

Galmed Pharmaceuticals Ltd.
Form 6-K
July 25, 2014

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 July 2014

001-36345

(Commission File Number)

GALMED PHARMACEUTICALS LTD.

(Exact name of Registrant as specified in its charter)

8 Shaul Hamelech Blvd.

Amot Hamishpat Bldg.

Tel Aviv 6473307, Israel

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover

Edgar Filing: Galmed Pharmaceuticals Ltd. - Form 6-K

Form 20-F or Form 40-F.

Form 20-F þ 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 condensed consolidated financial statements for the six months ended June 30, 2014, 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 July 25, 2014, the Company issued a press release announcing the filing of its financial results for the six months ended June 30, 2014 with the Securities and Exchange Commission. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

FINANCIAL INFORMATION

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

	Successor As of June 30, 2014 Unaudited	Predecessor As of December 31, 2013 Audited
Assets		
Current assets		
Cash and cash equivalents	\$ 37,399	\$ 137
Other accounts receivable	61	16
Total current assets	37,640	153
Property and equipment, net	24	13
Total assets	\$ 37,484	\$ 166
Liabilities and Stockholders' Deficiency		
Current liabilities		
Trade payables	\$ 301	\$ 1,355
Other accounts payable	393	334
Total current liabilities	694	1,689
Long-term liabilities		
Related parties	442	428
Total long-term liabilities	442	428
Stockholders' equity (deficiency):		
Ordinary shares par value NIS 0.01 per share; Authorized 50,000,000; Issued and outstanding: 11,100,453 shares as of June 30, 2014	32	-
Ordinary shares par value \$1 per share; Authorized 50,000 shares; Issued and outstanding: 9,739 shares as of December 31, 2013	-	10
Additional paid-in capital	67,876	25,681
Accumulated deficit	(31,560)	(27,642)
Total stockholders' equity (deficiency)	36,348	(1,951)

Edgar Filing: Galmed Pharmaceuticals Ltd. - Form 6-K

Total liabilities and stockholders' equity	\$ 37,484	\$ 166
--------------------------------------------	-----------	--------

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

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

	Successor Period from February 3 to June 30, 2014 Unaudited	Predecessor Period from January 1 to February 2, 2014 Unaudited	Six months ended June 30, 2013 Unaudited
Research and development expenses	\$ 2,246	\$501	\$ 1,294
General and administrative expenses	1,037	114	247
Capital loss	-	-	10
Total operating expenses	3,283	615	1,551
Financial expenses, net	11	9	9
Net loss	\$ 3,294	\$624	\$ 1,560
Basic and diluted net loss per share	\$ 0.33	\$0.09	\$0.31
Weighted average number of shares outstanding used in computing basic and diluted net loss per share	10,073,817	(*) 7,099,731	(*) 4,995,837

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

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

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

	Ordinary shares		Additional	Accumulated	
	Shares	Amount	paid-in	Deficit	Total
	(Unaudited)		capital		
Predecessor Balance - December 31, 2013	9,739	\$ 10	\$ 25,681	\$ (27,642)	\$(1,951)
Stock based compensation	-	-	40	-	40
Net loss	-	-	-	(624)	(624)
Predecessor Balance - February 2, 2014	9,739	10	25,721	(28,266)	(2,535)
Successor					
Reorganization and stock split (*)	7,099,731	20	25,711	(28,266)	(2,535)
Issuance of ordinary shares in February 2014	560,224	2	1,998	-	2,000
Issuance of ordinary shares upon initial public offering, net in March 2014 (**)	3,263,010	9	39,847	-	39,856
Cashless exercise of options	177,488	1	(1)	-	-
Stock based compensation	-	-	321	-	321
Net loss	-	-	-	(3,294)	(3,294)
Successor Balance – June 30, 2014	11,100,453	\$ 32	\$ 67,876	\$ (31,560)	\$36,348

(*) See also Note 1.

