

Foamix Pharmaceuticals Ltd.  
Form 10-Q  
November 07, 2018

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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, DC 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2018

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 001-001-36621

Foamix Pharmaceuticals Ltd.  
(Exact name of registrant as specified in its charter)

Israel  
(State or other jurisdiction of incorporation or organization)

Not Applicable  
(I.R.S. Employer Identification No.)

2 Holzman Street, Weizmann Science Park  
Rehovot 7670402, Israel  
(Address of principal executive offices, including zip code)

+972-8-9316233  
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes      No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes      No

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Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
Emerging growth company	

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes      No

The total number of shares outstanding of the registrant’s Ordinary Shares, par value NIS 0.16 per share, as of November 6, 2018, was 54,283,368.

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## DEFINITIONS

In this quarterly report on Form 10-Q, unless otherwise indicated, all references to the “company,” “we,” “us,” “our” and “Foamix” refer to Foamix Pharmaceuticals Ltd. and its subsidiary, Foamix Pharmaceuticals Inc., a Delaware corporation.

References to the “Companies Law” are to Israel’s Companies Law, 5759-1999, as currently amended

References to the “Exchange Act” are to the Securities Exchange Act of 1934, as amended

References to the “FDA” are to the United States Food and Drug Administration;

References to “Nasdaq” are to the Nasdaq Global Stock Market

References to “Ordinary Shares” are to our ordinary shares, par value of NIS 0.16 per share;

References to the “SEC” are to the United States Securities and Exchange Commission;

References to the “Securities Act” are to the Securities Act of 1933, as amended; and

References to “U.S. dollars” and “\$” are to currency of the United States of America, and references to “NIS” are to New Israeli Shekels.

PART I - FINANCIAL INFORMATION

ITEM 1. Condensed Consolidated Financial Statements

FOAMIX PHARMACEUTICALS LTD.

UNAUDITED CONDENSED CONSOLIDATED  
FINANCIAL STATEMENTS  
AS OF SEPTEMBER 30, 2018

FOAMIX PHARMACEUTICALS LTD.

UNAUDITED CONDENSED CONSOLIDATED  
FINANCIAL STATEMENTS  
AS OF SEPTEMBER 30, 2018

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The amounts are stated in US dollars in thousands (except for share data)

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FOAMIX PHARMACEUTICALS LTD.  
 CONDENSED CONSOLIDATED BALANCE SHEETS  
 (U.S. dollars in thousands, except per share data)  
 (Unaudited)

	September 30, 2018	December 31, 2017
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 87,877	\$ 15,956
Restricted cash	250	250
Short term bank deposits	6,099	19,443
Investment in marketable securities (Note 4)	15,041	31,797
Restricted investment in marketable securities (Note 4)	277	290
Accounts receivable:		
Trade	889	996
Other	1,624	772
TOTAL CURRENT ASSETS	112,057	69,504
NON-CURRENT ASSETS:		
Investment in marketable securities (Note 4)	793	8,533
Restricted investment in marketable securities (Note 4)	137	143
Property and equipment, net	2,157	2,042
Other	43	32
TOTAL NON-CURRENT ASSETS	3,130	10,750
TOTAL ASSETS	\$ 115,187	\$ 80,254

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

FOAMIX PHARMACEUTICALS LTD.  
 CONDENSED CONSOLIDATED BALANCE SHEETS  
 (U.S. dollars in thousands, except per share data)  
 (Unaudited)

	September 30, 2018	December 31, 2017
Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	\$5,322	\$6,436
Deferred revenues	-	62
Other	3,714	3,730
TOTAL CURRENT LIABILITIES	9,036	10,228
LONG-TERM LIABILITIES:		
Liability for employee severance benefits	379	437
Other liabilities	714	988
TOTAL LONG-TERM LIABILITIES	1,093	1,425
TOTAL LIABILITIES	10,129	11,653
COMMITMENTS (Note 6)		
SHAREHOLDERS' EQUITY:		
Ordinary Shares, NIS 0.16 par value - authorized: 90,000,000 Ordinary Shares as of September 30, 2018 and December 31, 2017; issued and outstanding: 54,270,174 and 37,498,128 Ordinary Shares as of September 30, 2018 and December 31, 2017, respectively	2,327	1,576
Additional paid-in capital	304,119	208,364
Accumulated deficit	(201,331)	(141,281)
Accumulated other comprehensive loss	(57)	(58)
TOTAL SHAREHOLDERS' EQUITY	105,058	68,601
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	\$115,187	\$80,254

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.



## FOAMIX PHARMACEUTICALS LTD.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(U.S. dollars in thousands, except per share data)

(Unaudited)

	Nine months ended September 30		Three months ended September 30	
	2018	2017	2018	2017
REVENUES (Note 7)	\$2,735	\$2,626	\$865	\$901
COST OF REVENUES	-	11	-	11
GROSS PROFIT	2,735	2,615	865	890
OPERATING EXPENSES:				
Research and development	52,809	42,400	13,142	15,785
Selling, general and administrative	10,019	9,206	3,309	2,933
TOTAL OPERATING EXPENSES	62,828	51,606	16,451	18,718
OPERATING LOSS	60,093	48,991	15,586	17,828
FINANCE INCOME, net	(471 )	(846 )	(119 )	(302 )
LOSS BEFORE INCOME TAX	59,622	48,145	15,467	17,526
INCOME TAX	463	209	13	57
NET LOSS FOR THE PERIOD	\$60,085	\$48,354	\$15,480	\$17,583
LOSS PER SHARE BASIC AND DILUTED	\$1.50	\$1.29	\$0.38	\$0.47
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE IN THOUSANDS	39,932	37,347	40,873	37,431

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

FOAMIX PHARMACEUTICALS LTD.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(U.S. dollars in thousands, except per share data)

(Unaudited)

	Nine months ended September 30		Three months ended September 30	
	2018	2017	2018	2017
NET LOSS	\$60,085	\$48,354	\$15,480	\$17,583
OTHER COMPREHENSIVE LOSS (INCOME):				
Net unrealized gains from marketable securities	(44 )	(48 )	(34 )	(6 )
Losses on marketable securities reclassified into net loss	(5 )	-	(3 )	-
Net unrealized losses (gains) on derivative financial instruments	68	(124 )	(13 )	(20 )
Gains (losses) on derivative financial instruments reclassified into net loss	(55 )	96	(20 )	8
TOTAL OTHER COMPREHENSIVE INCOME	(36 )	(76 )	(70 )	(18 )
TOTAL COMPREHENSIVE LOSS	\$60,049	\$48,278	\$15,410	\$17,565

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

FOAMIX PHARMACEUTICALS LTD.  
 CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS  
 (U.S. dollars in thousands)  
 (Unaudited)

	Nine months ended September 30	
	2018	2017
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$60,085	\$48,354
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	243	153
Loss from sale and disposal of fixed assets	39	128
Changes in marketable securities and bank deposits, net	165	80
Changes in accrued liability for employee severance benefits, net of retirement fund profit	(57 )	49
Share-based compensation	4,144	2,683
Non-cash finance expenses (income), net	20	(28 )
Changes in operating asset and liabilities:		
Decrease (increase) in trade and other receivables	(756 )	2,145
Increase in other non-current assets	(12 )	(22 )
Increase (decrease) in accounts payable and accruals	(1,467 )	2,622
Net cash used in operating activities	(57,766)	(40,544)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of fixed assets	(408 )	(1,159 )
Proceeds from sale of fixed assets	10	26
Investment in bank deposits	(27,500)	(8,000 )
Investment in marketable securities	(1,012 )	(18,191)
Proceeds from sale and maturity of marketable securities and bank deposits	66,255	57,314
Net cash provided by investing activities	37,345	29,990
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from exercise of options	43	145
Proceeds from exercise of warrants	840	-
Proceeds from issuance of shares, net of \$39 issuance costs	16,131	-
Proceeds from issuance of Ordinary Shares through public offerings, net of \$5,175 issuance costs	75,348	-
Payments in respect of bank borrowings	-	(21 )
Net cash provided by financing activities	92,362	124
<b>INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH</b>	<b>71,941</b>	<b>(10,430)</b>
<b>EFFECT OF EXCHANGE RATE ON CASH, CASH EQUIVALENTS AND RESTRICTED CASH</b>	<b>(20 )</b>	<b>29</b>
<b>CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT BEGINNING OF THE PERIOD</b>	<b>16,206</b>	<b>31,440</b>
<b>CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF THE PERIOD</b>	<b>\$88,127</b>	<b>\$21,039</b>
Cash and cash equivalents	87,877	20,789
Restricted cash	250	250
<b>TOTAL CASH, CASH EQUIVALENTS AND RESTRICTED CASH SHOWN IN STATEMENT OF CASH FLOWS</b>	<b>\$88,127</b>	<b>\$21,039</b>
<b>SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS:</b>		
Cashless exercise of warrants and RSUs	\$7	\$10

SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:

Cash paid for taxes	\$469	\$407
Interest received	\$784	\$927
Interest paid	\$-	\$*

\* Represents an amount less than \$1.

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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FOAMIX PHARMACEUTICALS LTD.

NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(U.S. dollars in thousands, except share and per share amounts)

NOTE 1 - NATURE OF OPERATIONS AND BASIS OF PRESENTATION:

a. Nature of operations

Foamix Pharmaceuticals Ltd. (hereinafter “Foamix”) is an Israeli company incorporated in 2003. Foamix is a clinical-stage specialty pharmaceutical company operating in one segment - the development and commercialization of foam-based formulations, using its proprietary technology, which includes its foam platforms. Foamix develops its own product candidates, mainly for the treatment of moderate-to-severe acne and other skin conditions. It also licenses its technology under development and licensing agreements to various pharmaceutical companies for development of certain products combining Foamix's foam technology with the licensee's proprietary drugs.

Since incorporation through September 30, 2018, Foamix and its subsidiary Foamix Pharmaceuticals Inc. (hereinafter “the Company”) incurred losses and negative cash flows from operations mainly attributable to its development efforts and has an accumulated deficit of \$201,331. The Company has financed its operations mainly through the issuance of shares through private and public financing rounds, convertible loans and payments received under its research and development and licensing agreements. Management believes the Company's cash and investments as of the issuance date of these financial statements will allow the Company to fund its operating plan through at least the next 12 months. However, the Company expects to continue to incur significant research and development and other expenses related to its ongoing operations and in order to continue its future operations, the Company will need to obtain additional funding until becoming profitable. If the Company is unable to obtain such funding, it will need to curtail or cease operations.

b. Basis of presentation

The unaudited interim condensed consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America (“US GAAP”) for interim financial statements. Accordingly, they do not contain all information and notes required by U.S. GAAP for annual financial statements. In the opinion of management, these unaudited condensed consolidated interim financial statements reflect all adjustments, which include only normal recurring adjustments, which are necessary for a fair statement of the Company's consolidated financial position as of September 30, 2018, the consolidated results of operations and comprehensive loss for the three and nine-month periods ended September 30, 2018 and 2017 and cash flows for the nine-month periods ended September 30, 2018 and 2017.

These unaudited interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's annual financial statements for the year ended December 31, 2017. The condensed consolidated balance sheet data as of September 30, 2018 was derived from the audited consolidated financial statements for the year ended December 31, 2017, included in the Company's annual report on Form 10-K/A filed with the Securities and Exchange Commission on March 1, 2018, but does not include all disclosures required by U.S. GAAP for annual financial statements.

The results for the three and nine-month periods ended September 30, 2018 are not necessarily indicative of the results expected for the year ending December 31, 2018.

FOAMIX PHARMACEUTICALS LTD.

NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(U.S. dollars in thousands, except share and per share amounts)

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES:

a. Principles of consolidation

The consolidated financial statements include the accounts of Foamix and its subsidiary. Intercompany balances and transactions including profits from intercompany sales not yet realized outside the Company, have been eliminated upon consolidation.

b. Fair value measurement

Fair value is based on the price that would be received from the sale of an asset or that would be paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, the guidance establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described as follows:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data or active market data of similar or identical assets or liabilities.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible and considers counterparty credit risk in its assessment of fair value.

c. Loss per share

Net loss per share, basic and diluted, is computed on the basis of the net loss for the year divided by the weighted average number of Ordinary Shares outstanding during the period. Diluted net loss per share is based upon the weighted average number of Ordinary Shares and of ordinary share equivalents outstanding when dilutive. Ordinary Share equivalents include outstanding share options and warrants which are included under the treasury share method when dilutive.

The following options, restricted share units ("RSUs") and warrants were excluded from the calculation of diluted net loss per ordinary share because their effect would have been anti-dilutive for the periods presented (share data):

	Nine and three months ended September 30	
	2018	2017
Outstanding options and RSUs	4,690,034	3,875,714
Warrants	-	1,394,558

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FOAMIX PHARMACEUTICALS LTD.

NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(U.S. dollars in thousands, except share and per share amounts)

NOTE 2—SIGNIFICANT ACCOUNTING POLICIES (continued):

d. Newly issued and recently adopted accounting pronouncements:

Accounting pronouncements adopted in period:

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2014-09, Revenue from Contracts with Customers (Topic 606), which supersedes existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is that a company should recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. ASU 2014-09 defines a five-step process that requires companies to exercise more judgment and make more estimates than under the current guidance. These may include identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price, and allocating the transaction price to each separate performance obligation.

The Company generates revenue primarily from its development and licensing agreements. The consideration the Company is eligible to receive under its agreements typically include upfront payments, reimbursement for research and development costs, contingent payments, royalties and other contingent payments for the achievement of certain sales targets.

The Company adopted the guidance as of January 1, 2018, under the modified retrospective method; however, as the current revenue of the Company is driven primarily from royalties and contingent payments as mentioned above, the Company’s adoption of the new standard did not have a material effect on its consolidated financial statements.

In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments-Overall (Subtopic 825-10), which addresses certain aspects of recognition, measurement, presentation and disclosure of financial instruments. The amended guidance requires changes in the fair value of equity investments to be recognized through net income, rather than other comprehensive income. Adoption of the standard will be applied through a cumulative one-time adjustment to retained earnings. This standard was adopted on January 1, 2018 and its accumulative adjustment had no material impact on the Company's consolidated financial statements. In addition, in February 2018, the FASB issued ASU No. 2018-03 which includes technical corrections and improvements to clarify the guidance in ASU No. 2016-01. This standard, adopted as of January 1, 2018, had no material impact on the Company’s consolidated financial statements.

In May 2017, the FASB issued ASU No. 2017-09, Compensation - Stock Compensation (Topic 718): Scope of Modification Accounting. ASU 2017-09 was issued to provide clarity and reduce both 1) diversity in practice and 2) cost and complexity when applying the guidance in Topic 718 to a change in the terms or conditions of a share-based payment award. ASU 2017-09 provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting under Topic 718. The amendments in ASU 2017-09 are applied prospectively to an award modified on or after the adoption date. This standard, adopted as of January 1, 2018, had no material impact on the Company’s consolidated financial statements.



FOAMIX PHARMACEUTICALS LTD.

NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(U.S. dollars in thousands, except share and per share amounts)

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

In March 2018, the FASB issued ASU No. 2018-05, Income Taxes (Topic 740), to insert the Securities and Exchange Commission's interpretive guidance from Staff Accounting Bulletin No. 118 into the income tax accounting codification under U.S. GAAP. The ASU permits companies to use provisional amounts for certain 4) income tax effects of the Tax Act during a one-year measurement period. The provisional accounting impacts for the Company may change in future reporting periods until the accounting analysis is finalized, however the Company anticipates that the adoption of the new standard will not have material effect on its consolidated financial statements.

Accounting pronouncements that are not yet effective and have not been early adopted by the Company:

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842), which supersedes the existing guidance for lease accounting, Leases (Topic 840). ASU 2016-02 requires lessees to recognize leases on their balance sheets, and leaves lessor accounting largely unchanged. Subsequently, the FASB issued ASU No. 2017-13 in September 2017, ASU No. 2018-01 in January 2018 and ASU No. 2018-10 and ASU No. 2018-11 in July 2018, which amends and clarifies ASU 2016-02. The amendments in this ASU are effective for interim and annual periods beginning 5) after December 15, 2018. Early application is permitted for all entities. ASU 2016-02 requires a modified retrospective approach for all leases existing at, or entered into after, the date of initial application, with an option to elect to use certain transition relief. The Company is currently reviewing its lease contracts and began analyzing the standard and identify potential differences and changes which would result from applying the requirements of the new standard. The Company currently anticipates that the adoption will result an increase in assets and liabilities on our consolidated balance sheet and will not have a material impact on our consolidated statement of operation or consolidated statement of cash flows.

In June 2018, the FASB issued ASU No. 2018-07, Compensation-Stock Compensation (Topic 718) Improvements to Nonemployee Share-based Payments. This ASU was issued to simplify the accounting for share-based transactions by expanding the scope of Topic 718 from only being applicable to share-based payments to employees to also include share-based payment transactions for acquiring goods and services from nonemployees. As a result, 6) nonemployee share-based transactions will be measured by estimating the fair value of the equity instruments at the grant date, taking into consideration the probability of satisfying performance conditions. This ASU is effective for annual and interim reporting periods beginning after December 15, 2018. Early adoption is permitted. The Company is currently evaluating the impact of this new standard on its consolidated financial statements, although the impact is currently expected to be immaterial.

## FOAMIX PHARMACEUTICALS LTD.

## NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(U.S. dollars in thousands, except share and per share amounts)

## NOTE 3 - FAIR VALUE PRESENTATION:

The Company's assets and liabilities that are measured at fair value as of September 30, 2018 and December 31, 2017 are classified in the tables below in one of the three categories described in Note 2b:

	September 30, 2018		
	Level		
	1	Level 2	Total
Marketable securities	\$982	\$15,266	\$16,248
Currency options designated as hedging instruments (current liabilities)	-	\$(2 )	\$(2 )

  

	December 31, 2017		
	Level		
	1	Level 2	Total
Marketable securities	\$987	\$39,776	\$40,763
Currency options designated as hedging instruments (current assets)	-	\$11	\$11

The Company's corporate debt securities are traded in markets that are not considered to be active, but are valued based on quoted market prices, broker or dealer quotations, or alternative pricing sources with reasonable levels of price transparency. Accordingly, these assets are categorized as Level 2.

## Foreign exchange risk management

The Company purchases and writes non-functional currency options in order to hedge the currency exposure on the Company's cash flow. The currency hedged items are denominated in New Israeli Shekels (NIS). The purchasing and writing of options is part of a comprehensive currency hedging strategy with respect to salary and rent expenses denominated in NIS. These transactions are at zero cost for periods of up to one year. The counterparties to the derivatives are major banks in Israel. As of September 30, 2018, the total hedged amount was NIS 5.6 million.

