

Edgar Filing: Shire plc - Form 425

Shire plc
Form 425
July 25, 2014

Filed by AbbVie Inc.

Pursuant to Rule 425

Under the Securities Act of 1933

Subject Company: Shire plc

Commission File No.: 0-29630

AbbVie Inc. held its second quarter earnings call today at 8 am CDT; the transcript from this call appears below, and a copy of this announcement is available on AbbVie's website at <http://www.abbvieinvestor.com/phoenix.zhtml?c=251551&p=irol-disclaimer-documents>:

AbbVie Second-Quarter 2014 Earnings Conference Call Transcript

July 25, 2014

Larry Peepo, Vice President of Investor Relations

Thank you.

Good morning, and thanks for joining us. On the call with me today are Rick Gonzalez, chairman of the board and chief executive officer, and Bill Chase, executive vice president of Finance and chief financial officer.

Rick will begin by discussing AbbVie's results from the second quarter, and then provide an update on our pipeline and some of the key milestones we expect this year.

Bill will give a more detailed review of our quarterly performance, and then provide an overview of our 2014 outlook.

As a reminder, we are currently operating under the UK Takeover Code and will be until the Shire transaction is completed. The UK Takeover Code governs what we are able to disclose regarding the specifics of the transaction as well as the various aspects of AbbVie's underlying business, including operating performance, product details and pipeline milestones.

Edgar Filing: Shire plc - Form 425

To help investors, we have added a Q&A section to our earnings news release, which addresses a number of typical questions we've received.

Due to the UK Takeover Code, we will only be providing prepared remarks during our conference call today. There will not be a question and answer portion of today's call.

Before I turn the call over to Rick, I remind you that some statements we make today may be considered forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995.

AbbVie cautions that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements.

Edgar Filing: Shire plc - Form 425

Additional information about the factors that may affect AbbVie's operations is included in our 2013 Annual Report on Form 10-K and in our other SEC filings.

AbbVie undertakes no obligation to release publicly any revisions to forward-looking statements as a result of subsequent events or developments, except as required by law.

On today's conference call, as in the past, non-GAAP financial measures will be used to help investors understand AbbVie's ongoing business performance. These non-GAAP financial measures are reconciled with comparable GAAP financial measures in our regulatory filings, which can be found on our website.

And with that, I'll now turn the call over to Rick.

Rick Gonzalez, Chairman and Chief Executive Officer

Thank you, Larry.

Good morning everyone and thank you for joining us this morning.

We're pleased to report strong second quarter results, with adjusted earnings per share of \$0.82, exceeding our guidance range for the quarter. This included sales growth of nearly five percent – also ahead of our outlook for the quarter – despite the negative impact from the loss of exclusivity in our lipids franchise.

Sales growth was led by continued robust performance from Humira and other key products, including Synthroid, Sevoflurane and Duodopa.

We've been pleased with our performance in the first half of the year, and as a reminder, last month we raised our full-year 2014 earnings-per-share guidance range to \$3.06 to \$3.16(1) on an adjusted basis, reflecting strong underlying business performance.

Beyond our strong financial performance, we had a very productive second quarter, with a number of important pipeline advancements, clinical trial results and other strategic activities.

We submitted our U.S. and EU regulatory applications for our interferon-free HCV combination. Both applications are currently under active priority review. We continue to anticipate U.S. approval later this year and EMA authorization in early 2015.

We're also working to advance our next-generation HCV assets, which are currently in Phase Two development. We expect data from the Phase Two B program in 2015 and plan to start Phase Three development next year, as well.

We've also made progress with several assets in our oncology pipeline:

(1) This statement constitutes a profit forecast under Rule 28 of the City Code on Takeovers and Mergers issued by the Panel on Takeovers and Mergers (the "Code"). Further information can be found in the Q2 2014 earnings announcement issued by AbbVie on 25 July 2014 and available on AbbVie's website at www.abbvieinvestor.com/phoenix.zhtml?c=251551&p=irol-disclaimer-documents.

At the recent ASCO and EHA meetings, we presented interim results from a Phase One clinical trial of ABT-199, our BCL-2 inhibitor, in combination with Rituxan in relapsed/refractory CLL patients. The data showed an overall response rate of 84 percent and a complete response rate of 36 percent, which compares favorably to trial results from other therapies in this patient population.

This combination is being investigated in an ongoing Phase Three clinical trial for the treatment of relapsed/refractory CLL. We're also evaluating ABT-199 in a variety of other cancer types, including AML. We expect to present data from the AML study at an upcoming medical meeting.

Also at ASCO, AbbVie released preliminary results from an ongoing Phase One study of ABT-414, an anti-EGFR monoclonal antibody drug conjugate, used in combination with chemotherapy.

