Galmed Pharmaceuticals

Galmed Pharmaceuticals Provides Business Update and Reports First Quarter 2020 Financial Results

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

TEL AVIV, Israel, May 14, 2020 /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, 2020. The Company will host a conference call and webcast at 08:30 ET today.

Galmed announces significant progress in the development of Aramchol meglumine, a salt version of Aramchol which has higher solubility, the same ADME profile, and is expected to have less variability in human plasma. Aramchol meglumine is considered a New Chemical Entity. As such, it is eligible for NCE patent protection until December 2034. Patents have been granted and maintained in 37 European territories, in Japan, Australia, China and Canada. Discussions on the patent protection in the USA with the USPTO are ongoing.

Results from a single and multiple oral administration doses of Aramchol free acid and Aramchol meglumine in a cross over PK study in dogs, demonstrated bioequivalence with reduced variability. In particular:

- after single dose administration, the AUCs Aramchol free acid and Aramchol meglumine are almost identical;
- after multiple dosing (steady state) AUC for the Aramchol meglumine was higher compared to Aramchol free acid;
- a three-fold reduction in coefficient variation in steady state in the Aramchol meglumine arm compared to Aramchol free acid suggesting lower variability among patients receiving Aramchol meglumine in the future;
- half-life of Aramchol while administration of both Aramchol free acid and Aramchol meglumine is identical in single and multiple dosing (steady state); and
- Cmax was higher in Aramchol meglumine compared to Aramchol free acid in steady state.

Galmed plans to submit these results along with other supportive data to the FDA and discuss with the FDA, as soon as practical, a plan to appropriately transition from Aramchol free acid to the Aramchol meglumine in the ongoing ARMOR Phase 3 study. Based on Galmed's regulatory and scientific review of relevant FDA guidance and precedents, the Company's assessment is that this change during Phase 3 could be considered acceptable provided bioequivalence of the two products is established and a number of other data considerations are addressed.

"Over the last few years, Galmed has been in the process of developing a new product, Aramchol meglumine, which is a salt form of Aramchol free acid. It is important to note that Aramchol meglumine and Aramchol acid circulate as Aramchol regardless of which drug product is administered. The markedly higher solubility of Aramchol meglumine results in lower variability which is a significant added benefit. We are excited to share with you today this important development. By developing a salt version of Aramchol we are able to take the important step towards gaining patent protection on the drug until December 2034. We have long understood the importance of securing a meaningful period of patent protected opportunity for our drug as we plan for our Phase 3 and beyond," said Allen Baharaff, Chief Executive Officer of Galmed.

Galmed plans on holding a virtual Analyst's Day in the coming months to discuss the details of this program.

Response to COVID-19

Galmed continues to monitor the impact of the COVID-19 pandemic on its operations and is committed to ensuring the health, safety and well-being of its clinical study participants, staff at its study sites and employees.

- Galmed implemented remote working and workplace protocols for our employees in accordance with Israeli Ministry of Health requirements;

- Galmed decided to temporarily halt the screening of new patients for the ARMOR study and aims to resume activity on a country by country, state by state and site by site basis as conditions improve;
- Galmed has utilized this time to advance the opening of new sites so that they are ready for activation when screening and randomization will be possible; and
- To help mitigate cost overrun, Galmed has taken several cost reduction measures including minimizing clinical related expenses, making certain adjustments to clinical staff pay according to the current and predicted level of activity, and reducing directors' cash fees by 50% for the first half of 2020.

During the second quarter of 2020, Galmed expects to lift some of the constraints in states in the US identified as "green states" allowing individual investigators to determine whether it is safe to resume screening activities. Galmed's current assessment is that by the fourth quarter of 2020, it will be able to resume recruitment in most of the ARMOR study sites. Accordingly, Galmed is updating its guidance for completion of recruitment of patients for the first part of the study from the second quarter of 2021 to the fourth quarter of 2021 and reporting of top-line results for the first part of the study from the fourth quarter of 2022 to the second half of 2023. The rapid development and fluidity of the COVID-19 pandemic precludes any firm estimates as to the ultimate effect this disease will have on the ARMOR study and is subject to change.