The derivative liability, in the amount of \$2 as of September 30, 2018, qualifies as hedge accounting.

As of September 30, 2018, the Company has a lien in the amount of \$277 on the Company's marketable securities and a lien in the amount \$250 on the Company's checking account, in respect of bank guarantees granted in order to secure the hedging transactions.

## NOTE 4 - MARKETABLE SECURITIES

Marketable securities as of September 30, 2018, and December 31, 2017 consist mainly of debt and equity securities. The debt securities are classified as available-for-sale and are recorded at fair value. Changes in fair value, net of taxes (if applicable), are reflected in other comprehensive loss. Realized gains and losses on sales of the securities, as well as premium or discount amortization, are included in the consolidated statement of operations as finance income or expenses.

As of January 1, 2018, following the adoption of ASU No. 2016-01, Financial Instruments-Overall (Subtopic 825-10), equity securities with readily determinable fair value are measured at fair value. The changes in the fair value of equity investments are recognized through net income. Adoption of the standard was applied through a cumulative one-time adjustment to the accumulated deficit.

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## FOAMIX PHARMACEUTICALS LTD.

## NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(U.S. dollars in thousands, except share and per share amounts)

## NOTE 4 - MARKETABLE SECURITIES (continued):

The following table sets forth the Company's marketable securities:

	September 30, 2018	December 31, 2017
Israeli mutual funds	\$ 982	\$ 987
Certificates of deposit	4,500	17,206
Government and agency bonds	10,766	22,570
Total	\$ 16,248	\$ 40,763

As of September 30, 2018 and December 31, 2017, the fair value, cost and gross unrealized holding gains and losses of the debt securities owned by the Company were as follows:

	September 30, 2018			
	Fair value	Cost or amortized cost	Gross unrealized holding losses	Gross unrealized holding gains
Certificates of deposit	\$4,500	\$ 4,522	\$ 22	\$ -
Government and agency bonds	10,766	10,799	33	-
Total	\$15,266	\$ 15,321	\$ 55	\$ -

  

	December 31, 2017			
	Fair value	Cost or amortized cost	Gross unrealized holding losses	Gross unrealized holding gains
Certificates of deposit	\$17,206	\$ 17,243	\$ 38	\$ 1
Government and agency bonds	22,570	22,638	68	-
Total	\$39,776	\$ 39,881	\$ 106	\$ 1

As of September 30, 2018, the unrealized losses attributed to the Company's debt marketable securities were primarily due to credit spreads and interest rate movements. The Company has considered factors regarding other than temporary impaired securities and determined that there are no securities with impairment that is other than temporary as of September 30, 2018 and December 31, 2017.

As of September 30, 2018, and December 31, 2017 the Company's debt securities had the following maturity dates:

	Market value	
	September 30, 2018	December 31, 2017
Due within one year	\$14,473	\$ 31,244
1 to 2 years	793	8,380
2 to 3 years	-	152

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Total	\$15,266	\$ 39,776
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During the nine months ended September 30, 2018 and September 30, 2017, the Company received proceeds of \$25,548 and \$32,314, respectively, upon sale and maturity of marketable securities.

\$414 and \$433 of the Company's marketable securities were restricted as of September 30, 2018 and December 31, 2017, respectively, due to a lien in respect of bank guarantees granted to secure hedging transaction and the Company's rent agreement. For more information, refer to Notes 3 and 6.

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## FOAMIX PHARMACEUTICALS LTD.

## NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(U.S. dollars in thousands, except share and per share amounts)

## NOTE 5 - SHARE CAPITAL:

## a. Securities Purchase Agreement

On April 13, 2018, the Company entered into a Securities Purchase Agreement with an existing shareholder pursuant to which the Company agreed to issue and sell, in a registered offering, an aggregate of 2,940,000 Ordinary Shares at a purchase price of \$5.50 per share. The net proceeds from the offering were \$16,131 after deducting transaction expenses. The closing of the issuance and sale of these shares took place on April 16, 2018.

## b. Follow-on Offering

On September 18, 2018, the Company completed a follow-on offering in which 13,420,500 Ordinary Shares were sold at a price of \$6.00 per share, which included the full exercise by the underwriters of their option to purchase additional Ordinary Shares. The net proceeds, including the underwriters' option, were approximately \$75,348, after deducting the underwriting discounts and commissions and other offering expenses.

## c. Warrants

During the nine months ended September 30, 2018, 1,394,558 warrants were exercised for 178,468 Ordinary Shares. As of September 30, 2018, there are no warrants outstanding. As of September 30, 2017, the total amount of warrants outstanding was 1,394,558.

## d. Share-based compensation

In May 2015, the Company's Board of Directors approved a new option plan (the "Plan") replacing the previous plan approved in 2009. The Plan included a pool of 2,690,694 Ordinary Shares for grant to Company employees, consultants, directors and other service providers. During the years ended December 31, 2016 and December 31, 2017, the Board of Directors approved an accumulated increase of 2,900,000 Ordinary Shares to the Plan. As of September 30, 2018, 1,383,078 Ordinary Shares remain available for grant under the Plan.

In the nine months ended September 30, 2018 and 2017, the Company granted options and RSUs to employees and directors as follows:

	Nine months ended September 30, 2018			
	Award amount	Exercise price range	Vesting period	Expiration
Employees:				
Options	571,530	\$5.06-\$6.40	4 years	10 years
RSUs	126,844		4 years	-
Directors:				
Options	174,373	\$5.02-\$5.06	1 years	10 years
RSUs	14,829		3 years	-

## FOAMIX PHARMACEUTICALS LTD.

## NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(U.S. dollars in thousands, except share and per share amounts)

## NOTE 5 - SHARE CAPITAL (continued):

Nine months ended September 30, 2017				
	Award amount	Exercise price range	Vesting period	Expiration
Employees:				
Options	804,838	\$5.22-\$10.31	4 years	10 years
RSUs	268,764	-	4 years	-
Directors:				
Options	189,709	\$4.69-\$4.76	4 years	10 years
RSUs	19,397	-	4 years	-

The fair value of options and RSUs granted to employees and directors during the nine months ended September 30, 2018 and September 30, 2017 was \$3,287 and \$6,860, respectively.

The fair value of RSUs granted to employees and directors is based on the share price on grant date.

The fair value of options granted to employees and directors on the date of grant was computed using the Black-Scholes model. The underlying data used for computing the fair value of the options are as follows:

	Nine months ended	
	September 30	
	2018	2017
Value of ordinary share	\$5.12-\$5.99	\$4.44-\$10.12
Dividend yield	0%	0%
Expected volatility	62.1%-62.6%	58.4%-59.7%
Risk-free interest rate	2.75%-2.84%	1.97%-2.09%
Expected term	6 years	6 years

On January 1, 2018, the Company and Dr. Dov Tamarkin agreed to terminate the consulting agreement signed in June 2017. Pursuant to the termination, the Board of Directors resolved that all options and RSUs previously granted to Dr. Tamarkin shall continue to vest and may be exercised until their expiration date.

The retention of the options and RSUs was considered a Type III modification for share-based compensation, and, as a result, on January 1, 2018, the Company re-measured the fair value of all outstanding options and RSUs granted to Dr. Tamarkin and recognized the residual amount of the fair value as an immediate expense. The compensation expenses recorded on January 1, 2018 were \$239.

In addition, following changes in circumstances, including Mr. Meir Eini's resignation from his position as an observer to the Board of Directors, the Company reassessed the services provided by Mr. Meir Eini and concluded they are not substantive in comparison to the value of the equity awards he received. Therefore, in January 2018, all expenses related to the awards previously granted to Mr. Eini were measured and the unrecognized amount of the fair value was fully recognized. The compensation expenses recorded in January 2018 were \$494.

## FOAMIX PHARMACEUTICALS LTD.

## NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(U.S. dollars in thousands, except share and per share amounts)

## NOTE 5 - SHARE CAPITAL (continued):

The following table illustrates the effect of share-based compensation on the statements of operations:

	Nine months ended September 30		Three months ended September 30	
	2018	2017	2018	2017
Cost of revenues	\$-	\$2	\$-	\$2
Research and development expenses	1,679	1,097	376	522
Selling, general and administrative	2,465	1,584	814	672
	\$4,144	\$2,683	\$1,190	\$1,196

## NOTE 6 – COMMITMENTS:

## Lease agreement

The Company leases office space for its headquarters and research and development facilities in Israel and the United States under several lease agreements. The office lease agreements for the facilities in Israel are linked to the Israeli CPI and expire in December 2020. The lease agreement in the United States is due to expire during March 2019. The Company has an option to extend the lease agreement in the United States for additional 3 years on similar conditions.

In July 2017, the Company has entered into operating lease agreements in connection with a number of vehicles. The lease periods are generally for three years and the payments are linked to the Israeli CPI. To secure the terms of the lease agreements, the Company has made certain prepayments to the leasing company, representing approximately three months of lease payments. These amounts have been recorded as other non-current assets.

