Galmed Pharmaceuticals Ltd.
Form 6-K
November 07, 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 November 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 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, 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 November 7, 2016, the Company issued a press release announcing the filing of its financial results for the three and nine months ended September 30, 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.

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

FINANCIAL INFORMATION

Financial Statements

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

	As of September 30, 2016 Unaudited	**As of December 31, 2015** Audited
Assets		
Current assets		
Cash and cash equivalents	$ 7,035	$ 4,156
Marketable securities	11,272	18,845
Other accounts receivable	366	379
Total current assets	18,673	23,380
Property and equipment, net	791	883
Total assets	$ 19,464	$ 24,263
Liabilities and stockholders' equity		
Current liabilities		
Trade payables	$ 1,703	$ 2,259
Other accounts payable	112	282
Short-term portion of deferred revenue	1,045	-
Total current liabilities	2,860	2,541
Long-term liabilities		
Related parties	222	177
Long-term portion of deferred revenue	852	-
Total long-term liabilities	1,074	177
Stockholders' equity:		
Ordinary shares par value NIS 0.01 per share; Authorized 50,000,000; Issued and outstanding: 12,149,226 shares as of September 30, 2016; 11,100,453 shares as of	34	32

December 31, 2015		
Additional paid-in capital	75,125	69,086
Accumulated other comprehensive loss	(135)	(206)
Accumulated deficit	(59,494)	(47,367)
Total stockholders' equity	15,530	21,545
Total liabilities and stockholders' equity	$ 19,464	$ 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 September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
Revenue	$193	$-	$193	$-
Research and development expenses	3,342	1,860	10,086	4,853
General and administrative expenses	656	637	2,236	2,677
Total operating expenses	3,805	2,497	12,129	7,530
Financial expenses (income), net	(78)	103	(108)	(113)
Loss before income taxes	3,727	2,600	12,021	7,417
Taxes on Income	105	-	106	-
Net loss	$3,832	$2,600	$12,127	$7,417
Basic and diluted net loss per share	$0.34	$0.23	$1.09	$0.67
Weighted-average number of shares outstanding used in computing basic and diluted net loss per share	11,150,023	11,100,453	11,101,360	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		Nine months ended	
	September 30,		September 30,	
	2016	2015	2016	2015
Net loss	$3,832	$2,600	$12,127	$7,417
Other comprehensive (loss) income:				
Net unrealized (loss) gain on available for sale securities	(31)	(5)	71	60
Comprehensive loss	$3,863	$2,595	$12,056	$7,477

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	-	-	1,307	-	-	1,307
Issuance of Ordinary Shares (*)	933,160	2	4,477	-	-	4,479
Option Exercise (**)	115,613	-	255			255
Unrealized (loss) gain from marketable securities	-	-	-	71	-	71
Net loss	-	-	-	-	(12,127)	(12,127)
Balance - September 30, 2016	12,149,226	$ 34	$ 75,125	$ (135)	$ (59,494)	$15,530

*) Net of issuance costs in the amount of $286 thousand, see also note 3.4
**) See note 3.7

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

	Nine months ended September 30,	
	2016	2015
Cash flow from operating activities		
Net loss	$(12,127)	$(7,417)
Adjustments required to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	118	32
Stock-based compensation expense	1,307	1,130
Amortization of discount/premium on marketable securities	18	195
Loss from Realization of marketable securities	150	-
Changes in operating assets and liabilities:		
Decrease (increase) in other accounts receivable	13	(181)
Increase (decrease) in trade payables	(556)	251
Decrease in other accounts payable	(173)	(43)
Increase in deferred revenue from collaboration agreement	1,897	-
Increase (decrease) in related party	45	(213)
Net cash used in operating activities	(9,305)	(6,246)
Cash flow from investing activities		
Purchase of property and equipment	(26)	(160)
Maturity of short term deposit	-	6,000
Investment in securities, available for sale	(2,480)	(25,132)
Maturity of securities, available for sale	9.956	6,265
Net cash provided in (used in) investing activities	7,450	(13,027)
Cash flow from financing activities		
Proceeds from issuance of stock offerings, net of issuance costs (*)	4,479	-
Proceeds from exercise of options (**)	255	-
Net cash used in financing activities	4,734	-
Increase (decrease) in cash and cash equivalents	2,879	(19,273)
Cash and cash equivalents at the beginning of the year	4,156	23,736
Cash and cash equivalents at the end of the period	$7,035	$4,463
Supplemental disclosure of cash flow information:		
Cash received from interest	$319	370