Financial Summary – First Quarter 2020 vs. First Quarter 2019:

- Cash and cash equivalents, restricted cash, short-term deposits and marketable debt securities totaled $69.0 million as of March 31, 2020, compared to $75.6 million at December 31, 2019.
- Net loss amounted to $6.1 million, or $0.29 per share, for the three months ended March 31, 2020, compared to a net loss of $3.5 million, or $0.17 per share, for the three months ended March 31, 2020.
- Research and development expenses amounted to approximately $5.6 million for the three months ended March 31, 2020, compared to approximately $3.3 million for the three months ended March 31, 2019. The increase resulted primarily from an increase in clinical trial expenses in connection with our ongoing ARMOR study.
- General and administrative expenses amounted to approximately $0.9 million for the three months ended March 31, 2020, compared to approximately $0.8 million for the three months ended March 31, 2019. The increase in general and administrative expenses for the three months ended March 31, 2020 resulted primarily from an increase in non-cash stock-based compensation expenses.
- Financial income, net amounted to $0.4 million for the three months ended March 31, 2020, compared to financial income, net of $0.5 million for the three months ended March 31, 2019. The decrease primarily relates to a decrease in financial income from financial assets.

Conference Call & Webcast:

Thursday, May 14th @ 8:30am Eastern Time.

Within the US:	1-877-425-9470
Outside the US:	1-201-389-0878
Israel Toll Free:	1-809-406-247
Conference ID:	13702167
Webcast:	http://public.viavid.com/index.php?id=139176

Replay Dial-In Numbers

Toll Free:	1-844-512-2921
Toll/International:	1-412-317-6671
Replay Pin Number:	13702167
Replay Start:	Thursday May 14, 2020, 11:30 AM ET
Replay Expiry:	Thursday May 28, 2020, 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.

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; completion and receiving favorable results of the ARMOR Study for Aramchol or any other pre-clinical or clinical trial; the impact of the coronavirus outbreak; 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 12, 2020, 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, 2020	As of December 31, 2019
Assets		

Current assets		
Cash and cash equivalents	$ 13,316	$ 15,931
Restricted Cash	113	112
Short-term deposits	32,106	27,938
Marketable debt securities	23,467	31,622
Other accounts receivable	790	827
Total current assets	69,792	76,430
Right of use assets	486	538
Property and equipment, net	161	171
Total non-current assets	647	709
Total assets	$ 70,439	$ 77,139
Liabilities and stockholders' equity		
Current liabilities		
Trade payables	$ 5,330	$ 5,999
Other accounts payable	703	935
Total current liabilities	6,033	6,934
Non-current liabilities		
Lease obligation	$ 302	$ 352
Total non-current liabilities	302	352
Ordinary shares par value NIS 0.01 per share; Authorized 50,000,000; Issued and outstanding:		
21,153,166 shares as of March 31, 2020; 21,139,385 shares as of December 31, 2019	58	58
Additional paid-in capital	177,272	176,696
Accumulated other comprehensive gain (loss)	(227)	35
Accumulated deficit	(112,999)	(106,936)
Total stockholders' equity	64,104	69,853
Total liabilities and stockholders' equity	$ 70,439	$ 77,139

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,	
	2020	**2019**
Research and development expenses	$ 5,550	$ 3,269
General and administrative expenses	912	771
Total operating expenses	6,462	4,040
Financial income, net	(399)	(548)
Net loss	$ 6,063	$ 3,492
Basic and diluted net loss per share from continuing operation	$ 0.29	$ 0.17

Weighted-average number of shares outstanding used in computing basic and diluted net loss per share	21,150,841	21,084,329

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Consolidated Statements of Cash Flows (Unaudited)

U.S. Dollars in thousands

	Three months ended March 31,	
	2020	**2019**
Cash flow from operating activities		
Net loss	$ (6,063)	$ (3,492)
Adjustments required to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	10	9
Stock-based compensation expense	515	416
Amortization of premium on marketable debt securities	(9)	(39)
Interest income from short-term deposits	(168)	(45)
Gain from realization of marketable debt securities	(11)	(5)
Changes in operating assets and liabilities:		
Increase (decrease) in other accounts receivable	37	(199)
Decrease in trade payables	(669)	(17)
Decrease in other accounts payable	(230)	(449)
Net cash used in operating activities	(6,588)	(3,821)
Cash flow from investing activities		
Purchase of property and equipment	-	(4)
Investment in available for sale securities	(7,400)	(48,717)
Investment in short term deposits	(4,000)	
Consideration from sale of available for sale securities	15,313	65,647
Net cash provided in investing activities	3,913	16,926
Cash flow from financing activities		
Proceeds from exercise of options	61	74
Net cash provided in financing activities	61	74
Increase (decrease) in cash and cash equivalents	(2,614)	13,179
Cash and cash equivalents at the beginning of the period	16,043	24,159
Cash and cash equivalents at the end of the period	$ 13,429	$ 37,338
Supplemental disclosure of cash flow information:		
Cash received from interest	$ 168	$ 535

SOURCE Galmed Pharmaceuticals Ltd.

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https://galmedpharma.investorroom.com/2020-05-14-Galmed-Pharmaceuticals-Provides-Business-Update-and-Reports-First-Quarter-2020-Financial-Results