Galmed Pharmaceuticals

Galmed Pharmaceuticals Provides Business Updates and Reports First Quarter 2021 Financial Results

- Conference Call and Webcast Today at 8:30 a.m. ET / 5:30 a.m. PT -

TEL AVIV, Israel, May 13, 2021 /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, reports financial results for the three months ended March 31, 2021. The Company will host a conference call and webcast at08:30 ET today.

Recent Clinical & Scientific Developments

- Histology Results from approximately one-third of the study population (~ 50 subjects) of the open label part of the ARMOR Phase 3 study with higher exposure of Aramchol are expected to be available in Q4 2021.
- The National Medical Products Administration (NMPA) has granted approval for the Investigational New Drug (IND) application for the ARMOR Phase 3 study of Aramchol for the treatment of NASH & fibrosis in China.
- Submitted to the FDA the results of the Aramchol meglumine Phase I study with a view to introducing Aramchol meglumine into the double-blind placebo controlled registrational part of the ARMOR Phase 3 study. Galmed is expecting to receive guidance from the FDA in Q3 2021 and initiate the double-blind part of the ARMOR Phase 3 study by the end of Q1 2022.
- Completed single administrated doses from 10mg to 180mg in first in human Phase I trial of Amilo-5-Mer. Following excellent safety and proportional PK, single dosing ascended to 360mg. Topline data is expected in second half of 2021 and a Phase 1b proof of concept study is planned for Q4 2021.

Financial Summary – First Quarter 2021 vs. First Quarter 2020:

- During February 2021, Galmed raised approximately $18.4 million in an underwritten public offering and from its at-the-market equity facility.
- Cash and cash equivalents, restricted cash, short-term deposits and marketable debt securities totaled $58.9 million as of March 31, 2021, compared to $50.9 million at December 31, 2020.
- Net loss amounted to $8.9 million, or $0.38 per share, for the three months ended March 31, 2021, compared to a net loss of $6.1 million, or $0.29 per share, for the three months ended March 31, 2020.
- Research and development expenses amounted to approximately $7.4 million for the three months ended March 31, 2021, compared to approximately $5.6 million for the three months ended March 31, 2020. The increase resulted primarily from an increase in drug development expenses in connection with the manufacturing of Aramchol API to support the ARMOR Study and the development of Aramchol meglumine.
- General and administrative expenses amounted to approximately $1.7 million for the three months ended March 31, 2021, compared to approximately $0.9 million for the three months ended March 31, 2020. The increase in general and administrative expenses for the three months ended March 31, 2021 resulted primarily from an increase in salaries and benefits, and as well from an increase in the cost of our D&O insurance policy premium.
- Financial income, net amounted to $0.2 million for the three months ended March 31, 2021, compared to financial income, net of $0.4 million for the three months ended March 31, 2020.

Conference Call & Webcast:

Thursday May 13, 2021, 8:30 AM ET

Toll Free: 1-877-425-9470

Toll/International: 1-201-389-0878

Israel Toll Free: 1 809 406 247

Conference ID: 13719139

Webcast: **http://public.viavid.com/index.php?id=144593**

Replay Dial-In Numbers

Toll Free: 1-844-512-2921

Toll/International: 1-412-317-6671

Replay Pin Number: 13719139

Replay Start: Thursday May 13, 2021, 11:30 AM ET

Replay Expiry: Thursday May 27, 2021, 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 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 registrational study. We are also collaborating with the Hebrew University in the development of Amilo-5MER, a 5 amino acid synthetic peptide and recently initiated a first in human 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 pivotal Phase 3 ARMOR trial, or the ARMOR Study or any other pre-clinical or clinical trials; completion and receiving favorable results of the ARMOR Study for Aramchol or any other pre-clinical or clinical trial; the impact of the COVID-19 pandemic; regulatory action with respect to Aramchol or any other product candidate 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 or any other product candidate in the countries in which it seeks to market the product; Galmed's ability to achieve favorable pricing for Aramchol or any other product candidate; Galmed's expectations regarding the commercial market for NASH patients or any other indication; third-party payor reimbursement for Aramchol or any other product candidate; Galmed's estimates regarding anticipated capital requirements and Galmed's needs for additional financing; market adoption of Aramchol or any other product candidate by physicians and patients; the timing, cost or other aspects of the commercial launch of Aramchol or any other product candidate; the development and approval of the use of Aramchol or any other product candidate 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 18, 2021, 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, 2021	As of December 31, 2020
	Unaudited	Audited
Assets		
Current assets		
Cash and cash equivalents	$ 13,385	$ 6,947
Restricted Cash	113	113
Short-term deposits	1,806	3,807
Marketable debt securities	43,614	40,132
Other receivable	784	812

