Galmed Pharmaceuticals Ltd.
Form 6-K
May 16, 2016

**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 2016

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 ý  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, 2016, 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 16, 2016, the Company issued a press release announcing the filing of its financial results for the three months ended March 31, 2016 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.**
**Consolidated Balance Sheets**
**U.S. Dollars in thousands, except share data and per share data**

| | As of March 31, 2016 Unaudited | As of December 31, 2015 Audited |
|---|---|---|
| Assets | | |
| Current assets | | |
| Cash and cash equivalents | $ 3,084 | $ 4,156 |
| Marketable securities | 16,882 | 18,845 |
| Other accounts receivable | 256 | 379 |
| Total current assets | 20,222 | 23,380 |
| Property and equipment, net | 859 | 883 |
| Total assets | $ 21,081 | $ 24,263 |
| Liabilities and stockholders' equity | | |
| Current liabilities | | |
| Trade payables | $ 2,951 | $ 2,259 |
| Other accounts payable | 73 | 282 |
| Total current liabilities | 3,024 | 2,541 |
| Long-term liabilities | | |
| Related parties | 177 | 177 |
| Total long-term liabilities | 177 | 177 |
| 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 | 69,359 | 69,086 |
| Accumulated other comprehensive loss | (160) | (206) |

| | | |
|---|---|---|
| Accumulated deficit | (51,351 ) | (47,367 ) |
| Total stockholders' equity | 17,880 | 21,545 |
| Total liabilities and stockholders' equity | $ 21,081 | $ 24,263 |

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 March 31, | |
|---|---|---|
| | 2016 | 2015 |
| Research and development expenses | $3,384 | $1,431 |
| General and administrative expenses | 719 | 1,073 |
| Total operating expenses | 4,103 | 2,504 |
| Financial income, net | (119) | (41) |
| Net loss | $3,984 | $2,463 |
| Basic and diluted net loss per share from continuing operations | $0.36 | $0.22 |
| Weighted-average number of shares outstanding used in computing basic and diluted net loss per share | 11,100,453 | 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,** | |
| | 2016 | 2015 |
| Net loss | $3,984 | $2,463 |
| Other comprehensive (income) loss: | | |
| Net unrealized (gain) loss on available for sale securities | (46) | 15 |
| Comprehensive loss | $3,938 | $2,478 |

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 | Accumulated other Comprehensive | Accumulated | |
|---|---|---|---|---|---|---|
| | Shares | Amount | capital | loss | Deficit | Total |
| Balance - December 31, 2015 | 11,100,453 | $ 32 | $ 69,086 | $ (206) | $ (47,367) | $ 21,545 |
| Stock based compensation | - | - | 273 | - | - | 273 |
| Unrealized gain from marketable securities | - | - | - | 46 | - | 46 |
| Net loss | - | - | - | - | (3,984) | (3,984) |
| Balance - March 31, 2016 | 11,100,453 | $ 32 | $ 69,359 | $ (160) | $ (51,351) | $ 17,880 |

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, | |
|---|---|---|
| | 2016 | 2015 |
| Cash flow from operating activities | | |
| Net loss | $(3,984) | $(2,463) |
| Adjustments required to reconcile net loss to net cash used in operating activities: | | |
| Depreciation and amortization | 32 | 3 |
| Stock-based compensation expense | 273 | 558 |
| Amortization of discount/premium on marketable securities | (62) | (185) |
| Loss from realization of marketable securities | 55 | 11 |
| Changes in operating assets and liabilities: | | |
| Increase in other accounts receivable | 123 | (223) |
| Increase in trade payables | 692 | 272 |
| Decrease in other accounts payable | (209) | (34) |
| Decrease in related party | - | (195) |
| Net cash used in operating activities | (3,080) | (2,256) |
| Cash flow from investing activities | | |
| Purchase of property and equipment | (8) | (2) |
| Investment in securities, available for sale | - | (19,445) |
| Realization of securities, available for sale | 2,016 | 307 |
| Net cash provided by (used in) investing activities | 2,008 | (19,140) |
| Increase (decrease) in cash and cash equivalents | (1,072) | (21,396) |
| Cash and cash equivalents at the beginning of the year | 4,156 | 23,736 |
| Cash and cash equivalents at the end of the period | $3,084 | $2,340 |
| Supplemental disclosure of cash flow information: | | |
| Cash received from interest | $140 | $65 |

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 a novel, once-daily, oral therapy 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 March 31, 2016 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 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, 2015 that are included in the Company's Annual Report on Form 20-F, filed with the Securities and Exchange Commission on March 22, 2016. The results of operations presented are not necessarily indicative of the results to be expected for the year ending December 31, 2016.

