

Galmed Pharmaceuticals Ltd.
Form 6-K
November 09, 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 November 2015

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.

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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 and nine months ended September 30, 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 November 9, 2015, the Company issued a press release announcing the filing of its financial results for the three and nine months ended September 30, 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.

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

	As of September 30, 2015	As of December 31, 2014
	Unaudited	Audited
Assets		
Current assets		
Cash and cash equivalents	\$ 4,463	\$ 23,736
Short-term deposit	-	6,000
Marketable securities	20,862	2,250
Other accounts receivable	346	165
Total current assets	25,671	32,151
Property and equipment, net	902	774
Total assets	\$ 26,573	\$ 32,925
Liabilities and stockholders' equity		
Current liabilities		
Trade payables	\$ 1,126	\$ 875
Other accounts payable	200	243
Total current liabilities	1,326	1,118
Long-term liabilities		
Related parties	187	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	69,246	68,116
Accumulated other comprehensive income (loss)	(56) 4
Accumulated deficit	(44,162) (36,745
Total stockholders' equity	25,060	31,407
Total liabilities and stockholders' equity	\$ 26,573	\$ 32,925

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

GALMED PHARMACEUTICALS LTD.

Consolidated Statements of Operations (Unaudited)

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

	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
Research and development expenses	\$1,860	\$2,791	\$4,853	\$5,538
General and administrative expenses	637	399	2,677	1,550
Total operating expenses	2,497	3,190	7,530	7,088
Financial expenses (income), net	103	16	(113)	36
Net loss	\$2,600	\$3,206	\$7,417	\$7,124
Basic and diluted net loss per share	\$0.23	\$0.29	\$0.67	\$0.71
Weighted-average number of shares outstanding used in computing basic and diluted net loss per share	11,100,453	11,100,453	11,100,453	10,074,939(*)

(*) 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 interim consolidated financial statements.

GALMED PHARMACEUTICALS LTD.

Consolidated Statement of Comprehensive Loss (Unaudited)

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

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2015	2014	2015	2014
Net loss	\$ 2,600	\$ 3,206	\$ 7,417	\$ 7,124
Other comprehensive loss:				
Net unrealized loss (gain) on available for sale securities	(5)	-	60	-
Comprehensive loss	\$ 2,595	\$ 3,206	\$ 7,477	\$ 7,124

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	Amount	Additional paid-in capital	Accumulated other Comprehensive Income (loss)	Accumulated Deficit	Total
Balance - December 31, 2014	11,100,453	\$ 32	\$ 68,116	\$ 4	\$ (36,745)	\$ 31,407
Stock based compensation	-	-	1,130	-	-	1,130
Unrealized loss from marketable securities	-	-	-	(60)	-	(60)
Net loss	-	-	-	-	(7,417)	(7,417)
Balance - September 30, 2015	11,100,453	\$ 32	\$ 69,246	\$ (56)	\$ (44,162)	\$ 25,060

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, except share data and per share data**

	Nine months ended	
	September 30,	
	2015	2014
Cash flow from operating activities		
Net loss	\$(7,417)	\$(7,124)
Adjustments required to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	32	8
Stock-based compensation expense	1,130	470
Amortization of investment premium, net	195	-
Changes in operating assets and liabilities:		
Increase in other accounts receivable	(181)	(51)
Increase (decrease) in trade payables	251	(108)
Increase (decrease) in other accounts payable	(43)	154
Increase (decrease) in related party	(213)	20
Net cash used in operating activities	(6,246)	(6,631)
Cash flow from investing activities		
Purchase of property and equipment	(160)	(20)
Realization of short term deposit	6,000	
Investment in securities, available for sale	(25,132)	-
Realization of securities, available for sale	6,265	-
Net cash used in investing activities	(13,027)	(20)
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	(19,273)	35,205
Cash and cash equivalents at the beginning of the year	23,736	137
Cash and cash equivalents at the end of the period	\$4,463	\$35,342
Supplemental disclosure of cash flow information:		
Cash received from interest	\$370	-

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

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 therapeutics for the treatment of liver diseases.

