

## Novel, Widespread Cancer Marker to Improve Cancer Diagnostics

### Snapshot

April 11, 2008

BioCurex, Inc. ("BioCurex" or "the Company") is a biotechnology company developing products for cancer diagnosis, imaging, and therapy that target a global oncology market forecast to reach over \$50 billion by 2009. The Company uses a novel, patented technology based on the RECAF™ cancer marker discovered by Dr. Ricardo Moro-Vidal, BioCurex's chief executive officer (CEO), president, and founder. RECAF™ is a molecule found on **malignant**<sup>†</sup> cells but absent from most normal or **benign** cells. BioCurex believes that the detection of this molecule in tissue or **serum** samples is the foundation for new cancer diagnostic tests and imaging techniques. The RECAF™ marker has been found on every cancer tissue that BioCurex has studied to date, including on many common, severe cancers: breast, lung, gastric, prostate, and leukemia. This characteristic indicates that RECAF™ is capable of detecting more than one type of cancer, which is a limitation of many currently available cancer markers. The Company's RECAF™ technology is reported to have high levels of clinical **sensitivity** and **specificity** (measures of cancer marker accuracy), successfully detecting over 90% of cancer in blood and tissue samples. A serum-based **assay** using RECAF™ recently identified twice as many prostate cancers as the current standard for prostate cancer detection, the **prostate-specific antigen (PSA)** test. In early 2006, a RECAF™-based test also detected 90% to 93% of **Stage I** and **Stage II** (early stage) breast cancer samples, without any **false positives**. This data supports BioCurex's aim of reducing human suffering through the early detection of cancer or cancer recurrence after treatment. Moreover, due to its ability to differentiate between cancerous and normal cells, RECAF™ technology may facilitate the administration of targeted therapeutics that attack cancer cells but do not damage healthy tissue.

### Recent Financial Data

Ticker (Exchange)	BOCX (OTC.BB)
Recent Price (04/10/08)	\$0.55
52-week Range	\$0.45 - \$0.88
Shares Outstanding*	42.7 million
Market Capitalization	\$23.5 million
Average 3-month Volume	39,800
Insider Owners +5%	16.5%
Institutional Owners	<1%
EPS (Yr. ended 12/31/07)	(\$0.08)
Employees**	15



\*As at March 31, 2008

\*\*Includes Pacific BioSciences Research Centre

### Key Points

- BioCurex maintains semi-exclusive license agreements with Abbott Laboratories (ABT-NYSE) and Inverness Medical Innovations, Inc. (IMA-AMEX) to commercialize products using RECAF™ technology. These licenses benefit BioCurex through the payment of milestone fees and royalties, as well as by giving the Company access to independent diagnostic expertise and validation of RECAF™.
- The Company has developed two diagnostic kits that identify cancerous tissue versus normal or benign tissue by targeting RECAF™: (1) Histo-RECAF™ (classified in the U.S. as a **Class I Medical Device**); and (2) Cryo-RECAF™. The Company is also finalizing Serum-RECAF™, an assay to detect RECAF™ levels in a patient's blood. Other product areas include tumor imaging and the development of a Rapid Test for initial point-of-care cancer detection.
- As of 2005, the global laboratory diagnostic test market exceeded \$25 billion annually, with molecular diagnostic testing growing at roughly 20% per year and estimated to reach over \$5 billion by 2009. In the diagnostics market, cancer testing, dominated by serum-based cancer markers, recently exceeded \$2 billion and is expected to experience some of the greatest growth over the next three to five years.
- BioCurex's management team has brought a research technology toward commercialization in a relatively short timeframe while also negotiating beneficial license agreements. The Company's Scientific Advisory Board (SAB) includes leaders in the global cancer marker field.
- At March 1, 2008, BioCurex had cash of approximately \$1.4 million.

<sup>†</sup>**BOLD WORDS ARE REFERENCED IN THE GLOSSARY ON PAGES 49-51.**

**Table of Contents**

Snapshot ..... 1

Recent Financial Data ..... 1

Key Points ..... 1

Executive Overview ..... 3

Growth Strategy..... 7

Intellectual Property..... 8

Partnerships ..... 9

Company Leadership ..... 11

Core Story ..... 14

    Cancer..... 14

    Cancer Markers ..... 16

    Market Dynamics ..... 18

    BioCurex's RECAF™ Technology ..... 21

    Product Pipeline ..... 28

Competition ..... 36

Potential Milestones ..... 38

Key Points to Consider ..... 39

Historical Financial Results ..... 41

Risks ..... 44

Recent Events ..... 47

Glossary ..... 49

## Executive Overview

BioCurex, Inc. (“BioCurex” or “the Company”) is a biotechnology company developing products based on a patented and proprietary technology in the areas of cancer diagnosis, imaging, and therapy. The Company uses a novel cancer marker called RECAF™ that is present on malignant cells but absent from most normal or benign cells. The RECAF™ marker has been found within every cancer tissue that BioCurex has studied to date, including many common, severe cancers such as breast, lung, gastric, prostate, and leukemia. Moreover, RECAF™ is reported to have high levels of clinical sensitivity and specificity (measures of cancer marker accuracy) for these cancers, successfully detecting over 90% of cancer in blood and tissue samples.

With RECAF™ technology, BioCurex seeks to reduce human suffering through the early detection of cancer or a cancer recurrence after treatment. The Company is working toward this goal by developing the RECAF™ cancer marker as the foundation for new cancer diagnostics tests and imaging techniques. In addition, due to its ability to differentiate between cancer and normal cells, RECAF™ technology may facilitate the administration of targeted therapeutics that do not damage healthy tissue.

### Cancer

The American Cancer Society (ACS) has estimated that there were over 12.3 million new cancer diagnoses worldwide and roughly 7.6 million deaths due to the disease during 2007 (Source: *Global Cancer Facts & Figures 2007*). By 2020, there are projected to be 16 million new cancer diagnoses annually, with 10 million related deaths (Source: the World Health Organization [WHO]). As the number of people developing cancer continues to increase, the demand for improved cancer products will likely also continue to expand, on a large scale. Two oncology areas that still have significant unmet need are the early detection of disease and targeted treatment options.

Cancer that is detected early, before it spreads to surrounding tissue, has the best prognosis. Surgical removal of a tumor is less effective once tumor cells have invaded additional locations, many of which are undetectable. While advances in early detection have improved the prognosis of many cancers thus far, lung and **bronchus**, prostate, and breast cancers are still among the most commonly diagnosed and the most fatal cancers. For example, if breast cancer is caught and treated at its earliest stages, patients have five-year survival rates between 81% and 100%. However, if the cancer progresses to **Stage IV** before it is diagnosed, a patient’s likelihood of survival at five years is only 20% (Source: MedlinePlus). RECAF™ technology may offer an improved, earlier diagnostic solution for patients with these deadly conditions.

In addition, researchers and organizations are focused on the development of molecularly targeted therapies that act primarily on the tumor and its associated tissue, rather than on all cells non-discriminately. BioCurex believes that its RECAF™ technology could enhance therapies by not attacking healthy cells, as it distinguishes between a cancer cell presenting the RECAF™ cancer marker and a healthy cell lacking the marker, thereby enabling a targeted treatment.

### Cancer Markers

A cancer marker is any substance that is expressed on cancer cells or created by the body’s immune system in response to cancer cells. These substances appear in tissue, blood, or urine, and the detection of a known cancer marker in higher-than-normal amounts in the body may signify the presence of cancer. Further identifying which specific cells express the marker and which do not enables the distinction between cancerous cells and healthy cells. Once a tumor has been located and associated with a marker, that marker can be used to monitor treatment and possible recurrence, indicate the likelihood of progression, and assist with a prognosis. Depending upon the patient and the cancer, post-treatment follow-up tests for a particular marker may continue for life, as frequently as every two to three months.

BioCurex views validating new cancer markers as one of the most important goals in cancer research, because, as the Company estimates, very few effective new markers have been discovered and put into clinical use in the past 40 years.

Current cancer markers are not used as the sole method to diagnose cancer due to the following limitations that prevent tests for these markers from functioning as wholly effective screens for many cancers: (1) Currently available markers are not 100% specific to a particular type of cancer, indicating that other, non-cancerous conditions can also cause an increase in certain cancer markers—which results in a false positive; (2) Many markers are restricted to only certain cancers; (3) The same marker is not always expressed on every patient’s cancer, even if it is related to the same organ, indicating that the marker does not have a high sensitivity for detecting a particular cancer; (4) The detection of “normal” levels of a cancer marker can occasionally be ambiguous; and (5) At present, there is a perceived lack of effective cancer markers for many cancer types.

