

MATERIAL CHANGE REPORT UNDER

SECURITIES ACT (BRITISH COLUMBIA) SECTION 85(1) FORM 27
SECURITIES ACT (ALBERTA) SECTION 146(1) FORM 27
THE SECURITIES ACT (SASKATCHEWAN) SECTION 84(1) FORM 25
THE SECURITIES ACT (MANITOBA)
SECURITIES ACT (ONTARIO) SECTION 75(2) FORM 27
SECURITIES ACT (QUEBEC) SECTION 73
THE SECURITIES ACT (NEWFOUNDLAND) SECTION 76(2) FORM 26
SECURITIES ACT (NOVA SCOTIA) SECTION 81(2) FORM 27
SECURITY FRAUDS PREVENTION ACT (NEW BRUNSWICK)
SECURITIES ACT (PRINCE EDWARD ISLAND)

1. Reporting Issuer:

Axcan Pharma Inc.
597, boul. Laurier
Mont-Saint-Hilaire
Quebec
J3H 6C4

2. Date of Material Change:

September 3, 2003

3. Press Release:

Press Release issued on September 3, 2003.

4. Summary of Material Change:

Axcan has acquired for an aggregate price of US \$ 75 million (of which US \$ 20 million are milestone payments tied to regulatory submissions and US \$ 45 million are milestone payments tied to regulatory approvals) an exclusive license for North America, the European Union (“EU”) (including the United Kingdom, France, Germany, Italy and Spain) and Latin America, from Abbott Laboratories (“Abbott”) to develop, manufacture and market, ITAX™ (Itopride hydrochloride), a patented oral gastroprokinetic drug with antiemetic properties for the treatment of gastrointestinal symptoms caused by reduced gastrointestinal motility. Axcan expects this acquisition to be accretive. If ITAX™ is approved by health authorities, management believes that within 3-5 years after full launch, sales of ITAX™ could generate annual revenue of approximately U.S. \$200-300 million and have a significant impact on net earnings..

5. Full Description of Material Change:

See press release attached as exhibit A.

6. Reliance on Confidentiality Provision of Material Change:

Not applicable.

7. Omitted Information:

No information has been omitted.

8. Senior Officers:

For further information, please contact **David W. Mims**, Executive Vice President and Chief Operating Officer at (205) 991-8085 ext. 223 or **Isabelle Adjahi**, Director, Investor Relations at (450) 467-2600 ext. 2000 or at the above mentioned address.

9. Statement of Senior Officer:

The foregoing accurately discloses the material change referred to in this report.

Mont Saint-Hilaire, Quebec.

September 3, 2003.

AXCAN PHARMA INC

BY: " *Isabelle Adjahi* "
Name: **Isabelle Adjahi**
Title: Director, Investor Relations

EXHIBIT A
PRESS RELEASE



AXCAN PHARMA INC.

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SOURCE:

AXCAN PHARMA INC.

TSX SYMBOL (Toronto Stock Exchange):
Nasdaq SYMBOL (Nasdaq National Market):

AXP
AXCA

DATE:
News release for immediate distribution

September 3, 2003

AXCAN LICENSES ITAX™ FROM ABBOTT LABORATORIES GASTROPROKINETIC DRUG HAS POTENTIAL TO BECOME AXCAN'S LARGEST PRODUCT

MONT SAINT-HILAIRE, Quebec – Axcán Pharma Inc. (“Axcán” or the “Company”) announced today that it has acquired an exclusive license for North America, the European Union (“EU”) (including the United Kingdom, France, Germany, Italy and Spain) and Latin America, from Abbott Laboratories (“Abbott”) to develop, manufacture and market, ITAX™ (Itopride hydrochloride), a patented oral gastroprokinetic drug with antiemetic properties for the treatment of gastrointestinal symptoms caused by reduced gastrointestinal motility. If ITAX™ is approved by health authorities, management believes that, based on the factors discussed below, within 3-5 years after full launch, sales of ITAX™ could generate annual revenue of approximately U.S. \$200-300 million and have a significant impact on net earnings.

“Obtaining an exclusive license for ITAX™ is a monumental achievement for Axcán Pharma. Treating patients with gastrointestinal symptoms caused by reduced gastrointestinal motility continues to present a major challenge for gastroenterologists. If approved, ITAX™ will address a significant unmet medical need for a gastroprokinetic drug. This drug therefore represents a major opportunity to which we will dedicate substantial resources,” said Léon F. Gosselin, Axcán’s President and CEO. “Should Axcán achieve sales corresponding to only 25% of 1999 sales of Cisapride, a prokinetic drug marketed by a leading pharmaceutical company for patients with heartburn and esophagitis due to GERD, ITAX™ would become by far Axcán’s largest product,” he concluded.

Cisapride was removed from the market in 2000 after achieving 1999 annual sales of over \$1 billion due to adverse events (*FDA Talk Paper-T00-14, March 23, 2000*).