*) See note 3.4
**) See note 3.7

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 September 30, 2016 and for the three and nine 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 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, with the exception of the described below:

Revenue Recognition

We have entered into a collaboration agreement with Samil Pharm. Co., Ltd., The terms of our collaboration agreement include deliverables such as non-refundable license fees, payments based upon achievement of developmental or regulatory approval milestones, and royalties on product sales.

We apply the accounting standard on revenue recognition for multiple element arrangements. The fair value of deliverables under the arrangement may be derived using a “best estimate of selling price” if vendor specific objective evidence and third-party evidence is not available. Deliverables under the arrangement will be separate units of accounting provided that (i) a delivered item has value to the customer on a standalone basis and (ii) if the arrangement includes a general right of return relative to the delivered item, delivery or performance of the undelivered item is considered probable and substantially in the control of the vendor.

Performance obligations are recognized as revenue over the estimated period of when the performance obligations are performed or deferred indefinitely until the undelivered performance obligation can be determined. We have been unable to demonstrate standalone value in our multiple element arrangements.

Whenever we determine that an arrangement should be accounted for as a single unit of accounting, we determine the period over which the performance obligations will be performed and revenue will be recognized. Revenue is recognized using either a proportional performance or straight-line method.

We recognize revenue under the arrangement on a straight-line basis over the period we are expected to complete our performance obligations. Revenue is limited to the lesser of the cumulative amount of payments received or the cumulative amount of revenue earned, as determined using the straight-line method, as of the period ending date.

Our collaboration agreement entitles us to additional payments upon the achievement of performance-based milestones. These milestones are categorized into two types; development milestones which are generally based on the advancement of our ongoing Phase IIb ARREST trial and potential pivotal study, and regulatory milestones which are based on the approval of a new drug application in the territory in respect of the product. Milestones that are tied to regulatory approval are not considered probable of being achieved until such approval is received. Upfront payments are not subject to refund if the development activities are not successful.

Amounts received prior to satisfying the above revenue recognition criteria are recorded as deferred revenue in the accompanying consolidated balance sheets. Although we follow detailed guidelines in measuring revenue, certain judgments affect the application of our revenue policy. For example, in connection with our existing license agreement, we have recorded on our consolidated balance sheet short-term and long-term deferred revenue based on our best estimate of when such revenue will be recognized. Short-term deferred revenue consists of amounts that are expected to be recognized as revenue in the next 12 months. Amounts that we expect will not be recognized within the next 12 months are classified as long-term deferred revenue. However, this estimate is based on our current operating plan and, if our operating plan should change in the future, we may recognize a different amount of deferred revenue over the next 12-month period.

Note 3 - Stockholders' Equity

1. In January 2016, the Company granted options to purchase 242,500 ordinary shares of the Company with a NIS 0.01 par value to certain employees, officers and consultants, with an exercise price of $7.61 per share, as well as,

41,250 restricted stock units (the “RSU's”) (the “January 2016 Allocation”). The January 2016 Allocation vest over a period of four years and shall expire in 10 years from the grant date.

2. In February 2016, the Company granted options to purchase 470,000 ordinary shares of the Company with a NIS 0.01 par value to certain officers and directors, with an exercise price between $5.49 and $5.94 per share as well as 37,500 RSU’s (the “February 2016 Allocation”). The February 2016 Allocation vest over various periods between three and four years and shall expire in 10 years from the grant date. The February 2016 Allocation was approved in May 2016 at the Company’s shareholders annual general meeting.

