THOMSON REUTERS STREETEVENTS

EDITED TRANSCRIPT

VRX.TO - Q1 2017 Valeant Pharmaceuticals International Inc Earnings Call

EVENT DATE/TIME: MAY 09, 2017 / 12:00PM GMT

OVERVIEW:

Co. reported 1Q17 YoverY reported revenue decline of 11%.

ACRUX DDS PTY LTD. et al.
EXHIBIT 1585
IPR Petition for
U.S. Patent No. 7,214,506

CORPORATE PARTICIPANTS

Elif McDonald *Valeant Pharmaceuticals International, Inc. - Director of IR*

Joseph C. Papa *Valeant Pharmaceuticals International, Inc. - Chairman of the Board and CEO*

Paul S. Herendeen *Valeant Pharmaceuticals International, Inc. - CFO and EVP of Finance*

William D. Humphries *Valeant Pharmaceuticals International, Inc. - EVP and Company Group Chairman of Dermatology*

CONFERENCE CALL PARTICIPANTS

Andrew Jay Finkelstein *Susquehanna Financial Group, LLLP, Research Division - Research Analyst*

Annabel Eva Samimy *Stifel, Nicolaus & Company, Incorporated, Research Division - MD*

Christopher Z. Neyor *JP Morgan Chase & Co, Research Division - Analyst*

David A. Amsellem *Piper Jaffray Companies, Research Division - MD and Senior Research Analyst*

David William Maris *Wells Fargo Securities, LLC, Research Division - Senior Analyst*

Gary Jay Nachman *BMO Capital Markets Equity Research - Analyst*

Gregory B. Gilbert *Deutsche Bank AG, Research Division - MD and Senior Analyst*

Onusa Chantanapongwanij *Morgan Stanley, Research Division - Research Associate*

Timothy Chiang *BTIG, LLC, Research Division - Analyst*

Umer Raffat *Evercore ISI, Research Division - Senior MD and Fundamental Research Analyst*

PRESENTATION

Operator

Good morning. My name is Melissa, and I will be your conference operator today. At this time, I would like to welcome everyone to the first quarter 2017 financial results conference call. (Operator Instructions)

Ms. Elif McDonald, Director of Investor Relations, you may begin your conference.

Elif McDonald - *Valeant Pharmaceuticals International, Inc. - Director of IR*

Thank you, Melissa. Good morning, everyone, and welcome to Valeant Pharmaceuticals First Quarter 2017 Financial Results Conference Call. Participating on today's call are Chairman and Chief Executive Officer, Mr. Joe Papa; Chief Financial Officer, Mr. Paul Herendeen; and Executive Vice President Dermatology, Mr. Bill Humphries.

In addition to the slide webcast, a copy of today's slide presentation and a replay of the conference call will be available on our website under the Investor Relations section.

Before we begin, we would like to remind you that our presentation today contains forward-looking information. We would ask that you take a moment to read the forward-looking statement legend at the beginning of our presentation as it contains important information. In addition, this presentation contains non-GAAP financial measures. For more information about these measures, please refer to Slide 2 of the presentation. Non-GAAP reconciliations can be found in the appendix to the presentation posted on our website.

Finally, the financial guidance in this presentation is effective as of today only. It is our policy generally -- to generally not update guidance until the following quarter and only update or affirm guidance through broadly disseminated public disclosure.

With that, it is my pleasure to turn the call over to Joe.

Joseph C. Papa - *Valeant Pharmaceuticals International, Inc. - Chairman of the Board and CEO*

Thank you, Elif. Good morning, everyone, and thanks for joining us today. Let me start with the topics we'll cover this morning. I'm going to begin with a high-level overview of the progress we've made so far in 2017, particularly since our last earnings call on February 28. I'll then turn the call over to CFO, Paul Herendeen, to review our first quarter financial results. He will also cover the update we have made to our 2017 guidance. I'll then comment on the performance and outlook for our Bausch & Lomb business, our GI business, before turning it over to Bill Humphries to talk about our Dermatology business. He'll wrap up with an update on our new product pipeline before taking your questions.

So let's begin. On Slide 4, I want to start with some of the positive developments since our last earnings call, beginning with the strong performance of our 2 largest segments: the B + L/International segment, which represents over half our business, and our Branded Rx segment increased adjusted EBITA by 8% and 12% respectively, year-over-year.

Debt reduction continues to be a priority. And I'm pleased to report that to date, we reduced the principal amount of our debt by $3.6 billion since quarter 1 2016. This includes $1.3 billion of debt retired in the first quarter of 2017 with proceeds from the noncore asset sales, including the sale of 3 skincare franchises to L'Oréal, which closed on March 3. And with the successful debt refinancing we completed in March, we extended our maturity profile. Paul Herendeen and Linda LaGorga and our finance team did a great job with the refinancing.