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

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

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

	Successor Period and cumulative from February 3 to June 30, 2014 Unaudited	Predecessor Period from January 1 to February 2, 2014 Unaudited	Six months ended June 30, 2013 Unaudited
Cash Flows from Operating Activities			
Net loss for the year	\$ (3,294) \$ (624) \$ (1,560)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	3	1	1
Capital loss	-	-	10
Stock based compensation expense	321	40	103
Changes in operating assets and liabilities:			
Decrease (increase) in other accounts receivable	(319) 274	8
Increase (decrease) in trade payables	(1,294) 240	793
Increase (decrease) in other accounts payable	(239) 292	6
Increase in related parties	19	1	22
Net cash provided by (used in) operating activities	(4,803) 224	(617)
Cash Flows from Investing Activities			
Purchase of property and equipment	(15) -	(6)
Proceeds from sale of property and equipment	-	-	16
Net cash provided by (used in) investing activities	(15) -	10
Cash Flows from Financing Activities			
Repayments of short term loan from bank	-	-	(20)
Issuance of ordinary shares	2,000	-	-
Issuance of ordinary shares upon IPO, net (*)	39,856	-	-
Net cash provided by (used in) financing activities	41,856	-	(20)
Increase (decrease) in cash and cash equivalents	37,038	224	(627)
Cash and cash equivalents at the beginning of the period	361	137	718
Cash and cash equivalents at the end of the period	\$ 37,399	\$ 361	\$ 91

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

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

GALMED PHARMACEUTICALS LTD.

Notes to Condensed Consolidated Financial Statements

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

Note 1 –Basis of presentation

Galmed Pharmaceuticals Ltd. (the “Company” or the “Successor”), an Israeli company, was formed on July 31, 2013. 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 Galmed Holdings Inc.’s business, including its subsidiary’s shares and net assets, was transferred to the Company. This Reorganization is considered a restructuring under common control in which the Company is the successor and Galmed Holdings Inc. (which was owned by the same shareholders that owned the Company in the same holding percentage as of the date of the Reorganization) is the predecessor (the “Predecessor”).

These condensed unaudited interim consolidated financial statements have been prepared as of June 30, 2014 and for the six-month period then ended. Accordingly, certain information and footnote disclosures normally included in annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. These condensed unaudited interim consolidated financial statements should be read in conjunction with the audited financial statements and the accompanying notes of the Predecessor for the year ended December 31, 2013 that are included in the Company’s Registration Statement on Form F-1, initially filed with the Securities and Exchange Commission on February 6, 2014 and declared effective on March 12, 2014. The results of operations presented are not necessarily indicative of the results to be expected for future quarters or for the year ending December 31, 2014.

Note 2- Summary of significant accounting policies

The significant accounting policies that have been applied in the preparation of the condensed unaudited consolidated interim financial statements are identical to those that were applied in preparation of the Predecessor’s most recent annual financial statements, with the exception described below.

Recently Issued Accounting Pronouncements

In June 2014, the Financial Accounting Standards Board issued Accounting Standards Update (“ASU”) 2014-10, Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements. ASU 2014-10 eliminates the distinction of a development stage entity and certain related disclosure requirements, including the elimination of inception-to-date information on the statements of operations, cash flows and stockholders’ equity. The amendments in ASU 2014-10 will be effective prospectively for annual reporting periods beginning after December 15, 2014, and interim periods within those annual periods, however early adoption is permitted. The Company adopted ASU 2014-10 during the quarter ended June 30, 2014, and thereby no longer presents or discloses any information required by Topic 915.

Note 3 - Stockholders' Equity

A. On February 3, 2014, the Company entered into a share purchase agreement with certain of its shareholders and new investors, pursuant to which the Company issued to such existing shareholders and new investors 560,224 ordinary shares, par value NIS 0.01 per share, at a price per share of \$3.57, for a total consideration in the amount of approximately \$2,000.

B. On March 12, 2014, the Company completed an initial public offering (the "IPO") and listed its ordinary shares on the NASDAQ Capital Market under the ticker-symbol “GLMD”. In the IPO, the Company issued under 3,263,010 shares, par value NIS 0.01 per share, for a total consideration of approximately \$39,856, which is net of offering costs in the amount of \$4,204.

GALMED PHARMACEUTICALS LTD.

Notes to Condensed Consolidated Financial Statements

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

Note 3 - Stockholders' Equity (Cont.)

C. During 2012, the Predecessor granted options (the "Old Options") to purchase 331 of its ordinary shares, par value \$1.00 per share, to the chairman of its Board of Directors. In connection with the Reorganization, the Company granted the chairman of the Board of Directors options (the "New Options") to purchase 241,299 of its ordinary shares, par value NIS 0.01 per share, to replace the Old Options (on a 729:1 basis as a result of a reverse share split of the Company's ordinary shares in connection with the Reorganization). The terms and conditions for the New Options were the same as for the Old Options, except the exercise price was reduced to \$3.57 accordingly. On March 12, 2014, upon the IPO, the chairman exercised the New Options by way of a cashless exercise into 177,488 ordinary shares of the Company based upon the initial public offering price of \$13.50 per share.

