

SECURITIES AND EXCHANGE COMMISSION

FORM ARS

Annual report to security holders

Filing Date: **2005-05-02** | Period of Report: **2004-12-31**
SEC Accession No. [999999997-05-022472](#)

([HTML Version](#) on [secdatabase.com](#))

FILER

IMMUNICON CORP

CIK: **1083132** | IRS No.: **000000000**
Type: **ARS** | Act: **34** | File No.: **000-50677** | Film No.: **05054050**
SIC: **3826** Laboratory analytical instruments

Business Address
3401 MASONS MILL RD
SUITE 100
HUNTINGTON VALLEY PA
19006
215 830 0777 X121

ARIS
P.E. 12/31/04

RECEIVED
MAY 02 2005
ICB

05054050



IMMUNICON®

Cellular Information for Better Healthcare

PROCESSED
MAY 06 2005
THOMSON
FINANCIAL

→ → → COMPANY OVERVIEW

Immunicon is developing and commercializing diagnostic and research products for rare cell analysis, with an initial focus on cancer. Reagent kits incorporating Immunicon proprietary technology are used with our instrument systems to capture, count and characterize cells and cellular material associated with circulating tumor cells in cancer patients or circulating endothelial cells, which are elevated in a variety of diseases. We believe our technology may be applied to other fields of medicine beyond cancer, including cardiovascular and inflammatory diseases, as well as to drug development and life science research.

Commercial Highlights

- ☛ Launched CellSearch™ Circulating Tumor Cell Kit, CellSpotter® Analyzer and CellTracks® AutoPrep System for *in vitro* diagnostic use.
- ☛ Entered into a contract with Quest Diagnostics in the USA, providing nationwide availability of the CellSearch™ Circulating Tumor Cell Test.
- ☛ Placed 12 systems throughout the United States, including major cancer centers and opinion leader accounts.
- ☛ Placed 4 systems in Europe and 2 systems in Japan, including SRL, the largest reference laboratory in Japan.

Scientific Highlights

- ☛ Published pivotal trial results in the New England Journal of Medicine in a paper entitled, "Circulating Tumor Cells Can Predict Progression-Free and Overall Survival in Patients with Metastatic Breast Cancer."
- ☛ Initiated pivotal clinical trials in prostate cancer and colorectal cancer.
- ☛ Completed development of and launched the CellTracks® Endothelial Cell Kit.

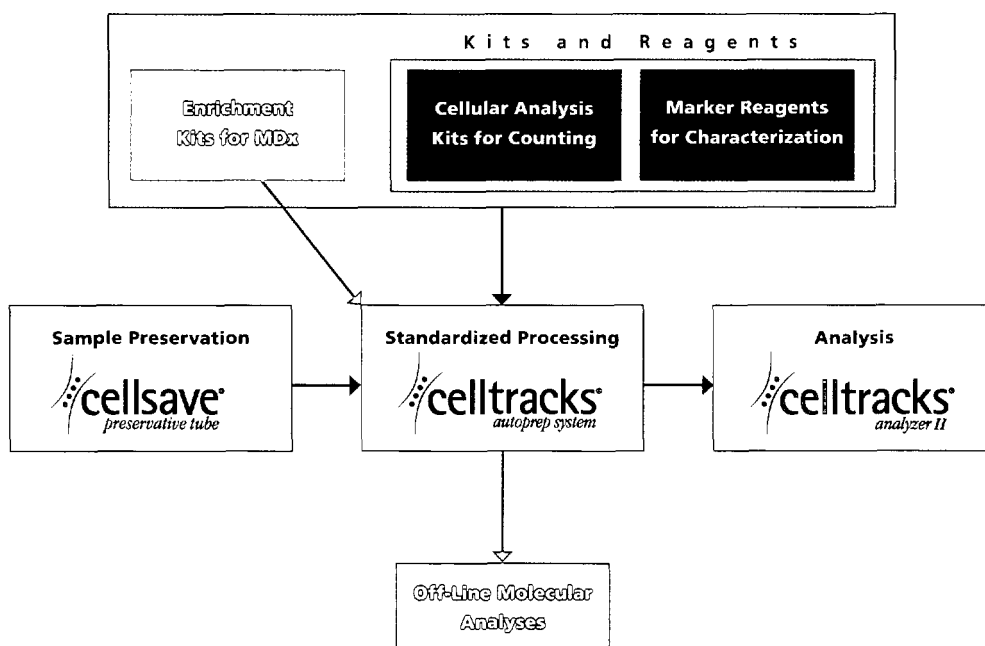
Financial Highlights

- ☛ Completed Initial Public Offering with net proceeds of approximately \$50 million.
- ☛ Obtained \$17 million of additional credit from Silicon Valley Bank and GE Capital.
- ☛ Product revenue for 2004 of \$1,127,000 of which \$944,000 was earned in the fourth quarter.

