Foamix Reports First Quarter 2017 Financial Results and Provides Business Update

Conference Call and Webcast on Wednesday, May 10, 2017 at 8:30am Eastern / 5:30am Pacific

REHOVOT, Israel, May 9, 2017 /PRNewswire/ -- **Foamix Pharmaceuticals Ltd.** (NASDAQ: FOMX) ("Foamix Pharmaceuticals" or the "Company"), a clinical stage specialty pharmaceutical company focused on developing and commercializing proprietary topical foams to address unmet needs in dermatology, announced today financial results for the three months ended March 31, 2017.

Clinical, business and corporate developments for the three months ended March 31, 2017 and to date:

- On March 27, 2017, we provided the top-line data from our two Phase 3 clinical trials (Trial 04 and 05) for FMX101 in the treatment of moderate-to-severe acne. In the intent-to-treat analysis, FMX101 demonstrated statistical significance compared to vehicle on both co-primary endpoints in Trial 05 (specifically the absolute reduction in inflammatory lesions at week 12, and investigator global assessment (IGA) treatment success at week 12 compared to baseline). In Trial 04, statistical significance was demonstrated for FMX101 compared to vehicle in the co-primary endpoint of absolute reduction in inflammatory lesions, however, statistical significance was not achieved in the co-primary endpoint of IGA treatment success.
- On May 3, 2017, we provided new data from our two Phase 3 clinical trials for FMX101, including pooled analysis of our co-primary endpoints and certain secondary clinical endpoints (absolute reduction of non-inflammatory lesions at week 12; and percent change in inflammatory lesions at weeks 3, 6, 9 and 12). Highlights from our further analyses included:
    - Statistical significance was demonstrated for FMX101 compared to vehicle in the pooled analysis of both co-primary endpoints – absolute reduction of inflammatory lesions and Investigator's Global Assessment (IGA)
    - % Change in inflammatory lesion count was statistically significant in both Trials 04 and 05 at all timepoints (beginning at Week 3)
    - Non-inflammatory lesion count reduction at Week 12 was statistically significant in both Trials 04 and 05
    - Overall high level of patient satisfaction with FMX101 (based on patient satisfaction questionnaires).
    - FMX101 was generally safe and tolerable. No serious adverse events

drug-related systemic side effects were recorded.

- Further to sharing the detailed analyses, we announced that based on the results of the first two pivotal trials (Trial 04 and 05), we intend to conduct a third U.S. Phase 3 trial in patients with moderate-to-severe acne. This double-blind, vehicle-controlled trial is planned to enroll 1,500 patients who will be randomized 1:1 (FMX101 vs vehicle) across an estimated 80 investigator sites. The trial is expected to commence mid-year. If the results are positive, this trial will form the basis for a New Drug Application (NDA) which the company plans to submit in the second half of 2018.
- The two Phase 3 clinical trials for FMX103 in patients with moderate-to-severe papulopustular rosacea are expected to commence mid-2017. We also announced on May 3, 2017, that we plan to increase the sample size for each of the two Phase 3 trials from 600 to 750 patients (total of 1,500 patients) randomized 2:1 (FMX103 vs vehicle) across an estimated 80 investigator sites in the U.S. FMX103 demonstrated clinically and statistically significant efficacy in treating moderate-to-severe rosacea in a Phase 2 trial which enrolled 233 patients across 18 sites in Germany.
- During the first quarter of 2017 we successfully manufactured three registration-quality batches for FMX101.
- U.S. Sales of Finacea® Foam, azelaic acid 15% for the treatment of rosacea, continue to grow.
    - Based on sales of Finacea® Foam reported by Bayer HealthCare AG for Q1, 2017 Foamix is entitled to royalty payments of $927,000, up 26% from the fourth quarter of 2016.
    - Finacea® Foam was developed through a research and development collaboration between Foamix and Bayer, utilizing Foamix's proprietary foam technology platform. The drug was launched by Bayer in the USA in September 2015.

