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# US Q3 Consumer Health Earnings Preview: Phenylephrine Question Punctuates Quarter

by [Malcolm Spicer](#)

Consumer health products sector's earnings reports for July-September period are its first since FDA advisory committee unanimously voted that results of research agency presented show oral phenylephrine at OTC monograph doses is ineffective to treat nasal congestion.

US OTC drug firms approach announcing their losses and gains from the latest quarter also looking ahead and calculating a loss should phenylephrine, in oral formulations marketed by most, lose its indication as a nasal decongestant.

Phenylephrine is the most commonly used OTC nasal decongestant and largely is part of multi-ingredient oral cough/cold formulations marketed in the US under numerous national brands and private label and store brand products available primarily through a Food and Drug Administration OTC monograph and also through approved applications.

However, the consumer health products sector's earnings reports for the July-September period are the first since an FDA advisory committee unanimously voted that results of research presented by the agency show oral phenylephrine at OTC monograph doses is ineffective to treat nasal congestion. (Also see "[US Advisory Panel Leaves No Room For Doubt: Oral Phenylephrine Ineffective As Nasal Decongestant](#)" - HBW Insight, 12 Sep, 2023.)

## ***Euro Q3 Consumer Health Earnings Preview: Reckitt, Bayer, Haleon, Sanofi***

By [Tom Gallen](#)

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Major Europe-based consumer health players Reckitt, Bayer, Haleon and Sanofi all feature in this sales and earnings preview, which highlights what to look out for and potential

The FDA reached the same conclusion before the meeting. The agency said afterward that it “will consider the input of this advisory committee, and the evidence, before taking any action on the status of oral phenylephrine” as part of the OTC cough, cold, allergy,

bronchodilator and antiasthma monograph. (Also see "[Fast Start To Oral Phenylephrine Efficacy Complaints As US FDA Considers 'Any Action'](#)" - HBW Insight, 14 Sep, 2023.)

talking points as these four companies report third-quarter results over the coming weeks.

[Read the full article here](#)

When OTC marketers make their latest earnings presentation, beginning on 18 October with [Procter & Gamble](#) – marketer of Vicks brand products containing phenylephrine, executives from the firms almost certainly will be fielding questions from market analysts about their strategies for a potential loss of oral phenylephrine as a nasal decongestant.

The executives likely will note the FDA has said it is “concerned about avoiding potential unintended consequences” for the industry in addition to consumers from a potential change to the generally regarded as safe and effective status of oral phenylephrine.

They’ll also point out the FDA review of phenylephrine didn’t find safety issues with orally products and that the efficacy of nasal sprays containing the ingredient isn’t questioned.

## Procter & Gamble

P&G hasn’t spent the first quarter of its fiscal year 2024 focused on the future of its Vicks line oral products containing phenylephrine, of course. One other item on its to-do list was the election of all 14 of its board nominees, which shareholders approved at its 2023 annual meeting on 10 October.

The approvals came despite a campaign by descendants of the company’s founders for environmental reforms at the Cincinnati-based firm. They announced before the meeting they’d ask shareholders to vote against four of P&G’s board nominees, including chairman, president and CEO Jon Moeller.

Elsewhere during the quarter, P&G extended its Clearblue home pregnancy and

- P&G forecasts its FY2024 all-in sales growth at 3% to 4%, or

fertility test line with Menopause Stage, entering the market for at-home menopause tests with the August launch of what it says is the first US product to indicate a woman's likely menopause stage. RS154072

Moeller in September said P&G is pursuing opportunities to streamline manufacturing and preparing to optimize its SKU portfolio entering the second year of its three- to five-year Supply Chain 3.0 productivity initiative it launched in 2022 with the expectation of generating annual savings of \$1.5bn. RS153995

4% to 5% organic, against a foreign exchange headwind of around 1 percentage point. It expects full-year diluted net earnings per share growth at 6% to 9% from its FY2023 EPS of \$5.90. In July, P&G reported \$20.6bn net sales for its FY2023 fourth quarter on 11% reported growth, 5% organic excluding impacts of foreign exchange, acquisitions and divestitures. It credited the growth to a 7% increase on higher pricing and 2% from a favorable mix, partially offset by a 1% decrease in shipment volumes. (Also see "[Whether Higher Sales Or Lower Volumes, Price Increases Make Presence Known For P&G And C&D](#)" - HBW Insight, 28 Jul, 2023.) Further explaining the impact of price increases on its results were a fourth-quarter gross margin increase of 380 basis points driven by 340 points of pricing benefit and 290 points of productivity savings but partially offset by 110 points of contract material price increases, 20 points of product and package reinvestments and 50 points of negative product mix and other impacts. P&G also reported 2% growth, 7% organic, in full-year net sales to \$82bn, with organic growth "due to a nine percent increase from higher pricing and a one percent increase from favorable mix, partially offset by a three percent decrease in shipment volumes."