The study showed a level of response not typically seen in patients with recurrent or unresectable GBM. GBM is the most common and most aggressive type of malignant primary brain tumor. Patients currently have few treatment options and the five-year survival rate for this type of cancer is less than three percent. We're working to quickly advance ABT-414.

We recently announced the initiation of a Phase Three study of our PARP inhibitor, ABT-888, in patients with HER2 negative breast cancer containing BRCA gene mutations. The start of this trial followed initiation of Phase Three clinical work in two other settings: non-small cell lung cancer and neoadjuvant treatment of triple negative breast cancer. This fall, we'll present data from the mid-stage trial in lung cancer that supported our decision to advance to Phase Three development. We have a number of other mid-stage trials that we expect to read out in the coming months.

In June, we announced positive top-line results from our Phase 3 Daclizumab study. It demonstrated patients treated with daclizumab had a statistically significant 45 percent reduction in annualized relapse rate versus an active comparator. We're excited about these results and we're in the process of working with our partner to complete our global regulatory applications.

In our immunology pipeline, we recently advanced two bi-specific, DVD-Ig's into Phase Two development: ABT-122 for RA, and ABT-981 for OA.

Additionally, we continue to make progress on our selective JAK 1 inhibitor programs. We recently initiated a second Phase Two trial in RA with our internal JAK-1 compound, ABT-494. And, we look forward to seeing data from the Phase Two B Galapagos collaboration early next year.

Since becoming an independent company 18 months ago, AbbVie has built a strong and sustainable strategy for the business. Last week, we announced an important step in taking that strategy to the next level—the proposed merger with Shire.

The combination of AbbVie and Shire represents a compelling opportunity to create a new, world-class biopharmaceutical company. The combined company would have leadership positions within multiple important areas of medicine, a deeper and broader pipeline and greater

access to its global cashflows.

This transaction offers significant strategic and financial benefits for our respective shareholders and companies, as well as the patients that we serve.

Edgar Filing: Shire plc - Form 425

The combined company would be a larger, more diversified company, with significant financial capacity for future strategic investment. Additionally, the proposed combination offers an opportunity for enhanced shareholder return of capital and shareholder value creation.

We're currently seeking the relevant approvals for the transaction and are working towards our stated goal for closing in the fourth quarter of 2014.

In summary, we're very pleased with the strong performance we've had in the first half of 2014. In the second quarter we saw strong performance across our portfolio, including double-digit growth from Humira. We've made significant progress advancing our pipeline and expect a number of additional milestones over the next 6-9 months. And, with the recent agreement to merge with Shire, I believe we've taken an important strategic action to enhance our position as a world-class biopharmaceutical company.

With that, I'll turn the call over to Bill. Bill

Bill Chase, Executive Vice President and Chief Financial Officer

Thank you, Rick.

This morning, I'll review our second quarter performance and provide an update on our outlook for the remainder of 2014.

As Rick said, we're very pleased with our results this quarter. We exceeded our guidance on both the top and bottom line. Total sales increased 4.8 percent on an operational basis, excluding a 0.2 percent favorable impact from foreign exchange. Excluding sales from our lipid franchise due to loss of exclusivity, total sales increased 12.3 percent on an operational basis.

Humira delivered global sales of nearly \$3.3 billion, up 25.4 percent on an operational basis and 26.2 percent on a reported basis.

In the United States, HUMIRA sales increased 35.6 percent, driven by continued market expansion, share gains, and particularly strong growth in the gastro segment. Growth in the second quarter benefitted from retail buying patterns and a favorable comparison to the prior year. Second quarter wholesaler inventory levels remain at roughly two weeks, consistent with the first quarter. We expect third-quarter HUMIRA sales growth in the U.S. to be reflective of underlying product demand and pricing trends, partially offset by a reduction in retail buying patterns. As a result, we are forecasting high-teens growth in the U.S. for HUMIRA in the third quarter.

Internationally, HUMIRA sales grew 16.2 percent on an operational basis and 17.8 percent on a reported basis. International growth continues to be driven by the uptake of new indications, share gains and double-digit market growth in most markets. Performance in the quarter also benefitted modestly from the timing of international shipments. We are forecasting low double-digit growth for HUMIRA internationally in the

Edgar Filing: Shire plc - Form 425

third quarter driven by strong underlying trends, partially offset by the timing of shipments in international markets.

On a global basis, we continue to expect double-digit sales growth for HUMIRA in 2014.

Edgar Filing: Shire plc - Form 425

AndroGel sales were \$218 million, down 15.6 percent from the prior year quarter. We continue to see a notable slowdown in the market, with overall prescriptions down more than 20 percent in recent months. We expect these market trends to continue.

