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05 May 2014 | **News**

Teva CEO Suits Up For Acquisitions As A Springboard For Growth

by Jessica Merrill

In his first public comments to investors, CEO Erez Vigodman said he will consider large acquisitions to drive growth at Teva, while deepening cost cuts and refocusing on generics to maintain Teva's leadership position.

A large acquisition could be in *Teva Pharmaceutical Industries Ltd.*'s future.

New CEO Erez Vigodman said, in his first public presentation to investors, that acquisitions are an important part of his turnaround strategy for Teva, along with deeper cost-cutting and organic growth by refocusing on generics and the specialty drug pipeline.

"While the focus remains on fixing the foundation and driving organic growth, we are aware of the opportunities around us, including potential larger transactions as long as they meet clear criteria," Vigodman said May 1 during the company's first quarter sales and earnings call. "We must engage in such transactions once conditions are met."

Teva is reviewing a list of possible acquisition targets and could execute transactions on multiple fronts, he said. Two key areas he highlighted as being ripe for deal-making are the central nervous system therapeutic area, building on Teva's strength in multiple sclerosis with its best-selling brand *Copaxone* (glatiramer acetate), and biosimilars, where he said Teva has fallen behind the competition.

"CNS is certainly one of the most attractive areas for us," he said when asked by analysts about his acquisition strategy. "We strongly believe that we can use the capabilities and assets we have in CNS in order to solidify further this TA. We look also at potential acquisitions of relevant technologies in the generics space and the specialty space."

Teva has not been as active on the deal-making front as some competitors. For example, the generic drug industry has seen significant change in the past 18 months as *Allergan PLC* merged

with *Watson Laboratories Inc.* in 2013 (Also see "*Watson Begins Anew As Actavis, Focuses On Organic Growth*" - Pink Sheet, 25 Jan, 2013.). Now the combined company is about to close a deal to acquire *Forest Laboratories Inc.* for $25 billion (Also see "*Actavis' Record-Breaking Quarterly Sales Show Success Of Merger Strategy*" - Pink Sheet, 30 Apr, 2014.). That deal will create a diversified generic/branded specialty drug maker that in some ways mirrors the ambition Teva tried to realize several years ago when it branched further into specialty drugs and oncology through acquisitions like *Cephalon Inc.* in 2011 (Also see "*Teva Swoops In To Snatch Cephalon For $6.7 Billion* " - In Vivo, 1 May, 2011.).

Copaxone Threat Imminent

While new products from Cephalon such as the excessive sleepiness drug *Nuvigil* and oncologic *Treanda* helped to diversify Teva's specialty portfolio, they have not been enough to reduce the company's reliance on Copaxone, a multi-blockbuster that could face generic competition as early as May 25. The threat to Copaxone – not only from generic drugs but also creeping competition from new oral brands – along with slowing growth in Teva's Western generic drug business, have become big overhangs for Teva in the last two years.

Teva's investors grew increasingly disheartened in 2013 when a hostile management shakeup further rattled the company. Jeremy Levin abruptly resigned as CEO in October 2013 over an apparent disagreement with the board of directors (Also see "*Levin Resigns Unexpectedly, Street Grills Teva's Chairman On Viability Of Corporate Governance*" - Pink Sheet, 30 Oct, 2013.).

Now, details on Vigodman's plans for Teva are welcome news to investors, who are looking to build on the momentum from a few positive developments for Teva so far in 2014. The company's stock is up 27% since the start of the year, and closed May 1 at $50.97, up 4% on the day.

Teva recently scored a legal win in its patent infringement case against generic rivals looking to sell the MS drug when the Supreme Court agreed to review an appeals court decision invalidating Teva's manufacturing process patent, potentially opening the door to an extra 15 months of exclusivity (Also see "*Supreme Court Copaxone Case May Weaken Federal Circuit Review Of Patent Claims*" - Pink Sheet, 31 Mar, 2014.). The company also launched an improved version of Copaxone that is dosed three times a week rather than every day, reducing the number of injections patients need to take each year by 200, and is moving quickly to switch patients to the new formula (Also see "*Copaxone Reduces Its Dosing Schedule, But Can It Shrink The Competition?*" - Pink Sheet, 30 Jan, 2014.).

If Teva can successfully extend the life of Copaxone, Vigodman will gain vital time to execute on his strategic plan. It's still not clear if the company will be able to do so, however.

Oral arguments in the Supreme Court case are scheduled to be heard in the fall, but the court did

not grant Teva's application for an injunction to block generic launches in the meantime. The question in the near-term is if FDA will approve generic versions of Copaxone, which while not a biologic, is considered a complex small molecule, and if it does, will any generic company launch the product at risk. Mylan, which claims to be first to file an ANDA, said it plans to move forward with a launch if its ANDA is approved by FDA.

Vigodman fired a warning shot to any generic filer that does launch. "We'll aggressively defend our IP and seek all available damages. This includes damages to both the 20 mg and 40 mg product for the full life of those products, he said. "Any company launching at risk faces significant potential exposure in the billions of dollars before trebling."