In October, P&G announced it was partnering with Israel "scent tech" firm Moodify Ltd. to integrate artificial intelligence for accelerated development of fragrances. Its fragrance development group will avail itself of Moodify White, which launched in March as "the world's first AI-based algorithmic malodor control." (Also see "[P&G Teams With Moodify To Leverage AI In Fragrance Development](#)" - HBW Insight, 5 Oct, 2023.)

## Kenvue

Among [Kenvue Inc.](#)'s potential third-quarter losses to be reported on 26 October, one also will be a gain in its separation from [Johnson & Johnson](#).

J&J in August announced it maintains 9.5% equity stake in Kenvue after some shareholders accepted an 8-for-1 share swap. It received from shareholders nearly 191m shares of its common stock in exchange for more than 1.5bn shares of Kenvue stock.

J&J in July still owned nearly 90% of Kenvue. That stake, combined with the handful of consumer health brands it continues to own, delivered \$4bn in second-quarter worldwide sales on 5.4% growth, with 6% in the US offset slightly by 5% internationally. It said it received \$13.2bn cash from its debt offering and initial public offering to spin out Kenvue earlier in 2023, providing it with “the opportunity to monetize the retained stake in a tax efficient manner in the next year.”

Skillman, NJ-based Kenvue, meanwhile, in August added Canada as a market for Zarbees honey-based children’s products made with B vitamins, zinc and naturally sourced honey, English ivy leaf and elderberry and available at grocery and drug stores and select online retailers. (Also see ["Kenvue Reaches Canada With Zarbees Line As J&J Reaches Final Step Of Spinoff Share Exchange"](#) - HBW Insight, 17 Aug, 2023.)

Also in August, Kenvue began offering UK consumers recycling options for its products’ plastic packaging in some Tesco supermarkets. The recycling points accept plastic packaging, blister packs and spoons from Kenvue brands. (Also see ["Kenvue Trials UK Plastics Recycling Scheme In Tesco Supermarkets"](#) - HBW Insight, 10 Aug, 2023.)

Deposited items are collected by recycle and reuse specialists MYGroup, which via its subsidiary ReFactory transforms the plastics into new objects – much like TerraCycle’s partnership with P&G in the US.

Kenvue continued during the quarter defending against a complaint filed against subsidiary Johnson & Johnson Consumer Inc. by a woman alleging her use while pregnant of Tylenol products, Kenvue’s acetaminophen oral analgesic line available under the internal analgesic, antipyretic and antirheumatic

- Kenvue’s second-quarter results announced in July, its first after J&J’s IPO, showed \$207m net sales for the quarter, up 5.4%, across its three divisions of products, self care, skin health and beauty and essential health. (Also see ["Newly On Its Own, Kenvue Still Emphasizes Traditional ‘Arsenal Of Tools’ To Deliver Results"](#) - HBW Insight, 20 Jul, 2023.) The strongest driver was self-care, which includes Tylenol and Motrin in the pain care sub-category, with reported sales up 12.2% to \$180m. Kenvue’s entry in the phenylephrine-containing product market, Sudafed PE, is in the cough/cold and allergy stack in the pain care category along with Zyrtec and Benadryl allergy remedies while the Nicorette smoking cessation line and the Pepcid heartburn remedy are in the “other” group. The skin health and beauty category, with

(IAAA) OTC monograph, caused her daughter to be born with autism spectrum disorder and attention-deficit hyperactivity disorder. (Also see "[Court Wants Defense Of Acetaminophen Pregnancy Warning, US FDA Provides Research Review](#)" - HBW Insight, 15 Sep, 2023.)

