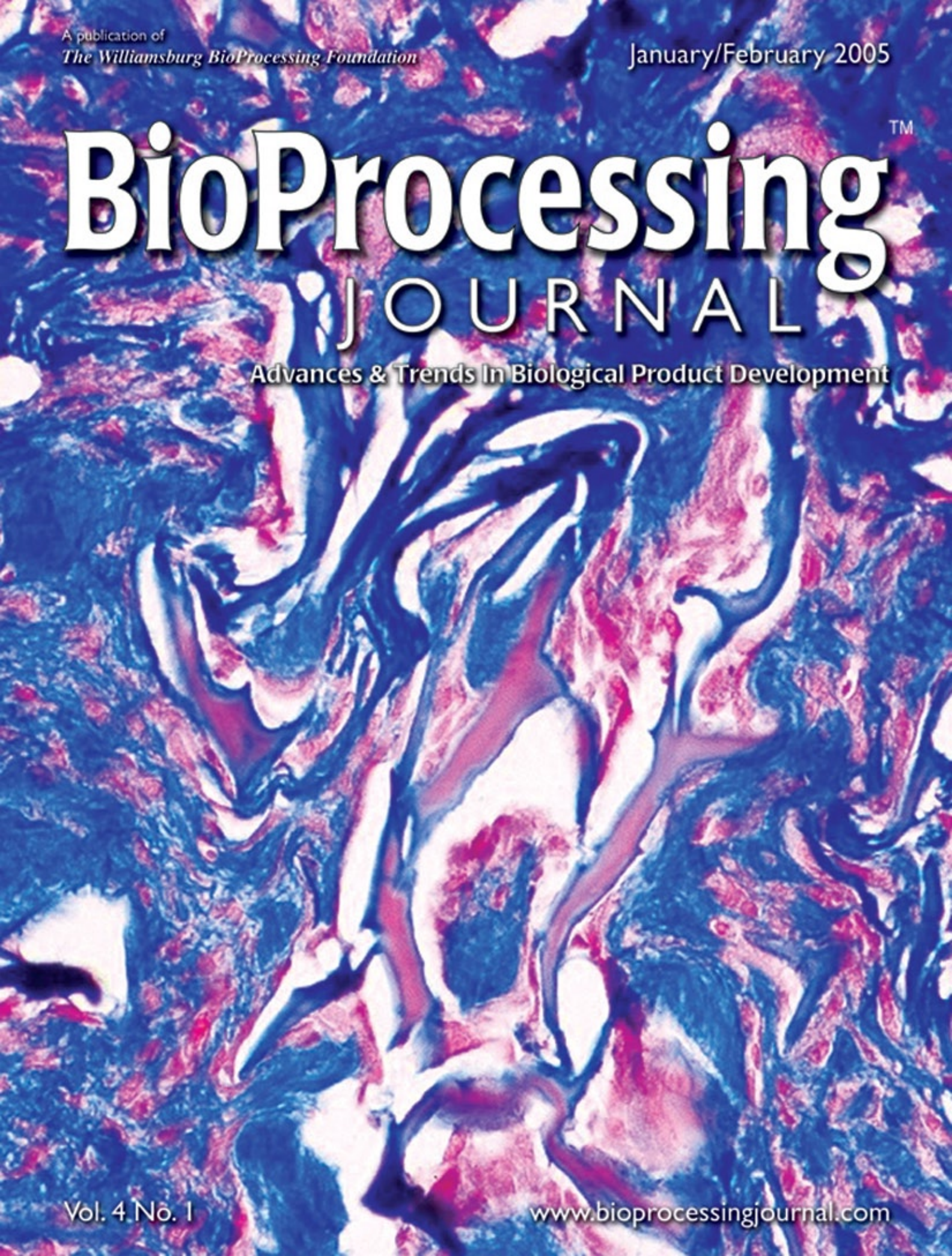
A publication of
*The Williamsburg BioProcessing Foundation*

January/February 2005

# BioProcessing™ JOURNAL

Advances & Trends In Biological Product Development



Vol. 4 No. 1

www.bioprocessingjournal.com

# Canadian Biomanufacturing Launches Strategy to Take Advantage of $15 Billion Biopharmaceutical Pipeline: *$450 Million Investment Recommended Over Seven Years*

Canada's lead in biotechnology, and biotech's rising influence, is providing a "second chance" at establishing a leading role in the global pharmaceutical industry. Half of all the new drugs approved by FDA are biologics. Why does that equate to a "second chance"? Well, with the skills, knowledge and physical manufacturing processes so completely different from the chemical synthesis of drug manufacture, the global pharma industry is "re-tooling" both its people and its facilities. Canada has the opportunity to leverage its leading biotech position to propel the biopharmaceutical industry forward in the changing landscape.

