Canada's Research-Based Pharmaceutical Companies (Rx&D) (the "**Company**")
on behalf of the Steering Committee, made up of members from:

- Rx&D;
- Industry Canada;
- Patented Medicine Prices Review Board; and
- Canadian Institutes of Health Research

Ottawa, Ontario
Canada

June 14, 2011

Summary of Pharmaceutical Survey Findings on R&D Spending and Investments by Rx&D Members - 2010

In connection with the Rx&D Member Survey project related to pharmaceutical spending, we enclose our *Summary of Pharmaceutical Survey Findings on R&D Spending and Investments by Rx&D Members – 2010* (the "Survey"). We caution that the information in this report is not intended to be used for any investment decisions or to be part of any kind of evaluation of financial or investment potential. We caution that this report was prepared for specific purposes as noted above and that it should be read in its entirety, excerpts should not be used, and readers are cautioned that the results may not be appropriate for uses outside of the scope as outlined above. KPMG disclaims any liability for failing to adhere to these cautions.

SCOPE AND OBJECTIVES

The Company has requested KPMG to compile the results of a Survey developed by KPMG, Rx&D and a Steering Committee chaired by Industry Canada and made up of members from Rx&D, Industry Canada, the Patented Medicine Prices Review Board ("PMPRB"), and the Canadian Institutes of Health Research ("CIHR"). The Survey process was administered by KPMG. KPMG compiled the results of this Survey and has detailed the information reported by Survey participants in summary form. KPMG has not audited the information contained in this report which was provided to KPMG directly from Survey participants.

KPMG's administration of the Survey, compilation of the results and work with the Steering Committee included:

- obtaining details of R&D spending submitted to the PMPRB;
- conducting phone interviews with certain Survey respondents to determine their understanding of the Survey questions and processes used to reports amounts and avoid double counting; and
- agreeing certain Survey data reported amounts.

The scope of the Survey and completion of the results were made under the terms of an engagement letter between KPMG and the Company. The procedures developed and performed do not constitute an audit and, therefore, KPMG expresses no opinion on the Survey data results or of the procedures performed.

The Steering Committee has provided KPMG with the following industry background as part of this engagement.

BACKGROUND

The nature of pharmaceutical research and development ("R&D") activity has undergone significant change due largely to the changing business model of the pharmaceutical industry. However, the way pharmaceutical R&D in Canada is measured has not changed significantly.

In Canada, pharmaceutical R&D is measured and reported by both Statistics Canada and the PMPRB. Each agency applies a somewhat different methodology and analyzes different target populations in an effort to fulfill their mandates.

In the case of Statistics Canada it has a role to report on Canadian pharmaceutical manufacturing innovation that happens within a firm to be used for international comparisons and domestic policy. The PMPRB has a role to report on R&D spending by companies who sell pharmaceutical products associated with patents and uses a legislated reporting standard which allows company R&D performance comparability over time.

While these agencies capture a large part of Canadian pharmaceutical R&D activities, it was postulated by Rx&D that industry R&D spending and varied investments occur that do not fit in the existing measurement and reporting models.

The Steering Committee

In January 2011, Rx&D undertook a project to work with Industry Canada to establish a group that intended to include members from the PMPRB, the CIHR, Rx&D and Industry Canada to help identify the nature and size of the pharmaceutical industry's investment spending in Canada by conducting a Survey of the Rx&D members. These groups agreed to form a Steering Committee (Chaired by Industry Canada) that guided the project and the original terms for this report.

Both Government and Rx&D agreed on the need to gain a better understanding of the full spectrum of Canadian pharmaceutical R&D spending and other investments and produce a report based on a Survey and the resulting data which could provide information on Rx&D members R&D and investments not normally captured by PMPRB or Statistics Canada to broadly inform policy-makers.