Operating lease expenses for the three and nine months ended September 30, 2018 and September 30, 2017, are as follows:

	Nine months ended September 30		Three months ended September 30	
	2018	2017	2018	2017
Rental expenses	\$581	\$461	\$191	\$184
Vehicle lease expenses	\$91	\$7	\$41	\$7

Future minimum lease commitments under non-cancelable operating lease agreements are as follows:

2018	\$213
2019	750
2020 and thereafter	732
Total	\$1,695



The Company has a lien in the amount of \$137 on the Company's marketable securities in respect of bank guarantees granted in order to secure the lease agreements.

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## FOAMIX PHARMACEUTICALS LTD.

## NOTES TO THE UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(U.S. dollars in thousands, except share and per share amounts)

## NOTE 7 - ENTITY-WIDE DISCLOSURES:

a. Net revenues by geographic area were as follows:

	Nine months ended September 30		Three months ended September 30	
	2018	2017	2018	2017
United States	\$62	\$86	\$-	\$86
Germany	2,468	2,540	660	815
Denmark	205	-	205	-
	\$2,735	\$2,626	\$865	\$901

b. Customers exceeding 10% of revenues:

During the three and nine months ended September 30, 2018 and September 30, 2017 the Company had one customer exceeding over 10% of total revenues. Revenues from the customer were \$2,468 and \$2,540 during the nine months ended September 30, 2018 and September 30, 2017, respectively. Revenues from the customer were \$660 and \$815 during the three months ended September 30, 2018 and September 30, 2017, respectively.

c. Net revenues by type of payment:

	Nine months ended September 30		Three months ended September 30	
	2018	2017	2018	2017
Development service payments	\$62	\$86	\$-	\$86
Royalties	2,673	2,540	865	815
Total revenues	\$2,735	\$2,626	\$865	\$901

## ITEM 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with (i) our condensed consolidated financial statements and the notes thereto included elsewhere in this quarterly report on Form 10-Q (ii) our audited consolidated financial statements and related notes and management's discussion and analysis of financial condition and results of operations included in our annual report on Form 10-K/A for the year ended December 31, 2017 filed with the Securities and Exchange Commission, or the SEC, on March 1, 2018. This Quarterly Report on Form 10-Q contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These statements are often identified by the use of words such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "project," "will," "would" or the negative or plural words or similar expressions or variations. Such forward-looking statements are subject to a number of risks, uncertainties, assumptions and other factors that could cause actual results and the timing of certain events to differ materially from future results expressed or implied by the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified herein, and those referred in the section titled "Risk Factors", set forth in Part II, Item 1A of this quarterly report on Form 10-Q, if any, and in our other SEC filings. Forward-looking statements are based on our management's beliefs and assumptions and on information currently available to our management. These statements, like all statements in this report, speak only as of the date of this quarterly report on Form 10-Q (unless another date is indicated), and, except as required by law, we undertake no obligation to update or revise these statements in light of future developments.

### Company Overview

We are a clinical-stage specialty pharmaceutical company focused on developing and commercializing our proprietary, innovative and differentiated topical drug candidates for dermatological therapy. Our lead product candidates, FMX101 (4% minocycline foam) for treatment of moderate-to-severe acne and FMX103 (1.5% minocycline foam) for treatment of moderate-to-severe papulopustular rosacea, are novel topical foam formulations of the antibiotic minocycline. Based on the results observed in our Phase II and Phase III clinical trials for FMX101 and our Phase II and Phase III clinical trials for FMX103, we believe these product candidates, if approved, have the potential to provide a fast, effective and well-tolerated treatment for their respective indications, which are currently underserved and commonly treated by oral prescription products such as oral minocycline, oral doxycycline and various other non-foam topical therapies.

We have been advancing our third pivotal Phase III clinical trial (Study 22) for FMX101. We announced the first patient enrolled in this trial on August 3, 2017 and had the last patient enrolled and dosed on May 7, 2018. We received positive top-line results from this trial in the third quarter of 2018. See "- Key Developments" below. Previously, in March 2017, we announced the results of the double-blind stage of our two initial Phase III clinical trials for FMX101. Statistical significance was observed in both co-primary efficacy endpoints in one study (Study 05); however, statistical significance was demonstrated in only one of the co-primary efficacy endpoints in the second study (Study 04). Statistical significance was also demonstrated for FMX101 compared to vehicle in the pooled analysis of the co-primary endpoints as well as key secondary endpoints for Studies 05 and 04. The third trial (Study 22) was initiated following a Type B meeting conducted with the FDA in June of 2017. During this meeting, we confirmed that achieving statistically significant results for FMX101 versus vehicle in both co-primary efficacy endpoints in a third independent clinical trial would be sufficient for establishing an efficacy claim in a new drug application ("NDA"), or NDA submission. A previous Phase II clinical trial of FMX101 also showed clinically and statistically significant results in all primary and secondary endpoints. As previously announced, in January 2018 we announced the completion of a long-term safety study that was an extension of our two initial Phase III clinical trials for FMX101. The results from the long-term safety study showed FMX101 to be well-tolerated and to have an acceptable safety profile.

We are also advancing our two pivotal Phase III clinical trials (known as Studies 11 and 12) in the U.S. for FMX103, minocycline foam for moderate-to-severe papulopustular rosacea. We announced the enrollment of the first patient in our Phase III trials on June 12, 2017, and had the last patient enrolled and dosed on June 27, 2018. Our Phase II clinical trial for FMX103 demonstrated clinically and statistically significant results in all primary and secondary endpoints. We received positive top-line results from these two trials in the fourth quarter of 2018. See “-Key Developments” below.

In addition, we successfully completed a Phase II clinical trial with FDX104, our proprietary doxycycline foam for the management of moderate-to-severe rash associated with epidermal growth factor receptor inhibitor (EGFRI) anticancer treatments. As the majority of our efforts and resources have been devoted to the development of FMX101 and FMX103 over the past year, limited work has been done during this year to further the development of FDX104. We are currently assessing our various options with regard to this product candidate.

We developed FMX101, FMX103 and FDX104 using our proprietary technology, which includes our foam-based platforms. Our technology enables us to formulate and stabilize a wide variety of product candidates and deliver them directly to their target site. We have independently developed a series of proprietary foam platforms, each having unique pharmacological features and characteristics. We believe our foam platforms may offer significant advantages over alternative delivery options and are suitable for multiple application sites. We believe our proprietary foam-based platforms may serve as a foundation in developing a potential pipeline of products across a range of conditions. In July 2015, an affiliate of Bayer HealthCare AG, or Bayer, received FDA approval for Finacea® Foam (azelaic acid 15%), or Finacea, a prescription foam product for the treatment of rosacea, which utilizes our proprietary foam technology.

Besides our in-house development projects, we have entered into development and license agreements relating to our technology with various pharmaceutical companies such as Bayer, Mylan N.V. and Actavis Laboratories. Our total revenues from these development and license agreements, since our inception through September 30, 2018, amounted to approximately \$30.9 million. The collaboration with Bayer, in particular, has led to the development and commercialization of Finacea, which uses one of our proprietary foam technology platforms. Bayer began selling Finacea in the United States in the third quarter of 2015. On September 4, 2018, LEO Pharma A/S, or LEO, acquired Bayer's prescription dermatology business in the United States, including Finacea. As part of the acquisition, our license agreement with Bayer with respect to Finacea was assigned to LEO. LEO has assumed all of the rights and responsibilities of Bayer under the license agreement as it relates to Finacea, including the payment of royalties to us and the litigation matters, which are discussed further below. Since its commercial launch through September 30, 2018, we received (or became entitled to receive) a total of \$9.4 million in royalties for this product from both Bayer and LEO. As previously disclosed, we received notifications from third party pharmaceutical companies that they had filed abbreviated NDAs with the FDA, seeking approval for generic versions of Finacea prior to the expiry of certain patents licensed by us to Bayer. In January and February of this year we and Bayer initiated legal action against such third parties. We are committed to defending our intellectual property rights globally, including patents we have licensed to other pharmaceutical companies as part of our collaboration efforts. Our FMX101 and FMX103 products are based on a different foam technology platform and different patents than those listed in the Approved Drug Products with Therapeutic Equivalence Evaluations, or Orange Book, for Finacea.

To date, we have not yet submitted any product candidates for approval by regulatory authorities and we do not currently have rights to any products that have been approved for marketing in any territory. We have financed our operations primarily through private and public placements of our shares, convertible loans and from development and licensing collaborations. We have incurred significant losses since our inception in 2003. Our accumulated deficit at September 30, 2018 was \$201.3 million and our net loss for the nine and three months ended September 30, 2018 was \$60.1 million and \$15.5 million respectively. A substantial amount of our net losses resulted from costs incurred in connection with our research and development programs and clinical trials and from general and administrative costs associated with our operations. The net losses and negative operating cash flows incurred to date, together with expected future losses, have had, and likely will continue to have, an adverse effect on our shareholders' equity and working capital. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate offsetting revenue, if any. We expect to continue to incur significant expenses and operating losses for the foreseeable future.

We do not expect to generate revenue from product sales unless and until we successfully complete clinical trials and obtain marketing approval from the FDA for one or more of our lead product candidates, FMX101 or FMX103. Accordingly, we anticipate that we will need to raise additional capital in order to complete the development and commercialization of FMX101 and FMX103 and to advance the development of our other product candidates. Until we can generate a sufficient amount of product revenue to finance our cash requirements, we expect to finance our future cash needs primarily through a combination of public and private equity offerings, debt or other structured financings, and entry into strategic collaborations. We may be unable to raise capital when needed or on attractive terms, which would force us to delay, limit, reduce or terminate our development programs or commercialization efforts. We will need to generate significant revenue to achieve and sustain profitability, and we may never be able to do so.

