

August 4, 2016



## Dipexium Pharmaceuticals Reports Second Quarter 2016 Financial Results

### **-Management to Host Conference Call Today, August 4, 2016, at 8:30 a.m. ET-**

NEW YORK, Aug. 4, 2016 /PRNewswire/ -- Dipexium Pharmaceuticals, Inc. (Nasdaq: DPRX), a late-stage pharmaceutical company focused on the development and commercialization of Locilex® (pexiganan cream 0.8%), a novel, broad-spectrum, topical antibiotic peptide, today reported financial results for the quarter ended June 30, 2016.

"In the second quarter we completed enrollment in the OneStep-1 and OneStep-2 pivotal Phase 3 clinical trials of Locilex in patients with mild infections of diabetic foot ulcers (Mild DFI) and expect to have top-line data in September. Pending the results of these trials, we anticipate submitting a New Drug Application to the U.S. Food and Drug Administration and a Marketing Authorization Application to the European Medicines Agency in the first half of 2017," said David P. Luci, President and CEO of Dipexium Pharmaceuticals. "Based on our market research, there is a significant unmet medical need for a non-invasive, topical treatment for Mild DFI with the target product profile of Locilex. If approved, Locilex, has the potential to be the first product specifically approved in the U.S. for the treatment of patients with Mild DFI."

### **Financial Results for the Second Quarter of 2016**

For the three months ended June 30, 2016, Dipexium reported a net loss of \$5.4 million, compared to a net loss of \$4.0 million for the three months ended June 30, 2015, an increase of \$1.4 million. The change was primarily due to a \$0.9 million increase in Phase 3 clinical trial enrollment and related clinical trial expenses, and \$0.5 million of increased manufacturing expenses relating to validation batches.

For the six months ended June 30, 2016, Dipexium reported a net loss of \$11.2 million, compared to a net loss of \$8.2 million for the six months ended June 30, 2015, an increase of \$3.0 million. This change was primarily due to a \$3.3 million increase in research and development expenses partially offset by a \$0.3 million decrease in selling, general, and administrative expenses. The increase in research and development expenses were due to \$2.7 million of increased Phase 3 trial enrollment and related clinical trial expenses, and a \$0.6 million increase in manufacturing expenses relating to validation batches. The decrease in general and administrative expenses is primarily attributable to a decrease of \$0.2 million for stock-based compensation expenses and a \$0.1 million decrease in professional fees.

Net cash used in operating activities for the six months ended June 30, 2016 was \$9.7 million versus \$6.2 million for the six months ended June 30, 2015. The increase in cash used in operating activities is primarily attributable to increased research and development expenses associated with increased Phase 3 trial enrollment and related clinical trial expenses.

At June 30, 2016, the Company had cash and short-term investments of \$22.6 million, compared to \$32.2 million at December 31, 2015. The Company's cash balance is currently anticipated to fund operations through 2017.

### **Conference Call & Webcast Information**

Dipexium will host a conference call today beginning at 8:30 a.m. Eastern Time, during which management will discuss Dipexium's financial results and recent developments. Access to the live call is available by dialing 877-407-8012 (U.S. & Canada) or 412-902-1013 (international) five minutes prior to the start of the call. A live and archived audio webcast of the conference call can be accessed through the Investor Relations section of the Company's website at [www.dipexiumpharmaceuticals.com](http://www.dipexiumpharmaceuticals.com), under the IR Calendar tab. The archived webcast will remain available on the Company's website for 30 days following the call.

### **About Dipexium Pharmaceuticals**

Dipexium Pharmaceuticals, Inc. (NASDAQ: DPRX) is a late-stage pharmaceutical company focused on the development and commercialization of Locilex (pexiganan cream 0.8%), a novel, broad-spectrum, topical antibiotic peptide. Initially, Locilex is targeted for the treatment of mild infections of diabetic foot ulcers. Based on a compilation of available clinical and microbiology data, Dipexium also considers Locilex to be a promising product candidate to treat other mild and moderate skin and skin structure infections, including infected decubitus ulcers, infected burns, infected surgical wounds, infected animal bites, and nasal colonization of methicillin-resistant *staphylococcus aureus* (MRSA). For more information, visit [www.dipexiumpharmaceuticals.com](http://www.dipexiumpharmaceuticals.com).

