• THANK THE TORONTO BOARD OF TRADE FOR THIS OPPORTUNITY TO SHARE A CANADIAN SUCCESS STORY – SANOFI PASTEUR – A STORY THAT BEGAN IN A SMALL STABLE IN TORONTO AND BECAME A BILLION DOLLAR A YEAR ENTERPRISE, WITH EXPORTS TO OVER 90 COUNTRIES.

• SANOFI PASTEUR IS THE VACCINE DIVISION OF THE SANOFI-AVENTIS GROUP, A LEADING GLOBAL, DIVERSIFIED HEALTH CARE COMPANY. IN CANADA, SANOFI-AVENTIS IS OUR PHARMACEUTICAL BUSINESS, HEADQUARTERED IN LAVAL AND SANOFI PASTEUR HEADQUARTERED IN TORONTO.

• OVER THE PAST 95 YEARS, SANOFI PASTEUR HAS CONTRIBUTED TO A CANADIAN LEGACY OF LEADERSHIP IN PUBLIC HEALTH AND VACCINE RESEARCH, DEVELOPMENT AND INNOVATION. THAT HISTORY HAS BEEN ONE OF REACTING TO EMERGING PUBLIC HEALTH THREATS AND COLLABORATING WITH GOVERNMENTS, INDUSTRY AND ACADEMIA TO COMMERCIALIZE INNOVATIVE VACCINES.
Value of Vaccines

- Vaccination saves more than **3 million lives** every year

- $1 spent on vaccines = $2 to $27 saved in healthcare expenses

• GREATEST PUBLIC HEALTH TRIUMPH AFTER IMPROVED ACCESS TO CLEAN AND SAFE DRINKING WATER.

• VACCINES SAVE MORE THAN 3M LIVES EACH YEAR. VACCINE-PREVENTABLE DISEASES KILL 3 MILLION PEOPLE AROUND THE WORLD EVERY YEAR (WHO ESTIMATES)

• PREVENTION VIA IMMUNIZATION IS KEY TO A COST EFFECTIVE, AND SUSTAINABLE HEALTHCARE SYSTEM.

• EXAMPLE: $1 SPENT ON VACCINES SAVE THE SYSTEM $2 TO $27 IN HEALTHCARE EXPENSE.
- SANOFI PASTEUR HAS CONTINUALLY HAD TO RE-INVENT ITSELF TO STAY COMPETITIVE AND SUCCESSFUL IN A CHANGING GLOBAL ENVIRONMENT.
- DESCRIBE ACQUISITION/MERGERS.
SANOFI PASTEUR HAD AN EXTREMELY HUMBLE BEGINNING IN A SMALL STABLE ON BARTON RD, MERE BLOCKS FROM WHERE WE ARE GATHER TODAY. A YOUNG DOCTOR NAMED JOHN FITZGERALD BEGAN PRODUCING THE ANTI-TOXIN IN A SMALL STABLE HE HAD BUILT WITH HIS WIFE’S DOWRY. HE HAD LEARNED TO PRODUCE VACCINES AT THE PASTEUR INSTITUTES IN PARIS AND BRUSSELS, AND RETURNED TO CANADA TO ADDRESS AN URGENT PUBLIC HEALTH ISSUE.

HIS GOAL WAS TO PRODUCE THE SERUM AND PROVIDE IT AT COST TO DOCTORS ACROSS THE PROVINCE AS A PUBLIC SERVICE. TO DO THAT, HE NEEDED PARTNERS. HE APPROACHED THE UNIVERSITY OF TORONTO – SEVERAL TIMES. HE WAS PERSISTENT. EVENTUALLY, HE WAS GIVEN A $500 DOLLAR ADVANCE BY THE UNIVERSITY, AND ON MAY 1, 1914, THE ANTI-TOXIN LABORATORIES WERE FOUNDED.

WE ARE FORTUNATE TO HAVE DR. FITZGERALD’S GRANDSON, JAMES JOIN US TODAY. JAMES IS AN AWARD WINNING WRITER WHO CHRONICLED HIS FAMILY’S MEMOIR IN THE BOOK “WHAT DISTURBS OUR BLOOD: a SON’S QUEST TO REDEEM THE PAST”.