We continue to be an "emerging growth company," as defined in Section 2(a) of the Securities Act and as modified by the JOBS Act. As such, we are eligible to, and take advantage of, certain exemptions from various reporting requirements applicable to other public companies that are not "emerging growth companies," such as not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002. We will remain an emerging growth company until the earliest of: (i) the last day of our fiscal year during which we have total annual gross revenues of at least \$1.07 billion; (ii) the last day of our fiscal year following the fifth anniversary of the closing of our initial public offering, specifically – December 31, 2019; (iii) the date on which we have, during

any three-year period, issued more than \$1.0 billion in non-convertible debt; or (iv) the date on which we are deemed to be a “large accelerated filer” under the Exchange Act with at least \$700 million of equity securities held by non-affiliates.

## Key Developments

Below is a summary of selected key developments affecting our business that have occurred since June 30, 2018:

On August 10, 2018, following our Type B meeting with the FDA on February 14, 2018, we received a letter from the FDA's Division of Dermatology requesting information on the canister, foaming pump and other device constituent parts of our FMX101 product candidate. The letter referred to FMX101 as a combination product and requested information relating to the quality and design control of the device, including (1) the device description documentation, (2) the design control documentation, (3) the traceability documentation, and (4) additional considerations related to the biocompatibility and sterility of the product candidate. We expect to provide the requested information to the FDA using readily available data derived from our Study 22. We also expect to compile such information for our NDA submission and file the NDA for FMX101, with no material increases of the expected budget or material changes to the anticipated timing of our NDA submission.

On September 11, 2018, we announced the positive results of our third pivotal Phase III clinical trial (Study 22) for FMX101 in the United States for the treatment of moderate-to-severe acne. The double-blind, randomized, vehicle-controlled Phase III trial included 1,507 patients with moderate-to-severe acne enrolled at 89 sites in the United States. Patients randomly received either FMX101 minocycline foam (4%) or vehicle foam once daily over a period of 12 weeks. The safety and tolerability of FMX101 were also evaluated and the safety profile of FMX101 was found to be consistent with that observed from the two prior Phase III trials. The most commonly reported adverse events in the clinical trial related to upper respiratory tract infections. There were no treatment-related serious adverse events. FMX101 was observed in the clinical trial to have a generally favorable safety profile and to be generally well tolerated. Based on the efficacy and safety profile observed in clinical studies to date, we believe FMX101, if approved, may present an attractive option for the treatment of moderate-to-severe acne. We intend to file the NDA for FMX101 by the end of 2018.

On September 18, 2018, following the announcement of the positive results of our third pivotal Phase III clinical trial for FMX101, we completed a follow-on offering pursuant to an effective shelf registration statement and issued 13,420,500 Ordinary Shares at a price of \$6.00 per share, which included the full exercise by the underwriters of their option to purchase additional Ordinary Shares. We raised net proceeds, after expenses and underwriting discounts and commissions, of approximately \$75.3 million.

On November 7, 2018, we announced the positive results of our Phase III clinical trials (Studies 11 and 12) for FMX103 in the United States for the treatment of moderate-to-severe papulopustular rosacea. Studies 11 and 12 were identical, double-blind, randomized, vehicle-controlled studies that enrolled a total of 1,522 subjects (Study 11: 751 subjects, Study 12: 771 subjects) with moderate-to-severe papulopustular rosacea at a total of 100 sites in the United States. Patients were randomized 2:1 to receive either FMX103 minocycline foam (1.5%) or vehicle foam, respectively, once daily over a period of 12 weeks. The safety and tolerability of FMX103 were also evaluated. The most commonly reported adverse events in the clinical trial related to upper respiratory tract infections. There were no treatment-related serious adverse events. FMX103 was observed in the clinical trial to have a generally favorable safety profile and appeared to be generally well tolerated. Based on the efficacy and safety profile observed in clinical studies to date, we believe FMX103, if approved, may present an attractive option for the treatment of moderate-to-severe papulopustular rosacea. Our goal is to file an NDA for FMX103 in 2019.

## Revenues

To date, we have not generated any revenues from sales of FMX101 or any of our other product candidates. We do not expect to commercially launch FMX101 or other product candidates or generate any revenues from sales of any of our product candidates before the end of 2019, until after completion of their development and clinical testing and after obtaining approvals for their marketing in the U.S. Our ability to generate revenues from sales will depend on the successful commercialization of FMX101 and our other product candidates.

As of September 30, 2018, we generated cumulative revenues of approximately \$30.9 million under development and license agreements, of which approximately \$18.4 million were development service payments, approximately \$3.1 million were contingent payments and \$9.4 million were royalty payments. The royalties were paid in relation to Finacea, the prescription foam product that we developed in collaboration with Bayer. In the three and nine months ended September 30, 2018 we received (or became entitled to receive) royalty payments in an amount of \$865,000 and \$2.7 million, respectively. We may become entitled to additional contingent payments, subject to achievement of the applicable clinical results by our other licensees. In light of the current phase of development under these agreements, we do not expect to receive significant payments in the near term, if at all.

## Cost of Revenues

Our total cost of revenues for the three and nine months ended September 30, 2017, was \$11,000 and there was no cost of revenues for the three and nine months ended September 30, 2018, as revenues consist almost entirely from royalties, which do not bear related cost of revenue.

We do not expect substantial changes in cost of revenue unless and until we obtain regulatory approval for our lead product candidates and begin serial production of such products, whether internally or through third party manufacturers, at which point we expect our cost of revenues to grow along with the growth of our sales and inventory needs.

## Operating Expenses

### Research and development expenses

Research and development activities are, and will continue to be, central to our business. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect research and development costs to increase significantly for the foreseeable future assuming our pipeline products progress into clinical trials. However, we do not believe that it is possible at this time to accurately project total program-specific expenses to reach commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will affect our clinical development programs and plans.



Our research and development expenses relate primarily to the development of FMX101 and FMX103. From January 1, 2007 until September 30, 2018, we cumulatively spent approximately \$157.7 million on research and development of FMX101, FMX103 and our other product candidates. Our total research and development expenses for the three-month ended September 30, 2018 and 2017 were approximately \$13.1 million and \$15.8 million, respectively, and for the nine-month periods ended September 30, 2018 and 2017 were approximately \$52.8 and \$42.4 million, respectively. We charge all research and development expenses to operations as they are incurred.

The successful development of FMX101, FMX103 and additional product candidates is highly uncertain. As such, at this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of our technology for additional indications. This uncertainty is due to numerous risks and variables associated with developing products, including the uncertainty of:

- the scope, rate of progress and expense of our research and development activities;
- preclinical results;
- clinical trial results;
- the terms and timing of regulatory approvals;
- our ability to file, prosecute, obtain, maintain, defend and enforce patents and other intellectual property rights and the expense of taking such actions;
- the ability to market, commercialize and achieve market acceptance for FMX101, FMX103 or any other product candidate that we may develop in the future; and
- our ability to identify, evaluate, acquire or obtain licenses for intellectual property, if needed, to facilitate the commercialization of our products and technologies.

A change in the outcome of any of these variables with respect to the development of FMX101, FMX103 or our other product candidates could result in a significant change in the costs and timing associated with their development. For example, if the FDA or foreign regulatory authority were to require us to conduct preclinical studies and clinical trials beyond those which we currently anticipate for the completion of clinical development of our product candidates, or if we experience significant delays in enrollment in any clinical trials, we could be required to expend significant additional time and financial resources on the completion of the clinical development.

Research and development expenses consist primarily of:

- employee-related expenses, including salaries, benefits and related expenses, including share-based compensation expenses;
- expenses incurred under agreements with third parties, including subcontractors, suppliers and consultants that conduct regulatory activities, clinical trials and preclinical studies;
- expenses incurred to acquire, develop and manufacture clinical trial materials;
  - facilities, depreciation and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance, and other operating costs; and
- other costs associated with preclinical and clinical activities and regulatory operations.

We have managed to finance our research and development operations and expenses without the aid of government grants, other than a loan in the amount of approximately \$450,000 received from the Israel-U.S. Bi-national Industrial Research and Development Foundation, or BIRD, in 2008, which was fully repaid in 2016. Accordingly, we are not subject to the provisions of the Law for Encouragement of Research and Development in the Industry, 5744-1984, nor to any directives issued by the Israel Innovation Authority, previously known as the Office of the Chief Scientist of the Ministry of the Economy.

Selling, general and administrative expenses

Our selling, general and administrative expenses consist principally of:

- employee-related expenses, including salaries, benefits and related expenses, including share-based compensation expenses;
- costs associated with market research and business development activities in preparation for future marketing and sales, including activities intended to select the most promising product candidates for further development and commercialization;
- legal and professional fees for auditors and other consulting expenses not related to research and development activities or to market research or business development activities;
- cost of office space, communication and office expenses;

- information technology expenses;
- depreciation of tangible fixed assets related to our general and administrative activities or to our market research and business development activities; and
- costs associated with filing, prosecuting, obtaining and maintaining patents and other intellectual property.

As part of our growth strategy, we have begun building up our dedicated U.S. marketing and business development team and infrastructure, and we intend to further increase such U.S. infrastructure, as well as expand our marketing effort to new markets. We therefore expect selling and marketing expenses to increase in absolute terms as a percentage of our revenues. Our total selling, general and administrative expenses for the three-month periods ended September 30, 2018 and 2017 were approximately \$3.3 million and \$2.9 million, respectively, and for the nine-month periods ended September 30, 2018 and 2017 were approximately \$10.0 million and \$9.2 million, respectively.

