



May 6, 2011

Mr. James Rosenberg
Senior Assistant Chief Accountant
United States Securities and Exchange Commission
Division of Corporation Finance
Mail Stop 4720
100 F Street NE
Washington, D.C. 20549

RE: File Number 001-02189

Dear Mr. Rosenberg:

In reply to your letter of March 31, 2011, we have enclosed our response to comment 2 in the attachment to this letter.

As per your request, Abbott acknowledges that we are responsible for the adequacy and accuracy of the disclosure in the filing; staff comments or changes to disclosure in response to staff comments do not foreclose the Commission from taking any action with respect to the filing; and Abbott may not assert staff comments as a defense in any proceeding initiated by the Commission or any person under the federal securities laws of the United States.

Very truly yours,

/s/ Thomas C. Freyman

Thomas C. Freyman
Executive Vice President, Finance
and Chief Financial Officer

Enclosure



Abbott Laboratories
Form 10-K for Fiscal Year ended December 31, 2010
Filed February 18, 2011
File No. 001-02189

Management's Discussion and Analysis of Financial Condition and Results of Operations

Research and Development Programs, page 38

2. In order to help us evaluate your disclosure about your research and development activities, please provide us the following information:
 - The description of research and development process for each of your segments including whether an approval is required by the FDA;
 - Research and development expenses incurred during 2010 and 2009 by segment;
 - For those projects that require an FDA approval, quantify the number of projects that were in preclinical phase, Phase 1, Phase 2, and Phase 3 of the clinical development and those for which a NDA was filed as of December 31, 2010;
 - For each segment requiring FDA approval, the breakout of research and development expense incurred during 2010, if practicable, by development phase (i.e. preclinical, phase 1, phase 2, phase 3) and by therapeutic class;
 - For those late phase development projects (i.e. Phase 3 projects) listed here, indicate the month and the year that it entered that phase;
 - For those late phase development projects (i.e. Phase 3 projects) listed here, identify the significant patents associated with the project and their expiration date; and
 - Tell us about any late stage projects that are not listed here and the reason not listed.

Response:

Given that Abbott operates globally, the description of the R&D process below applies generally to products to be sold in markets throughout the world and that require regulatory approval from multiple government regulatory agencies. Of course, there may be exceptions and differences from this process based on among other things, scientific, medical and legal factors.

Pharmaceutical R&D Process

In the Pharmaceuticals segment, the R&D process generally begins with discovery research which focuses on the identification of a molecule that has a desired effect against a given disease. Once a pharmaceutical compound candidate is identified, preclinical testing in animals is performed to primarily assess safety prior to human testing. If preclinical testing proves successful, the compound moves into clinical development which generally includes the following phases:

- Phase I — involves the first human tests in a small number of healthy volunteers to assess tolerability and potential dosing.

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- Phase II — tests the molecule's efficacy against the disease in patients and results in the determination of effective dosing and appropriate delivery method.
- Phase III — molecules that demonstrate favorable results in the earlier phases are tested in a significantly larger patient population to further demonstrate efficacy and safety based on regulatory criteria.

The clinical trials from all of the development phases provide the data required to prepare and submit a New Drug Application (NDA), a Biological License Application (BLA) or other submission for regulatory approval to the U.S. Food and Drug Administration (FDA) or similar government agencies outside the U.S. In the U.S., European Union (EU), Japan, China, and many other countries, regulatory approval is required for all new pharmaceutical products as well as new indications and formulations for existing products. The specific requirements (e.g., scope of clinical trials) for obtaining regulatory approval vary across different countries and/or geographic regions.

The trials in each phase are designed for the particular compound in development. Concurrent with the clinical development, significant effort is also expended on development of a safe, large-scale production process for the drug. The R&D process from discovery through a new drug launch typically takes 8 - 12 years and can be even longer. As we discussed in our response to your comment letter on our Form 10-K for the year ended December 31, 2009 and in the Risk Factors to our Form 10-K, there is a significant amount of uncertainty inherent in the research and development of new pharmaceutical products and there is no guarantee when, or if, a drug will receive the regulatory approval required to launch a new drug or indication.

In addition to the process described above for the development of new products and new formulations, R&D projects also may include Phase IV trials, sometimes called post-marketing studies. For such projects, clinical trials are designed and conducted to collect additional data regarding, among other parameters, the benefits and risks of an approved drug.

Diagnostics R&D Process

In the Diagnostics segment, the R&D process generally includes the following:

- Discovery: This phase focuses on identification of a product that will address a specific therapeutic area, platform, or unmet clinical need. Testing in the discovery phase may include external studies to demonstrate the clinical utility of a new product.
- Concept/Feasibility: This phase includes assessment of materials and manufacturing processes. Testing may include product characterization, evaluation of multiple lots of materials, and additional testing to confirm clinical utility.
- Development: In this phase, extensive testing is performed to demonstrate that the product meets specified design requirements (design verification) and that the design specifications conform to user needs and intended uses (design validation).