More Cost Cuts Ahead

Vigodman only took over the top spot at Teva on Feb. 11, but he came to the first quarter sales and earnings call May 1 prepared to discuss his initial plans for driving growth at the company. He joins Teva as an industry outsider, and investors are anxious to see that he has the know-how to transform a top player in the complex health care market. Vigodman previously sat on Teva's board but worked as CEO of the generic crop chemical company *Makhteshim Agan Industries Ltd.*, where he orchestrated a turnaround.

At the top of Vigodman's to-do list are deeper cost cuts to cushion the bottom line. The company is already in the midst of a restructuring initiative put in place under Levin, aimed at saving $2 billion annually by the end of 2017, half of which will be realized by the end of 2014 (Also see "*Teva Makes The Cut: 5,000 Jobs To Be Eliminated*" - Pink Sheet, 10 Oct, 2013.).

Teva is on track to deliver that $1 billion reduction in gross expenses by the end of the year and $2 billion by 2017, but Vigodman envisions more cost cutting. "I strongly believe that we can be more ambitious on the savings," he said. "Therefore, we have been assessing all of the operational aspects of our business in order to identify the relevant opportunities that will enable us to increase the net savings that will impact our net profits by 2017."

Management is working through the details of the plan and expects to provide investors with a revised target after a new five-year plan has been established, Vigodman said. He did, however, point to a few potential areas for deeper cuts, including manufacturing. Teva already is planning to close or divest 11 manufacturing plants, but he said 16 additional plants are under evaluation. The company is also exploring opportunities within its active pharmaceutical ingredient (API) business, including terminating products and regional geographies that do not meet profitability standards. API sales to third parties declined 7% in the first quarter to $179 million.

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Teva also must renew its focus on generic drugs to maintain its leadership position in the market, including an increased emphasis on complex generics and biosimilars, Vigodman declared.

"We are fully aware of the opportunities and the importance of biosimilars in our industry as we go along," he said. While Teva was in a good position to meet the opportunity in the first wave of biosimilars, it missed the second wave, he said. "We will be accelerating the process. This will enable us to gain a leading position in wave three of biosimilars." And, he said the company will be reviewing acquisitions to enhance its position and reposition the company better in wave two.

For example, Teva was one of the early leaders developing biosimilars like its bio-better version of *Amgen Inc.*'s *Neupogen* (filgrastim), which was approved by FDA through a traditional BLA pathway in 2012 (Also see "*Teva's G-CSF Product Clears FDA, Leaving Appeal Of Biosimilar Pathway Uncertain*" - Pink Sheet, 3 Sep, 2012.). But others have jumped ahead of Teva in the pursuit of biosimilar versions of blockbuster monoclonal antibody brands like *Johnson & Johnson*'s *Remicade* (infliximab) and *AbbVie Inc.*'s *Humira* (adalimumab).

Chief Scientific Officer Michael Hayden described the third wave of biosimilars as drugs that are coming to the end of their patent life in the 2020s. "Teva has significant assets for those drugs that are coming off of patent life in the 2020s," he said, though he acknowledged the company has only made limited progress developing drugs in the second wave.

Two Pillars: Generic And Specialty

While Vigodman highlighted Teva's renewed emphasis on generic drugs, he said the specialty business will continue to be central to the company. The business is divided nearly evenly between generics and specialty medicines in terms of sales. In the first quarter generic medicine revenues were $2.4 billion, up 3% over the first quarter of 2013, and profit was $499 million, up 30.6%. Specialty revenues were $2.1 billion in the first quarter, up 3%, with half of those sales, $1.07 billion, coming from Copaxone. Profitability was $1.1 billion, a decrease of 1%.

Vigodman said breaking up the generics and specialty businesses simply is not an option. "We strongly believe that basically weaving together the assets, capabilities, expertise from the two fronts will enable Teva to possess a business model which is unique in this industry."

He pointed to the company's specialty pipeline as an asset that is under-appreciated by Wall Street. The pipeline includes 15 products in Phase III development, four products in Phase II and 18 new therapeutic entities (NTEs), a concept championed by Levin involving delivery or other improvements to established molecules (Also see "*Teva's NTE Strategy Initially Emphasizes Pain, Glaucoma, Schizophrenia*" - Pink Sheet, 4 Dec, 2013.).

Vigodman called out *DuoResp Spiromax*, an inhaled corticosteroid and long-acting beta2-adrenoceptor agonist for asthma and chronic obstructive pulmonary disease, the migraine patch *Zecuity,* and *Adasuve*, an inhalable form of loxapine for acute treatment of agitation associated with schizophrenia or bipolar disorder, as three commercial-stage opportunities that will drive growth. The three drugs have combined estimated peak sales of more than $1 billion, he said.

Investors will have to wait for more specifics on Vigodman's plans for Teva as he conducts a strategic review, but he said more updates will be provided throughout 2014.

But he said Teva will rediscover its place in the changing market. "I strongly believe that in this industry with the huge changes that we have been undergoing, there is a huge opportunity for Teva to claim a space which is unique and differentiated," he said.