Biotechnology's transformative impact on the global pharma industry landscape relates to the manufacturing challenges, requiring new skill sets and organizational capabilities and competencies. This period of transformation presents a chance for Canada to capitalize on its position of strength in early-stage biopharmaceutical development and build national economic advantage.

### CBI—A National Biopharma Manufacturing Strategy

A $450-million investment is required over the next seven years if Canada is to retain its leading position in the rapidly growing biopharmaceutical industry and capitalize on the $15 billion the country has already invested in the development of 700 new, biologically based drugs, according to the Centre for Biopharmaceutical Manufacturing.

Canada's apparent success at starting companies must be matched by a resolve to grow them — commercialization cannot be a success without sustainability. To achieve this, the challenges of bringing biopharmaceuticals to market must be addressed. Availability of production facilities for clinical trial materials (pilot scale capacity), development of an economically viable and scaleable process and access to highly qualified personnel are the critical challenges facing biopharmaceutical SMEs.

In releasing the Canadian Bioprocessing Initiative, developed over the past two years by more than 70 government, academic, and private-sector stakeholders, the recommendations form a "Made-in-Canada" biopharmaceutical manufacturing strategy. The Initiative integrates university and college activites with capacities in semi-industrial scale public facilities, and industry's research and training needs.

The work identified bottlenecks in Canada's commercialization infrastructure and recommended an investment of $450 million over seven years to build capacity in biomanufacturing, research, and training in major clusters across the country. The recommendations require support from all levels of government and private industry, and participation from the academic community.

The Centre stated that these investments will cement Canada's position at the forefront of a biotechnology revolution that is changing the way new drugs are made.

### Recommendations Having a National Impact

The recommendations provide an initial propelling injection of resources to kick-start the engine for biopharmaceutical manufacturing industry growth across Canada. Almost all of our biopharma firms are in Canada's largest cities in clusters across the country. One of the primary guidelines of the CBI recommendations is to ensure that these regionally-distributed clusters are strengthened and able to support their cluster's growth. Helping biopharma clusters succeed will expand job growth and economic health in these cities.

The investment is projected to yield $1 billion of direct economic impact by 2010 and $2 billion each year thereafter, and reverse the trend of Canada developing a persistent and growing trade deficit in pharmaceuticals.

### Connecting to International Efforts

An essential driver of the Canadian Bioprocessing Initiative vision is to build Canada's global prominence in biopharmaceutical manufacturing. Canada already has the second highest number of biotech firms (most of which are in Human Health) and ranks fifth worldwide in terms of

biopharmaceutical inventions. Canada's early biopharma leadership position underscores the importance of integrating with international efforts, particularly the growing activities related to modernizing regulatory processes and shortening time to market.

To connect with these international efforts, the CBI vision includes a plan to collaborate with other global biomanufacturing clusters to establish a globally-recognized Common Body of Knowledge for training in the biopharmaceutical manufacturing industry; to share curriculum development, thereby creating international training standards; and to consider the opportunity to establish consistent certifications. With the formation of a Centre for Biopharmaceutical Manufacturing, the CBI recommendations also include collaboration opportunities in biopharmaceutical manufacturing research and regulatory foresighting projects.

**And, If We Do Nothing …**

The status quo sees Canada productive in biopharmaceutical discovery, launching small companies to start the development process and then selling out at low value to international players. Canada effectively acts as a publicly-subsidized intellectual property supply chain whose real benefits will then be realized elsewhere. Time is of the essence since some of our critical challenges will require many years of sustained effort to correct.

Doing nothing is not an option. With more than $15 billion invested in the past ten years, commercialization of our 700 biopharma drugs within Canada is a "must."

In helping our biopharma firms to develop Canada's 700 biopharmaceuticals successfully, Canada will support the national health care system, consolidate its international biotech leadership, and enable the Canadian public to capture the benefits of its "innovation investments." That's a fix that will provide benefits to several generations.

A summary of the Canadian Bioprocessing Initiative recommendations and support materials are available at *www.olsc.ca*.

*- By Ken Lawless, President and CEO of the Ottawa Life Sciences Council and Chair of the CBI Founders Committee*