The Steering Committee established a technical Working Group to assist in the development of the Survey questionnaire and to provide advice to the Steering Committee and KPMG on the scope of the data to be collected and on potential measurement and collection issues. This Working group included representatives from Rx&D, Industry Canada, PMPRB, and CIHR. Other participants that assisted the Working Group included government analysts and industry financial officers to assist in scoping the technical aspects of the desired R&D and other investment measurements.

KPMG assisted the Steering Committee with the Survey development, administered the Survey and compiled the results.

The results of the Survey that came out of these efforts, jointly funded by Rx&D and CIHR, provide an initial understanding of R&D and other investments made by Rx&D members. The Steering Committee may consider further analysis of the results.

THE SURVEY

KPMG and the Steering Committee developed the questions to be included in the Survey and the methodology to be employed by KPMG to conduct the Survey and compile the results.

A broad list of the types of potential R&D and investments that Rx&D members have made but that which is not reported to PMPRB under the existing regulations was developed and circulated amongst the Working Group for discussion and analysis. Numerous iterations were created and a final version of the desired data for Survey purposes was created by consensus and confirmed by the Steering Committee which involved separating the Survey into 3 distinct sections.

Types of R&D and Other Investment Data to be Surveyed by Rx&D Members

Three areas of expenditures on R&D and other investments in Canada were requested of the Survey respondents, as follows:

- Section 1: R&D Expenditures and Investments that Qualify for SR&ED Tax Credits
- Section 2: R&D Expenditures and Other Investments that Do Not Qualify for SR&ED Tax Credits
- Section 3: Non-R&D Expenditures Which Are Part of the Industry's Investments in Canada

Data was compiled on expenditures incurred by Rx&D Member companies during the period January 1 to December 31, 2010 and only direct costs were to be reported (i.e. no overhead amounts).

Methodology

Prior to the Survey being launched, KPMG provided education and instruction to members of Rx&D on how to complete the Survey by conducting 2 webinars to explain what data each question was looking to obtain, the importance of using consistent and standardized reporting as well as highlighting the importance to the Survey respondents that they ensure no amounts are reported twice. The webinars contained a PowerPoint presentation which was provided to the respondents in advance of the webinar so that they had an opportunity to review each of the questions that were included in the Survey and consider any preliminary comments and/or questions that they may have. The webinars included the ability to ask questions during the webinar presentations.

The Survey was conducted by KPMG using an online, secure and confidential submission form.

As part of the Survey design, each question had an area for the respondents to note any comments or questions they may have. Each Survey question contained a link to a confidential email which the respondents could use to send a request directly to KPMG in order to clarify any comments or answer any questions they may have.

Once the Survey was completed by the participant, the results were sent directly to a secure and confidential repository at KPMG.

The following details the 3 Sections of the Survey and the various questions posed to the Survey respondents.

Section 1 R&D Expenditures and Investments that Qualify for SR&ED Tax Credits

Question 1.1: Expenditures eligible for SR&ED tax credits based on the definition pursuant to the *Income Tax Act* (Canada) on December 1, 1987.

- These are the expenditures covered by the definitions used for PMPRB reporting purposes pursuant to the 1987 SR&ED definition as per PMPRBs legislative mandate to report under the Patented Medicines Regulations. The amounts reported should be equal to the amounts reported by PMPRB filers on their Form 3 for the totals noted in Block 5 (current expenditures) and Block 6 (capital expenditures). SR&ED for this purpose is defined in and guidance is provided for completing Form 3 in the PMPRB Guide (see Appendix 2).

Question 1.2: Additional expenditures above and beyond those amounts reported in Question 1.1 which are eligible for SR&ED tax credits based on the current 2010 definition pursuant to subsection 248(1) of the *Income Tax Act* (Canada).

- In general, the data requested in Question 1.2 relates to SR&ED eligible labour amounts incurred outside of Canada (i.e. up to a maximum of 10% of the total Canadian labour amount claimed for SR&ED purposes) as well as leased and capital equipment that is used between 50% and 90% for SR&ED performed in Canada (see Appendix 3).