In terms of execution, we're raising adjusted EBITDA guidance, which is good news that Paul will cover in more detail later.

In Dermatology, we have stabilized our average selling price or ASPs. Importantly, we saw strong growth in Asia led by China, which was up 11% in volume.

Our Xifaxan Primary Care sales team is gaining new Rx shares since the launch of the sales team in February 2017, and cash flow from operations was great at $954 million for the quarter.

Moving on to our new product pipeline. We have many positive developments this year, and I'll talk about some of these in more detail later. But briefly, in January, we reported the result of a confirmatory Phase III study of IDP-118, a topical treatment for psoriasis. We are optimistic about these results which demonstrate that the novel formulation IDP-118 could, if approved, be a promising treatment for patients who use a corticosteroid/retinoid combination to treat psoriasis.

We also received 2 510(k) clearances last month. The first was for the Stellaris Elite vision enhancement system, a next-generation cataract platform that offers many cutting-edge innovations. The second 510(k) clearance was for Vitesse, the first and only hypersonic device for vitreous removal.

We also have filed Luminesse, our novel treatment for ocular redness, with the FDA, and we have received a PDUFA date of December 27, 2017. And finally, we've resubmitted Vyzulta with a PDUFA date of August 24, 2017.

Turning now to some of the challenges. Notwithstanding the progress we've made in stabilizing our sales force over the last 3 quarters of 2016, we have been working through some recent challenges. While we recently added more than 250 sales professionals to our GI sales force, those additions were offset by the loss of a number of reps to a new market entrant. We recently took steps to rightsize the Dermatology field force, following a review by our new management.

Moving now to products. While Xifaxan underperformed our expectations in the first quarter, recent TRx market share was up by 200 basis points, and we remain on plan for the year, largely due to the addition of the Primary Care sales force.

Finally, we're in the process of winding down the Commonwealth business, which will further simplify our portfolio and reduce complexity.

Also, we continue to make progress in resolving the company's legacy legal matters. As you know, we settled the Salix class action litigation last quarter, and separately, we've increased our legal reserve by $76 million this quarter.

In addition, with respect to the SHOWER to SHOWER lawsuits, it is our belief that J&J has obligations to pay for our legal defense and to indemnify Valeant. We have provided Johnson & Johnson with notice that the various lawsuits filed against Valeant relating to SHOWER to SHOWER.

On that note, I'll turn the call over to Paul to go through our first quarter financial results in details.

Paul S. Herendeen - *Valeant Pharmaceuticals International, Inc. - CFO and EVP of Finance*

Thank you, Joe. On a reported basis, revenue was down 11% compared with Q1 of '16. Unfavorable movements in FX rates accounted for roughly 200 basis points of the decline. As expected, the lion's share of the decline came from our Diversified segment, where revenue was down $206 million.

From a revenue perspective, B + L/International posted a solid quarter. It was flat on a reported basis but up 4% on a constant currency basis.

Branded Rx was down 9% or $61 million versus the year-ago quarter. Our adjusted gross margin was down roughly 310 basis points compared with Q1 of '16, and most of that decline in overall gross margin was due to mix, as the revenue declines were in our higher gross margin business units.

In operating expenses, selling, advertising and promotional expenses were down $108 million compared with last year, almost entirely due to lesser A&P spending. Adjusted G&A costs were up $22 million as we incurred costs in Q1 of 2017, but outside legal services in connection with ongoing actions and for consulting services in connection with our continuing efforts to streamline our global operations.

Our investment in R&D was down $7 million from the prior year quarter. However, this was due to the timing of costs on our various R&D projects and does not portend a reduction in our R&D activity. We continue to expect our investment in R&D for the full year of 2017 to be an increase over 2016.

Our adjusted EBITDA declined $147 million or 15% compared with Q1 of '16. If you wanted to pick 1 factor that most contributed to the decline in adjusted EBITDA, it would be the impact of LOEs on our Diversified segment. Together, the neuro and Generics units saw a revenue decline by $214 million, and those are high-margin revenues.

Let me cover some of the major themes in our 3 segments, starting with the B + L/International segment. On a reported basis, the segment was flat compared with the first quarter of '16. However, as I said, on a constant currency basis, it grew 4% with roughly 140 basis points of that growth coming from realized net price increases across the segment. The international portion of the segment delivered 3% reported revenue growth but 15% growth on a constant currency basis. A portion of that increase was due to the steps we took in early 2016 to destock the pipeline inventories of several of our Eastern European units. Regardless, our international units delivered a strong first quarter.

Global Ophtho Rx revenue was up 1% on a reported basis and 3% on a constant currency basis, with our international units more than offsetting a slight decline in the U.S. The Global Consumer business showed modest revenue growth while Global Surgical and Vision Care declined.

