

# Pfizer And Astrazeneca Enter Into Agreement For Over-The-Counter Nexium

Monday, August 13, 2012 - 04:44pm

# NEXIUM 20mg Retail Launch in the U.S. Targeted for 2014, Subject to Regulatory Approval

# Pfizer Updates Certain Elements of 2012 Financial Guidance to Reflect the Transaction

NEW YORK--(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) today announced that it has entered into an agreement with AstraZeneca for the over-the-counter (OTC) rights for NEXIUM (esomeprazole magnesium), a leading prescription drug currently approved to treat the symptoms of gastroesophageal reflux disease (GERD). Under the terms of the agreement, Pfizer will acquire the exclusive global rights to market NEXIUM for the approved over-the-counter indications in the United States, Europe and the rest of the world. Under the agreement, Pfizer will make an upfront payment of \$250 million to AstraZeneca, and AstraZeneca is eligible to receive milestone and royalty payments based on product launches and sales.

NEXIUM, a Proton Pump Inhibitor was launched by AstraZeneca in Europe in 2000 and the U.S. in 2001. AstraZeneca will continue to manufacture and market the prescription product, as well as supply Pfizer with the OTC product upon the receipt of regulatory approval. A Marketing Authorisation Application for OTC NEXIUM in a 20mg tablet form was filed with the European Medicines Agency in June 2012. A New Drug Application filing for OTC NEXIUM in the U.S. in 20mg delayed release capsules is targeted for the first half of 2013. If approved, Pfizer anticipates commercializing this product in the U.S. beginning in 2014 with launches in other markets to follow.

"Through its strong connection to our core biopharmaceutical business and to emerging markets and pharmacy customers worldwide, Pfizer Consumer Healthcare will have the opportunity to help more consumers better manage their health, while extending the value of certain important pharmaceutical brands."

In addition, both companies are exploring the potential for a strategic partnership that could include similar agreements for other AstraZeneca prescription brands for which OTC versions might be appropriate. The companies have signed an agreement giving Pfizer a right of first refusal regarding OTC rights for Rhinocort Aqua, a pump spray containing the glucocorticosteroid budesonide, with a local anti-inflammatory effect, for the treatment of noninfectious rhinitis (such as hay fever and house dust mite allergy).

Pfizer Consumer Healthcare President Paul Sturman said, "NEXIUM is one of the most recognized and respected products in its class with tremendous brand equity and loyalty. We are proud to be AstraZeneca's partner of choice for OTC NEXIUM. By working with AstraZeneca to offer upon regulatory approval an over-the-counter version of NEXIUM – a brand people know and trust – we are taking another crucial step to empower consumers by providing convenient access to important healthcare products."

"Pfizer is continuing to enhance the value of our Consumer Healthcare business," stated lan Read, Pfizer's chairman and chief executive officer. "Through its strong connection to our core biopharmaceutical business and to emerging markets and pharmacy customers worldwide, Pfizer Consumer Healthcare will have the opportunity to help more consumers better manage their health, while extending the value of certain important pharmaceutical brands."

Tony Zook Executive Vice President of AstraZeneca's Global Commercial Organisation said, "AstraZeneca has long been a leader in the gastrointestinal sector, and we believe that an OTC version of NEXIUM will complement this globally successful prescription medicine and help bring relief to more patients around the world. We're pleased to work with Pfizer Consumer Healthcare and believe their sales and marketing of consumer health products makes them the optimal partner to commercialise OTC NEXIUM globally. This agreement will help AstraZeneca realize the substantial, long-term value of this brand and potentially other brands in our portfolio."

## Impact on Pfizer's Financial Guidance for 2012

As a result of this transaction, Pfizer is updating its previous 2012 Adjusted R&D Expense(1) guidance range from \$6.5 - \$7.0 billion to \$6.75 - \$7.25 billion and its previous 2012 Adjusted Diluted EPS(1) guidance range from \$2.14 - \$2.24 to \$2.12 -

\$2.22 and its previous 2012 Reported Diluted EPS(1) guidance range from \$1.23 - \$1.38 to \$1.21 - \$1.36, while maintaining the other elements of its 2012 financial guidance.

The following table provides a reconciliation of 2012 Adjusted income(1) and Adjusted diluted EPS(1) guidance to 2012 Reported net income attributable to Pfizer Inc. and Reported diluted EPS attributable to Pfizer Inc. common shareholders guidance(a)

BILLIONS OF DOLLARS, EXCEPT PER SHARE AMOUNTS) INCOME/(EXPENSE) Full-Year 2012 Guidance

Net Income(b)

Net Income(b)

Adjusted income/diluted EPS(1) guidance

Purchase accounting impacts of transactions completed as of 7/1/12 Acquisition-related costs

Non-acquisition-related restructuring costs(c)

Other certain significant items incurred as of 7/1/12

Income from discontinued operations(d)

~\$15.9 -

\$16.7

(3.6)

