

Galmed Pharmaceuticals Provides Business Update and Reports Fourth Quarter and Year End 2021 Financial Results

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

TEL AVIV, Israel, May 2, 2022 /[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 twelve months ended December 31, 2021.

Recent Clinical & Scientific Developments

- Announced positive interim results from Open-Label part of the ARMOR study showing that treatment with Aramchol 300mg BID resulted in a high rate of fibrosis improvement using three separate biopsy reading methodologies (NASH CRN, Ranked paired reading and a Quantitative Digital Pathology image analysis and artificial intelligence (AI) method), with a larger treatment effect with longer duration of therapy.
- Results of post baseline biopsies performed either at 24 weeks or at 48 weeks from 46 subjects with NASH and F1-3 that received Aramchol showed greater histological improvement at week 48 in both paired and AI evaluations (65% and 100% respectively) compared to NASH CRN scoring (40%).

Financial Summary - Full Year 2021 vs. Full Year 2020; 4Q21 vs. 4Q20:

For the three and twelve months ended December 31, 2021, the Company recorded a net loss of \$7.5 million and \$32.5 million or \$0.30 and \$1.32 per share, respectively, compared with a net loss of \$10.3 million and \$28.8 million, or \$0.48 and \$1.35 per share, for the three and twelve months ended December 31, 2020.

Research and development expenses were \$27.2 million for the twelve months ended December 31, 2021, compared with \$26.1 million for the twelve months ended December 31, 2020. The increase for the twelve months resulted primarily from an increase in clinical trial expenses in

connection with the Company's ongoing ARMOR study, partially offset by a decrease in expenses related to CMC and formulation expenses.

For the three months ended December 31, 2021, research and development expenses totaled \$6.3 million, which compares with \$9.0 million for the same period in 2020. The decrease for the three months resulted primarily from a decrease in clinical trial expenses and a decrease in expenses related to CMC and formulation expenses.

The Company incurred general and administrative expenses of \$5.7 million for the twelve months ended December 31, 2021, compared with \$4.1 million for the twelve months ended December 31, 2020. The increase for the twelve months primarily resulted from an increase in salaries and benefits expenses, and as well from an increase in the cost of the Company's D&O insurance policy premium.

For the three months ended December 31, 2021, general and administrative expenses totalled \$1.2 million, which compares with \$1.3 million for the same period in 2020.

Financial income, net amounted to \$0.4 million for the twelve months ended December 31, 2021, compared with \$1.4 million for the twelve months ended December 31, 2020. For the three months ended December 31, 2021, financial income, net totalled \$0.04 million, which compares with \$0.07 million for the same period in 2020.

- Cash and cash equivalents, restricted cash, short-term deposits, and marketable debt securities totaled \$34.9 million as of December 31, 2021, compared with \$51.0 million as of December 31, 2020.

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:

May 2, 2022, 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: 13727793

Webcast: https://viaavid.webcasts.com/starthere.jsp?ei=1535647&tp_key=893b75d833

Replay Dial-In Numbers

Toll Free: 1-844-512-2921

Toll/International: 1-412-317-6671

Replay Pin Number: 13727793

Replay Start: Monday May 2, 2022, 11:30 AM ET

Replay Expiry: Monday May 16, 2022, 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.

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 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.

GALMED PHARMACEUTICALS LTD.

Consolidated Balance Sheets (Audited)

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

	As of December 31,	
	2021	2020
Assets		
Current assets		
Cash and cash equivalents	\$ 2,884	\$ 6,947
Restricted cash	114	113
Short-term deposits	-	3,807
Marketable debt securities		

	31,931	40,132
Other accounts receivable		
	1,125	812
Total current assets		
	36,054	51,811
Operating lease right-of-use assets		
	406	394
Property and equipment, net		
	145	176
Total non-current assets		
	551	570
Total assets		
	\$ 36,605	\$ 52,381
Liabilities and stockholders' equity		
Current liabilities		
Trade payables		
	\$ 4,871	\$ 7,046
Other accounts payable		
	1,008	966
Total current liabilities		
	5,879	8,012
Non-current liabilities		
Operating lease liabilities, net of current portion		
	\$ 229	\$ 216
Total non-current liabilities		
	229	216
Stockholders' equity		

Ordinary shares, par value NIS 0.01 per share; Authorized 50,000,000 shares;

Issued and outstanding: 25,088,414 shares as of December 31, 2021;
21,325,975
shares as of December 31, 2020

	70	58
Additional paid-in capital		
	198,772	179,530
Accumulated other comprehensive income (loss)		
	(171)	272
Accumulated deficit		
	(168,174)	(135,707)
Total stockholders' equity		
	30,497	44,153
Total liabilities and stockholders' equity		
	\$ 36,605	\$ 52,381

GALMED PHARMACEUTICALS LTD.