U.S. sales of Synthroid were \$166 million, up 8.7 percent year-over-year. Synthroid maintains strong brand loyalty and market leadership, despite the entry of generics into the market many years ago. The overall market has experienced low-single digit growth, with Synthroid growth outpacing the market, including product pricing trends.

U.S. Creon sales were \$110 million in the quarter, up 4.1 percent. Creon maintains its leadership position in the pancreatic enzyme market, where the product continues to capture the vast majority of new prescription starts.

Global Lupron sales were \$186 million in the quarter, down 5.2 percent on an operational basis. Lupron continues to hold a leadership position and maintains significant share of the market. Performance this quarter is roughly in line with our full-year expectations, and is also consistent with recent market trends.

Sales of Synagis were \$74 million in the second quarter, up 16.3 percent on an operational basis. Synagis, which protects at-risk infants from severe respiratory disease, is a seasonal product with the majority of sales in the first and fourth quarters of the year. Growth in the quarter was driven by continued product uptake and strong commercial execution.

Sales of Duodopa, our therapy for advanced Parkinson's disease approved in Europe and other international markets, were \$56 million, up 24.2 percent on an operational basis this quarter. Performance in the quarter is in line with recent trends as well as our full-year outlook for the product.

And, sales of Niaspan and TriCor/Trilipix were both down significantly due to generic competition. We expect these trends to continue for the remainder of 2014.

I'll now turn to the P&L profile for the second quarter. The adjusted gross margin ratio was 79.6 percent, in line with our expectations. This reflects loss of exclusivity in our lipid franchise, offset by favorable mix impacts across the portfolio and margin enhancing initiatives we've implemented.

Adjusted R&D was 16.1 percent of sales in the second quarter. R&D spending was up sequentially over the first quarter as we increased funding of our mid- and late-stage pipeline assets and additional Humira indications.

Adjusted SG&A was 27.1 percent of sales in the second quarter. As expected, SG&A spending increased from the first quarter, reflecting continued investment in our growth brands and preparations for our upcoming HCV launch.

Edgar Filing: Shire plc - Form 425

Net interest expense was \$69 million, and the adjusted tax rate was 22.2 percent in the quarter.

Second-quarter adjusted earnings per share, excluding non-cash amortization expense and specified items, were \$0.82, exceeding our previous guidance range of \$0.75 to \$0.77. On a GAAP basis, earnings per share were \$0.68.

Moving on to our outlook for the remainder of 2014. For the full year, we are confirming our recently-increased adjusted earnings per share guidance of \$3.06 to \$3.16(2).

For the third quarter, we expect adjusted earnings per share of \$0.77 to \$0.79(2).

We are forecasting low- to mid-single-digit operational sales growth in both the third and fourth quarters of 2014. As a reminder, our 2014 outlook excludes any potential revenue from the expected 2014 U.S. launch of our HCV therapy.

We expect the third-quarter gross margin ratio to be approximately 79 percent. For the fourth quarter, the ratio is expected to be somewhat lower than the third quarter driven by product mix, particularly an increase in lower-margin Synagis sales.

As noted on our fourth-quarter earnings call in January, we are forecasting a higher level of SG&A expense in 2014, driven primarily by investments we are making for the upcoming launch of our HCV regimen in the U.S. and Europe.

For the third quarter, we expect a modest sequential increase in absolute SG&A expense from the second quarter. For the fourth quarter, given the proximity to the U.S. HCV launch, we'd expect a more meaningful sequential increase in absolute SG&A expense from the third-quarter level. This has been reflected in our recently-increased adjusted earnings-per-share guidance.

We currently have a significant number of Phase 3 programs in active development including exciting opportunities in oncology, HCV, immunology and other areas that warrant investment. As a result, we expect R&D expense to be above 16 percent of sales for the full-year 2014, reflecting a meaningful increase in spending over the prior year.

For the third quarter, we expect a sequential increase in absolute R&D investment from the second-quarter level. For the fourth quarter, we are forecasting a more modest sequential increase from the third-quarter level. This has been reflected in our recently-increased adjusted earnings-per-share guidance.

So, overall, we're pleased with our strong quarter performance in the second quarter as well as our outlook for the remainder of 2014. With that, I'll turn it back over to Larry.

Larry Peepo

Thanks Bill. That concludes today's conference call. As a reminder, we will not be opening the line for questions, but there is a comprehensive Q&A in this morning's earnings news release which can be found on our website, abbvieinvestor.com.

Thanks again for joining us today.