Financial highlights for the three months ended March 31, 2017:

- Total revenues were $927,000 compared with $745,000 for the three months ended March 31, 2016. The increase is due to increase in sales of Finacea® Foam by Bayer HealthCare AG.
- Research and development expenses were $12.7 million, compared with $3.6 million in the three months ended March 31, 2016. This increase resulted primarily from an increase in costs relating to the FMX101 and FMX103 clinical trials as well as an increase in payroll and related expenses due to an increase in the number of R&D employees.
- Selling, general and administrative expenses were $2.8 million, compared with $1.7 million in the three months ended March 31, 2016. The increase in

selling, general and administrative expenses resulted primarily from increases in payroll and other payroll-related expenses, market research costs, advisors, maintenance and office expenses.
- Operating expenses totaled $15.5 million, compared with $5.3 million in the three months ended March 31, 2016.
- Net loss was $14.4 million or $0.39 per share, basic and diluted, compared with a loss of $4.5 million or $0.15 per share, basic and diluted, for the three months ended March 31, 2016.
- Cash and investments as of March 31, 2017 totaled $118.7 million, compared with $131.0 million as of December 31, 2016.

Management overview

- On March 27, 2017, we provided the top-line data from our two Phase 3 clinical trials (Trial 04 and 05) for FMX101 in the treatment of moderate-to-severe acne. In the intent-to-treat analysis, FMX101 demonstrated statistical significance compared to vehicle on both co-primary endpoints in Trial 05 (specifically the absolute reduction in inflammatory lesions at week 12, and investigator global assessment (IGA) treatment success at week 12 compared to baseline). In Trial 04, statistical significance was demonstrated for FMX101 compared to vehicle in the co-primary endpoint of absolute reduction in inflammatory lesions, however, statistical significance was not achieved in the co-primary endpoint of IGA treatment success. On May 3, 2017, we provided new data from our two Phase 3 clinical trials for FMX101, including pooled analysis of our co-primary endpoints and certain secondary clinical endpoints (absolute reduction of non-inflammatory lesions at week 12; and percent change in inflammatory lesions at weeks 3, 6, 9 and 12). Statistical significance was demonstrated for FMX101 compared to vehicle in the pooled analysis of the co-primary endpoints as well as the secondary endpoints presented.

Co-primary endpoint - Absolute change from baseline in inflammatory lesion count at week 12:

- Trial 04: reduction of 14.16 lesions (or -14.16) for FMX101 and reduction of 11.17 lesions (or -11.17) for the vehicle ($p<0.01$)
- Trial 05: -13.46 for FMX101 and -10.72 for vehicle ($p<0.01$)
- *Pooled Analysis: Absolute change in inflammatory lesion count was -13.79 for the FMX101, 4% treatment group and -10.94 for vehicle (p=0.0001)*

Co-primary endpoint - Proportion of patients with Investigator's Global Assessment (IGA) success at week 12:

- Trial 04: IGA treatment success for FMX101, 4% treatment group was 8.09% versus 4.77% in vehicle (p=0.2178)
- Trial 05: IGA treatment success for FMX101, 4% treatment group was 14.67% versus 7.89% in vehicle (p<0.05)
- *Pooled Analysis: IGA treatment success was 11.51% for FMX101, 4% treatment group and 6.34% for vehicle (p<0.05)*

Secondary efficacy endpoint - Percent change from baseline in inflammatory lesion count at weeks 3, 6, 9 and 12:

- Trial 04: reduction of 29% for FMX101 vs. reduction of 19% for vehicle, or -29% vs. -19%, at week 3 (p<.001); -37% vs. -26% at week 6 (p<.001); -42% vs. -28% at week 9 (p<.0001); and -44% vs. -34% at week 12 (p<0.01)
- Trial 05: reduction of 34% for FMX101 vs. reduction of 21% for vehicle, or -34% vs. -21%, at week 3 (p<.0001); -39% vs. -27% at week 6 (p<.0001); -43% vs. -31% at week 9 (p<.001); and: -43% vs. -34% at week 12 (p<0.01)

Secondary efficacy endpoint – Absolute change from baseline in non-inflammatory lesion count at week 12:

- Trial 04: reduction of 16.45 lesions (or -16.45) for the FMX101, 4% treatment group and reduction of 10.30 lesions (or -10.30) for the vehicle (p<0.01)
- Trial 05: reduction of 13.20 (or -13.20) for the FMX101, 4% treatment group and reduction of 7.00 (or -7.00) for the vehicle (p<0.05)
- *Pooled Analysis: Absolute change in non-inflammatory lesion count was -14.76 for the FMX101, 4% treatment group and -8.64 for vehicle (p<0.01)*

