# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D. C. 20549

## **FORM 10-Q**

X QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2015

OR

" TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

to

For the transition period from

Commission File No. 1-31946

## HOSPIRA, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

20-0504497

(I.R.S. Employer Identification No.)

Accelerated filer o

Smaller reporting company o

275 North Field Drive Lake Forest, Illinois 60045

(Address of principal executive offices, including zip code)

(224) 212-2000

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No "

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data file required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No "

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer x

Non-accelerated filer o

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes "No x

As of July 27, 2015, Registrant had outstanding 172,934,361 shares of common stock, par value \$0.01 per share.



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## Hospira, Inc.

### Quarterly Report on Form 10-Q

## Index

### Part I — Financial Information

|                             | <u>Item 1.</u> | Financial Statements  |           |  |  |  |  |  |  |
|-----------------------------|----------------|---|-----------|--|--|--|--|--|--|
|                             |                | Condensed Consolidated Statements of Income and Comprehensive Income (Unaudited) — Three and Six Months Ended June 30, 2015 and June 30, 2014 | <u>6</u>  |  |  |  |  |  |  |
|                             |                | Condensed Consolidated Statements of Cash Flows (Unaudited) - Six Months Ended June 30, 2015 and June 30, 2014                                | <u>7</u>  |  |  |  |  |  |  |
|                             |                | Condensed Consolidated Balance Sheets (Unaudited) — June 30, 2015 and December 31, 2014   | <u>8</u>  |  |  |  |  |  |  |
|                             |                | Condensed Consolidated Statement of Changes in Shareholders' Equity (Unaudited) — Six Months Ended June 30, 2015                              | <u>9</u>  |  |  |  |  |  |  |
|                             |                | Notes to Condensed Consolidated Financial Statements (Unaudited)  | <u>10</u> |  |  |  |  |  |  |
|                             | <u>Item 2.</u> | Management's Discussion and Analysis of Financial Condition and Results of Operations   | <u>26</u> |  |  |  |  |  |  |
|                             | Item 3.        | Quantitative and Qualitative Disclosures About Market Risk  | <u>42</u> |  |  |  |  |  |  |
|                             | Item 4.        | Controls and Procedures   | <u>43</u> |  |  |  |  |  |  |
| Part II — Other Information |                |   |           |  |  |  |  |  |  |
|                             | Item 1.        | Legal Proceedings   | <u>44</u> |  |  |  |  |  |  |
|                             | Item 1A.       | Risk Factors  | <u>44</u> |  |  |  |  |  |  |
|                             | Item 2.        | Unregistered Sales of Equity Securities and Use of Proceeds   | <u>44</u> |  |  |  |  |  |  |
|                             | Item 3.        | Defaults Upon Senior Securities   | <u>45</u> |  |  |  |  |  |  |
|                             | Item 4.        | Mine Safety Disclosures   | <u>45</u> |  |  |  |  |  |  |
|                             | Item 5.        | Other Information   | <u>45</u> |  |  |  |  |  |  |
|                             | Item 6.        | Exhibits  | <u>45</u> |  |  |  |  |  |  |
|                             |                |   |           |  |  |  |  |  |  |

2

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#### Table of Contents

#### Performance Share Awards

No performance share awards were granted in the six months ended June 30, 2015. For prior grants, the weighted average grant date fair value using the Monte Carlo simulation model and the corresponding weighted average assumptions were as follows:

|                                  | Six Mon | ix Months Ended June<br>30, |  |  |
|----------------------------------|---------|-----------------------------|--|--|
|                                  | 2014    |                             |  |  |
| Expected volatility              |         | 30.8%                       |  |  |
| Risk-free interest rate          |         | 0.6%                        |  |  |
| Expected dividend yield          |         | 0.0%                        |  |  |
| Fair value per performance share | \$      | 54.55                       |  |  |

#### Restricted Stock and Units

During the six months ended June 30, 2015, 0.8 million restricted stock and units were granted to certain employees and non-employee directors primarily as part of the 2015 annual grant. Hospira issues restricted stock and units that generally vest in approximately equal amounts on the first, second and third anniversaries of the grant date. The weighted average grant date fair value of restricted stock and units granted for the six months ended June 30, 2015 and 2014 was \$87.51 and \$42.96 per restricted award, respectively.