(0.5 - 0.7)

(1.6 - 1.8)

(1.3)

0.4

~\$2.12 -

```
$2.22
(0.48)
(0.07 - 0.09)
(0.20 - 0.23)
(0.17)
```

0.06

Reported net income attributable to Pfizer Inc./diluted EPS guidance  $\sim$ \$8.9 - \$10.1  $\sim$ \$1.21 - \$1.36

(a) The current exchange rates assumed in connection with the 2012 financial guidance are a blend of the actual exchange rates in effect during the first six months of 2012 and the mid-July 2012 exchange rates for the remainder of the year,. (b) Includes the revenues and expenses related to the Nutrition business, which is reflected as a discontinued operation, but does not include the gain on the pending sale of the Nutrition business. Does not assume the completion of any businessdevelopment transactions not completed as of August 13, 2012, including any one-time upfront payments associated with such transactions. Also excludes the potential effects of the resolution of litigation-related matters not substantially resolved as of August 13, 2012. (c) Includes amounts related to our initiatives to reduce R&D spending, including our realigned R&D footprint, and amounts related to other cost-reduction and productivity initiatives. These amounts are included in Certain Significant Items. (d) Income attributable to Pfizer's Nutrition business.

(1)"Adjusted income" and "adjusted diluted earnings per share (EPS)" are defined as reported U.S. generally accepted accounting principles (GAAP) net income attributable to Pfizer Inc. and reported diluted EPS attributable to Pfizer Inc. common shareholders excluding purchase accounting adjustments, acquisition-related costs, discontinued operations and certain significant items. Adjusted R&D Expenses is an income statement line item prepared on the same basis and, therefore, is a component of the overall adjusted income measure. As described under Adjusted Income in the Management's Discussion and Analysis of Financial Condition and Results of Operations section of Pfizer's Form 10-Q for the fiscal quarter ended July 1, 2012, management uses adjusted income, among other factors, to set performance goals and to measure the performance of the overall company. We believe that investors' understanding of our performance is enhanced by disclosing this measure. The adjusted income and adjusted diluted EPS

measures are not, and should not be viewed as, substitutes for U.S. GAAP net income and diluted EPS.

Pfizer Legal Alliance (PLA) firm Kirkland & Ellis LLP acted as legal counsel for Pfizer. The PLA is a collaborative partnership between Pfizer and 19 law firms.

## **About Pfizer**

At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world's best- known consumer products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as the world's leading biopharmaceutical company, we also collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more about our commitments, please visit us at www.pfizer.com.

#### **About AstraZeneca**

AstraZeneca is a global, innovation-driven biopharmaceutical business with a primary focus on the discovery, development and commercialisation of prescription medicines for gastrointestinal, cardiovascular, neuroscience, respiratory and inflammation, oncology and infectious disease. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: www.astrazeneca.com.

## **PFIZER DISCLOSURE NOTICE:**

The information contained in this release is as of August 13, 2012. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information that involves substantial risks and uncertainties with respect to an agreement whereby AstraZeneca grants Pfizer exclusive global marketing rights to non-prescription NEXIUM, including regarding the anticipated

timing of the filing of a New Drug Application in the U.S. and of the launch of non-prescription NEXIUM; regarding the possibility of similar agreements with respect to other AstraZeneca products; and regarding Pfizer's updated financial guidance for 2012. Such risks and uncertainties include, among other things, (i) the possibility that, due to regulatory, market or other factors, a New Drug Application will not be filed in the U.S. within the anticipated time period or at all; that regulatory approvals in the U.S., EU and other jurisdictions in which applications have been or will be filed will not be approved within the anticipated time period or at all; and that over-the-counter NEXIUM will not be launched within the anticipated time period or at all; (ii) the possibility that Pfizer and AstraZeneca will not enter into similar agreements with respect to other AstraZeneca products; (iii) competitive developments; and (iv) with regard to Pfizer's updated financial guidance for 2012, the uncertainties and variables inherent in business financial and operating performance, including among other things, general economic, political, business, industry, regulatory and market conditions.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2011 and in its reports on Form 10-Q and Form 8-K.

Contacts Pfizer Media Inquiries Joan Campion (Media), +1 212 733 2798 or Pfizer Investor Inquiries Chuck Triano (Investors), +1 212 733 3901 or AstraZeneca Media Inquiries Esra Erkal-Paler, +44 20 7604 8030 Sarah Lindgreen, +44 20 7604 8033 or AstraZeneca Investor Inquiries UK James Ward-Lilley, +44 20 7604 8122 mob: +44 7785 432613 Karl Hård, +44 20 7604 8123 mob: +44 7789 654364 Nicklas Westerholm, +44 20 7604 8124 mob: +44 7585 404950

or

**AstraZeneca Investor Inquiries US** Ed Seage, +1 302 886 4065 mob: +1 302 373 1361 Jorgen Winroth, +1 212 579 0506 mob: +1 917 612 4043