D. In February 2014, the Company granted options to purchase 8,583 of its ordinary shares, par value NIS 0.01 per share, to a member of the Board of Directors. The options are fully vested and expire in September 2023. The exercise price is \$3.57 per share and the fair value of such options at the grant date was \$95.

E. In February 2014, the Company granted options to purchase either 26,240 or 69,973 (based upon the occurrence of several performance-based conditions) of its ordinary shares, par value NIS 0.01 per share, to a consultant. The option vesting period depends on the occurrence of several performance-based conditions, as set forth in the agreement signed by the parties. The fair values of the 26,240 and 69,973 options were \$314 and \$838, respectively. As of June 30, 2014, the Company estimated that the performance-based conditions set forth in the agreement would not be met and accordingly did not record expenses due to the options.

F. In March 2014, the Company granted options to purchase 17,166 of its ordinary shares, par value NIS 0.01 per share, to a member of the Board of Directors. The options vest over three years and expire in September 2023. The exercise price is \$3.57 per share and the fair value of such options at the grant date was \$190. As of June 30, 2014, none of such options were vested.

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 Registration Statement on Form F-1 (File No. 333-193792), initially filed on February 6, 2014 and declared effective on March 12, 2014, as amended, or the Registration Statement, and our interim financial statements and accompanying notes to such financial statements contained herein. 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 Registration Statement.

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 Securities and Exchange Commission, or the SEC, press releases or oral statements made by or with the approval of one of our authorized executive officers. Forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements, including, but not limited to, the factors summarized below:

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

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

· our ability to achieve favorable pricing for aramchol;

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

- third-party payor reimbursement for aramchol;
- our estimates regarding anticipated capital requirements and our needs for additional financing;
- patient market size and market adoption of aramchol by physicians and patients;
- the timing, cost or other aspects of the commercial launch of aramchol;
- the timing and cost of Phase IIb and Phase III trials for aramchol or whether such trials will be conducted at all;
- completion and receiving favorable results of Phase IIb and Phase III trials for aramchol;
- the development and approval of the use of aramchol for additional indications or in combination therapy; and
- our expectations regarding in-licensing, acquisitions and strategic operations.

We believe these forward-looking statements are reasonable; however, these statements are only current predictions and are subject to known and unknown risks, uncertainties and other factors that may cause our or our industry's actual results, levels of activity, performance or achievements to be materially different from those anticipated by the forward-looking statements. We discuss many of these risks in the Registration Statement in greater detail under the heading "Risk Factors" and elsewhere in the Registration Statement and this report. Given these uncertainties, you should not rely upon forward-looking statements as predictions of future events.

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

Overview

We are an emerging clinical-stage biopharmaceutical company primarily focused on the development and commercialization of novel therapeutics to treat liver diseases and cholesterol gallstones utilizing our proprietary family of synthetic fatty-acid/bile-acid conjugates, or FABACs. Our product candidate, aramchol, has the potential to be a disease modifying treatment for fatty liver disorders, specifically NASH, which we believe constitutes a large unmet medical need.

We have successfully completed three clinical trials of aramchol. During the second half of 2014, we intend to begin a multi-center, double-blind, randomized Phase IIb placebo-controlled clinical trial of aramchol in 240 NASH patients who are overweight or obese, and who also suffer from Type II Diabetes or elevated fasting glucose levels. Our current regulatory path for the development of aramchol for NASH is in accordance with the study design recommended by the United Kingdom's Medicines and Healthcare Products Regulatory Agency, which has been deemed acceptable or satisfactory, respectively, by two European medical agencies, Germany's Bundesinstitut für Arzneimittel und Medizinprodukte and France's Agence Nationale de Sécurité du Médicament et des Produits de Santé, and was confirmed as acceptable by the FDA. These two agencies have confirmed that if successful, this Phase IIb trial may serve as a basis for Phase III pivotal trials of aramchol. If the Phase III trials are completed successfully, we intend to seek regulatory approval of aramchol for the treatment of NASH in the United States and Europe. This Phase IIb trial will have co-primary end-points, which are a significant reduction of liver fat content measured by Nuclear Magnetic Resonance Spectroscopy, or NMRS, and a resolution, or clearance, of inflammation measured by two biopsies, one at the beginning of the trial and one at the end. We currently expect results from the Phase IIb trial to be available in the second half of 2016. In addition, during this Phase IIb trial and once 120 patients complete six months of treatment, we intend to conduct an interim analysis of the efficacy of aramchol based on a reduction in liver fat as measured by NMRS and the safety of aramchol based on the observation of clinical adverse events and blood safety tests. We currently expect results from such interim analysis to be available in the second half of 2015. We also currently plan to conduct, but provide no assurance that we will conduct, a Phase IIa proof-of-concept clinical trial of aramchol for the treatment of cholesterol gallstones. To date, we have not generated revenue from the sale of any

product, and we do not expect to generate any significant revenue unless and until we commercialize aramchol. As of June 30, 2014, the company had a deficit of approximately \$31.6 million.