• THE NEW LABORATORY WAS UNIQUELY POSITIONED WHEN THE FIRST WORLD WAR BROKE OUT. IT EXPANDED RAPIDLY, SUPPLYING ANTI-TOXINS FOR THE BRITISH EMPIRE WHILE MAINTAINING ITS FOCUS ON PUBLIC HEALTH IN CANADA.
• In the early 1920’s, Connaught Laboratories worked with doctors Banting and Best to begin commercializing insulin. That partnership, and the Nobel Prize for the discovery, resulted in a $1.2 million donation from the Rockefeller Foundation for the establishment of the School of Hygiene at the University of Toronto.

• The School of Hygiene and Connaught Labs would go on to receive international recognition for their extensive contributions to public health, providing research, education and biological development and production during the Great Depression.
• IN THE EARLY 1930’S, DOCTOR FITZGERALD’S GOAL TO CONTROL DIPHTHERIA IN ONTARIO WAS REALIZED WHEN TORONTO AND HAMILTON WERE DECLARED THE FIRST DIPHTHERIA-FREE CITIES IN THE WORLD.

• DURING THE SECOND WORLD WAR, CONNAUGHT LABS AGAIN PLAYED A LEAD ROLE IN THE ALLIED EFFORT. IN ADDITION TO VACCINES, THE COMPANY HELPED COMMERCIALIZE LIFE-SAVING PENICILLIN – AN INNOVATIVE NEW INTERVENTION AT THE TIME.
WHEN THE FEAR OF A WIDE-SPREAD POLIO EPIDEMIC ACROSS NORTH AMERICA IN THE 1950’S LED TO AN INTENSE EFFORT TO DEVELOP A VACCINE, CANADA – AND CONNAUGHT LABORATORIES – WAS AGAIN UNIQUELY POSITIONED. OUR COMPANY’S INVOLVEMENT IN THE INJECTIBLE POLIO VACCINE IS AN INTERESTING CASE STUDY IN COLLABORATION – AND THE HOPE THAT IS PLACED ON VACCINES AND IMMUNOLOGY TO RESPOND TO EMERGING PUBLIC HEALTH THREATS.

CANADA WAS NOT IMMUNE FROM THE POLIO OUTBREAKS OF THE 1950’S, AND IN MAJOR CITIES SUCH AS WINNIPEG, THERE WAS WIDESPREAD FEAR. LITTLE WAS UNDERSTOOD ABOUT HOW THE DISEASE WAS SPREAD, BUT EVERYONE KNEW THE DEVASTATING CONSEQUENCES OF CONTRACTING POLIO.

OUR COMPANY PLAYED AN INSTRUMENTAL ROLE IN THE FIGHT AGAINST POLIO BY DEVELOPING TECHNIQUES WHICH ALLOWED DR. JONAS SALK TO PRODUCE HIS VACCINE ON A LARGE SCALE, BRINGING AN END TO THE POLIO EPIDEMICS IN NORTH AMERICA IN THE 1950s.)
HAVING PLAYED A LEAD ROLE IN CONTROLLING POLIO, CONNAUGHT LABORATORIES BEGAN FOCUSING ON COMBINING THE INJECTIBLE VACCINE WITH OTHER PRODUCTS. THAT RESEARCH AND DEVELOPMENT WORK LED TO AN EXPERTISE IN COMBINATION VACCINE TECHNOLOGY, AN AREA WHERE SANOFI PASTEUR IS NOW RECOGNIZED AS A GLOBAL LEADER.
1960s – 1970s: Smallpox

**WHO Smallpox Eradication Program**

- **35 million doses** to WHO Smallpox Eradication Program

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**AT THE TIME, THESE DISEASE TARGETS WERE AS CHALLENGING AS THOSE WE FACE TODAY AND THEY NEVER WOULD HAVE BEEN OVERCOME WITHOUT COLLABORATION.**
ONE OF THE CORNERSTONES OF CURRENT PUBLIC IMMUNIZATION PROGRAMS IS THE PERTUSSIS VACCINE. PERTUSSIS – OR WHOOPING COUGH – IS A SERIOUS PUBLIC HEALTH THREAT, AND IT CAN BE FATAL FOR INFANTS.

UNTIL THE MID 1990’S, PERTUSSIS VACCINE HAD BEEN BASED ON A ‘WHOLE CELL’ APPROACH. THE ENTIRE BACTERIA WAS CRUSHED UP, PURIFIED, AND MADE INTO A VACCINE. WHILE THIS WAS EFFECTIVE, IT ALSO CAUSED SIGNIFICANT LOCAL SIDE EFFECTS. THOSE SIDE EFFECTS WERE A BARRIER TO DEVELOPING COMBINATION VACCINES.

