

Galmed Pharmaceuticals Reports Third Quarter 2020 Financial Results

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

TEL AVIV, Israel, Nov. 12, 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, reports financial results for the three and nine months ended September 30, 2020. The Company will host a conference call and webcast at 08:30 ET today.

Financial Summary - Third Quarter 2020 vs. Third Quarter 2019:

- Cash and cash equivalents, restricted cash, short-term deposits and marketable debt securities totaled \$58.7 million as of September 30, 2020, compared to \$75.6 million at December 31, 2019.
- Net loss amounted to \$6.9 million, or \$0.32 per share, for the three months ended September 30, 2020, compared to a net loss of \$4.5 million, or \$0.21 per share, for the three months ended September 30, 2019.
- Research and development expenses amounted to approximately \$6.5 million for the three months ended September 30, 2020, compared to approximately \$4.1 million for the three months ended September 30, 2019. The increase resulted primarily from an increase in clinical trial expenses in connection with our ongoing ARMOR study.
- General and administrative expenses amounted to approximately \$1.1 million for the three months ended September 30, 2020, compared to approximately \$1.0 million for the three months ended September 30, 2019. The increase in general and administrative expenses for the three months ended September 30, 2020 resulted primarily from an increase in the cost of the Company's D&O insurance policy premium.
- Financial income, net amounted to \$0.7 million for the three months ended September 30, 2020, compared to financial income, net of \$0.5 million for the three months ended September 30, 2019. The increase primarily relates to realization of unrealized gains from prior periods.

Conference Call & Webcast:

Thursday November 12, 2020, 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: 13711943

Webcast: <http://public.viavid.com/index.php?id=141982>

Replay Dial-In Numbers

Toll Free: 1-844-512-2921

Toll/International: 1-412-317-6671

Replay Pin Number: 13711943

Replay Start: Thursday November 12, 2020, 11:30 AM ET

Replay Expiry: Thursday November 26, 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 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 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 September 30, 2020	As of December 31, 2019
Assets		
Current assets		
Cash and cash equivalents	\$ 16,648	\$ 15,931
Restricted Cash	113	112
Short-term deposits	10,423	27,938
Marketable debt securities	31,514	31,622
Other receivable	642	827
Total current assets	59,340	76,430

Right of use assets		437		538
Property and equipment, net		176		171
Total non-current assets		<u>613</u>		<u>709</u>
Total assets	\$	<u>59,953</u>	\$	<u>77,139</u>
Liabilities and stockholders' equity				
Current liabilities				
Trade payables	\$	5,151	\$	5,999
Other payables		899		935
Total current liabilities		<u>6,050</u>		<u>6,934</u>
Non-current liabilities				
Lease obligation	\$	247	\$	352
Total non-current liabilities		<u>247</u>		<u>352</u>
Ordinary shares par value NIS 0.01 per share; Authorized 50,000,000; Issued and outstanding:				
21,312,043 shares as of September 30, 2020; 21,139,385 shares as of December 31, 2019				
		58		58
Additional paid-in capital		178,938		176,696
Accumulated other comprehensive gain		90		35
Accumulated deficit		(125,430)		(106,936)
Total stockholders' equity		<u>53,656</u>		<u>69,853</u>
Total liabilities and stockholders' equity	\$	<u>59,953</u>	\$	<u>77,139</u>

GALMED PHARMACEUTICALS LTD.

Consolidated Statements of Operations (Unaudited)

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

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2020	2019	2020	2019
Research and development expenses	\$ 6,536	\$ 4,054	\$ 17,057	\$ 10,817
General and administrative expenses	1,054	953	2,811	2,931
Total operating expenses	7,590	5,007	19,868	13,748
Financial income, net	(685)	(493)	(1,374)	(1,573)

Net loss	\$	<u>6,905</u>	\$	<u>4,514</u>	\$	<u>18,494</u>	\$	<u>12,175</u>
Basic and diluted net loss per share	\$	<u>0.32</u>	\$	<u>0.21</u>	\$	<u>0.87</u>	\$	<u>0.58</u>
Weighted-average number of shares outstanding used in computing basic and diluted net loss per share		<u>21,268,730</u>		<u>21,123,418</u>		<u>21,191,196</u>		<u>21,109,421</u>

GALMED PHARMACEUTICALS LTD.

Consolidated Statements of Cash Flows (Unaudited)

U.S. Dollars in thousands

	Nine months ended	
	September 30	
	2020	2019
	\$ (18,494)	\$ (12,175)
Adjustments required to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	28	27
Stock-based compensation expense	1,474	1,546
Amortization of premium (discount) on marketable debt securities	36	(93)
Interest income from short-term deposits	(268)	(161)
Gain from realization of marketable debt securities	(522)	(10)
Changes in operating assets and liabilities:		
Decrease (Increase) in other accounts receivable	185	(680)
Increase (decrease) in trade payables	(848)	928
Decrease in other accounts payable	(40)	(253)
Net cash used in operating activities	<u>(18,449)</u>	<u>(10,871)</u>
Cash flow from investing activities		
Purchase of property and equipment	(33)	(9)
Investment in available for sale securities	(45,226)	(72,600)
Investment in short term deposits, net	17,783	(14,180)
Consideration from sale of available for sale securities	45,875	91,697
Net cash provided by investing activities	<u>18,399</u>	<u>4,908</u>
Cash flow from financing activities		
Proceeds from exercise of options	61	95

Issuance of Ordinary shares upon ATM, net of issuance cost	707	-
Net cash provided in financing activities	<u>768</u>	<u>95</u>
Increase (decrease) in cash and cash equivalents and restricted cash		
Cash and cash equivalents and restricted cash at the beginning of the period		
Cash and cash equivalents and restricted cash at the end of the period	718	(5,868)
	<u>16,043</u>	<u>24,159</u>
	<u>\$ 16,761</u>	<u>\$ 18,291</u>

Supplemental disclosure of cash flow information:

Cash received from interest	\$ 966	\$ 1,542
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Non-cash transactions:

Recognition of right-of-use asset and lease liability from adoption of ASU 2016-02	\$ -	\$ 679
Assets acquired under operating leases	\$ 35	\$ -

SOURCE Galmed Pharmaceuticals Ltd.

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

<https://galmedpharma.investorroom.com/2020-11-12-Galmed-Pharmaceuticals-Reports-Third-Quarter-2020-Financial-Results>