

17 Jul 2022 | **Analysis**

US Q2 Consumer Health Earnings Preview: Horizon Brightens Beyond Current Questions, Challenges?

by Malcolm Spicer

Consumer health product firms' vistas include challenges of supply chain disruptions lingering from pandemic's impact as well as potential for marketplace restrictions as additional varieties of the novel coronavirus spread. Clouds also include shifts in consumer spending, increases in costs caused by inflation and foreign exchange headwinds as the value of the US dollar strengthens against other currencies.

The US consumer health products industry could be looking ahead and seeing an improving outlook for growth since the Food and Drug Administration published a long-awaited proposal for facilitating additional OTC drug switches.

Manufacturers and marketers also likely are seeing a brighter marketplace on the horizon after a <u>Perrigo Company PLC</u> business submitted the first-ever proposal to the FDA for making a daily oral contraceptive available OTC.

Their immediate-term views, however, are a bit more clouded. As consumer health product firms join public companies across industries in reporting their latest sales and earning results, their vistas include challenges of supply chain disruptions lingering from the COVID-19 pandemic's impact as well as the potential for marketplace restrictions as additional varieties of the novel coronavirus begin to spread.

Another factor in their earnings forecast calculus, in addition to shifts in consumer spending and increases in firms' costs caused by inflation and threats of a looming recession, will be currency exchange headwinds as the value of the US dollar strengthens against other currencies.

China's pandemic-driven lockdowns also will have the US consumer health industry's attention as firms report their results for the April-June period, beginning with Johnson & Johnson on 19 July, and Russia's continuing invasion of Ukraine will continue to directly or indirectly disrupt some revenue streams.

Still, during OTC drug firms' earnings briefings, analysts likely will ask for executives' expectations about potential industry growth linked to the FDA's "Nonprescription Drug Product with an Additional Condition for Nonprescription Use [ACNU]" proposed rule published in June. (Also see "Expanding US OTC Switches Turns On Flexibility In FDA Drug Approval Process And For Consumers" - HBW Insight, 27 Jun, 2022.)

Under the proposal, switch sponsors would be required to submit, along with new or abbreviated drug applications, separate documents supporting making

Euro Q2 Consumer Health Earnings Preview: Volatility, Delay, Upturn And Goodbye

By Tom Gallen

17 Jul 2022

Major Europe-based consumer health players Bayer, Sanofi, Reckitt and GSK feature in this sales and earnings preview, which highlights what to look out for as these four firms report their Q2 2022 results over the coming weeks.

Read the full article here

drugs available through an ACNU approval, which will be needed when a firm convinces the agency that labeling on a package isn't sufficient to ensure a consumer can appropriately self-select and use a drug as a nonprescription product.

And analysts' questions about the NDA submitted by Perrigo's HRA Pharma business for OTC access to 0.075% norgestrel daily oral contraceptive likely won't be limited to Perrigo. Other pharma's interest in marketing nonprescription birth control pills as well as their expectations for the norgestrel switch NDA. (Also see "*HRA Proposes OTC Norgestrel Birth Control*" - HBW Insight, 11 Jul, 2022.)

HRA's Norgestrel NDA And More For Perrigo

The HRA norgestrel switch NDA is most recent as well as historic for Dublin-based Perrigo, but it wasn't the OTC private label and store brand giant's only development during the quarter.

In May, it reached another first in its transition to being entirely consumer health-focused with US approval of proton pump inhibitor omeprazole magnesium 20-mg delayed-released in minicapsule format. (Also see "*Perrigo Has First US Approval For OTC Omeprazole Mini-Capsule*" - HBW Insight, 26 May, 2022.)

In another OTC PPI first, Perrigo's Prevacid 24HR in June became the first to add a label warning

due to a potential risk of rare skin reaction. The product's active ingredient, lansoprazole, and the two other OTC PPI ingredients, esomeprazole and omeprazole, along with several other ingredients available only Rx and commonly used to treat frequent heartburn were linked to a potential risk of acute generalized exanthematous pustulosis after the FDA in 2019 found a trend in adverse event reports. (Also see "*Prevacid 24HR First OTC PPI With Skin Reaction Warning*" - HBW Insight, 30 Jun, 2022.)

