





Corporate Presentation

APOTEX

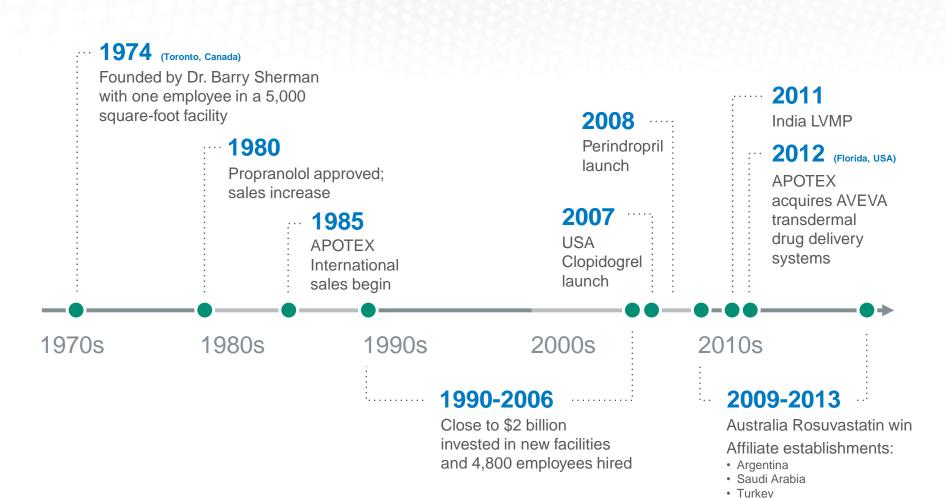
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Ukraine





## **Employment**

+7,500 employees worldwide and growing



#### **Global Presence**

Export to +115 countries



### Capabilities

+4,000 dosages & formats

Expansive product portfolio includes a wide range of therapeutic classes including:

- Cardiovascular
- Anti-infectives
- Gastrointestinal
- Central nervous system and pain management



## Corporate Responsibility

The APOTEX Foundation has donated more than \$50 million to charities across Canada

APOTEX has donated more than \$21.7 million to specific Canadian University schools of pharmacy

Apo-Triavir Rwanda Donation (2008 & 2009) – APOTEX is the only pharmaceutical company to have developed & donated a triplecombination generic for the treatment of AIDS in developing countries



#### Canada

- APOTEX ranks #1 in market coverage
- Remains the leader in total number of first-to-market launches
- APOTEX competes in 5 out of 5 best sellers of the market: Atorvastatin, Rosuvastatin, Pantoprazole, Amlodipine, Esomeprazole

Source: IMS Health Data, May, 2013



#### USA

#### U.S. Market Presence

- Top 10 in sales\*
- Top 15 in scripts\*\*

#### **R&D** Engine

- Approximately 235
   ANDAs approved
- Currently submitting 40-50 ANDAs per year

Source: \* IMS, 2012 Reported

\*\* IMS MAT, June 2013 Reported





**APOTEX** 

Quality is an intricate part of our business and we continue to invest in capital and intellectual infrastructure.

- Hiring >1,100 new employees
- In the past few years, investment of +\$16 million
- Millions of dollars in Facility and Equipment upgrades



At **APOTEX** we all have the responsibility to live and breathe quality, and we achieve this with our "**Commitment** to Excellence."

We support this vision by having **excellent systems**, practicing **excellent science**, and, above all, employing **excellent people**.



As a result of our vision, we continue to achieve compliance approvals by various global health authorities on a regular basis:



Health Canada

























We challenge patents and take risks to bring key molecules to market sooner, and in turn generate value to all our partners.

APOTEX has spent +\$800 million over the past 10 years in patent litigation costs to bring versions of brand name pharmaceuticals to market sooner:

- Australia
- Canada
- USA



## Top five ANDA defendants: 1995–2012

| DEFENDANT  | NUMBER OF CASES |
|--|-----------------|
| <b>Teva</b> (including, Barr Laboratories, Cephalon & Novopharm) | 32              |
| Apotex   | 16              |
| Mylan  | 14              |
| Watson (including Andrx Pharmaceutical)                          | 8               |
| Sandoz   | 7               |

Source: 2013 Patent Litigation Study, Chart 11d. USA.

