash balance will be sufficient to maintain its current operations into the second half of 2017.

"The Company's main focus remains the advancement of the ARREST Study, which is progressing generally as planned," stated Allen Baharaff, Galmed's President and Chief Executive Officer. "At December 31, 2015, we had a total of 42 sites activated. In the first quarter of 2016, we added another 5 sites; 3 in the US and 2 in Mexico, both high-screening countries. During the second quarter 2016, we expect to activate another 30 sites, which include 13 sites in Italy, and 6 sites in Germany."

Mr. Baharaff continued, "Importantly, worldwide, we have now screened over 400 subjects for the ARREST Study. As of March 20th, 2016, we had randomized 75 patients and have another 15 subjects that are eligible to be randomized. In addition, 68 subjects are currently within the screening process, which normally takes between 6-8 weeks. We expect the 120th patient to be randomized by the end of the second quarter, 2016, and the 240<sup>th</sup> patient by the end of 2016. Based on the current rate of screening and enrollment, we now expect results from the Interim Analysis to be available by December 2016, or early first-quarter 2017, and top-line data for the complete study by the first quarter, 2018, inclusive of the three-month follow-up period. Now that we have six months of active global screening in the ARREST Study behind us, we feel very comfortable with our estimates."

"We also announced a couple weeks ago that we have now begun patient randomization in the ARRIVE Study, which is a proof-of-concept Investigator Initiated Trial to evaluate the safety and efficacy of Aramchol in up to 50 patients with HIV-associated lipodystrophy and NAFLD."

Mr. Baharaff concluded, "Continued execution on the ARREST Study, as well as fortifying our pipeline, are our clear priorities for this year."

***Conference Call & Webcast:***

***Tuesday, March 22nd, 2016, 8:30 am Eastern Time / 5:30 am Pacific Time***

Participant Dial-In Numbers:

Toll-Free: +1-888-430-8691

Toll/International: +1-719-325-2491

Conference ID: 7194562

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

**Replay, available until April 5, 2016**

Replay Dial-In Numbers:

Toll-Free: +1-877-870-5176  
Toll/International: +1-858-384-5517  
Passcode: 7194562

**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**

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

	<b>As of December 31,</b>	
	<b>2015</b>	<b>2014</b>
<b>Assets</b>		
<b>Current assets</b>		
Cash and cash equivalents	\$ 4,156	\$ 23,736
Short-term deposit	-	6,000
Marketable securities	18,845	2,250
Other accounts receivable	379	165
<b>Total current assets</b>	<b>23,380</b>	<b>32,151</b>
Property and equipment, net	883	774
<b>Total assets</b>	<b>\$ 24,263</b>	<b>\$ 32,925</b>
<b>Liabilities and stockholders' equity</b>		
<b>Current liabilities</b>		
Trade payables	2,259	875
Other accounts payable	282	243
<b>Total current liabilities</b>	<b>2,541</b>	<b>1,118</b>
<b>Long-term liabilities</b>		
Related parties	177	400
<b>Total long-term liabilities</b>	<b>177</b>	<b>400</b>
<b>Stockholders' equity</b>		
Ordinary shares, par value NIS 0.01 per share; Authorized 50,000,000 shares; Issued and outstanding: 11,100,453 shares as of December 31, 2015	32	32
Additional paid-in capital	69,086	68,116
Accumulated other comprehensive income (loss)	(206)	4
Accumulated deficit	(47,367)	(36,745)
<b>Total stockholders' equity</b>	<b>21,545</b>	<b>31,407</b>
<b>Total liabilities and stockholders' equity</b>	<b>\$ 24,263</b>	<b>\$ 32,925</b>

