

Galmed Pharmaceuticals Announces the Commencement of Patient Screening in the ARREST Study in the United States and Latin America, and Reports Second Quarter 2015 Financial Results

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

TEL AVIV, Israel, Aug. 13, 2015 /PRNewswire/ -- Galmed Pharmaceuticals Ltd. (Nasdaq: GLMD) ("Galmed"), a clinical-stage biopharmaceutical company focused on the development of a once-daily, oral therapy for the treatment of liver diseases, today announced that it has commenced patient screening for the ARREST Study in the United States and Latin America, as well as reported financial results for the three and six months ended June 30, 2015.

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

- Net loss of \$2.4 million, or \$0.21 per share, for the three months ended June 30, 2015, compared to a net loss of \$1.8 million, or \$0.14 per share, for the three months ended June 30, 2014. This period's net loss included \$0.3 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 \$1.6 million for the three months ended June 30, 2015, compared to \$1.2 million for the three months ended June 30, 2014. The increase in 2015 primarily resulted from an increase in research and development subcontractor expenses in connection with Aramchol™'s clinical development program.
- General and administrative expenses of \$1.0 million for the three months ended June 30, 2015, compared to \$0.5 million for the three months ended June 30, 2014. The increase in 2015 primarily resulted from an increase in salaries and benefits as the result of new hires, including higher non-cash, stock-based compensation and an increase in professional services.
- Cash and cash equivalents and marketable securities totaled \$27.8 million as of June 30, 2015, compared to \$31.9 million at December 31, 2014. The decrease in 2015 primarily resulted 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 2017.

"The ARREST Study has made significant strides in the second quarter," stated Allen Baharaff, Galmed's President and Chief Executive Officer. "We now have received country approval in five out of our expected nine countries to be included in the ARREST Study, including the United States, Germany, France, Chile and Israel. Currently, fifty-two (52) sites out of our expected seventy three (73) sites have been approved by their respective Ethics Committees.

Importantly, patient screening has now commenced in the United States and Latin America, and remains ongoing in Israel. Regarding our activities in Europe, we expect our first patients to be screened in September.

We remain confident that we will have enrolled the first 120 patients in the trial by the end of 2015, which we believe should allow us to stay on track for releasing the interim results around June 2016.

Based on the trial's protocol, 240 patients will need to have completed 12 months of treatment of Aramchol™, followed by a three month follow-up period in order to complete the study. We will then need several weeks to complete the statistical analysis before we release the data. Based on our current estimates, therefore, we now believe that top-line data will be available in the third quarter of 2017.

Finally, we would like to formally announce the appointment of Dr. Michal Ayalon who will serve as the Company's Vice President, Research and Development. Dr. Ayalon will lead the initiation of our pipeline and next generation molecules. We intend to share our advancements in these efforts during the balance of this year.

Prior to joining Galmed, Dr. Ayalon led the development of a Phase II, GI/Inflammatory investigational drug as Vice President Product Development at Immune Pharmaceuticals. Dr. Ayalon previously led the development and discovery of multiple products in inflammatory and metabolic diseases at BioLineRx, Ltd. and Compugen Ltd. Dr. Ayalon earned her PhD in Biology from Tel-Aviv University, MSc from the Department of Cell Research and Immunology at Tel Aviv University and a BSc in Life Sciences from Tel Aviv University; she gained post-doctoral training at the Weizmann Institute of Science. We are happy to have Dr. Ayalon aboard and wish her much success in accomplishing our shared objectives.

Mr. Baharaff concluded, "timely execution of the ARREST Study remains our main goal. With the rapid advancement of the regulatory approvals, 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. EDT / 5:30 a.m. PDT 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 +1-888-503-8175 from the United States or +1-719-457-2085 for international callers, and use Conference ID 6082132. A replay will be available through August 27, 2015, by dialing +1-877-870-5176 (United States) or +1-858-384-5517 (international); Passcode 6082132. 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 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 June 30, 2015 Unaudited	As of December 31, 2014 Audited
Assets		
Current assets		
	\$ 7,324	\$ 23,736
Cash and cash equivalents	-	
Short-term deposit	20,486	6,000
Marketable securities	385	2,250
Other accounts receivable	165	165
Total current assets	28,195	32,151
Property and equipment, net	915	774
Total assets	\$ 29,110	\$ 32,925
Liabilities and stockholders' equity		
Current liabilities		
Trade payables	\$ 1,229	\$ 875
Other accounts payable	272	243
Total current liabilities	1,501	1,118
Long-term liabilities		
Related parties	194	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	69,006	68,116

Accumulated other comprehensive income (loss)	(61)	4
Accumulated deficit	(41,562)	(36,745)
Total stockholders' equity	27,415	31,407
Total liabilities and stockholders' equity	\$ 29,110	\$ 32,925

GALMED PHARMACEUTICALS LTD.