SCIENTISTS AT CONNAUGHT LABORATORIES BEGAN RESEARCHING WAYS TO IMPROVE THE PERTUSSIS VACCINE. THEIR RESEARCH LED TO A PRODUCT THAT HAS BECOME THE GLOBAL GOLD STANDARD IN PERTUSSIS IMMUNIZATION, ISOLATING FIVE SPECIFIC COMPONENTS OF THE VACCINE. OUR VACCINE IS THE ONLY ONE IN THE WORLD WITH THOSE 5 COMPONENTS.

OUR FIVE COMPONENT PERTUSSIS VACCINE AND ITS COMBINATIONS IS NOW LICENSED IN 62 COUNTRIES. A PRODUCT DEVELOPED INITIALLY FOR THE CANADIAN MARKET HAS GROWN SUBSTANTIALLY FROM THE 2 MILLION DOSES IN 1997 TO 50M TODAY.
• THE HEADQUARTERS FOR OUR CANADIAN VACCINE ACTIVITIES IS LOCATED IN NORTH TORONTO, AT THE CORNER OF DUFFERIN AND STEELES.

• THE SITE IS HOME TO OVER 1100 EMPLOYEES.

• THE TORONTO CAMPUS COVERS 54 ACRES, WITH 40 ACTIVE BUILDINGS AND OVER 1M SQUARE FEET OF WORKING SPACE.

• AT OUR TORONTO SITE, WE MANUFACTURE VACCINES FOR PERTUSSIS, DIPHTHERIA, TETANUS, AND POLIO. BCG FOR TREATMENT OF A FORM OF BLADDER CANCER. WE ALSO FILL AND PACK INFLUENZA VACCINES.
• TODAY, SANOFI PASTEUR’S TORONTO SITE IS ONE OF FOUR KEY MANUFACTURING FACILITIES IN SANOFI PASTEUR’S GLOBAL OPERATION.

• WE HAVE MORE THAN 700 PEOPLE IN THE INDUSTRIAL OPERATIONS GROUP.

• IN 2009, WE PRODUCED MORE THAN 80M DOSES OF VACCINES TO SUPPLY MORE THAN 90 COUNTRIES.

• OUTPUT FROM THE TORONTO SITE ACCOUNTED FOR ABOUT 11% OF ALL GLOBAL INDUSTRIAL OPERATIONS AND 23% OF GLOBAL SALES FOR SANOFI PASTEUR.

• APPROXIMATELY, 95% PRODUCTS WE MANUFACTURE IN TORONTO ARE EXPORTED - ABOUT HALF TO THE US AND A QUARTER TO THE EUROPEAN MARKET.
Vaccine Success Story: 5-acP

- Researched, developed and manufactured in Canada
- Only site that manufactures 5-component acellular pertussis vaccine (5-acP)
- Worldwide net sales of more than $1B CDN
- Plan to double capacity

- To get to where we are today has not been an easy journey. There have been setbacks and at times, there has been uncertainty of our future in Canada. However, our 5 component acellular pertussis success story demonstrates how innovation can help secure new mandates and build wealth for the nation.

- 5-CP was researched and developed in Canada. Originally, the vaccine was developed for a domestic market of two million doses. However, last year, 5-CP vaccines generated worldwide net sales of over $1B CDN.

- Toronto is the only site that manufactures 5-component acellular pertussis vaccine. The global demand for 5-ACP combination vaccines continues to raise - licensed in 62 countries. Our manufacturing capacity has expanded several times to the current to meet demand.

- As success begets success, we are planning to again expand manufacturing capacity at the Toronto campus. In the background is an artist's rendition of the proposed new 5-CP building that we would like to build at the Toronto campus. This facility will allow us to double our capacity to 100m doses.

- This story is a clear example of how innovation leads to wealth creation, for the benefits of Toronto, the GTA and Canada.
• ONE YEAR AGO, WE COMPLETED OUR $101M, 145,000 SQ. FT R&D FACILITY, FUNDED IN PARTNERSHIP WITH THE ONTARIO GOVERNMENT THROUGH THE BIOPHARMACEUTICAL INVESTMENT PROGRAM (BIP).