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 September 30, 2015 and for the three and nine months periods 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 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 “Annual Report”). 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 unaudited consolidated interim financial statements are identical to those that were applied in preparation of the Company’s most recent annual financial statements.

Note 3 - Stockholders’ Equity

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On March 30, 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 amounts of the options will vest over a period of two years and 1. 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 of these options is \$9.73 per share and the fair value of such options at the grant date was \$111 thousand.

On May 11, 2015, the Company held its Annual General Shareholders meeting, whereby the shareholders approved the grant of 160,000 options to purchase ordinary shares, par value NIS 0.01 per share, to certain employees and 2. directors. The options will vest over four years and will expire in May 2025 or at an earlier date upon termination. The exercise price of these options is \$5.49 per share and the fair value of such options at the grant date was \$662 thousand.

On August 6, 2015, the Company granted options to purchase 100,000 of its ordinary shares, par value NIS 0.01 3. per share, to certain subcontractors and officers. The options will vest over a period of four years and will expire in August 2025 or at an earlier date upon termination. The exercise price of these options is between \$9.13 and \$10.14 per share and the fair value of such options at the grant date was \$660 thousand.

On May 11, 2015, the Company's shareholders at its annual shareholders meeting approved the increase in the 4. number of shares available under the Company's 2013 incentive share option plan by an additional 750,000 ordinary shares.

GALMED PHARMACEUTICALS LTD.

Notes to Consolidated Financial Statements

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 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, or 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.

GALMED PHARMACEUTICALS LTD.

Notes to Consolidated Financial Statements

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 of novel therapeutics to treat liver diseases 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.

We have successfully completed four clinical trials of Aramchol™. On February 1, 2015, we began our ARREST Study with the commencement of screening in our Israeli-approved sites. The ARREST Study is a Phase IIb, multi-center, double-blind, randomized, 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. These two European agencies have confirmed that if successful, the ARREST Study may serve as a basis for Phase III pivotal trials of Aramchol™.

We submitted our original Investigational New Drug application, or IND, to the FDA in July 2014. Subsequently, the FDA granted us 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 that treat a serious or life-threatening condition and fill an unmet medical need. In March 2015, we submitted an update to our original IND (which, among other things, included the ARREST Study protocol) to the FDA, in order to initiate the ARREST Study in the United States, which has since become effective. Patient screening has commenced in the United States, Latin America and Europe and remains ongoing in Israel.

If the Company conducts and completes a Phase III trial(s) successfully, we would expect to then submit an NDA to the FDA and 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. The analysis will be performed by an independent statistician and the decision to continue the study or stop it will be made by an independent advisory board, based on criteria pre-defined in the study protocol. The study will be continued if and only if (i) no safety signals become apparent and (ii) there is a difference in the trend of decrease in the liver fat content (measured by MRS) of subjects in the treatment arms as compared to those in the placebo arm. In order to continue the study, the data will remain blinded to all parties, except for the advisory board mentioned above and Galmed will be aware only of the go/no go decision. Therefore, we will be unable to communicate additional data.

We currently expect results from such interim analysis to be available in the second half of 2016. In addition, based on the trial's protocol, 240 patients will need to have completed 12 months of treatment of Aramchol™, followed by a three month follow-up period in order to complete the ARREST Study. The Company will then need several weeks to complete the statistical analysis before it releases the data. Therefore, based on the timelines provided in the Study protocol, we currently expect complete top-line results from our ARREST Study to be available in the second quarter of 2017.

GALMED PHARMACEUTICALS LTD.