→ → → **FINANCIAL HIGHLIGHTS**

| As of December 31, | 2004 | 2003 | 2002 |
|---|----------|----------|----------|
| <i>Financial Position (in thousands):</i> | | | |
| Cash, cash equivalents and short-term investments | \$53,103 | \$30,601 | \$21,540 |
| Working capital | 47,041 | 23,836 | 16,157 |
| Total assets | 61,064 | 35,735 | 24,676 |
| Long-term obligations, less current portion | 2,587 | 3,792 | 2,336 |
| Total stockholders' equity | 48,838 | 24,666 | 16,610 |
| Product revenue | \$ 1,127 | \$ — | \$ — |
| Total revenue | 1,565 | 2,974 | 932 |

→ → → **PRODUCT PORTFOLIO**



→ → → **CHAIRMAN'S LETTER**

2004

was a year of substantial achievement for Immunicon Corporation. We established and completed a number of major objectives for the year, including:

- obtaining the necessary regulatory clearances and certifications for our first cancer diagnostic products;
- beginning commercialization through our relationship with Veridex, LLC, a Johnson & Johnson company;
- making initial system placements with key customers and opinion leaders in major markets;
- conducting additional research studies and regulatory clinical trials in cancer;
- completing development of a new research kit with potential applications in other fields of medicine, such as cardiovascular diseases;
- building infrastructure in manufacturing and other departments to support commercialization; and
- completing strategic financings, including our initial public offering, to fund these objectives.

On behalf of the Board of Directors, I congratulate and thank our employees, collaborators, advisors and consultants who made all of this happen and more.

Significant Scientific Accomplishments

During my business career, I have participated in many debates about whether a company should be market- or technology-driven. The simple answer is, of course, that great companies across most industries are both. Nevertheless, given our stage of development and the nature of our products, superb science and excellent technology are essential.

*In 2004, we completed the development of our first diagnostic products. The initial clinical indication is in the management of patients with metastatic breast cancer. The results of the prospective study sponsored by Immunicon supporting this indication were presented in June at the annual meeting of the American Society of Clinical Oncology and published in the *New England Journal of Medicine* in August 2004. The data showed that the number of circulating tumor cells, or CTCs, in a sample of blood taken from women with metastatic breast cancer predicts progression-free and overall survival. This significant finding received extensive media coverage including separate pieces in the August 19 issue of *The Wall Street Journal* and the August 18 ABC broadcast of *World News Tonight*.*

In December, we presented three abstracts at the San Antonio Breast Cancer Symposium including data showing the potential advantages of our technology over traditional radiographic imaging techniques, such as computed tomography, or CT, scans.

We believe our technology has application beyond breast cancer. In fact, it may be useful in virtually all carcinomas, which constitute the majority of all forms of cancer. For example, at the American Association for Cancer Research meeting in 2004, we presented data from a research study that assessed the possible relationship between CTCs and survival in prostate cancer patients. Patients with 5 or more CTCs in a test tube-size sample of their blood had a statistically significant decreased median survival versus those with fewer than 5 CTCs. This paralleled the results we obtained in breast cancer patients. Additionally, CTCs appear to be a better predictor of patient outcomes than prostate specific antigen, or PSA, the most widely used blood tumor marker for prostate cancer.

In the fourth quarter of 2004, we launched a research product for the detection and analysis of circulating endothelial cells, or CECs, in blood. Endothelial cells line the blood vessels of the body and are implicated in many diseases, most notably cardiovascular disease, but they appear to play an important role in the growth of tumors as well. The CellTracks® Endothelial Cell Kit, as this product is called, works with existing Immunicon platform technologies and is a useful tool for medical researchers trying to understand the role of these cells in many diseases.