**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 2016, the Company granted 242,500 options to purchase ordinary shares of the Company with a NIS 0.01 par value to certain employees and consultants, as well as, 41,250 restricted stock units (the "RSU's"). The options and RSU's vest over a period of four years and shall expire in 10 years from the grant date. The exercise price of the options is $7.61 per share.

2. In February 2016, the Company granted 470,000 options to purchase ordinary shares of the Company with a NIS 0.01 par value to certain employees and directors, as well as 37,500 RSU's. The options and RSU's vest over a period of four years. The options expire in 10 years from the grant date. The exercise price of the options is $5.94 per share. The grant of such options and RSU's to employees and directors is subject to the approval of the Company’s shareholders at the general shareholders meeting.

***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, 2015 filed with the Securities and Exchange Commission, or the SEC, on March 22, 2016 (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 with Non-Alcoholic Steato-Hepatitis, or NASH, and who are overweight or obese and who suffer from type II diabetes or are pre-diabetic (hereinafter OD patients), or whether Phase III trials will be conducted at all;

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

- 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;
- our expectations regarding the commercial market for NASH in OD patients;
- our ability to achieve favorable pricing for Aramchol;
- the timing, cost or other aspects of the commercial launch of Aramchol;
- the commercial launch and future sales of Aramchol or any other future products or product candidates;
- third-party payor reimbursement for Aramchol;
- market adoption of Aramchol by physicians and patients;
- our ability to comply with all applicable post-market regulatory requirements for Aramchol in the countries in which we seek to market the product;
- the development and approval of the use of Aramchol for additional indications or in combination therapy; and
- our expectations regarding product licensing, mergers & acquisitions and other strategic corporate activities.

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 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, a multi-center, double-blind, randomized, placebo-controlled, dose-ranging Phase IIB clinical trial of Aramchol, which we intend to conduct in 240 patients who have been biopsy-diagnosed as having NASH and who are OD patients. We have initiated this study in Israel, Europe, Latin America and in the United States (pursuant to an IND authorized by FDA). Our ARREST Study for Aramchol in patients with NASH and who are OD patients is in accordance with the study design recommended by the Medicines and Healthcare Products Regulatory Agency, or MHRA, and has been deemed acceptable by Bundesinstitut für Arzneimittel und Medizinprodukte, a German medical agency, or BfArM, and deemed satisfactory by Agence nationale de sécurité du médicament, a French medical agency, or ANSM. The BfArM and ANSM also confirmed, in minutes of each of their respective scientific advisory meetings, that if successful, the ARREST Study may serve as a basis for Phase III pivotal trials of Aramchol. The FDA and MHRA invited us to discuss the next steps in the development of Aramchol after we analyze the results of the ARREST Study. If we conduct Phase III trial(s) and such trials are successful, we intend to submit directly or using third parties an NDA to the FDA and an MAA to the EMA for the approval of Aramchol for the treatment of NASH in OD patients in the United States and Europe. More information about the ARREST Study may be found on ClinicalTrials.gov identifier: NCT02279524.

We submitted an IND application to FDA to initiate the ARREST Study, and hope to expand the scope of the IND in the future to conduct pivotal Phase III clinical trials for NASH and other clinical trials in the United States. The FDA cleared our IND application, allowing us to conduct the Phase IIB ARREST Study in the United States. In September 2014, the FDA granted Fast Track designation status to Aramchol for the treatment of NASH. Fast Track designation may accelerate the development process and may expedite the review of drugs that show promise in treating serious, life-threatening medical conditions for which no other drug either exists or is as effective.

Originally, we intended to perform a 'futility analysis' as part of the 'interim analysis' for half the ARREST Study's total patients (n=120), after having completing six months of treatment. The futility analysis would have evaluated the data both for safety signals, as well as for determining whether or not subjects who had been receiving Aramchol showed an observable reduction in liver fat concentration, as measured by MRS. The independent Drug and Safety Monitoring Board (DSMB) would have then made a "go/no go" decision based on safety data and the MRS data at six months . The absence of significant MRS-related results at the six month point could have resulted in the termination of the ARREST Study and was, therefore, considered a 'futility analysis.'