For example, elevated levels of the prostate-specific antigen (PSA), a marker for prostate cancer, do not always signal a malignant condition. The National Cancer Institute (NCI) reports that only 25% to 30% of men who express higher-than-normal amounts of PSA in the blood actually have prostate cancer, as benign prostate conditions, such as inflammation, can also cause an increase in PSA levels. BioCurex believes that the ideal cancer marker, yet to be commercialized, would be a molecule that is expressed on all cancer cells regardless of type, but not in healthy or benign tumor cells.

### **The RECAF™ Cancer Marker**

The RECAF™ cancer marker is found to be present on cancer cells, but not on most healthy or benign tumor cells. As a result, RECAF™ is less likely to return a false positive test result. False positives cause patients to undergo unnecessary and potentially costly **biopsy** procedures.

RECAF™ is a receptor for another widely used cancer marker, **alpha-fetoprotein (AFP)**, which was first described in 1963 by a member of BioCurex’s Scientific Advisory Board (SAB), Dr. Garri Abelev. Both AFP and RECAF™ first emerge in the fetus, but disappear by birth. After birth, RECAF™ is only known to exist in a cancerous state, where tissues re-express the ability to take up AFP via the RECAF™ receptor.

Yet, these two markers are not the same: AFP is primarily used to detect only liver and testicular cancer, which have a relatively low incidence in many countries, whereas RECAF™ may become a more widespread cancer marker, in part due to its ability to detect many types of cancers. In addition, AFP’s sensitivity as a marker for liver cancers is only approximately 60%, meaning that roughly 40% of patients with liver cancer do not have an elevated AFP and would not be detected with an AFP test (Source: MedicineNet, Inc.). Alternatively, studies with RECAF™ have detected over 90% of early stage breast cancers and 75% of early stage prostate cancers.

BioCurex anticipates that RECAF™ has potential as a new cancer marker for the following reasons:

- Current serum markers are deficient in terms of sensitivity and specificity, creating a need for enhanced markers;
- Current markers for breast and lung cancers (among the most fatal cancers) are not especially useful for diagnostics—areas that RECAF™ seeks to address;
- Routine RECAF™ testing may be able to establish a normal RECAF™ level for an individual, creating a personalized detection test to recognize early deviations from a patient’s normal readings; and
- There is not yet an all-inclusive cancer marker, thus oncologists use different markers for each cancer. Even so, BioCurex believes that only a few markers are available and useful. The Company is developing RECAF™ as a widespread marker, potentially capable of detecting many cancers with high sensitivity and specificity.

### **Products Based on RECAF™ Technology**

As listed in Table 1 (page 5), BioCurex has developed two RECAF™-based diagnostic kits that identify cancerous tissue—Histo-RECAF™ and Cryo-RECAF™—and is working toward the development of both a RECAF™-based serum assay that detects levels of the marker in a patient’s blood (called Serum-RECAF™) and a Rapid Test that is targeted for point-of-care cancer detection. In addition,

RECAF™ technology is being evaluated as a technique for tumor imaging. Based on preliminary studies, RECAF™ technology may also enable the future administration of targeted therapeutics that could selectively kill only cancer cells and not the surrounding healthy cells. Each product being developed by BioCurex is briefly described below and on page 6 and is detailed within the Core Story on pages 28-35.

Table 1  
BioCurex, Inc.  
PRODUCT PIPELINE

<b>Histology and Cytology</b>
<i>Histo-RECAF™</i>
<i>Cryo-RECAF™</i>
<b>Blood and Serum Tests</b>
<i>Serum-RECAF™</i>
<i>Rapid Test</i>
<b>Tumor Imaging</b>
<b>Leukemia (Therapeutic Application)</b>

Source: Crystal Research Associates, LLC.

- *Histo-RECAF™* is a histological cancer detection kit for staining RECAF™-expressing cells in a tissue sample. It stains malignant and regenerating cells brown, which distinguishes the diseased cells from other normal, healthy cells also present in the tissue. The U.S. Food and Drug Administration (FDA) has classified Histo-RECAF™ as a Class I Medical Device (an FDA designation indicating that the device is subject to the least regulatory control) for use as an adjunct to standard light microscopy staining methods in order to aid in the identification of cancer in breast and **axillary** (armpit) node tissue.
- *Cryo-RECAF™* is a diagnostic kit for use by pathologists during surgery. Often, it is still unclear by the time of surgery whether cells are benign or malignant. This kit allows surgeons and pathologists to excise, freeze, slice, stain, and examine tissue while the patient remains under anesthesia, returning results within approximately 15 minutes. BioCurex has not yet applied for FDA approval of *Cryo-RECAF™*.
- *Serum-RECAF™* is a blood test designed to screen patients who are at risk for developing cancer (e.g., older patients), to help evaluate patients who have symptoms of cancer, and to monitor patients who have already been treated for cancer. Since 2004, BioCurex has performed over 120,000 tests on more than 4,000 serum samples, collectively demonstrating that *Serum-RECAF™* has between a 80% and 90% sensitivity for a variety of cancers, with a 95% specificity for lung, breast, stomach, and ovarian cancers. Moreover, data has found that this assay can perform better than many current tests for detecting prostate cancer as well as at discriminating between malignant and benign tumors in many types of cancers. In October 2006, BioCurex presented data demonstrating that *Serum-RECAF™* detected more than twice as many prostate cancers as did the PSA test, a common blood test used to help detect prostate cancer in men.

As the PSA test often incorrectly identifies benign prostate conditions as cancerous, BioCurex believes that using RECAF™ with PSA could create a test that is highly specific for a prostate condition (as the PSA marker comes only from the prostate gland) and yet also able to better distinguish between a benign and a malignant tumor (via the RECAF™ marker). The advantage for BioCurex is that PSA is already an established marker and the PSA test is recommended for all males over the age of 50. As of 2002, sales of the PSA test were approximated at \$450 million annually (Source: *The Worldwide Market for Cancer Diagnostics* by Kalorama Information). The Company hopes to capitalize on PSA's use to help create a general market for RECAF™.

BioCurex is developing the Serum-RECAF™ assay in a **colorimetric** format, where light is emitted as the result of a chemical reaction. This format is used by many high-throughput automated laboratory instruments, which may help encourage adoption of Serum-RECAF™.

- A *Rapid Test* is in development for initial point-of-care cancer detection in physicians' offices, third-world countries, or areas with large rural populations, such as China and India. As these locales may have limited access to large clinical laboratories, a Rapid Test must be able to provide a significant discrimination between cancer cells and normal cells in order to accurately display either "yes" or "no" to cancer in a process similar to a pregnancy test kit. For verification of the Rapid Test, BioCurex expects to recommend the more detailed Serum-RECAF™ laboratory test. Ideally, the two tests could function in concert, with the Rapid Test serving to expand the use of Serum-RECAF™.

### **License Agreements**

BioCurex has semi-exclusively licensed aspects of its RECAF™ technology to Abbott Laboratories, a worldwide leader in diagnostics, and Inverness Medical Innovations, Inc., a global supplier of *in vitro* diagnostic products for pregnancy, fertility/ovulation, and professional diagnostics.

### **Market Opportunities**

According to PharmaLive.com/Engel Publishing Partners, the global oncology market is forecast to grow at an average annual growth rate of 5.49% to \$53.1 billion in 2009, up from \$38.5 billion in 2003. As of 2005, the global market for laboratory-based diagnostic tests exceeded \$25 billion annually, with molecular diagnostic testing growing by approximately 20% each year and forecast to reach over \$5 billion by 2009 (Source: Caris & Company, Inc. 2005). Within the diagnostics market, cancer testing is anticipated to experience some of the greatest growth over the next three to five years, having recently exceeded \$2 billion (Source: TriMark Publications, LLC's *Cancer Diagnostic Testing World Markets 2007*).

Cancer testing is dominated by serum-based cancer markers, which had 2003 worldwide sales of approximately \$860 million (Source: *Cancer biomarkers—a mission to the U.S.* by DTI Global Watch Missions). BioCurex estimates that there are over 100 million serum screening tests performed each year. In *The Nation's Investment in Cancer Research: A Plan and Budget Proposal for Fiscal Year 2008*, the NCI emphasized the need for improved markers for prostate cancer as well as the development of more markers for hard-to-detect cancers. In addition, the NCI specifically listed validating cancer markers for disease prognosis, metastasis, treatment response, and progression as one of its future strategies.

Global expansion of cancer marker technologies are expected to be fueled by an increased marketing of new diagnostic tests to physicians, a growing number of people that are considered to be at high risk for developing cancer due to the aging population, and rising healthcare costs that may boost emphasis on more cost-effective approaches to disease management (e.g., screening and accurate diagnostic testing to facilitate early detection of potentially very costly, severe afflictions).

