

Galmed Pharmaceuticals Ltd.
Form 6-K
May 13, 2015

**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 2015

001-36345
(Commission File Number)

GALMED PHARMACEUTICALS LTD.

(Exact name of Registrant as specified in its charter)

8 Shaul Hamelech Blvd.

Amot Mishpat Bldg.

Tel Aviv 6473307, 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 Form 40-F

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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 condensed consolidated financial statements for the three months ended March 31, 2015, 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 13, 2015, the Company issued a press release announcing the filing of its financial results for the three months ended March 31, 2015 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.

FINANCIAL INFORMATION

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

	As of March 31, 2015 Unaudited	As of December 31, 2014 Audited
Assets		
Current assets		
Cash and cash equivalents	\$ 2,340	\$ 23,736
Short-term deposit	6,000	6,000
Marketable securities	21,547	2,250
Other accounts receivable	388	165
Total current assets	30,275	32,151
Property and equipment, net	773	774
Total assets	\$ 31,048	\$ 32,925
Liabilities and stockholders' equity		
Current liabilities		
Trade payables	\$ 1,147	\$ 875
Other accounts payable	209	243
Total current liabilities	1,356	1,118
Long-term liabilities		
Related parties	205	400
Total long-term liabilities	205	400
Stockholders' equity:		
Ordinary shares par value NIS 0.01 per share; Authorized 50,000,000; Issued and outstanding: 11,100,453 shares	32	32
Additional paid-in capital	68,674	68,116
Accumulated other comprehensive income (loss)	(11)	4
Accumulated deficit	(39,208)	(36,745)
Total stockholders' equity	29,487	31,407

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Total liabilities and stockholders' equity	\$ 31,048	\$ 32,925
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The accompanying notes are an integral part of the condensed interim consolidated financial statements.

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

	Three months ended	
	March 31,	
	2015	2014
Research and development expenses	\$1,431	\$1,502
General and administrative expenses	1,073	633
Total operating expenses	2,504	2,135
Financial expenses (income), net	(41) 26
Net loss	\$2,463	\$2,161
Basic and diluted net loss per share from continuing operations	\$0.22	\$0.27
Weighted-average number of shares outstanding used in computing basic and diluted net loss per share	11,100,453	7,979,989(*)

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

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

GALMED PHARMACEUTICALS LTD.

Condensed Consolidated Statements of Comprehensive Loss (Unaudited)

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

	Three months ended March 31,	
	2015	2014
Net loss	\$2,463	\$2,161
Other comprehensive loss:		
Net unrealized loss on available for sale securities	15	–
Comprehensive loss	\$2,478	\$2,161

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

GALMED PHARMACEUTICALS LTD.

Condensed 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	Accumulated other Comprehensive Income (loss)	Accumulated Deficit	Total
	Shares	Amount	capital			
Balance - December 31, 2014	11,100,453	\$ 32	\$ 68,116	\$ 4	\$ (36,745)) \$31,407
Stock based compensation	—	—	558	—	—	558
Unrealized loss from marketable securities	—	—	—	(15)	—	(15)
Net loss	—	—	—	—	(2,463)	(2,463)
Balance – March 31, 2015	11,100,453	\$ 32	\$ 68,674	\$ (11)	\$ (39,208)) \$29,487

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

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

	Three months ended March 31,	
	2015	2014
Cash flow from operating activities		
Net loss	\$(2,463)	\$(2,161)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3	2
Stock-based compensation expense	558	209
Interest income from marketable securities	(174)	-
Changes in operating assets and liabilities:		
Increase in other accounts receivable	(223)	(78)
Increase (decrease) in trade payables	272	(255)
Increase (decrease) in other accounts payable	(34)	64
Increase (decrease) in related party	(195)	2
Net cash used in operating activities	(2,256)	(2,217)
Cash flow from investing activities		
Purchase of property and equipment	(2)	(7)
Investment in securities, available for sale	(19,445)	-
Realization of securities, available for sale	307	-
Net cash provided by (used in) investing activities	(19,140)	(7)
Cash flow from financing activities		
Issuance of ordinary shares	-	2,000
Issuance of ordinary shares upon IPO, net (*)	-	39,856
Net cash provided by financing activities	-	41,856
Increase (decrease) in cash and cash equivalents	(21,396)	39,632
Cash and cash equivalents at the beginning of the year	23,736	137
Cash and cash equivalents at the end of the period	\$2,340	\$39,769
Supplemental disclosure of cash flow information:		
Cash received from interest	\$65	-

(*) Net of offering expenses in the amount of \$4,204

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

GALMED PHARMACEUTICALS LTD.

