Galmed Pharmaceuticals Provides Business Update and Reports Second Quarter 2022 Financial Results

TEL AVIV, Israel, Aug. 4, 2022 /PRNewswire/ -- Galmed Pharmaceuticals Ltd. (Nasdaq: GLMD) ("Galmed" or the "Company"), a clinical-stage biopharmaceutical company focused on the development of Aramchol™, an oral therapy for the treatment of nonalcoholic steatohepatitis, or NASH, fibrosis and other fibrotic indications, provides today a business update and reports financial results for the three and six months ended June 30, 2022.

Recent Developments

- Discontinuing the Open Label Part of the ARMOR study having reached its objectives while refocusing research and development on advancing Aramchol for new anti-fibrotic indications.
- Implementing a cost reduction plan that includes reduction in headcount and full-time positions and discontinuing any non-essential research and development activities.
- Evaluating the continuation of development of Aramchol and Amilo-5MER and unable to estimate if and when the registrational part of the ARMOR study will be initiated.
- Continuing to explore strategic alternatives and structuring to best optimize resources to enhance shareholder value and achieve goals.

Financial Summary - Second Quarter 2022 vs. Second Quarter 2021:

- Cash and cash equivalents, restricted cash and marketable debt securities totaled\$22.5 million as of June 30, 2022, compared to \$34.9 million at December 31, 2021.
- Net loss amounted to \$3.7 million, or \$0.15 per share, for the three months endedJune 30, 2022, compared to a net loss of \$8.4 million, or \$0.33 per share, for the three months endedJune 30, 2021.
- Research and development expenses amounted to approximately \$2.6 million for the three months ended June 30, 2022, compared to approximately \$7.0 million for the three months ended June 30, 2021. The decrease resulted primarily from a decrease in clinical trial expenses in connection with the discontinuation of the Open Label Part of the ARMOR study.
- General and administrative expenses amounted to approximately \$1.1 million for the three months endedJune 30, 2022, compared to approximately \$1.4 million for the three months endedJune 30, 2021. The decrease in general and administrative expenses for the three months ended June 30, 2022 resulted primarily from a decrease in professional services expenses.

About Galmed Pharmaceuticals Ltd.

Galmed Pharmaceuticals Ltd. is a clinical stage drug development biopharmaceutical company for liver, metabolic and inflammatory diseases.

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 COVID-19; 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; Galmed's expectations regarding licensing, acquisitions and strategic operations; Galmed's ability to maintain the listing of its common stock on The Nasdag Capital Market; and the outcome of any evaluation of Galmed's strategic alternatives. 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 May 2, 2022, 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.

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Consolidated Balance Sheets

		As of	As of	
	Ju	June 30, 2022		ember 31,
				2021
Assets				
Current assets				
Cash and cash equivalents	\$	1,980		2,884
Restricted Cash		114		114
Marketable debt securities		20,422		31,931
Other receivable		614		1,125
Total current assets		23,130		36,054
Right of use assets		315		406
Property and equipment, net		130		145
Total non-current assets		445		551
Total assets	\$	23,575	\$	36,605
Liabilities and stockholders' equity				
Current liabilities				
Trade payables	\$	2,089	\$	4,871
Other accounts payables		640		1,008
Total current liabilities		2,729		5,879

Non-current liabilities

Operating lease liabilities, net of current portion	\$ 134	\$ 229
Total non-current liabilities	134	229
Ordinary shares par value NIS 0.01 per share; Authorized 300,000,000; Issued and outstanding:		
25,088,414 shares as of June 30, 2022 and December 31, 2021	70	70
Additional paid-in capital	199,675	198,772
Accumulated other comprehensive loss	(982)	(171)
Accumulated deficit	(178,051)	(168,174)
Total stockholders' equity	 20,712	30,497
Total liabilities and stockholders' equity	\$ 23,575	\$ 36,605

The accompanying notes are an integral part of the interim consolidated financial statements.

GALMED PHARMACEUTICALS LTD.

Consolidated Statements of Operations (Unaudited)

Three months ended

Six months ended

June 30,

June 30,

2022	2021	2022	2021
2,580	7,036	7,376	14,416
1,150	1,376	2,446	3,128
3,730	8,412	9,822	17,544
4	(16)	55	(243)
3,374	\$ 8,396	\$ 9,877	\$ 17,301
0.15	\$ 0.33	\$ 0.39	\$ 0.72
25,088,414	25,083,914	25,088,414	24,099,132
	2,580 1,150 3,730 4 3,374 0.15	2,580 7,036 1,150 1,376 3,730 8,412 4 (16) 3,374 \$ 8,396 0.15 \$ 0.33	2,580 7,036 7,376 1,150 1,376 2,446 3,730 8,412 9,822 4 (16) 55 3,374 \$ 8,396 \$ 9,877 0.15 \$ 0.33 \$ 0.39

GALMED PHARMACEUTICALS LTD.

Consolidated Statements of Cash Flows (Unaudited)

U.S. Dollars in thousands

Six months ended

	2022	2021	
Cash flow from operating activities			
Net loss	\$ (9,877)	\$ (17,301)	
Adjustments required to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	18	21	
Stock-based compensation expense	903	943	
Amortization of premium on marketable debt securities	35	126	
Interest income from short-term deposits	-	(7)	
Loss (gain) from realization of marketable debt securities	201	(19)	
Finance expenses	(42)	-	
Changes in operating assets and liabilities:			
Decrease in other accounts receivable	511	325	
Decrease in trade payables	(2,782)	(1,417)	
Increase (decrease) in other accounts payable	(330)	412)	
Net cash used in operating activities	(11,363)	(16,917)	
Cash flow from investing activities			
Purchase of property and equipment	(3)	(8)	
Investmentin available for sale securities		(7,831)	

Sale (investment) in short term deposits, net	-	2,005
Consideration from sale of available for sale securities	10,462	6,359
Net cash provided by (used in) investing activities	10,459	525
Cash flow from financing activities		
Proceeds from exercise of options (*)	-	(*)
Issuance of Ordinary shares, net of issuance cost	-	17,368
Net cash provided in financing activities	 -	 17,368
Increase (decrease) in cash and cash equivalents and restricted cash	(904)	976
Cash and cash equivalents and restricted cash at the beginning of the period	2,998	7,060
Cash and cash equivalents and restricted cash at the end of the period	\$ 2,094	\$ 8,036
Supplemental disclosure of cash flow information:		
Cash received from interest	\$ 138	\$ 347
Non-cash transactions:	 	
Right-of-use assets obtained in exchange for new operating lease liabilities, net	\$ -	\$ 530

(*) Represents amount less than \$1.

SOURCE Galmed Pharmaceuticals Ltd.

For further information: Guy Nehemya, Chief Operating Officer, Galmed Pharmaceuticals Ltd.,

Additional assets available online: Photos (1)

 $\underline{https://galmedpharma.investorroom.com/2022-08-04-Galmed-Pharmaceuticals-Provides-Business-Update-and-Reports-Second-Quarter-2022-Financial-Results}$