Question 1.3: Was added to accommodate those Rx&D members that are not required to report to PMPRB and therefore do not otherwise make any distinctions between Questions 1.1 and Question 1.2, as well as for other amounts that were otherwise unreported to PMPRB. The purpose of having this question was to avoid having a total Survey amount for Section 1.1 that significantly differed from the total PMPRB figure for Rx&D member reported amounts.

Section 2 R&D Expenditures and Other Investments in Canada that Do Not Qualify for SR&ED Tax Credits

Question 2.1: Expenditures similar to those identified, but not included, in Question 1.2:

- Additional salaries of Canadian personnel directly engaged in SR&ED eligible work performed outside Canada above and beyond the 10% amount that was reported in Question 1.2;
- The cost of new capital equipment utilized less than 50% of its useful life for R&D; and
- The cost of leased capital equipment utilized less than 50% of its useful life for R&D.

Question 2.2: Additional cost of individuals charged to a Canadian payroll for services performed in Canada (i.e. the individual either receives a Canadian T4 slip or those that are paid by a related foreign company but for which their salary costs are charged to a Canadian entity) above and beyond that which is already reported in Section 1, but which have a direct impact on the R&D function in Canada.

Question 2.3: Investments in used equipment utilized in R&D activities in Canada (i.e. only include the cost of the actual percentage utilized in R&D).

Question 2.4: Amounts paid by a Canadian company to Canadian pharmaceutical service providers related to the portion of milestone payments, management fees, etc. which have been excluded from SR&ED reporting because the payments related to management, etc. of foreign trials (i.e. only include amounts above and beyond those which have already been reported in Section 1).

- For clarity, this question only asked Survey respondents to include the portion of milestone payments, management fees, etc. that relate to foreign trials that are not be reported in Section 1 and should not include the payments/funding made for the actual foreign trials. The portion of the milestone payments, management fees, etc. that relate to Canadian trials should already have been reported in Section 1 along with the payments/funding of the actual Canadian trials.

Question 2.5: Foreign entity payments (i.e. made by a related entity to the Survey respondent) made for R&D to be conducted in Canada by other companies or organizations (i.e. the funding from the foreign entity does not flow to the related Canadian entity, but rather directly to an arm's length Canadian R&D performer). This question targets the inclusion of the Canadian portion of foreign R&D funding.

Question 2.6: Lease/rental costs related to research facilities infrastructure only (e.g. buildings, labs, etc. but excluding land) which are not already reported in Question 1.2 or Question 2.1. The inclusion amount should be based on the portion of R&D square footage of the infrastructure over the total square footage.

Question 2.7: Other R&D related activities: only include direct costs of employee labour and contract payments (i.e. exclude indirect costs such as support or supervision labour costs, overhead, research marketing studies, etc.). This question targets the following items and should only be reported where the R&D activities are clearly defined and are part of research studies conducted in Canada:

- Pre-competitive research
- Economic and/or cost analysis component of pharmacoeconomic studies
- Pharmacovigilance research studies
- Collection of epidemiology information and/or screening established databases
- Research in bioethics or other social sciences or humanities
- Comparative effectiveness studies/trials
- Regulatory affairs/administration expenses in clinical trials application
- Post launch or post-regulatory approval surveillance of new drugs as part of NOC/c commitment

Question 2.8: Investments made in Canadian venture capital.

Question 2.9: Payments for University Chair Endowments (i.e. Ph.D. and post-doctoral fellowships).

Question 2.10: Donations to Canadian charities for the purpose of conducting health research (e.g. Heart and Stroke Society, Canadian Diabetes Association, Canadian Breast Cancer Foundation, Canadian AIDS Society).

Question 2.11: Donations, grants and non-commercial sponsorships to entities that promote the health and well-being of Canadians for support of documented research funding activities, as follows:

- Associations/Societies of Health Professionals;
- Patient Advocacy and Health Promotion & Education Groups;
- Direct Service Agencies;
- Hospitals and Health Clinics; and
- Hospice & Palliative Care Programs.