Notes to Condensed Consolidated Financial Statements

Note 1 –Basis of presentation

Galmed Pharmaceuticals Ltd. (the “Company”) is a clinical-stage biopharmaceutical company primarily focused on the development and commercialization of therapeutics for the treatment of liver diseases and cholesterol gallstones.

The Company was incorporated in Israel on July 31, 2013 as a privately held company, and did not commence operations until February 2, 2014. However, our business has been operating since 2000 under a different group of companies established in the same year, referred to herein as the Group. Originally, we operated under Galmed Holdings Inc. 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 fully owned subsidiary, Galmed 2000, were transferred to the Company. Contemporaneously, the Company effected a stock split of 729:1.

These condensed unaudited interim consolidated financial statements have been prepared as of March 31, 2015 and for the three month period then ended. Accordingly, certain information and footnote disclosures normally included in annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. These condensed 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, 2014 that are included in the Company's Annual Report on Form 20-F, filed with the Securities and Exchange Commission on March 31, 2015. The results of operations presented are not necessarily indicative of the results to be expected for the year ending December 31, 2015.

Note 2 - Summary of significant accounting policies

The significant accounting policies that have been applied in the preparation of the condensed 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

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On March 31, 2015, the Company granted options to purchase 19,000 of its ordinary shares, par value NIS 0.01 per share, to certain subcontractors and officers. Certain options will vest over a period of two years and the rest of the options will vest over four years. The options will expire in March 2025 or at an earlier date upon termination. The exercise price is \$9.73 per share, and the fair value of such options at the grant date was \$111 thousand.

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, 2014 filed with the Securities and Exchange Commission, or the SEC (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:

· U.S. Food and Drug Administration, or FDA, approval of, or European Medicines Authority, or EMA, or other regulatory action with respect to, our product candidate, aramchol;

· the commercial launch and future sales of aramchol or any other future products or product candidates;

· our ability to achieve favorable pricing for aramchol;

· our expectations regarding the commercial market of Non-Alcoholic Steato-Hepatitis, or NASH, in patients who also suffer from obesity and insulin resistance and our expectations regarding the commercial market of patients with

cholesterol gallstones;

- third-party payor reimbursement for aramchol;

- our estimates regarding anticipated capital requirements and our needs for additional financing;

- the timing and cost of Phase IIb and Phase III trials for aramchol or whether such trials will be conducted at all;

- completion and receiving favorable results of Phase IIb and Phase III trials for aramchol;

- patient market size and 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 an emerging clinical-stage biopharmaceutical company primarily focused on the development and commercialization of novel therapeutics to treat liver diseases and cholesterol gallstones utilizing our proprietary family of synthetic fatty-acid/bile-acid conjugates, or FABACs. Our product candidate, aramchol, has the potential to be a disease modifying treatment for fatty liver disorders, specifically NASH, which we believe constitutes a large unmet medical need. The FDA cleared our Investigational New Drug, or IND, application in July 2014, which permits us to conduct clinical trials of aramchol in the United States for the treatment of fatty liver disorders, and granted Fast Track Designation status to aramchol for the treatment of NASH in September 2014. Fast Track Designation is a designation by the FDA that facilitates the development, and expedites the review, of drugs which treat a serious or life-threatening condition and fill an unmet medical need. In March 2015, we submitted to the FDA an update of our existing IND filing, in order to initiate the ARREST Study, as described below, in the United States.

