

Galmed Pharmaceuticals Provides Business Update and Reports Second Quarter 2019 Financial Results

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

TEL AVIV, Israel, Aug. 5, 2019 /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, 2019. The Company will host a conference call and webcast at 08:30 ET today.

Financial Summary - Second Quarter 2019 vs. Second Quarter 2018

- Cash and cash equivalents, short-term deposits and marketable securities totaled \$83.6 million as of June 30, 2019, compared to \$90.2 million at December 31, 2018.
- Net loss of \$4.2 million, or (\$0.20) per share, for the three months ended June 30, 2019, compared to a net loss of \$2.7 million, or (\$0.17) per share, for the three months ended June 30, 2018.
- Research and development expenses amounted to approximately \$3.5 million for the three months ended June 30, 2019, compared to approximately \$1.9 million for the three months ended June 30, 2018. The increase resulted primarily from an increase in clinical and pre-clinical trial expenses.
- General and administrative expenses amounted to approximately \$1.2 million for the three months ended June 30, 2019, compared to approximately \$1.1 million for the three months ended June 30, 2018.
- Financial expenses amounted to \$0.5 million for the three months ended June 30, 2019, compared to financial income of \$0.1 million for the three months ended June 30, 2018. The increase primarily relates to an increase in financial income from financial assets.

Conference Call & Webcast:

Monday, August 5th @ 8:30am Eastern Time.

Toll Free: 1-877-425-9470

Toll/International: 1-201-389-0878

Israel Toll Free: 1-809-406-247

Conference ID: 13692794

Webcast: <http://public.viavid.com/index.php?id=135464>

Replay Dial-In Numbers

Toll Free: 1-844-512-2921

Toll/International: 1-412-317-6671

Replay Pin Number: 13692794

Replay Start: Monday August 5, 2019, 11:30 AM ET

Replay Expiry: Monday August 19, 2019, 11:59 PM ET

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. During 2018, Galmed 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 to initiate a Phase 3/4 clinical study in the third quarter of 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 pivotal Phase 3/4 ARMOR trial, or the ARMOR Study or whether a pivotal trial will be conducted at all; completion and receiving favorable results of the ARMOR Study 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 patients; 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, 2019, 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, 2019 <u>Unaudited</u>	As of December 31, 2018 <u>Audited</u>
Assets		
Current assets		
Cash and cash equivalents	\$ 25,778	\$ 24,159
Short-term deposits	15,282	6,067
Marketable debt securities	42,563	59,962
Other accounts receivable	705	218

Total current assets	84,328	90,406
Right of use assets	603	-
Property and equipment, net	180	194
Total non-current assets	783	194
Total assets	\$ 85,111	\$ 90,600
Liabilities and stockholders' equity		
Current liabilities		
Trade payables	\$ 2,578	\$ 1,814
Other accounts payable	704	892
Total current liabilities	3,282	2,706
Non-current liabilities		
Lease obligation	\$ 442	\$ -
Total non-current liabilities	442	-
Ordinary shares par value NIS 0.01 per share; Authorized 50,000,000; Issued and outstanding: 21,121,337 shares as of June 30, 2019; 21,018,919 shares as of December 31, 2018	58	58
Additional paid-in capital	175,424	174,322
Accumulated other comprehensive gain (loss)	41	(11)
Accumulated deficit	(94,136)	(86,475)
Total stockholders' equity	81,387	87,894
Total liabilities and stockholders' equity	\$ 85,111	\$ 90,600

GALMED PHARMACEUTICALS LTD.

Consolidated Statements of Operations (Unaudited)

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

Three months ended	Six months ended
June 30,	June 30,

	2019	2018	2019	2018
Revenue	\$ -	\$ 270	\$ -	\$ 538
Research and development expenses	3,494	1,940	6,763	3,884
General and administrative expenses	1,207	1,105	1,978	1,988
Total operating expenses	4,701	2,775	8,741	5,334
Financial income, net	532	90	1,080	143
Net loss	\$ 4,169	\$ 2,685	\$ 7,661	\$ 5,191
Basic and diluted net loss per share	\$ 0.20	\$ 0.17	\$ 0.36	\$ 0.34
Weighted-average number of shares outstanding used in computing basic and diluted net loss per share	21,120,085	15,711,736	21,102,306	15,243,785

GALMED PHARMACEUTICALS LTD.
Consolidated Statements of Cash Flows (Unaudited)

U.S. Dollars in thousands

	Six months ended June 30,	
	2019	2018
Cash flow from operating activities		
Net loss	\$ (7,661)	\$ (5,191)

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

Depreciation and amortization	18	118
Stock-based compensation expense	1,007	417
Interest income from short-term deposits	(215)	-
Amortization of discount on marketable securities	(71)	(4)
Loss (gain) from realization of marketable securities	(9)	5
Changes in operating assets and liabilities:		
Decrease (increase) in other accounts receivable	(487)	(213)
Increase in trade payables	764	70
Increase (decrease) in other accounts payable	(349)	424
Decrease in deferred revenue	-	(538)
Net cash used in operating activities	(7,003)	(4,912)
Cash flow from investing activities		
Purchase of property and equipment	(4)	(1)
Investment in available for sale securities	(68,717)	(85,174)
Investment in short-term deposits	(9,000)	-
Consideration from sale of available for sale securities	86,248	3,173
Net cash provided in (used in) investing activities	8,527	(82,002)
Cash flow from financing activities		
Issuance of ordinary shares and warrants, net of issuance costs	-	79,164
Proceeds from exercise of options	95	880
Net cash provided in financing activities	95	80,044
Increase (Decrease) in cash and cash equivalents	1,619	(6,870)
Cash and cash equivalents at the beginning of the period	24,159	13,021
Cash and cash equivalents at the end of the period	\$ 25,778	\$ 6,151
Supplemental disclosure of cash flow information:		
Cash received from interest	\$ 1,057	171

SOURCE Galmed Pharmaceuticals Ltd.

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