Galmed Pharmaceuticals

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

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

TEL AVIV, Israel, Nov. 6, 2019 /PRNewswire/ -- Galmed Pharmaceuticals Ltd. (Nasdaq: GLMD) ("Galmed" or the "Company"), a clinical-stage biopharmaceutical company focused on the development of Aramchol, a liver targeted, oral SCD1 modulator currently in a Phase 3/4 clinical trial for the treatment of nonalcoholic steatohepatitis ("NASH") and fibrosis provides today a business update and reports financial results for the three and nine months ended September 30, 2019. The Company will host a conference call and webcast at 08:30 ET today.

Business Development

During the past quarter, the Company announced the initiation of its Phase 3/4 ARMOR, a double-blind, placebo-controlled, global study, to evaluate the efficacy and safety of Aramchol in subjects with NASH and fibrosis. The study is designed to consist of two parts. In the first part (Histology-Based) 1200 subjects will be treated with Aramchol or matching placebo for 52 weeks. The Histology-Based data will serve as the basis for the submission of a marketing authorization application under regulatory provisions of accelerated/conditional approval. In the second part (clinically-based), all subjects will continue with the same treatment assignment until study completion to confirm clinical efficacy.

The ARMOR study will be conducted in approximately 185 sites in the U.S.,Europe, Latin America and Asia and the Company aims to complete enrollment by the second quarter of 2021 and report top-line results by the fourth quarter of 2022.

Financial Summary - Third Quarter 2019 vs. Third Quarter 2018:

- Cash and cash equivalents, short-term deposits and marketable securities totaled $79.7 million as of September 30, 2019, compared to $90.2 million at December 31, 2018.
- Net loss of $4.5 million, or ($0.21) per share, for the three months ended September 30, 2019, compared to a net loss of $1.0 million, or ($0.05) per share, for the three months ended September 30, 2018.
- Research and development expenses amounted to approximately $4.1 million for the three months ended September 30, 2019, compared to approximately $1.7 million for the three months ended September 30, 2018. The increase resulted primarily from an increase in clinical, pre-clinical trial expenses and drug development expenses related to our continuing preparations of the ARMOR trial.
- General and administrative expenses amounted to approximately $1.0 million for the three months ended September 30, 2019, compared to approximately $1.0 million for the three months ended September 30, 2018.
- Financial expenses amounted to $0.5 million for the three months ended September 30, 2019, compared to financial income of $0.3 million for the three months ended September 30, 2018. The increase primarily relates to an increase in financial income from financial assets.

Conference Call & Webcast:

Wednesday, November 6th @ 8:30am Eastern Time.

Toll Free:	1-855-327-6837

Toll/International:	1-631-891-4304
Israel Toll Free:	1-809-458-327
Conference ID:	10007881
Webcast:	http://public.viavid.com/index.php?id=136591

Replay Dial-In Numbers

Toll Free:	1-844-512-2921
Toll/International:	1-412-317-6671
Replay Pin Number:	10007881
Replay Start:	Monday November 6, 2019, 11:30 AM ET
	Monday November 20, 2019, 11:59 PM
Replay Expiry:	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 Pharmaceuticals Ltd. is a clinical stage drug development biopharmaceutical company for liver, metabolic and inflammatory diseases. Our lead compound, Aramchol™, a backbone drug candidate for the treatment of NASH and fibrosis is currently in a Phase 3/4 registrational study.

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; 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 September 30, 2019	As of December 31, 2018
	Unaudited	Audited
Assets		
Current assets		
Cash and cash equivalents	$ 18,291	$ 24,159
Short-term deposits	20,408	6,067
Marketable debt securities	41,031	59,962
Other accounts receivable	898	218
Total current assets	80,628	90,406
Right of use assets	548	-
Property and equipment, net	176	194
Total non-current assets	724	194
Total assets	$ 81,352	$ 90,600
Liabilities and stockholders' equity		
Current liabilities		
Trade payables	$ 2,742	$ 1,814
Other accounts payable	798	892
Total current liabilities	3,540	2,706
Non-current liabilities		

Lease obligation	$ 389	$ -
Total non-current liabilities	389	-
Ordinary shares par value NIS 0.01 per share; Authorized 50,000,000; Issued and outstanding: 21,124,110 shares as of September 30, 2019; 21,018,919 shares as of December 31, 2018	58	58
Additional paid-in capital	175,963	174,322
Accumulated other comprehensive gain (loss)	52	(11)
Accumulated deficit	(98,650)	(86,475)
Total stockholders' equity	77,423	87,894
Total liabilities and stockholders' equity	$ 81,352	$ 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 September 30,		Nine months ended September 30,	
	2019	**2018**	**2019**	**2018**
Revenue	$ -	$ 1,500	$ -	$ 2,038
Research and development expenses	4,054	1,693	10,817	5,577
General and administrative expenses	953	987	2,931	2,975
Total operating expenses	5,007	1,180	13,748	6,514
Financial income, net	493	296	1,573	439
Loss before income taxes	4,514	884	12,175	6,075
Taxes on Income	-	75	-	75
Net loss	$ 4,514	$ 959	$ 12,175	$ 6,150
Basic and diluted net loss per share	$ 0.21	$ 0.05	$ 0.58	$ 0.36
Weighted-average number of shares outstanding used in computing basic and diluted net loss per share	21,123,418	20,953,421	21,109,421	17,167,911

GALMED PHARMACEUTICALS LTD.

Consolidated Statements of Cash Flows (Unaudited)

U.S. Dollars in thousands

	Nine months ended September 30,	
	2019	**2018**
Cash flow from operating activities		
Net loss	$ (12,175)	$ (6,150)
Adjustments required to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	27	261
Stock-based compensation expense	1,546	1,045
Interest income from short-term deposits	(161)	(21)
Amortization of discount on marketable securities	(93)	(81)
Loss (gain) from realization of marketable securities	(10)	13
Changes in operating assets and liabilities:		
Increase in other accounts receivable	(680)	(131)
Increase (decrease) in trade payables	928	(988)
Decrease in other accounts payable	(253)	(183)
Decrease in deferred revenue	-	(538)
Net cash used in operating activities	(10,871)	(6,773)
Cash flow from investing activities		
Purchase of property and equipment	(9)	(53)
Investment in available for sale securities	(72,600)	(88,180)
Investment in short-term deposits, net	(14,180)	(6,000)
Consideration from sale of available for sale securities	91,697	33,907
Net cash provided in (used in) investing activities	4,908	(60,326)
Cash flow from financing activities		
Issuance of ordinary shares and warrants, net of issuance costs	-	79,118
Proceeds from exercise of options	95	943
Net cash provided in financing activities	95	80,061
Increase (Decrease) in cash and cash equivalents	(5,868)	12,962
Cash and cash equivalents at the beginning of the period	24,159	13,021
Cash and cash equivalents at the end of the period	$ 18,291	$ 25,983
Supplemental disclosure of cash flow information:		
Cash received from interest	$ 1,542	513
Non-cash transactions:		
Recognition of right-of-use asset and lease liability from adoption of ASU 2016-02	$ 679	-

Logo - http://mma.prnewswire.com/media/595923/Galmed_Pharmaceuticals_Ltd_Logo.jpg

SOURCE Galmed Pharmaceuticals Ltd.

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Additional assets available online: Photos (1)

https://galmedpharma.investorroom.com/2019-11-06-Galmed-Pharmaceuticals-Provides-Business-Update-and-Reports-Third-Quarter-2019-Financial-Results