Galmed Pharmaceuticals

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

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

TEL AVIV, Israel, May 7, 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™, an oral therapy for the treatment of nonalcoholic steatohepatitis, or NASH and fibrosis, provides today updated information on the Company's clinical development program and reports financial results for the three months ended March 31, 2019. The Company will host a conference call and webcast at 08:30 ET today.

Business Update

Completion of End of Phase 2 Meeting With FDA

In April 2019, the Company announced that it completed its End-of-Phase 2 meeting with the Food and Drug Administration (FDA) and reached general agreement on key aspects of the Phase 3/4 development and registration plan for Aramchol and on the pivotal registration study ARMOR. General agreement has been reached with FDA on key aspects of the ARMOR study including patient population, study endpoints, study dose and treatment duration.

Updates on the ARMOR study design

The planned Phase 3/4 ARMOR study is a multi-national, multi-center, randomized, double blind, placebo-controlled study designed to evaluate the efficacy and safety of Aramchol as compared to placebo in subjects with NASH and fibrosis. The ARMOR study will enroll subjects with pre-diabetes or type II diabetes, overweight or obese and a baseline fibrosis score of 2-3. The study is designed to consist of two parts. In the first part (histology-based) subjects will be treated with Aramchol or matching placebo for 52 weeks until the second biopsy. In the second part (clinically-based), subjects will continue with the same treatment assignment until study completion to confirm clinical efficacy. Assuming the results in the first part are positive, the Company plans to submit a marketing authorization application under regulatory provisions of accelerated/conditional approval.

The ARMOR study will evaluate the safety and efficacy of Aramchol and is expected to enroll approximately 2000 patients dosed with 300mg of Aramchol twice daily or placebo in a 2:1 randomization ratio. The Company plans to perform an analysis of the primary histology-based endpoints after the first 1,200 patients complete 52 weeks of treatment. The trial is being powered to meet the two alternative key histology-based endpoints: (i) NASH resolution without worsening of liver fibrosis, and (ii)

fibrosis improvement without NASH worsening. Under FDA guidance, meeting one of these endpoints is expected to suffice for the study success of the first part

The Company plans on opening around 150 recruiting sites around the globe including in the U.S., Europe, Latin America and Asia.

The Company is on track to submit its study protocol and other design elements of its ARMOR trial to the FDA this quarter with study commencement expected in the third quarter of 2019. Following commencement, the Company anticipates completion of randomization within 18 months and based on current timelines the Company aims to report the results of the first part of the study in the fourth quarter of 2022.

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

- Cash and cash equivalents, short-term deposits and marketable debt securities totalled $86.6 million as of March 31, 2019, compared to $90.2 million at December 31, 2018.
- Net loss amounted to $3.5 million, or $0.17 per share, for the three months ended March 31, 2019, compared to a net loss of $2.5 million, or $0.17 per share, for the three months ended March 31, 2019.
- Research and development expenses amounted to approximately $3.3 million for the three months ended March 31, 2019, compared to approximately $1.9 million for the three months ended March 31, 2018. The increase resulted primarily from an increase in expenses in connection with the manufacturing of Aramchol for the ARMOR study.
- General and administrative expenses amounted to approximately $0.8 million for the three months ended March 31, 2019, compared to approximately $0.9 million for the three months ended March 31, 2018. The decrease in general and administrative expenses for the three months ended March 31, 2019 resulted primarily from a decrease in professional fees.
- Financial income, net amounted to $0.5 million for the three months ended March 31, 2019, compared to financial income, net of $0.1 million for the three months ended March 31, 2018. The increase primarily relates to an increase in financial income from financial assets.

Conference Call & Webcast:

Tuesday, May 7th @ 8:30am Eastern Time.