#### Financial Income

Financial income consists primarily of gains from interest earned from our bank deposits and financial income on our marketable securities.

#### Taxes on Income

The standard corporate tax rate in Israel during the year 2018 is 23%, a decrease compared to the 24% tax rate during 2017.

We have yet to generate taxable income in Israel, as we have historically incurred operating losses resulting in carry forward tax losses totaling approximately \$88.6 million as of December 31, 2017. We anticipate that we will be able to carry forward these tax losses to future tax years. Accordingly, we do not expect to pay taxes in Israel until we have taxable income after the full utilization of our carry-forward tax losses. We provided a full valuation allowance with respect to the deferred tax assets related to these carry-forward losses.

During the three-month periods ended September 30, 2018 and 2017 we incurred tax expenses of \$13,000 and \$57,000, respectively, in our U.S. subsidiary, Foamix Pharmaceuticals Inc., and during the nine-month periods ended September 30, 2018 and 2017 we incurred tax expenses of \$463,000 and \$209,000, respectively.

#### Comparison of the Three-Month Periods Ended September 30, 2018 and 2017

##### Revenues

Our total revenues decreased by \$36,000, or 4.0%, from \$901,000 in the three months ended September 30, 2017 to \$865,000 in the three months ended September 30, 2018. The change is due to a decrease in development service payments, which was offset by an increase in royalty payments from Bayer and LEO for sales of Finacea.

##### Cost of revenues

Our total cost of revenues for the three months ended September 30, 2017 was \$11,000 and there was no cost of revenues for the three-month period ended September 30, 2018, as revenues consist entirely from royalties, which bear no related cost of revenue.

##### Research and development expenses

Our research and development expenses for the three months ended September 30, 2018 were \$13.1 million, representing a decrease of \$2.7 million, or 17.1%, compared to \$15.8 million for the three months ended September 30, 2017. The decrease in research and development expenses resulted primarily from a decrease of \$3.6 million in costs relating predominantly to FMX101 and FMX103 clinical trials, offset by an increase of \$434,000 in payroll and payroll-related expenses including share-based compensation primarily due to an increase in salary raises, an increase of \$139,000 in advisors, consultants and other professional services expenses, and an increase of \$120,000 in travel expenses.

#### Selling, general and administrative expenses

Our general and administrative expenses for the three months ended September 30, 2018 were \$3.3 million, representing an increase of \$376,000, or 13.0%, compared to \$2.9 million for the three months ended September 30, 2017. The increase in selling, general and administrative expenses resulted primarily from an increase of \$270,000 in payroll and payroll-related expenses including share-based compensation primarily due to an increase in headcount and salary raises, and an increase of \$104,000 in expenses related to our Board of Directors.

## Operating loss

Our operating loss for the three months ended September 30, 2018 was \$15.6 million, representing a decrease of \$2.2 million, or 12.4%, compared to an operating loss of \$17.8 million for the three months ended September 30, 2017.

## Finance income

In the three-month periods ended September 30, 2018 and 2017, our financial income included mostly gains from marketable securities and interest earned on our bank deposits.

The finance expenses (income) by cash and non-cash components are as follows:

	Three months ended September 30, 2018    2017 (in thousands of U.S. dollars)	
Interest on bank deposits	\$(51 )	\$(113)
Gain from marketable securities, net	(107)	(163)
Foreign exchange gain, net	-	(28 )
Total income	(158)	(304)
Less:		
Foreign exchange loss, net	35	-
Other expenses	4	2
Total expenses	39	2
Finance income, net	\$(119)	\$(302)

## Taxes on income

During the three-month periods ended September 30, 2018 and 2017 we did not generate taxable income in Israel. However, we had incurred tax expenses in our U.S. subsidiary, Foamix Pharmaceuticals Inc., in the amount of \$13,000 and \$57,000 for the three-month periods ended September 30, 2018 and 2017, respectively.

## Net Loss

Our net loss for the three months ended September 30, 2018 was \$15.5 million, compared to \$17.6 million for the three months ended September 30, 2017, a decrease of \$2.1 million, or 11.9%.

## Comparison of the Nine-Month Periods Ended September 30, 2018 and 2017

### Revenues

Our total revenues increased by \$109,000, or 4.2%, from \$2.6 million in the nine months ended September 30, 2017 to \$2.7 million in the nine months ended September 30, 2018. The increase is mainly due to an increase in royalty payments from Bayer and LEO for sales of Finacea.

### Cost of revenues

Our total cost of revenues for the nine months ended September 30, 2017 was \$11,000 and there was no cost of revenues for the nine-month period ended September 30, 2018, as revenues consist entirely from royalties, which bear no related cost of revenue.

#### Research and development expenses

Our research and development expenses for the nine months ended September 30, 2018 were \$52.8 million, representing an increase of \$10.4 million, or 24.5%, compared to \$42.4 million for the nine months ended September 30, 2017. The increase in research and development expenses resulted primarily from (a) an increase of \$8.5 million in costs relating predominantly to FMX101 and FMX103 clinical trials, (b) an increase of \$2.0 million in payroll and payroll-related expenses, including share-based compensation, primarily due to a change in the measurement of share based compensation expenses of a consultant and an increase in headcount and salary raises, (c) an increase of \$504,000 in travel expenses, and (d) an increase of \$225,000 in advisors, consultants and other professional services expenses. Such increases were offset by a decrease of \$1.2 million in compensation to one of our co-founders in the nine months ended September 30, 2017.

## Selling, general and administrative expenses

Our general and administrative expenses for the nine months ended September 30, 2018 were \$10.0 million, representing an increase of \$813,000, or 8.8%, compared to \$9.2 million for the nine months ended September 30, 2017. The increase in selling, general and administrative expenses resulted primarily from (a) an increase of \$1.9 million in payroll and payroll-related expenses, including share-based compensation, mostly due to an increase in headcount, salary raises and accounting modification relating to share based compensation of a consultant, (b) an increase of \$512,000 in advisors and other professional services expenses, and (c) an increase of \$256,000 in expenses related to our Board of Directors. Such increases were offset by (i) a decrease of \$1.5 million in compensation to one of our co-founders in the nine months ended September 30, 2017, and (ii) a decrease of \$201,000 in travel expenses.

## Operating loss

Our operating loss for the nine months ended September 30, 2018 was \$60.1 million, compared to an operating loss of \$49.0 million for the nine months ended September 30, 2017, an increase of \$11.1 million, or 22.7%.

## Finance income

In the nine-month periods ended September 30, 2018 and 2017, our financial income included mostly gains from marketable securities and interest earned on our bank deposits.

The finance expenses (income) by cash and non-cash components are as follows:

	Nine months ended September 30, 2018    2017 (in thousands of U.S. dollars)	
Interest on bank deposits	\$(205)	\$(438)
Gain from marketable securities, net	(326)	(448)
Total income	(531)	(886)
Less:		
Other expenses	13	12
Foreign exchange loss, net	47	28
Total expenses	60	40
Finance income, net	\$(471)	\$(846)

## Taxes on income

During the nine-month periods ended September 30, 2018 and 2017 we did not generate taxable income in Israel. However, we had incurred tax expenses in our U.S. subsidiary, Foamix Pharmaceuticals Inc., in the amount of \$463,000 and \$209,000 for the nine-month periods ended September 30, 2018 and 2017, respectively. The increase in tax expenses resulted mainly from an increase in operations of Foamix Pharmaceuticals Inc.

## Net Loss

Our net loss for the nine months ended September 30, 2018 was \$60.1 million, compared to \$48.4 million for the nine months ended September 30, 2017, an increase of \$11.7 million, or 24.2%.

## Liquidity

Since our inception, we have incurred losses from operations and negative cash flows from our operations. For the nine months ended September 30, 2018 we incurred a net loss of \$60.1 million, which included \$57.7 million used for operating activities. For the nine months ended September 30, 2017 we incurred a net loss of \$48.4 million, which included \$40.5 million used for operating activities.

As of September 30, 2018 and September 30, 2017 we had a working capital surplus of \$103.0 million and \$70.8 million, respectively, and an accumulated deficit of \$201.3 million and \$123.9 million, respectively. Our principal source of liquidity as of September 30, 2018 consisted of cash and investments of \$110.5 million.



In September 2014, we completed our initial public offering in which we sold 6,700,000 Ordinary Shares for \$6.00 per share raising total net proceeds, after expenses, of approximately \$35.7 million. In October 2014 the underwriters exercised their option to purchase an additional 968,200 Ordinary Shares. The proceeds from the exercise of the option, net of underwriters' commission, were approximately \$5.4 million, bringing the total net proceeds from the initial public offering, after expenses, to approximately \$41.1 million.

In April 2015, we completed a follow-on offering in which we sold 7,419,353 Ordinary Shares, including the exercise of an underwriter option, for \$9.30 per share, raising total net proceeds, after expenses, of approximately \$64.2 million.

On September 30, 2016 we completed another follow-on offering under an effective shelf registration statement, in which we sold 5,700,000 Ordinary Shares for \$9.50 per share, raising net proceeds, after expenses and underwriter commissions, of approximately \$50.4 million. An additional 300,000 Ordinary Shares were sold by certain selling shareholders. In October 2016 the underwriters partially exercised the option granted to them in the underwriting agreement and purchased an additional 411,959 Ordinary Shares. The proceeds from the exercise of the option, net of expenses and underwriter commissions, were approximately \$3.7 million, bringing the total net proceeds from the offering to approximately \$54.1 million.