Commercialization Progress

Unlike academic institutions, our job is not only to make advances in science and technology, but also to create products that can be used by scientists and physicians to understand the diseases that afflict human beings and, ultimately, diagnose and guide treatment for those diseases. In 2004, we began the transition from development stage to a company actively manufacturing and marketing products that can have a real impact on practice of medicine and life science research.

Early in 2004, we were notified by Veridex that they had received clearance by the U.S. Food and Drug Administration for the CellSearch™ Circulating Tumor Cell Kit, which incorporates certain Immunicon reagents and other technologies, for use in metastatic breast cancer. This kit represents our first FDA cleared product in human diagnostics and is used in conjunction with Immunicon platform technologies—the CellSave® Preservative Tube for blood sample collection and preservation, the CellTracks® AutoPrep System for blood sample preparation and the CellSpotter® Analyzer for cell analysis.

Our goal is to be the leader in the development and commercialization of specialized cellular analysis products that deliver high clinical impact for use in human diagnostics, life science research and pharmaceutical development.

Following completion of certain additional regulatory milestones, manufacturing validation and other pre-launch activities, we and Veridex announced the release for sale of the CellSearch® Circulating Tumor Cell Kit for *in vitro* diagnostic use in August 2004. During the last four months of the year, we completed many important commercialization goals including initial system shipments in the U.S., Europe and Japan. We and Veridex signed agreements with Quest Diagnostics, the largest reference laboratory company in the U.S., and made an initial placement at SRL, Japan's largest reference laboratory company. At the end of the year, we had shipped cumulatively a total of 18 complete systems including 12 in the U.S., 4 in Europe and 2 in Japan. By type of customer, we had shipped 3 systems to reference laboratories, 7 to hospital/medical research laboratories, 1 to a pharmaceutical company and 7 systems to various Johnson & Johnson units, including Veridex, for training, quality control, and demonstration purposes.

Financing Activity

Obviously, because of the early stage of commercialization, traditional financial measures for 2004 do not yet reflect our substantial progress. Nevertheless, we began generating revenue immediately following release for sale for *in vitro* diagnostic use of our initial products and we recorded a gross profit on product sales in the fourth quarter. Revenue for 2004 was \$1,565,000, including \$1,127,000 in product sales and \$438,000 in revenue associated with milestone payments made principally by Veridex to Immunicon. Our net loss after taxes was \$27,933,000, which represents a loss per share on a fully diluted basis of \$1.70.

Of even greater importance is the fact that we completed major financing activities during 2004 including an initial public offering of our common stock which, together with the exercise of the underwriters' over allotment option, added approximately \$50 million in net proceeds to Immunicon's balance sheet. We also completed credit facilities with two major financial institutions, Silicon Valley Bank and GE Capital, totaling approximately \$17 million. We closed the year with cash, cash equivalents and short-term investments on our balance sheet of \$53,632,000.

Two thousand and five has already been a very busy year. Our principal goal is to manufacture and support our cancer diagnostic products through our agreement with Veridex. We are conducting important clinical trials in colorectal and prostate cancer that we believe will lead to regulatory submissions in 2006 in these major fields of cancer. Other clinical research studies in cancer are also underway. We recently completed the launch of a new analysis platform, the CellTracks[®] Analyzer II, which provides additional functionality and important customer benefits over the CellSpotter[®] Analyzer. We are also working on products in the field of nucleic acid analysis (often referred to as molecular diagnostics) that use our sample preparation and enrichment technology and are intended to complement our cell analysis products.

We are also developing a research kit that can enumerate tumor cells in the bone marrow of cancer patients. Published clinical data suggest that the presence of tumor cells in bone marrow at the time of diagnosis has considerable prognostic significance, but there is currently no automated, highly reproducible method for reliable analysis of bone marrow aspirates drawn from patients. We believe our technology can provide such a method to further scientific research in this field.

Finally, we intend to invest in fields outside of cancer, such as cardiovascular disease, through our circulating endothelial cell kit. We hope to identify a specific clinical indication for this kit within the next 12 months.

