

Galmed Pharmaceuticals Ltd.
Form 6-K
November 05, 2018

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 2018

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)

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Indicate by check mark whether the registrant files or will file annual reports under cover
Form 20-F or Form 40-F.

Form 20-F Form 40-F

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): _____

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, 2018, 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 5, 2018, the Company issued a press release announcing the filing of its financial results for the three and nine months ended September 30, 2018 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 and the text under the heading “Financial Summary – Third Quarter 2018 vs. Third Quarter 2017” in Exhibit 99.1 is incorporated by reference into the Company’s Registration Statements on Form S-8 (Registration No. 333-206292 and 333-227441) and the Company’s Registration Statement on Form F-3 (Registration No. 333-223923).

FINANCIAL INFORMATION

*Financial Statements***GALMED PHARMACEUTICALS LTD.****Consolidated Balance Sheets**

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

	As of	As of
	September	December 31,
	30,	2017
	2018	2017
	Unaudited	Audited
Assets		
Current assets		
Cash and cash equivalents	\$ 25,983	\$ 13,021
Marketable debt securities	60,313	5,976
Short-term deposits	6,021	-
Other accounts receivable	286	155
Total current assets	92,603	19,152
Property and equipment, net	284	491
Total assets	\$ 92,887	\$ 19,643
Liabilities and stockholders' equity		
Current liabilities		
Trade payables	\$ 1,288	\$ 2,276
Other accounts payable	851	1,034
Short-term portion of deferred revenue	-	538
Total current liabilities	2,139	3,848
Stockholders' equity:		
Ordinary shares par value NIS 0.01 per share; Authorized 50,000,000; Issued and outstanding: 21,003,828 shares as of September 30, 2018; 14,435,161 shares as of December 31, 2017	58	40
Additional paid-in capital	173,469	92,381
Accumulated other comprehensive loss	(10) (7
Accumulated deficit	(82,769) (76,619

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Total stockholders' equity	90,748	15,795
Total liabilities and stockholders' equity	\$ 92,887	\$ 19,643

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		Nine months ended	
	September 30,		September 30,	
	2018	2017	2018	2017
Revenue	\$1,500	\$273	\$2,038	\$811
Research and development expenses	1,693	2,331	5,577	7,421
General and administrative expenses	987	697	2,975	2,110
Total operating loss	1,180	2,755	6,514	8,720
Financial expenses (income), net	(296)	46	(439)	(65)
Loss before income taxes	884	2,801	6,075	8,655
Taxes on Income	75	-	75	-
Net loss	\$959	\$2,801	\$6,150	\$8,655
Basic and diluted net loss per share	\$0.05	\$0.23	\$0.36	\$0.71
Weighted-average number of shares outstanding used in computing basic and diluted net loss per share	20,953,421	12,364,249	17,167,911	12,274,536

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,	
	2018	2017	2018	2017
Net loss	\$ 959	\$ 2,801	\$ 6,150	\$ 8,655
Other comprehensive loss (income):				
Net unrealized loss (gain) on available for sale securities	(19)	(12)	3	(77)
Comprehensive loss	\$ 940	\$ 2,789	\$ 6,153	\$ 8,578

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

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

	Ordinary shares		Additional paid-in capital	Accumulated other Comprehensive loss		Accumulated Deficit	Total
	Shares	Amount					
Balance - December 31, 2017	14,435,161	\$ 40	\$ 92,381	\$ (7)	\$ (76,619) \$ 15,795
Stock based compensation	-	-	1,045	-	-	-	1,045
Options and Restricted stock units Exercise	419,407	1	942	-	-	-	943
Issuance of Ordinary Shares and warrants *)	1,000,000	3	5,948	-	-	-	5,951
Issuance of Ordinary Shares (Underwriter agreement) **)	5,000,000	14	70,258	-	-	-	70,272
Issuance of Ordinary Shares (ATM offering) ***)	149,260	-	2,895	-	-	-	2,895
Unrealized loss from Marketable debt securities	-	-	-	(3)	-	(3)
Net loss	-	-	-	-	-	(6,150) (6,150)
Balance - September 30, 2018	21,003,828	\$ 58	\$ 173,469	\$ (10)	\$ (82,769) \$ 90,748

*) See notes 3.3.

