

Galmed Pharmaceuticals Ltd.
Form 6-K
May 15, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

Report of Foreign Private Issuer Pursuant to Rule 13a-16 or 15d-16

Under the Securities Exchange Act of 1934

For the Month of May 2017

001-36345

(Commission File Number)

GALMED PHARMACEUTICALS LTD.

(Exact name of Registrant as specified in its charter)

16 Tiomkin St.

Tel Aviv 6578317, Israel

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover

Form 20-F or Form 40-F.

Form 20-F x Form 40-F ..

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): _____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): _____

EXPLANATORY NOTE

This Form 6-K contains the quarterly report of Galmed Pharmaceuticals Ltd. (the “Company”), which includes the Company’s unaudited consolidated financial statements for the three months ended March 31, 2017, together with related information and certain other information. The Company is not subject to the requirements to file quarterly or certain other reports under Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended. The Company does not undertake to file or cause to be filed any such reports in the future, except to the extent required by law.

On May 15, 2017, the Company issued a press release announcing the filing of its financial results for the three months ended March 31, 2017, with the Securities and Exchange Commission. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

This Form 6-K is incorporated by reference into the Company's Registration Statement on Form S-8 filed with the Securities and Exchange Commission on August 11, 2015 (Registration No. 333-206292) and its Registration Statement on Form F-3 filed with the Securities and Exchange Commission on March 31, 2015 (Registration No. 333-203133).

FINANCIAL INFORMATION

*Financial Statements***GALMED PHARMACEUTICALS LTD.****Consolidated Balance Sheets****U.S. Dollars in thousands, except share data and per share data**

	As of March 31, 2017 Unaudited	As of December 31, 2016 Audited
Assets		
Current assets		
Cash and cash equivalents	\$ 1,660	\$ 3,097
Marketable securities	9,993	12,351
Other accounts receivable	336	284
Total current assets	11,989	15,732
Property and equipment, net	665	718
Total assets	\$ 12,654	\$ 16,450
Liabilities and stockholders' equity		
Current liabilities		
Trade payables	\$ 2,538	\$ 3,122
Other accounts payable	196	363
Short-term portion of deferred revenue	1,085	1,094
Total current liabilities	3,819	4,579
Long-term liabilities		
Related parties	267	267
Long-term portion of deferred revenue	270	529
Total long-term liabilities	537	796
Stockholders' equity:		
Ordinary shares par value NIS 0.01 per share; Authorized 50,000,000; Issued and outstanding: 12,168,912 shares as of March 31, 2017; 12,149,226 shares as of December	34	34

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31, 2016

Additional paid-in capital	75,807	75,446
Accumulated other comprehensive loss	(61)	(85)
Accumulated deficit	(67,482)	(64,320)
Total stockholders' equity	8,298	11,075
Total liabilities and stockholders' equity	\$ 12,654	\$ 16,450

The accompanying notes are an integral part of the interim consolidated financial statements.

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GALMED PHARMACEUTICALS LTD.
Consolidated Statements of Operations (Unaudited)
U.S. Dollars in thousands, except share data and per share data

	Three months ended	
	March 31,	
	2017	2016
Revenue	\$268	\$-
Research and development expenses	2,743	3,384
General and administrative expenses	789	719
Total operating expenses	3,264	4,103
Financial income, net	(102)	(119)
Net loss	\$3,162	\$3,984
Basic and diluted net loss per share	\$0.26	\$0.36
Weighted-average number of shares outstanding used in computing basic and diluted net loss per share	12,164,983	11,100,453

The accompanying notes are an integral part of the interim consolidated financial statements.

GALMED PHARMACEUTICALS LTD.
Consolidated Statements of Comprehensive Loss (Unaudited)
U.S. Dollars in thousands

	Three months ended	
	March 31,	
	2017	2016
Net loss	\$ 3,162	\$ 3,984
Other comprehensive income:		
Net unrealized gain on available for sale securities	(24)	(46)
Comprehensive loss	\$ 3,138	\$ 3,938

The accompanying notes are an integral part of the interim consolidated financial statements.