Our financing activities are described below under “Liquidity and Capital Resources”. Obtaining approval of a New Drug Application from the FDA and a Marketing Authorization Application from the European Medicines Agency, or the EMA, or other similar application is an extensive, lengthy, expensive and uncertain process, and the FDA, EMA and other regulatory agencies may delay, limit or deny approval of our product.

Financial Overview

Since inception, we have incurred significant losses in connection with our research and development. At December 31, 2013, we had an accumulated deficit of \$27.6 million and at June 30, 2014, we had an accumulated deficit of \$31.6 million. 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.

Since inception, we have not generated any revenue. We have funded our operations primarily through the sale of equity and debt securities in private equity offerings and debt financings in Israel to our affiliates, shareholders and third-party investors, and as of March 18, 2014, through the sale of our ordinary shares in our initial public offering. As of June 30, 2014, we had \$37.4 million in cash and cash equivalents and an accumulated deficit of approximately \$31.6 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 through 2017.

Business Developments

During the second quarter of 2014, we had the following major developments:

On April 29, 2014, we announced that we commenced patient screening on April 28, 2014 for pharmacokinetic, or PK, and food effect studies of aramchol. In written correspondence from December 2013 regarding a requested pre-Investigational New Drug, or IND, application meeting, the U.S. Food and Drug Administration recommended that we conduct such studies prior to commencing our planned Phase IIb clinical trial of aramchol for the treatment of NASH. We are conducting the study at the Sourasky Medical Center in Tel Aviv, Israel. The studies are designed for the enrollment of 66 healthy male volunteers who will receive the same two doses of aramchol that we propose to use in our planned Phase IIb clinical trial. We expect the studies to also provide additional safety data to further support existing safety data from our prior pre-clinical studies and Phase I and Phase IIa clinical trials of aramchol. We anticipate completing the studies by the end of the third quarter of this year but there is no assurance that we will do so. Following the completion of the PK and food effect studies, we currently plan to initiate our Phase IIb clinical trial of aramchol first at locations in Israel and Latin America, and then in Europe, with drug administration currently scheduled to begin prior to year-end.

On June 4, 2014, we announced that recently published data in the April 2014 issue of *Biochimie* supports the importance of the regulation of ABCA1-induced reverse cholesterol transport on the pathogenesis of NASH. ABCA1 is an enzyme that induces “reverse cholesterol transport,” which is essential for maintaining cholesterol balance in the body. Excess levels of “bad” cholesterol are deposited mainly in vascular walls, causing atherosclerosis, or a vascular disease in which an artery wall thickens as a result of the accumulation of calcium and fatty materials. Activation of the reverse cholesterol transport beneficially reduces the bad cholesterol deposited in vascular walls and mediates the elimination of cholesterol from cells through “good” cholesterol. The recently published pre-clinical data suggests that an increase in ABCA1 activity in mice may not only lead to a reduction in “bad” cholesterol levels through reverse cholesterol transport, but also a reduction in liver fat content, both of which we believe to be important factors in the pathogenesis of NASH. Our product candidate, aramchol, has been shown in the Company’s studies to increase ABCA1 activity in experimental animal models by between 300% and 400%. This data was published in *Biochemical Journal*, the *Archives of Medical Research* and the *Current Opinion in Lipidology* in 2006, 2010 and 2014, respectively.