(2) This statement constitutes a profit forecast under Rule 28 of the City Code on Takeovers and Mergers issued by the Panel on Takeovers and Mergers (the "Code"). Further information can be found in the Q2 2014 earnings announcement issued by AbbVie on 25 July 2014 and available on AbbVie's website at www.abbvieinvestor.com/phoenix.zhtml?c=251551&p=irol-disclaimer-documents.

[CALL ENDS]

No Offer or Solicitation

This transcript is provided for informational purposes only and does not constitute an offer to sell, or an invitation to subscribe for, purchase or exchange, any securities or the solicitation of any vote or approval in any jurisdiction, nor shall there be any sale, issuance, exchange or transfer of the securities referred to in this transcript in any jurisdiction in contravention of applicable law.

Additional Information and Where to Find it

In furtherance of the combination, AbbVie Private Limited (Holdco) intends to file with the SEC a registration statement on Form S-4 containing a Proxy Statement of AbbVie that will also constitute a Prospectus of Holdco relating to the Holdco Shares to be issued to Holdco Stockholders in the combination. In addition, AbbVie, Holdco and Shire may file additional documents with the SEC. INVESTORS AND SECURITY HOLDERS OF ABBVIE AND SHIRE ARE URGED TO READ THE PROXY STATEMENT/PROSPECTUS, AND OTHER DOCUMENTS FILED WITH THE SEC IN CONNECTION WITH THE TRANSACTION CAREFULLY AND IN THEIR ENTIRETY, BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION. Those documents, if and when filed, as well as AbbVie's and Holdco's other public filings with the SEC may be obtained without charge at the SEC's website at www.sec.gov, at AbbVie's website at www.abbvieinvestor.com and at Shire's website at www.shire.com. It is expected that the Holdco shares to be issued to Shire shareholders under a scheme of arrangement will be issued in reliance upon the exemption from the registration requirements of the Securities Act of 1933, as amended, provided by Section 3(a)(10) thereof.

Participants in the Solicitation

AbbVie, its directors and certain of its executive officers may be considered participants in the solicitation of proxies in connection with the transactions contemplated by the Proxy Statement/Prospectus. Information about the directors and executive officers of AbbVie is set forth in its Annual Report on Form 10-K for the year ended December 31, 2013, which was filed with the SEC on February 21, 2014, and its proxy statement for its 2014 annual meeting of stockholders, which was filed with the SEC on March 24, 2014. Other information regarding potential participants in the proxy solicitations and a description of their direct and indirect interests, by security holdings or otherwise, will be contained in the Proxy Statement/Prospectus when it is filed.

Forward-Looking Statements

This transcript contains certain forward-looking statements with respect to a combination involving AbbVie and Shire. The words believe, expect, anticipate, project and similar expressions, among others, generally identify forward-looking statements. These forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Such risks and uncertainties include, but are not limited to, the possibility that necessary regulatory approvals or stockholder approvals will not be obtained or any of the other conditions to the

combination will not be satisfied, adverse effects on the market price of AbbVie Shares and on AbbVie's or Shire's operating results because of a failure to complete the combination, failure to realise the expected benefits of the possible combination, negative effects relating to the announcement of the possible combination or any further announcements relating to the possible combination or the consummation of the possible combination on the market price of AbbVie shares or Shire shares, significant transaction costs and/or unknown liabilities, general economic and business conditions that affect the combined companies following the consummation of the possible combination, changes in global, political, economic, business, competitive, market and regulatory forces, future exchange and interest rates, changes in tax laws, regulations, rates and policies, future business combinations or disposals and competitive developments. These forward-looking statements are based on numerous assumptions and assessments made in light of AbbVie's or, as the case may be, Shire's experience and perception of historical trends, current conditions, business strategies, operating environment, future developments and other factors it believes appropriate. By their nature, forward-looking statements involve known and unknown risks and uncertainties because they relate to events and depend on circumstances that will occur in the future. The factors described in the context of such forward-looking statements in this transcript could cause AbbVie's plans with respect to Shire, AbbVie's or Shire's actual results, performance or achievements, industry results and developments to differ materially from those expressed in or implied by such forward-looking statements. Although it is believed that the expectations reflected in such forward-looking statements are reasonable, no assurance can be given that such expectations will prove to have been correct and persons reading this transcript are therefore cautioned not to place undue reliance on these forward-looking statements which speak only as at the date of this transcript. Additional information about economic, competitive, governmental, technological and other factors that may affect AbbVie is set forth in Item 1A, Risk Factors, in AbbVie's 2013 Annual Report on Form 10-K, which has been filed with the SEC, the contents of which are not incorporated by reference into, nor do they form part of, this transcript. Neither AbbVie nor Shire undertakes any obligation to release publicly any revisions to forward-looking statements as a result of subsequent events or developments, except as required by law.