GALMED PHARMACEUTICALS LTD.
Consolidated Statements of Changes in Stockholders' Equity (Unaudited)

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

	Ordinary shares		Additional paid-in capital	Accumulated other Comprehensive loss	Accumulated Deficit	Total
	Shares	Amount				
Balance - December 31, 2016	12,149,226	\$ 34	\$ 75,446	\$ (85) \$ (64,320) \$11,075
Stock based compensation	-	-	361	-	-	361
Issuance of shares	19,686	-	-	-	-	-
Unrealized gain from marketable securities	-	-	-	24	-	24
Net loss	-	-	-	-	(3,162) (3,162)
Balance - March 31, 2017	12,168,912	\$ 34	\$ 75,807	\$ (61) \$ (67,482) \$8,298

The accompanying notes are an integral part of the interim consolidated financial statements.

GALMED PHARMACEUTICALS LTD.
Consolidated Statements of Cash Flows (Unaudited)
U.S. Dollars in thousands

	Three months ended	
	March 31,	
	2017	2016
Cash flow from operating activities		
Net loss	\$ (3,162)	\$ (3,984)
Adjustments required to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	60	32
Stock-based compensation expense	361	273
Amortization of discount/premium on marketable securities	(140)	(62)
Loss from Realization of marketable securities	78	55
Changes in operating assets and liabilities:		
Decrease (increase) in other accounts receivable	(52)	123
Increase (decrease) in trade payables	(584)	692
Decrease in other accounts payable	(167)	(209)
Decrease in deferred revenue	(268)	-
Net cash used in operating activities	(3,874)	(3,080)
Cash flow from investing activities		
Purchase of property and equipment	(7)	(8)
Consideration of securities, available for sale	2,444	2,016
Net cash provided in investing activities	2,437	2,008
Decrease in cash and cash equivalents	(1,437)	(1,072)
Cash and cash equivalents at the beginning of the year	3,097	4,156
Cash and cash equivalents at the end of the period	\$ 1,660	\$ 3,084
Supplemental disclosure of cash flow information:		
Cash received from interest	\$ 88	140

The accompanying notes are an integral part of the interim consolidated financial statements.

GALMED PHARMACEUTICALS LTD.
Notes to Consolidated Financial Statements

Note 1 - Basis of presentation

Galmed Pharmaceuticals Ltd. (the “Company”) is a clinical-stage biopharmaceutical company focused on the development of Aramchol, a first in class, novel once-daily, oral therapy for the treatment of Non-Alcoholic Steato-Hepatitis (“NASH”) for variable populations, as well as other liver associated disorders.

The Company in its current legal structure was incorporated in Israel on July 31, 2013 as a privately held company, and formally commenced operations on February 2, 2014; however, our business has been operating since 2000 under a different group of companies established in 2000 (the “Group”). On February 2, 2014, upon a pre-ruling from the Israeli Tax Authorities, the Company underwent a reorganization (the “Reorganization”), pursuant to which all of the business of our predecessor, Galmed Holdings Inc., including net assets and shares in its wholly-owned subsidiary, Galmed 2000, were transferred to the Company. Contemporaneously, the Company effected a 729-for-1 stock split.

These unaudited interim consolidated financial statements have been prepared as of March 31, 2017, and for the three months period then ended. Accordingly, certain information and footnote disclosures normally included in annual financial statements prepared in accordance with U.S. GAAP have been omitted. These unaudited interim consolidated financial statements should be read in conjunction with the audited financial statements and the accompanying notes of the Company for the year ended December 31, 2016, that are included in the Company's Annual Report on Form 20-F, filed with the Securities and Exchange Commission on March 23, 2017. The results of operations presented are not necessarily indicative of the results to be expected for the year ending December 31, 2017.

Note 2 - Summary of significant accounting policies

The significant accounting policies that have been applied in the preparation of the unaudited consolidated interim financial statements are identical to those that were applied in preparation of the Company's most recent annual financial statements in connection with our Annual Report on Form 20-F.