Notes to Consolidated Financial Statements

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 a New Drug Application from the FDA and a Marketing Authorization Application from the European Medicines Agency, or 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

At September 30, 2015, we had current assets of \$25.7 million, which is mainly comprised of short-term investment securities of \$20.9 million and cash and cash equivalents of \$4.5 million. This compares with current assets of \$32.2 million at December 31, 2014, which is mainly comprised of short-term investment securities of \$8.2 million and cash and cash equivalents of \$23.7 million.¹ 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 (which has subsequently been converted in whole to 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. 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 third quarter of 2015, we had the following developments:

On July 8, 2015 we announced that we entered into a Research, Option and License Agreement (“License Agreement”) with One Way Liver Genomics S.L. (“OWL”), for the development of a non-invasive, blood-based companion diagnostic tool. Pursuant to the terms of the License Agreement, we will partially fund the research and development of the diagnostic tool in the amount of up to Euro 437,000 based on reaching development milestones. Subject to development under the License Agreement, we have an option to exclusively license from OWL a companion diagnostic tool for NASH using Aramchol™, in consideration for the payment of a 10% royalty to OWL based on the annual net sales of the companion diagnostic product. In addition, if OWL develops any other companion diagnostic tool for NASH not using Aramchol™, it will pay us a royalty from revenues.

Concurrently with the License Agreement, we entered into a Share Purchase Agreement with OWL pursuant to which we undertook to invest Euro 175,000 in OWL, subject to certain specified milestones. In addition, OWL has granted us an option which will allow us to purchase additional shares up to 19.9% of OWL at the higher of the valuation at the then current round of financing or at a 15% premium on OWL's valuation in the most recent equity investments

On August 13, 2015 we announced the appointment of Dr. Michal Ayalon as Vice President, Research and Development.

· On August 13, 2015 we announced the commencement of patient screening in United States and Latin America.

GALMED PHARMACEUTICALS LTD.

Notes to Consolidated Financial Statements

Costs and Operating Expenses

Our 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 clinical development and potentially 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, business development and investor relations. Our other significant general and administrative expenses include facilities costs (including, the rental expense for our offices in Tel Aviv, Israel), 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 and are hiring since our initial public offering to address the anticipated growth of our company.

GALMED PHARMACEUTICALS LTD.**Notes to Consolidated Financial Statements****Financial Expenses (Income), Net**

Our financial income consists of 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 and nine months ended September 30, 2014 as compared to the three and nine months ended September 30, 2015.

	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
	(In thousands, except per share data)			
Research and development expenses	1,860	2,791	4,853	5,538
General and administrative expenses	637	399	2,677	1,550
Operating loss	2,497	3,190	7,530	7,088
Financial expenses (income), net	103	16	(113)	36
Net loss	2,600	3,206	7,417	7,124
Comprehensive loss	2,595	3,206	7,477	7,124
Basic and diluted net Loss per share	\$ 0.23	\$ 0.29	\$ 0.67	\$ 0.71

Research and Development Expenses

Our research and development expenses amounted to \$1.9 million and \$4.9 million during the three and nine months ended September 30, 2015, respectively, representing a decrease of \$931 thousand, or 33%, and a decrease of \$685 thousand, or 12%, respectively, as compared to such expenses for the comparable prior year periods.

The decrease during the three months ended September 30, 2015 primarily resulted from a decrease in chemistry and clinical studies of \$814 thousand, research and development subcontractor expenses in connection with Aramchol™'s clinical development program of \$1.1 million.

The decrease during the nine months ended September 30, 2015 primarily resulted from a decrease in chemistry and clinical studies of \$1.8 million, primarily offset by an increase in clinical related activities in connection with Aramchol™'s clinical development program of \$1.0 million, and salaries and benefits to new employees hired since the comparable prior year period, consisting of non-cash stock-based compensation of \$216 thousand and salaries paid to employees in the amount of \$221 thousand.

General and Administrative Expenses

Our general and administrative expenses amounted to \$0.6 million and \$2.7 million during the three and nine months ended September 30, 2015, respectively, representing an increase of \$238 thousand, or 60%, and an increase of \$1.1 million, or 73%, respectively, as compared to such expenses for the comparable prior year periods.