We have successfully completed four clinical trials of aramchol. On February 1, 2015, we received all necessary approvals to begin our ARREST Study in Israel, a multi-center, double-blind, randomized Phase IIb placebo-controlled clinical trial of aramchol, which we intend to conduct in 240 biopsy-diagnosed NASH patients who also suffer from obesity and insulin resistance. Our current regulatory path for the development of aramchol for NASH is in accordance with the study design recommended by the United Kingdom's Medicines and Healthcare Products Regulatory Agency, which has been deemed acceptable or satisfactory, respectively, by two European medical agencies, Germany's Bundesinstitut für Arzneimittel und Medizinprodukte and France's Agence Nationale de Sécurité du Médicament et des Produits de Santé, and was confirmed as acceptable by the FDA. These two European agencies have confirmed that, if successful, this Phase IIb trial may serve as a basis for Phase III pivotal trials of aramchol. If the Phase III trials are completed successfully, we intend to submit a New Drug Application, or NDA, to the FDA and a Marketing Authorization Application, or an MAA, to the EMA for the approval of aramchol for the treatment of NASH in the United States and Europe. Once 120 patients in our ARREST Study complete six months of treatment, we intend to conduct an interim analysis for safety and futility of aramchol based on MRS analysis. We currently expect results from such interim analysis to be available in the first half of 2016. In addition, we currently

expect complete results from our ARREST Study to be available at the end of 2016.

As previously communicated, during the fourth quarter of 2014, we initiated a single-center, double blind, randomized Phase IIa placebo-controlled proof-of-concept clinical trial of aramchol in 36 patients for the treatment of newly formed cholesterol gallstones following bariatric surgery. Enrollment pace of the study has tracked significantly slower than anticipated. Therefore, we decided to expand the trial into 3 additional centers. Unfortunately, notwithstanding the significant efforts involved in the opening of the additional sites, enrollment has still continued to disappoint (only 9 patients to date). Consequently we have filed a request with the principal investigator to cease enrollment in the initial, underperforming center. Accordingly, we are taking this opportunity to reexamine the study design in order to achieve a better recruitment.

To date, we have not generated revenue from the sale of any product, and we do not expect to generate any significant revenue unless and until we commercialize aramchol. Obtaining approval of an NDA from the FDA and an MAA from the EMA, or other similar application is an extensive, lengthy, expensive and uncertain process, and the FDA, EMA and other regulatory agencies may delay, limit or deny approval of our product.

Financial Overview

Since inception in 2000, we have incurred significant losses in connection with our research and development, and operations, and have not generated any revenue to date. At December 31, 2014, we had an accumulated deficit of \$36.7 million, cash and cash equivalents of \$23.7 million and \$8.2 million in short-term deposit and marketable securities, as compares to an accumulated deficit of \$39.2 million, cash and cash equivalents of \$2.3 million and \$27.5 million in short-term deposit and marketable securities as of March 31, 2015. We have funded our operations primarily through the sale of equity and debt securities in private equity offerings and debt financings in Israel to our affiliates, shareholders and third-party investors, and through the sale of our ordinary shares in our initial public offering, which closed on March 18, 2014. Although we provide no assurance, we believe that such existing funds and the proceeds from our initial public offering will be sufficient to continue our business and operations as currently conducted into 2017. 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 further develop our research and development programs.

Business Developments

During the first quarter of 2015, we had the following major developments:

On January 5, 2015, we announced the appointment of Mr. Josh Blacher as our Chief Financial Officer, effective as of January 1, 2015, to replace Mr. Ray Morris.

On January 28, 2015, we announced that we entered into a Manufacturing Services Agreement, referred to herein as the Perrigo Agreement with Perrigo API Ltd., or Perrigo, a subsidiary of Perrigo Company plc (NYSE: PRGO), for, among other things, the large-scale production of the active pharmaceutical ingredient, or API, of our product candidate, aramchol. According to the terms of the Agreement, Perrigo will provide scale-up and manufacturing process optimization services for large-scale production of the aramchol API, manufacture the aramchol API pursuant to current good manufacturing processes and perform additional development services regarding manufacturing optimization for the aramchol API (collectively, the "Project"). The Agreement also provides Perrigo with the option to negotiate an exclusive commercial contract for the manufacture of commercial supplies of the aramchol API in the future for a minimum term of five years, pursuant to which Perrigo will also provide further services to validate the API manufacturing process, subject to certain conditions, including the successful completion of all clinical trials and obtaining regulatory approval of aramchol to market the drug. In addition to standard mutual termination provisions, including for uncured breach, financial condition and certain corporate transactions, we may terminate the Agreement upon thirty (30) days' prior written notice in the event of a failure in our current or future clinical trials or the receipt of inconclusive results from such trials, or if we otherwise decide in our discretion not to proceed with the commercialization of aramchol. Either party may terminate the Agreement upon fourteen (14) days' prior written notice in the event of a substantial delay (defined as more than three (3) months in the aggregate) by the other party in the timeline of the Project, provided that the parties cannot agree on a new timeframe for the Project. We may also terminate the Agreement upon thirty (30) days' prior written notice in the event of a change of control of

