Galmed Pharmaceuticals

Galmed Pharmaceuticals Reports Fourth Quarter and Full Year 2018 Financial Results and Provides Business Update

- Conference Call and Webcast Today at 8:30 a.m. EST / 5:30 a.m. PST -

TEL AVIV, Israel, March 13, 2019 /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, today reported financial results for the three and twelve months ended December 31, 2018. The Company will host a conference call and webcast at 08:30 ET today.

Business Update

Updates on progress towards the initiation of "ARMOR", Aramchol's Phase 3/4 pivotal study of Aramchol

The Company is scheduled to meet the FDA for its end of Phase2b meeting later this month with the aim of initiating the ARMOR, Phase 3/4 pivotal study of Aramchol at the end of the second quarter of 2019 or early in the third quarter of 2019. The Company plans to discuss with the FDA its planned clinical trial design for the ARMOR study and the results of its recently announced dose splitting PK study. Preparations for the commencement of the study are ongoing.

Dose Splitting Pharmacokinetic (PK) Study

The Company recently conducted a Phase I, open-label, two-period, randomized, crossover PK study to assess whether dose splitting of Aramchol 600mg to twice daily 300mg will significantly increase plasma levels. Results of the study showed that the administration of Aramchol 300 mg twice daily resulted in 24-hour plasma concentrations significantly greater than those observed with the administration of Aramchol 600 mg once daily. ($P<0.0001$). The average plasma levels (exposure) were 53% higher and exposure was greater in all 16 subjects with the twice daily dosing. The treatment in both dosing regimens were similar in terms of safety and were well tolerated.

Phase 2b Data Presented During Late-Breaking Abstract Oral Session of The Liver Meeting® 2018

In November 2019, an oral abstract presentation of the one-year results of the Company's Phase2b ARREST study of Aramchol in NASH was presented at the Late Breaking Abstract Oral Session at The Liver Meeting® 2018 during the American Association for the Study of Liver Diseases 2018 Annual Meeting in San Francisco.

Financial Summary – Full Year 2018 vs. Full Year 2017; 4Q18vs. 4Q17:

- For the three and twelve months ended December 31, 2018, the Company recorded a net loss of $3.7 and $9.9 million or $0.18 and $0.54 per share, respectively, compared with a net loss of $3.6 million and $12.3 million, or $0.27 and $0.98 per share, for the three and twelve months ended December 31, 2017.

- The Company recognized $2.0 million of revenue for the twelve months ended December 31, 2018, compared to $1.1 million for the same period in 2017. This years' revenue included a milestone payment of $1.5 million in connection with the Company's license agreement with Samil Pharm Co., Ltd.

- Research and development expenses were $8.3 million for the twelve months ended December 31, 2018, compared with $9.7 million for the twelve months ended December 31, 2017. For the three months ended December 31, 2018, research and development expenses totaled $2.7 million, which compares with $2.2 million for the same period in 2017.

- The Company incurred general and administrative expenses of $4.4 million for the twelve months ended December 31, 2018, compared with $3.8 million for the twelve months ended December 31, 2017. For the three months ended December 31, 2017, general and administrative expenses totaled $1.5 million, which compares with $1.7 million for the same period in 2017.

- During the three and twelve months ended December 31, 2018 the Company recognized a net financial income of $0.5 million and $0.9 million, respectively, compares with $0.01 and $0.1 million during 2017.

- Cash and cash equivalents, short-term deposits and marketable debt securities totaled $90.2 million as of December 31, 2018, compared with $19.0 million as of December 31, 2017. The increase is mainly attributable to the approximately $70.3 million in net proceeds raised in an underwritten public offering that was completed in June 2018, together with $5.9 million in net proceeds raised in a registered direct offering during April 2018.

Conference Call & Webcast:

Wednesday, March 13th @ **8:30am Eastern Time**
Within the US: 877-425-9470

Outside the US: 201-389-0878

From Israel: 1 809 406 247

Conference ID: 13687890

Webcast: http://public.viavid.com/index.php?id=133389

A replay of the webcast will be available shortly after the live presentation at the Company's website, https://www.galmedpharma.com/, on the For Investors section's Events & Presentations page and will be available for one year.

