

Galmed Pharmaceuticals Provides Business Update and Reports Fourth Quarter and Year End 2019 Financial Results

- Conference Call and Webcast Today at 8:30 a.m. EDT / 5:30 a.m. PDT -

TEL AVIV, Israel, March 12, 2020 /PRNewswire/ -- Galmed Pharmaceuticals Ltd. (Nasdaq: GLMD) ("Galmed" or the "Company"), a clinical-stage biopharmaceutical company focused on the development of Aramchol, a liver targeted, oral, SCD1 modulator, currently in a Phase 3 clinical trial for the treatment of nonalcoholic steatohepatitis (NASH) and fibrosis provides today a business update and reports financial results for the three and twelve months ended December 31, 2019. The Company will host a conference call and webcast at 08:30 ET today.

Financial Summary - Full Year 2019 vs. Full Year 2018; 4Q19 vs. 4Q18:

- For the three and twelve months ended December 31, 2019, the Company recorded a net loss of \$8.3 and \$20.5 million or \$0.39 and \$0.97 per share, respectively, compared with a net loss of \$3.7 million and \$9.9 million, or \$0.18 and \$0.54 per share, for the three and twelve months ended December 31, 2018.
- Research and development expenses were \$18.2 million for the twelve months ended December 31, 2019, compared with \$8.3 million for the twelve months ended December 31, 2018. For the three months ended December 31, 2019, research and development expenses totaled \$7.4 million, which compares with \$2.7 million for the same period in 2018. The increase during the three and twelve months is mainly due to the preparation and initiation of the ARMOR study.
- The Company incurred general and administrative expenses of \$4.2 million for the twelve months ended December 31, 2019, compared with \$4.4 million for the twelve months ended December 31, 2018. For the three months ended December 31, 2018, general and administrative expenses totaled \$1.3 million, which compares with \$1.5 million for the same period in 2018. The decrease primarily resulted from a decrease in salaries and benefits expenses of approximately \$0.5 million due to lower year-end bonuses.
- During the three and twelve months ended December 31, 2019, the Company recognized a net financial income of \$0.3 million and \$1.9 million, respectively, compared with \$0.5 and \$0.9 million, respectively, during 2018. The increase during the twelve months ended December 31, 2019 is mainly due to an increase in interest income from marketable debt securities and short-term deposits, as compared to such income in 2018.
- Cash and cash equivalents, restricted cash, short-term deposits and marketable debt securities totaled \$75.6 million as of December 31, 2019, compared with \$90.2 million as of December 31, 2018. The decrease is mainly attributable to our \$14.9 million negative cash flow from operations during the twelve months ended December 31, 2019.

Conference Call & Webcast:

Thursday, March 12th @ 8:30am Eastern Time.

Toll Free: 1-877-425-9470

Toll/International: 1-201-389-0878

Israel Toll Free: 1-809-406-247

Conference ID: 13699345

Webcast: <http://public.viavid.com/index.php?id=138184>

Replay Dial-In Numbers

Toll Free: 1-844-512-2921
Toll/International: 1-412-317-6671
Replay Pin Number: 13699345
Thursday, March 12, 2020, 11:30 AM
Replay Start: ET
Replay Expiry: Thursday, March 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.

Forward-Looking Statements:

his 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; completion and receiving favorable results of the ARMOR Study for Aramchol or any other pre-clinical or clinical trial; regulatory action with respect to Aramchol 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 in the countries in which it seeks to market the product; Galmed's ability to achieve favorable pricing for Aramchol; Galmed's expectations regarding the commercial market for NASH patients; third-party payor reimbursement for Aramchol; Galmed's estimates regarding anticipated capital requirements and Galmed's needs for additional financing; market adoption of Aramchol by physicians and patients; the timing, cost or other aspects of the commercial launch of Aramchol; the development and approval of the use of Aramchol 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 (Audited)

