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TARO PHARMACEUTICAL INDUSTRIES LTD

Form 6-K

December 03, 2002

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 November 2002

Taro Pharmaceutical Industries Ltd.

(Translation of registrant's name into English)

14 Hakitor Street, Haifa Bay 26110, Israel

(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 November 26, 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)

TARO NEWS

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

TUESDAY, NOVEMBER 26, 2002

TARO RECEIVES APPROVAL FOR ECONAZOLE NITRATE CREAM 1% ANDA Generic Equivalent to Spectazole(R) Cream

HAWTHORNE, NY, NOVEMBER 26, 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 Econazole Nitrate Cream 1% ("Econazole Cream").

Taro's Econazole Cream is bioequivalent to Ortho Dermatological's Spectazole(R) Cream. This prescription pharmaceutical is used primarily in treating fungal infections of the skin. Taro believes it has the first U.S. approval to manufacture and market a generic equivalent to Spectazole(R).

According to industry sources, U.S. sales of Spectazole(R) Cream were approximately \$54 million in 2001. Taro is a leader in the U.S. markets for topical corticosteroids and antifungal medications, including both prescription and over-the-counter drugs.

"This approval again demonstrates Taro's ability to conduct the extensive clinical studies required by the FDA for approval of topical antifungal products," said Barrie Levitt, M.D., Chairman of the Company.

Taro currently has 17 ANDAs on file with the U.S. Food and Drug Administration, including one tentative 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.

Certain statements in this release may be 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 generic Econazole Cream, the future size of the market for Econazole Cream, 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: December 2, 2002

By:/s/ Kevin Connelly

Kevin Connelly
Senior Vice President and Chief
Financial Officer