3. In May 2016, the Company granted options to purchase 14,000 ordinary shares of the Company with a NIS 0.01 par value to one of its consultants, with an exercise price of $5.04 per share. The options vest over a period of two years and shall expire in 10 years from the grant date.

4. On May 31, 2016, the Company entered into a Controlled Equity Offering℠ Sales Agreement (the "'At-The-Market' Offering" or the "ATM Offering") with Cantor Fitzgerald & Co., as the Company's sales agent ("Cantor Fitzgerald"), to issue and sell, from time to time through Cantor Fitzgerald, ordinary shares having an aggregate offering price of up to $16 million. Under the ATM Offering, the Company may sell ordinary shares by any method permitted by law and deemed to be an "at-the-market" offering, as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. The Company is not obligated to make any sales under the Sales Agreement. The Company intends to use the net proceeds raised through any ATM sales for (i) further clinical and pre-clinical development of existing and new programs, (ii) business development related activities and (iii) general corporate purposes. As of September 30, 2016 the Company had sold 933,160 ordinary shares through its ATM Offering for total proceeds of approximately $4.5 million, net of issuance expenses. The Company paid Cantor Fitzgerald a sales commission equal to 3% of the aggregate gross proceeds, plus it reimbursed Cantor Fitzgerald certain expenses in connection with entering into the ATM Offering in the amount of $50 thousand. The offering of ordinary shares pursuant to the ATM Offering will terminate upon the earliest of (i) the sale of all of the ordinary shares subject to the Sales Agreement, (ii) the termination of the Sales Agreement by Cantor Fitzgerald or the Company, as permitted therein, or (iii) the third anniversary of the date of the ATM Offering.

5. In July 2016**,** the Company granted options to purchase 90,000 ordinary shares of the Company with a NIS 0.01 par value to certain employees, officers and consultants, with an exercise price of $4.47 per share. The options vest over a period of two years and shall expire in 10 years from the grant date. The vesting of certain of the options granted are also subject to achievement of performance objectives.

6. In September 2016**,** the Company granted options to purchase 40,000 ordinary shares of the Company with a NIS 0.01 par value to one of its officers, with an exercise price of $4.05 per share. The options vest over a period of two years and shall expire in 10 years from the grant date.

7. During September 2016, certain officers and former employees exercised 115,613 options into ordinary shares of the Company with a NIS 0.01 par value for a total consideration of $255 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, 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. We believe that 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 the 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, China 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 completed 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 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 planning to conduct based on information from 120 patients in our ARREST Study that 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.

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 in 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.

As we previously reported on March 30, 2016, we have data demonstrating significant anti-fibrotic activity of Aramchol™ in MCD diet in mice suggesting potential effect of Aramchol in NASH induced fibrosis. We have also received additional data showing similar results in our other pre-clinical models which will be submitted for presentation at EASL.

Financial Overview

To date, we have funded our operations primarily through the sale of equity and debt securities in private equity and debt financings in Israel to our affiliates (which has subsequently been converted in whole into common equity; no debt remains on our balance sheet), shareholders and third-party investors, and as of March 18, 2014, through the sale of our ordinary shares in our initial public offering and ATM offering. At September 30, 2016, we had current assets of $18.7 million, which consists of cash and cash equivalents of $7.0 million and short-term investment securities of $11.3 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 will be sufficient to continue our business and operations as currently conducted through 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 third quarter of 2016, we announced the following developments:

- On July 28, 2016, we announced that we signed a License Agreement with Samil Pharm. Co., Ltd. (the “Samil”), for an exclusive, royalty-bearing license for the commercialization of Aramchol (with an option to manufacture) for the treatment of fatty liver indications including NASH in the Republic of Korea. Under the terms of the agreement, we have received a gross up-front payment of approximately $2.1 million. Samil has also agreed to pay additional clinical- and regulatory-based milestone payments, which may aggregate to $6.0 million, as well as tiered, double-digit royalties payable on sales (under certain limitations). Additionally, following the ARREST Study, Samil has an option to extend the License to Vietnam, which, if exercised, would increase the clinical- and regulatory-based milestone payments.