The increase during the three months ended September 30, 2015 primarily resulted from an increase in professional services of \$150 thousand, which includes primary investor relations and business development expenses.

The increase during the nine months ended September 30, 2015 primarily resulted from an increase in salaries and benefits to new employees hired since the comparable prior year period, consisting of non-cash stock-based compensation of \$443 thousand and salaries paid to employees in the amount of \$146 thousand. The increase in the general and administrative expenses is also as a result of an increase in professional services of \$433 thousand, which includes primary investor relations and business development expenses.

GALMED PHARMACEUTICALS LTD.

Notes to Consolidated Financial Statements

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 and nine months ended September 30, 2015, our operating loss was \$2.5 million and \$7.5 million, respectively, representing a decrease of \$693 thousand, or 22%, and an increase of \$442 thousand, or 6%, respectively, as compared to our operating loss for the comparable prior year period.

The decrease for the three months ended September 30, 2015 primarily resulted from a decrease in our research and development expenses, including a decrease in connection with Aramchol™'s clinical development program, as set forth above.

The increase for the nine months ended September 30, 2015 primarily resulted from an increase in our general and administrative expenses, including an increase in salaries and benefits to and professional services, as set forth above.

Financial Income (Expenses), Net

Our financial income (expenses) amounted to (\$103) thousand and \$113 thousand during the three and nine months ended September 30, 2015, respectively, representing an increase of (\$87) thousand and \$149 thousand, respectively, as compared to such income (expenses) for the comparable prior year period.

The increase for the three months ended September 30, 2015 resulted primarily from an increase in foreign currency exchange expenses. The increase for the nine months ended September 30, 2015 resulted primarily from an increase in interest income from marketable securities and short-term deposit.

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 and nine months ended September 30, 2015 our net loss was \$2.6 million and \$7.4 million, respectively, representing a decrease of \$606 thousand, or 19%, and an increase of \$293 thousand, or 4%, respectively, 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 September 30, 2015, we had an accumulated deficit of approximately \$44.1 million and positive working capital (current assets less current liabilities) of \$24.3 million. We expect that losses will continue for the foreseeable future.

As of September 30, 2015, we had cash and cash equivalents of \$4.5 million as compared to \$23.7 as of December 31, 2014. This decrease of \$19.3 million is primarily due to a transfer of a significant portion of our cash to interest-bearing marketable securities in the amount of \$18.7, net million and our operating activity (see note 'Financial Income' above regarding the interest earned on this portfolio).

We had negative cash flow from operating activities of \$6.2 million for the nine months ended September 30, 2015 as compared to a negative cash flow from operating activities of \$6.6 million for the nine months ended September 30, 2014. The negative cash flow from operating activities for the nine months ended September 30, 2015 is mainly attributable to our net loss of \$7.4 million, offset by a stock based compensation expense of \$1.1 million.

We had negative cash flow from investing activities of \$13.0 million for the nine months ended September 30, 2015 as compared to a negative cash flow from investing activities of \$20 thousand for the nine months ended September 30, 2014. The negative cash flow from investing activities for the nine months ended September 30, 2015 was primarily due to the investment in marketable securities, offset by a realization of marketable securities and short-term deposit.

GALMED PHARMACEUTICALS LTD.

Notes to Consolidated Financial Statements

We did not have any cash flow from financing activities for the nine months ended September 30, 2015 as compared to a positive cash flow from financing activities of \$41.9 million for the nine months ended September 30, 2014. The positive cash flow from financing activities for the nine months ended September 30, 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 or combination therapies, 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. Accordingly, we have filed a universal shelf offering for the issuance of up to \$150 million in securities with the SEC on Form F-3, which became effective on July 1, 2015.

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.

EXHIBIT INDEX

Exhibit No. Description

99.1 Press Release, dated November 9, 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: November 9, 2015 By: /s/ Allen Baharaff
Allen Baharaff

President and Chief Executive Officer