Galmed Pharmaceuticals

Galmed Pharmaceuticals Provides Business Update and Reports Fourth Quarter and Year End 2020 Financial Results

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

TEL AVIV, Israel, March 18, 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 and twelve months ended December 31, 2020. The Company will host a conference call and webcast at08:30 ET today.

Recent Clinical, Scientific & Business Developments

- In December last year, we announced the addition of an open-label part to our ARMOR Phase 3 registrational study designed to evaluate the treatment response, pharmacokinetics and safety as well as several Non-Invasive Tests (including ProC3, ELF and Fibroscan) associated with NASH and fibrosis of twice daily administration (BID) of Aramchol 300mg for the treatment duration of 24, 48 and 72 weeks. Results from approximately one-third of the study population (~ 50 subjects) that has completed the post-baseline liver biopsy are expected to be available in Q4 2021 as planned.

- ARMOR's double blind, placebo-controlled, registrational part is expected to initiate by the end of Q1 2022 based on once daily administration (QD) of Aramchol meglumine 300mg which is a salt form of Aramchol free acid with an improved target product profile. PK data showed that Aramchol meglumine and Aramchol free acid, the drug product that is currently being evaluated in the open label part of ARMOR, have the same PK profile i.e. same half-life and same Cmax and circulate in the blood as Aramchol regardless of which drug product is administered. Furthermore, Aramchol Meglumine has higher solubility which results in better homogeneity in blood levels. A Type C meeting with the FDA is planned for Q2 2021 to discuss a plan to introduce Aramchol meglumine into the double-blind, placebo-controlled, registrational part of the ARMOR Phase 3 study.

- A Phase 1a clinical trial of Amilo-5MER was initiated earlier this quarter as planned for single and multiple dosing and includes also oral dosing. Topline data is expected to be available in H2 2021. In LPS induced inflammation in mice, the animal model for systemic inflammation, Amilo-5MER reduced IL-6, TNF a, IFN g and IL-1b levels in the serum. Elevated levels of these pro inflammatory cytokine is the hallmark of acute and chronic inflammatory conditions and are symptomatic also among COVID-19 patients.

- During February 2021, Galmed raised approximately $18.4 million in an underwritten public offering and from its at-the-market equity facility. Galmed intends to use the net proceeds of these offerings for the continued development of our pipeline products, as well as the advancement of new programs, business development activities, and general corporate purposes.

- A new paper entitled "Aramchol Downregulates Stearoyl CoA-Desaturase 1 (SCD1) in Hepatic Stellate Cells to Attenuate Cellular Fibrogenesis" was published in the JHEP Reports. The paper summarizes a longstanding research collaboration by Prof. Scott Friedman, Chief of the Division of Liver Diseases, Icahn School of Medicine at Mount Sinai, New York and Prof. Jose Mato of

the Precision Medicine and Metabolism Laboratory, CIC bioGUNE, Spain describing for the first time the role of SCD1 in hepatic fibrogenesis and outlining the mechanism by which Aramchol exerts its anti-fibrotic effect directly by down regulation of SCD1 in hepatic stellate cells (HSCs). Data further support Aramchol's role in fibrosis reversal, including the potential antifibrotic activity in the ongoing Phase 3 ARMOR study in patients with NASH and fibrosis.

Financial Summary – Full Year 2020 vs. Full Year 2010; 4Q20vs. 4Q19:

- For the three and twelve months ended December 31, 2020, the Company recorded a net loss of $10.3 million and $28.8 million or $0.48 and $1.35 per share, respectively, compared with a net loss of $8.3 million and $20.5 million, or $0.39 and $0.97 per share, for the three and twelve months ended December 31, 2019.

- Research and development expenses were $26.1 million for the twelve months ended December 31, 2020, compared with $18.2 million for the twelve months ended December 31, 2019. For the three months ended December 31, 2020, research and development expenses totalled $9.0 million, which compares with $7.4 million for the same period in 2019.

  The increase for the three and twelve months resulted primarily from an increase in clinical trial expenses in connection with the Company's ongoing ARMOR study as well 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.

  The Company incurred general and administrative expenses of $4.1 million for the twelve months ended December 31, 2020, compared with $4.2 million for the twelve months ended December 31, 2019. For the three months ended December 31, 2020, general and administrative expenses totaled $1.3 million, which compares with $1.3 million for the same period in 2019.

- The decrease for the twelve months ended December 31, 2020 primarily resulted from a decrease in stock-based compensation expenses and professional services, partially offset by an increase in the cost of the Company's D&O insurance policy premium.

  Financial income, net amounted to $1.4 million for the twelve months ended December 31, 2020, compared with $1.9 million for the twelve months ended December 31, 2019. For the three months ended December 31, 2020, financial income, net totaled $0.1 million, which compares with $0.3 million for the same period in 2019.

- Cash and cash equivalents, restricted cash, short-term deposits and marketable debt securities totaled $51.0 million as of December 31, 2020, compared with $75.6 million as of December 31, 2019. The amount as of December 31, 2020 does not include $17.5 million of net proceeds raised during February 2021 in an underwritten public offering and the Company's at-the-market equity facility.

More detailed information can be found in the Company's Annual Report on Form 20-F, a copy of which has been filed with the Securities and Exchange Commission and posted on the Company's website at www.galmedpharma.com. You may request a copy of the Company's Form 20-F, at no cost to you, by writing to the Chief Financial Officer of the Company at 16 Tiomkin Street, Tel Aviv, Israel, 6578317 or by calling +972-3-693-8448.