Personally, I am very pleased with Immunicon's progress and the important contributions we have already made to the practice of medicine and biomedical research. We believe our ultimate customer is the patient, and we strive to deliver products that will add considerable clinical value and make a real difference in the diagnosis and treatment of serious illnesses such as cancer. If we achieve this and manage our operations effectively, we believe we will reward our shareholders with attractive returns commensurate with risk. We look forward to keeping you updated on our progress and to an exciting 2005 and beyond.

Sincerely,



Edward L. Erickson

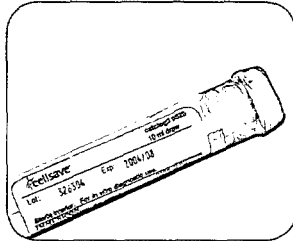
*Chairman, President and Chief Executive Officer
Immunicon Corporation*



Diagnostic Products with High Potential Clinical Impact

Immunicon has developed a portfolio of products to capture, count and characterize rare cells and cellular material from blood and other types of patient samples. Our initial products are in the cancer field and are based on analysis of circulating tumor cells (CTCs). The scientific challenge was to develop a method to capture literally one CTC from a background of billions of cells in a tube of blood. Immunicon met this challenge using a comprehensive systems approach.

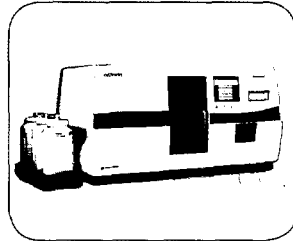
Blood Collection & Preservation



cellsave
preservative tube

The CellSave® Preservative Tube is used for the collection and preservation of circulating tumor cells.

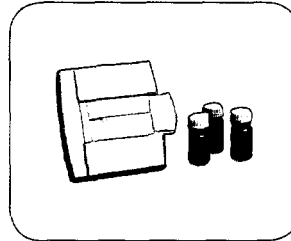
Standardized Sample Processing



celltracks
autoprep system

The CellTracks® AutoPrep System is an automated sample preparation system used to capture and stain rare cells. Standardization is critical for optimal recovery and reproducible results.

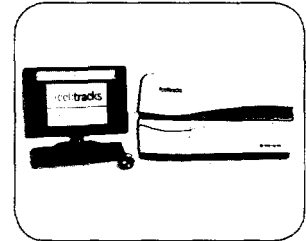
Kits and Marker Reagents



**Kits and Marker
Reagents**

Kits and Marker Reagents are available for isolation and analysis of circulating tumor cells (CTCs) and circulating endothelial cells (CECs).

Analysis



celltracks
analyzer II

The CellTracks® Analyzer II is used to count and characterize rare cells based on their fluorescence signals.

Products for Cell Analysis and Molecular Research

With instrument development programs completed and fundamental reagent formulations and assay parameters developed for the CellSearch™ Circulating Tumor Cell Kit, development of future applications for capturing and characterizing new rare cell types will build on existing expertise and technology and represent comparatively modest incremental investment. Immunicon offers cell analysis and enrichment kits for CTCs and CECs. Examples of current products and some under development are listed below.

Cell Analysis Kits

Cellular analysis kits contain all of the reagents and supplies to immunomagnetically capture rare cells and fluorescently stain them for analysis. Marker reagents are processed simultaneously with the kit to further characterize the cells.

- CellSearch™ Circulating Tumor Cell Kit
 - CTC Marker Reagents: HER-2/neu, EGFR, MUC-1
- CellTracks® Endothelial Cell Kit
 - CEC Marker Reagents: Endoglin, VEGFr*

Enrichment Kits

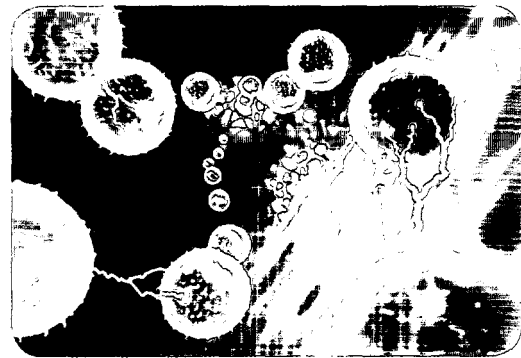
Cellular enrichment kits are processed using the CellTracks® AutoPrep System. The unwanted white blood cells are removed from the samples, leaving the target cells. The researcher can process these samples off-line using a variety of molecular diagnostic tools.