A judge in US District Court for Southern New York has denied a pre-trial motion by Kenvue attorneys to dismiss based on federal preemption of state laws, the first in litigation alleging damages from using an OTC monograph drug to find against federal preemption.

Neutrogena and Aveeno in both in the face and body and hair, sun and other groups, showed 1.9% reported growth to \$21m. Sales for Kenvue's other product division, essential health with Listerine the lone oral care stack brand along with Johnson's and Desitin in baby care and Band-Aid bandages and Polysporin antibiotic topicals in the other group, were flat at 0.5% reported growth to \$6m.

The judge included in the April ruling a question for the FDA about warning labels for acetaminophen OTCs. In September, the agency declined to comment on pending litigation but instead submitted a recent review of available epidemiological evidence for the ingredient.

The review likely will make clear the FDA's current thinking on the safety for women using acetaminophen during pregnancy, but just as likely won't sway the judge from a previously stated conclusion, that a warning about the risks of in utero exposure could be added to a drug containing the ingredient and available under an OTC monograph without violating FDA regulations.

## Bausch + Lomb

[Bausch + Lomb, Corporation](#), unlike Kenvue, doesn't market a phenylephrine formulation. Like Kenvue, it launched as a spinout. But B+L's potential losses for the quarter reported 1 November won't include a reduction in shares owned by its parent firm, [Bausch Health Companies Inc.](#)

Vaughan, ON-based B+L's management is using this period of Bausch Health's near-full ownership to plan for the future. "When the spin comes, then we can spend a lot more time with our investors. But right now, I just have to take the elevator down two floors and I can see the 90% shareholder," said president and CEO Brent Saunders at a September investor conference. (Also see "[Bausch + Lomb Patiently 'Semi-Private' While Bausch Health Plots Path To Spin-Out Completion](#)" - HBW Insight, 8 Sep, 2023.)

Offering contact lens and surgical technology and Rx ophthalmology products as well as eye health OTC drugs and dietary supplements, B+L has operated as a separate, publicly traded company since Laval, Quebec-based Bausch Health in May 2022 sold 10% of its shares, half the amount it originally planned.

Since then, analysts have noted B+L's growth could be stymied by investors alleging Bausch Health conducted a fraudulent conveyance, an unlawful attempt to avoid fulfilling debts, by spinning out B+L. Analysts reported following both firms' second-quarter earnings announcements that Bausch Health could change its strategy for its planned completion of the spin, which involves selling 80% of its shares. (Also see "[Bausch Health's Securities Litigation Casts Shadow Over B+L's Future As Independent Firm](#)" - HBW Insight, 18 Apr, 2023.)

In play around Bausch Health's decision, in addition to investors' litigation, is whether Bausch Health will distribute 80% of B+L shares needed for a tax-free completion of the spin-out. But to do that, it needs to release 38.6% of the shares it currently has pledged as collateral against \$1bn debt.

On the business front, in September B+L extended its Lumify OTC eye drop brand in the US with three hypoallergenic cosmetic products developed to cleanse and brighten the eye area and containing an ingredient commonly used in dietary supplements to promote skin health.

Each product contains hyaluronic acid, a substance found in many areas of the human body including the skin, eyes, and synovial fluid of the joints which acts as a cushion and lubricant in the joints and other tissues; the 3-in-1 Micellar and Hydra-Gel also contain vitamin C, according to the firm's announcement. (Also see "[Bausch + Lomb Spreads Into US Cosmetics Market, Extends Lumify Brand With Eye Illuminations Line](#)" - HBW Insight, 26 Sep, 2023.)

- B+L's second-quarter results announced in August showed its consumer health brands accounted for 67% of its vision care sales of \$646m, which accounted for well above half B+L's total revenues just short of \$1.04bn in the second quarter, up 10% reported – including the impact of foreign exchange. (Also see "[Consumer Health Brands Pull Their Weight For Bausch + Lomb To Be 'Non-Pharma' Company](#)" - HBW Insight, 2 Aug, 2023.) Its OcuVite and PreserVision eye health supplements were its top sellers overall, up \$10m from the year-ago period to \$104m. Lumify sales grew nearly 23% to \$43m while B+L's contact lens solution brands showed nearly 7% sales growth to \$134m. However, it reported a \$32m net loss for the quarter after reporting \$5m net income a year ago. It says the results primarily were due to an increase in interest expense and foreign exchange headwinds.