**) See notes 3.4.

***) See note 3.5.

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,	
	2018	2017
Cash flow from operating activities		
Net loss	\$(6,150)	\$(8,655)
Adjustments required to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	261	180
Stock-based compensation expense	1,045	1,066
Amortization of discount/premium on marketable debt securities	(81)	(187)
Interest from short-term deposits	(21)	-
Loss from Realization of marketable debt securities	13	130
Changes in operating assets and liabilities:		
Decrease (increase) in other accounts receivable	(131)	113
Decrease in trade payables	(988)	(1,157)
Decrease in other accounts payable	(183)	(144)
Decrease in related party	-	(117)
Decrease in deferred revenue	(538)	(812)
Net cash used in operating activities	(6,773)	(9,583)
Cash flow from investing activities		
Purchase of property and equipment	(53)	(10)
Investment in available for sale securities	(88,180)	(1,447)
Investment in short term deposits	(6,000)	7,589
Consideration from sale of available for sale securities	33,907	-
Net cash provided in (used in) investing activities	(60,326)	(6,132)
Cash flow from financing activities		
Issuance of Ordinary Shares and warrants *)	79,118	2,655
Proceeds from exercise of options	943	313
Net cash provided in financing activities	80,061	2,968
Increase in cash and cash equivalents	12,962	(483)
Cash and cash equivalents at the beginning of the period	13,021	3,097
Cash and cash equivalents at the end of the period	\$ 25,983	\$ 2,614
Supplemental disclosure of cash flow information:		
Cash received from interest	\$ 513	169

*) See notes 3.3, 3.4 and 3.5

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 primarily focused on the development of therapeutics for the treatment of liver diseases. The Company was incorporated in Israel on July 31, 2013 and commenced operations on February 2, 2014. The Company holds a wholly owned subsidiary, Galmed International Ltd., which was incorporated in Malta. Galmed International Ltd. holds a wholly owned subsidiary, Galmed Medical Research Ltd., which was incorporated in Israel and has been an inactive company since 2015. The Company also holds a wholly owned subsidiary, Galmed Research and Development Ltd., which was incorporated in Israel.

These unaudited interim consolidated financial statements have been prepared as of September 30, 2018 and for the three and nine months period then ended. Accordingly, certain information and footnote disclosures normally included in annual financial statements prepared in accordance with U.S. GAAP have been omitted. These unaudited interim consolidated financial statements should be read in conjunction with the audited financial statements and the accompanying notes of the Company for the year ended December 31, 2017 that are included in the Company's Annual Report on Form 20-F, filed with the Securities and Exchange Commission on March 13, 2018 (the "Annual Report"). The results of operations presented are not necessarily indicative of the results to be expected for the year ending December 31, 2018.

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 its Annual Report on Form 20-F.

Note 3 - Stockholders' Equity

During the nine months ended September 30, 2018, certain officers, employees and former employees exercised 1. options into an aggregate of 408,626 ordinary shares of the Company, NIS 0.01 par value per share, for total consideration of \$0.9 million.

2. During the nine months ended September 30, 2018, restricted stock units held by certain officers and employees vested resulting in the issuance of 10,781 ordinary shares of the Company, NIS 0.01 par value per share.

3. On April 5, 2018, the Company sold to Biotechnology Value Fund, L.P. and certain of its affiliates in a registered direct offering 1,000,000 ordinary shares and warrants to purchase 1,000,000 ordinary shares, for a purchase price of \$6.00 per share and related warrant. Each warrant may be exercised at any time and from time to time through and including the one-year anniversary of the initial exercise date at an exercise price of \$15.00 per share, subject to certain adjustments. The net proceeds to the Company, after deducting offering expenses, were \$5.96 million.

4. On June 22, 2018, the Company completed an underwritten public offering of 5,000,000 ordinary shares, at a public offering price of \$15.00 per share. The net proceeds to the Company, after deducting the underwriting discounts and commissions and offering expenses, were \$70.3 million.

5. On December 22, 2017, the Company entered into an At-the-Market Equity Offering Sales Agreement (the "Stifel Sales Agreement") with Stifel, Nicolaus & Company, Incorporated, as the Company's sales agent ("Stifel"). Pursuant to the prospectus relating to the Company's shelf registration statement on Form F-3 filed with the SEC on March 26, 2018 (File No. 333-223923) the Company may offer and sell, from time to time through Stifel, its ordinary shares having an aggregate offering price of up to \$35 million. During the nine months ended September 30, 2018, the Company sold 149,260 ordinary shares under the Stifel Sales Agreement for total net proceeds of approximately \$2.9 million.