As with pharmaceutical products, the regulatory requirements for diagnostic products vary significantly across different countries and regions. For this reason, our response will focus on the United States and the EU requirements.

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The FDA classifies diagnostic products into classes (I, II, or III) and the classification determines the regulatory process for approval. While the Diagnostics segment has products in all three classes, the vast majority of its products are categorized as Class I or Class II. Class I and Class II devices are defined by the FDA as products that do not support or sustain human life, are not of substantial importance in preventing impairment of human health, and do not present a potential, unreasonable risk of illness or injury. Class I products are viewed as lower risk to patient safety than Class II products. For example, a simple analytical test for cholesterol could be placed in Class I, but a test for measuring thyroid stimulating hormone is identified as Class II. Class III assays include, for example, tumor markers. The FDA maintains the database of product classifications.

Submission of a separate regulatory filing is not required for Class I products. Class II devices typically require pre-market notification to the FDA by submission of a regulatory filing known as a 510(k) submission. Under the 510(k) regulatory process, the device's performance is evaluated against defined performance standards. Generally, if the company demonstrates that the product meets the defined performance standards, the FDA reviewer clears the product for sale. Most Class III products are subject to approval requirements referred to as pre-marketing approval (PMA) requirements. Some other Class III products, such as those used to screen blood, require the submission and approval of a BLA.

In the EU, diagnostic products are also categorized into different categories and the regulatory process, which is governed by the European In Vitro Diagnostic Medical Device Directive, depends upon the category. Generally, the manufacturer issues a declaration of conformity for its products. Then, depending upon the product category, an independent company, known as a Notified Body, which has been accredited by the regulatory authority will assess the manufacturer's submission and its quality system and perform an audit as required under the applicable sections of the Directive. The Notified Body must issue an approval of conformity or a design examination certificate before the manufacturer can affix a CE mark to the product to show compliance with the Directive.

Vascular R&D Process

In the Vascular segment, the R&D process begins with research on a specific technology that is evaluated for feasibility and commercial viability. If the research program passes that hurdle, it moves forward into development. In the first phase of development, the appropriate design inputs, as well as the

clinical framework for the development of the new product, are identified. Multiple designs and prototypes are then evaluated based on pre-clinical studies, the design input criteria, regulatory and clinical requirements, and commercial criteria. A product design is selected to be tested in clinical trials. Also, the manufacturing process is verified and validated to ensure its repeatability and ability to consistently meet pre-determined specifications.

Achieving market approval involves a significant number of filings with government regulatory agencies. Similar to the diagnostic products discussed above, in the U.S., vascular products are classified as Class I, II, or III. Vascular products that involve implantation of a device within the human body (e.g., stent) generally fall under Class III and are subject to the PMA process. Vascular products that do not involve

implantation (e.g. guide wires) would typically be categorized as Class II devices and follow the 510(k) regulatory process. Most of Abbott's vascular products are classified as Class II or III devices in the U.S.

In the EU, vascular device products are also categorized into different classes and the regulatory process, which is governed by the European Medical Device Directive, varies by class. Each product must bear a CE mark to show compliance with the Directive. Some products require that a file known as a design dossier be submitted to the appropriate regulatory authority for review and approval prior to CE marking of the device. For other products, the company is required to prepare a technical file which includes testing results and clinical evaluations but can self-certify to be able to apply the CE mark to the product. As discussed previously, outside the U.S. and the EU, the regulatory requirements vary across different countries and regions.

After approval and commercial launch of some vascular products, post-market trials may be conducted either due to a conditional requirement of the regulatory market approval or with the objective of proving product superiority.

Nutritional R&D Process

In the Nutritional segment, the R&D process generally focuses on identifying and developing ingredients and products that address the nutritional needs of particular populations (e.g., infants, athletes) or patients (e.g., people with diabetes). Depending upon the country and/or region, if claims regarding a product's efficacy will be made, clinical studies typically must be conducted. Most other product developments, such as a product form change from liquid to powder, generally do not necessitate clinical studies.

In the U.S., the FDA requires that it be notified of proposed new formulations and formulation or packaging changes related to infant formula products. Prior to the launch of an infant formula or product packaging change, Abbott obtains the FDA's confirmation that it has no objections to the proposed product or packaging. For other nutrition products, notification or pre-approval from the FDA is not required unless the product includes a new food additive (i.e., an ingredient not generally recognized as safe by the scientific community). In some countries, regulatory approval may be required for certain nutritional products, including infant formula and medical nutritional products.

2010 and 2009 R&D Expenses

Abbott is separately submitting its response to your request for R&D expenses by segment.

Number of Projects

In the Pharmaceuticals segment, 19 projects were in preclinical development, 22 in Phase I, 16 in Phase II and 12 in Phase III. There were 4 projects for which a submission seeking U.S. approval had been made and was pending as of December 31, 2010.

In the Vascular segment, there were 3 projects for which an original PMA filing was submitted and pending as of December 31, 2010. There were 3 vascular projects in clinical development which will be subject to PMA requirements. In the Diagnostics segment,

there was 1 project for which a BLA was submitted and pending as of December 31, 2010. There was 1 diagnostic project in development at December 31, 2010 which will be subject to PMA requirements.