- As we announced on May 3, 2017, based on the results of the first two pivotal trials (Studies 04 and 05), the company intends to conduct a third U.S. Phase 3 trial in patients with moderate-to-severe acne. If the results are positive, this trial will form the basis for an NDA which the company plans to submit in the second half of 2018. This planned clinical trial will be conducted at approximately 80 investigator sites in the U.S. In order to achieve the necessary statistical power compared with the prior Phase 3 trials, the target patient enrollment number has been increased to 1,500. Patients will be randomized 1:1 to receive either FMX101 (minocycline foam 4%) or vehicle foam once daily over 12 weeks. The co-primary efficacy endpoints will be identical to the prior Phase 3 trials: (1) mean change from baseline in the inflammatory lesion count, and (2) proportion of patients with IGA scores of "Clear" or "Almost Clear", with improvement of at least two grades from baseline. The inclusion criteria will be consistent with the prior Phase 3 trials.
- We intend to meet with the FDA to review the results of our Phase 3 clinical

trials for FMX101 (Trial 04 and 05) and our third Phase 3 trial, which we expect to commence mid-year.

- Following the results of the first two pivotal trials for FMX101 in moderate-to-severe acne, we have also reviewed our Phase 3 program for FMX103 in papulopustular rosacea, which is expected to commence around mid-2017. Based on the outcome of the Phase 3 studies for FMX101, and the planned increase in the number of patients to be enrolled in the third Phase 3 trial in acne, we also intend to increase the sample size for the two planned Phase 3 studies for FMX103 in papulopustular rosacea. The sample size will be increased from 600 patients per trial to 750 patients per trial, for a total of 1,500 patients across the two studies.
- Regarding manufacturing, we have successfully completed the scale-up process for FMX101 to a commercial batch size of one-ton. The production of three registration batches has been completed.
- In addition to our internal drug development pipeline, we have development and license agreements relating to our proprietary foam technology with other pharmaceutical companies, including Bayer Healthcare and others, in various stages of development and commercialization. Our agreements with these licensees entitle us to development fees, contingent payments and royalties upon commercialization.
- In September 2015, Bayer Healthcare began selling Finacea® Foam (azelaic acid 15% for the treatment of rosacea) in the U.S. Finacea® foam is a prescription foam product which was developed as part of a research and development collaboration between Foamix and Bayer, utilizing Foamix's proprietary foam technology platform. According to our license agreement with Bayer, we are entitled to royalties upon commercialization of Finacea Foam. For the three months ended March 31, 2017, we were entitled to royalties from Bayer in an amount of $927,000, up 26% from the fourth quarter of 2016.
- The Company is currently well-capitalized and has sufficient cash to fund our key development programs (FMX101 and FMX103) through NDA registration.

Financial results for the three months ended March 31, 2017

Revenues

Total revenues for the three-month ended March 31, 2017 were $927,000 compared with $745,000 for the three months ended March 31, 2016. The increase is due to increase in sales of Finacea® Foam by Bayer HealthCare AG.

Operating Expenses

Our operating expenses for the three months ended March 31, 2017, and three months ended March 31, 2016, were as follows:

Research and Development Expenses

Research and development expenses increased by $9.1 million, or 255%, from $3.6 million in the three months ended March 31, 2016, to $12.7 million in the three months ended March 31, 2017. The increase in research and development expenses resulted primarily from an increase of $7.9 million in costs relating to the FMX101 and FMX103 clinical trials and an increase of $1.1 million in payroll and payroll related expenses (including bonuses and equity-based compensation) due to an increase in the number of R&D employees.

Selling, General and Administrative Expenses

Selling, general and administrative expenses increased by $1.1 million, or 65%, from $1.7 million in the three months ended March 31, 2016, to $2.8 million in the three months ended March 31, 2017. The increase in selling, general and administrative expenses resulted primarily from an increase of $300,000 in payroll and other payroll-related expenses (including bonuses and equity-based compensation), an increase of $250,000 in advisors, consultants and other professional services, $102,000 in market research costs and $122,000 in rent, maintenance and office expenses.

Finance Income, Net

For the three months ended March 31, 2017, we recorded financial income of $257,000 compared to financial income of $174,000 recorded for the three months ended March 31, 2016. The financial income for the three months ended March 31, 2017 and 2016 resulted mostly from interest and financial gains from our cash investments.

Net Loss

For the three months ended March 31, 2017, we recorded a loss of $14.4 million or $0.39 per share, basic and diluted, compared with a loss of $4.5 million or $0.15 per share, basic and diluted, for the three months ended March 31, 2016.

Liquidity and Capital Resources

As of March 31, 2017, we had cash and investments of $118.7 million, compared

with $131.0 million as of December 31, 2016. The decrease was mostly due to operating expenses primarily relating to the clinical trials. During the three months ended March 31, 2017 we used $12.1 million in cash in our operations compared to $7.0 million used in operating activities in the three months ended March 31, 2016.