Within the US:	1-855-327-6837
Outside the US:	1-631-891-4304
Israel Toll Free:	1 809 458 327

Conference ID: 10006680
Webcast: http://public.viavid.com/index.php?id=134310

Replay Dial-In Numbers

Toll Free: 1-844-512-2921
Toll/International: 1-412-317-6671
Replay Pin Number: 10006680
Replay Start: Tuesday May 7, 2019, 11:30 AM ET
Replay Expiry: Tuesday May 21, 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, 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 2b 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 March 31, 2019	As of December 31, 2018
	Unaudited	Audited
Assets		
Current assets		
Cash and cash equivalents	$ 37,338	$ 24,159
Short-term deposits	6,112	6,067
Marketable debt securities	43,112	59,962
Other accounts receivable	417	218
Total current assets	86,979	90,406
Right of use assets	668	-
Property and equipment, net	189	194
Total non-current assets	857	194
Total assets	$ 87,836	$ 90,600
Liabilities and stockholders' equity		
Current liabilities		
Trade payables	$ 1,797	$ 1,814
Other accounts payable	612	892
Total current liabilities	2,409	2,706
Non-current liabilities		
Lease obligation	$ 499	$ -
Total non-current liabilities	499	-
Ordinary shares par value NIS 0.01 per share; Authorized 50,000,000; Issued and outstanding: 21,113,066 shares as of March 31, 2019; 21,018,919 shares as of December 31, 2018	58	58
Additional paid-in capital	174,812	174,322
Accumulated other comprehensive gain (loss)	25	(11)
Accumulated deficit	(89,967)	(86,475)
Total stockholders' equity	84,928	87,894
Total liabilities and stockholders' equity	$ 87,836	$ 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 March 31,	
	2019	**2018**
Revenue	$ -	$ 268
Research and development expenses	3,269	1,944
General and administrative expenses	771	883
Total operating expenses	4,040	2,559
Financial income, net	(548)	(53)
Net loss	$ 3,492	$ 2,506
Basic and diluted net loss per share from continuing operation	$ 0.17	$ 0.17
Weighted-average number of shares outstanding used in computing basic and diluted net loss per share	21,084,329	14,467,627

GALMED PHARMACEUTICALS LTD.

Consolidated Statements of Cash Flows (Unaudited)

U.S. Dollars in thousands

	Three months ended March 31,	
	2019	**2018**
Cash flow from operating activities		
Net loss	$ (3,492)	$ (2,506)
Adjustments required to reconcile net loss to net cash used in operating activities		

Depreciation and amortization	9	59
Stock-based compensation expense	416	330
Amortization of discount (premium) on marketable debt securities	(39)	9
Interest income from short-term deposits	(45)	-
Loss (gain) from realization of marketable debt securities	(5)	3
Changes in operating assets and liabilities:		
Increase in other accounts receivable	(199)	(210)
Decrease in trade payables	(17)	(80)
Decrease in other accounts payable	(449)	(802)
Decrease in deferred revenue	-	(268)
Net cash used in operating activities	(3,821)	(3,465)
Cash flow from investing activities		
Purchase of property and equipment	(4)	(1)
Investment in available for sale securities	(48,717)	(8,185)
Consideration from sale of available for sale securities	65,647	1,249
Net cash provided in (used in) investing activities	16,926	(6,937)
Cash flow from financing activities		
Proceeds from exercise of options	74	12
Net cash provided in financing activities	74	12
Decrease (increase) in cash and cash equivalents	13,179	(10,390)
Cash and cash equivalents at the beginning of the period	24,159	13,021
Cash and cash equivalents at the end of the period	$ 37,338	$ 2,631
Supplemental disclosure of cash flow information:		
Cash received from interest	$ 535	$ 46
Non-cash transactions		
Recognition of right-of-use asset and lease liability from adoption of ASU 2016-02	$ 679	$ -

SOURCE Galmed Pharmaceuticals Ltd.

For further information: Guy Nehemya, Chief Operating Officer, Galmed Pharmaceuticals Ltd., guy@galmedpharma.com

Additional assets available online: Photos (1)

https://galmedpharma.investorroom.com/2019-05-07-Galmed-Pharmaceuticals-Provides-Business-Update-and-Reports-First-Quarter-2019-Financial-Results