Note 3 - Stockholders' Equity

1. In January 2017, the Company granted 130,000 options to purchase ordinary shares of the Company with a NIS 0.01 par value to certain officers and employees. The options will vest over a period of four years. The options will expire 10 years from the grant date. The exercise price of the options is \$3.84 per share. The aggregate grant date fair value of such options is \$376 thousand.

2. Subsequent to the balance sheet date, in April 2017, the Company granted 30,000 options to purchase ordinary shares of the Company with a NIS 0.01 par value to two of its consultants. The options will vest over a period of between one and four years. The options will expire 10 years from the grant date. The exercise prices of the options ranges between \$4.75 and \$4.87 per share. The aggregate grant date fair value of such options is \$99 thousand.

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Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our annual report on Form 20-F for the fiscal year ended December 31, 2016, filed with the Securities and Exchange Commission (the "SEC ") on March 23, 2017 (the "Annual Report"), and in subsequent filings with the SEC. In addition to historical financial information, the following discussion contains forward-looking statements that reflect our plans, estimates and beliefs. Our actual results could differ materially from those discussed in the forward-looking statements. Factors that could cause or contribute to these differences include those discussed below under "Cautionary Note Regarding Forward-Looking Statements" and elsewhere in this report, as well as those set forth under the same heading and the heading "Risk Factors" in the Annual Report.

Cautionary Note Regarding Forward-Looking Statements

This report contains forward-looking statements about our expectations, beliefs or intentions regarding, among other things, our product development efforts, business, financial condition, results of operations, strategies or prospects. In addition, from time to time, we or our representatives have made or may make forward-looking statements, orally or in writing. Forward-looking statements can be identified by the use of forward-looking words such as "believe," "expect," "intend," "plan," "may," "should," "anticipate," "could," "might," "seek," "target," "will," "project," "forecast," "continue" or variations of these words or other comparable words or by the fact that these statements do not relate strictly to historical matters. These forward-looking statements may be included in, among other things, various filings made by us with the SEC, press releases or oral statements made by or with the approval of one of our authorized executive officers. Forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements, including, but not limited to, the factors summarized below:

the timing and cost of our ongoing Phase IIB ARREST Study, and planned Phase III trials, for our product candidate, Aramchol™ (hereinafter referred to as "Aramchol") for the treatment of patients who are overweight or obese and have pre diabetes or type II diabetes mellitus (hereinafter OD patients) with Non-Alcoholic Steato-Hepatitis, or NASH, or whether Phase III trials will be conducted at all;

- completion and receiving favorable results of these Phase IIB ARREST Study and Phase III trials for Aramchol;
- regulatory action with respect to Aramchol by the U.S. Food and Drug Administration, or FDA, or the European Medicines Authority, or EMA, including but not limited to acceptance of an application for marketing authorization,

review and approval of such application, and, if approved, the scope of the approved indication and labeling;

- the commercial launch and future sales of Aramchol or any other future products or product candidates;

our ability to comply with all applicable post-market regulatory requirements for Aramchol in the countries in which we seek to market the product;

- our ability to achieve favorable pricing for Aramchol;

- our expectations regarding the commercial market for NASH in OD patients;

- third-party payor reimbursement for Aramchol;

- our estimates regarding anticipated capital requirements and our 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
- our expectations regarding licensing, acquisitions and strategic operations.

We believe these forward-looking statements are reasonable; however, these statements are only current predictions and are subject to known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. We discuss many of these risks in the Annual Report in greater detail under the heading "Risk Factors" and elsewhere in the Annual Report and this report. Given these uncertainties, you should not rely upon forward-looking statements as predictions of future events.

All forward-looking statements attributable to us or persons acting on our behalf speak only as of the date hereof and are expressly qualified in their entirety by the cautionary statements included in this report. We undertake no obligations to update or revise forward-looking statements to reflect events or circumstances that arise after the date made or to reflect the occurrence of unanticipated events. In evaluating forward-looking statements, you should consider these risks and uncertainties.