On June 9, 2014, we announced our filing of a provisional patent application in the United States for the use of aramchol for the treatment of lipodystrophy. Lipodystrophy is a medical condition characterized by abnormal or degenerative conditions of adipose tissue, or body fat, including the loss of body fat from various regions of the body and its redistribution and accumulation in other areas. Lipodystrophy may be hereditary, but is commonly associated with HIV and AIDS patients who develop lipodystrophy from treatment with highly active antiretroviral therapies, or HAARTs, or other protease inhibitors. There is currently no approved medical treatment for lipodystrophy or its associated conditions. According to AIDS Reviews, 2005, approximately 40% of HIV patients treated for over one year with a protease inhibitor will develop induced lipodystrophy. Patients with HAART-induced lipodystrophy may also develop non-alcoholic fatty liver disease, or NAFLD, with some of such patients progressing to cirrhosis, hypertriglyceridemia, or high triglyceride blood levels, or diabetes. In our Phase IIa clinical trial of aramchol in 60 NAFLD patients, we observed a significant reduction in liver fat and improvement of certain metabolic parameters. We currently intend to seek potential collaborations with U.S. academic centers to explore the use of aramchol for the treatment of lipodystrophy.

On June 12, 2014, we held a Special General Meeting of Shareholders, or the Meeting. At the Meeting, the our shareholders voted on a proposal to elect two directors to serve as external directors of our board of directors under Israeli law and to approve their terms of service as described in the proxy statement in connection with the Meeting, which we filed with the SEC on May 7, 2014 as an exhibit to our report on Form 6-K. This proposal was approved by the shareholders by the requisite majority in accordance with the Israeli law.

Since the end of the second quarter of 2014 (subsequent to the balance sheet date), we had the following major developments:

On July 8, 2014, we announced the publication of the results of our Phase IIa clinical trial of aramchol in the peer-reviewed *Clinical Gastroenterology and Hepatology Journal*. The trial manuscript, entitled "The Fatty Acid–Bile Acid Conjugate Aramchol Reduces Liver Fat Content in Patients with Nonalcoholic Fatty Liver Disease," provides the full report of the Phase IIa trial, which was completed in January 2012 and presented at the 47th Annual Meeting of the European Association for the Study of the Liver in 2012.

On July 22, 2014, we announced that the FDA cleared our IND application, permitting us to conduct clinical trials of aramchol in the United States for the treatment of fatty liver disorders. In connection with such clearance, we submitted a request to the FDA for the approval of a Fast Track Designation for aramchol. Fast Track Designation is a designation by the FDA that facilitates the development, and expedites the review, of drugs which treat a serious or life-threatening condition and fill an unmet medical need.

Costs and Operating Expenses

Our current costs and operating expenses consist of three components: (i) research and development expenses; (ii) general and administrative expenses; and (iii) capital loss (primarily from the disposal of property and equipment).

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, drug and laboratory supplies and costs for facilities and equipment. We charge all research and development expenses to operations as they are incurred. We expect our research and development expense to remain our primary expense in the near future as we continue to develop our products. Increases or decreases in research and development expenditures are attributable to the number and/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 preclinical and clinical development projects. Due to the inherently unpredictable nature of preclinical and clinical development processes, we are unable to estimate with any certainty the costs we will incur in the continued development of aramchol for NASH and other indications in our pipeline for potential commercialization. Clinical development timelines, the probability of success and development costs can differ materially from expectations. We expect to continue to test our product candidate in preclinical studies for toxicology, safety and efficacy, and to conduct additional clinical trials for our product candidate.

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

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

General and Administrative Expenses

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

We expect our general and administrative expenses, such as accounting and legal fees, to increase as we grow and operate as a public company, and we expect increases in the number of our executive and administrative personnel due to the anticipated growth of our company.

Financial Expenses, Net

Our financial expense consists of bank fees and loan interest. Our financial income consists of income from short term bank deposits.

Results of Operations

The table below provides our results of operations (which reflect the results of operations of GHI, our predecessor, prior to the Reorganization) for the six months ended June 30, 2013 as compared to the six months ended June 30, 2014.

Six months ended June 30,

Edgar Filing: Galmed Pharmaceuticals Ltd. - Form 6-K

	2014 (unaudited)	2013 (unaudited)
	(In thousands, except per share data)	
Research and development expenses	2,747	1,294
General and administrative expenses	1,151	247
Capital loss	-	10
Operating loss	3,898	1,551
Financial expenses, net	20	9
Net loss	3,918	1,560
Loss per share	\$ 0.42	\$ 0.31

Research and Development Expenses

Our research and development expenses amounted to \$2.7 million during the six months ended June 30, 2014, representing an increase of \$1.5 million, or 112%, as compared to such expenses for the comparable prior year period. This increase primarily resulted from an increase in research and development subcontractor expenses in connection with aramchol's clinical development program of \$1.2 million and an increase of \$190,000 in salaries and benefits paid to three employees hired during the second half of 2014, including a chief medical officer, a director of clinical operations and a director of drug development.