#### Note 24 — Commitments and Contingencies

Hospira is involved in various claims and legal proceedings, as well as product liability claims, regulatory matters and proceedings related to Hospira's business, including in some instances when Hospira operated as part of Abbott Laboratories.

#### Precedex™ Matters

Hospira is currently involved in two lawsuits relating to the ability of Eurohealth International Sarl and West-Ward Pharmaceutical Corp. (collectively "Eurohealth") to market generic forms of Hospira's Precedex<sup>™</sup> (dexmedetomidine hydrochloride), a proprietary sedation agent. The two cases, No. 14-cv-00487 (filed April 18, 2014) and No. 14-cv-01008 (filed August 1, 2014), are both pending in U.S. District Court for the District of Delaware and are based on Eurohealth's ANDAs filed with the FDA for generic versions of Precedex<sup>™</sup>, one of which is a premix product. Hospira seeks a judgment of infringement based on the claims of U.S. Patent No. 6,716,867, injunctive relief and costs. Eurohealth International Sarl purchased the assets of Ben Venue Laboratories, Inc. d/b/a Bedford Laboratories. West-Ward Pharmaceutical Corp. is Eurohealth's agent in the U.S.

On August 18, 2014, the FDA allowed a carved-out label for generic competitors of Precedex<sup>TM</sup>. Immediately following that decision, Mylan Institutional, LLC and Par Sterile Products, LLC launched generic versions of Precedex<sup>TM</sup> concentrate. On August 19, 2014, Hospira initiated litigation over the FDA's action, which was settled on October 28, 2014.

In addition to the previously reported settlements, Hospira entered during the second quarter of 2015 into confidential settlement agreements regarding Precedex<sup>TM</sup> patent-related litigation with Sun Pharmaceutical Industries, Inc. and Gland Pharma Ltd., in April 2015, Akorn, Inc., in May 2015, and Actavis US Holding LLC and Actavis LLC, in May 2015.

Hospira also has received a "Paragraph IV" notice from Amneal Pharmaceuticals related to patents associated with Hospira's premix Precedex<sup>TM</sup> product. Hospira has 45 days from the date the notice was received to initiate a lawsuit alleging infringement of the various patents included in the notice. Such a lawsuit would result in a 30 month stay of approval from the FDA of Amneal's proposed generic product.

#### Stockholder Litigation

Hospira and members of its Board of Directors are named as defendants in five class action lawsuits filed in the Delaware Court of Chancery alleging breaches of fiduciary duty in connection with the Merger Agreement. Pfizer and Merger Sub are also named as defendants. The lawsuits, which seek to enjoin the proposed transaction, allege generally that the Merger Agreement resulted from an unfair process and fails to maximize value for Hospira stockholders. The lawsuits were filed by the following named plaintiffs, on behalf of themselves and all others similarly situated: Robert J. Casey II, Samuel Montini, Charles Zimmerman, Jason Chen and Patricia Takach.



#### Table of Contents

#### **Regulatory Matters**

Hospira's businesses are subject to regulatory inspections by regulatory authorities across the globe. Such regulatory inspections may lead to observations (commonly referred to as Form 483 observations in the U.S.), untitled letters, warning letters or similar correspondence, voluntary or involuntary product recalls, consent decrees, injunctions to halt manufacture and distribution of products, seizures of violative products, import and export bans or restrictions, monetary sanctions, delays in product approvals or clearances, civil penalties, criminal prosecution and other restrictions on operations.

Hospira has received warning letters from the FDA related to matters affecting its pharmaceutical manufacturing facility in Mulgrave, Victoria, Australia, pharmaceutical and device manufacturing facilities in Clayton and Rocky Mount, North Carolina, its device manufacturing facility in La Aurora de Heredia, Costa Rica, its pharmaceutical manufacturing facility in Irungattukottai, India, its device quality systems and governance in Lake Forest, Illinois and its pharmaceutical manufacturing facility in Liscate, Italy. The Company has responded fully, and in a timely manner, to these warning letters. By letter dated April 16, 2015, the FDA advised Hospira that it had completed its evaluation of the Company's corrective actions in response to the April 2010 warning letter relating to Hospira's Rocky Mount and Clayton, North Carolina, pharmaceutical manufacturing facilities.

The remediation plans in response to the warning letters involve commitments by Hospira to enhance its quality system, products, facilities, employee training, quality processes and procedures, and technology. While Hospira continues implementing its remediation plans, the plans are subject to update and revision based on issues encountered during the remediation process, or on further interaction with the FDA or other regulatory bodies. Hospira cannot, however, give any assurances as to the expected date of resolution of the matters identified in the warning letters.