Yes, we're in the process of reorganizing and reconfiguring the B&L and International businesses to ensure efficiency in our operations and to provide the support for future growth. In Q1 of 2017, you can see a bit of improved operating expense efficiency within SG&A, as SG&A declined compared with 2016. We believe the improved revenue growth will follow. Adjusted EBITA for the segment on a constant currency basis grew faster than revenue, up 8%, a solid performance.

On to Slide 7 and the Branded Rx segment, where revenue was down 9% with both our GI and Derm businesses off 11% compared with Q1 of '16. Before I start, the change in wholesale pipeline inventories was not particularly notable in the quarter. We've included a schedule in the appendix on Slide 32 that you can use to gain additional perspective into the sales growth or declines in our Rx units, including Derm, GI, Ophtho, Neuro and Generics.

So Derm. Yes, the transition of the Derm business away from the specialty pharmacy-driven models continues. As a result, Derm revenues are down on lesser volumes, but that's not the entire story. In the quarter, we enjoyed higher ASPs and higher gross profit margins, and those revenues and profits were driven by leaner, more focused sales force. 2017 is a transitional year for Derm. But importantly, we expect the Derm unit to contribute a similar amount of profit in 2017 as in 2016. Also of note in Q1 '17 versus '16, we realized 530 basis points of increased net pricing across the Derm unit, with roughly 1/3 of that increase coming from improved management of gross-to-net items.

On to GI. GI is all about Xifaxan. The story here is that we lost some momentum over the fourth quarter of last year and into the first quarter of '17. That was due, in part, to the rumored sale of Salix last year and then early this year when we lost a number of sales reps to a new competitor all at one time.

Over the last 9 weeks, however, our sales forces have regained their footing, and we have seen Xifaxan 550 gain roughly 200 basis points of TRx share in its segment. In the quarter, we realized about 310 basis points of increased net selling price in the Salix unit.

Below the sales line in Branded Rx, our gross margin was essentially flat. Selling, advertising and promotional expenses were down $87 million. In Q1 of 2016, we spent heavily on direct-to-consumer advertising in support of several brands, particularly Jublia and Xifaxan. We're not repeating those activities in 2017.

Within SA&P, our selling expenses were essentially flat compared with the prior year quarter, a fact that highlights our efforts to allocate capital responsibly within our businesses. Selling expense in Q1 of '17 includes the cost of the new Primary Care sales force to promote Xifaxan and other products in the Primary Care setting and the expansion of our patient access and sales operations teams. But a good portion of those increased costs were offset by the rightsizing of our Derm sales force. G&A costs in the segment were up $9 million mainly due to increased legal expenses. Segment EBITA was up 12%, with the year-over-year decrease in A&P spending in the quarter a major driver of that growth.

On to Slide 8, the Diversified segment. The diversified segment is comprised -- mainly comprised of product assets and businesses that are noncore. We manage these assets for cash generation. And while you may not see it because of the overwhelming impact of LOEs on this portfolio, our diversified team has done a very good job of actively managing these assets. The story in Q1 is the impact of the LOEs in the Neuro and Generics units. In conjunction with our guidance back in February, we provided a look at our expectations for the impact of the LOE products on 2017. We've updated that exhibit on Slide 23 in the appendix.

LOE products drove the decline in the Diversified segment in Q1. Revenues were down 37%, and adjusted EBITDA down 43%. There's a lot of material in our slides, so that's all I'll cover for now with respect to our operating results, but I do want to take a few minutes to talk about our liquidity and the series of debt transactions that we completed during the quarter.

Just a few things to point out on our balance sheet summary on Slide 9. We ended the quarter with $1.2 billion of cash on hand and reduced our debt by almost $1.3 billion in the quarter. Compared with March 31, 2016, our quarter-end debt balance was down $3.4 billion, and you did see that we paid down an additional $220 million of debt just last week. We believe strongly that we have clear pathways to get our capital structure in order by: one, reducing our leverage throughout the sales; two, through cash generation; and three, the best way, through growth our operating earnings. That said, as we entered 2017, we were facing a wall of maturities in 2018, '19 and '20, and we're operating the financial covenants that left us with only a modest margin of error and restricted our ability to take actions to improve our prospects.

So what do we do about it? Turn to Slide 10. Slide 10 shows our upcoming debt maturities after using of the proceeds from the sale of the skincare assets to reduce debt and then the completion of our debt transactions back in March. We think that completing the debt transaction was a significant event that, in my opinion, was underappreciated by the markets. By refinancing the debt, we now have a very manageable debt pay down schedule for the next several years. We shifted about -- to about 75% fixed versus floating rate debt. And finally, we substantially improved our covenant position.

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.