However, in light of the FDA and AASLD clinical guidance for the development of diagnostic and therapeutic modalities for the treatment of NASH published in early 2015, it has become increasingly clear that MRS-related data alone will not be sufficient to seek regulatory approval for NASH drugs; and, a resolution of NASH as measured by histological data (*i.e.*, liver biopsy data) will be absolutely required for such regulatory approvals. This conclusion was further supported by two recent Phase III protocols (REGENERATE study,' NCT02548351, and RESOLVE-IT study,' NCT02704403), which also require resolution of NASH as measured by histological data. As such, the entire twelve month histological dataset will be necessary in order to judge the viability of Aramchol, and potential further development thereof.

Thus, the scope of the interim analysis we are currently planning on conducting once 120 patients in our ARREST Study have completed six months of treatment, will be limited to analysis of safety-related signals *only*, conducted by the DSMB. The interim analysis, therefore, *will not* include a review of the data with respect to any efficacy endpoints, including that of a reduction of liver fat content as measured by MRS.

At the point of the interim analysis, the DSMB will then decide whether or not to continue studying both doses of Aramchol (400 MGs and 600 MGs), or move all patients to one dose, if one is found to be safer than the other. We do not anticipate the interim results to lead to the stoppage of our ARREST Study, but no assurance can be given. We currently expect results from the interim analysis to be completed by December 2016, or early first-quarter 2017 and top-line data for the ARREST Study to be completed in the first quarter of 2018, inclusive of the three-month follow-up period.

**Financial Overview**

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. At March 31, 2016, we had current assets of $20.2 million, which consists of cash and cash equivalents of $3.1 million and short-term investment securities of $16.9 million. This compares with current assets of $23.4 million at December 31, 2015, which consists of cash and cash equivalents of $4.2 million and short-term investment securities of $18.8 million. 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 the second half of 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 complete the ARREST Study, and further develop our research and development programs.

**Business Developments**

During the first quarter of 2016, we had the following major developments:

- On March 30, 2016 we announced pre-clinical data demonstrating significant anti-fibrotic activity of Aramchol in methionine and choline deficient (MCD) diet in mice;

- On March 1, 2016 we announced the Enrollment of the first Patient in the ARRIVE Study (**AR**amchol for the **R**eversal of H**IV**-Associat**E**d Lipodystrophy and nonalcoholic fatty liver disease); and

- On February 11, 2016, we announced the retirement of our Chief Medical Officer, Dr. Maya Halpern, from the Company as Chief Medical Officer and from our Board of Directors effective as of April 9, 2016 due to her reaching retirement age.

Since the end of the first quarter of 2016 (subsequent to the balance sheet date), we had the following development:

- On May 3, 2016, we announced that we will collaborate with Mount Sinai in an investigator initiated Phase IIa clinical trial to evaluate the effect of Aramchol™ in Combination with vitamin D for the treatment of patients with fibrotic nonalcoholic fatty liver disease.

**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 Expenses***

Our research and development expenses consist primarily of outsourced development expenses, salaries and related personnel expenses and fees paid to external service providers, patent-related legal fees, costs of preclinical studies and clinical trials and drug and laboratory supplies. We charge all research and development expenses to operations as they are incurred. We expect our research and development expenses to remain our primary expenses in the near future as we continue to conduct clinical activities, as well as develop our products. Increases or decreases in research and development expenditures are attributable to the number and/or 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 clinical and, to a lesser extent, preclinical development projects. Due to the inherently unpredictable nature of clinical and preclinical 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 for any given study, and development costs can differ materially from expectations. We expect to continue to conduct additional clinical trials for our product candidate, and to test our product candidate in preclinical studies for toxicology, safety and efficacy.

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 potentially 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***

General and administrative expenses consist primarily of compensation for employees in executive and operational roles, including accounting, finance, legal and investor relations. Our other significant general and administrative expenses include non-cash stock-based compensation costs and facilities costs (including the rental expense for our offices in Tel Aviv, Israel), professional fees for outside accounting and legal services, travel costs, investors relations, 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, as well as performance-based salary increases and bonuses, if at all.