#### Environmental Matters

India's National Green Tribunal ("NGT") and the Maharashtra Pollution Control Board ("MPCB") are actively reviewing various industrial facilities in the vicinity of Aurangabad, India, to determine whether those facilities have contributed to alleged groundwater and soil contamination in the area. On July 15, 2015, the NGT issued an order directing Hospira India, as the owner of a manufacturing facility in Aurangabad, and the unrelated owners of other facilities, to deposit in escrow an amount up to approximately \$2.0 million each. A deposit by a company would be applied to any required costs of remediation if that company is determined to have responsibility for the alleged contamination. Subsequent to the NGT order, MPCB ordered the immediate closure of Hospira India's Aurangabad facility; however, based on Hospira India's application, the NGT stayed the closure order until at least August 24, 2015, when a further hearing is scheduled. The NGT also reduced the escrow deposit for Hospira India to approximately \$0.9 million. Hospira continues to evaluate its response with local counsel, local environmental consultants and local governmental consultants. A prolonged closure of the Aurangabad facility would affect production at that facility, as well as production at Hospira India's Irungattukottai, India facility, and could have a material adverse effect on Hospira's results of operations.

#### Litigation Exposure Evaluation

Hospira's litigation exposure, including product liability claims, is evaluated each reporting period. Hospira's accruals, which are not significant at June 30, 2015 and December 31, 2014, are the best estimate of loss. Based upon information that is currently available, management believes that the likelihood of a material loss in excess of recognized amounts is remote.

Additional legal proceedings may occur that may result in a change in the estimated accruals recognized by Hospira. It is not feasible to predict the outcome of such proceedings with certainty and there can be no assurance that their ultimate disposition will not have a material adverse effect on Hospira's financial position, cash flows or results of operations.

#### Note 25 — Segment Information

Hospira conducts operations worldwide and is managed in three reportable segments: Americas, EMEA and APAC. The Americas reportable segment includes three operating segments, the U.S., Canada and Latin America; the EMEA reportable segment includes one operating segment, Europe, the Middle East and Africa; and the APAC reportable segment includes two operating segments, Asia and Japan and Australia and New Zealand. In all segments, Hospira sells a broad line of products, including Specialty Injectable Pharmaceuticals, Medication Management and Other Pharmaceuticals. Specialty Injectable Pharmaceuticals include generic injectables, proprietary specialty injectables and, in certain markets, biosimilars. Medication Management includes infusion pumps, related software and services, dedicated administration sets, gravity administration sets and other device products. Other Pharmaceuticals include large volume I.V. solutions, nutritionals and contract manufacturing.

Hospira's underlying accounting records are maintained on a legal-entity basis for government and public reporting requirements. Segment disclosures are on a performance basis consistent with internal management reporting. For internal management reporting, intersegment transfers of inventory are recognized at standard cost and are not a measure of segment income from operations. The costs of certain corporate functions, stock-based compensation, Interest expense and Other income, net that benefit the entire organization are not allocated. The following segment information has been prepared in accordance with the internal accounting policies of Hospira, as described in "Part II, Item 8. Financial Statements and Supplementary Data, Note 1" in Hospira's 2014 Form 10-K.

#### Reportable segment information:

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The table below presents information about Hospira's reportable segments for the three months ended June 30:

|                           | Net Sales |         |      |         | Income From Operations |        |      |        |
|---------------------------|-----------|---------|------|---------|------------------------|--------|------|--------|
| (dollars in millions)     | 2015      |         | 2014 |         | 2015                   |        | 2014 |        |
| Americas                  | \$        | 964.4   | \$   | 913.2   | \$                     | 273.0  | \$   | 136.6  |
| EMEA                      |           | 129.1   |      | 132.7   |                        | (19.7) |      | (11.7) |
| APAC                      |           | 90.1    |      | 89.9    |                        | 6.9    |      | 12.2   |
| Total reportable segments | \$        | 1,183.6 | \$   | 1,135.8 |                        | 260.2  |      | 137.1  |
| Corporate functions       |           |         |      |         |                        | (26.6) |      | (19.9) |
| Stock-based compensation  |           |         |      |         |                        | (15.0) |      | (17.7) |

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