General and Administrative Expenses

Our general and administrative expenses amounted to \$1.2 million during the six months ended June 30, 2014, representing an increase of \$900,000, or 366%, as compared to such expenses for the comparable prior year period. This increase primarily resulted from an increase in salaries and benefits of \$430,000, consisting of non-cash stock-based compensation of \$310,000 and salaries paid to two employees hired during the second half of 2014, including a director of operations and a controller. The increase in the general and administrative expenses is also a result of an increase in professional services of \$240,000, including legal, accounting and consulting services.

Operating Loss

As a result of the foregoing research and development and general and administrative expenses, as well as our failure to generate operating revenues since our inception, for the six months ended June 30, 2014 our operating loss was \$3.9 million, representing an increase of \$2.3 million, or 151%, as compared to our operating loss for the comparable prior year period. This increase primarily resulted from an increase in our research and development expenses, including an increase in our research and development subcontractor expenses and an increase in our salaries and expenses, as set forth above, and an increase in our general and administrative expenses, including an increase in salaries and our benefits expense and an increase in our professional fees, as set forth above.

Financial Expense, Net

Our financial expense amounted to \$20,000 during the six months ended June 30, 2014, representing an increase of \$11,000, or 122%, as compared to such expenses for the comparable prior year period. This increase resulted primarily from an increase in interest expenses and bank commissions of \$244,000, offset by an increase in interest income from deposits of \$233,000.

Net Loss

As a result of the foregoing research and development and general and administrative expenses, as well as our failure to generate revenues from operations since our inception, for the six months ended June 30, 2014 our net loss was \$3.9 million, representing an increase of \$2.4 million, or 151%, as compared to our net loss for the comparable prior year period.

Liquidity and Capital Resources

Overview

We have incurred substantial losses since our inception. As of June 30, 2014, we had an accumulated deficit of approximately \$31.6 million and positive working capital (current assets less current liabilities) of \$36.9 million. We expect that losses will continue for the foreseeable future.

As of June 30, 2014, we had cash and cash equivalents of \$37.4 million as compared to \$137,000 as of December 31, 2013. This increase of \$37.3 million is primarily due to net proceeds from our initial public offering of approximately \$39.9 million.

We had negative cash flow from operating activities of \$4.6 million for the six months ended June 30, 2014 as compared to a negative cash flow from operating activities of \$600,000 for the six months ended June 30, 2013. The negative cash flow from operating activities for the six months ended June 30, 2014 is mainly attributable to our net loss of \$3.9 million, a decrease in accounts payable of \$1 million and an increase in accounts receivable of \$45,000, offset by a stock based compensation expense of \$360,000.

We had negative cash flow from investing activities of \$15,000 for the six months ended June 30, 2014 as compared to a positive cash flow from investing activities of \$10,000 for the six months ended June 30, 2013. The negative cash flow from investing activities for the six months ended June 30, 2014 was due to the purchase of equipment, while the positive cash flow from investing activities for the six months ended June 30, 2013 was due to the proceeds from the sale of equipment in the amount of \$16,000, offset by the purchase of equipment in the amount of \$6,000.

We had positive cash flow from financing activities of \$41.9 million for the six months ended June 30, 2014 as compared to a negative cash flow from financing activities of \$20,000 for the six months ended June 30, 2013. The positive cash flow from financing activities for the six months ended June 30, 2014 was primarily due to the issuance of our ordinary shares in our initial public offering for net proceeds of approximately \$39.9 million and the issuance of our ordinary shares in the amount of \$2,000,000 in a financing round we completed in February 2014, prior to the consummation of the initial public offering. The negative cash flow from financing activities for the six months ended June 30, 2013 was due to the repayment of a short-term loan from a bank in the amount of \$20,000.

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 approximately through 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.

Trend Information

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

Quantitative and Qualitative Disclosures About Market Risk

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

Controls and Procedures

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

OTHER INFORMATION

Use of Proceeds

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

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

As of June 30, 2014, the net proceeds from our initial public offering were invested in a variety of capital preservation investments, including short-term, investment grade, interest bearing instruments such as corporate debt securities, and certain short-term money market investments. We have broad discretion in the use of the net proceeds from our initial public offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our ordinary shares.

EXHIBIT INDEX

Exhibit No. Description

99.1 Press Release, dated July 25, 2014

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: July 25, 2014 By: /s/ Allen Baharaff
Allen Baharaff
Chief Executive Officer