- On August 1, 2016, we announced the appointment of Professor Ran Oren, M.D., as Chief Medical Officer, effective as of August 1, 2016.

- On September 8, 2016, we announced the appointment of Dr. Liat Hayardeny, Ph.D. MBA, as Chief Scientific Officer, effective as of September 7, 2016.

- On September 22, 2016 we announced that we and the University of California, San Diego entered into an Investigator-Initiated Clinical Trial Agreement to assess Aramchol effects on the juvenile population.

- On September 29, 2016 we announced we have has raised approximately $5.0 Million to date under our ATM offering.

- Josh Blacher, the Company's Chief Financial Officer, has notified the Company of his wish to leave the Company to pursue other opportunities, effective January 31, 2017. The Company accepted Mr. Blacher's decision and intends to appoint a new CFO in due course. In the meantime, CPA Yohai Stenzler, the Company's director of finance, will act as interim CFO.

Revenues:

We have entered into a collaboration Agreement with Samil, for the commercialization of Aramchol in Korea. Under the terms of the agreement, we have received a gross up-front payments of $2.1 million, and may be eligible to receive up to approximately $6.0 million in additional payments for development and regulatory milestones for Aramchol in the licensed territories.

For accounting purposes, the up-front payment has been recorded as deferred revenue. The deferred revenue is then amortized over time and milestone payments are recognized once earned. Accordingly, during the three and nine months ended September 30, 2016, we recognized revenue of $193 thousand. We anticipate that we will recognize revenue of the remaining $1.9 million through the second quarter of 2018.

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.

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Results of Operations

The table below provides our results of operations for the three and nine months ended September 30, 2016 as compared to the three and nine months ended September 30, 2015.

	Three months ended September 30,		Nine months ended September 30,	
	2016 (unaudited)	2015 (unaudited)	2016 (unaudited)	2015 (unaudited)
	(In thousands, except per share data)			
Revenue	193	-	193	-
Research and development expenses	3,342	1,860	10,086	4,853
General and administrative expenses	656	637	2,326	2,677
Operating loss	3,805	2,497	12,129	7,530
Financial expenses (income), net	(78)	103	(108)	(113)
Income Taxes	105	-	106	-
Net loss	3,832	2,600	12,127	7,417
Other comprehensive (loss) income:	(31)	(5)	71	60
Comprehensive loss	3,863	2,595	12,056	7,477
Basic and diluted net Loss per share	$0.34	$ 0.23	$1.09	$ 0.67

Revenue

Licensing revenue was $193 thousand for the three and nine months ended September 30, 2016. The above mentioned revenue resulted from the amortization of the up-front payments under the license agreement with Samil.

Research and Development Expenses

Our research and development expenses amounted to $3.3 million and $10.1 million during the three and nine months ended September 30, 2016, respectively, representing an increase of $1.5 million and $5.2 million, respectively, compared to $1.9 million and $4.9 million for the comparable period in 2015.

The increase during the three months ended September 30, 2016 primarily resulted from an increase of $1.3 million in research and development subcontractor expenses in connection with the ARREST Study as compared to such expenses for the comparable period in 2015.

The increase during the nine months ended September 30, 2016 primarily resulted from an increase of $3.9 million in research and development subcontractor expenses in connection with the ARREST Study, as well as an increase of $517 thousand in non-cash stock-based compensation expenses, as compared to such expenses for the comparable period in 2015.

General and Administrative Expenses

Our general and administrative expenses amounted to $656 thousand and $2.2 million during the three and nine months ended September 30, 2016, respectively, representing an increase of $19 thousand, or 3%, and a decrease of $441 thousand, or 16%, respectively, compared to $637 thousand and $2.7 million for the comparable period in 2015.