**GALMED PHARMACEUTICALS LTD.**

**Consolidated Statements of Operations**

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

	<b>Three months ended December 30 (unaudited),</b>		<b>Twelve months ended December 30 (audited),</b>	
	<b>2015</b>	<b>2014</b>	<b>2015</b>	<b>2014</b>
Research and development expenses	\$ 2,776	\$ 1,126	\$ 7,629	\$ 6,664
General and administrative expenses	569	928	3,246	2,478
<b>Total operating expenses</b>	<b>3,345</b>	<b>2,054</b>	<b>10,875</b>	<b>9,142</b>
Financial income, net	(140)	(76)	(253)	(40)
<b>Loss before income taxes</b>	<b>\$ 3,205</b>	<b>\$ 1,978</b>	<b>\$ 10,622</b>	<b>\$ 9,102</b>
Income taxes	-	1	-	1
<b>Net loss</b>	<b>\$ 3,205</b>	<b>\$ 1,979</b>	<b>\$ 10,622</b>	<b>\$ 9,103</b>
Basic and diluted net loss per share	\$ 0.29	\$ 0.17	\$ 0.96	\$ 0.88
Other Comprehensive (income) loss	150	-	210	(4)
<b>Comprehensive loss</b>	<b>\$ 3,355</b>	<b>\$ 1,979</b>	<b>\$ 10,832</b>	<b>\$ 9,099</b>
Weighted-average number of shares outstanding used in computing basic and diluted net loss per share	11,100,453	11,100,453	11,100,453	10,323,886

**GALMED PHARMACEUTICALS LTD.**

**Consolidated Statements of Cash Flows (audited)**

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

	<b>Year ended December 31,</b>	
	<b>2015</b>	<b>2014</b>
Cash flow from operating activities		
Net loss for the year	\$ (10,622)	\$ (9,103)

Adjustments required to reconcile net loss to net cash used in operating activities:

Depreciation and amortization	50	9
Amortization of discount/premium on marketable securities	92	-
Loss from realization of marketable securities	50	-
Stock-based compensation expense	970	601
Changes in operating assets and liabilities:		
Increase in other accounts receivable	(214)	(149)
Increase (decrease) in trade payables	1,384	(480)
Increase (decrease) in other accounts payable	39	(91)
Increase (decrease) in related party	(223)	(28)
Net cash used in operating activities	(8,474)	(9,241)

Cash flow from investing activities

Purchase of property and equipment	(159)	(770)
Investment in securities, available for sale	(26,541)	(2,246)
Proceeds from securities, available for sale	9,594	-
Disposal of (Investment in) short-term deposit	6,000	(6,000)
Net cash provided by (used in) investing activities	(11,106)	(9,016)

Cash flow from financing activities

Issuance of ordinary shares	-	2,000
Issuance of ordinary shares upon IPO, net *)	-	39,856
Net cash provided by financing activities	-	41,856
Increase (decrease) in cash and cash equivalents	(19,580)	23,599
Cash and cash equivalents at the beginning of the year	23,736	137
Cash and cash equivalents at the end of the year	\$ 4,156	\$ 23,736

Supplemental disclosure of cash flow information:

Cash received from interest	\$ 473	\$ -
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## **GALMED PHARMACEUTICALS LTD.**

### **Notes to Consolidated Statements of Operations (audited)**

**U.S. Dollars in thousands**

#### **Research and Development Expenses:**

	<b>Year ended December 31,</b>	
	<b>2015</b>	<b>2014</b>
	<b>(in thousands)</b>	
Chemistry and formulation studies	\$ 1,902	\$ 3,923

Salaries and benefits

	808	573
Stock-based compensation	111	-
Research and preclinical studies	637	865
Clinical studies	3,671	1,148
Regulatory and other expenses	500	155
	<u>\$ 7,629</u>	<u>\$ 6,664</u>

**General and Administrative Expenses:**

	<b>Year ended December 31,</b>	
	<b>2015</b>	<b>2014</b>
	(in thousands)	
Stock-based compensation	\$ 858	\$ 601
Professional fees		
	741	625
Salaries and benefits	747	588
Traveling and conference costs	65	30
Rent and office-maintenance fees	359	284
Investor relations and business development	457	337
Other	19	13
	<u>\$ 3,246</u>	<u>\$ 2,478</u>

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

SOURCE Galmed Pharmaceuticals Ltd.

For further information: Investor - Josh Blacher, CFO, Galmed Pharmaceuticals Ltd.,  
josh@galmedpharma.com, +1-646-780-7605

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

<https://galmedpharma.investorroom.com/2016-03-22-Galmed-Pharmaceuticals-Reports-Full-Year-2015-Financial-Results-and-Provides-Business-Update>