Galmed Pharmaceuticals

Galmed Pharmaceuticals Provides Additional Positive Data from the Open Label Part of ARMOR Study and Reports Third Quarter 2021 Financial Results

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

TEL AVIV, Israel, Nov. 8, 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, provides today updated information on the Company's scientific and clinical development programs and reports financial results for the three and nine months ended September 30, 2021.

Recent Clinical & Scientific Developments

- Announced positive results of the efficacy of a higher daily Aramchol dose on fibrosis improvement of the first 16 patients in the ARMOR study Open Label Part. Data published as a late breaking abstract at the Liver Meeting organized by the American Association for the Study of Liver Diseases (AASLD) and will be featured in the December issue of the scientific journal Hepatology -
- Announced histology data from first 20 patients from the ARMOR study Open Label Part showing that treatment with Aramchol 300mg BID resulted in clinically significant greater histological improvement in 12 out of 20 (60%) of patients. Data is corroborated by biomarkers associated with liver fibrosis including ALT, AST, Fib-4 and ProC-3 in ~50 patient providing the potential to predict similar histology response in larger cohort -
- Results of Phase 2b ARREST Trial of Aramchol Published in Nature Medicine –
- FDA and MHRA Agree with Galmed's plan to use Aramchol meglumine in the randomized double-blind placebo-controlled part of the Phase 3 ARMOR study —

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

- Cash and cash equivalents, restricted cash and marketable debt securities totaled $42.0 million as of September 30, 2021, compared to $50.9 million at December 31, 2020.
- Net loss amounted to $7.7 million, or $0.31 per share, for the three months ended September 30, 2021, compared to a net loss of $6.9 million, or $0.32 per share, for the three months ended September 30, 2020.
- Research and development expenses amounted to approximately $6.5 million for the three months ended September 30, 2021, compared to approximately $6.5 million for the three months ended September 30, 2020.
- General and administrative expenses amounted to approximately $1.3 million for the three months ended September 30, 2021, compared to approximately $1.1 million for the three months ended September 30, 2020.
- Financial income, net amounted to $0.1 million for the three months ended September 30, 2021, compared to financial income, net of $0.7 million for the three months ended September 30, 2020.

Conference Call & Webcast:
Monday November 8, 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: 13724243
Webcast: **https://viavid.webcasts.com/starthere.jsp?ei=1511856&tp_key=e9490761d4**

Replay Dial-In Numbers
Toll Free: 1-844-512-2921
Toll/International: 1-412-317-6671
Replay Pin Number: 13724243
Replay Start: Monday November 8, 2021, 11:30 AM ET
Replay Expiry: Monday November 22, 2021, 11:59 PM ET

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.

About ARMOR Study

ARMOR is a Phase 3 study comprised of two-parts, an open-label part and a randomized, double-controlled, placebo part, designed to evaluate the safety and efficacy of Aramchol in approximately 200 sites in the U.S., Europe and Latin America.

The first part, an open-label study, is designed to evaluate treatment response kinetics, pharmacokinetics and safety of twice daily administration of Aramchol 300mg in approximately 150 subjects with NASH and liver fibrosis stage 1-3 (F1 capped at 30 subjects), subjects with NASH who may or may not be overweight, and subjects with NASH who may or may not have type 2 diabetes or be pre-diabetic. Patients are randomized (1:1:1) into three groups with post-baseline liver biopsy being performed at 24 weeks, 48 weeks, or 72 weeks, respectively. A second post-baseline liver biopsy will be conducted after one year for subjects whose post-baseline liver biopsy at week 24, 48 or 72 does not show at least one stage improvement in fibrosis. The open label part is being conducted at approximately 50 selected sites in the U.S., and around the world which have been less affected by the COVID-19 pandemic.