- CellSearch™ Profile Kit
- CellCapture™ CEC Kit*

*Under development

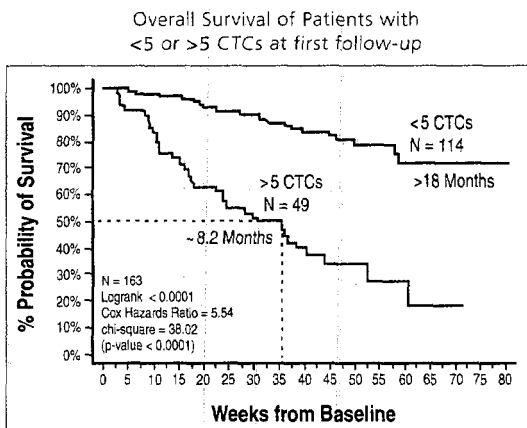
About Circulating Tumor Cells

Carcinomas are the most common types of cancer and derive from the epithelium. Metastasis occurs when tumor cells detach from primary mass and travel to other tissues in the body. Scientists have long suspected that circulating tumor cells could be a valuable biomarker for cancer management. For the first time, Immunicon has assembled a system of products that enable reproducible isolation and analysis of these extremely rare cells.



B cells (pink) signaling T cells (blue) to attack a tumor (center).

In 2004, we completed a multi-center prospective, longitudinal clinical trial to determine whether the number of CTCs correlates with disease progression in patients with metastatic breast cancer. The conclusions reached in this trial support a fundamental change in the way metastatic breast cancer patients are treated:



The presence of CTCs is associated with decreased progression-free survival and decreased overall survival in patients treated for metastatic breast cancer.

New England Journal of Medicine Volume 351:781-791 (August 19, 2004)
 © 2005 Massachusetts Medical Society. All rights reserved.

Data from this pivotal study were the basis for the FDA submission for the CellSearch™ CTC Kit for *in vitro* diagnostic use (IVD). Data from this study also supported an oral presentation that was given at the annual meeting of the American Society of Clinical Oncology (ASCO) in May 2004, several posters that were presented at ASCO and at the San Antonio Breast Cancer Symposium in December 2004, and a paper that was published in the *New England Journal of Medicine* in August 2004.

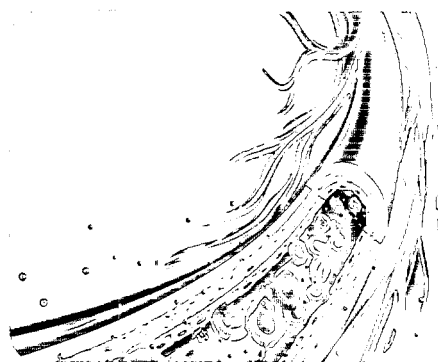
What Do CTCs Mean for Doctors and Patients?

The CTC count may help oncologists to make therapy decisions with their metastatic breast cancer patients. For example, a CTC count above the threshold might help the physician and patient to decide to be aggressive with therapy or elect to change therapy to one that has the potential to be more effective. In the future, molecular or cellular markers on the surface of the tumor cell may help to choose the most appropriate therapy, however studies must be conducted to prove this.



About Circulating Endothelial Cells

Endothelial cells form the inner wall of blood vessels and can be shed into the blood stream during formation, damage or destruction of blood vessels. Analysis of these cells may be useful to elucidate biological mechanisms of various diseases including cancer, cardiovascular and inflammatory diseases. The CellTracks® Endothelial Cell Kit is available for sale for research use only (RUO).

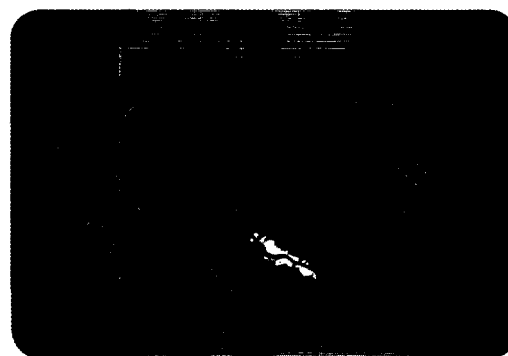


The Potential Role of CECs in Cancer

Endothelial Cells are involved in neoangiogenesis, or the formation of new blood vessels. The recent introduction of anti-angiogenesis drugs are designed to disrupt the neoangiogenesis that tumors need to grow. Other cancer therapies may lead to vascular damage and measurement of CEC may provide an early indication of such toxicity. The CellTracks® Endothelial Cell Kit may have utility in monitoring the efficacy and toxicities of anti-angiogenesis and other anti-cancer drugs.

