

TARO PHARMACEUTICAL INDUSTRIES LTD

Form 6-K

January 06, 2003

SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER  
PURSUANT TO RULE 13A-16 OR 15D-16  
OF THE SECURITIES EXCHANGE ACT OF 1934

For the month of December 2002

Taro Pharmaceutical Industries Ltd.

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(Translation of registrant's name into English)

14 Hakitor Street, Haifa Bay 26110, Israel

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(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F  Form 40-F

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934. Yes  No

The following is included in this Report on Form 6-K:

1. Press release dated December 19, 2002.

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TARO PHARMACEUTICAL INDUSTRIES LTD.  
C/O TARO PHARMACEUTICALS U.S.A., INC.  
Five Skyline Drive  
Hawthorne, New York 10532  
(Nasdaq/NMS: TARO)

AT THE COMPANY  
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Daniel Saks  
Vice President, Corporate Affairs  
(914) 345-9000 ext. 208

Kevin Connelly  
Chief Financial Officer  
(914) 345-9000 ext. 338

FOR IMMEDIATE RELEASE  
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THURSDAY, DECEMBER 19, 2002

TARO RECEIVES APPROVAL FOR KETOCONAZOLE CREAM, 2% ANDA

AMIODARONE TABLETS, 100 MG AND 400 MG ANDA ALSO APPROVED

HAWTHORNE, NY, DECEMBER 19, 2002 - Taro Pharmaceutical Industries Ltd. (Nasdaq/NMS: TARO) reported today that the Company has received approval from the U.S. Food and Drug Administration ("FDA") for its Abbreviated New Drug Application ("ANDA") for Ketoconazole Cream, 2% ("Ketoconazole Cream").

Taro's Ketoconazole Cream is bioequivalent to Nizoral(R) Cream, a product of Janssen Pharmaceutica Products, L.P. Nizoral is a prescription pharmaceutical product used primarily for the treatment of fungal infections of the skin. According to industry sources, the annual U.S. market for Ketoconazole Cream is approximately \$54 million.

"Ketoconazole Cream is an important addition to Taro's line of antifungal products and strengthens our leadership position in the U.S. topical prescription market," said Barrie Levitt, M.D., Chairman of the Company.

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Taro Pharmaceutical Industries Ltd.  
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AMIODARONE HCL TABLETS, 100 MG AND 400 MG ANDA APPROVED

The Company has also received FDA approval for its ANDA for Amiodarone Tablets, 100 mg and 400 mg. Amiodarone is used in treating atrial fibrillation and other cardiovascular conditions. While the 400 mg tablet is bioequivalent to Upsher-Smith's Pacerone(R) Tablets, Taro believes it is currently the only company with a 100 mg Amiodarone Tablet. In 2001, Taro received ANDA approval for 200 mg Amiodarone Tablets.

"By offering the choice among 100 mg, 200 mg and 400 mg Amiodarone Tablets, Taro hopes to enable physicians to simplify dosing regimens and more easily tailor treatment to the needs of individual patients," Dr. Levitt stated.

Taro currently has 16 ANDAs on file with the FDA, including one tentative

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approval. In addition, the Company has multiple regulatory filings in Canada, Israel and other countries around the world.

Taro is a multinational, science-based pharmaceutical company dedicated to meeting the needs of its customers through the discovery, development, manufacturing and marketing of the highest quality healthcare products.

For further information on Taro Pharmaceutical Industries Ltd., please visit the Company's website at [www.taro.com](http://www.taro.com).

Certain statements in this release are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Although Taro Pharmaceutical Industries Ltd. believes the expectations reflected in such forward-looking statements to be based on reasonable assumptions, it can give no assurance that its expectations will be attained. Factors that could cause actual results to differ include industry and market conditions, slower than anticipated penetration of new markets, marketplace acceptance of Taro's generic Ketoconazole Cream, 2% or Amiodarone Tablets, 100 mg, 200 mg and 400 mg, the future size of the market for these four products, changes in the Company's financial position, regulatory actions, and other risks detailed from time to time in the Company's SEC reports, including its 2001 Annual Report on Form 20-F.

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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.

Taro Pharmaceutical Industries Ltd.

Date: January 6, 2003

By: /s/ Kevin Connelly

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Kevin Connelly  
Senior Vice President and Chief  
Financial Officer