The second part, a randomized, double-blind, placebo-controlled study, is designed to evaluate the safety and efficacy of twice daily administration of Aramchol 300 mg to support regulatory approval, with both a histology-based phase and a clinically-based phase. As currently designed, a total of 2000 subjects with NASH and liver fibrosis stage 2 and 3 who are overweight and are either pre-diabetic or have type 2 diabetes are expected to be randomized 2:1 to receive Aramchol 300mg BID or matching placebo. In the histology-based phase, we intend to treat 1000 subjects with Aramchol or matching placebo for 72 weeks until the second biopsy. The histology-based data is intended to serve as the basis for the submission of a Sub-part H marketing authorization application under regulatory provisions of accelerated/conditional approval. The primary histology-based endpoint is NASH resolution without worsening of fibrosis or fibrosis improvement without NASH worsening. In the clinically-based phase, all subjects will continue with the same treatment assignment for up to seven years until study completion to confirm clinical efficacy. We may announce end-of-study at the time when a total of 380 subjects have experienced at least

one pre-specified clinical event or at five years from last subject randomization, whichever comes first. The primary clinically-based endpoint is expected to be based on clinical events including all-cause mortality, histological progression to cirrhosis, MELD score >15, and hepatic decompensation events (e.g., hepatic encephalopathy, variceal bleeding, ascites).

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 September 30, 2021	As of December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 3,490	$ 6,947
Restricted Cash	113	113
Short-term deposits	-	3,807
Marketable debt securities	38,415	40,132
Other receivables	1,674	812
Total current assets	43,692	51,811
Right of use assets	452	394
Property and equipment, net	154	176
Total non-current assets	606	570
Total assets	$ 44,298	$ 52,381
Liabilities and stockholders' equity		
Current liabilities		
Trade payables	$ 5,233	$ 7,046
Other payables	1,115	966
Total current liabilities	6,348	8,012
Non-current liabilities		
Lease obligation	$ 274	$ 216
Total non-current liabilities	274	216
Ordinary shares par value NIS 0.01 per share; Authorized 50,000,000; Issued and outstanding: 25,083,914 shares as of September 30, 2021; 21,325,975 shares as of December 31, 2020	70	58
Additional paid-in capital	198,403	179,530
Accumulated other comprehensive gain	(75)	272
Accumulated deficit	(160,722)	(135,707)
Total stockholders' equity	37,676	44,153
Total liabilities and stockholders' equity	$ 44,298	$ 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 September 30,		Nine months ended September 30,	
	2021	**2020**	**2021**	**2020**
Research and development expenses	6,541	6,536	20,957	17,057
General and administrative expenses	1,304	1,054	4,432	2,811
Total operating expenses	7,845	7,590	25,389	19,868
Financial income, net	(131)	(685)	(374)	(1,374)
Net loss	$ 7,714	$ 6,905	$ 25,015	$ 18,494
Basic and diluted net loss per share	$ 0.31	$ 0.32	$ 1.02	$ 0.87
Weighted-average number of shares outstanding used in computing basic and diluted net loss per share	25,083,914	21,268,730	24,432,220	21,191,196

GALMED PHARMACEUTICALS LTD.

Consolidated Statements of Cash Flows (Unaudited)

U.S. Dollars in thousands

	Nine months ended September 30,	
	2021	**2020**
Cash flow from operating activities		
Net loss	$ (25,015)	$ (18,494)
Adjustments required to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	32	28
Stock-based compensation expense	1,517	1,474
Amortization of premium on marketable debt securities	115	36
Interest income from short-term deposits	7	(268)
Gain from realization of marketable debt securities	(32)	(522)

Changes in operating assets and liabilities:				
Decrease (increase) in other accounts receivable	(862)		185
Decrease in trade payables	(1,813)		(848)
Increase (decrease) in other accounts payable	149		(40)
Net cash used in operating activities	(25,902)		(18,449)
Cash flow from investing activities			
Purchase of property and equipment	(10)		(33)
Investment in available for sale securities	(12,069)		(45,226)
Sale (investment) in short term deposits, net	-		17,783
Maturity of short term deposits	3,800		-
Consideration from sale of available for sale securities	13,356		45,875
Net cash provided by (used in) investing activities	5,077		18,399
Cash flow from financing activities			
Proceeds from exercise of options (*)		(*)	61
Issuance of Ordinary shares upon ATM	8,147		707
Issuance of Ordinary shares, net of issuance cost	9,221		-
Net cash provided in financing activities	17,368		768
Increase (decrease) in cash and cash equivalents and restricted cash	(3,457)		718
Cash and cash equivalents and restricted cash at the beginning of the period	7,060		16,043
Cash and cash equivalents and restricted cash at the end of the period	$ 3,603		$ 16,761
Supplemental disclosure of cash flow information:			
Cash received from interest	$ 474		$ 966
Non-cash transactions:			
Recognition of right-of-use asset and lease liability from adoption of ASU 2016-02	$ 497		$ 35

(*) Represents amount less than $1.

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