On April 13, 2018 we entered into a Securities Purchase Agreement with OrbiMed Partners Master Fund Limited, or OrbiMed, pursuant to which we agreed to issue and sell, in a registered offering by the Company, an aggregate of 2,940,000 Ordinary Shares, par value NIS 0.16 per share, at a purchase price equivalent to \$5.50 per share, representing a premium to the Company's Ordinary Shares' last closing price, for aggregate net proceeds of approximately \$16.1 million, after deducting offering expenses. The closing of the issuance and sale of these securities took place on April 16, 2018, pursuant to our shelf registration statement on Form S-3, which was filed with the SEC on April 2, 2018 and became effective on April 12, 2018.

On September 18, 2018 we completed an additional follow-on offering, under a shelf registration statement filed with the SEC on Form S-3 (File No. 333-224084) on April 2, 2018 and declared effective on April 12, 2018, in which we sold 11,670,000 Ordinary Shares for \$6.00 per share, raising net proceeds, after expenses and underwriter commissions, of approximately \$65.5 million. Upon closing of the offering, the underwriters further exercised the option granted to them in the underwriting agreement and purchased 1,750,500 additional Ordinary Shares at the per share price of the offering. The proceeds from the exercise of the option, net of expenses and underwriter commissions, were approximately \$9.8 million, bringing the total net proceeds from the offering to approximately \$75.3 million.

We anticipate that with our existing cash and investments we will be able to fund our planned operating expenses and capital expenditure requirements through mid 2020. These planned expenses and expenditures include: (a) the full development and filing of an NDA for FMX101, which we expect to submit by the end of 2018, (b) completion of our two Phase III clinical trials for FMX103, (c) full development and filing of an NDA for FMX103, which we expect to submit in 2019, (d) certain pipeline development activities and (e) any pre-commercialization and launch preparations for FMX101. We expect we will need additional funding to support our operating expenses and capital requirements for 2020 and beyond, including with regard to the commercialization of our product candidates and to fund our internal and external research and development efforts. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

## Capital Resources

### Overview

To date, we have financed our operations through private and public placements of our Ordinary Shares, convertible loans and through fees, cost reimbursements and royalties received from our licensees.

From inception through September 30, 2018, we have received net cash proceeds of approximately \$280.1 million from the issuance of Ordinary Shares, preferred shares, exercise of options and warrants and from convertible loans.

## Cash flows

The following table summarizes our statement of cash flows for the nine-month periods ended September 30, 2018 and 2017:

	Nine months ended September 30, 2018      2017 (in thousands of U.S. dollars)	
Net cash (used in) / provided by:		
Operating activities	\$(57,766)	\$(40,544)
Investing activities	\$37,345	\$29,990
Financing activities	\$92,362	\$124

## Net cash used in operating activities

The use of cash in all periods resulted primarily from our net losses adjusted for non-cash charges and measurements and changes in components of working capital. Adjustments to net income for non-cash items mainly include depreciation and amortization and share-based compensation.

Net cash used in operating activities was \$57.8 million in the nine months ended September 30, 2018, compared to \$40.5 million in the nine months ended September 30, 2017. The increase was attributable primarily to increased net losses resulting from the increase in activity related mostly to clinical trials and payroll expenses.

## Net cash provided by investing activities

Net cash provided by investing activities has been primarily related to proceeds from the sale and maturity of marketable securities and bank deposits. Net cash provided by investing activities was \$37.3 million in the nine months ended September 30, 2018, compared to net cash provided by investing activities of \$30.0 million in the nine months ended September 30, 2017. The increase in cash provided by investing activities was attributable primarily to an increase in proceeds from the sale and maturity of marketable securities and bank deposits, a decrease in investment in marketable securities, offset by an increase in investment in bank deposits.

## Net cash provided by financing activities

Net cash provided by financing activities was \$92.4 million in the nine months ended September 30, 2018, compared to \$124,000 in the nine months ended September 30, 2017. The increase was attributable primarily to (i) the proceeds from the issuance of shares to OrbiMed based on the aforementioned Securities Purchase Agreement, in an aggregate net amount of approximately \$16.1 million after deducting offering expenses, (ii) the increase in the amount of \$840,000 in proceeds from the exercise of warrants, and (iii) the proceeds from the issuance of shares in the underwritten follow-on offering which closed on September 18, 2018, in an aggregate net amount of approximately \$75.3 million after deducting offering expenses and underwriters' commissions.

## Cash and funding sources

The table below summarizes our main sources of financing for the nine-month periods ended September 30, 2018 and 2017:

Proceeds from	Proceeds from	Payments from	Total
------------------	------------------	------------------	-------

	our	issuance	licensees	
	offerings	of		
	(1)	Ordinary		
		Shares		
	(in thousands of U.S. dollars)			
Nine months ended September 30, 2018	\$91,479	\$ 883	\$ 2,797	\$95,159
Nine months ended September 30, 2017	-	\$ 145	\$ 4,961	\$5,106

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(1) Net of issuance costs.

Our sources of financing in the nine months ended September 30, 2018 totaled \$95.2 million and consisted primarily of \$16.1 million of net proceeds from our registered direct offering to OrbiMed, \$75.3 million of net proceeds from our underwritten follow-on offering which closed on September 18, 2018, and \$2.8 million of payments from licensees.

Our sources of financing in the nine months ended September 30, 2017 totaled \$5.1 million and consisted primarily of payments from licensees.

We have no ongoing material financial commitments (such as lines of credit) that may affect our liquidity over the next five years.

## Funding requirements

We anticipate that with our existing cash and investments we will be able to fund our planned operating expenses and capital expenditure requirements through mid-2020. These planned expenses and expenditures include: (a) the full development and filing of an NDA for FMX101, which we expect to submit by the end of 2018, (b) completion of our two Phase III clinical trials for FMX103, (c) full development and filing of an NDA for FMX103, which we expect to submit in 2019, (d) certain pipeline development activities and (e) any pre-commercialization and launch preparations for FMX101. We expect we will need additional funding to support our operating expenses and capital requirements for all of 2020 and beyond, including with regard to the commercialization of our product candidates and to fund our internal and external research and development efforts. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect.

Our present and future funding requirements will depend on many factors, including, among other things:

- the progress, timing and completion of preclinical testing and clinical trials for FMX101, FMX103 or any future pipeline product candidate;

- selling, marketing and patent-related activities undertaken in connection with the anticipated commercialization of FMX101, FMX103 and any other product candidates and costs involved in the development of an effective sales and marketing organization;

- the time and costs involved in obtaining regulatory approval for FMX101, FMX103 and our other pipeline products and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of these products;

- the number of potential new products we identify and decide to develop;

- the costs involved in filing and prosecuting patent applications and obtaining, maintaining and enforcing patents or defending against claims or infringements raised by third parties, and license royalties or other amounts we may be required to pay to obtain rights to third party intellectual property rights; and

- the amount of revenues, if any, we may derive either directly or in the form of royalty payments from future sales of FMX101, FMX103 and any other pipeline product that is commercialized.

For more information as to the risks associated with our future funding needs, see “Part I, Item 1A—Risk Factors—Risks Related to Our Business and Industry—We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, other operations or commercialization efforts” in our Annual Report on Form 10-K/A for the year ended December 31, 2017, as filed with the Securities and Exchange Commission on March 1, 2018.

Our capital expenditures for the nine-month periods ended September 30, 2018 and 2017 amounted to \$408,000 and \$1.2 million, respectively. During the nine months ended September 30, 2018, these expenditures were primarily related to laboratory equipment, software and leasehold improvements.

## Off-Balance Sheet Arrangements

As of September 30, 2018, we did not have any off-balance sheet arrangements.

## Contractual Obligations

Our significant non-cancelable contractual obligations as of September 30, 2018 are summarized in the following table:

	Payments due by period					
		Less than 1	1-3	3-5	More than 5	
	Total	year	years	years	years	Other
	(in thousands of U.S. dollars)					
Operating lease obligations <sup>(1)</sup>	\$1,695	\$775	\$920	-	-	-
Liability for employee severance benefits <sup>(2)</sup>	\$379	-	-	-	-	\$379
Total	\$2,074	\$775	\$920	-	-	\$379

<sup>(1)</sup>Operating lease obligations consist of lease of our facilities and lease of vehicles.

<sup>(2)</sup>The liability for employee severance benefits is considered long term. However, we cannot estimate the exact period in which such benefits will be paid.

## Critical Accounting Policies and Significant Judgments and Estimates

We prepare our consolidated financial statements in accordance with generally accepted accounting principles in the United States. The preparation of consolidated financial statements also requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, expenses and related disclosures. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results could differ significantly from the estimates made by our management. To the extent that there are differences between our estimates and actual results, our future financial statement presentation, financial condition, results of operations and cash flows will be affected.

