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J&J's Multiple Myeloma Launches Pick Up Momentum

by Jessica Merrill

Johnson & Johnson delivered solid third quarter sales and earnings, which led the company to raise 2023 financial guidance.

[Johnson & Johnson](#) has several new multiple myeloma drugs that investors are closely tracking as the company looks to maintain its dominance in the therapeutic area and treat patients across the full spectrum of the disease. Management told the company's third quarter sales and earnings call on 17 October that three new multiple myeloma launches – Carvykti (ciltacabtagene autoleucel), Tecvayli (teclistamab) and Talvey (talquetamab) – are gaining momentum.

J&J's multiple myeloma portfolio is anchored by the mega-blockbuster Darzalex (daratumumab), a CD38-directed antibody that was first approved in 2015, but the three new launches are expected to drive the company's growth in oncology in the second part of the decade. They each represent pioneering areas of cancer medicine like cell therapy or bispecific antibodies and are all approved by the US Food and Drug Administration for the latest lines of multiple myeloma therapy, after four or more prior treatments.

Carvykti, a B-cell maturation antigen (BCMA)-directed cell therapy, was approved by the FDA in February 2022. (Also see "[Janssen/Legend Plan Phased US Launch For BCMA-Targeting CAR-T Carvykti](#)" - Scrip, 28 Feb, 2022.) While it has demonstrated impressive efficacy, the manufacturing and administration complexities have limited uptake. Tecvayli, which was approved in Europe in August 2022 and in the US in October 2022, is a BCMA-directed bispecific antibody that can be administered subcutaneously, and Talvey, the newest addition, was approved by the FDA in August as a first-in-class GPRC5DxCD3-targeted bispecific antibody. (Also see "[J&J Hits Another Myeloma Milestone With FDA Approval Of Talvey](#)" - Scrip, 10 Aug, 2023.)

Carvykti has been on the market the longest, but so far demand has outstripped supply. The

launch has been held back by manufacturing capacity, an issue that has dogged others in the space as well. (Also see "[Myeloma Market Snapshot: Backlogs Dog BCMA CAR-Ts As Treatment Paradigm Evolves](#)" - Scrip, 26 Jul, 2023.) Carvykti picked up some steam in the third quarter, generating \$152m versus \$55m in the year-ago quarter. The sales also compared favorably on a quarterly basis; second quarter sales of Carvykti were \$117m.

"As you have seen in the progression quarter-over-quarter of Carvykti, we continue to have on one hand, strong demand, and on the other hand, progress in our manufacturing," CEO Joaquin Duato said during the call.

Exec VP-Pharmaceuticals R&D John Reed, who recently took over the leadership role at J&J from [Sanofi](#), said progress has been made on the manufacturing front.

"We've been progressively adding more and more capacity," he said. "That's included at our original launch site in New Jersey, but we're close to having an additional manufacturing site up and rolling in Europe, in Belgium, and also have recently increased our capacity by using some excess capacity that Novartis had to further bolster the number of slots that we can accommodate."

J&J has also made advancements on the viral vector component of the technology, which has been one of the limiting factors, he added.

"There we've made really outstanding progress in house, mastering that technology, increasing the scale at our factory in Switzerland," he said. "We're building, I think it'll be available next year, another factory in the Netherlands to support the lentivirus component."

"Altogether, the capacity continues to ramp up and we continue to perfect the technology," he added.

The launches of Tecvayli and Talvey are exceeding early initial forecasts, Duato added. The company did not break out sales of either drug yet, generally a sign the revenues aren't material to sales and earnings. However, J&J said the two products have surpassed internal expectations and contributed to growth in a line item categorized as "other oncology," which grew 34.5% in the third quarter to \$229m. Tecvayli revenues will be broken out separately beginning in 2024, the firm said.

Strong sales of Darzalex, which grew 21.9% in the quarter to \$2.5bn, and top-selling Stelara (ustekinumab), which grew 16.9% to \$2.86bn, powered growth in J&J's newly minted "innovative medicines" business unit, which grew 5.1% to \$13.89bn. (See *Table for financial information*).

The third quarter marks the first reporting period for J&J without the consumer products

business. In May, the business was spun out of J&J into a new company called Kenvue, but since the company remained a majority shareholder it continued to report consumer products financials in the second quarter. In August, the company completed a share exchange offer, after which it now owns approximately 9.5% of Kenvue and is positioned as a two-segment company with businesses in pharmaceuticals and medical technology.

The solid quarter led J&J to slightly increase its 2023 financial forecast to revenue of \$84.4bn-\$84.8bn from a prior forecast of \$83.6bn-\$84.4bn. The forecast would represent growth of 7% at the midpoint over 2022 revenues. The earnings per share forecast also was raised from \$10.02-\$10.08 to \$9.90-\$10.00.

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