Galmed Pharmaceuticals

Galmed Pharmaceuticals Provides Business Update and Reports Second Quarter 2018 Financial Results

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

TEL AVIV, Israel, Aug. 2, 2018 /PRNewswire/ -- Galmed Pharmaceuticals Ltd. (Nasdaq: GLMD) ("Galmed" or the "Company"), a clinical-stage biopharmaceutical company focused on the development of the liver targeted SCD1 modulator Aramchol, a once-daily, oral therapy for the treatment of nonalcoholic steatohepatitis, or NASH, today provides business update and reports financial results for the three and six months ended June 30, 2018. The Company will host a conference call and webcast at 08:30 ET today.

Business Update

- In June 2018, the Company reported top line results in its global, 52 week, Phase IIb ARREST study on 247 NASH patients demonstrating that Aramchol™ 600 mg achieved a regulatory approvable endpoint showing NASH resolution without worsening of fibrosis. Full top line results can be viewed in the Company's press release dated June 12, 2018 and in a corporate presentation dated June 2018, both of which are available on the Company's website and in the Company's filings with the SEC. The Company is preparing for an end of Phase IIb meeting with the FDA to discuss the results of the ARREST study and the design of a pivotal study.
- In June 2018, the Company completed an underwritten public offering of 5,000,000 ordinary shares, at a price of $15.00 per share. Net proceeds, after deducting underwriting discounts and commissions and offering expenses, were $70.3 million.
- In April 2018, the Company sold to Biotechnology Value Fund, L.P. and certain of its affiliates 1,000,000 ordinary shares for a purchase price of $6.00 per share, and one-year warrants to purchase an additional 1,000,000 ordinary shares, with an exercise price of $15.00 per share. Net proceeds to the Company were $5.9 million.

Financial Summary - First Quarter 2018 vs. First Quarter 2017:

- Cash and cash equivalents and marketable securities totaled $94.1 million as of June 30, 2018, compared to $19.0 million at December 31, 2017. The increase is mainly attributable to the approximately $70.3 million in net proceeds raised in an underwritten public offering that was completed in June 2018, together with $5.9 million in net proceeds raised in a registered direct offering during April 2018.
- Net loss of $2.7 million, or ($0.17) per share, for the three months ended June 30, 2018, compared to a net loss of $2.7 million, or ($0.22) per share, for the three months ended June 30, 2018.
- The Company recognized $0.3 million of revenue for the three months ended June 30, 2018, the same amount as in the corresponding quarter in 2017. The revenue relates to the amortization of the up-front payments under the license agreement with Samil Pharma.
- Research and development expenses amounted to approximately $1.9 million for the three months ended June 30, 2018, compared to approximately $2.3 million for the three months ended June 30, 2017. The decrease resulted primarily from a decrease in expenses in connection with clinical studies.
- General and administrative expenses amounted to approximately $1.1 million for the three months ended June 30, 2018, compared to approximately $0.6 million for the three months ended June 30, 2017. The increase in general and administrative expenses for the three months ended June 30, 2018 resulted primarily from a provision for employees' year-end compensation, as well as an increase in professional services.

- Financial expenses amounted to $0.1 million for the three months ended June 30, 2018, compared to financial income of $0.01 million for the three months ended June 30, 2017.

Conference Call & Webcast:

Thursday, August 2 @ 8:30am Eastern Time	
Within the US:	888-394-8218
Outside the US:	323-701-0225
From Israel:	1809 212 883
Conference ID:	5856233
Webcast:	http://public.viavid.com/index.php?id=130659
Replays, Available through August 16:	
Domestic:	844-512-2921
International:	412-317-6671
Replay PIN:	5856233

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 downregulation of the three key pathologies of NASH: steatosis, inflammation and fibrosis. The effect of Aramchol on fibrosis is mediated by downregulation of steatosis and directly on human collagen producing cells. Aramchol has been granted Fast Track designation status by the FDA for the treatment of NASH.

NASH is an emerging world crisis impacting an estimated 3% to 5% of the U.S. population and an estimated 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. Galmed recently announced top-line results of 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 is currently preparing for an end of Phase IIb meeting with the FDA to discuss the results of the ARREST Study and a Phase III study protocol, with a view to initiating a Phase III clinical study of Aramchol in 2019.