Conference Call

Management will host an investment community conference call on May 10, 2017 at 8:30 a.m. Eastern / 5:30 a.m. Pacific / 3:30 p.m. Israel to discuss these results and answer questions. Shareholders and other interested parties may participate in the conference call by dialing Domestic: 888-438-5519; International: +1-719-457-1506. Conference ID: 2254081. Webcast: http://public.viavid.com/index.php?id=124151

A replay of the call will be accessible two hours after its completion through May 24, 2017 by dialing Domestic: 844-512-2921; International: +1-412-317-6671; Passcode: 2254081. The call will also be archived for 90 days at www.streetevents.com and www.foamixpharma.com.

About Foamix

Foamix is a specialty pharmaceutical company focused on the development and commercialization of proprietary, innovative and differentiated topical drugs for dermatological therapy. Our clinical stage product candidates include FMX101, our novel minocycline foam for the treatment of moderate-to-severe acne, FMX102 for the treatment of impetigo, FMX 103 for the treatment of rosacea and FDX104, our doxycycline foam for the management of acne-like rash induced by EGFRI anticancer drugs.

In addition, we have development and license agreements relating to our technology with various pharmaceutical companies including Bayer HealthCare and others.

Cautionary Note Regarding Forward-Looking Statements

This release includes forward-looking statements within the meaning of Section 27A of the U.S. Securities Act of 1933, as amended, Section 21E of the U.S. Securities Exchange Act of 1934, as amended, and the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts, such as statements regarding assumptions, expectations, forecasts, beliefs or intentions related to

financial results, commercial results, timing and results of clinical trials and U.S. FDA and other regulatory agencies authorizations. Forward-looking statements are based on our current knowledge and our present beliefs and expectations regarding possible future events and are subject to risks, uncertainties and assumptions. Actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of various factors including, but not limited to, unexpected delays, excess costs or unfavorable results of clinical trials, delays or denial in the U.S. FDA approval process, additional competition in the acne market, denial of reimbursement by third party payors or inability to raise additional capital. We discuss many of these risks in greater detail under the heading "Risk Factors" in our most recent Annual Report on Form 20-F (File No. 17625089) filed on February 21, 2017, and elsewhere in that Annual Report. Although we believe these forward-looking statements are reasonable, they speak only as of the date of this announcement and Foamix undertakes no obligation to update publicly such forward-looking statements to reflect subsequent events or circumstances, except as otherwise required by law. Given these risks and uncertainties, you should not rely upon forward-looking statements as predictions of future events.

Finacea® is a registered trademark of Bayer Healthcare.

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FOAMIX PHARMACEUTICALS LTD.

CONSOLIDATED BALANCE SHEETS

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

(Unaudited)

	March 31 2017	**December 31 2016**
A s s e t s		
CURRENT ASSETS:		
Cash and cash equivalents	$26,157	$31,190

Restricted cash	250	250
Short term bank deposits	38,488	38,351
Investment in marketable securities	35,875	43,275
Restricted investment in marketable securities	276	261
Accounts receivable:		
Trade	2,413	3,236
Other	1,718	438
TOTAL CURRENT ASSETS	105,177	117,001
NON-CURRENT ASSETS:		
Investment in marketable securities	17,529	17,532
Restricted investment in marketable securities	137	129
Property and equipment, net	1,084	938
Other	35	35
TOTAL NON-CURRENT ASSETS	18,785	18,634
TOTAL ASSETS	$123,962	$135,635

FOAMIX PHARMACEUTICALS LTD.

CONSOLIDATED BALANCE SHEETS

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

(Unaudited)

	March 31, 2017	**December 31, 2016**

Liabilities and shareholders' equity		
CURRENT LIABILITIES:		
Current maturities of bank borrowing	$13	$20
Accounts payable and accruals:		
Trade	5,061	2,267
Other	1,873	2,984
TOTAL CURRENT LIABILITIES	6,947	5,271
LONG-TERM LIABILITIES:		
Liability for employee severance benefits	470	379
TOTAL LONG-TERM LIABILITIES	470	379
TOTAL LIABILITIES	7,417	5,650
COMMITMENTS (Note 6)		
SHAREHOLDERS' EQUITY:		
Ordinary Shares, NIS 0.16 par value - authorized: 50,000,000 Ordinary Shares as of March 31, 2017 and December 31, 2016; issued and outstanding: 37,223,485 and 37,167,791 Ordinary Shares as of March 31, 2017 and December 31, 2016, respectively	1,564	1,561
Additional paid-in capital	204,952	204,052
Accumulated deficit	(89,950)	(75,566)
Accumulated other comprehensive loss	(21)	(62)
TOTAL SHAREHOLDERS' EQUITY	116,545	129,985
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$123,962	$135,635

FOAMIX PHARMACEUTICALS LTD.

