

Galmed Pharmaceuticals Provides Business Update and Reports Year-To-Date 2014 Financial Results

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

TEL AVIV, Israel, Nov. 12, 2014 /PRNewswire/ -- Galmed Pharmaceuticals Ltd. (Nasdaq: GLMD) ("Galmed"), a clinical-stage biopharmaceutical company focused on the development and commercialization of a once-daily, oral therapy for the treatment of liver diseases and cholesterol gallstones, today announced select third quarter 2014 and recent corporate highlights, as well as financial results for the nine months ended September 30, 2014.

Select Third Quarter 2014 and Recent Corporate Highlights:

- Galmed's Investigational New Drug application, or IND, for aramchol for the treatment of fatty liver disorders, filed with the U.S. Food and Drug Administration, or FDA, become effective, thereby permitting Galmed to conduct clinical studies for the targeted indication and additional proof-of-concept studies in the United States in the future. Galmed was subsequently granted Fast Track Designation by the FDA for aramchol for the treatment of Non-Alcoholic Steato-Hepatitis, or NASH.
- Successfully completed two, six-month chronic toxicology studies of aramchol without observable significant adverse events, thereby supporting Galmed's planned Phase IIb clinical trial of aramchol in NASH patients suffering from obesity and insulin resistance, which Galmed intends to initiate during the fourth quarter of 2014. The Phase IIb trial will be conducted in the European Union, Israel and Latin America. These two studies will continue into December 2014 to satisfy an initial FDA requirement to complete nine-month pre-clinical toxicology studies of aramchol prior to conducting clinical trials in the United States.
- Published the results of its Phase IIa clinical trial of aramchol in the peer-reviewed Clinical Gastroenterology and Hepatology journal.
- Announced the purchase of 60 EndoPAT™ devices and accessories from Itamar Medical Ltd. to assess endothelial, or arterial, function in NASH patients suffering from obesity and insulin resistance participating in its planned Phase IIb clinical trial of aramchol.

Financial Summary for the Nine Months Ended September 30, 2014 and 2013:

- Reported a net loss of \$7.1 million, or \$0.71 per share, for the nine months ended September 30, 2014, compared with a net loss of \$2.2 million, or \$0.44 per share, for the comparable prior year period, primarily attributable to increased research and development activities.
- Reported research and development expenses of \$5.5 million for the nine months ended September 30, 2014, compared with \$1.9 million for the comparable prior year period, primarily resulting from increases in research and development subcontractor expenses in preparation for the initiation of Galmed's clinical trials initiated or to be initiated following the end of the period, as well as an increase in salaries and benefits due to an increase in clinical staff.
- Reported general and administrative expenses of \$1.6 million for the nine months ended September 30, 2014, compared with \$333,000 for the comparable prior year period, resulting from an increase in professional services, salaries and benefits, including non-cash stock-based compensation.

- Reported cash and cash equivalents of \$35.3 million at September 30, 2014, compared with \$137,000 at December 31, 2013 as a result of the net proceeds from Galmed's initial public offering in March 2014. Galmed currently expects that this existing cash balance will be sufficient to maintain its current operations through 2017.

"I am pleased to report that we have completed all of the short-term milestones that we set for the first three quarters of 2014 at the time of our initial public offering," stated Allen Baharaff, Galmed's Chief Executive Officer. "Most importantly, our IND application for aramchol became effective, which we believe is the result of our chemistry, manufacturing and controls, toxicology, pre-clinical and clinical activities to date, and further supports our future development plan. We are also excited to have received FDA Fast Track Designation of aramchol, which we believe could expedite the regulatory process with the FDA."

"We are currently prepared to initiate our Phase IIb trial of aramchol in NASH patients as scheduled, which, if successful, may serve as a basis for Phase III pivotal trials for the treatment of NASH to be conducted in the United States and Europe. We expect to report interim results of this Phase IIb trial in the second half of 2015, and final results in the second half of 2016."

"Overall, we are very pleased with our progress and the status of our clinical development programs to date," concluded Mr. Baharaff.