Question 2.12: Other expenditures which have not otherwise been reported for R&D incurred in Canada.

Section 3 Non-R&D Expenditures Which Are Part of the Industry's Investments in Canada
Question 3.1: Similar to Question 2.11 related to donations, grants and non-commercial sponsorships to entities that promote the health and well-being of Canadians, but which is for non-R&D funding/activities.

Question 3.2: Product donations at factory gate list price, (i.e. medicines provided through compassionate use and special access programs for use in Canada).

Question 3.3: Community programs - contributions that address human welfare and social needs such as United Way / Centraide, deliver community-based amateur sports and recreation programs, and celebrate local community events, festivals and other activities.

Question 3.4: Education - contributions that support and promote education/training at the primary, secondary and post-secondary levels, including scholarships, fellowships, bursaries, etc. (but excluding payments for education at the graduate and post-graduate levels (i.e. Ph.D. and post-doctoral fellowships as these should be reported in Question 2.9).

Question 3.5: Environment - contributions that promote environmental responsibility, recycling, conservation, reclamation and land and wildlife preservation.

Question 3.6: Arts and Culture - contributions that support the arts and other cultural activities in Canada such as opera and ballet companies, symphonies, museums, broadcasters and theatres.

Procedures Performed by KPMG

KPMG performed the following procedures for 16 of the total 37 Survey respondents in order to obtain approximately 80% coverage of the total dollar amounts reported in Sections 1 and 2.

Question 1.1: KPMG obtained from the Survey respondents a copy of its signed and filed Form 3 report on R&D expenditures submitted to the PMPRB for 2010 (i.e. as required under the *Patented Medicines regulations*) in order to agree the amounts reported in the Survey data to that which was reported to PMPRB in Block 5 (Current R&D) and Block 6 (Capital Expenditures).

Question 1.2 and 1.3 and Section 2: KPMG conducted phone interviews with respondents and spoke with members of the company personnel who were tasked with the completion of the Survey data in order to:

- determine that the Survey respondents understood what each question was directed towards in order to obtain consistent reporting;
- understand the process the Survey respondents used to obtain and complete each question of the Survey data and avoid double-counting of any figures; and
- agree the amounts reported in the Survey to various forms of company provided data (i.e. financial statements, accounting system reports or summaries, and/or other internal calculations and communications).

In general, KPMG found that the interviewed Survey respondents understood the Survey purpose, and appeared knowledgeable of the data requested and importance of consistent, appropriate and non-double counting of the Survey data. The respondents began with the PMPRB reported amounts and were able to identify amounts that were excluded from such reporting in order to identify the additional amounts being requested in the Survey.

Section 3: KPMG did not undertake any specific procedures for Section 3 data reported by the Survey respondents other than to compile the results reported.

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SURVEY DATA RESULTS

Participation

Only Rx&D members participated in the Survey. A total of 42 members were contacted for the Survey. A total of 37 companies responded to the Survey representing an 88% response rate.

4 of the 37 Survey respondents had not reported R&D investments to PMPRB but then were included in the Survey results.

5 entities did not respond and are therefore not included in the Survey results. Rx&D noted that they are small research based firms with minimal revenue but possibly significant R&D spending and/or other investments.

Pharmaceutical R&D Expenditures and Investments by Rx&D Members in 2010

A summary of the reported Survey data is provided below (see Appendix 1 for a detailed summary):

- The Survey respondents reported total expenditures of $1.494 billion in 2010.
- $1.085 billion represents expenditures that are traditionally reported to PMPRB.
- An additional $48 million that may qualify for SR&ED tax credits is not part of what was reported to PMPRB as the legislative mandate of PMPRB only captures the 1987 SR&ED definition and is limited to patentees.
- An additional $151 million was directed to R&D expenditures and other investments that do not qualify for SR&ED tax credits and therefore has not been reported to the PMPRB. This includes

amounts paid to persons engaged in various R&D activities, studies required for regulatory and reimbursement approvals as well as research-related donations.