• AS A DIRECT RESULT OF THIS INVESTMENT, THE TORONTO SITE SECURED A SIGNIFICANT MANDATE – WE ARE THE NORTH AMERICAN "CENTRE OF EXCELLENCE" IN ANALYTICAL AND BIOPROCESS RESEARCH AND DEVELOPMENT FOR SANOFI PASTEUR.

• THIS NEW MANDATE MAINTAINS 300 HIGHLY EDUCATED AND SKILLED POSITIONS IN TORONTO, AND MAKES TORONTO A KEY SITE FOR INNOVATION. THE FACILITY ALLOWS US TO CONSOLIDATE OUR R&D EFFORTS – NOW ALL UNDER ONE ROOF WITH THE SOLE MANDATE TO MOVE OUR NEW VACCINE PROJECTS THROUGH THE PIPELINE FASTER. THESE PROJECTS INCLUDE VACCINES FOR PNEUMOCOCCAL, CHLAMYDIA AND TUBERCULOSIS DISEASE.

• SINCE 2000, WE HAVE INVESTED OVER $600M IN CAPITAL INVESTMENTS AT THE CONNAUGHT CAMPUS.

• EACH YEAR, SANOFI PASTEUR INVESTS APPROXIMATELY $100M IN R&D IN CANADA.
Some of Our Key Success Factors

- Government as first adopter of our innovations
- Partnerships with public and private stakeholders
- Ongoing investments in research, development and manufacturing
- Continually reinvented ourselves

Even though the Canadian market is small, it’s an important market for us. In the past, the Canadian government was standing by to purchase made-in-Canada products. The government was looking for value and not making procurement decision base solely on the price of the product.

Collaboration is a key important ingredient to our success – partnerships with our patients, governments, public health agencies, and internal stakeholders.

Continually invest in R&D. In 2009, Sanofi Pasteur invested about $100M in R&D in Canada. The reality is that this level may change depending on market conditions and we have internal competition for resources and mandates.

There is a continual need to re-invent ourselves. We have embraced the mergers and acquisitions and they have become a part of our company’s rich history. And as company in Canada, we have emerged in a better position each time.

Unfortunately, the combination of success factors that helped launch our company is much harder to assemble today. The emergence of the "BRIC" countries and, we face challenges to maintain and build on our mandates here in Canada.
Industry Challenges

- Patent Cliff
- Regulatory approval becoming more complex
- Canada’s intellectual property regime
- Threats to sustainability of the industry in Canada

- IN ADDITION, OUR INDUSTRY IN CANADA IS FACING SIGNIFICANT CHALLENGES: FROM SIGNIFICANT LOSS OF REVENUES BECAUSE OF THE "PATENT CLIFF", HIGHER R&D COSTS, AND INCREASE GLOBAL COMPETITION FOR INVESTMENT DOLLARS.

- THE TERM "PATENT CLIFF" IS USED IN OUR INDUSTRY TO IDENTIFY A PERIOD WHERE KEY BLOCKBUSTER DRUGS ARE COMING OFF PATENTS. ACCORDING TO FIGURES FROM ONE SOURCE - DATAMONITOR, THE GLOBAL PHARMA INDUSTRY IS SET TO LOSE $78 BILLION IN SALES IN 2014 VERSUS 2009 AS A RESULT OF THE PATENT CLIFF.

- IN ADDITION TO LOSING TOP LINE REVENUES, THE REGULATORY APPROVAL PROCESS IS BECOMING MORE COMPLEX – INCREASING DEVELOPMENT COSTS THAT CAN EXCEED $1B IN SOME CASES PER PRODUCT. TYPICALLY, IT TAKES LONGER THAN A DECADE TO BRING A PRODUCT TO MARKET, IF AT ALL.

- IN CANADA, OUR INTELLECTUAL PROPERTY REGIME REQUIRES REFORM TO ADDRESS ISSUES RELATED TO RIGHT OF APPEALS, PATENT TERM RESTORATION AND DATA PROTECTION TERMS.

