# Foamix Reports Third Quarter 2018 Financial Results and Provides Corporate Update

November 7, 2018

**Conference Call and Webcast Thursday, November 8, @ 8.30 am Eastern Time**

REHOVOT, Israel, Nov. 07, 2018 (GLOBE NEWSWIRE) -- Foamix Pharmaceuticals Ltd. (NASDAQ: FOMX) ("Foamix" 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 its financial results for the third quarter and nine months ended September 30, 2018.

"We have recently made very substantial progress in the clinic with positive Phase 3 top line data on our two lead programs, FMX101 for the treatment of moderate-to-severe acne, and FMX103 for moderate-to-severe papulopustular rosacea," said David Domzalski, CEO of Foamix. "The success of these programs provides further validation for our proprietary foam platform and sets us on a path to potentially have 2 products approved within a year of each other. Our clinical and regulatory teams are now focused on completing the necessary steps to prepare regulatory submissions, beginning with a planned NDA for FMX101 in the U.S. before year-end 2018. We hope to follow this, pending the outcome of the ongoing long-term safety study, with an NDA for FMX103 in 2019."

**Clinical and Corporate Update:**

- On November 7th, announced the topline results from its Phase 3 program evaluating FMX103 1.5% minocycline foam, in the treatment of moderate-to-severe papulopustular rosacea.
  - Studies FX2016-11 and FX2016-12 met both co-primary endpoints of (1) absolute change from baseline in inflammatory lesion count at Week 12, and (2) Investigator Global Assessment ("IGA") treatment success at Week 12, defined as an IGA score of 0 or 1, and at least a 2-grade improvement (decrease) from baseline.
  - FMX103 was found to be generally safe and well tolerated.
  - Data from study FX2016-13 evaluating the long-term safety of FMX103 are expected to be reported in the first half of 2019.
  - The Company plans to file a New Drug Application (NDA) for FMX103 as a treatment for moderate-to-severe papulopustular rosacea in 2019.
- In September, announced positive topline results of its third Phase 3 clinical trial (FX2017-22) of FMX101 for the treatment of moderate-to-severe acne.
  - The study met both co-primary endpoints of: (1) absolute change from baseline in inflammatory lesion count at Week 12, and (2) Investigator Global Assessment ("IGA") treatment success at Week 12, with statistical significance.
  - The safety profile of FMX101 was found to be consistent with that determined from the two prior Phase 3 studies (FX2014-04 and FX2014-05).
  - The Company expects to file an NDA with the FDA for FMX101 in moderate-to-severe acne by the end of 2018.
- In September, the Company completed a follow-on offering in which 13,420,500 Ordinary Shares were sold, which included the full exercise by the underwriters of their option to purchase additional Ordinary Shares. The net proceeds, net of expenses and underwriter commissions, were approximately $75.3 million.

***Cash & Investments***

At September 30, 2018, the Company had $110.5 million in cash and investments compared to $76.4 million at December 31, 2017. The Company anticipates that with its existing cash and investments will be sufficient to fund 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 the Company expects to submit by the end of 2018, (b) completion of its two Phase 3 clinical trials for FMX103, (c) full development and filing of an NDA for FMX103, which the Company expects to submit in 2019, (d) certain pipeline development activities, and (e) certain pre-commercialization and launch preparations for FMX101 towards the end of 2019.

**Financial Results for the Third Quarter Ended September 30, 2018**

***Revenues***

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.

***Operating Expenses***

*Research and Development Expenses*

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*
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 the Company's board of directors.

***Net Loss***
The loss for the three months ended September 30, 2018 was $15.5 million, or ($0.38) per share, basic and diluted, compared to $17.6 million, or ($0.47) per share, basic and diluted, for the three months ended September 30, 2017, a decrease of $2.1 million.

**Financial Results for the Nine Months Ended September 30, 2018**
***Revenues***
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 increase in royalty payments from Bayer and LEO for sales of Finacea.

***Operating Expenses***
*Research and Development Expenses*
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 the company's co-founders in the nine months ended September 30, 2017.

*Selling, General and Administrative Expenses*
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 the Company's board of directors. Such increases were offset by (i) a decrease of $1.5 million in compensation to one of the company's co-founders in the nine months ended September 30, 2017, and (ii) a decrease of $201,000 in travel expenses.

***Net Loss***
Net loss for the nine months ended September 30, 2018 was $60.1 million, or ($1.50) per share, basic and diluted, compared to a net loss of $48.4 million, or ($1.29) per share, basic and diluted, for the nine months ended September 30, 2017, an increase of $11.7 million.

***Conference Call & Webcast Thursday, November 8 @ 8:30am Eastern Time***

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|---|---|
| Toll Free: | 866-548-4713 |
| International: | 323-794-2093 |
| Conference ID: | 3929053 |
| Webcast: | http://public.viavid.com/index.php?id=131716 |

*Replays, Available through November 22:*

| | |
|---|---|
| Toll-Free: | 844-512-2921 |
| International: | 412-317-6671 |
| Conference ID: | 3929053 |

A replay will also be archived on the Company's website at www.foamix.com promptly after the conference call.

**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 leading clinical stage product candidates are FMX101, our novel minocycline foam for the treatment of moderate-to-severe acne and FMX103, our novel minocycline foam for the treatment of rosacea. We continue to pursue research & development of our proprietary, innovative foam technologies for the treatment of various skin conditions. We currently have development and license agreements relating to our technology with various pharmaceutical companies including LEO Pharma and others.

Foamix uses its website (www.Foamix.com) as a channel to distribute information about Foamix and its product candidates from time to time. Foamix may use its website to comply with its disclosure obligations under Regulation FD. Therefore, investors should monitor the Foamix website in addition to following its press releases, filings with the Securities & Exchange Commission ("SEC"), public conference calls, and webcasts.

**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 created by those sections. 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 in clinical trials or announcement of results, excess costs or unfavorable results of clinical trials, delays or denial in the U.S. FDA approval process, additional competition in the acne and dermatology markets, denial of reimbursement by third party payors or inability to raise additional capital, our ability to recruit and retain key employees and our ability to stay in compliance with applicable laws, rules and regulations. We discuss many of these risks in greater detail in our annual and other periodic filings with the SEC, including

under the heading “Risk Factors” in our most recent 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.


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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 |
|---|---|---|
| A s s e t s | | |
| 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 | 15,041 | 31,797 |
| Restricted investment in marketable securities | 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 | 793 | 8,533 |
| Restricted investment in marketable securities | 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 |

| | 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 |

| | | | | |
|---|---|---|---|---|
| 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 | |

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 | $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 |

Source: Foamix, Ltd.