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

	As of December 31,	
	2019	2018
Assets		
Current assets		
Cash and cash equivalents	\$ 15,931	\$ 24,159
Restricted cash	112	-
Short-term deposits	27,938	6,067
Marketable debt securities	31,622	59,962
Other accounts receivable	827	218
Total current assets	76,430	90,406
Right of use assets	538	-
Property and equipment, net	171	194
Total non-current assets	709	194
Total assets	\$ 77,139	\$ 90,600
Liabilities and stockholders' equity		
Current liabilities		
Trade payables	\$ 5,999	\$ 1,814
Other accounts payable	935	892
Total current liabilities	6,934	2,706
Non-current liabilities		
Lease obligation	\$ 352	\$ -
Total non-current liabilities	352	-
Stockholders' equity		
Ordinary shares, par value NIS 0.01 per share; Authorized 50,000,000 shares; Issued and outstanding: 21,139,385 shares as of December 31, 2019; 21,018,919 shares as of December 31, 2018	58	58
Additional paid-in capital	176,696	174,322
Accumulated other comprehensive income (loss)	35	(11)
Accumulated deficit	(106,936)	(86,475)
Total stockholders' equity	69,853	87,894
Total liabilities and stockholders' equity	\$ 77,139	\$ 90,600

GALMED PHARMACEUTICALS LTD.**Consolidated Statements of Operations (Audited)**

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

	Year ended December 31,		
	2019	2018	2017
Revenue	\$ -	\$ 2,038	\$ 1,085
Research and development expenses	18,180	8,313	9,650
General and administrative expenses	4,196	4,440	3,799
Total operating loss	22,376	10,715	12,364
Financial income, net	(1,915)	(934)	(65)
Loss before income taxes	20,461	9,781	12,299
Income taxes	-	75	-
Net loss	\$ 20,461	\$ 9,856	\$ 12,299
Basic and diluted net loss per share	\$ 0.97	\$ 0.54	\$ 0.98
Weighted-average number of shares outstanding used in computing basic and diluted net loss per share	21,114,399	18,137,689	12,487,349

GALMED PHARMACEUTICALS LTD.**Consolidated Statements of Cash Flows (Audited)**

U.S. Dollars in thousands

	Year ended December 31,		
	2019	2018	2017
Cash flow from operating activities			
Net loss for the year	\$ (20,461)	\$ (9,856)	\$ (12,299)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	35	387	239
Amortization of discount/premium on marketable debt securities	(105)	(144)	21
Loss (gain) on sale of marketable debt securities	(9)	12	143
Linked difference of marketable debt securities	-	-	(167)
Interest income from short-term deposits	(63)	-	-
Stock-based compensation expense	2,231	1,783	1,394
Changes in operating assets and liabilities:			
Decrease in deferred revenue from collaboration agreement	-	(538)	(1,085)

Decrease (increase) in other accounts receivable	(609)	(63)	129
Increase (decrease) in trade payables	4,185	(462)	(846)
Increase (decrease) in other accounts payable	(141)	(142)	671
Increase (decrease) in related party	-	-	(267)
Net cash used in operating activities	(14,937)	(9,023)	(12,067)
Cash flow from investing activities			
Purchase of property and equipment	(12)	(90)	(12)
Investment in securities, available for sale	(72,600)	(92,279)	(3,869)
Proceeds from sale of securities, available for sale	101,098	38,421	10,325
Investment in short-term deposits, net	(21,808)	(6,067)	-
Net cash provided by (used in) investing activities	6,678	(60,015)	6,444
Cash flow from financing activities			
Issuance of ordinary shares and warrants, net of issuance costs (*)	-	79,149	15,017
Proceeds from exercise of options	143	1,027	530
Net cash provided by financing activities	143	80,176	15,547
Increase (decrease) in cash and cash equivalents and restricted cash	(8,116)	11,138	9,924
Cash and cash equivalents and restricted cash at the beginning of the year	24,159	13,021	3,097
Cash and cash equivalents and restricted cash at the end of the year	\$ 16,043	\$ 24,159	\$ 13,021
Supplemental disclosure of cash flow information:			
Cash received from interest	\$ 1,953	\$ 865	\$ 202
Cash paid for taxes	\$ -	\$ 75	\$ -
Non-cash transactions:			
Recognition of right-of-use asset and lease liabilities from adoption of ASU 2016-02	\$ 653	\$ -	\$ -

SOURCE Galmed Pharmaceuticals Ltd.

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

<https://galmedpharma.investorroom.com/2020-03-12-Galmed-Pharmaceuticals-Provides-Business-Update-and-Reports-Fourth-Quarter-and-Year-End-2019-Financial-Results>