The HRA switch NDA for norgestrel, though, will get the most attention. Although Perrigo already had reported sales boosts from the French pharma's product lines after closing its acquisition in May, the switch NDA marked a significant step in Perrigo leveraging bringing HRA under its roof to move beyond relying on OTC generic equivalents as its dominant revenue stream. (Also see "*Room Available In US Pharma Industry For OTC Switch Leader: Has Perrigo Made A Reservation?*" - HBW Insight, 9 Sep, 2021.)

In a 27 June research note – published before HRA submitted the norgestrel NDA but after the Supreme Court published its ruling allowing states to ban access to abortion services – Raymond James specialty pharmaceuticals analysts said Perrigo is far and away best-positioned to benefit from the ruling.

Perrigo "should be at the forefront of any discussions regarding potential financial beneficiaries from changes in the reproductive health landscape that will likely emerge from the ruling. There is simply no company that could benefit more than [Perrigo] from a potential shift towards more accessible contraception options that could be catalyzed by the Dobbs decision and the resulting financial impact could be significant," wrote Elliot Wilbur and Michael Parolari.

Perrigo, yet to set a date for its secondquarter earnings briefing, will be reporting its first results after, with its first-quarter results, raising its full-year guidance for net sales growth to 8% to 9%, up from earlier 7% to 8% forecast. It's also reporting for the first time after adding HRA Pharma's Rx and OTC birth control and other drug lines in a \$1.9bn cash deal that closed in May. Its acquisition of the French firm is expected to add €55m to €65m (\$58.03m to \$68.6m) to its adjusted operating income for May through December this year. It overall net sales during the January-March period were up 6.5% to \$1.07bn. (Also see "Perrigo Boosts 2022 Guidance Shifting From Changing Organization To Delivering Results" - HBW Insight, 11 May, 2022.)

They also noted oral contraceptives account for around half, \$2.8bn, of the

annual US sales of around \$5.5B for products in the category. The oral contraceptive market led by generics and most large pharmas and most innovators in the space have moved to long-acting reversible contraceptives.

Perrigo executives, like many pharma industry stakeholders, likely will be cautious discussing the NDA. The FDA's history with delaying approval of an OTC emergency contraceptive due to political pressures gives some pause when considering the agency's handling of a daily oral contraceptive switch. (Also see "*Will Influences Behind US FDA's Delayed Approval For OTC Plan B Also Shadow 'Plan A' Switch?*" - HBW Insight, 12 Jul, 2022.)

The Raymond James analysts anticipate that support for expanding access to birth control will stifle the influence of opponents.

They noted "widespread backing from key constituents" from among medical professionals including the American College of Obstetricians and Gynecologists, the American Medical Association and the American Academy of Family Physicians.

"Even politically, at least best we can tell, expanded access to contraceptive options appears to enjoy support from both sides of the aisle. The Dobbs decision is likely the catalyst needed to put OTC access to oral contraceptives on the front page, limiting FDA's ability to further stonewall a decision on the initiative," say Wilbur and Parolari.

Bausch + Lomb Reports On Its Own

Bausch + Lomb Corp.'s results for the April-June period won't be its first quarterly totals but will be the first for the eye health and vision care business making and marketing Rx and OTC drug and dietary supplements as well as surgical technologies based on operating as a standalone company following its May separation from <u>Bausch Health Companies Inc.</u> through an initial public offering of shares.

The Vaughan, Ontario-based firm, yet to schedule its second-quarter earnings release, in June published first-quarter results which had been included in Bausch Health's published in May on the same day it closed its IPO to spin out the eye health and vision care business making and marketing Rx and OTC drug and dietary supplements as well as surgical technologies. (Also see "Bausch + Lomb's First Results Look Familiar" - HBW Insight, 8 Jun, 2022.)