The active ingredient in Lumify eye drops, brimonidine tartrate, isn't used in the products, which are for topical application rather than ophthalmic. Lumify eye drops have been a consumer health segment sales driver for B+L since their 2018 launch in the US as an OTC switch making brimonidine available nonprescription for the first time.

B+L also started the second quarter expanding its eye care portfolio. It is paying J&J's Johnson & Johnson Surgical Vision Inc. business \$106.5m cash for Blink eye and contact lens drops.

The acquired products are Blink Tears (polyethylene glycol 400 0.25%) lubricating eye drops also available in preservative free and gel formulations as well as the "Triple Care" version – instant soothing, extra long-lasting and locking in moisture; and Blink Contacts and Blink-N-Clean contact lens drops. (Also see "[In J&J's 'Mutually Beneficial' Frame For Selling Blink OTC Eye Drops To B+L, Kenvue Also Wins](#)" - HBW Insight, 6 Jul, 2023.)

J&J Vision didn't include in the deal Blink brand eye lid wipes and the brand's RevitaLens multi-purpose disinfecting solution and TotalCare lens solution marketed outside the US.

## Perrigo

[Perrigo Company PLC](#) has a big stake in the phenylephrine market as the predominant supplier of private label and store brand OTC drugs in the US. The Dublin-based firm, which will announce its third-quarter results on a date to be announced, also will have the biggest stake in the OTC birth control market early in 2024 when it launches the first nonprescription daily oral contraceptive approved by the FDA.

The FDA in July announced approval of Perrigo subsidiary HRA Pharma's new drug application for OTC sales of Opill (0.075-mg norgestrel). Sales in stores and online are expected to start early in the 2024 first quarter.

At an investor conference during the third quarter, however, Perrigo executives described plans for becoming even bigger in the OTC private label and store brand product space rather than highlighting its national brand play prominently featuring Opill. (Also see "[OTC Brands In Hand, Perrigo Prepares To Pump More Revenue From Private Label Portfolio](#)" - HBW Insight, 16 Aug, 2023.)

"We're seeing as national brands have stepped up pricing significantly over the last couple of years, and while a store brand we saw a pickup in volume and not so pricing to the same level. We believe that there is a big space there for us to differentiate ourselves from other store brand suppliers and so that's really a great opportunity," said chief financial officer Eduardo Bezerra in

August.

Bezerra said president and CEO Patrick Lockwood-Taylor, who joined Perrigo in June, “is bringing a different language and approach on how to look into consumer to be very differentiated in our US business.”

Part of that difference apparently is looking to Perrigo’s traditional strength of making private label and store brand copies of national brands as a growth

driver rather than emphasizing marketing its own national brands, as his predecessor Murray Kessler did when he took the firm’s helm.

Perrigo also has a different head of its Americas business with Catherine “Triona” Schmelter in September named president for Consumer Self-Care Americas and of global portfolio optimization, a new post at the firm, and an executive vice president. (Also see “[US Health And Wellness Executive Decisions: Perrigo, Nestle, Flexpower Health, Herbalife, More](#)” - HBW Insight, 29 Sep, 2023.)

Reporting to Lockwood-Taylor, Schmelter will lead the strategic direction, growth and profitability of the Americas business in addition to overseeing the global portfolio evolution process to deliver Perrigo's long-term growth algorithm.

## Prestige Consumer Healthcare

[Prestige Consumer Healthcare Inc.](#) will announce its FY2024 second-quarter results on 1 November after reporting in July first-quarter revenues increasing 0.8% to \$279.3m, or 1.8%

- Perrigo in August, announcing its first results with Lockwood-Taylor at the helm, reported \$1.2bn second-quarter net sales, up 6.4%, or 6.6% on a constant currency basis, while the organic measure – excluding additions, divestments or other changes since the prior-year period – was 0.8% growth after a 2.7 percentage point drag from stockkeeping unit prioritization moves made in the supply chain reinvention. (Also see “[Perrigo Prepares To Pioneer US OTC Birth Control Sales As ‘Supply Chain Reinvention’ Continues](#)” - HBW Insight, 8 Aug, 2023.) Its Americas region net sales grew 3.1% from the year-ago quarter to \$750.8m, offset 4.1 percentage points from SKU prioritization; nets sales in its international markets during the April-June period grew 12.4%, or 7.1% on an organic measure, to \$442.4m. Perrigo maintained its full-year 2023 reported net sales growth guidance of 7% to 11%, and organic at 3% to 6%, and adjusted diluted EPS of \$2.50 to \$2.70.



excluding the impact of foreign currency exchange. (Also see "[Dramamine, Nix Drive Prestige Consumer Sales](#)" - HBW Insight, 3 Aug, 2023.)