### **Headquarters, Business, and Employees**

Whispering Oaks International, Inc., doing business as BioCurex, Inc., incorporated in December 1997. The Company was initially in the business of acquiring and selling thoroughbred racehorses, but transitioned to cancer diagnostics and therapeutics at the start of 2001. At this time, BioCurex acquired all of the issued and outstanding shares of Lagostar Trading S.A. (a former Uruguayan biotechnology company), as well as intellectual property relating to early cancer detection and therapeutics. Following, BioCurex also acquired patents and proprietary technology, among other assets, from Pacific BioSciences Research Centre (formerly named Curex Technologies Inc. [detailed on page 10]).

To date, BioCurex has 15 full-time employees, which include those employed by Pacific BioSciences, where the Company's research and development (R&D) and some administrative duties are conducted. BioCurex also rents 5,000 square feet in Richmond, British Columbia (Canada), from Pacific BioSciences. The Company's Common Stock is traded in the U.S. on the Over-The-Counter Bulletin Board (OTC.BB) under the symbol "BOCX."

## Growth Strategy

BioCurex's RECAF™ technology has possibility in a wide variety of applications, including as a serum-based assay, a point-of-care cancer detection blood test, tissue-based stains, a technique for tumor imaging, and therapeutics. Due to its platform potential, the Company has implemented a strategy that focuses on obtaining non-exclusive licensing agreements for each application of RECAF™ technology. Since 2004, BioCurex has sought to follow these steps: (1) develop a specific product using RECAF™ technology; (2) license that product; and (3) begin to develop the next application.

With this strategy, instead of BioCurex having to allocate all of its funding in an attempt to commercialize one product, the Company selects licensees that have strategic advantages over BioCurex when it comes to commercialization (e.g., its licenses with Abbott and Inverness, as detailed on pages 9-10). Part of this strategy entails that BioCurex provide all the assistance that it can to its licensees; however, the third parties are responsible for obtaining regulatory approvals and bringing the products to market.

Market distribution channels for a diagnostic test kit typically entail accessing the automated diagnostic platforms of one or more of the larger diagnostic companies, such as Abbott, F. Hoffmann-La Roche (ROG-VTX), or Bayer AG (BAYRY.PK-OTC). These companies provide automated diagnostic instruments that are capable of processing a variety of laboratory tests. For example, the instrument menu on Ortho-Clinical Diagnostics, Inc.'s (a Johnson & Johnson company [JNJ-NYSE]) VITROS® ECI Immunodiagnostic System contains six oncology assays, including two for PSA and AFP. In addition, the VITROS® ECI, like many diagnostic platforms, also contains thyroid, cardiac, reproductive endocrinology, anemia, and metabolism assays. Some instruments can process 1,200 clinical chemistry and 200 **immunoassay** tests each hour. Via outlicensing, BioCurex seeks to place its cancer assays, e.g., Serum-RECAF™, on the instrument menu of these diagnostic platforms.

Thus far, BioCurex has fully developed Serum-RECAF™ and is obtaining licenses for the product. The Company is working toward the completion of its Rapid Test, which is expected to be licensed next, and has recently began research into imaging and therapeutic uses for RECAF™.

## Intellectual Property

BioCurex's patents, currently registered in 22 countries, cover over 40 claims and relate to methods for diagnosis and treatment of cancer using the RECAF™ cancer marker. The Company's U.S. patent expires in 2014, and its patents in Australia, Russia, and China expire in 2015.

In March 2008, the European Patent Office (EPO) granted BioCurex's patent claims for cancer diagnostic serum tests based on the RECAF™ marker. This development is particularly beneficial for BioCurex as granted patent claims can generate a higher royalty for the Company than pending claims (per BioCurex's existing license agreements). In addition, the Company believes that the European healthcare and medical insurance systems are more familiar and supportive of cancer markers than are other locales. As a result, BioCurex anticipates that regulatory approval for diagnostic tests in Europe could be easier and faster than in the U.S. Patent applications filed with the EPO related to therapy and imaging applications of RECAF™ remain pending.

The U.S. Patent and Trademark Office (USPTO) granted to BioCurex patent number 6,514,685 ("Detection of cancer using antibodies to the AFP receptor") in March 2003. This patent includes 17 claims and protects technologies used in the Company's Histo-RECAF™, Cryo-RECAF™, and Serum-RECAF™ kits. The patent also entails *in vitro* applications for diagnosis, screening, and follow-up of cancer and leukemia. At present, BioCurex is working toward the submission of additional patent applications related to RECAF™ as well.

Due to the complexity of RECAF™ technology, BioCurex believes that its proprietary know-how for developing the technology and working with the RECAF™ family of molecules is critical and extends beyond patented information. Accordingly, the Company includes know-how in its licensing packages in order to obtain royalties in countries where the Company does not have patent protection.

## Partnerships

### License to Abbott Laboratories

In March 2005, Abbott entered into a worldwide, semi-exclusive licensing agreement with BioCurex to commercialize products using RECAF™ technology, such as Serum-RECAF™. In addition, Abbott has a non-exclusive license to the Company's Rapid Test for point-of-care cancer detection. BioCurex is developing the Serum-RECAF™ assay in a colorimetric (or chemiluminescence) format, where light is emitted as the result of a chemical reaction. This format is used by high-throughput automated instruments. Through collaborative research, Abbott has found high sensitivities and specificities for cancer detection with RECAF™. Results from some of these tests were presented at an international cancer congress, as announced in the Company's September 20, 2007, press release.

In March 2008, BioCurex announced that it reached an agreement in principle to amend its original licensing agreement with Abbott. The proposed amendment relieves Abbott of future due diligence obligations to commercialize or perform further R&D on the RECAF™ technology as well as its obligation to pay the annual minimum royalty. BioCurex is continuing to develop a chemiluminescence-based Serum-RECAF™ test at its facilities, and Abbott may resume its R&D work and commercialize products incorporating the RECAF™ technology, as per the original agreement. In consideration for the amendment, BioCurex gained a higher royalty on any RECAF™ products that may be sold by Abbott. BioCurex also obtained the right to terminate the license at any time, if Abbott, following notice from BioCurex, does not agree within 90 days to new due diligence obligations for the commercialization of any products using the RECAF™ technology.

Manual chemiluminescence and other colorimetric-based RECAF™ tests are excluded from the semi-exclusive restrictions of the original agreement by a previous amendment. Thus, BioCurex may commercialize and license radioactive as well as non-radioactive manual tests to as many licensees as it deems appropriate. The remainder of the original licensing agreement is ratified and affirmed and remains in full force and effect.

#### *Abbott Laboratories*

Abbott ([www.abbott.com](http://www.abbott.com)) is a global healthcare company with products that range from nutritional products and laboratory diagnostics to medical devices and pharmaceutical therapies. Headquartered in Chicago, Illinois, Abbott has over 65,000 employees. The company's history in cancer diagnostics includes introducing the IMx® diagnostic instrument for medium-sized laboratories in the late 1980s, and developing the first automated PSA test in 1991. In addition, Abbott and its wholly owned Vysis Inc. subsidiary have commercialized several genomic tests, including UroVysion™ and PathVysion®. UroVysion™ aids in the diagnosis and monitoring of bladder cancer. PathVysion® detects levels of the human epidermal growth factor receptor 2 (HER2) gene in breast cancer patients to determine if the patient is an appropriate candidate for Genentech, Inc.'s (DNA-NYSE) Herceptin® therapy. (Herceptin® is for patients whose breast cancer expresses the HER2 gene, which is characteristic of only approximately 25% of patients.)

### License to Inverness Medical Innovations, Inc.

In January 2008, BioCurex entered into a second semi-exclusive, worldwide licensing agreement for its RECAF™ material and technology. This agreement allows Inverness Medical Innovations, Inc. ([www.invernessmedical.com](http://www.invernessmedical.com)) to commercialize products using the RECAF™ technology (which includes Serum-RECAF™), in exchange for paying upfront fees, product and development milestones, and royalties on product sales to BioCurex. Inverness has a non-exclusive license for BioCurex's Rapid Test as well. Inverness is responsible for obtaining FDA approvals, and managing manufacturing, marketing, and distribution for clinical laboratory testing. BioCurex believes that the initiation of this license to Inverness is a significant milestone in the commercialization of cancer detection products and represents an important step in the Company's development.

### *Inverness Medical Innovations, Inc.*

Inverness creates advanced consumer and professional medical diagnostic products worldwide. In particular, the company is focused on supplying consumer pregnancy and fertility/ovulation tests (e.g., the ClearBlue® product line of home pregnancy and fertility/ovulation prediction tests) as well as rapid point-of-care diagnostics. Recent development areas at Inverness include the application of patented technologies to products for cardiology, women's health, and infectious diseases. Additionally, Inverness sells a wide variety of vitamins and nutritional supplements. The company has R&D facilities in the U.S., UK, Germany, and Israel, with manufacturing sites in the U.S., UK, China, and Japan. Inverness was founded in 2001 and is headquartered in Waltham, Massachusetts.