APOTEX is the right partner for potential licensors who are interested in registering and commercializing their pharmaceutical products in APOTEX target markets:

- Australia
- Canada
- Europe
- USA



# As your partner of choice, we offer a wide range of skills and experience:

- Sales & marketing
  - Canada; ranked #1 in the country, where 1 in 5 products are filled with an APOTEX product
  - Australia; ranked #2 in the country
  - U.S.A; ranked within the top 10 generic pharmaceutical players
  - Coverage of all sales channels, including government, private, retail, and institutional market segments



- Pricing and reimbursement, bids, tenders, government/customer contracts
- Regulatory and medical affairs
- Intellectual property
- Clinical development
- Pharmacovigilance



- Supply chain
  - Logistics (importing and exporting), wholesaling, and distribution
- Release testing (as required)
   and qualified person resources

We offer our licensees **cost-effective access** to currently registered products, as well as our product development pipeline.

#### Services offered include:

- Dossier supply
- Regulatory support
- Long-term product manufacturing
- More than 400 combined registered products:
  - Australia, Canada & Europe
- Logistics services
- Bioequivalence studies



# Vertical integration enables us to develop our own active ingredients and formulations.

- +24 Billion tablets/capsules per year
- +4,000 Dosages and Formats
- 15 Million eaches of liquids

| MARKET        | FACILITY   |
|---------------|--|
| North America | ACCUCAPS, APOTEX Pharmachem, AVEVA, Etobicoke, Richmond Hill, Signet |
| South America | Mexico   |
| Europe        | Netherlands  |
| Asia Pacific  | APOTEX Pharmachem India APOTEX Research Private Ltd.                 |

## We are proud to be part of the global community.

#### **Affiliates Distributors**

Argentina
Australia
Belgium
Canada
Czech
Republic
Mexico
Netherlands

New Zealand Poland

Saudi Arabia

Spain Turkey Ukraine

**United States** 

| Kuwait         | Aruba             |
|----------------|-------------------|
| Lebanon        | Bahamas           |
| Libya          | Bahrain           |
| Malaysia       | Barbados          |
| Moldova        | Belarus           |
| Nigeria        | Bermuda           |
| Nicaragua      | Botswana          |
| Panama         | China             |
| Philippines    | Cayman Islands    |
| Russia         | Costa Rica        |
| Singapore      | Curacao           |
| Taiwan         | Eastern Caribbean |
| Thailand       | Islands           |
| Trinidad &     | El Salvador       |
| Tobago         | Guyana            |
| United         | Haiti             |
| Arab Emirates  | Hong Kong         |
| United Kingdom | Hungary           |
| Vietnam        | Indonesia         |
|                |                   |

Iraq

Jamaica

Yemen

Zimbabwe

Vertical integration facilitates our ability to push boundaries on a daily basis. As a result, we are able to bring to market valuable, affordable high-quality pharmaceutical products.

Since 2005, APOTEX has dedicated +\$1.1billion in funds towards development of products in various categories:

- Bioequivalent Generics
- Biosimilars



R&D is the key to our success, not the exception. Over the **next 10 years** we plan to dedicate +\$2.1 billion towards launching products again to meet our customers needs.

Our **technological advantages** allow us to address a vast range of product opportunities.

## Some of the many areas where we provide valuable solutions include:

- Capsules / tablets
- Nasals
- Ophthalmic
- Liquids
- Soft gel capsules
- Transdermal drug delivery systems









ACCUCAPS is a fully integrated global developer and manufacturer of soft gelatin capsules, consistently delivering on their promise of value.

#### Some of their key features include:

- Micro-colloid system to deliver lipophilic API
- Nano-emulsion system to deliver lipophilic API
- Formulation-based patents
- Process technologies with IP
- Proprietary manufacturing technologies



AVEVA is a fully integrated global developer and manufacturer, providing complete transdermal solutions.

## Fentanyl transdermal system filings/approvals/rights licensed:\*

USA • Canada • Australia • Saudi Arabia Egypt • South Africa • Brazil

# Nicotine transdermal system filings/approvals/rights licensed:\*

USA • Canada • Europe (Denmark, Hungary, Malta, Poland, Sweden, Finland, France, Iceland, Portugal, United Kingdom)
Colombia • Australia/New Zealand • Brazil



**APOTEX** 

**APOTEX** is leading the way in developing safe, effective and affordable alternatives to biologic therapies.

Relative to biologics, the vast majority of generic pharmaceuticals are based on small, easy to replicate molecules. Whereas newer biologic therapies utilize larger, much more complex molecules.



**APOTEX** 

# An attractive new opportunity for our business partners:

- New biopharmaceutical division in place
  - Monoclonal Antibodies key R&D initiative
- G-CSF (co-development with Intas) started in May 2008 for Europe and North America
  - Approval and launch EU 2014
- Among the top 10 Major Generic in follow-on-biologics development\*



# Thank you.

**APOTEX** 

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