The Potential Role of CECs in Cardiovascular Disease

In cardiovascular disease, circulating endothelial cells are markers of vascular damage and are implicated in ischemic heart disease. Published data suggests that elevated CECs are an indicator of an emerging acute myocardial infarction (AMI), or heart attack, and are predictive for a major coronary event following a confirmed AMI. Our standardized technology may lead to a valuable clinical test.



↑ CIRCULATING ENDOTHELIAL CELLS



Commercialization

Veridex, LLC, a Johnson & Johnson company, markets our cell analysis products in the cancer market. In August, we and Veridex announced the IVD launch of the CellTracks® AutoPrep System, the CellSearch™ Circulating Tumor Cell Kit and the CellSpotter® Analyzer. We recently launched our next generation analyzer to replace the CellSpotter® Analyzer, the CellTracks® Analyzer II, which provides additional functionality through improved user interface and data management features that are important to customers.

We have installed systems at some of the most prestigious cancer centers in the U.S. and Europe as well as at Quest Diagnostics and SRL, the two largest reference laboratory companies in the U.S. and Japan, respectively. The reference labs not only provide nationwide access of the test, but their sales teams also augment the communication efforts to make oncologists aware of the benefits of the CellSearch™ Circulating Tumor Cell test.



We will continue to support commercialization efforts for our cancer products by developing additional indications across multiple cancers, across the disease continuum and by expanding our product portfolio. Pivotal clinical trials are underway in prostate and colorectal cancer, and several research trials are ongoing. We are also testing a new kit to isolate tumor cells from bone marrow. The standardization of bone marrow processing by the CellTracks® AutoPrep System may prove to be a valuable diagnostic tool.

Product Portfolio Expansion: Molecular Analysis of Rare Cells

Molecular analysis of rare cells presents special challenges because of the overwhelming background of other cells in the sample, leukocytes in particular. We believe that significant scientific advances can be achieved using our new tools for rare cell enrichment, namely the CellTracks® AutoPrep System along with the CellSearch™ Profile Kit for CTCs or the CellCapture™ CEC Kit for CECs.



Forward-Looking Statements

The information, disclosure and analysis contained in this report include "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements provide our current expectations or forecasts of future events, and are often preceded by words such as "hope," "may," "believe," "anticipate," "plan," "expect," "intend," "assume," "will" and similar expressions. We caution investors not to place undue reliance on the forward-looking statements contained in this report. Forward-looking statements included in this report relate to such matters as financing and capital needs and resources, product development, our relationship with Veridex, research, development and sales based milestones and related payments from Veridex, expansion of research and development activities and increases in research and development costs, instrument system and platform improvement activities and costs, expansion of clinical trials and related costs, use of IPO net proceeds and other funds, and other statements regarding matters that are not historical facts. Forward-looking statements speak only as of the date of this report, reflect management's current expectations and involve certain factors, such as risks and uncertainties, which may cause actual results to be far different from those suggested by our forward-looking statements. These factors include, but are not limited to, risks associated with our dependence on Veridex; our capital and financing needs; research and development and clinical trial expenditures; commercialization of our product candidates; our ability to use licensed products and to obtain new licenses from third parties; our ability to manage growth; obtaining necessary regulatory approvals; reliance on third party manufacturers and suppliers; reimbursement by third party payors to our customers for our products; compliance with applicable manufacturing standards; the ability to earn license and milestone payments under our agreement with Veridex; retaining key management or scientific personnel; delays in the development of new products or to planned improvements to our products; effectiveness of our products compared to competitors' products; protection of our intellectual property and other proprietary rights; conflicts with the intellectual property of third parties; product liability lawsuits that may be brought against us; labor, contract or technical difficulties; competitive pressures in our industry; other risks and uncertainties discussed elsewhere in this report; and other risks and uncertainties, as may be detailed from time to time in our public announcements and SEC filings.

