Galmed Pharmaceuticals

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

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

TEL AVIV, Israel, Nov. 5, 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 a business update and reports financial results for the three and nine months ended September 30, 2018. The Company will host a conference call and webcast at 08:30 ET today.

Business Update

Updates on progress towards the initiation of "ARMOR", Aramchol's Phase 3 pivotal study of Aramchol

The Company is planning to initiate the ARMOR, Phase 3 pivotal study of Aramchol at the end of the second quarter of 2019 or early in the third quarter of 2019. Manufacturing of the first batch of the Phase 3 active pharmaceutical ingredients is due to be completed during the fourth quarter of 2018. Selection of the regions and countries where the study will be conducted has been completed and specific site feasibility is in process. The Company is working on advancing the regulatory submissions process.

Appointment of a new member to the Board

In October 2018, Marshall Heinberg was appointed to the Board of Directors. Mr. Heinberg currently serves as a Senior Advisor to Burford Capital, a leading publicly traded litigation finance company. Mr. Heinberg also serves as Executive Chairman of the Board of Ecology and Environment, a Nasdaq-listed environmental consulting firm. Until July 2012, he was Head of Investment Banking at Oppenheimer & Co., Inc. and was formerly Head of U.S. Investment Banking for CIBC World Markets. Over the course of his career, Mr. Heinberg has been responsible for managing corporate finance, mergers and acquisitions, leveraged finance, financial sponsors and merchant banking activity in the United States.

Key appointments to clinical operation team

- In September, 2018, Ronen Mansuri, was appointed Vice President, Clinical Operations and Biometrics reporting to Dr. Tali Gorfine, Chief Medical Officer. Prior to joining Galmed, Mr. Mansuri spent 12 years in various senior positions in Teva Pharmaceutical's Biometrics, Data Management and Operations Management, most recently as Senior Director, Head of Global Clinical Data Programming and holding key positions in Teva Global R&D.
- In November, 2018, Dr. Jonathan Yovell, was appointed as Medical Director, reporting to Dr. Gorfine. Prior to joining Galmed Dr. Yovell was Medical Manager Oncology at Merck Serono Ltd. in Israel where he was responsible for the clinical plan and led the scientific and clinical activities related to Merck's portfolio of oncology drugs in Israel.

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

- Cash and cash equivalents, short term deposits and marketable debt securities totaled $92.3 million as of September 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 $1.0 million, or ($0.05) per share, for the three months ended September 30, 2018, compared to a net loss of $2.8 million, or ($0.23) per share, for the three months ended September 30, 2018.

- The Company recognized $1.5 million of revenue for the three months ended September 30, 2018, compared to approximately $0.3 million for the three months ended September 30, 2017. The revenue relates to a milestone payment received under the license agreement with Samil Pharma.
- Research and development expenses amounted to approximately $1.7 million for the three months ended September 30, 2018, compared to approximately $2.3 million for the three months ended September 30, 2017. The decrease resulted primarily from a decrease in expenses in connection with clinical studies.
- General and administrative expenses amounted to approximately $1.0 million for the three months ended September 30, 2018, compared to approximately $0.7 million for the three months ended September 30, 2017. The increase in general and administrative expenses for the three months ended September 30, 2018 resulted primarily from an increase in non-cash stock based compensation expenses.
- Financial income amounted to $0.3 million for the three months ended September 30, 2018, compared to a financial income of $0.01 million for the three months ended September 30, 2017. The increase primarily relates to an increase in financial income from marketable securities.

