Galmed Pharmaceuticals

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

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

TEL AVIV, Israel, Aug. 6, 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 scientific and clinical development programs and reports financial results for the three and six months ended June 30, 2020. The Company will host a conference call and webcast at08:30 ET today.

Recent Clinical & Scientific Developments

- The Data Monitoring Committee (DMC) of the ARMOR study held a scheduled meeting and recommended that the ARMOR Phase 3 trial for NASH and fibrosis can continue with no changes to the protocol.
- Galmed resumed recruitment in some of ARMOR study sites in theUSA, Canada, France, Mexico, Chile, Spain, Belgium, Turkey and South Korea (one quarter earlier than previously anticipated). Galmed maintains its guidance for completion of recruitment of patients for the first part of the study by the fourth quarter of 2021 and reporting of top-line results for the first part of the study in the second half of 2023.
- 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. The rapid development and fluidity of the COVID-19 pandemic precludes any firm estimates as to the ultimate effect this disease will have on Galmed's clinical trials and is subject to change.
- Galmed intends to approach the regulatory agencies during the first quarter of 2021 to discuss its Aramchol Meglumine program. A preliminary bioequivalence (BE) study is planned for the third quarter of 2021 this year for identifying the equivalent dose to 300mg BID of aramchol acid, currently being used in the ARMOR study. This study is intended to serve as calibration for the regulatory BE study that Galmed plans on performing during the second quarter of 2021 with the identified Aramchol meglumine dose.
- Galmed is announcing phase 1 readiness of its pipeline program, Amilo-5MER. Amilo-5MER is being developed through a research collaboration between Galmed and the Lautenberg Center for General and Tumor Immunology, the Hebrew University — Hadassah Medical School Jerusalem. A Phase 1 study in healthy volunteers is planned for initiation in fourth quarter of 2020 to support its development for IBD and potentially for severe COVID-19 acute respiratory distress syndrome (ARDS).

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

- Cash and cash equivalents, restricted cash, short-term deposits and marketable debt securities totaled $63.5 million as of June 30, 2020, compared to $75.6 million at December 31, 2019.
- Net loss amounted to $5.5 million, or $0.26 per share, for the three months endedJune 30, 2020, compared to a net loss of $4.2 million, or $0.20 per share, for the three months endedJune 30, 2020.
- Research and development expenses amounted to approximately $5.0 million for the three months ended June 30, 2020, compared to approximately $3.5 million for the three months ended June 30, 2019. The increase resulted primarily from an increase in expenses related to CMC and formulation studies 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 $0.8 million for the three months ended June 30, 2020, compared to approximately $1.2 million for the three months ended June 30, 2019. The decrease in general and administrative expenses for the three months ended June 30, 2020 resulted primarily from a decrease in professional services expenses and investor relations related expenses.
- Financial income, net amounted to $0.3 million for the three months ended June 30, 2020, compared to financial income, net of $0.5 million for the three months ended June 30, 2019. The decrease primarily relates to a decrease in interest income from

financial assets. During the three months ended June 30, 2020, the Company recorded unrealized gains of $0.7 million as a result of change in the market value of its marketable debt securities.

Conference Call & Webcast:

Thursday August 6, 2020, 8:30 AM Eastern Time.

Toll Free: 1-800-954-0643
Toll/International: 1-212-231-2904
Israel Toll Free: 1-809-457-756
Conference ID: 21966797
Webcast: http://public.viavid.com/index.php?id=140960

Replay Dial-In Numbers

Toll Free: 1-844-512-2921
Toll/International: 1-412-317-6671
Replay Pin Number: 21966797
Replay Start: Thursday August 6, 2020, 11:30 AM ET
Replay Expiry: Thursday August 20, 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. We are also collaborating with the Hebrew University in the development of Amilo-5MER, a 5 amino acid synthetic peptide and plan to initiate a first in human study by the fourth quarter of 2020.

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 coronavirus outbreak; 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 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 June 30, 2020	As of December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	$ 5,553	$ 15,931
Restricted Cash	113	112
Short-term deposits	27,406	27,938
Marketable debt securities	30,470	31,622
Other receivables	669	827
Total current assets	64,211	76,430
Right of use assets	481	538
Property and equipment, net	157	171
Total non-current assets	638	709
Total assets	$ 64,849	$ 77,139
Liabilities and stockholders' equity		
Current liabilities		
Trade payables	$ 3,876	$ 5,999
Other payables	838	935

Total current liabilities	4,714	6,934
Non-current liabilities		
Lease obligation	$ 251	$ 352
Total non-current liabilities	251	352
Ordinary shares par value NIS 0.01 per share; Authorized 50,000,000; Issued and outstanding:		
21,153,166 shares as of June 30, 2020; 21,139,385 shares as of December 31, 2019	58	58
Additional paid-in capital	177,853	176,696
Accumulated other comprehensive gain	498	35
Accumulated deficit	(118,525)	(106,936)
Total stockholders' equity	59,884	69,853
Total liabilities and stockholders' equity	$ 64,849	$ 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 June 30,		Six months ended June 30,	
	2020	**2019**	**2020**	**2019**
Research and development expenses	4,971	3,494	10,521	6,763
General and administrative expenses	845	1,207	1,757	1,978
Total operating expenses	5,816	4,701	12,278	8,741
Financial income, net	290	532	689	1,080
Net loss	$ 5,526	$ 4,169	$ 11,589	$ 7,661
Basic and diluted net loss per share	$ 0.26	$ 0.20	$ 0.55	$ 0.36
Weighted-average number of shares outstanding used in computing basic and diluted net loss per share	21,153,166	21,120,085	21,152,003	21,102,306

GALMED PHARMACEUTICALS LTD.

Consolidated Statements of Cash Flows (Unaudited)

U.S. Dollars in thousands

	Six months ended June 31,	
	2020	**2019**
Cash flow from operating activities		
Net loss	$ (11,589)	$ (7,661)
Adjustments required to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	19	18
Stock-based compensation expense	1,096	1,007

Amortization of premium (discount) on marketable debt securities	16	(215)
Interest income from short-term deposits	(268)	(71)
Gain from realization of marketable debt securities	(10)	(9)
Changes in operating assets and liabilities:		
Decrease (increase) in other accounts receivable	158	(487)
Increase (decrease) in trade payables	(2,123)	764
Decrease in other accounts payable	(141)	(349)
Net cash used in operating activities	(12,842)	(7,003)
Cash flow from investing activities		
Purchase of property and equipment	(5)	(4)
Investment in available for sale securities	(26,979)	(68,717)
Investment in short term deposits	(4,000)	(9,000)
Maturity of short term deposits	4,800	-
Consideration from sale of available for sale securities	28,588	86,248
Net cash provided by investing activities	2,404	8,527
Cash flow from financing activities		
Proceeds from exercise of options	61	95
Net cash provided in financing activities	61	95
Increase (decrease) in cash and cash equivalents and restricted cash	(10,377)	1,619
Cash and cash equivalents and restricted cash at the beginning of the period	16,043	24,159
Cash and cash equivalents and restricted cash at the end of the period	$ 5,666	$ 25,778
Supplemental disclosure of cash flow information:		
Cash received from interest	$ 708	$ 1,057
Non-cash transactions:		
Recognition of right-of-use asset and lease liability from adoption of ASU 2016-02	$ 35	$ 679

SOURCE Galmed Pharmaceuticals Ltd.

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https://galmedpharma.investorroom.com/2020-08-06-Galmed-Pharmaceuticals-Provides-Business-Update-and-Reports-Second-Quarter-2020-Financial-Results