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 is a clinical-stage biopharmaceutical company focused on the development of Aramchol, a first in class, novel, oral therapy for the treatment of NASH for variable populations. Galmed recently announced top-line results of the ARREST Study, a multicenter, randomized, double blind, placebo-controlled Phase IIb clinical study designed to evaluate the efficacy and safety of Aramchol in subjects with NASH, who are overweight or obese, and who are pre-diabetic or type-II-diabetic. Galmed is currently preparing for an end of Phase 2b meeting with the FDA to discuss the results of the ARREST Study and a Phase 3/4 study protocol, with a view to initiating a Phase 3/4 clinical study of Aramchol in 2019.

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 planned Phase III trial for Aramchol, or whether a Phase III trial will be conducted at all; completion and receiving favorable results of a Phase III trial 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;

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 13, 2018, 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 December 31,	
	2018	**2017**
Assets		
Current assets		
Cash and cash equivalents	$ 24,159	$ 13,021
Short-term deposits	6,067	-
Marketable debt securities	59,962	5,976
Other accounts receivable	218	155
Total current assets	90,406	19,152
Property and equipment, net	194	491
Total assets	$ 90,600	$ 19,643
Liabilities and stockholders' equity		
Current liabilities		
Trade payables	1,814	2,276
Other accounts payable	892	1,034
Deferred revenue	-	538
Total current liabilities	2,706	3,848
Stockholders' equity		
Ordinary shares, par value NIS 0.01 per share; Authorized 50,000,000 shares; Issued and outstanding: 21,018,919 shares as of December 31, 2018; 14,435,161 shares as of December 31, 2017	58	40

Additional paid-in capital	174,322	92,381
Accumulated other comprehensive loss	(11)	(7)
Accumulated deficit	(86,475)	(76,619)
Total stockholders' equity	87,894	15,795
Total liabilities and stockholders' equity	$ 90,600	$ 19,643

GALMED PHARMACEUTICALS LTD.

Consolidated Statements of Operations

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

	Year ended December 31,		
	2018	**2017**	**2016**
Revenue	$ 2,038	$ 1,085	$ 467
Research and development expenses	8,313	9,650	14,271
General and administrative expenses	4,440	3,799	3,078
Total operating loss	10,715	12,364	16,882
Financial income, net	(934)	(65)	(35)
Loss before income taxes	9,781	12,299	16,847
Income taxes	75	-	106
Net loss	$ 9,856	$ 12,299	$ 16,953
Basic and diluted net loss per share from continuing operations	$ 0.54	$ 0.98	$ 1.49
Weighted-average number of shares outstanding used in computing basic and diluted net loss per share	18,137,689	12,487,349	11,374,653

GALMED PHARMACEUTICALS LTD.

Consolidated Statements of Cash Flows

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

	Year ended December 31,		
	2018	**2017**	**2016**
Cash flow from operating activities			
Net loss for the year	$ (9,856)	$ (12,299)	$ (16,953)

Adjustments required to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	387	239	169
Amortization of discount/premium on marketable debt securities	(144)	21	44
Loss on sale of marketable debt securities	12	143	231
Linked difference of marketable debt securities	-	(167)	–
Stock-based compensation expense	1,783	1,394	1,628
Changes in operating assets and liabilities:			
Increase (decrease) in deferred revenue from collaboration agreement	(538)	(1,085)	1,623
Decrease (increase) in other accounts receivable	(63)	129	95
Increase (decrease) in trade payables	(462)	(846)	863
Increase (decrease) in other accounts payable	(142)	671	81
Increase (decrease) in related party	-	(267)	90
Net cash used in operating activities	(9,023)	(12,067)	(12,129)
Cash flow from investing activities			
Purchase of property and equipment	(90)	(12)	(17)
Proceeds from sale of property and equipment	–	–	13
Investment in securities, available for sale	(92,279)	(3,869)	(7,615)
Proceeds from sale of securities, available for sale	38,421	10,325	13,955
Investment in short-term deposits	(6,067)	–	–
Net cash provided by (used in) investing activities	(60,015)	6,444	6,336
Cash flow from financing activities			
Issuance of ordinary shares and warrants, net of issuance costs	79,149	15,017	4,479
Proceeds from exercise of options	1,027	530	255
Net cash provided by financing activities	80,176	15,547	4,734
Increase (decrease) in cash and cash equivalents	11,138	9,924	(1,059)
Cash and cash equivalents at the beginning of the year	13,021	3,097	4,156
Cash and cash equivalents at the end of the year	$ 24,159	$ 13,021	$ 3,097
Cash received from interest	$ 865	$ 202	$ 382
Cash paid for taxes	$ 75	$ –	$ 106

SOURCE Galmed Pharmaceuticals Ltd.

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