TERMS OF THE AGREEMENT

Under the terms of this license agreement, Axcán will pay Abbott US \$75 million in cash, comprised of:

- U.S. \$10 million in upfront payments;
- U.S. \$20 million in regulatory submission milestones; and
- U.S. \$45 million in regulatory approval milestones.

Axcán will also pay a royalty on net sales and assume approximately \$2 million in research contract liability.

Axcan expects to initiate and conduct two controlled Phase III studies (one in North America and one internationally) and will target completion for both in 2005. This should allow Axcan to submit ITAX™ for FDA approval in 2006. Once the product is approved, Axcan expects to benefit from a minimum of 5 years of marketing exclusivity following the launch in the United States, and a minimum of 10 years in the EU since ITAX™ is a patented new chemical entity that will fill a significant unmet medical need. Axcan also plans to conduct special population studies once its first indication is approved.

POTENTIAL INDICATIONS FOR GASTROPROKINETIC DRUGS

Prokinetic drugs represent an attractive alternative treatment strategy for patients with non-ulcer dyspepsia (NUD), gastroesophageal reflux disease (GERD) and diabetic gastroparesis. However, this strategy is limited by the availability of drugs, especially in the United States.

NUD, a functional disorder of the upper gastrointestinal system, affects up to 25% of the US population annually and accounts for up to 5% of all visits to primary care physicians (*Talley et al Gastroenterology 1992;102:1259-1268*). In Europe, the prevalence is similar to the US as demonstrated by UK data estimating that 21% of the local population suffers from dyspepsia, accounting for 40% of all gastroenterological consultations (*Jones RH et al. Gut 1990;31:401-405*).

The prevalence of gastroesophageal reflux disease, a condition in which partially-digested food in the stomach backs up into the esophagus, is estimated at approximately 5-7% of the US population (*IFFGD at www.aboutgerd.org and NIDDK 1985*).

Diabetic gastroparesis, often a complication of type 1 diabetes, is a disorder in which the stomach takes too long to empty its contents. It affects up to 50% of the diagnosed type 1 diabetes patients (*National Institutes of Diabetes and Digestive and Kidney Disease NIH publication No. 99-4348 May 1999 and Smith DS, Ferris CD Drugs 2003;63 (13):1339-58*).

Collectively, these indications represent a substantial market opportunity.

MECHANISM OF ACTION

Itopride hydrochloride's mechanism of action has been shown to involve an amplification of the prokinetic action of acetylcholine in the gastrointestinal tract by increasing the release of acetylcholine through the inhibition of the D2 receptors, as well as decreasing the metabolism of this transmitter by inhibiting the acetylcholinesterase enzyme.

Axcan believes that Itopride is unlikely to cause any significant pharmacokinetic drug interactions or cardiac arrhythmias due in part to the lack of significant interaction and metabolism via the P450 CYP 3A4 enzymatic pathway. Furthermore, Itopride does not appear to cause 5HT4 receptor stimulation in the enteric nervous system or in the cardiac atrial sinus. Taken together, this information provides evidence why Itopride is likely to be a safer prokinetic.

Axcan will host a conference call at 10:30 A.M. EST, on September 3, 2003. Accompanying slides will be available on the Company's website. Interested parties may also access the conference call by way of web cast at www.axcan.com. The web cast will be archived for 90 days.

The telephone numbers to access the conference call are (800) 814-4853 (Canada and United States) or (416) 640-4127 (international). A replay of the call will be available until September 10, 2003. The telephone number to access the replay of the call is (416) 640-1917 code: 21016191.

Axcan is a leading specialty pharmaceutical company involved in the field of gastroenterology. Axcan markets a broad line of prescription products sold for the treatment of symptoms in a number of gastrointestinal diseases and disorders such as inflammatory bowel disease, irritable bowel syndrome, cholestatic liver diseases and complications related to cystic fibrosis. Axcan's products are marketed by its own sales force in North America and Europe. Its common shares are listed on the Toronto Stock Exchange under the symbol "AXP" and on the Nasdaq National Market under the symbol "AXCA".

"Safe Harbor" statement under the Private Securities Litigation Reform Act of 1995.

To the extent any statements made in this release contain information that is not historical, these statements are essentially forward looking and are subject to risks and uncertainties, including the difficulty of predicting FDA and EU regulatory approvals, acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, new product development and launch, reliance on key strategic alliances, availability of raw materials, the regulatory environment, fluctuations in operating results and other risks detailed from time to time in the company's filings with the Securities and Exchange Commission and the Canadian Securities Commissions. No assurance can be given that health authorities will provide approval in a timely manner or that expected revenue would be realized.

In particular, the projected revenue level of ITAX after full launch would be reduced significantly if one of FDA or EU regulatory approval were not obtained. If ITAX secures regulatory approval, full commercial launch may require more time than expected especially in territories where Axcan does not have an appropriate sales or distribution network. Axcan declines any obligation to update any forward-looking statement contained herein.

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