- THREATS TO SUSTAINABILITY OF THE INDUSTRY IN CANADA – COMPANIES FOCUSING THEIR INVESTMENTS IN EMERGING MARKETS.
Opportunities for Canada

- **Biopharma** is a growing field, and Canada is well positioned to be a leader
- R&D and manufacturing jobs that flow from innovation and investments
- The Biopharma “ecosystem” and clusters
- A sustainable healthcare system

• As the pharma industry is becoming more patient centric, the movement to personalized medicine is gaining momentum. This is aided in part by advancements in detection and diagnosis methods and in the area of stem cell research. The GTA has world-class academic institutions and research hospitals with expertise in these areas. In Ontario, we have about 25 research and academic hospitals, employing 10,000 scientists, clinical investigators and other researchers. Ontario is the largest hub of early stage biomedical research activity in Canada, and the fourth largest biomedical research centre in North America.

• We need to fight to maintain R&D and manufacturing jobs – the high-value jobs that we so cherish will soon follow those low-value jobs that we did not fight hard enough to keep.

• Development of ecosystems – developing a biopharma cluster in Toronto that rivals the best in the world. I think MaRS is a great start, but it needs our support to regain momentum. Large companies — small companies— financiers — government: all have key roles to play in the ecosystem.

• The national dialogue on sustainability of our healthcare system is gaining momentum and it is a discussion we absolutely need to have. Healthcare innovations such as vaccines and prescription medicines are viewed simply as a costs rather than being recognized for the enormous contribution to Canada’s economy, health and well being of our citizens.
Public Policy Options to Capitalize on the Opportunities

- Adopt the world’s strongest intellectual property regime
- Incentivize risk capital
- Employ strategic procurement as a public policy instrument
- Capitalize on the national dialogue

• CANADA NEEDS TO ENCOURAGE INNOVATION AND SPUR INVESTMENT IN BIOPHARMA. THIS CAN BE ACHIEVED BY ENSURING THAT CANADA HAS THE WORLD’S STRONGEST INTELLECTUAL PROPERTY REGIME – THE RIGHT OF APPEAL FOR INNOVATORS, PATENT TERM RESTORATION WHICH CANADA DOES NOT HAVE, AND DATA PROTECTION TERMS THAT ARE COMPARABLE TO THOSE AROUND THE WORLD. THESE REFORMS CAN REASSURE COMPANIES AND THEIR INVESTORS THAT THEY CAN EXPECT TO REAP BENEFITS OF THEIR INVESTMENT.

• CLEARLY, THE PLAYING FIELD IS NOT LEVEL FOR CANADA ON THE GLOBAL MARKET – A PLAYING FIELD THAT OUR COUNTRY HAS CHOSEN FOR ITSELF. GLOBAL COMPANIES ARE ALSO LOOKING FOR GREENER PASTURES FOR THEIR BUSINESSES. INCENTIVES SUCH AS THE SCIENTIFIC RESEARCH AND EXPERIMENTAL DEVELOPMENT TAX CREDITS ARE IMPORTANT PROGRAMS TO HAVE TO ATTRACT RISK CAPITAL.

• A WILLINGNESS ON THE PART OF GOVERNMENTS TO RECOGNIZE THAT PUBLIC HEALTHCARE SPENDING IS A VALUABLE ECONOMIC DEVELOPMENT TOOL. GOVERNMENT SHOULD EMPLOY STRATEGIC PROCUREMENT AS A PUBLIC POLICY INSTRUMENT TO SPUR INVESTMENT AND INNOVATION.

• CAPITALIZE ON THE NATIONAL DIALOGUE ON INNOVATION IN HEALTHCARE
Our Vision

- A world in which no one suffers or dies from a vaccine preventable disease

- THANK YOU FOR LISTENING TO THE SANOFI PASTEUR STORY - HOW A VISION THAT BEGAN IN A STABLE, GREW AND MATUERED OVER THE LAST 98 YEARS TO BRING SIGNIFICANT ECONOMIC AND SOCIAL BENEFITS TO TORONTO, CANADA AND THE REST OF THE WORLD.

- SANOFI PASTEUR’S VISION IS A WORLD IN WHICH NO ONE SUFFERS OR DIES FROM A VACCINE PREVENTABLE DISEASE AND OUR MISSION IS TO PROTECT AND IMPROVE HUMAN HEALTH WORLDWIDE.

- WE HAVE THE ABILITY TO DO THAT RIGHT HERE IN TORONTO AS WE ADD MORE CHAPTERS TO OUR STORY: SANOFI PASTEUR: A BILLION DOLLAR VACCINE BUSINESS GROWN IN YOUR BACKYARD.