During the latest quarter, B+L made multiple Rx and tech business announcements. Its consumer health • With its first-quarter results published on its own in June, B+L projected full-year revenues between \$3.75bn and \$3.8bn on 4% to 5% organic growth, and full-year adjusted earnings before interest, taxation and amortization of \$740m to \$780m on around 5% base performance growth. It reported first-quarter revenue of \$889m, a 1% increase from the year-ago period. Sales growth was driven by OTC brands Lumify (brimonidine tartrate) eye drops and Biotrue, which includes glycerin eye

news came in early June with the US launch of Biotrue Hydration Plus Multi-Purpose contact lens solution formulated with bio-inspired ingredients to provide more moisture on lenses and "a triple disinfectant system" that helps deliver exceptional disinfection.

drops as well as eyelid wipes and contact lens solutions. (Also see "*Bausch + Lomb's First Results Look Familiar*" - HBW Insight, 8 Jun, 2022.)

J&J's Planned Consumer Spinout Has Leaders

While Bausch + Lomb reports its first request following a quarter on its own, <u>Johnson & Johnson</u>'s discussion of its latest results on 19 July will include an update on the planned separation of its consumer health business.

It marked a step in May in the process it expects to complete in 2023 by appointing Thibaut Mongon continue to head its consumer health care business when the firm splits it off into a standalone business and the division's current chief financial officer, Paul Ruh, to move with him. (Also see "*Familiar Leadership For J&J's Planned Consumer Spinoff*" - HBW Insight, 11 May, 2022.)

The standalone business, with name and headquarters still to be determined, retain J&J's portfolio of consumer health brands including Tylenol, Listerine, Band Aid, Neutrogena, and Aveeno.

The split is unrelated to J&J's LTL Management LLC spinoff, a subsidiary it created to manage its liability for talc injury claims, spurring immediate

With its first-quarter results in April, J&J trimmed its 2022 guidance for reported sales to a range of \$94.8bn to \$95.8bn, on growth from 3.8% to 4.8%, from its initial forecast of \$95.9bn \$96.9bn; the forecast includes an incremental \$1.1bn hit from foreign exchange. Limited availability and rising prices of commodities and increased costs for labor, energy and transportation influenced the change, with the impacts "pervasive across the enterprise but most notable in consumer health." It also reported nearly \$3.6bn, up 1.5%, in worldwide consumer and personal health product sales, including OTC drugs up 14.8% to nearly \$1.5bn; skin health and beauty up13% to \$1.01bn; women's health up2.6% to \$228m; baby care up 8.6% to \$355m; oral care up 12.2% to \$366m; and wound care and other products up 7.4% to \$164m. (Also see "J&I Sees Clear But Bumpy Road Ahead For Consumer Health, Personal Care Business Growth" - HBW Insight, 19 Apr, 2022.)

pushback and court challenges from attorneys representing clients in damages claims. (Also see

"J&J Cosmetic Talc Lawsuits Halted, \$2Bn Trust Created, As Subsidiary Takes Liabilities Into Bankruptcy" - HBW Insight, 17 Oct, 2021.)

However, shareholders in the New Brunswick, NJ-based firm's annual meeting in April voted down a proposal by activist investors and consumer groups to stop all talc-containing powder sale, while approving a separate proposal requiring J&J's board to consider an audit into whether the firm marketed the products to minority women despite asbestos concerns. (Also see "*Proposal For J&J To Halt Talc Powder Sales Worldwide Fails In Shareholder Vote*" - HBW Insight, 2 May, 2022.)

P&G Emphasizes Premium Value Drives Growth

<u>Procter & Gamble</u> approaches reporting fourth-quarter and full-year results for its fiscal year 2022 on 29 July acknowledging that consumers are becoming more sensitive to product prices while still expecting its premium-priced lines to drive its sales growth.

Earlier in July, CEO Jon Moeller told investors the firm should do more to explain its products' value exceeds competitors and are worth higher prices while also providing lower-priced options.