While our significant accounting policies are more fully described in Note 2, Summary of Significant Accounting Policies, to the consolidated financial statements included in “Item 8—Financial Statements and Supplementary Data” of our Annual Report on Form 10-K/A for the year ended December 31, 2017, as filed with the Securities and Exchange Commission on March 1, 2018, and refer also to Note 2, “Significant Accounting Policies,” in the accompanying notes to the condensed consolidated financial statements, we believe that the following accounting policies are the most critical to assist shareholders and investors reading the consolidated financial statements in fully understanding and evaluating our financial condition and results of operations. These policies relate to the more significant areas involving management’s judgments and estimates and they require our most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of the matters that are inherently uncertain.

### Clinical trial accruals

Clinical trial costs are charged to research and development expense as incurred. We accrue for expenses resulting from obligations under contracts with CROs. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided. Our objective is to reflect the appropriate trial expense in the consolidated financial statements by matching the appropriate expenses with the period in which services and efforts are expended. In the event advance payments are made to a CRO, the payments will be recorded as other assets, which will be recognized as expenses as services are rendered. The CRO contracts generally include pass-through fees including, but not limited to, regulatory expenses, investigator fees, travel costs and other miscellaneous costs. We estimate our clinical accruals based on reports from and discussion with clinical personnel and the CRO as to the progress or state of completion of the trials. We estimate accrued expenses as of each balance sheet date in the consolidated financial statements based on the facts and circumstances known at that time. Our clinical trial accrual is dependent, in part, upon the receipt of timely and accurate reporting from the CROs.

### Equity-based compensation

The fair value of equity-based payment transactions is recognized as an expense over the requisite service period and computed using the Black-Scholes model. We recognize compensation costs for awards that are conditioned only on continued service and which have a graded vesting schedule using the straight-line method based on the multiple-option award approach. When options and RSUs are granted as consideration for services provided by consultants and other non-employees, the grant is accounted for based on the fair value of the consideration received or the fair value of the awards issued, whichever is more reliably measurable. The fair value of the awards granted is measured on a final basis at the end of the related service period and is recognized over the related service period using the straight-line method.

### Recently Issued Accounting Pronouncements

For a discussion of certain recently issued accounting pronouncements, refer to Note 2, “Significant Accounting Policies,” in the accompanying notes to the condensed consolidated financial statements.

ITEM 3. Quantitative and Qualitative Disclosures about Market Risk

Market risk is the risk of loss related to changes in market prices, including interest rates, foreign exchange rates and prices of financial instruments that may adversely impact our financial position, results of operations or cash flows. As of September 30, 2018 we did not have any financial instruments sensitive to market risk. We therefore have little exposure to market risks in the ordinary course of our operations, and such risks are primarily related to changes in foreign currency exchange rates and in interest rates.



## Foreign Currency Exchange Risk

The U.S. dollar is our functional and reporting currency. Although a substantial portion of our expenses (mainly salaries and related costs) are denominated in New Israeli shekels (NIS), accounting for 13.2% and 15.9% of our expenses in the nine month ended September 30, 2018 and 2017, respectively, almost all our revenues were generated under agreements denominated in U.S. dollars and our proceeds from our public offerings, which are the main source of our financing, are denominated in U.S. dollars. Furthermore, while we anticipate that a portion of our expenses, principally salaries and related personnel expenses in Israel, will continue to be denominated in NIS, we expect to incur an increasing amount of expenses in U.S. dollars as we expand our operations in the U.S. We also have expenses, although to a much lesser extent, in other non-dollar currencies, in particular the Swiss Franc. Moreover, for the next few years we expect that the substantial majority of our revenues, if any, will be denominated in U.S. dollars from the sale of FMX101, if approved, and potentially other product candidates in the United States. Having the substantial majority of our revenues denominated in U.S. dollars while having a substantial portion of our expenses denominated in NIS and other non-U.S. currencies exposes us to risk, associated with exchange rate fluctuations vis-à-vis the U.S. dollar. For further discussion of this risk, please review “Item 1A—Risk Factors—Risks Related to Our Business and Industry—Exchange rate fluctuations between the U.S. dollar and the Israeli NIS may negatively affect our earnings” in our Annual Report on Form 10-K/A for the year ended December 31, 2017, as filed with the Securities and Exchange Commission on March 1, 2018.

A devaluation of the NIS in relation to the U.S. dollar has the effect of reducing the U.S. dollar amount of our expenses or payables that are payable in NIS, unless those expenses or payables are linked to the U.S. dollar. Conversely, any appreciation of the NIS in relation to the U.S. dollar has the effect of increasing the U.S. dollar value of our unlinked NIS expenses, which would have a negative impact on our profit margins. In the nine months ended September 30, 2018, the value of the NIS depreciated in relation to the U.S. dollar by 4.6%, the effect of which was partially offset by inflation in Israel at a rate of approximately 1.1%. In the nine months ended September 30, 2017, the value of the NIS appreciated in relation to the U.S. dollar by 8.2%, the effect of which was compounded by inflation in Israel at a rate of approximately 0.3%.

Because exchange rates between the U.S. dollar and the NIS (as well as between the U.S. dollar and other currencies) fluctuate continuously, such fluctuations have an impact on our results and period-to-period comparisons of our results. The effects of foreign currency re-measurements are reported in our statements of operations.

The following table presents information about the changes in the exchange rates of the NIS against the U.S. dollar:

Nine-month period ended September 30,	NIS against the U.S. dollar
2018	(4.6)%
2017	8.2%

We will continue to monitor our exposure to currency fluctuations. Since February 2015, we have engaged in currency hedging activities in order to reduce our exposure to currency fluctuations. Instruments that are used to hedge future risks may include foreign currency forward contracts, swap contracts and options. These instruments may be used to selectively manage risks, but we may not be fully protected against material foreign currency fluctuations.

## Inflation-Related Risks

We do not believe that the rate of inflation in Israel has had a material impact on our business, financial condition or results of operations during the year ended December 31, 2017 or nine months ended September 30, 2018. However, our costs in Israel will increase if inflation in Israel exceeds the devaluation of the NIS against the U.S. dollar, or if the timing of such devaluation lags behind inflation in Israel.

## ITEM 4. Controls and Procedures

#### Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act and regulations promulgated thereunder) as of September 30, 2018, or the Evaluation Date. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer, have concluded that, as of the Evaluation Date, our disclosure controls and procedures were effective at the reasonable assurance level in recording, processing, summarizing and reporting, on a timely basis, information required to be included in periodic filings under the Exchange Act and that such information was accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

#### Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended September 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### Limitations on Effectiveness of Controls and Procedures

In designing and evaluating the disclosure controls and procedures and internal control over financial reporting, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures and internal control over financial reporting must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

## PART II - OTHER INFORMATION

## ITEM 1. Legal Proceedings

## Legal Proceedings

From time to time, we may become involved in litigation or other legal proceedings relating to claims that we consider to be arising from the ordinary course of our business. There are currently no claims or actions pending against us that, in the opinion of our management, are likely to have a material adverse effect on our business.

Currently, we are not involved in any legal proceedings other than the complaints filed by Bayer and Foamix in the U.S. In January 2018, we, along with Bayer, filed complaints against affiliates of Teva and in February 2018 against affiliates of Perrigo, alleging patent infringement arising out of ANDA submissions seeking approval to manufacture and sell a generic version of Bayer's Finacea® Foam prior to the expiry of patents licensed by Foamix to Bayer. For more information, (see "Part I, Item 1A-Risk Factors-Risks Related to Our Intellectual Property-We have received notice letters of ANDAs submitted for drug products that are generic versions of Finacea® Foam and we are involved in lawsuits to protect or enforce our patents, which could be expensive, time consuming and unsuccessful" in our most recent Annual Report on Form 10-K/A for the year ended December 31, 2017, as filed with the Securities and Exchange Commission on March 1, 2018). We consider such actions to be a part of the ordinary course of our business. We may become parties to additional litigation or other legal proceedings that we consider to be a part of the ordinary course of our business, and may also become involved in material legal proceedings.

## ITEM 1A. Risk Factors

There have been no material changes from the risk factors previously disclosed in "Part I, Item 1A—Risk Factors" of our Annual Report on Form 10-K/A for the year ended December 31, 2017, as filed with the Securities and Exchange Commission on March 1, 2018.

## ITEM 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

## ITEM 3. Defaults Upon Senior Securities

Not applicable.

## ITEM 4. Mine Safety Disclosures

Not applicable.

## ITEM 5. Other Information

None.

## ITEM 6. Exhibits

<u>Exhibit Number</u>	<u>Description Of Document</u>	<u>Form</u>	<u>SEC File No.</u>	<u>Exhibit</u>	<u>Filing Date</u>	<u>Filed Herewith</u>
3.1	<u>Amended and Restated Articles of Association of Foamix Pharmaceuticals Ltd.</u>					X
31.1						X

	<u>Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>	
<u>31.2</u>	<u>Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002</u>	X
<u>32.1*</u>	<u>Certification of the Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>	X
<u>32.2*</u>	<u>Certification of the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002</u>	X

101.INS	XBRL Instance Document	X
101.SCH	XBRL Taxonomy Extension Schema Document	X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	X
101.DEF	XBRL Taxonomy Extension Definition Document	X
101.LAB	XBRL Taxonomy Extension Label Document	X
101.PRE	XBRL Taxonomy Presentation Linkbase Document	X

\* These certifications are being furnished solely to accompany this quarterly report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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.

FOAMIX  
PHARMACEUTICALS  
LTD.

Date: November 7, 2018 By: /s/ David Domzalski  
David Domzalski  
Chief Executive Officer

Date: November 7, 2018 By: /s/ Ilan Hadar  
Ilan Hadar  
Chief Financial Officer