Conference Call & Webcast:

Thursday, March 18, 2021, 8:30 AM Eastern Time.

Toll Free: 1-877-425-9470

Toll/International: 1-201-389-0878

Israel Toll Free: 1 809 406 247

Conference ID: 13716813

Webcast: http://public.viavid.com/index.php?id=143695

Replay Dial-In Numbers

Toll Free: 1-844-512-2921

Toll/International: 1-412-317-6671

Replay Pin Number: 13716813

Replay Start: Thursday March 18, 2021, 11:30 AM ET

Replay Expiry: Thursday April 1, 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 (Audited)

U.S. Dollars in thousands, except share data and per share data

	As of December 31,	
	2020	**2019**
Assets		
Current assets		
Cash and cash equivalents	$ 6,947	$ 15,931
Restricted cash	113	112

Short-term deposits	3,807	27,938
Marketable debt securities	40,132	31,622
Other accounts receivable	812	827
Total current assets	51,811	76,430
Right of use assets	394	538
Property and equipment, net	176	171
Total non-current assets	570	709
Total assets	$ 52,381	$ 77,139
Liabilities and stockholders' equity		
Current liabilities		
Trade payables	$ 7,046	$ 5,999
Other accounts payable	966	935
Total current liabilities	8,012	6,934
Non-current liabilities		
Lease obligation	$ 216	$ 352
Total non-current liabilities	216	352
Stockholders' equity		
Ordinary shares, par value NIS 0.01 per share; Authorized 50,000,000 shares; Issued and outstanding: 21,325,975 shares as of December 31, 2020; 21,139,385 shares as of December 31, 2019	58	58
Additional paid-in capital	179,530	176,696
Accumulated other comprehensive income	272	35
Accumulated deficit	(135,707)	(106,936)
Total stockholders' equity	44,153	69,853
Total liabilities and stockholders' equity	$ 52,381	$ 77,139

GALMED PHARMACEUTICALS LTD.

Consolidated Statements of Operations (Audited)

U.S. Dollars in thousands, except share data and per share data

	Year ended December 31,		
	2020	**2019**	**2018**
Revenue	$ -	$ -	$ 2,038
Research and development expenses	26,082	18,180	8,313
General and administrative expenses	4,128	4,196	4,440
Total operating loss	30,210	22,376	10,715
Financial income, net	(1,439)	(1,915)	(934)
Loss before income taxes	28,771	20,461	9,781
Income taxes	-	-	75
Net loss	$ 28,771	$ 20,461	$ 9,856

Basic and diluted net loss per share	$ 1.35	$ 0.97	$ 0.54
Weighted-average number of shares outstanding used in computing basic and diluted net loss per share	21,280,787	21,114,399	18,137,689

GALMED PHARMACEUTICALS LTD.

Consolidated Statements of Cash Flows (Audited)

U.S. Dollars in thousands

	Year ended December 31,		
	2020	**2019**	**2018**
Cash flow from operating activities			
Net loss for the year	$ (28,771)	$ (20,461)	$ (9,856)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	39	35	387
Amortization of discount/premium on marketable debt securities	90	(105)	(144)
Loss (gain) on sale of marketable debt securities	(527)	(9)	12
Interest income from short-term deposits	(285)	(63)	-
Stock-based compensation expense	2,066	2,231	1,783
Changes in operating assets and liabilities:			
Decrease in deferred revenue from collaboration agreement	-	-	(538)
Decrease (increase) in other accounts receivable	15	(609)	(63)
Increase (decrease) in trade payables	1,047	4,185	(462)
Increase (decrease) in other accounts payable	39	(141)	(142)
Net cash used in operating activities	(26,287)	(14,937)	(9,023)
Cash flow from investing activities			
Purchase of property and equipment	(44)	(12)	(90)
Investment in securities, available for sale	(55,034)	(72,600)	(92,279)
Proceeds from sale of securities, available for sale	47,198	101,098	38,421
Proceeds (investment) in short-term deposits, net	24,416	(21,808)	(6,067)
Net cash provided by (used in) investing activities	16,536	6,678	(60,015)
Cash flow from financing activities			
Issuance of ordinary shares and warrants, net of issuance costs (*)	707	-	79,149
Proceeds from exercise of options	61	143	1,027
Net cash provided by financing activities	768	143	80,176
Increase (decrease) in cash and cash equivalents and restricted cash	(8,983)	(8,116)	11,138
Cash and cash equivalents and restricted cash at the beginning of the year	16,043	24,159	13,021
Cash and cash equivalents and restricted cash at the end of the year	$ 7,060	$ 16,043	$ 24,159
Supplemental disclosure of cash flow information:			
Cash received from interest	$ 1,192	$ 1,953	$ 865
Cash paid for taxes	$ -	$ -	$ 75

Non-cash transactions:				
Recognition of right-of-use asset and lease liabilities from adoption of ASU 2016-02	$ 35	$ 653	$ -	

SOURCE Galmed Pharmaceuticals Ltd.

For further information: Guy Nehemya, Chief Operating Officer, Galmed Pharmaceuticals Ltd., investor.relations@galmedpharma.com, +972-3-693-8448

Additional assets available online: Photos (1)

https://galmedpharma.investorroom.com/2021-03-18-Galmed-Pharmaceuticals-Provides-Business-Update-and-Reports-Fourth-Quarter-and-Year-End-2020-Financial-Results