"We need to be even more deliberate on communication of the value that our brands provide consumers," Moeller said.

The Cincinnati-based firm's chief brand officer, Marc Pritchard, offered a similar evaluation in June at an investment bank's conference in Paris. Prichard acknowledged the role businesses can have driving positive change external to their commerce, but sales growth is necessary to make that possible.

"The marketing community has stepped up to focus on community impact ... They stepped up on equality, inclusion, and [are] stepping up now on sustainability," • In April, P&G reported a 7% increase in net sales during its FY2022 third quarter to \$19.4bn despite COVID-19 lockdowns in China limiting overall sales growth for its beauty, baby, feminine and family care product lines. The total included 13% growth in health care product sales of \$2.and 7% growth for its baby, feminine and family lines to \$4.9bn. (Also see "China Lockdown Offsets P&G Sales Growth Across Product Categories In All Other Regions" - HBW Insight, 20 Apr, 2022.)

he said, but added, "what I think has happened in the industry in general is that it's just gone a little bit too far into the good, potentially not paying enough attention to growth." (Also see "Consumer Brands Should Be Forces For Good, But Growth First – P&G's Marc Pritchard" - HBW Insight, 22 Jun, 2022.)

C&D Trimming Package Sizes

<u>Church & Dwight Co. Inc.</u> Inc. isn't expecting consumers to be willing to pay more for its products but is pivoting to offering smaller packages of its products at the same price.

Consumers aren't willing to pay more for products after prices already had increased once or more over the previous 18 months, said C&D president and CEO Matthew Farrell in June. The Ewing, NJ-based firm has announced higher prices for 80% of its portfolio, with prices for some products increased more than once, and other firms in the consumer health space also have noted changes to similar amounts of products. (Also see "Consumers' Inflation Fatigue, Recession Fears May Put Health, Beauty Product Price Increases On Hold" - HBW Insight, 21 Jun, 2022.)

Instead, "it's more likely that we and others will resort to pack size changes," said president and CEO Matthew Farrell. Reducing package sizes, while keeping a SKU's price the same, comes with capital expenditure costs which C&D will acknowledge in its plans.

C&D on 27 July likely will report sales growth in some categories, with consumer health and personal care products likely not included, according to William Blair analysts.

Consumption – retail sales – of the firm's product was up 4.7% in the four weeks through 26 June compared to a year-ago period, but sales of vitamins, down 7.3%, and sexual health products, off 1% dragged down year-over-year gains for laundry detergent, 7.9%, cat litter, 15.1% and laundry care, 9.7%, William Blair analysts noted in a 5 July report.

C&D in April reported consumer demand for its products grew in January through March, but it was demand it couldn't 's satisfy as its supply chain problems continued. One example was vitafusion and L'il Critters: demand was high as consumption grew 11% but case fill was low. Net sales grew 4.7% from the yearago period to \$1.297bn and its 83 cents earnings per share was off 5.7% though it exceeded its 75 cents forecast. The total included 4.6% growth in worldwide consumer product sales to \$1.21bn. (Also see "Church & Dwight 'Left Money On Table' In O1, Same Supply Chain Problems Expected O2 Before Easing" - HBW Insight, 29 Apr, 2022.)

For sales for 12 weeks ending on that day, the year-ago comparison retail sales of C&D's vitafusion, L'il Critters and other vitamin products was down 8.9% to \$82.5m; for the 52-week period, the category's results were down 5.4% to \$408.4m.

Prestige's Recent Retail Results Slump

<u>Prestige Consumer Healthcare Inc.</u>'s recent retail sales results weren't as strong as more of its categories slumped than grew, according to the William Blair report.

The Tarrytown, NY-based firm's consumption in the four-week period decreased 4.2% compared to the same period a year ago, when consumer spending soared due to COVID-19, but the results were 6.3% in a two-year comparison.

