TARO PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
May 02, 2016

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 6-K
REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of May, 2016

Commission File Number 001-35463
Taro Pharmaceutical Industries Ltd.
(Translation of registrant's name into English)

14 Hakitor Street, Haifa Bay 2624761, 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 if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): _____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): _____

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

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-_____.

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.
Date: May 2, 2016
TARO PHARMACEUTICAL INDUSTRIES LTD.

By: /s/ Subramanian Kalyanasundaram
Name: Subramanian Kalyanasundaram
Title: Chief Executive Officer and Director

Taro Pharmaceutical Industries Ltd.
c/o Taro Pharmaceuticals U.S.A., Inc.
Three Skyline Drive
Hawthorne, New York 10532
(NYSE: TARO)

FOR IMMEDIATE RELEASE

CONTACT:
William J. Coote
(914) 345-9001
William.Coote@taro.com

TARO TO MAKE KEVEYIS™ AVAILABLE TO DISTRIBUTORS FREE OF COST

Effort Seeks to Address Needs of People with Periodic Paralysis, an Ultra Rare Disease

Hawthorne, NY, May 2, 2016 – Taro Pharmaceutical Industries Ltd. (NYSE: TARO) ("Taro" or the "Company") today announced that its U.S. subsidiary, Taro Pharmaceuticals U.S.A., Inc., will now make Keveyis™ (dichlorphenamide) available to distributors at no cost for the treatment of primary periodic paralysis, an ultra-rare and debilitating disease. As a result, Taro will cease commercial sales and related promotional activities for Keveyis and bear all costs associated with its manufacture. In the near term, patients will continue to receive the medicine through Diplomat as the Company evaluates the best option for keeping pharmacy dispensing fees to patients as low as possible.

"We embarked on this decade-long journey to help a patient community in need and we are proud that it resulted in Keveyis, the first medicine approved for the treatment of periodic paralysis," said Kal Sundaram, Chief Executive Officer of Taro USA. "Through heartfelt testimonials, patients have told us how their lives have changed for the better thanks to this treatment being available. This decision extends our desire to ensure that anyone with a prescription will continue to have access to the medicine regardless of insurance status or ability to pay."

In establishing the original price for Keveyis, Taro sought to balance the investment needed to educate the patient and physician community about a largely unknown disease while also ensuring that access to patients wasn't hindered. Through its Keys2Care support program, patients have had an average out-of-pocket cost of less than $25 per month. For some, treatment has been free through the Company's Patient Assistance Program.

Although Taro expected to treat only a few hundred patients with Keveyis, it has become clear that reaching such a small pool of people is more difficult than previously anticipated. Among the 5,000 people estimated to be living with Periodic Paralysis, less than 1,500 are believed to be diagnosed.[1] Among these patients, a mix of lifestyle modifications and medicines prescribed off-label are often used to manage their disease. While we have continued to invest significantly in this effort, sales have been less than one million dollars since launch.

Given the high costs and resources required to identify and reach a limited number of viable patients, Taro realizes that it cannot sustain its current level of investment. Based on these learnings, Taro now believes that it can better serve all stakeholders, including patients, by ceasing commercial sales and related promotional activities for Keveyis.

About Periodic Paralysis

Periodic paralyses are a group of rare hereditary disorders that cause episodes of muscle weakness or paralysis. Many patients often endure decades of diagnostic 'missteps,' with a significant delay between the onset of symptoms and diagnosis.[2][3] Types of periodic paralyses are differentiated by criteria including underlying genetic mutations and changes in blood-potassium during attack. Hypokalemic and hyperkalemic are two common types of periodic paralyses.[4]

About Keveyis

Keveyis is indicated for the treatment of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants.

IMPORTANT SAFETY INFORMATION

In clinical studies, the most common side effects of Keveyis were a burning or pricking sensation, difficulty thinking and paying attention, changes in taste, and confusion. These are not all of the possible side effects that you may experience with Keveyis. Talk to your doctor if you have any symptoms that bother you or do not go away.

Keveyis is not for everyone. Do not take Keveyis if you:

- Are on a high-dose aspirin regimen
- Are allergic to sulfa-based drugs
- Have liver, kidney, or certain lung conditions
- Are pregnant, planning to become pregnant, or nursing
- Are under 18 years old

Taking Keveyis may cause a drop in the amount of potassium (an electrolyte) in your body, which can lead to heart problems. Ask your doctor if you need to eat foods that contain high amounts of potassium while taking Keveyis.

Your body may produce too much acid or may not be able to remove enough acid from body fluids while taking Keveyis. Your doctor will run tests on a regular basis to check for signs of acid buildup and may reduce your dose or stop your treatment with Keveyis.

Keveyis may also increase the risk of falls, especially in elderly patients and patients taking high doses of Keveyis. Use caution when driving, operating machinery, or performing any other hazardous activities while taking Keveyis, as this medication may cause drowsiness.

Tell your doctor if you experience worsening of your periodic paralysis symptoms.

For additional safety information, please see Full Prescribing Information at www.keveyis.com.

The release will be accessible on Taro’s website at www.taro.com.

About Taro

Taro Pharmaceutical Industries Ltd. 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.

SAFE HARBOR STATEMENT

Certain statements in this release may be considered forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements that do not describe historical facts or that refer or relate to events or circumstances that the Company “estimates,” “believes,” or “expects” to happen or similar language. Although the Company believes the expectations reflected in such forward-looking statements to be based on reasonable assumptions, it can give no assurances that its expectations will be attained. Factors that could cause actual results or events to differ include risks related to industry, market and regulatory conditions, delays or prevention caused by governmental regulation of pharmaceutical products, and other risks detailed from time to time in the Company’s SEC reports, including its Annual Reports on Form 20-F. Forward-looking statements are applicable only as of the date on which they are made. The Company undertakes no obligations to update, change or revise any forward-looking statement, whether as a result of new information, additional or subsequent developments or otherwise.

References

[1] inVentiv Health, United Health Claims Database Analysis, October 2014.

[2] Charles, G., Zheng, C., Lehmann-Horn, F., Jurkat-Rott, K., & Levitt, J. (2013). Characterization of hyperkalemic periodic paralysis: a survey of genetically diagnosed individuals. Journal of Neurology, 260(10), 2606–2613.

[3] Cavel-Greant, D., Lehmann-Horn, F., & Jurkat-Rott. The impact of permanent muscle weakness on quality of life in periodic paralysis: a survey of 66 patients. Acta Myologica, 31(2), 126–133.

[4] National Institute of Neurological Disorders and Stroke. NINDS Familial Periodic Paralyses Information Page. Available at: http://www.ninds.nih.gov/disorders/periodic_paralysis/periodic_paralysis.htm. Published March 12, 2012. Accessed February 29, 2016.