## Forward-Looking Statements

This press release may contain, in addition to historical information, forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements may include statements relating to our anticipated clinical and regulatory development of our product candidate, including development for the European market and development of an intravenous formulation; our cash position; cash flows; business strategies and initiatives; and other matters. We have based these forward-looking statements on the assumptions, expectations and projections about future events that we hold at the time the statements are made. We use words like "believe," "anticipate," "intend," "estimate," "expect," "project" and similar expressions to identify forward-looking statements, although not all forward-looking statements contain these words. These forward-looking statements are necessarily estimates reflecting the best judgment of our senior management and involve a number of risks and uncertainties that could cause actual results to differ materially from those suggested by the forward-looking statements.

Investors should consider the information contained in our filings with the U.S. Securities and Exchange Commission (the "SEC"), including our Annual Report on Form 10-K, especially in the "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Risk Factors" sections, our most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K. Other unknown or unpredictable factors also could have material adverse effects on our future results, performance or achievements. In light of these risks, uncertainties, assumptions and factors, the forward-looking events discussed in this press release may not occur. You are cautioned not to place undue reliance on these forward-looking statements, which reflect our beliefs at the time the statements are made. We do not undertake any obligation to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, nor any other information provided in a conference call, webcast, news release, SEC filing or website.

### DIPEXIMUM PHARMACEUTICALS, INC. CONDENSED BALANCE SHEETS

	June 30, 2016	December 31, 2015
	(unaudited)	
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash	\$ 7,586,270	\$ 5,234,953
Short-term Investments	14,983,711	26,977,362
Prepaid Expenses	207,559	146,145
<b>TOTAL CURRENT ASSETS</b>	<b>22,777,540</b>	<b>32,358,460</b>
<b>OTHER ASSETS</b>		
Security Deposit	56,630	49,385
<b>TOTAL OTHER ASSETS</b>	<b>56,630</b>	<b>49,385</b>
<b>TOTAL ASSETS</b>	<b>\$ 22,834,170</b>	<b>\$ 32,407,845</b>

### LIABILITIES AND SHAREHOLDERS' EQUITY

CURRENT LIABILITIES		
Accounts Payable and Accrued Expenses	\$ 945,357	\$ 1,606,307
TOTAL LIABILITIES	<u>945,357</u>	<u>1,606,307</u>
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY		
Common Stock: \$.001 par value, 30,000,000 shares authorized, 10,351,613 and 10,301,114 shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively		
	10,351	10,301
Additional paid-in capital	74,164,907	71,852,692
Accumulated deficit	<u>(52,286,445)</u>	<u>(41,061,455)</u>
TOTAL SHAREHOLDERS' EQUITY	<u>21,888,813</u>	<u>30,801,538</u>
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	<u>\$ 22,834,170</u>	<u>\$ 32,407,845</u>

**DIPEXIMUM PHARMACEUTICALS, INC.**  
**CONDENSED STATEMENTS OF OPERATIONS**  
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
<u>REVENUES</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ -</u>
<u>EXPENSES</u>				
OPERATING EXPENSES				
Research and Development Expenses	3,700,913	2,290,266	7,284,581	3,999,665
Selling, General and Administrative Expenses	<u>1,722,230</u>	<u>1,744,257</u>	<u>3,969,438</u>	<u>4,222,684</u>
TOTAL OPERATING EXPENSES	<u>5,423,143</u>	<u>4,034,523</u>	<u>11,254,019</u>	<u>8,222,349</u>
LOSS FROM OPERATIONS	(5,423,143)	(4,034,523)	(11,254,019)	(8,222,349)
Interest Income	<u>14,786</u>	<u>2,615</u>	<u>29,029</u>	<u>3,208</u>
NET LOSS	<u>\$ (5,408,357)</u>	<u>\$ (4,031,908)</u>	<u>\$ (11,224,990)</u>	<u>\$ (8,219,141)</u>
LOSS PER SHARE				
Basic and diluted net loss per common share	<u>\$ (0.52)</u>	<u>\$ (0.47)</u>	<u>\$ (1.09)</u>	<u>\$ (0.96)</u>
Weighted average common shares outstanding basic and diluted	<u>10,339,514</u>	<u>8,584,554</u>	<u>10,327,620</u>	<u>8,568,441</u>

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