### **Additional Licensing Opportunities**

As the license agreements with Abbott and Inverness are semi-exclusive, BioCurex is free to negotiate with additional potential licensees for some of its cancer diagnostics tests. Further, the Company's RECAF™ technology has additional applications that could be licensed, including imaging functions and therapeutic uses. Ultimately, BioCurex seeks to non-exclusively license out specific aspects of its technology to as many partners as possible, striving to achieve a significant market share by selecting licensees that can support this goal in an efficient and aggressive fashion. With the introduction of RECAF™ in a commercialized format to a space dominated by few cancer markers, licensees may be able to expand BioCurex's market share.

### **Research and Development Partnerships**

#### *Pacific BioSciences Research Centre*

Research and development relating to BioCurex's technology is conducted by the Pacific BioSciences Research Centre. Pacific BioSciences, formerly named Curex Technologies Inc., is wholly owned by BioCurex's chief executive officer (CEO) and president, Dr. Ricardo Moro-Vidal (biography on page 11). Recently, Pacific BioSciences has also provided administrative services for the Company.

#### *Goshen Health System's Center for Cancer Care*

In July 2005, BioCurex entered into a development collaboration with Indiana's Goshen Health System's Center for Cancer Care ([www.cancermidwest.com](http://www.cancermidwest.com)). Under this relationship, the Company aimed to expand potential applications for its RECAF™ technology in terms of serum and biopsy tests, imaging, and target delivery of therapeutic agents to selectively kill cancer cells. Investigating RECAF™ for therapeutic prospects could include the initiation of clinical trials and is contingent upon successful preclinical studies in animal and culture models.

The Goshen Health System's Center for Cancer Care participates in programs with the National Surgical Adjuvant Breast and Bowel Project (NSABP), the Eastern Cooperative Oncology Group (ECOG), Hoosier Oncology Group (HOG), the NCI's Clinical Trials Support Unit (CTSU), and Michigan State University (MSU). The center's medical director is Douglas J. Schwartzentruber, M.D., F.A.C.S. Dr. Douglas Schwartzentruber has completed a fellowship in immunotherapy at the NCI, where he subsequently worked for 13 years as a senior investigator. He also serves on the Editorial Board for the *American Journal of Oncology Review* and the *Journal of Translational Medicine*.

#### *N.N. Blokhin Cancer Research Center*

In December 2006, BioCurex entered into a collaboration agreement with Moscow's N.N. Blokhin Cancer Research Center, Russian Academy of Medical Sciences for further development and evaluation of the RECAF™ technology. This agreement focuses on using RECAF™ serum samples for cancer screening, diagnosis, and follow-up of treated patients. Through the collaboration, BioCurex benefits from access to the center's patients, final diagnoses, biopsies, and serum samples. In addition, the center provides the Company with opportunities for prospective studies, options to evaluate and adjust its assays to practical and routine laboratory needs, and a chance to gather data that may be later presented to regulatory agencies. The center was created in 1951 in Moscow, Russia. Supported by the NCI, it is part of the American-Russian Cancer Alliance, which also includes the University of Maryland's Greenebaum Cancer Center, the Kurchatov Institute, and the Fox Chase Cancer Center (Philadelphia, Pennsylvania).

## Company Leadership

### Management and Board of Directors

Table 2 summarizes BioCurex's key management and Board of Directors, followed by detailed biographies.

Table 2 BioCurex, Inc. MANAGEMENT AND BOARD OF DIRECTORS	
Ricardo Moro-Vidal, M.D.	Chief Executive Officer, President, and Director, Board of Directors
Gerald Wittenberg, D.M.D., M.S.	Chief Financial Officer, Secretary-Treasurer, and Chairman, Board of Directors
Phil Gold, C.C., O.Q., M.D., Ph.D.	Chairman, Scientific Advisory Board and Director, Board of Directors

*Source: BioCurex, Inc.*

#### *Ricardo Moro-Vidal, M.D., Chief Executive Officer, President, and Director, Board of Directors*

Dr. Moro-Vidal is the CEO, president, and founder of BioCurex. Previously, he developed a new diagnostic system (conductivity ELISA) and a microchip used by the National Aeronautics and Space Administration (NASA) in space. Dr. Moro-Vidal also discovered the RECAF™ cancer marker, the core of BioCurex's technology. He has been an officer and director of BioCurex since March 2001. Since 1996, Dr. Moro-Vidal has also been president of Pacific BioSciences Research Centre, where he developed the RECAF™ cancer marker concept. From 1980 to 1985, he worked in cancer research at the French National Cancer Institute near Paris, France. From late 1985 to 1988, he worked at the University of Alberta, Edmonton on oncogene developmental biology. From 1989 to 1996, Dr. Moro-Vidal was engaged in various entrepreneurial ventures relating to diagnostics and instrumentation.

#### *Gerald Wittenberg, D.M.D., M.S., Chief Financial Officer, Secretary-Treasurer, and Chairman, Board of Directors*

Dr. Wittenberg has been an officer and director of BioCurex since March 2001. He is a specialist in oral and maxillofacial surgery and has been in private practice since 1981. Dr. Wittenberg has held positions as president of the British Columbia Association of Oral and Maxillofacial Surgeons, head of the division of Oral and Maxillofacial Surgery at British Columbia's BC Children's Hospital, and consultant to the Cancer Control Agency of British Columbia. He established the Facial and Laser Surgery Center in Vancouver for facial reconstructive and facial aging surgery, and is a Fellow of the British Columbia College and a Member of the Royal College, American Association of Oral and Maxillofacial Surgeons, and the American Academy of Cosmetic Surgeons. He obtained a D.M.D. at the University of British Columbia and an M.S. at the University of Minnesota. Dr. Wittenberg has been active in public companies as both a director and a financier, with experience in early stage business enterprises. He combines business, research, and medical/surgical judgment applicable to venture situations.

#### *Phil Gold, C.C., O.Q., M.D., Ph.D., Chairman, Scientific Advisory Board and Director, Board of Directors*

Dr. Gold has been a director of BioCurex since March 2001. He attended McGill University, where he obtained four degrees, including a Ph.D. His thesis, "**Carcinoembryonic Antigens (CEAs)** of the Human Digestive System," and his description of AFP are credited with ushering in the modern era of human tumor marker research, along with the diagnostic ramifications that this work has had over the past quarter century. The CEA assay, developed by Dr. Gold, has become one of the most used markers for human cancer diagnosis and monitoring. More recently, in experimental attempts to eradicate tumors with **monoclonal antibodies (MAbs)**, anti-CEA antibody has been used as a homing device for cancer cell **cytotoxic** agents. In recognition of his scientific contributions, Dr. Gold has received numerous international awards and honors. He is currently the physician-in-chief, Department of Medicine, at the

Montréal General Hospital; the Douglas G. Cameron professor of medicine at McGill University; a professor in the Departments of Physiology and Oncology at McGill University; and the director of the McGill University Medical Clinic at Montréal General Hospital.

### Scientific Advisory Board (SAB)

BioCurex's SAB includes several leaders of the cancer marker field, including Dr. Gold, who discovered CEA, and Dr. Garri Abelev, who found AFP. The SAB also has an established international presence, with members from Canada, the U.S., France, Russia, Spain, and Japan. Table 3 provides a summary of SAB members, followed by detailed biographies.

Table 3  
BioCurex, Inc.  
SCIENTIFIC ADVISORY BOARD

Phil Gold, C.C., O.Q., M.D., Ph.D.	Chairman
Garri Abelev, Ph.D., M.D.	Member
José Uriel, Ph.D., M.D.	Member
María José Villacampa, Ph.D.	Member
Taiki Tamaoki, Ph.D.	Member
Elliot Alpert, M.D., Ph.D.	Member
Michel Sadelain, M.D., Ph.D.	Member
Strath Wilson, Ph.D.	Member
Stewart Sell, M.D.	Member

*Source: BioCurex, Inc.*

*Phil Gold, C.C., O.Q., M.D., Ph.D., Chairman, Scientific Advisory Board and Director, Board of Directors*

Biography on page 11.

*Garri Abelev, Ph.D., M.D.*

Dr. Abelev and his colleagues first described the association between AFP and liver cancer in 1963. AFP was one of the first reported cancer markers of clinical use. Dr. Abelev's work can be credited with facilitating the launch of the tumor marker field into its present industry, and some consider him to be the dean of the cancer marker community. He has contributed in significant ways to understanding the functions of AFP. Dr. Abelev continues work in his laboratory at the Cancer Research Center, Immunochemistry Division (Moscow, Russia).

*José Uriel, Ph.D., M.D.*

Dr. Uriel has worked at the Pasteur Institute and was research director of the Centre National de la Recherche Scientifique ([CNRS] the National Center for Scientific Research). He also worked at the Laboratory of Immunology, National Institutes of Health ([NIH] Bethesda, Maryland). From 1963 to 1995, he directed the Laboratory of Protein Chemistry at the French Research Cancer Institute, where he was later the director. In 1970, Dr. Uriel received the Rosen Award in cancer research, and in 1972, became laureate of the French National Academy of Medicine (Leon Berat prize). He has published over 220 scientific papers and written several chapters in books related to cancer research. He has made major contributions to the understanding of the physiology of AFP and cancer markers.

