

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	As of
	September	December
	30,	31,
	2016	2015
	Unaudited	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

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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		Nine months ended	
	September 30,		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 capital	Accumulated other Comprehensive loss	Accumulated Deficit	Total
	Shares	Amount				
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,

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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.

In February 2016, the Company granted options to purchase 470,000 ordinary shares of the Company with a NIS 2.001 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 t