6. In May 2018, the Company granted options to purchase an aggregate of 21,500 ordinary shares of the Company to one of its employees and one of its consultants. The options are exercisable at \$6.05 per share, have a 10 year term and vest over a period that varies between two to four years. The aggregate grant date fair value of such options is approximately \$0.09 million.

7. In July 2018, the Company granted options to purchase 16,000 ordinary shares of the Company to one of its consultants. The options are exercisable at \$11.56 per share, have a 10 year term and vest over a period of two years. The grant date fair value of such options is approximately \$0.14 million.

8. In July 2018, the Company approved the grant of options to purchase an aggregate of 630,000 ordinary shares of the Company to its directors and officers. The options are exercisable at \$11.56 per share, have a 10 year term and vest over a period of four years. The grant date fair value of such options is approximately \$5.6 million.

Note 4 - Revenue

In September, 2018 the Company received a milestone payment of \$1.5 million from Samil Pharma. Co., Ltd. ("Samil") under the license agreement entered into with Samil for the commercialization of Aramchol (with the option to manufacture) in the Republic of Korea.. For accounting purposes, milestone payments are recognized as revenue once earned.

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

All references to "we," "us," "our," "the Company" and "our Company", in this Form 6-K are to Galmed Pharmaceuticals Ltd. and its subsidiaries, unless the context otherwise requires. All references to "shares" or "ordinary shares" are to our ordinary shares, NIS 0.01 nominal par value per share. All references to "Israel" are to the State of Israel. "U.S. GAAP" means the generally accepted accounting principles of the United States. Unless otherwise stated, all of our financial information presented in this Form 6-K has been prepared in accordance with U.S. GAAP. Any discrepancies in any table between totals and sums of the amounts and percentages listed are due to rounding. Unless otherwise indicated, or the context otherwise requires, references in this Form 6-K to financial and operational data for a particular year refer to the fiscal year of our company ended December 31 of that year.

Our reporting currency and financial currency is the U.S. dollar. In this Form 6-K, "NIS" means New Israeli Shekel, and "\$," "US\$" and "U.S. dollars" mean United States dollars.

Cautionary Note Regarding Forward-Looking Statements

This Form 6-K 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," "continue" or their negatives 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 planned Phase III trial, for our product candidate, Aramchol™ ("Aramchol") for the treatment of patients with Non-Alcoholic Steato-Hepatitis ("NASH"), or whether a Phase III trial will be conducted at all;

completion and receiving favorable results of our planned Phase III trial for Aramchol or any other pre-clinical or clinical trial;

regulatory action with respect to Aramchol by the U.S. Food and Drug Administration (the “FDA”) or the European Medicines Authority including but not limited to acceptance of an application for marketing authorization, review and approval of such application, and, if approved, the scope of the approved indication and labeling;

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

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

·our ability to achieve favorable pricing for Aramchol;

·our expectations regarding the commercial market for NASH;

·third-party payor reimbursement for Aramchol;

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

·market adoption of Aramchol by physicians and patients;

·the timing, cost or other aspects of the commercial launch of Aramchol;

·the development and approval of the use of Aramchol for additional indications or in combination therapy; and

·our expectations regarding licensing, acquisitions and strategic operations.

We believe these forward-looking statements are reasonable; however, these statements are only current predictions and are subject to known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. We discuss many of these risks in our Annual Report on Form 20-F for the year ended December 31, 2017 filed with the SEC on March 13, 2018 in greater detail under the heading "Risk Factors" and elsewhere in the Annual Report and this Form 6-K. Given these uncertainties, you should not rely upon forward-looking statements as predictions of future events.

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

Overview

We are a clinical-stage biopharmaceutical company focused on the development of Aramchol, a liver targeted SCD1 modulator, first in class, novel, once-daily, oral therapy for the treatment of NASH for variable populations. In June 2018, we announced top line data from our ARREST Phase IIb clinical study, a multicenter, randomized, double blind, placebo-controlled study, designed to evaluate the efficacy and safety of Aramchol in 247 subjects with NASH, who are overweight or obese, and who are pre-diabetic or type-II-diabetic. We are currently focused on preparing for an end of Phase IIb meeting with the FDA to discuss the results of the ARREST Study and a Phase III study protocol, with a view to initiating a Phase III clinical study of Aramchol in 2019.