*María José Villacampa, Ph.D.*

Dr. Villacampa is a full professor in the Department of Biochemistry and Cellular and Molecular Biology at the University of Zaragoza (Spain). She was part of the team that initially characterized RECAF™ and has published a significant number of papers related to the different aspects of this molecule in collaborations with Dr. Uriel and Dr. Moro-Vidal.

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*Taiki Tamaoki, Ph.D.*

Dr. Tamaoki obtained a degree in 1960 at the University of Wisconsin. He then moved to the University of Alberta, Cancer Research Unit, where he worked as an associate professor and then as a faculty professor at the University of Calgary. He held positions as research associate of the National Cancer Institute of Canada and at the Terry Fox Cancer Research Institute, which is an initiative sponsored by the Terry Fox Foundation, the second largest non-governmental benefactor of cancer research in Canada. Dr. Tamaoki is a molecular biologist, and it was in his laboratory that AFP was cloned for the first time. His paper was published in the *Proceedings of the National Academy of Sciences*. He is regarded as a worldwide authority in AFP structure.

*Elliot Alpert, M.D., Ph.D.*

Dr. Alpert is a member of the New York Academy of Sciences (Canada) and is also considered to be a pioneer in AFP and the cancer marker field. Dr. Alpert is responsible for the workshop for evaluation of cancer markers for the International Society of Oncodevelopmental Biology and Medicine (ISOBM), a leading international forum for cancer markers that originated in the early 1970s.

*Michel Sadelain, M.D., Ph.D.*

Dr. Sadelain is a director of one of the gene therapy units approved by the FDA in the U.S.—Sloan-Kettering Memorial, NCI. The laboratory he manages is actively involved with genetic engineering applied to the immune system, a combination of fields that could prove valuable for future work with RECAF™. Dr. Sadelain has also previously worked with Dr. Moro-Vidal using RECAF™ in experiments showing complete abrogation of tumor growth in animal models.

*Strath Wilson, Ph.D.*

Formerly, Dr. Wilson was a director of the Diagnostic Business Unit in one of Canada's largest biotechnology companies, Connaught Laboratories Ltd. (now Sanofi Pasteur Ltd., a subsidiary of sanofi-aventis [SNY-NYSE]). At Connaught, Dr. Wilson contributed to the FDA approval, licensing, and distribution of multiple diagnostic kits. He provides BioCurex with a unique combination of scientific and managerial skills that are instrumental in advancing the Company toward a prominent global position in cancer diagnostics and therapeutics.

*Stewart Sell, M.D.*

Dr. Sell has been a member of BioCurex's SAB since October 2005. He was recently awarded an ISOBM-Abbott award for his lifetime achievements in cancer research, immunology, developmental biology, and stem cell research. Dr. Sell has written text books that are currently used by medical students, and previously received an award for 25 years of teaching cancer biology by the American Association of Cancer Research (AACR). He has published over 350 scientific papers and 14 books. In 1984, his paper on activation of lymphocytes by reaction of ligands with surface immunoglobulin was listed as a Citation Classic. Dr. Sell has been named both a Distinguished Alumnus of the School of Medicine (Hench Award) and a Legacy Laureate of the University of Pittsburgh (the highest honor for a Pittsburgh graduate). In 1998, he was cited as a distinguished scientist by the International Academy of Tumor Marker Oncology (IATMO). In 2005, he received the Rudolf Virchow Award (LeadershipMedica, Italy) and, in 2007, his paper on cancer stem cells was cited as a Scientific Landmark publication by the AACR. Dr. Sell is presently the senior research physician at the Wadsworth Center of the New York State Department of Health and the Ordway Research Institute (Albany, New York). He obtained an M.D. at the University of Pittsburgh and performed his residency in pathology at Massachusetts General Hospital and his research in immunology at the NIH and the University of Birmingham.

## Core Story

BioCurex, Inc. (“BioCurex” or “the Company”) is a biotechnology company developing products based on a patented and proprietary technology in the areas of cancer diagnosis, imaging, and therapy. BioCurex’s technology utilizes a novel cancer marker called RECAF™ that is present on malignant cells in many cancers but absent from most normal or benign cells. With its RECAF™ technology, the Company seeks to reduce human suffering through the early detection of cancer or cancer recurrences.

BioCurex believes that the RECAF™ cancer marker could be used in the development of new cancer diagnostic tests. Preliminary studies have reported a high level of clinical sensitivity and specificity for RECAF™ in many common cancers, including prostate, breast, colorectal, stomach, ovarian, and lung cancers as well as leukemia. In oncology, sensitivity is the ability of a test to detect cancer. If all cancer patients test positive for having cancer with a particular test, the test’s sensitivity would be 100%. Specificity measures how well the test detects cancer, i.e., whether it identifies patients as having cancer when they do not. If a test does not return any false positives, it has 100% specificity.

To date, cumulative Company data indicates that RECAF™ successfully detects over 90% of cancer in blood and tissue samples, which BioCurex views as a significant improvement over present cancer markers. In addition, due to its ability to differentiate between cancer and normal cells, RECAF™ may enable targeted treatments that do not damage healthy tissue.

## CANCER

The American Cancer Society (ACS) has estimated that there would be over 12.3 million new cancer diagnoses worldwide and roughly 7.6 million deaths during 2007, of which nearly 40% would be in developed nations (Source: *Global Cancer Facts & Figures 2007*). Although the U.S. has reported declining cancer-related deaths for the past few years, the World Health Organization (WHO) estimates that there will likely be 16 million new cancer diagnoses annually by the year 2020, with roughly 10 million related deaths around the world each year as well. Over the next 20 years, the global incidence of cancer is projected to increase by 50% (Source: WHO). BioCurex believes that the growing numbers of people developing and living with cancer will continue to increase the demand for cancer products. Table 4 (page 15) depicts the ACS’s estimates for 2008 of new diagnoses and annual deaths, delineated by cancer type and patient gender, from a variety of common cancers.

### Need for Improved Early Detection Methods

Cancer that is detected early has the best prognosis. If tumors are diagnosed early in the disease process, before they spread (metastasize) to surrounding tissue, physicians are more likely to be able to successfully treat the patient and the likelihood of survival can be significantly increased. Surgical removal of a tumor is much less effective once tumor cells have invaded additional locations, many of which are undetectable. Moreover, when cancer cannot be fully eliminated through surgery, patients may receive radiation or chemotherapy—two treatments that are associated with significant risk, including immunosuppression, anemia, vomiting, hair loss, fatigue, decreased blood cell counts, infertility, and damage to the heart, lungs, nerves, kidneys, or reproductive organs.

While advances in early detection have improved the prognosis of many cancers thus far, prostate, lung and bronchus, and breast cancers are still among the most commonly diagnosed and the most fatal cancers. Specifically, among both men and women, lung and bronchus cancers are the number one cause of cancer-related death (depicted in Table 4), which is believed to be due to the lack of early detection methods. By the time of diagnosis, only approximately 16% of lung cancer patients have tumors that are still in an early stage. For these patients, the survival rate is 49% versus a five-year survival rate of only 15% when more advanced tumors are also included (Source: the ACS’s *Cancer Facts and Figures 2008*). BioCurex aims to facilitate early detection of cancers, including lung cancer, through its alternative, investigational cancer marker—RECAF™ (described on pages 21-27).