Consolidated Statements of Operations (unaudited)

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

	Six months ended June 30,		Three months ended June 30,	
	2015	2014	2015	2014
Research and development expenses	\$ 2,993	\$ 2,747	\$ 1,562	\$ 1,245
General and administrative expenses	2,040	1,151	967	518
Total operating expenses	5,033	3,898	2,529	1,763
Financial expenses (income), net	(216)	20	(175)	(6)
	\$ 4,817	\$ 3,918	\$ 2,354	\$ 1,757
Net loss				
Basic and diluted net loss per share from continuing operations	\$ 0.43	\$ 0.41	\$ 0.21	\$ 0.14
Weighted-average number of shares outstanding used in computing basic and diluted net loss per share	11,100,453	9,553,684	11,100,453	11,100,453

GALMED PHARMACEUTICALS LTD.

Consolidated Statements of Cash Flows (Unaudited)

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

	Six months ended June 30,	
	2015	2014
Cash flow from operating activities		

Net loss	\$ (4,817)	\$ (3,918)
Adjustments required to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	13	4
Stock-based compensation expense	890	361
Amortization of investment premium, net	(27)	-
Changes in operating assets and liabilities:		
Increase in other accounts receivable	(220)	(45)
Increase (decrease) in trade payables	354	(1,054)
Increase in other accounts payable	29	53
Increase (decrease) in related party	(206)	20
Net cash used in operating activities	<u>(3,984)</u>	<u>(4,579)</u>
Cash flow from investing activities		
Purchase of property and equipment	(154)	(15)
Maturity of short term deposit	6,000	
Investment in securities, available for sale	(21,839)	-
Maturity of securities, available for sale	3,565	-
Net cash used in investing activities	<u>(12,428)</u>	<u>(15)</u>
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	<u>-</u>	<u>41,856</u>
Increase (decrease) in cash and cash equivalents	<u>(16,412)</u>	<u>37,262</u>
Cash and cash equivalents at the beginning of the year	<u>23,736</u>	<u>137</u>
Cash and cash equivalents at the end of the period	<u>\$ 7,324</u>	<u>\$ 37,399</u>
Supplemental disclosure of cash flow information:		
Cash received from interest	<u>\$ 245</u>	<u>-</u>

GALMED PHARMACEUTICALS LTD.

Consolidated Statements of Cash Flows (Unaudited)

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

Research and development expense:	Six months ended		Three months ended	
	June 30,		June 30,	
	2015	2014	2015	2014
Chemistry and formulation studies	\$ 712	\$ 1,721	\$ 325	\$ 453
Salaries and benefits	361	210	203	210
Stock-based compensation	128	-	35	-
Research and preclinical studies	265	119	144	85
Clinical studies	1,231	254	783	97
	296		72	
Regulatory and other expenses		443		400
Total R&D expenses	\$ 2,993	\$ 2,747	\$ 1,562	\$ 1,245

General and administrative expenses:	Six months ended		Three months ended	
	June 30,		June 30,	
	2015	2014	2015	2014
Stock-based compensation	\$ 762	\$ 360	\$ 296	\$ 151
Professional fees	458	361	222	183
Salaries and benefits	356	240	188	34
Rent and office-maintenance fees	171	83	110	68
Investor relations and business development	285	88	148	65
Other	8	19	3	17
Total G&A expenses	\$ 2,040	\$ 1,151	\$ 967	\$ 518

SOURCE Galmed Pharmaceuticals Ltd.

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

<https://galmedpharma.investorroom.com/2015-08-13-Galmed-Pharmaceuticals-Announces-the-Commencement-of-Patient-Screening-in-the-ARREST-Study-in-the-United-States-and-Latin-America-and-Reports-Second-Quarter-2015-Financial-Results>