Total current assets	59,702	51,811
Right of use assets	509	394
Property and equipment, net	166	176
Total non-current assets	675	570
Total assets	$ 60,377	$ 52,381
Liabilities and stockholders' equity		
Current liabilities		
Trade payables	$ 5,803	$ 7,046
Other payables	1,334	966
Total current liabilities	7,137	8,012
Non-current liabilities		
Lease obligation	$ 283	$ 216
Total non-current liabilities	283	216
Ordinary shares par value NIS 0.01 per share; Authorized 50,000,000; Issued and outstanding: 25,083,914 shares as of March 31, 2021; 21,325,975 shares as of December 31, 2020	70	58
Additional paid-in capital	197,357	179,530
Accumulated other comprehensive gain	142	272
Accumulated deficit	(144,612)	(135,707)
Total stockholders' equity	52,957	44,153
Total liabilities and stockholders' equity	$ 60,377	$ 52,381

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,	
	2021	**2020**
Research and development expenses	$ 7,380	$ 5,550
General and administrative expenses	1,752	912
Total operating expenses	9,132	6,462
Financial income, net	(227)	(399)
Net loss	$ 8,905	$ 6,063
Basic and diluted net loss per share	$ 0.38	$ 0.29
Weighted-average number of shares outstanding used in computing basic		

and diluted net loss per share	23,374,061	21,150,841

GALMED PHARMACEUTICALS LTD.

Consolidated Statements of Cash Flows (Unaudited)

U.S. Dollars in thousands

	Three months ended March 31,	
	2021	**2020**
Cash flow from operating activities		
Net loss	$ (8,905)	$ (6,063)
Adjustments required to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	11	10
Stock-based compensation expense	471	515
Amortization of premium (discount) on marketable debt securities	21	(9)
Interest income from short-term deposits	(4)	(168)
Gain from realization of marketable debt securities	15	(11)
Changes in operating assets and liabilities:		
Decrease in other accounts receivable	28	37
Increase (decrease) in trade payables	(1,243)	(669)
Decrease in other accounts payable	320	(230)
Net cash used in operating activities	(9,286)	(6,588)
Cash flow from investing activities		
Purchase of property and equipment	(1)	-
Investment in available for sale securities	(10,007)	(7,400)
Sale (investment) in short term deposits, net	2,005	(4,000)
Consideration from sale of available for sale securities	6,359	15,313
Net cash provided by investing activities	(1,644)	3,913
Cash flow from financing activities		
	(*)	
Proceeds from exercise of options		61
Issuance of Ordinary shares, net of issuance cost	17,368	-
Net cash provided in financing activities	17,368	61
Increase (decrease) in cash and cash equivalents and restricted cash	6,438	(2,614)
Cash and cash equivalents and restricted cash at the beginning of the period Cash	7,060	16,043
Cash equivalents and restricted cash at the end of the period	$ 13,498	$ 13,429
Supplemental disclosure of cash flow information:		
Cash received from interest	$ 179	$ 168

Non-cash transactions:		
Recognition of right-of-use asset and lease liability from adoption of ASU 2016-02	$ 497	$ -

(*) Represents amount less than $1.

SOURCE Galmed Pharmaceuticals Ltd.

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Additional assets available online: Photos (1)

https://galmedpharma.investorroom.com/2021-05-13-Galmed-Pharmaceuticals-Provides-Business-Updates-and-Reports-First-Quarter-2021-Financial-Results