Table 4  
ESTIMATED NEW CANCER CASES AND DEATHS BY SEX, U.S., 2008\*

	Estimated New Cases			Estimated Deaths		
	Both Sexes	Male	Female	Both Sexes	Male	Female
<b>All sites</b>	1,437,180	745,180	692,000	565,650	294,120	271,530
Oral cavity & pharynx	35,310	25,310	10,000	7,590	5,210	2,380
Tongue	10,140	7,280	2,860	1,880	1,210	670
Mouth	10,820	6,590	4,230	1,840	1,120	720
Pharynx	12,410	10,060	2,350	2,200	1,620	580
Other oral cavity	1,940	1,380	560	1,670	1,260	410
Digestive system	271,290	148,560	122,730	135,130	74,850	60,280
Esophagus	16,470	12,970	3,500	14,280	11,250	3,030
Stomach	21,500	13,190	8,310	10,880	6,450	4,430
Small intestine	6,110	3,200	2,910	1,110	580	530
Colon <sup>†</sup>	108,070	53,760	54,310	49,960	24,260	25,700
Rectum	40,740	23,490	17,250			
Anus, anal canal, & anorectum	5,070	2,020	3,050	680	250	430
Liver & intrahepatic bile duct	21,370	15,190	6,180	18,410	12,570	5,840
Gallbladder & other biliary	9,520	4,500	5,020	3,340	1,250	2,090
Pancreas	37,680	18,770	18,910	34,290	17,500	16,790
Other digestive organs	4,760	1,470	3,290	2,180	740	1,440
Respiratory system	232,270	127,880	104,390	166,280	94,210	72,070
Larynx	12,250	9,680	2,570	3,670	2,910	760
Lung & bronchus	215,020	114,690	100,330	161,840	90,810	71,030
Other respiratory organs	5,000	3,510	1,490	770	490	280
Bones & joints	2,380	1,270	1,110	1,470	820	650
Soft tissue (including heart)	10,390	5,720	4,670	3,680	1,880	1,800
Skin (excluding basal & squamous)	67,720	38,150	29,570	11,200	7,360	3,840
Melanoma	62,480	34,950	27,530	8,420	5,400	3,020
Other non-epithelial skin	5,240	3,200	2,040	2,780	1,960	820
Breast	184,450	1,990	182,460	40,930	450	40,480
Genital system	274,150	195,660	78,490	57,820	29,330	28,490
Uterine cervix	11,070		11,070	3,870		3,870
Uterine corpus	40,100		40,100	7,470		7,470
Ovary	21,650		21,650	15,520		15,520
Vulva	3,460		3,460	870		870
Vagina & other genital, female	2,210		2,210	760		760
Prostate	186,320	186,320		28,660	28,660	
Testis	8,090	8,090		380	380	
Penis & other genital, male	1,250	1,250		290	290	
Urinary system	125,490	85,870	39,620	27,810	18,430	9,380
Urinary bladder	68,810	51,230	17,580	14,100	9,950	4,150
Kidney & renal pelvis	54,390	33,130	21,260	13,010	8,100	4,910
Ureter & other urinary organs	2,290	1,510	780	700	380	320
Eye & orbit	2,390	1,340	1,050	240	130	110
Brain & other nervous system	21,810	11,780	10,030	13,070	7,420	5,650
Endocrine system	39,510	10,030	29,480	2,430	1,110	1,320
Thyroid	37,340	8,930	28,410	1,590	680	910
Other endocrine	2,170	1,100	1,070	840	430	410
Lymphoma	74,340	39,850	34,490	20,510	10,490	10,020
Hodgkin lymphoma	8,220	4,400	3,820	1,350	700	650
Non-Hodgkin lymphoma	66,120	35,450	30,670	19,160	9,790	9,370
Myeloma	19,920	11,190	8,730	10,690	5,640	5,050
Leukemia	44,270	25,180	19,090	21,710	12,460	9,250
Acute lymphocytic leukemia	5,430	3,220	2,210	1,460	800	660
Chronic lymphocytic leukemia	15,110	8,750	6,360	4,390	2,600	1,790
Acute myeloid leukemia	13,290	7,200	6,090	8,820	5,100	3,720
Chronic myeloid leukemia	4,830	2,800	2,030	450	200	250
Other leukemia <sup>‡</sup>	5,610	3,210	2,400	6,590	3,760	2,830
Other & unspecified primary sites <sup>‡</sup>	31,490	15,400	16,090	45,090	24,330	20,760

\*Rounded to the nearest 10; est. new cases exclude basal and squamous cell skin cancers and in situ carcinomas except urinary bladder. About 67,770 female carcinoma in situ of the breast and 54,020 melanoma in situ will be newly diagnosed in 2008. †Est. deaths for colon and rectum cancers are combined. ‡More deaths than cases suggests lack of specificity in recording underlying causes of death on death certificates.

Source: the American Cancer Society, Inc., Surveillance Research (2008).

## Need for Targeted Treatments

In addition to accelerating products to market that are capable of early detection, researchers and organizations are also focused on the development of molecularly targeted therapies that act primarily on the tumor and its associated tissue, rather than on all cells non-discriminately. BioCurex believes that its RECAF™ technology has the potential to address the need for enhanced therapies that do not attack healthy cells, as it distinguishes between a cancer cell presenting the RECAF™ cancer marker and a healthy cell lacking the marker, thereby enabling a targeted treatment.

## CANCER MARKERS

A cancer marker, also called a tumor marker, serum marker, or biomarker, can be any of a number of substances expressed on cancer cells or created by the body's immune system in response to cancer cells. These substances can appear in body tissue, blood, or urine. Detecting a cancer marker in higher-than-normal amounts in the body may signify the presence of cancer. For some indications, the expressed amount of a particular marker can also signal the disease's stage (i.e., how far the cancer has progressed). For instance, a common cancer marker for liver cancer, alpha-fetoprotein (AFP), not only signals the potential presence of liver cancer, but can also indicate the size of the tumor. Levels of AFP below 10 nanograms per milliliter (ng/ml) are considered to be normal, while from 10 ng/ml up to 500 ng/ml can be detected in patients with chronic hepatitis, and over 500 ng/ml is likely to be hepatocellular carcinoma (HCC), a common type of liver cancer. Above 500 ng/ml, the blood level of AFP may relate to the size of the tumor. However, it is important to note that AFP's sensitivity as a cancer marker is only approximately 60%, meaning that roughly 40% of patients with liver cancer do not have an elevated AFP.

After testing for a cancer marker, further identifying which cells express the marker may enable the distinction between cancerous cells and healthy cells. In addition, once a tumor has been located and associated with a marker, that marker can be used to monitor the effects of treatment and possible recurrence, indicate the likelihood of progression, and assist with a prognosis.

Oncologists measure marker levels to assess a patient's response to treatment, evaluate appropriate future treatments, and check for signs that the cancer may be recurring. If, after treatment, marker levels have decreased from the level at diagnosis, it may indicate that the cancer is responding favorably to the treatment. Conversely, if marker levels rise, the oncologist may consider an alternative therapy option, as the tumor is not likely responding to treatment. Depending upon the patient and the cancer, these follow-up tests may be continued for life, occurring as frequently as every two to three months.

## Limitations of Current Cancer Markers

Although there has been significant historical research into cancer diagnostics, BioCurex estimates that few cancer markers have been accepted into clinical use over the past 40 years. Moreover, markers alone are not used today as the sole method to diagnose cancer, due to several factors (listed below and on page 17) that limit the capabilities of current cancer markers to accurately diagnose the disease. Thus far, these limitations have prevented cancer marker tests from functioning as wholly effective screens for many cancers. BioCurex believes that the ideal cancer marker, yet to be commercialized, would be a molecule that is expressed on all cancer cells regardless of type, but not in healthy or benign tumor cells.

- *Currently available markers are not 100% specific to a particular type of cancer, indicating that other, non-cancerous conditions can also cause an increase in certain cancer markers.* For example, elevated levels of the prostate-specific antigen (PSA), a marker for prostate cancer, do not always signal a malignant condition. The National Cancer Institute (NCI) reports that only 25% to 30% of men that express higher-than-normal amounts of PSA in the blood actually have prostate cancer. The remaining 70% to 75% of men have benign prostate conditions, such as inflammation, which also cause an increase in PSA levels.

If the minimum PSA value is increased (where men would have to show even higher levels of the marker in order to enable detection by a PSA test), the PSA could be considered to be more accurate, as more men will likely be correctly identified as having prostate cancer and not a benign condition. However, for many of these men, waiting for their PSA levels to increase to an amount detectable by a more stringent test also prevents early detection of the prostate cancer. BioCurex estimates that if the PSA cut-off value is increased, over 50% of men may not be diagnosed with

prostate cancer until after their tumor has spread beyond the prostate gland, significantly decreasing the likelihood of successful treatment. As a result, there is still an unmet need for a clinically effective diagnostic technique for the early detection of prostate cancer.

- *Many markers are also restricted to only certain cancers.* For example, the PSA test can help detect prostate cancer, but would not be used to screen for breast cancer.
- *The same marker is not always expressed on every patient's cancer, even if it is related to the same organ.* For instance, Genentech's Herceptin® treats metastatic breast cancer that is positive for human epidermal growth factor receptor 2 (HER2). However, HER2 overexpression occurs in only approximately 25% of women with breast cancer (Source: Genentech, Inc.).
- *The detection of "normal" levels of a cancer marker can occasionally be ambiguous.* For some cancer markers (such as CA-125, which is more prevalent in ovarian cancer cells than other cells), even individuals without the cancer can demonstrate varying levels of the marker. In some cases, CA-125 expression depends on age and gender, with women under 50 having higher amounts of this protein in their bodies than women over 50 or men. Like other markers, benign conditions, including infections and **endometriosis**, can also cause elevated CA-125 levels. As a result, the classification of a normal value is difficult. MedlinePlus, a service of the U.S. National Library of Medicine and the National Institutes of Health (NIH), reports that perceived normal CA-125 levels vary depending on which laboratory is administering the test. Consequently, CA-125 tests are more effectively used to monitor the progression of ovarian cancer and the patient's response to treatment, rather than to diagnose the cancer in an otherwise healthy individual.