The increase during the three months ended September 30, 2016 primarily resulted from an increase of $68 thousand in salaries and benefits and an increase of $33 thousand in rent and office maintenance fees, which was partially offset by a decrease of $71 thousand in investor relations and business development related expenses, as compared to such expenses for the comparable period in 2015.

The decrease during the nine months ended September 30, 2016 primarily resulted from a decrease of $197 thousand in investor relations and business development expenses; and as well, a decrease of $339 thousand in non-cash stock-based compensation expenses, as compared to such expenses for the comparable period in 2015.

Operating Loss

As a result of the foregoing, for the three and nine months ended September 30, 2016, our operating loss was $3.8 million and $12.1 million, respectively, representing an increase of $1.3 million and $4.6 million, respectively, as compared to our operating loss for the comparable prior year period. These increases for the three and nine months ended September 30, 2016, primarily resulted from an increase in our research and development expenses, including an increase in research and development subcontractor expenses in connection with the ARREST Study partially offset by the increase in revenue from the amortization of the up-front payments under the license agreement with Samil, as set forth above.

Financial Income (Expense), Net

Our financial income amounted to $78 thousand and $108 thousand during the three and nine months ended September 30, 2016, respectively, compared to a financial expense of $103 thousand and a financial income of $113 thousand for the comparable period in 2015.

The decrease during the three and nine months ended September 30, 2016, respectively, primarily resulted from an increase in currency exchange rates expenses, as compared to such expenses for the comparable period in 2015.

Income Taxes

Our income taxes amounted to $105 thousand and $106 thousand during the three and nine months ended September 30, 2016, respectively, compared to none income tax for the comparable period in 2015.

The increase during the three and nine months ended September 30, 2016, respectively, primarily resulted from a tax withheld from the up-front payments received under the license agreement with Samil, as set forth above.

Net Loss

As a result of the foregoing, for the three and nine months ended September 30, 2016, our Net loss was $3.8 million and $12.1 million, respectively, representing an increase of $1.2 million, and $4.7 million, respectively, as compared to our operating loss for the comparable prior year period.

Liquidity and Capital Resources

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 and our ATM Offering.

We have incurred substantial losses since our inception. As of September 30, 2016, we had an accumulated deficit of approximately $59.5 million and positive working capital (current assets less current liabilities) of $15.8 million. We expect that operating losses will continue for the foreseeable future.

As of September 30, 2016, we had cash and cash equivalents of $7.0 million and marketable securities of $11.3 million invested in accordance with our investment policy, totaling $18.3 million, 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 $12.1 million during the nine months ended, September 30, 2016; partially offset by net proceeds of approximately $4.5 million raised through our ATM offering.

We had negative cash flow from operating activities of $9.3 million for the nine months ended September 30, 2016, as compared to negative cash flow from operating activities of $6.3 million for the nine months ended September 30, 2015. The negative cash flow from operating activities for the nine months ended September 30, 2016 is mainly attributable to our net loss of $12.1 million, offset by an increase in deferred revenue from the collaboration agreement of $2.1 thousand and non-cash stock based compensation of $1.3 million.

We had positive cash flow from investing activities of $7.5 million for the nine months ended September 30, 2016, as compared to negative cash flow from investing activities of $13.0 million for the nine months ended September 30, 2015. The positive cash flow from investing activities for the nine months ended September 30, 2016 was primarily due to the realization of marketable securities, while the negative cash flow from investing activities for the nine months ended September 30, 2015 was due to an investment in marketable securities.

We had positive cash flow from financing activities of $4.7 million for the nine months ended September 30, 2016, as compared to no cash flow from financing activities for the nine months ended September 30, 2015. The positive cash flow from financing activities for the nine months ended September 30, 2016 was due to the proceeds from the issuance of stock offerings, net of issuance costs; as well as proceeds from exercise of options.

Although there can be no assurance, we believe that our existing cash resources will be sufficient to fund our projected cash requirements through 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.

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EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated November 7, 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: November 7, 2016 By: /s/ Allen Baharaff
Allen Baharaff
President and Chief Executive Officer