Consolidated Statements of Operations (Audited)

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

	Year ended December 31,		
	2021	2020	2019
Research and development expenses			
	27,220	26,082	18,180
General and administrative expenses			
	5,661	4,128	4,196
Total operating loss			

	32,881	30,210	22,376
Financial income, net			
	(414)	(1,439)	(1,915)
Net loss			
	\$ 32,467	\$ 28,771	\$ 20,461
Basic and diluted net loss per share			
	\$ 1.32	\$ 1.35	\$ 0.97
Weighted-average number of shares outstanding used in computing basic and diluted net loss per share			
	24,597,638	21,280,787	21,114,399

GALMED PHARMACEUTICALS LTD.

Consolidated Statements of Cash Flows (Audited)

U.S. Dollars in thousands

	Year ended December 31,		
	2021	2020	2019
Cash flow from operating activities			
Net loss for the year			
	\$ (32,467)	\$ (28,771)	\$ (20,461)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization			

	42	39	35
Amortization of discount (premium) on marketable debt securities			
	121	90	(105)
Gain on sale of marketable debt securities			
	(37)	(527)	(9)
Finance expenses			
	6	31	3
Interest income from short-term deposits			
	7	(285)	(63)
Stock-based compensation expense			
	1,886	2,066	2,231
Changes in operating assets and liabilities:			
Decrease (increase) in other accounts receivable			
	(313)	15	(609)
Increase (decrease) in trade payables			
	(2,175)	1,047	4,185
Increase (decrease) in other accounts payable			
	38	8	(144)
Net cash used in operating activities			
	<u>(32,892)</u>	<u>(26,287)</u>	<u>(14,937)</u>
Cash flow from investing activities			
Purchase of property and equipment			
	(11)	(44)	(12)
Increase in restricted deposit			
	(1)	-	-
Investment in securities, available for sale			
	(13,569)	(55,034)	(72,600)
Proceeds from sale of securities, available for sale			
	21,243	47,198	101,098
Proceeds from (investment in) short-term deposits, net			
	<u>3,800</u>	<u>24,416</u>	<u>(21,808)</u>

Net cash provided by investing activities	<u>11,462</u>	<u>16,536</u>	<u>6,678</u>
Cash flow from financing activities			
Issuance of ordinary shares in at-the-market offering, net of issuance costs	8,147	-	-
Issuance of ordinary shares, net of issuance costs ^(**)	9,221	707	-
Proceeds from exercise of options	(*)		
		61	143
Net cash provided by financing activities	<u>17,368</u>	<u>768</u>	<u>143</u>
Decrease in cash, cash equivalents and restricted cash	(4,062)	(8,983)	(8,116)
Cash and cash equivalents and restricted cash at the beginning of the year	<u>7,060</u>	<u>16,043</u>	<u>24,159</u>
Cash, cash equivalents and restricted cash at the end of the year	<u>\$ 2,998</u>	<u>\$ 7,060</u>	<u>\$ 16,043</u>
Supplemental disclosure of cash flow information:			
Cash received from interest	\$ 562	\$ 1,192	\$ 1,953
Non-cash transactions:			
Recognition of right-of-use asset and lease liabilities from adoption of ASU 2016-02, net	\$ -	\$ -	\$ 653
Right-of-use assets obtained in exchange for new operating lease liabilities, net	\$ 199	\$ 35	\$ -

(*) Represents amount less than \$1

SOURCE Galmed Pharmaceuticals Ltd.

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Additional assets available online: [Photos \(1\)](#)

<https://galmedpharma.investorroom.com/2022-05-02-Galmed-Pharmaceuticals-Provides-Business-Update-and-Reports-Fourth-Quarter-and-Year-End-2021-Financial-Results>