In addition, in the early stages of cancer, many patients express relatively normal levels of known cancer markers, evading detection by current cancer marker tests. As a result, even widespread markers—such as carcinoembryonic antigen (CEA), which can be found in patients with a variety of cancers—are not effective at detecting **occult** (hidden) cancers (Source: WebMD, Inc.). The CEA assay, discovered by Dr. Phil Gold, chairman of BioCurex's Scientific Advisory Board (SAB), was one of the first successful blood tests to enter general clinical use.

Table 5 lists several common cancer markers, what they target, and associated data. A more complete marker list is available on the ACS's website at [www.cancer.org](http://www.cancer.org). Table 5 is followed by an overview of cancer testing as well as details of the oncology, cancer diagnostics, and cancer marker markets.

Table 5  
SELECTED PROMINENT, CURRENTLY AVAILABLE CANCER MARKERS

Cancer Marker	Indication	Related Data
Alpha-Fetoprotein (AFP)	Liver Cancer	Only ~60% of HCC patients have elevated AFP.
Carcinoembryonic Antigen (CEA)	Colon, Rectal, Pancreas, Breast, Ovary, or Lung Cancers	CEA's sensitivity and specificity varies depending on the indication and whether CEA is combined with another marker.
Prostate-Specific Antigen (PSA)	Prostate Cancer	Only 25% to 30% of men with elevated PSA have prostate cancer.
Tissue Polypeptide Antigen (TPA)	Lung, Bladder, Breast, and Other Cancers	TPA has a 70% to 90% sensitivity for Stage IV breast cancer and ~70% for lung cancer.
Cancer Antigen (CA)-125	Ovarian Cancer	Only ~3 of 100 women with elevated CA-125 have ovarian cancer, and ~20% of women with the cancer never have detectable CA-125.
Cancer Antigen (CA) 15-3	Breast Cancer	CA 15-3 is elevated in ~30% of women with localized breast cancer and in ~75% of women with metastatic breast cancer. Also, 25% to 30% of women with advanced breast cancer have tumors that do not shed CA 15-3.

*Sources: BioCurex, Inc., MedicineNet, Inc., NCI, WebMD, Inc., MedlinePlus, and Crystal Research Associates, LLC.*

## Types of Cancer Testing

Globally, cancer testing encompasses a wide variety of products and technologies, including the following: (1) receptor assays (a test to analyze a substance), hormone assays, and immunoassays for serum cancer markers; (2) mammographies (a breast X-ray to detect tumors); (3) clinical chemistry or deoxyribonucleic acid (DNA) reagents; (4) cytological and **immunocytochemistry** products; and (5) histological and **immunohistochemistry** products. Each of these products is used for at least one of three tasks—screening, diagnosis/monitoring, or imaging—all of which are briefly overviewed below.

### *Screening*

Cancer screening entails performing regular tests on people who have no symptoms. Mammograms, Papanicolaou (Pap) smears, and PSA tests are all examples of cancer screens. These tests can reveal hidden diseases, but need further corroboration, such as a tissue biopsy, to provide a final diagnosis. Most cancer marker tests do not have high enough measures of sensitivity or specificity (as exemplified in Table 5 [page 17]) to be considered useful as a cancer screen. Even the PSA test, which is routinely used to screen men, is still debated as to its appropriateness. However, the PSA test is implemented because it has two advantages over other cancer markers: (1) PSA is only made by the prostate cells, thus, even if not cancer, it is fairly specific to a prostate problem; and (2) PSA levels typically rise even in the early stages of prostate cancer, enabling earlier detection of the disease (Source: ACS). Prostate cancer staging is addressed in the Glossary on page 51.

### *Diagnosis/Monitoring*

As addressed on pages 16-17, cancer markers are primarily used for diagnostic and monitoring purposes. While typically markers alone are not used to diagnose a disease, they do help determine if cancer is likely. They also help monitor the cancer's progression, response to treatment, and potential for recurrence. To test for a marker, a sample of the patient's blood or urine is sent to a laboratory, where it is combined with manmade antibodies that have been designed to react with that specific protein. Techniques to measure cancer markers include **histology** (study of tissues) and cervical **cytology** (study of cells), as well as immunocytochemical and immunohistochemical stains. A stain is essentially a dye, reagent, or other coloring material that is used to make structures visible under a microscope.

### *Imaging*

In healthcare, imaging is the process by which physicians obtain pictures of the body's interior. Oncologists use imaging as a noninvasive, safe method to help see tumors and detect occult metastatic cancer. Special dyes that are either swallowed or administered through a needle or tube are used to enable organs to show up better on film. Imaging may also use **radiolabeled** monoclonal antibodies (MAbs) to facilitate detection of occult cancers that elude conventional diagnostic imaging methods. BioCurex believes that there are two primary unmet needs in imaging at present: (1) the existence of an agent that can detect cancerous cells before the disease clinically manifests; and (2) the presence of a marker to identify secondary cancer after the primary treatment has begun.

## MARKET DYNAMICS

The oncology market is one of the largest pharmaceutical markets. According to PharmaLive.com/Engel Publishing Partners (a publisher of business and marketing information to the pharmaceutical industry), the global cancer market is forecast to grow at an average annual growth rate of 5.49% to \$53.1 billion in 2009, up from \$38.5 billion in 2003.

Overall costs of cancer in 2007 were estimated to be \$219.2 billion, composed of \$89 billion for direct medical costs (total of all health expenditures), \$18.2 billion for indirect morbidity costs (cost of lost productivity due to illness), and \$112 billion for indirect mortality costs (cost of lost productivity due to premature death) (Source: the NIH). It is predicted that a 1% decrease in cancer mortality could result in a \$500 billion impact on the U.S. economy (Source: *Journal of Political Economy* 2006).

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## Worldwide Cancer Diagnostics Market

As of 2005, the global market for laboratory-based diagnostic tests exceeded \$25 billion annually, with molecular diagnostic testing growing by approximately 20% each year and forecast to reach over \$5 billion by 2009 (Source: Caris & Company). Within this larger diagnostics market, cancer testing is anticipated to experience some of the most robust growth over the next three to five years, having recently exceeded \$2 billion (Source: *Cancer Diagnostic Testing World Markets*). BioCurex believes that the primary drivers for sales of diagnostic products for cancer markers are uniqueness, product performance, price, service, and marketing. At present, the three largest markets for these products are the U.S., Japan, and Europe.

Cancer testing is dominated by serum-based cancer markers, including CEA, PSA, CA-125, bladder tumor antigen (BTA), and TruQuant BR (for monitoring breast cancer). In 2003, worldwide sales of these serum assays were approximately \$860 million (Source: *Cancer biomarkers—a mission to the U.S. by DTI Global Watch Missions*). BioCurex estimates that there are over 100 million serum screening tests performed each year.

Other significant components of the cancer diagnostic market are immunocytochemistry and immunohistochemistry, which had sales of \$234 million in 2001 that were predicted to reach \$333 million by 2007 (Source: *Cancer biomarkers—a mission to the U.S.*).

### *Reasons for Growth of Cancer Diagnostics*

The following factors may affect the size and growth of the worldwide cancer diagnostic market:

- demographic shifts due to an aging population;
- technological innovation;
- reimbursement, third-party payers, and financing for companies developing diagnostics;
- government funding for basic and disease-related research;
- biotechnology and pharmaceutical companies' research and development (R&D) spending; and
- an increased focus on lowering healthcare spending via improved diagnostic testing and patient monitoring that can reduce the costs of misdiagnosis (further addressed on pages 20-21).

The NIH (which is not the only government agency to sponsor research) invests over \$28 billion annually in medical research, of which an estimated \$5.5 billion may be spent on cancer research in particular during fiscal year 2008 (Source: the NIH). Additionally, R&D spending is increasing, with the top 100 biotechnology companies having spent approximately \$14.8 billion on R&D during 2006, up from \$12.6 billion in 2005 and \$11.2 billion in 2004 (Source: *MedAdNews*).

## The Cancer Marker Segment

BioCurex views validating new cancer markers as one of the most important goals in cancer research, because, as the Company estimates, very few effective new markers have been discovered in the past 40 years. To this extent, in *The Nation's Investment in Cancer Research: A Plan and Budget Proposal for Fiscal Year 2008*, the NCI emphasized the need for improved markers for prostate cancer as well as the development of more markers for hard-to-detect cancers, such as those in the ovary and pancreas. In addition, the NCI specifically listed validating cancer markers for disease prognosis, metastasis, treatment response, and progression as one of its future strategies. The continuing need for enhanced cancer diagnostic markers is partly due to the limitations of current markers, as detailed on pages 16-17.

