



July 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 June 3, 2011, we have enclosed our response to comments 1 and 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



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

Research and Development Programs, page 38

1. Refer to your response to comment two. Please address the following by providing us proposed disclosure to be included in future periodic reports:
  - The amount of R&D expense by segment, and the amount not allocated to a segment and what that amount represents;
  - A description of the R&D process by segment similar to what you provided in your response;
  - How you manage the research and development expenses (i.e. on a portfolio basis to achieve a targeted spend);
  - That you do not regularly accumulate research and development expenses for a particular therapeutic area or development phase or make management decisions based on this data; and
  - The month and the year that you entered the late phase for those projects that you disclose in late phase development.

We encourage you to propose any additional disclosure that you believe is necessary to describe limitations necessary to provide further context to the disclosures requested above.

Response:

Beginning with our 2011 Form 10-K, we will include additional disclosure in the format below. We reserve the right to revise the specific language covering the description of the R&D process based on further review.

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. If preclinical testing of an identified compound 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.
- Phase II — tests the molecule's efficacy against the disease in a small group of patients.

- Phase III — tests a molecule that demonstrates favorable results in the earlier phases 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 filing for regulatory approval to the U.S. Food and Drug Administration (FDA) or similar government agencies outside the U.S. The specific requirements

(e.g., scope of clinical trials) for obtaining regulatory approval vary across different countries and geographic regions.

The R&D process from discovery through a new drug launch typically takes 8 - 12 years and can be even longer. 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 molecule will receive the regulatory approval required to launch a new drug or indication.

In addition to 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 phases of the R&D process include:

- Discovery which focuses on identification of a product that will address a specific therapeutic area, platform, or unmet clinical need,
- Concept/Feasibility during which the materials and manufacturing processes is evaluated, testing may include product characterization and analysis is performed to confirm clinical utility, and
- Development during which extensive testing is performed to demonstrate that the product meets specified design requirements and that the design specifications conform to user needs and intended uses.

As with pharmaceutical products, the regulatory requirements for diagnostic products vary across different countries and geographic regions. In the U.S., 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. Submission of a separate regulatory filing is not required for Class I products. Class II devices typically require pre-market notification to the FDA through a regulatory filing known as a 510(k) submission. Most Class III products are subject to the FDA's Pre-Marketing Approval (PMA) requirements. 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. Certain product categories require review and approval by an independent company, known as a Notified Body, before the manufacturer can affix a CE mark to the product to show compliance with the Directive. Other products only require a self-certification process.

#### 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. The development process includes evaluation and selection of a product design, completion of clinical trials to test the product's safety and efficacy, and validation of the manufacturing process to demonstrate its repeatability and ability to consistently meet pre-determined specifications.

Similar to the diagnostic products discussed above, in the U.S., vascular products are classified as Class I, II, or III. Most of Abbott's vascular products are classified as Class II devices that follow the 510(k) regulatory process or Class III devices that are subject to the PMA process.

In the EU, vascular 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 submission of a design dossier 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 its ability to apply the CE mark to the product. 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, the company is required to obtain 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. In some countries, regulatory approval may be required for certain nutritional products, including infant formula and medical nutritional products.

With respect to R&D expenses by segment, we have previously disclosed that the majority of R&D expenditures are concentrated on pharmaceutical products (page 35 of our 2010 10-K). We will add discussion similar to the following:

\$2.537 billion of Abbott's 2010 R&D expenses related to Abbott's pharmaceutical products, of which \$2.1 billion was directly allocated to the pharmaceuticals segment. In 2010 research and development expenditures totaled \$387 million for the vascular segment, \$276 million for the diagnostics segment, and \$150 million for the nutritionals segment.

On page 40 of our 2010 10-K, we stated that "Abbott plans to continue to manage our portfolio of projects to achieve research and development spend equal to approximately 9.5 percent to 10 percent of sales each year." We will include a similar statement on

how we manage R&D expenses in our future 10-K filings. We will add a statement that 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 discussion of Abbott's R&D programs, we will include information on the month and year that the registration submission was made for those programs with a pending registration submission. For example, for our 2010 10-K, we would have incorporated the following (sentences highlighted) into the 4<sup>th</sup> paragraph on page 39 of our 2010 10-K:

In addition, new formulations of Abbott's existing pharmaceutical products, including *Lupron* 6-month depot and *AndroGel* 1.62%, are currently under FDA review. **The *Lupron* 6-month depot and *AndroGel* 1.62% formulations were submitted to the FDA for regulatory approval in December 2009 and February 2009, respectively. New formulations for the central precocious puberty indication of *Lupron* were submitted to the FDA for regulatory approval in July 2010 and are also under FDA review.**

2. Refer to your response to comment two. As previously requested, provide us information regarding the remaining term of patents for each late stage project you disclose. If you do not know or cannot estimate the remaining patent life for a particular patent(s) associated with a project(s), please tell us the specific facts and circumstances governing this limitation.

Response:

We continue to believe that the request for data is neither necessary nor appropriate for the reasons articulated in our May 6, 2011 letter. However, we respectfully request a telephone conversation on these points, prior to another written response. Anna Hudak, Abbott's Assistant Corporate Controller, will call Kei Nakada to arrange that discussion.