Perrigo or if Perrigo publically announces that it has entered into an agreement pursuant to which such change of control will occur. However, in the event of our change of control, we may, subject to complying with certain conditions, including the payment of a fee, terminate the Agreement upon thirty (30) days' prior written notice. Under the Agreement, we own all confidential information and intellectual property rights relating to the aramchol API, including any inventions specific to any API discovered by Perrigo in the course of providing services under the Agreement and as a result of performing the Project, including all results and deliverables in connection with the Project. Perrigo, on the other hand, owns all intellectual property and inventions discovered in the course of the Agreement related to the research, development and manufacturing methodologies which are not specific to the aramchol API. Notwithstanding the foregoing, subject to our payment of the consideration for a certain part of the Project, Perrigo shall grant us a perpetual, non-exclusive license such that we, our affiliates and any third party on our behalf may use the Perrigo-owned inventions solely to manufacture the aramchol API or the final aramchol product.

On March 9, 2015, we announced the beginning of enrollment in our Phase IIb clinical trial, or our ARREST Study, of aramchol in patients with Non-Alcoholic Steato-Hepatitis, or NASH, who also suffer from obesity and insulin resistance.

On March 22, 2015, we entered into a lease agreement with Mintz K. Construction Company Ltd., for approximately 356 square meters of space for our new headquarters (the "New Lease"). The initial term of the New Lease expires on March 21, 2019, but we have an option to extend the term of the New Lease for two additional years after the expiration of the initial term. The aggregate monthly rental payment under the New Lease for the initial term, together with adjustments and maintenance fees, is approximately \$8,159.

Since the end of the first quarter of 2015 (subsequent to the balance sheet date), we had the following development:

· On April 2, 2015, we announced the appointment of George Tonelli as our Vice President of Clinical Operations.

Costs and Operating Expenses

Our current costs and operating expenses consist of two components: (i) research and development expenses; and (ii) general and administrative expenses.

Research and Development Expense

Our research and development expenses consist primarily of outsourced development expenses, salaries and related personnel expenses and fees paid for employees in the medical department and external service providers, including professional fees, patent-related legal fees, costs of preclinical studies and clinical trials, drug development, manufacturing and supply, laboratory supplies and costs for facilities and equipment. We charge all research and development expenses to operations as they are incurred. We expect our research and development expense to remain our primary expense in the near future as we continue to develop our products. Increases or decreases in research and development expenditures are attributable to the number and duration of the preclinical and clinical studies that we conduct.

We expect that a large percentage of our research and development expense in the future will be incurred in support of our current and future preclinical and clinical development projects. Due to the inherently unpredictable nature of preclinical and clinical development processes, we are unable to estimate with any certainty the costs we will incur in the continued development of aramchol for NASH and other indications in our pipeline for potential commercialization. Clinical development timelines, the probability of success and development costs can differ

materially from expectations. We expect to continue to test our product candidate in preclinical studies for toxicology, safety and efficacy, and to conduct additional pre-clinical and clinical trials for our product candidate.

While we are currently focused on advancing our product development, our future research and development expenses will depend on the clinical success of our product candidate, as well as ongoing assessments of the candidate's commercial potential. As we obtain results from clinical trials, we may elect to discontinue or delay clinical trials for our product candidate in certain indications in order to focus our resources on more promising indications for such product candidate. Completion of clinical trials may take several years or more, but the length of time generally varies according to the type, complexity, novelty and intended use of a product candidate.

We expect our research and development expenses to increase in the future from current levels as we continue the advancement of our clinical product development and to the extent we in-license new product candidates. The lengthy process of completing clinical trials and seeking regulatory approval for our product candidate requires the expenditure of substantial resources. Any failure or delay in completing clinical trials, or in obtaining regulatory approvals, could cause a delay in generating product revenue and cause our research and development expenses to increase and, in turn, have a material adverse effect on our operations. Because of the factors set forth above, we are not able to estimate with any certainty when we would recognize any net cash inflows from our projects.