Conference Call and Webcast Details

Galmed will host a conference call and webcast today at 8:30 a.m. EST/5:30 a.m. PST to discuss its financial results and to provide an update on current developments with respect to its clinical program for aramchol. Investors interested in participating in the call can dial 888-287-5563 from the United States or 719-325-2484 internationally, and use Conference ID: 5293623. A replay will be available through November 26, 2014 by dialing 877-870-5176 from the United States or 858-384-5517 internationally, and using Passcode: 5293623. A webcast will also be available at <http://galmedpharma.investorroom.com/events-and-presentations> through November 26, 2014.

About Galmed Pharmaceuticals Ltd.

Galmed is a clinical-stage biopharmaceutical company focused on the development and commercialization of a novel, once-daily, oral therapy for the treatment of liver diseases and cholesterol gallstones utilizing its proprietary first-in-class family of synthetic fatty-acid/bile-acid conjugates, or FABACs. Galmed believes that its product candidate, aramchol, has the potential to be a disease modifying treatment for fatty liver disorders, including NASH, which is a chronic disease that Galmed believes constitutes a large unmet medical need.

Forward-Looking Statements

This press release includes forward-looking statements. Such forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statements. Applicable risks and uncertainties include those identified under the heading "Risk Factors" included in the registration statement on Form F-1 (File No. 333-193792), initially filed with the Securities and Exchange Commission, or the SEC, on February 6, 2014 and declared effective by the SEC on March 12, 2014, 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 reflect Galmed's current views with respect to future events, and Galmed does not undertake and specifically disclaims any obligation to update any forward-looking statements.

GALMED PHARMACEUTICALS LTD.

Condensed Consolidated Statement of Operations

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

	Successor	Predecessor	
	Period from February 3 to September 30, 2014	Period from January 1 to February 2, 2014	Nine months ended September 30, 2013
	Unaudited	Unaudited	Unaudited
Research and development expenses	\$ 5,037	\$ 501	\$ 1,873
General and administrative expenses	1,436	114	333
Capital loss	-	-	10
Total operating expenses	6,473	615	2,216
Financial expenses, net	27	9	4
Operating loss before income taxes	\$ 6,500	\$ 624	\$ 2,220
Taxes on income	-	-	2
Net loss	\$ 6,500	\$ 624	\$ 2,222
Basic and diluted net loss per share	\$ 0.62	\$ 0.09	\$ 0.44
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	10,467,361	(*) 7,099,731	(*) 4,955,837

(*) Retroactively adjusted to reflect the 729:1 share split, which occurred upon the consummation of the Reorganization.

The notes included in Galmed's Form 6-K, furnished to the U.S. Securities and Exchange Commission, on November 12, 2014, are an integral part of the condensed interim consolidated financial statements.

GALMED PHARMACEUTICALS LTD.

Condensed Consolidated Balance Sheet

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

Successor	Predecessor
As of	

	September 30, 2014	As of December 31, 2013
	Unaudited	Audited
Assets		
Current assets		
		137
Cash and cash equivalents	\$ 35,342 67	\$
Other accounts receivable		16
Total current assets	35,409	153
Property and equipment, net	775	13
Total assets	\$ 36,184	\$ 166
Liabilities and Stockholders' Deficiency		
Current liabilities		
Trade payables	\$ 1,997	\$ 1,355
Other accounts payable	568	334
Total current liabilities	2,565	1,689
Long-term liabilities		
Related parties	368	428
Total long-term liabilities	368	428
Stockholders' equity (deficiency):		
Ordinary shares par value NIS 0.01 per share; Authorized 50,000,000; Issued and outstanding: 11,100,453 shares as of September 30, 2014	32	-
Ordinary shares par value \$1 per share; Authorized 50,000 shares; Issued and outstanding: 9,739 shares as of December 31, 2013	-	10
Additional paid-in capital	67,985	25,681
Accumulated deficit	(34,766)	(27,642)
Total stockholders' equity (deficiency)	33,251	(1,951)
Total liabilities and stockholders' equity	\$ 36,184	\$ 166

SOURCE Galmed Pharmaceuticals Ltd.

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<https://galmedpharma.investorroom.com/2014-11-12-Galmed-Pharmaceuticals-Provides-Business-Update-and-Reports-Year-To-Date-2014-Financial-Results>