The significant projects were discussed on pages 38-40 of our 2010 Form 10-K. We believe that the disclosures provide investors sufficient information needed to understand our R&D pipeline.

Breakout of R&D Expense

A break-out of R&D spend by development phase and by therapeutic area will not be helpful because it will cause confusion to investors who may view the amount of spend in a particular area as an indication of its commercial value or consider changes in the rate of spend across periods an indicator of the project's likelihood of success or failure. However, such conclusions should not be drawn as the amount spent in an individual therapeutic area or development phase depends upon many factors, including a clinical trial's specific requirements (e.g. number of patients and clinical sites, trial length, required testing, etc.) and the timing of particular trials. In addition, development costs in some therapeutic areas may be higher simply due to the nature of the area. Variations across periods that trigger unnecessary concern among investors that a project is experiencing difficulty or losing priority might actually be in line with internal expectations. Therefore, data categorized in this manner may be misinterpreted or misleading if it was provided in the 10-K.

Because such data do not provide a meaningful comparison across areas or periods, we do not regularly accumulate or make management decisions based on the total expenses incurred for a particular development phase in a given period. In the pharmaceutical segment, we do not regularly report internally to senior management total expenses incurred for each therapeutic area. We generally manage our portfolio of projects to achieve a targeted rate of R&D spend each year. Achievement of such a target may cause short-term fluctuations in the level of spend in an individual area but such fluctuations should not be viewed as indicating any changes in a project's priority. However, data by therapeutic area would highlight such short-term fluctuations and therefore, could be misleading to investors.

The disclosure of cost information by therapeutic area or development phase could also cause Abbott competitive harm. Such disclosures could provide competitors information on Abbott's R&D strategies that they might use to compete against Abbott, thus harming our investors.

Late Stage R&D Projects

We consider a "Late Stage R&D Program" to encompass a pharmaceutical product that, as of December 31, 2010, was either being studied in Phase III clinical studies or had a pending registration submission (e.g. NDA or BLA) with the FDA or other major regulatory authority. For those programs with a pending registration submission, the table below summarizes the month and year that the registration submission was made.

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Program	Regulatory Submission Date
Ozespa	September 2010
Lupron - Central Precocious Puberty	July 2010
Lupron - 6 month depot fomulation	December 2009
Androgl 1.62%	February 2009

We do not believe that it is appropriate for us to provide the dates that programs entered Phase III or information on the patent expirations associated with projects under development because it would not be meaningful, and may potentially mislead or confuse investors. With respect to the Phase III dates, the length of a Phase III clinical study program can vary widely depending on the number and size of the studies and enrollment criteria specified in the clinical trial design, as well as requests from the FDA or other regulatory agencies. An extended clinical study length neither indicates that a trial is experiencing difficulties nor is it correlated with the probability of regulatory approval.

With respect to patent expirations related to projects under development, a list of current patents and expiration dates does not consider separate regulatory exclusivity that may be granted as a part of the product approval, patent extensions that may be granted in the future based on local laws, or pending patent applications, all of which can be significant in determining all of the various exclusivities that may protect a product. Prior to approval, it is unlikely that we can provide accurate expiration dates because of extensions that may later be granted. Furthermore, in view of our practice of identifying patents associated with approved products, assigning patent dates to developing products may lead investors to believe that there is less risk that such products will be approved than is the case.

In addition, multiple patents with varying expiration dates can cover a product in development. Applicable patents may include formulation, manufacturing, and indication patents, as well as composition of matter patents. Providing the expiration dates of the numerous patents related to a product would not be meaningful if the dates span multiple years, which is normally the case. At the same time, it may be difficult to predict at this stage of development which patent or patents will be most critical in protecting the product. Providing information on the patents that relate to a product in development may also encourage competitors to take actions that would cause competitive harm to Abbott. A list of patents would provide a competitor with a collection of significant information at a much earlier date than we otherwise would provide through, for example, the FDA's Orange Book.

The importance of multiple patents is especially true with respect to our vascular and diagnostic products where each device incorporates a variety of complex and differing technologies. Each of these technologies can, and generally are, covered by myriad different patents and other intellectual property (e.g., trade secrets). Because we do not believe that any single patent within our vascular or diagnostic portfolio is the critical driver for the sales potential of any product in development, providing listings of dozens of patents that cover particular aspects of a singular device product will not assist in understanding the vascular or diagnostics R&D pipeline.

Furthermore, the expiration dates of any applicable patents are only relevant if the drug or device receives regulatory approval and can be launched. There is no

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guarantee when, or if, a drug or device will receive regulatory approval. For the pharmaceutical segment, in particular, given the relatively high rate of failure that can be expected for compounds that enter Phase III development based on the industry's historical experience, information on the status of significant programs, which Abbott included on pages 38-40 of our 2010 Form 10-K, provides more relevant information for projects in development.

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