Upper respiratory product sales were up 21.8% but were offset by slumps in feminine care

• In May, Prestige capped its FY2022 with reported revenues of \$1.09bn, up 15.2%, as its January-Marcy income jumped more than 45% despite inflationary pressures as it avoided supply chain and shipping bottlenecks hitting many other consumer health product companies by sourcing 80% of products from manufacturers in the US and Canada. Net income for its fourth quarter was \$52.1m, up 46.7% from \$35.5m, and revenues were \$266.9m, up 12.3% from the prior-year period. It began its FY2023 planning additional prices increases across its portfolio and expecting price hikes to contribute to two-thirds of its full-year revenue growth, approximately \$15m to \$16m. (Also see "Prestige Consumer Supply Chain Prowess Helps Offset Inflationary Pressures For Record Results" - HBW Insight, 6 May, 2022.)

products, 7.8%, internal analgesics, 9.5%, eye and contact lens care, 3.8%, and other health remedies, 11.6%, the William Blair report notes.

For the 12 weeks ending on 26 June, accounting for nearly all of Prestige's FY2023 first quarter, its overall consumption was \$15.2m, up 5.2% from the same period a year ago; for the 52 weeks through that date, its sales at retail were up 9.9% to \$68.4m, the report states.

Abbott Turning Corner On Formula Setback

<u>Abbott</u>'s latest results coming on 20 July could be its last showing a substantial drop in infant formula sales following the closure of a key plant in Michigan and broad recalls of three brands due to potential bacterial contamination.

Improvements in sales by its Abbott Nutrition business should start during the current quarter and product volumes should be at "normal levels" during the fourth quarter, JP Morgan medical supplies and devices said in a 12 July research report.

A return to store shelves stocked with Abbott's formula brands and to robust online sales would be "a far better outcome than once feared" considering supply shortages and formula isn't "used by any one consumer for a very long time, and women getting pregnant now likely

 Abbott in April lowered its full-year sales forecast due to its formula recalls as firstquarter worldwide nutrition sales, which

won't be that aware of the recall by the time they give birth," they added.

As well, with shelf space not "reallocated to other products, we expect volumes to get up and running in short order."

Abbott also appears positioned to weather a currency exchange headwind better than most of its competitors in the medical technology space, the JP Morgan analysts noted. For "many/most" medtech firms the headwind will "result in [earnings per share] guidance downgrades, but Abbott "is an exception, in our view, due to Covid testing."

The Abbott Park, IL-based firm has said even though strong COVID-19 diagnostic test sales aren't likely to continue throughout the year, it anticipates some continuing demand for tests for viral include adult as well as infant products, dropped a reported 7% to \$1.89bn. Excluding US sales of those products during the quarter and the prior-yearperiod, reported nutrition sales for January-March would have been measured as up 5%, but reported US sales of those brands were \$59m in the quarter, well below \$288m in the prior-year period. Its company-wide worldwide sales for the quarter were reported as up 13.8% to \$11.9bn on 28% US growth to \$4.9bn and 5.1% international growth to \$6.96bn. (Also see "Recall Sours Abbott's Infant Formula Results; COVID-19 Test Sales Expected To Cool" - HBW Insight, 20 Apr, 2022.)

threats. (Also see "<u>OTC COVID-19 Tests Have Abbott Seeing Continuing Demand For At-Home Diagnostics</u>" - HBW Insight, 23 Apr, 2021.)

As for its formula business, Abbott restarted production at its Sturgis, MI, plant, where it makes around half of its total US formula supply, in early June only to close it again after less than two weeks when severe thunderstorms and heavy rains with high winds through southwestern Michigan caused power outages and flood damage. (Also see "*Abbott Among Firms Gaining Formula Import Approvals As Flood Closes Its Michigan Plant*" - HBW Insight, 20 Jun, 2022.)

The firm is among the numerous formula providers which have received approval, under the FDA's temporary guidance for enforcement discretion announced in May, to import product made in foreign countries. (Also see "*US FDA Turns To Temporary Enforcement Discretion For Boosting Infant Formula Supply*" - HBW Insight, 16 May, 2022.)