

Galmed Pharmaceuticals Announces Commencement of Patient Screening for the ARREST Study in Europe, and Reports Third Quarter 2015 Financial Results

- Conference Call and Webcast Today at 8:30 a.m. EST / 5:30 a.m. PST -

TEL AVIV, Israel, Nov. 9, 2015 /[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 announced the commencement of patient screening for the ARREST Study in Europe, and reported financial results for the three and nine months ended September 30, 2015.

Financial Summary - Third Quarter 2015 vs. Third Quarter 2014:

- Net loss of \$2.6 million, or \$0.23 per share, for the three months ended September 30, 2015, compared to a net loss of \$3.2 million, or \$0.29 per share, for the three months ended September 30, 2014. This period's net loss included \$0.2 million of non-cash, stock-based compensation expense versus \$0.1 million of non-cash stock-based compensation expense incurred during the corresponding period in 2014.
- Research and development expenses of \$1.9 million for the three months ended September 30, 2015, compared to \$2.8 million for the three months ended September 30, 2014. The decrease in 2015 primarily resulted from lower chemistry and formulation study expenses, which were partially offset by other line-items, as our ARREST Study progresses.
- General and administrative expenses of \$0.6 million for the three months ended September 30, 2015, compared to \$0.4 million for the three months ended September 30, 2014. The increase in 2015 primarily resulted from an increase in salaries and benefits as the result of additional employees, including higher non-cash, stock-based compensation and an increase in professional services.
- Current assets totaled \$25.7 million as of September 30, 2015, largely comprised of cash and cash equivalents, and marketable securities, compared to \$32.2 million at December 31, 2014. The decrease in 2015 primarily resulted from our ongoing clinical studies and operating activities. Galmed continues to expect that its cash balance will be sufficient to maintain its current operations into 2017.

"At the end of the third quarter of 2015, we had received country approval in 6 out of our expected 8 countries to be included in the ARREST Study, including the United States, Germany, France, Mexico, Chile and Israel," stated Allen Baharaff, Galmed's President and Chief Executive Officer. Currently, 55 (fifty-five) sites out of our expected 72 (seventy-two) sites have been approved by their respective regulatory bodies and ethics committees."

"Importantly, patient screening has now commenced in Europe, and remains ongoing in the United States and Latin America, as anticipated."

In addition, our collaboration with OWL to develop a non-invasive, blood-based diagnostic tool continues to progress nicely. We believe that this technology could replace liver biopsy in testing the ongoing efficacy of patient treatment, which may enhance the market penetration of Aramchol™.

Mr. Baharaff reiterated, "The timely execution of the ARREST Study remains our main focus. We are confident that patient enrollment will continue to gain momentum."

Conference Call Details

Galmed will host a conference call and webcast today at 8:30 a.m. EST / 5:30 a.m. PST to discuss its financial results and to provide an update on current developments with respect to its clinical program for Aramchol™. Investors interested in participating in the call can dial +1-888-359-3624 from the United States or +1-719-785-1753 for international callers, and use Conference ID 1521094. A replay will be available through November 23, 2015, by dialing +1-877-870-5176 (United States) or +1-858-384-5517 (international); Passcode 1521094. A webcast will also be available at <http://galmedpharma.investorroom.com>.

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 non-alcoholic steatohepatitis, or NASH, which is a chronic disease that Galmed believes constitutes a large unmet medical need.

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 31, 2015, 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, 2015	As of December 31, 2014
	Unaudited	Audited
Assets		
Current assets		
Cash and cash equivalents	\$ 4,463	\$ 23,736
Short-term deposit	-	6,000
Marketable securities	20,862	2,250
Other accounts receivable	346	165
Total current assets	25,671	32,151
Property and equipment, net	902	774
Total assets	\$ 26,573	\$ 32,925
Liabilities and stockholders' equity		
Current liabilities		
Trade payables	\$ 1,126	\$ 875
Other accounts payable	200	243
Total current liabilities	1,326	1,118
Long-term liabilities		
Related parties	187	400

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	69,246	68,116
Accumulated other comprehensive income (loss)	(56)	4
Accumulated deficit	(44,162)	(36,745)
Total stockholders' equity		
	25,060	31,407
Total liabilities and stockholders' equity	\$ 26,573	\$ 32,925

GALMED PHARMACEUTICALS LTD.**Consolidated Statements of Operations (unaudited)**

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

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Research and development expenses	\$ 1,860	\$ 2,791	\$ 4,853	\$ 5,538
General and administrative expenses	637	399	2,677	1,550
Total operating expenses	2,497	3,190	7,530	7,088
Financial expenses (income), net	103	16	(113)	36
Net loss	\$ 2,600	\$ 3,206	\$ 7,417	\$ 7,124
Basic and diluted net loss per share	\$ 0.23	\$ 0.29	\$ 0.67	\$ 0.71
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	10,074,939

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

	Nine months ended September 30,	
	2015	2014
Cash flow from operating activities		
Net loss	\$ (7,417)	\$ (7,124)
Adjustments required to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	32	8
Stock-based compensation expense	1,130	470
Amortization of investment premium, net	195	-
Changes in operating assets and liabilities:		
Increase in other accounts receivable	(181)	(51)
Increase (decrease) in trade payables	251	(108)
Increase (decrease) in other accounts payable	(43)	154
Increase (decrease) in related party	(213)	20
Net cash used in operating activities	(6,246)	(6,631)
Cash flow from investing activities		
Purchase of property and equipment	(160)	(20)
Maturity of short term deposit	6,000	
Investment in securities, available for sale	(25,132)	-
Maturity of securities, available for sale	6,265	-
Net cash used in investing activities	(13,027)	(20)
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	(19,273)	35,205
Cash and cash equivalents at the beginning of the year	23,736	137
Cash and cash equivalents at the end of the period	<u>\$ 4,463</u>	<u>\$ 35,342</u>
Supplemental disclosure of cash flow information:		
Cash received from interest	<u>\$ 370</u>	<u>-</u>

GALMED PHARMACEUTICALS LTD.

Notes to Consolidated Statements of Operations (unaudited)

U.S. Dollars in thousands

Research and development expenses:

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Chemistry and formulation studies	\$ 372	\$ 1,186	\$ 1,084	\$ 2,907
Salaries and benefits	196	126	557	336
Stock-based compensation	88	-	216	-
Research and preclinical studies	139	181	404	200
Clinical studies	1,028	962	2,259	1,216
Regulatory and other expenses	37	336	333	879
Total R&D expenses				
	<u>\$ 1,860</u>	<u>\$ 2,791</u>	<u>\$ 4,853</u>	<u>\$ 5,538</u>

General and administrative expenses:

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Stock-based compensation	\$ 151	\$ 110	\$ 913	\$ 470
Professional fees	153	69	611	430
Salaries and benefits	129	99	485	339
Rent and office-maintenance fees	59	67	230	150
Investor relations and business development	142	48	427	136

Other	3	6	11	25
Total G&A expenses				
	\$ 637	\$ 399	\$ 2,677	\$ 1,550

SOURCE Galmed Pharmaceuticals Ltd.

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

<https://galmedpharma.investorroom.com/2015-11-09-Galmed-Pharmaceuticals-Announces-Commencement-of-Patient-Screening-for-the-ARREST-Study-in-Europe-and-Reports-Third-Quarter-2015-Financial-Results>