General and Administrative Expenses

Our general and administrative expenses consist primarily of compensation for employees in executive and operational roles, including general management, accounting, finance, legal and investor relations. Our other significant general and administrative expenses include facilities costs (including, the rental expense for our offices in Tel Aviv, Israel and our sub-leased office in New York, New York), professional fees for outside accounting and legal services, travel costs, insurance premiums and depreciation.

We expect our general and administrative expenses, such as accounting and legal fees, to increase as we grow and operate as a public company, and we expect an increase in our salary and benefits expense as a result of the additional management and operational personnel that we hired since our initial public offering to address the anticipated growth of our company.

Financial Expenses (Income), Net

Our financial income consists of interest income from short term bank deposits and from marketable securities. Our financial expense mainly consists of bank fees.

Results of Operations

The table below provides our results of operations for the three months ended March 31, 2015 as compared to the three months ended March 31, 2014.

Three months ended March 31,

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	2015		2014
	(unaudited)		(unaudited)
	(In thousands, except per share data)		
Research and development expenses	1,431		1,502
General and administrative expenses	1,073		633
Operating loss	2,504		2,135
Financial expenses (income), net	(41)	26
Net loss	2,463		2,161
Comprehensive loss	2,478		2,161
Loss per share	\$ 0.22		\$ 0.27

Research and Development Expenses

Our research and development expenses amounted to \$1.4 million during the three months ended March 31, 2015, representing a decrease of \$71 thousand, or 5%, as compared to such expenses for the comparable prior year period. This decrease resulted primarily from a decrease in research and development subcontractor expenses of \$322 thousand in connection with aramchol's clinical development program, offset by and an increase of \$251 thousand in salaries and benefits to new employees hired since the comparable prior year period, consisting of non-cash stock-based compensation of \$93 thousand and salaries paid to employees in the amount of \$158 thousand.

General and Administrative Expenses

Our general and administrative expenses amounted to \$1.1 million during the three months ended March 31, 2015, representing an increase of \$440 thousand, or 70%, as compared to such expenses for the comparable prior year period. This increase primarily resulted from an increase of non-cash-stock-based compensation to employees and directors of \$257 thousand. The increase in the general and administrative expenses is also as a result of an increase in professional services of \$221 thousand, which includes primary investor relations and business development expenses.

Operating Loss

As a result of the foregoing research and development and general and administrative expenses, as well as our failure to generate operating revenues since our inception, for the three months ended March 31, 2015 our operating loss was \$2.5 million, representing an increase of \$369 thousand, or 17%, as compared to our operating loss for the comparable prior year period. This increase primarily resulted from an increase in our general and administrative expenses, including an increase in non-cash-stock-based compensation to employees and directors and an increase in professional services, as set forth above.

Financial Income (Expenses), Net

Our financial income (expenses) amounted to \$41 thousand during the three months ended March 31, 2015, representing an increase of \$67 thousand, as compared to such income (expenses) for the comparable prior year period. This increase resulted primarily from an increase of \$118 thousand in interest income from short term deposit and marketable securities.

Net Loss

As a result of the foregoing research and development and general and administrative expenses, as well as our failure to generate revenues from operations since our inception, for the three months ended March 31, 2015, our net loss was \$2.5 million, representing an increase of \$302 thousand, or 14%, as compared to our net loss for the comparable prior year period.

Liquidity and Capital Resources

Overview

We have incurred substantial losses since our inception. As of March 31, 2015, we had an accumulated deficit of approximately \$39.2 million and positive working capital (current assets less current liabilities) of \$28.9 million. We expect that losses will continue for the foreseeable future.

As of March 31, 2015, we had cash and cash equivalents of \$2.3 million as compared to \$23.7 as of December 31, 2014. This decrease of \$21.4 million is primarily due to an investment in marketable securities of \$19.4 million.