Overview

We are a clinical-stage biopharmaceutical company focused on the development of Aramchol™, a first in class, novel, once-daily, oral therapy for the treatment of NASH for variable populations, as well as other liver associated disorders. We are currently conducting the ARREST Study, a multicenter, randomized, double blind, placebo-controlled Phase IIb clinical study designed to evaluate the efficacy and safety of Aramchol™ in 248 subjects with NASH, who are overweight or obese, and who are pre-diabetic or type-II-diabetic. Top line Data from the ARREST Study are expected to be available during the second quarter of 2018.

We also sponsor the ARRIVE Study, a proof-of-concept Phase IIa clinical trial designed to evaluate the safety and efficacy of Aramchol™ in up to 50 patients with HIV-associated NAFLD (Non-Alcoholic Fatty Liver Disease) and lipodystrophy. The ARRIVE Study is an investigator-initiated trial, conducted at the University of California San Diego by Professor Rohit Loomba. More information about the ARREST Study and the ARRIVE Study may be found on ClinicalTrials.gov identifiers: NCT02279524 and NCT02684591, respectively.

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 down regulation of the three key pathologies of NASH; steatosis, inflammation and fibrosis. The effect of Aramchol™ on fibrosis is mediated by down regulation of steatosis and directly on human collagen producing cells. We are investing efforts into better understanding the mechanisms by which Aramchol™ down regulates steatosis and fibrosis. Additional animal models are being investigated with variety of treatment regimens. The data, thus far, demonstrates dual mode of action of Aramchol on fibrosis via improvement of Fatty Acid oxidation as well a direct impact on stellate cells which are the collagen producing cells in the liver which results in reversing fibrosis. Aramchol™ has been granted by the FDA Fast Track designation status for the treatment of NASH.

Financial Overview

To date, we have funded our operations primarily through the sale of equity and debt securities in private equity and debt financings in Israel to our affiliates (which has subsequently been converted in whole into common equity; no debt remains on our balance sheet), shareholders and third-party investors, and as of March 18, 2014, through the sale of our ordinary shares in our initial public offering and ATM offering. On March 31, 2017, we had current assets of \$12.0 million, which consists of cash and cash equivalents of \$1.7 million and short-term investment securities of \$10.0 million. This compares with current assets of \$15.7 million at December 31, 2016, which consists of cash and cash equivalents of \$3.1 million and short-term investment securities of \$12.4 million. Although we provide no assurance, we believe that such existing funds will be sufficient to continue our business and operations as currently conducted through the first half of 2018. However, we will continue to incur operating losses, which may be substantial over the next several years, and we may need to obtain additional funds to complete the ARREST Study, and further develop our research and development programs.

Business Developments

During the first quarter of 2017, we announced the following developments:

· On January 9, 2017, we announced that we completed patient recruitment to the ARREST Phase IIb NASH Study.

On March 15, 2017, we announced certain organizational changes in our management, which include: (i) the appointment of Dr. Tali Gorfine, our then Senior Medical Director, as our Chief Medical Officer, in lieu of Prof. Ran Oren, which was appointed to serve as a member of our board of directors and continues to provide us services as a member of our scientific advisory board; (ii) the appointment of Adv. Guy Nehemya, our then Director of Operations, as Vice President, Operations; and (iii) the appointment of Adv. Yael Hollander, our then General Counsel and Corporate Secretary, as Vice President, Legal Affairs & Strategy.

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We previously announced that CPA Yohai Stenzler, our then director of finance, will act as interim Chief Financial Officer, in lieu of Mr. Josh Blacher. On March 15, 2017, we announced the appointment of Mr. Stenzler as our permanent Chief Financial Officer.

On March 23, 2017, we announced new independent research is pointing towards potential direct effect of Aramchol on liver fibrosis.

Revenues:

On July 28, 2016, we entered into a license agreement, referred to herein as the Samil Agreement, with Samil Pharma. Co., Ltd. for the commercialization of Aramchol (with the option to manufacture) in the Republic of Korea. Under the terms of the Samil Agreement, we have received upfront payments of \$2.1 million, and may be eligible to receive up to approximately \$6.0 million in additional payments for development and regulatory milestones for Aramchol in the licensed territories. For accounting purposes, the upfront payment has been recorded as deferred revenue. The deferred revenue is then amortized on a straight-line basis over the contractual period and milestone payments are recognized once earned.