Its North American OTC sales were up 1.5% from the year-ago period to \$246.1m with growth shown across its brands, led by dermatological products, including Compound W wart remo

ver as well as Nix, and its gastrointestinal line led by Dramamine. North American sales growth was offset by a nearly 3.8% drop in international revenues to \$33.2m due to a \$1.9m loss to currency exchange.

The Tarrytown, NJ-based firm's reported net income for the April-June period was \$53.3m, off 3.6% from the year-ago period. Diluted earnings per share were \$1.06, down from \$1.09 a year ago.

As for its Nix, lice treatment line, PCH is making the brand a consumer choice for needs other than removing lice while the outlook for demand is strong. The firm says "head lice season is gradually returning to more normalized pre-COVID levels."

## Church & Dwight

[Church & Dwight Co. Inc.](#), announcing its third-quarter results on 3 November, in July announced \$1.45bn second-quarter net sales on 9.7% reported growth, 5.4% organic, "driven by positive product mix and pricing of 5.8% while volume was down slightly but exceeded expectations." (Also see "[Whether Higher Sales Or Lower Volumes, Price Increases Make Presence Known For P&G And C&D](#)" - HBW Insight, 28 Jul, 2023.)

Consumer health and personal care product sales grew a reported 17.9% to \$509m while its household products showed 8.1% reported growth to \$691.2m.

Its reported earnings per share were 89 cents, up more than 21% from the year-ago period.

Ewing, NJ-based C&D reported its gross margin increased 270 basis points to 43.9% on improved pricing, productivity and the impact of its Hero acne patch line acquisition offset by the impact of higher manufacturing costs.

## Herbalife

Nutrition and wellness product direct seller [Herbalife Nutrition Ltd.](#) in August appointed a chief

strategy officer and the next month a vice president to lead global corporate communications. It also launched its vegan product line in the US during the July-September period, results for which it's announcing on 1 November.

Chief strategy officer Stephan Gratziani has been an independent distributor with business in 70 markets across North America, South America, Europe and Asia. Recognized as one of Herbalife's three top independent distributors worldwide for 2022 when he earned around \$5.1m in compensation, Gratziani, reports directly to CEO Michael Johnson and works with the Los Angeles-based company's senior management team to implement and advance strategic initiatives including the Herbalife One digital technology platform and business verticals. (Also see "[US Health And Wellness Executive Decisions: Herbalife, Bausch + Lomb, Cascadia Capital](#)" - HBW Insight, 7 Aug, 2023.)

Gratziani resigned from the firm's board and agreed to become an employee; as required by the company's conflict of interest policy, he agreed to suspend his Herbalife distributorship and waived any rights to his distributorship earnings during the term of his employment through December 2025.

The current CSO, John DeSimone, will transition to special advisor to the company.

- Herbalife's second-quarter results showed an 11% boost from price increases was its only revenue driver as net sales slipped 5.7% to \$1.3bn and results for all regions other than Latin America fell as much as 15% or were flat. (Also see "[Herbalife Sees 'Saturation' In Price Increases, Potential Marketing To Weight Loss Drug Patients](#)" - HBW Insight, 3 Aug, 2023.)

As communications chief, Susan Brown reports to executive VP and chief of staff Ibi Montesino. Brown's responsible for Herbalife's communications function, leading development and execution of all internal and external communications, overseeing corporate reputation and advancing communications strategy in support of the company's business objectives. (Also see "[US Health And Wellness Executive Decisions: Perrigo, Nestle, Flexpower Health, Herbalife, More](#)" - HBW Insight, 29 Sep, 2023.)

She has more than two decades of strategic, corporate and crisis communications experience and previously was global corporate communications head for Tyson Foods and Price Waterhouse Coopers and had communications leadership roles at SITA, an airlines IT provider, and Emirates Airline & Group.