We do not intend to update any of these factors or to publicly announce the results of any revisions to any of these forward-looking statements other than as required under the federal securities laws.

CellSpotter®, CellTracks®, CellSave®, and MagNest® are registered trademarks of Immunivest Corporation. CellSearch™ is a trademark of Veridex, LLC.

The products and/or associated components thereof, and procedures and instrument systems described herein, are protected by United States patents and corresponding international patents and pending patent applications, owned by Immunivest Corporation, a subsidiary of Immunicon Corporation, and include one or more of the following: US Patent Numbers 5,186,827; 5,512,332; 5,466,574; 5,597,531; 5,698,271; 5,985,153; 6,120,856; 6,136,182; 6,365,362; 6,551,843; 6,620,627; 6,623,982; 6,645,731; and 6,861,259.

Equal Opportunity Statement

Immunicon Corporation is an Equal Opportunity employer and does not discriminate against any individual on the basis of sex, gender, race, color national origin, religion, ethnicity, sexual orientation or other characteristic protected by law.

EXECUTIVE MANAGEMENT



Edward L. Erickson
*Chairman of the Board,
President and Chief
Executive Officer (CEO)*



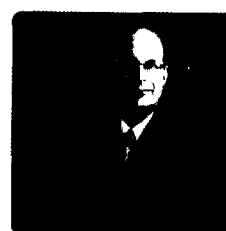
Byron D. Hewett
*Chief Operating
Officer (COO)*



Leon W.M.M.
Terstappen, M.D., Ph.D.
*Sr. VP, R&D and Chief
Scientific Officer*



James G. Murphy, CPA
*Sr. VP, Finance &
Administration and Chief
Financial Officer (CFO)*



James L. Wilcox, JD
*VP, Chief Counsel
and Secretary*

Mark Connelly, Ph.D.
VP, Reagent Development

Teresa Lipcsey
VP and Controller

Michael T. Kagan
VP, Operations

John Verrant
VP, Engineering

Carrie Mulherin
VP, Marketing

Peter Scott
*VP, Quality Assurance
and Regulatory Affairs*

CORPORATE INFORMATION

Corporate Headquarters

Immunicon Corporation
3401 Masons Mill Road, Suite 100
Huntingdon Valley, PA 19006

Board of Directors

Edward L. Erickson
Chairman of the Board, President and CEO

Jonathan Cool
*Managing General Partner,
Foundation Medical Partners*

J. William Freytag, Ph.D.
CEO, Myogen, Inc.

Brian Geiger, CMA
The Hermes Group

Zola P. Horovitz, Ph.D.
Independent Consultant

Allen J. Lauer
Chairman of the Board, Varian, Inc.

Seth A. Rudnick, M.D.
General Partner, Canaan Partners

Elizabeth E. Tallett
Principal, Hunter Partners, LLC

Auditors

Deloitte & Touche

SEC Counsel

Morgan, Lewis & Bockius, LLP

Investor Relations

The Ruth Group

Corporate Governance

The following documents are available on the Immunicon web site:
Code of Conduct
Audit and Compliance Committee Charter
Compensation Committee Charter
Nominating and Governance Committee Charter

Registrar and Transfer Agent

The transfer agent is responsible for, among other things, handling shareholder questions regarding lost stock certificates, address changes including duplicate mailings and changes in ownership or name in which shares are held. These requests may be directed to the following address:

StockTrans
44 West Lancaster Avenue
Ardmore, PA 19003
610-649-7300

Annual Shareholders' Meeting

The annual shareholders' meeting will be held at 10 AM on Wednesday, June 15, 2005 at Immunicon Corporation, 1800 Byberry Road, Suite 800, Huntingdon Valley, PA 19006.

Form 10-K

A copy of the Immunicon Annual Report on Form 10-K for the fiscal year ended December 31, 2004 is included with this Annual Report and is incorporated by reference.



IMMUNICON®

Cellular Information for Better Healthcare

3401 Masons Mill Road, Suite 100
Huntingdon Valley, PA 19006

phone: 215.830.0777

fax: 215.914.1117

web: www.immunicon.com