- Other reported expenditures were $210 million. These expenditures include additional donations to charities and entities that promote health and well being of Canadians ($103 million), product donations to patients through compassionate use and special access programs ($90 million) and community, educational, environmental and arts and cultural investments in Canada.

Survey Question/Section	Reported amounts in CDN (rounded to the nearest million)
Question 1.1 R&D Reported to PMPRB on Form 3	$1,085,000,000
Question 1.2 and 1.3 R&D and Investments Eligible for Tax Credits	48,000,000
Section 2 R&D and Other Investments Not Eligible for Tax Credits	151,000,000
Section 3 Non-R&D Expenditures but Other Investments in Canada	210,000,000
Total Pharmaceutical R&D Expenditures and Investments	**$1,494,000,000**

Limitations of Survey Results

Limitation #1 – Three companies were unable to complete the Survey because they do not report to PMPRB and therefore were not able to generate the data required to complete the Survey in the time frame requested.

- Only patentees of medicines being sold in Canada are required to report to PMPRB, therefore, Rx&D member companies that conduct research but are not selling a patented medicine do not report even though they may have significant R&D expenditures.
- As a result, those companies that do not have the necessary internal reporting systems required for PMPRB reporting were not able to participate in the Survey and therefore the total amounts reported in Section 1 and 2 may be understated.

Limitation #2 - The timeframe for reporting R&D expenditures to PMPRB is not aligned with timeframes for Canada Revenue Agency which generated some issues for both PMPRB reporters and other companies which affected the process of and delayed the Survey results.

- For PMPRB purposes, patentees are generally required to file their Form 3 by March 1st following each calendar year whereas for tax purposes, companies are generally required to file for SR&ED tax credits within 6 months after their tax year end which is June 30th for most of the Survey respondents.
- As a result, companies are required to perform some estimation/forecasting for PMPRB reporting as well as for the Survey completion purposes given that their actual R&D reporting for tax credit purposes is not due until at least 4 months after the PMPRB filing due date (i.e. entities can file for R&D tax credits up to 18 months after their tax year end).

Limitation #3 - PMPRB and CRA use different definitions of R&D (1987[1] versus the current enacted definition pursuant to subsection 248(1) of the *Income Tax Act* (Canada)) which represented complexities relative to reporting and completing the Survey. $2.7 million was reported as being the difference between the PMPRB definitions versus the current enacted definition in the *Income Tax Act* (Canada).

Limitation #4 - The Survey only included companies that are members of Rx&D and therefore did not include other biopharmaceutical companies that may conduct R&D in Canada.

Limitation #5 – Not all of the various identified types of data that could have been surveyed was included in the final submission for approval by the Steering Committee. As such, additional amounts are being spent on other categories of R&D and other investments that were not captured in the Survey.

Limitation #6 – The entities surveyed often can be large and complex entities and as such, not all of the surveyed data may have been readily available to capture all of the amounts that could have otherwise been reported.

Limitation #7 – KPMG only performed procedures for Sections 1 and 2 and only for 16 of 37 Survey respondents. Procedures for Section 3 for all respondents and any part of the Survey for the other 21 respondents may impact the amounts above.

Additional Findings

Finding #1 – There are additional amounts being invested in Canada by Rx&D members above and beyond the amounts currently being reported to PMPRB.

Finding #2 – Allowing more time for companies to respond to PMPRB could improve response rate and accuracy (i.e. aligning the reporting deadline to the SR&ED deadline).

Finding #3 – Additional amounts invested by non-Rx&D members involving pharmaceutical companies that conduct R&D in Canada have not been measured in the Survey but that which may represent additional R&D in Canada.