***Financial Income, Net***

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

**Results of Operations**

The table below provides our results of operations for the three months ended March 31, 2016 as compared to the three months ended March 31, 2015.

| | Three months ended March 31, | |
|---|---|---|
| | 2016 | 2015 |
| | (unaudited) | (unaudited) |
| | (In thousands, except per share data) | |
| Research and development expenses | 3,384 | 1,431 |
| General and administrative expenses | 719 | 1,073 |
| Operating loss | 4,103 | 2,504 |
| Financial expenses (income), net | (119) | (41) |
| Net loss | 3,984 | 2,463 |
| Other Comprehensive (gain) loss | (46) | 15 |
| Comprehensive loss | $3,977 | 2,478 |
| Loss per share | $0.36 | $ 0.22 |

***Research and Development Expenses***

Our research and development expenses amounted to $3.4 million during the three months ended March 31, 2016, representing an increase of $2.0 million, or 136%, compared to $1.4 million for the comparable period in 2015. The increase primarily resulted from an increase of $1.6 million in research and development subcontractor expenses in connection with the ARREST Study; and as well, an increase of $490 thousand in drug development related expenses, as compared to such expenses for the comparable period in 2015.

***General and Administrative Expenses***

Our general and administrative expenses amounted to $719 thousand during the three months ended March 31, 2016, representing a decrease of $354 thousand, or 33%, compared to $1.1 million for the comparable period in 2015. The decrease primarily resulted from a decrease of $307 thousand in non-cash-stock-based compensation to employees and directors.

***Operating Loss***

As a result of the foregoing, for the three months ended March 31, 2016 our operating loss was $4.1 million, representing an increase of $1.6 million, or 64%, compared to $2.5 million for the comparable period in 2015.

***Financial Income, Net***

Our financial income amounted to $119 thousand during the three months ended March 31, 2016, representing an increase of $78 thousand, or 190%, compared to $41 thousand for the comparable period in 2015. This increase resulted primarily from an increase of $146 thousand in currency exchange rate income.

***Net Loss***

As a result of the foregoing, for the three months ended March 31, 2016, our net loss was $4.0 million, representing an increase of $1.5 million, or 62%, compared to $2.5 million for the comparable period in 2015.

***Liquidity and Capital Resources***

***Overview***

To date, we have funded our operations primarily through the sale of equity and debt securities in privately-negotiated equity and debt financings in Israel to our affiliates (which instruments have 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.

We have incurred substantial losses since our inception. As of March 31, 2016, we had an accumulated deficit of approximately $51.4 million and positive working capital (current assets less current liabilities) of $17.2 million. We expect that losses will continue for the foreseeable future.

As of March 31, 2016, we had cash and cash equivalents of $3.1 million and marketable securities of $16.9 million invested in accordance with our investment policy, as compared to $4.1 million and $18.8 million as of December 31, 2015, totaling $23.0 million. The decrease is mainly attributable to our net loss of $4.0 million.

We had negative cash flow from operating activities of $3.1 million for the three months ended March 31, 2016 as compared to negative cash flow from operating activities of $2.3 million for the three months ended March 31, 2015. The negative cash flow from operating activities for the three months ended March 31, 2016 is mainly attributable to our net loss of $4.0 million, offset by an increase in trade payables of $692 thousand.

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 positive cash flow from investing activities of $2.0 million for the three months ended March 31, 2016, as compared to negative cash flow from investing activities of $19.1 million for the three months ended March 31, 2015. The positive cash flow from investing activities for the three months ended March 31, 2016 was primarily due to the realization of marketable securities, while the negative cash flow from investing activities for the three months ended March 31, 2015 was due to an investment in marketable securities.

We had negative cash flow from investing activities of $19.1 million for the three months ended March 31, 2016, as compared to a negative cash flow from investing activities of $7 thousand for the three months ended March 31, 2015. The negative cash flow from investing activities for the three months ended March 31, 2016 was primarily due to the investment in marketable securities, while the negative cash flow from investing activities for the three months ended March 31, 2015 was due to the purchase of equipment.

We didn't have any cash flow from financing activities for the three months ended March 31, 2016 and as well for the three months ended March 31, 2015.

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 the second half of 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 may choose to raise such additional capital, which would be authorized by our Board of Directors, at their 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”.

**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 May 16, 2016. |

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 16, 2016 By: /s/ Allen Baharaff
Allen Baharaff
President and
Chief Executive
Officer