Conference Call & Webcast:

Monday, November 5 @ 8:30am Eastern Time
Within the US: 800-239-9838
Outside the US: 323-794-2551
From Israel: 1809 212 883
Conference ID: 9320949
Webcast: http://public.viavid.com/index.php?id=131686

Replays, Available through November 19:
Domestic: 844-512-2921
International: 412-317-6671
Replay PIN: 9320949

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 September 30, 2018	As of December 31, 2017
	Unaudited	Audited
Assets		
Current assets		

Cash and cash equivalents	$ 25,983	$ 13,021
Marketable debt securities	60,313	5,976
Short-term deposits	6,021	-
Other accounts receivable	286	155
Total current assets	92,603	19,152
Property and equipment, net	284	491
Total assets	$ 92,887	$ 19,643
Liabilities and stockholders' equity		
Current liabilities		
Trade payables	$ 1,288	$ 2,276
Other accounts payable	851	1,034
Short-term portion of deferred revenue	-	538
Total current liabilities	2,139	3,848
Stockholders' equity:		
Ordinary shares par value NIS 0.01 per share; Authorized 50,000,000; Issued and outstanding: 21,003,828 shares as of September 30, 2018; 14,435,161 shares as of December 31, 2017	58	40
Additional paid-in capital	173,469	92,381
Accumulated other comprehensive loss	(10)	(7)
Accumulated deficit	(82,769)	(76,619)
Total stockholders' equity	90,748	15,795
Total liabilities and stockholders' equity	$ 92,887	$ 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 September 30,		Nine months ended September 30,	
	2018	**2017**	**2018**	**2017**
Revenue	$ 1,500	$ 273	$ 2,038	$ 811
Research and development expenses	1,693	2,331	5,577	7,421

General and administrative expenses	987	697	2,975	2,110
Total operating loss	1,180	2,755	6,514	8,720
Financial expenses (income), net	(296)	46	(439)	(65)
Loss before income taxes	884	2,801	6,075	8,655
Taxes on Income	75	-	75	-
Net loss	$ 959	$ 2,801	$ 6,150	$ 8,655
Basic and diluted net loss per share	$ 0.05	$ 0.23	$ 0.36	$ 0.71
Weighted-average number of shares outstanding used in computing basic and diluted net loss per share	20,953,421	12,364,249	17,167,911	12,274,536

GALMED PHARMACEUTICALS LTD.

Consolidated Statements of Cash Flows (Unaudited)

U.S. Dollars in thousands

	Nine months ended September 30,	
	2018	**2017**
Cash flow from operating activities		
Net loss	$ (6,150)	$ (8,655)
Adjustments required to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	261	180
Stock-based compensation expense	1,045	1,066
Amortization of discount/premium on marketable debt securities	(81)	(187)
Interest from short-term deposits	(21)	-
Loss from Realization of marketable debt securities	13	130
Changes in operating assets and liabilities:		
Decrease (increase) in other accounts receivable	(131)	113
Decrease in trade payables	(988)	(1,157)
Decrease in other accounts payable	(183)	(144)
Decrease in related party	-	(117)
Decrease in deferred revenue	(538)	(812)
Net cash used in operating activities	(6,773)	(9,583)

Cash flow from investing activities		
Purchase of property and equipment	(53)	(10)
Investment in available for sale securities	(88,180)	(1,447)
Investment in short term deposits	(6,000)	7,589
Consideration from sale of available for sale securities	33,907	-
Net cash provided in (used in) investing activities	(60,326)	(6,132)
Cash flow from financing activities		
Issuance of Ordinary Shares and warrants *)	79,118	2,655
Proceeds from exercise of options	943	313
Net cash provided in financing activities	80,061	2,968
Increase in cash and cash equivalents	12,962	(483)
Cash and cash equivalents at the beginning of the period	13,021	3,097
Cash and cash equivalents at the end of the period	$ 25,983	$ 2,614
Supplemental disclosure of cash flow information:		
Cash received from interest	$ 513	169

SOURCE Galmed Pharmaceuticals Ltd.

For further information: Timothy McCarthy, LifeSci Advisors, LLC, 212-915-2564, tim@lifesciadvisors.com, Guy Nehemya, Vice President, Operations, Galmed Pharmaceuticals Ltd., guy@galmedpharma.com

---

https://galmedpharma.investorroom.com/2018-11-05-Galmed-Pharmaceuticals-Provides-Business-Update-and-Reports-Third-Quarter-2018-Financial-Results