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The comments contained in this report are based on the facts, assumptions and representations stated herein. You have represented to us that you have provided us with all facts and circumstances that you know or have reason to know are pertinent to this report. If any of these facts, assumptions or representations is not entirely complete or accurate, it could have a material affect on our comments. Our comments take into account the applicable provisions and judicial and administrative interpretations of the relevant taxing statutes, the regulations thereunder and applicable tax treaties. Our comments also take into account all specific proposals to amend these authorities or other relevant statutes and tax treaties publicly announced prior to the date of our report, based on the assumption that these amendments will

[1] The PMPRB utilizes the 1987 SR&ED as per its legislative mandate to report under the Patented Medicines Regulations

be enacted substantially as proposed. Our comments do not otherwise take into account or anticipate any changes in law or practice, by way of judicial, governmental or legislative action or interpretation. These authorities are subject to change, retroactively and/or prospectively, and any such changes could have an effect on the validity of our comments. Unless you specifically request otherwise, we will not update our comments to take any such changes into account.

KPMG's comments are for the sole use of the Company. The comments are based on the specific facts and circumstances and the scope of KPMG's engagement and are not intended to be relied upon by any other person. KPMG disclaims any responsibility or liability for any reliance that any person other than the Company may place on these comments.

Thank you for the opportunity to work with Rx&D on this engagement and we trust you will find the above of value to the organization.

Respectfully submitted,

APPENDIX 3

2010 definition of SR&ED Pursuant to Subsection 248(1) of the *Income Tax Act* (Canada)

> *"scientific research and experimental development" means systematic investigation or search that is carried out in a field of science or technology by means of experiment or analysis and that is*
> *(a) basic research, namely, work undertaken for the advancement of scientific knowledge without a specific practical application in view,*
> *(b) applied research, namely, work undertaken for the advancement of scientific knowledge with a specific practical application in view, or*
> *(c) experimental development, namely, work undertaken for the purpose of achieving technological advancement for the purpose of creating new, or improving existing, materials, devices, products or processes, including incremental improvements thereto,*
> *and, in applying this definition in respect of a taxpayer, includes*
> *(d) work undertaken by or on behalf of the taxpayer with respect to engineering, design, operations research, mathematical analysis, computer programming, data collection, testing or psychological research, where the work is commensurate with the needs, and directly in support, of work described in paragraph (a), (b), or (c) that is undertaken in Canada by or on behalf of the taxpayer,*
> *but does not include work with respect to*
> *(e) market research or sales promotion,*
> *(f) quality control or routine testing of materials, devices, products or processes,*
> *(g) research in the social sciences or the humanities,*
> *(h) prospecting, exploring or drilling for, or producing, minerals, petroleum or natural gas,*
> *(i) the commercial production of a new or improved material, device or product or the commercial use of a new or improved process,*
> *(j) style changes, or*
> *(k) routine data collection;"*

In general, there have not been significant changes to the definition of SR&ED since 1987. In summary, the ability to include limited additional salaries of Canadian employees that spend time outside of Canada on eligible activities has been added as well as the ability to include capital and lease costs that are used between 50% to 90% of the time on SR&ED activities (i.e. as opposed to just those which are used greater than 90% of the time).

In general, the following are types of eligible expenditures for SR&ED purposes:

- Salaries of Canadian personnel directly engaged in SR&ED eligible work performed in Canada and limited outside Canada (i.e. maximum of 10% of total eligible SR&ED labour costs in Canada)
- Salaries of Canadian personnel directly supporting SR&ED eligible work performed in Canada for:
  - Engineering
  - Design
  - Operations Research
  - Mathematical Analysis
  - Computer Programming
  - Data Collection
  - Testing
  - Psychological Research

- Contract payments made to Canadian entities: commercial laboratories, private practitioners, consultants, manufacturing and other companies, or other research-performing organizations
- Materials consumed or transformed during the performance of SR&ED eligible work in Canada
- New capital equipment or leased equipment used 50% or more of its useful life dedicated to SR&ED