Financial Overview

To date, we have funded our operations primarily through proceeds from private placements and public offerings. At September 30, 2018, we had current assets of \$92.6 million, which includes cash and cash equivalents of \$26.0 million, short term deposits of \$6.0 million and short-term debt securities of \$60.3 million. This compares with current assets of \$19.2 million at December 31, 2017, which consisted of cash and cash equivalents of \$13.0 million and short-term debt securities of \$6.0 million. Although we provide no assurance, we believe that such existing funds will be sufficient to continue our business and operations as currently conducted for more than 12 months from the date of issuance of this Form 6-K. 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.

Revenues

On July 28, 2016, we entered into a license agreement with Samil Pharma. Co., Ltd. (the “Samil Agreement”) for the commercialization of Aramchol (with the option to manufacture) in the Republic of Korea. Under the terms of the Samil Agreement, we have received upfront and milestone payments in the total amount of \$3.6 million (including a recent \$1.5 million milestone payment), and may be eligible to receive up to \$4.5 million in additional payments for development and regulatory milestones for Aramchol in the licensed territories. For accounting purposes, the upfront payment has been recorded as deferred revenue and amortized on a straight-line basis over the contractual period and the milestone payment is recognized as revenue once earned.

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 pre-clinical studies and clinical trials and drug and laboratory supplies. We account for all research and development expenses 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 Aramchol. Increases or decreases in research and development expenditures are primarily attributable to the number and/or duration of the pre-clinical and clinical studies that we conduct.

We expect that a substantial amount of our research and development expense in the future will be incurred in support of our current and anticipated pre-clinical and clinical development projects. Due to the inherently unpredictable nature of pre-clinical and clinical development studies, 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 partnering and/or commercialization. Clinical development timelines, the probability of success and development costs can differ materially from expectations. We currently expect to continue testing Aramchol in pre-clinical studies for toxicology, safety and efficacy, and to conduct additional clinical trials for Aramchol.

While we are currently focused on advancing Aramchol's development, our future research and development expenses will depend on the clinical success of Aramchol, as well as ongoing assessments of the Aramchol'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 to advance of our clinical product development and, potentially, the in-licensing of additional product candidates.

The lengthy process of completing clinical trials and seeking regulatory approval for Aramchol 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 finance/accounting, legal and other operating positions in connection with our activities. 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.

Financial Income, Net

Our financial income consists of interest income from marketable debt securities and our financial expense consists of fees associated with banking activities and losses from realization of marketable debt securities.

Results of Operations

The table below provides our results of operations for the three and nine months ended September 30, 2018 as compared to the three and nine months ended September 30, 2017.

	Three months ended September 30,		Nine months ended September 30,	
	2018 (unaudited)	2017 (unaudited)	2018 (unaudited)	2017 (unaudited)
	(In thousands, except per share data)			
Revenue	1,500	273	2,038	811
Research and development expenses	1,693	2,331	5,577	7,421
General and administrative expenses	987	697	2,975	2,110
Total operating loss	1,180	2,755	6,514	8,720
Financial expenses (income), net	(296)	46	(439)	(65)
Taxes on income	75	-	75	-
Net loss	959	2,801	6,150	8,655
Other comprehensive)income(loss:	(19)	(12)	3	(77)
Comprehensive loss	940	2,789	6,153	8,578
Basic and diluted net loss per share	\$ 0.05	\$ 0.23	\$ 0.36	\$ 0.71

Revenue

Licensing revenue was approximately \$1.5 million and approximately \$2.0 million for the three and nine months ended September 30, 2018, respectively, representing an increase of approximately \$1.2 million, or 450%, and approximately \$1.2 million, or 151%, respectively, compared to approximately \$0.3 million and approximately \$0.8 million for the comparable period in 2017.

The increase during the three and nine months ended September 30, 2018 resulted from the recognition of the \$1.5 million milestone payment received under the Samil Agreement in September 2018.

Research and Development Expenses

Our research and development expenses amounted to approximately \$1.7 million and approximately \$5.6 million during the three and nine months ended September 30, 2018, respectively, representing a decrease of approximately \$0.6 million, or 26%, and approximately \$1.8 million, or 24%, respectively, compared to approximately \$2.3 million and approximately \$7.4 million for the comparable period in 2017.

The decrease during the three and nine months ended September 30, 2018 primarily resulted from a decrease of approximately \$0.7 million and \$2.0 million, respectively, in subcontractor expenses in connection with our clinical studies, as compared to such expenses for the comparable period in 2017.

General and Administrative Expenses

Our general and administrative expenses amounted to approximately \$1.0 million and approximately \$3.0 million during the three and nine months ended September 30, 2018, respectively, representing an increase of approximately \$0.3 million, or 43%, and \$0.9 million, or 43%, respectively, compared to approximately \$0.7 million and approximately \$2.1 million for the comparable period in 2017.