We had negative cash flow from operating activities of \$2.3 million for the three months ended March 31, 2015 as compared to negative cash flow from operating activities of \$2.2 million for the three months ended March 31, 2014. The negative cash flow from operating activities for the three months ended March 31, 2015 is mainly attributable to our net loss of \$2.5 million, offset by a stock based compensation expense of \$558 thousand.

We had negative cash flow from investing activities of \$19.1 million for the three months ended March 31, 2015, as compared to a negative cash flow from investing activities of \$7 thousand for the three months ended March 31, 2014. The negative cash flow from investing activities for the three months ended March 31, 2015 was primarily due to the investment in marketable securities, while the negative cash flow from investing activities for the three months ended March 31, 2014 was due to the purchase of equipment.

We didn't have any cash flow from financing activities for the three months ended March 31, 2015 as compared to a positive cash flow from financing activities of \$41.9 million for the three months ended March 31, 2014. The positive cash flow from financing activities for the three months ended March 31, 2014 was primarily due to the issuance of our ordinary shares in our initial public offering for net proceeds of approximately \$39.9 million and the issuance of our ordinary shares in the amount of \$2.0 million in a private placement financing completed in February 2014, prior to the consummation of the initial public offering.

Although there can be no assurance, we believe that our existing cash resources and the net proceeds from our initial public offering will be sufficient to fund our projected cash requirements into 2017. Nevertheless, we will require significant additional financing in the future to fund our operations if and when we progress into Phase III trials of aramchol and clinical trials for other indications, obtain regulatory approval of aramchol and commercialize the drug. Our management, including our board of directors, may choose to raise such additional capital at its discretion.

Trend Information

We are a development stage company, and it is not possible for us to predict with any degree of accuracy the outcome of our research, development or commercialization efforts. As such, it is not possible for us to predict with any degree of accuracy any significant trends, uncertainties, demands, commitments or events that are reasonably likely to have a material effect on our net sales or revenues, income from continuing operations, profitability, liquidity or capital resources, or that would cause financial information to not necessarily be indicative of future operating results or financial condition. However, to the extent possible, certain trends, uncertainties, demands, commitments and events are in this “Management’s Discussion and Analysis of Financial Condition and Results of Operations”.

Quantitative and Qualitative Disclosures about Market Risk

As a “smaller reporting company”, we have elected not to provide qualitative or quantitative disclosures about market risk at this time.

Controls and Procedures

As a “foreign private issuer”, we are only required to conduct the evaluations required by Rules 13a-15(b) and 13a-15(d) of the Exchange Act as of the end of each fiscal year and therefore have elected not to provide disclosure regarding such evaluations at this time.

OTHER INFORMATION

Use of Proceeds

On March 18, 2014, we completed our initial public offering of 3,263,010 ordinary shares at a public offering price of \$13.50 per share, which included 425,610 ordinary shares issued upon the exercise in full of the underwriters' option to purchase additional ordinary shares to cover over-allotments, for aggregate gross proceeds of approximately \$44.1 million. Maxim Group LLC acted as sole book-running manager of the offering, and MLV & Co. and Feltl and Company acted as co-managers of the offering. The offer and sale of all of the shares in the offering were registered under the Securities Act pursuant to a registration statement on Form F-1, which was declared effective on March 12, 2014 (File No. 333-193792), and a registration statement on Form F-1 filed pursuant to Rule 462(b) of the Securities Act (File No. 333-194526).

We received aggregate net proceeds from the offering of approximately \$39.9 million, after deducting approximately \$3.1 million of underwriting discounts and commissions and approximately \$1.1 million of estimated offering expenses directly payable by us. None of the underwriting discounts and commissions or other offering expenses were incurred or paid to our directors or officers or their associates or to persons owning ten percent or more of our ordinary shares or to any of our affiliates.

As of March 31, 2015, the net proceeds from our initial public offering are held in cash and cash equivalents, and in a variety of additional capital preservation investments, including short-term, investment grade, interest-bearing instruments, such as corporate debt securities, and certain short-term money market investments. We have broad discretion in the use of the net proceeds from our initial public offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our ordinary shares.

EXHIBIT INDEX

Exhibit No. Description

99.1 Press Release, dated May 13, 2015.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Galmed Pharmaceuticals Ltd.

Date: May 13, 2015 By: /s/ Allen Baharaff
Allen Baharaff
President and Chief Executive Officer