CONSOLIDATED STATEMENTS OF OPERATIONS

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

(Unaudited)

	Three months ended March 31,	
	2017	**2016**
REVENUES	$927	$745
COST OF REVENUES	-	31
GROSS PROFIT	927	714
OPERATING EXPENSES:		
Research and development	12,675	3,566
Selling, general and administrative	2,822	1,710
TOTAL OPERATING EXPENSES	15,497	5,276
OPERATING LOSS	14,570	4,562
FINANCE INCOME, net	(257)	(174)
LOSS BEFORE INCOME TAX	14,313	4,388
INCOME TAX	71	120
NET LOSS FOR THE PERIOD	$14,384	$4,508
LOSS PER SHARE BASIC AND DILUTED	$0.39	$0.15
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING USED IN COMPUTATION OF BASIC AND DILUTED LOSS PER SHARE IN THOUSANDS	37,188	30,654

FOAMIX PHARMACEUTICALS LTD.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(U.S. dollars in thousands)

(Unaudited)

	Three months ended March 31,	
	2017	**2016**
NET LOSS	$14,384	$4,508
OTHER COMPREHENSIVE INCOME:		
Net unrealized gains from marketable securities	(6)	(156)
Gains on marketable securities reclassified into net loss	-	2
Net unrealized gains on derivative financial instruments	(75)	(78)
Gains on derivative financial instruments reclassified into net loss	40	4
TOTAL OTHER COMPREHENSIVE INCOME	(41)	(228)
TOTAL COMPREHENSIVE LOSS	$14,343	$4,280

FOAMIX PHARMACEUTICALS LTD.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(U.S. dollars in thousands)

(Unaudited)

	Three months ended March 31,	
	2017	**2016**
CASH FLOWS FROM OPERATING ACTIVITIES:		

Net Loss	$(14,384)	$(4,508)
Adjustments required to reconcile net loss to net cash used in		
operating activities:		
Depreciation and amortization	44	30
Loss from disposal of fixed assets	102	
Changes in marketable securities and bank deposits, net	96	(2)
Changes in accrued liability for employee severance benefits,		
net of retirement fund profit	91	22
Share-based compensation	766	533
Non-cash finance expenses (income), net	(47)	2
Changes in operating asset and liabilities:		
Increase in trade and other receivable	(392)	(2,346)
Increase (decrease) in accounts payable and accruals	1,671	(759)
Net cash used in operating activities	(12,053)	(7,028)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of fixed assets	(280)	(115)
Investment in bank deposits	(13,207)	(13,000)
Investment in marketable securities	(2,913)	(700)
Proceeds from sale and maturity of marketable securities and bank deposits	23,273	21,149

Net cash provided by investing activities	6,873	7,334
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of options	137	-
Payments in respect of bank borrowings	(8)	(8)
Net cash provided by financing activities	129	(8)
INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(5,051)	298
EFFECT OF EXCHANGE RATE ON CASH, CASH EQUIVALENTS AND RESTRICTED CASH	18	9
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT BEGINNING OF THE PERIOD	31,440	18,795
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF THE PERIOD	$26,407	$19,102
Cash and cash equivalents	$26,157	$19,102
Restricted cash	250	-
TOTAL CASH, CASH EQUIVALENTS AND RESTRICTED CASH SHOWN IN STATEMENT OF CASH FLOWS	$26,407	$19,102
SUPPLEMENTARY INFORMATION ON INVESTING AND FINANCING ACTIVITIES NOT INVOLVING CASH FLOWS -		
Property and equipment purchases included in accounts payable and accruals	$39	$-
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION:		
Cash paid for taxes	$-	$91
Interest received	$178	$-
Interest paid		

$*-	$*-

* Represents an amount less than $1.

SOURCE Foamix Pharmaceuticals Ltd

Additional assets available online: Photos (1)

http://investors.foamixpharma.com/2017-05-09-Foamix-Reports-First-Quarter-2017-Financial-Results-and-Provides-Business-Update