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. Many factors could cause Galmed's actual activities or results to differ materially from the activities and results anticipated in forward-looking statements, including, but not limited to, the following: the timing and cost of Galmed's planned Phase III trial for Aramchol, or whether a Phase III trial will be conducted at all; completion and receiving favorable results of a Phase III trial for Aramchol or any other pre-clinical or clinical trial; regulatory action with respect to Aramchol by the FDA or the EMA; the commercial launch and future sales of Aramchol or any other future products or product candidates; Galmed's ability to comply with all applicable post-market regulatory requirements for Aramchol in the countries in which it seeks to market the product; Galmed's ability to achieve favorable pricing for Aramchol; Galmed's expectations regarding the commercial market for NASH; third-party payor reimbursement for Aramchol; Galmed's estimates regarding anticipated capital requirements and Galmed's needs for additional financing; market adoption of Aramchol by physicians and patients; the timing, cost or other aspects of the commercial launch of Aramchol; the development and approval of the use of Aramchol for additional indications or in combination therapy; and Galmed's expectations regarding licensing, acquisitions and strategic operations. More detailed information about the risks and uncertainties affecting Galmed is contained under the heading "Risk Factors" included in Galmed's most recent Annual Report on Form 20-F filed with the SEC on March 13, 2018, 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, 2018	As of December 31, 2017
	Unaudited	Audited
Assets		

Current assets		
Cash and cash equivalents	$ 6,151	$ 13,021
Marketable securities	87,954	5,976
Other accounts receivable	368	155
Total current assets	94,473	19,152
Property and equipment, net	374	491
Total assets	$ 94,847	$ 19,643
Liabilities and stockholders' equity		
Current liabilities		
Trade payables	$ 2,346	$ 2,276
Other accounts payable	1,458	1,034
Short-term portion of deferred revenue	-	538
Total current liabilities	3,804	3,848
Stockholders' equity:		
Ordinary shares par value NIS 0.01 per share; Authorized 50,000,000; Issued and outstanding: 20,912,754 shares as of June 30, 2018; 14,435,161 shares as of December 31, 2017	58	40
Additional paid-in capital	172,824	92,381
Accumulated other comprehensive loss	(29)	(7)
Accumulated deficit	(81,810)	(76,619)
Total stockholders' equity	91,043	15,795
Total liabilities and stockholders' equity	$ 94,847	$ 19,643

GALMED PHARMACEUTICALS LTD.

Consolidated Statements of Operations (Unaudited)

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

	Three months ended June 30,		Six months ended June 30,	
	2018	**2017**	**2018**	**2017**
Revenue	$ 270	$ 270	$ 538	$ 538
Research and development expenses	1,940	2,347	3,884	5,090

General and administrative expenses	1,105	624	1,988	1,413
Total operating expenses	2,775	2,701	5,334	5,965
Financial expenses (income), net	(90)	(9)	(143)	(111)
Loss before income taxes	2,685	2,692	5,191	5,854
Taxes on Income	-	-	-	-
Net loss	$ 2,685	$ 2,692	$ 5,191	$ 5,854
Basic and diluted net loss per share	$ 0.17	$ 0.22	$ 0.34	$ 0.48
Weighted-average number of shares outstanding used in computing basic and diluted net loss per share	15,711,736	12,175,147	15,243,785	12,171,668

GALMED PHARMACEUTICALS LTD.

Consolidated Statements of Cash Flows (Unaudited)

U.S. Dollars in thousands

	Six months ended June 30,	
	2018	**2017**
Cash flow from operating activities		
Net loss	$ (5,191)	$ (5,854)
Adjustments required to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	118	120
Stock-based compensation expense	417	709
Amortization of discount/premium on marketable securities	(4)	(207)
Loss from Realization of marketable securities	5	115
Changes in operating assets and liabilities:		
Decrease (increase) in other accounts receivable	(213)	18
Increase (decrease) in trade payables	70	(757)
Increase (decrease) in other accounts payable	424	(178)
Decrease in related party	-	(117)

Decrease in deferred revenue	(538)	(538)
Net cash used in operating activities	(4,912)	(6,689)
Cash flow from investing activities		
Purchase of property and equipment	(1)	(8)
Investment in available for sale securities	(85,174)	-
Consideration from sale of available for sale securities	3,173	5,100
Net cash provided in (used in) investing activities	(82,002)	5,092
Cash flow from financing activities		
Issuance of Ordinary Shares	79,164	-
Proceeds from exercise of options	880	247
Net cash provided in financing activities	80,044	247
Decrease in cash and cash equivalents	(6,870)	(1,350)
Cash and cash equivalents at the beginning of the period	13,021	3,097
Cash and cash equivalents at the end of the period	$ 6,151	$ 1,747
Supplemental disclosure of cash flow information:		
Cash received from interest	$ 171	136

SOURCE Galmed Pharmaceuticals Ltd.

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Additional assets available online: Photos (1)

https://galmedpharma.investorroom.com/2018-08-02-Galmed-Pharmaceuticals-Provides-Business-Update-and-Reports-Second-Quarter-2018-Financial-Results