The increase during the three months ended September 30, 2018 primarily resulted from an increase of approximately \$0.2 million in non-cash stock-based compensation expenses, while the increase during the nine months ended September 30, 2018 primarily resulted from an increase of approximately \$0.3 million in salaries and benefits due to a provision for year-end compensation as well as an increase of approximately \$0.2 million in non-cash stock-based compensation expenses, as compared to such expenses for the comparable period in 2017.

Operating Loss

As a result of the foregoing, for the three and nine months ended September 30, 2018, our operating loss was approximately \$1.2 million and approximately \$6.5 million, respectively, representing a decrease of \$1.6 million, or 57%, and a decrease of \$2.2 million, or 25%, respectively, as compared to approximately \$2.8 million and approximately \$8.7 million for the comparable period in 2017. The decrease in both periods primarily resulted from the increase in revenue from the recognition of the \$1.5 million milestone payment received under the Samil Agreement in September 2018 as well as a decrease in research and development expenses.

Financial Income, Net

Our financial income, net amounted to approximately \$0.3 million and approximately \$0.4 million during the three and nine months ended September 30, 2018, respectively, compared to \$0.01 million of financial expense, net and

\$0.1 million of financial income, net for the comparable period in 2017.

The increase during the three and nine months ended September 30, 2018 primarily resulted from an increase in interest income from marketable debt securities, as compared to such income for the comparable period in 2017.

Net Loss

As a result of the foregoing, for the three and nine months ended September 30, 2018, our net loss was approximately \$1.0 million and approximately \$6.2 million, respectively, representing a decrease of \$1.8 million, or 64%, and a decrease of \$2.5 million, or 29%, respectively, as compared to approximately \$2.8 million and approximately \$8.7 million for the comparable period in 2017.

Liquidity and Capital Resources

To date, we have funded our operations primarily through proceeds from private placements and public offerings. Under our existing ATM offering, as of the date hereof, we may sell, from time to time, up to approximately \$32.0 million of additional ordinary shares. During the nine months ended September 30, 2018, we sold 149,260 ordinary shares under our existing ATM offering for total net proceeds of approximately \$2.9 million.

We have incurred substantial losses since our inception. As of September 30, 2018, we had an accumulated deficit of approximately \$82.8 million and positive working capital (current assets less current liabilities) of approximately \$90.5 million. We expect that operating losses will continue for the foreseeable future.

As of September 30, 2018, we had cash and cash equivalents of approximately \$26.0 million, short-term deposits of \$6.0 million and marketable debt securities of approximately \$60.3 million invested in accordance with our investment policy, totaling approximately \$92.3 million, as compared to approximately \$13.0 million of cash and cash equivalents and approximately \$6.0 million of marketable debt securities as of December 31, 2017, totaling approximately \$19.0 million. The increase is mainly attributable to the approximately \$70.3 million in net proceeds raised in an underwritten public offering that was completed in June 2018, and the \$5.9 million in net proceeds raised in our registered direct offering during April 2018.

We had negative cash flow from operating activities of approximately \$6.8 million for the nine months ended September 30, 2018, as compared to negative cash flow from operating activities of approximately \$9.6 million for the nine months ended September 30, 2017. The negative cash flow from operating activities for the nine months ended September 30, 2018 is mainly attributable to our net loss of approximately \$6.2 million.

We had negative cash flow from investing activities of approximately \$60.3 million for the nine months ended September 30, 2018, as compared to positive cash flow from investing activities of approximately \$6.1 million for the nine months ended September 30, 2017. The negative cash flow from investing activities for the nine months ended September 30, 2018 was primarily due to the net investment of marketable debt securities and short-term deposits.

We had positive cash flow from financing activities of approximately \$80.1 million for the nine months ended September 30, 2018, as compared to positive cash flow from financing activities of approximately \$3.0 million for the nine months ended September 30, 2017. The positive cash flow from financing activities for the nine months ended September 30, 2018 is mainly attributable to the net proceeds from our underwritten public offering and registered direct offering.

Although there can be no assurance, we believe that our existing cash resources will be sufficient to fund our projected cash requirements for more than 12 months from the date of issuance of this Form 6-K. 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 and other research and development activities. 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 November 5, 2018

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 5, 2018 By: /s/ Allen Baharaff
Allen Baharaff
President and Chief Executive Officer