BioCurex anticipates that its RECAF™ technology could have potential as a new cancer marker due to the following reasons:

- Current serum markers may be deficient in terms of sensitivity and specificity, creating a need for enhanced serum markers;
- Current markers for breast and lung cancers (among the most fatal cancers) are not especially useful for diagnostics—areas that RECAF™ seeks to address; and
- There is not yet an all-inclusive cancer marker, thus oncologists are using different markers for each cancer. The Company is developing RECAF™ as a more widespread cancer marker, potentially capable of detecting a variety of cancers with high sensitivity and specificity.

#### *Growth Factors for Cancer Markers*

According to the NCI, 85% of cancer patients are treated in community-based, private practice oncology settings. Accordingly, global expansion of cancer marker technologies may be fueled by an increased marketing of new diagnostic tests to physicians (Source: *Cancer Diagnostic Testing World Markets*).

In addition, as a growing number of people are considered to be at high risk for developing cancer, diagnostic tests may also be administered more frequently. To date, men have a **lifetime risk** of developing or dying from cancer that is slightly less than 1 in 2; for women, the lifetime risk is just over 1 in 3 (Source: ACS). While risk factors for cancer include tobacco and alcohol use, diet, and sun exposure, one of the most significant factors is age. For example, more than 65% of all prostate cancers occur in men over the age of 65, and overall, approximately 77% of all cancers are diagnosed in individuals over the age of 55 (Sources: the Prostate Cancer Foundation [[www.prostatecancerfoundation.org](http://www.prostatecancerfoundation.org)] and ACS).

To this extent, the United Nations (UN) has documented a rapidly aging population worldwide. In developed countries, the number of individuals over 60 years old exceeded the number of children under 15 years old for the first time in 1998. By 2047, the effects of the aging population are expected to be seen globally in developing countries as well as developed nations. By 2050, nearly two billion older persons are expected to be alive. In comparison, there were only 700 million people over 60 alive in 2006 (Source: *World Population Ageing 2007* from the UN's Department of Economic and Social Affairs, Population Division).

#### **The Impact of Rising Healthcare Costs**

In 2006, U.S. healthcare expenditures totaled approximately \$2.2 trillion, forecast to reach \$2.9 trillion in 2009 and \$4 trillion by 2015 (Sources: Blue Cross and Blue Shield Association and the National Coalition on Health Care [[www.nchc.org](http://www.nchc.org)]). For 2005, healthcare accounted for 16% of the gross domestic product (GDP) in the U.S. versus 10.9% of Switzerland's, 10.7% of Germany's, 9.7% of Canada's, and 9.5% of France's GDP. U.S. healthcare premiums increased by 8.8% between 2004 and 2005. The largest cause of this increase was a greater utilization of services, accounting for approximately 43% of the rise in premiums (Source: PricewaterhouseCoopers' *The Factors Fueling Rising Healthcare Costs 2006*). PricewaterhouseCoopers attributes growing utilization to new medical treatments, more intensive diagnostic testing (i.e., defensive medicine), an aging population (which requires more medical attention), and progressively unhealthy lifestyles.

As a result of rising costs, BioCurex estimates that there is a demand for more cost-effective approaches to disease management, specifically for cancer, as well as for emphasis on screening and accurate diagnostic testing to facilitate early detection of potentially very costly, severe afflictions. Likewise, a poll conducted by the Harvard School of Public Health found that 43% of respondents felt that high costs was one of the most important healthcare issues for the government to address (Source: the National Coalition on Health Care). BioCurex also approximates that up to 20% of all diagnostic tests may eventually be performed in non-laboratory settings, such as by patients or non-medical professionals.

## Reimbursement

In the U.S., healthcare providers can be reimbursed for the costs of performing a variety of medical procedures, including diagnostic laboratory tests, for beneficiaries of the nation's Medicare system. Medicare is a federal health insurance program for individuals over age 64 and disabled citizens. Under Medicare guidelines, provider reimbursement is governed by the American Medical Association's (AMA) **Current Procedural Terminology (CPT®) codes**, which identify specific services.

For instance, as listed in Table 6, the CPT® code 82378 indicates a CEA test, and is associated with a reimbursement allowance of \$26.22. This is similar to reimbursement amounts for the PSA test as well as other cancer marker tests, which are \$25.42 and \$28.76, respectively. Code 86316 is a general code used to bill for a variety of cancer marker tests that may not yet have been assigned a separate number. BioCurex views the Medicare reimbursement amounts as a benchmark for cancer marker pricing, as many patients who receive these tests are covered by Medicare.

Table 6  
MEDICARE REIMBURSEMENT FOR CANCER MARKER TESTS

CPT® Code	Test Type	Reimbursed Amount
82378	CEA	\$26.22
84153	PSA	\$25.42
86316	General Tumor Markers	\$28.76

CPT® codes are copyright of the AMA.

Source: BioCurex, Inc.

Like Medicare, other health insurance providers also reimburse for medical procedures, but often at different rates. Blue Shield of New York pays \$70 for a CEA test, while other New York Health Maintenance Organizations (HMOs) only pay, for example, \$12 for the same test. BioCurex believes that higher payments for CEA may reflect a perceived added value in the test. Likewise, the Company proposes that a RECAF™ test to evaluate many types of cancer may also be viewed to have added value.

Due to cost containment practices of managed care organizations as well as federal healthcare programs, certain testing technologies may be used more selectively by medical providers. The Company estimates that reducing healthcare expenses could lead to the reduction or the elimination of cancer markers with low associated sensitivities and specificities. Conversely, BioCurex seeks to commercialize RECAF™ as a high value-added test with widespread utility and significant predictive value that can be marketed within current cost containment guidelines.

## BIOCUREX'S RECAF™ TECHNOLOGY

RECAF™ is a molecule that BioCurex has found to be present on cancer cells. However, it is not found on healthy cells or benign tumor cells, such as a **breast fibroadenoma**, which is not dangerous to health. This characteristic enables RECAF™ to more accurately detect cancer than many current tumor markers, as RECAF™ is less likely to return a false positive result.

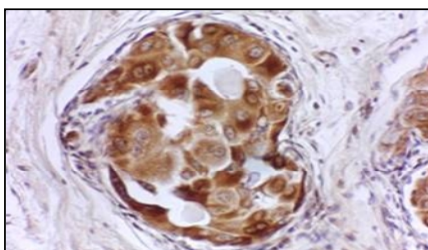
RECAF™ is a receptor for AFP that binds to and takes up circulating AFP. Both AFP and RECAF™ first emerge in the fetus, but disappear by birth. AFP transports small molecules, such as fatty acids, and penetrates cells to release the fatty acids via the RECAF™ receptor, after which it leaves to fetch additional molecules. Once a fetal organ or tissue reaches its maturity, it no longer takes up AFP nor expresses RECAF™. After birth, RECAF™ is only known to exist in a cancerous state, where tissues re-express the ability to take up AFP via the RECAF™ receptor. This implies that expression of RECAF™ is related to rapid tissue growth, which is characteristic of both cancer and fetal development. RECAF™ is classified as an oncofetal antigen due to its presence on both fetal tissues that incorporate AFP and on malignant tissues in later life. However, it is important to note that RECAF™ and AFP are not the same: AFP is primarily used to detect only liver and testicular cancer, whereas RECAF™ may become a more widespread cancer marker.

## Applications of RECAF™ Technology

Three primary applications of RECAF™ technology relate to cancer diagnosis: (1) pathology, (2) blood tests, and (3) tumor imaging. In addition, work at BioCurex could demonstrate that RECAF™ may have potential as a cancer therapeutic. Each RECAF™ application, including therapeutics, is briefly addressed below. The Company's specific product candidates in these areas are further detailed on pages 28-35.

### Pathology

Figure 1  
BioCurex, Inc.  
CANCER CELLS STAINED FOR RECAF™



Source: BioCurex, Inc.

To aid the determination of disease pathology, cells expressing the RECAF™ marker are stained a different color to distinguish them from surrounding normal cells and structures. BioCurex has two cancer detection kits—Histo-RECAF™ and Cryo-RECAF™ (pages 28-30 and 31, respectively)—used to stain tissue, making the cancer clearly visible. Figure 1 illustrates this effect. Lumps and strings of cancer cells that express RECAF™ are stained darker than the adjacent healthy cells. Once the presence of RECAF™ is confirmed, a final cancer diagnosis can be more readily determined under a microscope using either a tissue sample, biopsy, or Pap or sputum (phlegm) smear.

In order to obtain a tissue sample that can be viewed under a microscope, the soft tissue must be cut into sections that are only five microns thick. For comparison, the average width of a human hair is 100 microns. Due to the difficulty in sizing soft tissue to five microns, it is usually combined with **paraffin** (wax) to create a more solid sample. After cutting, paraffin can be removed from the tissue with **solvents**. The tissue is then re-hydrated and can be stained. Alternatively, tissue samples can be frozen into a hardened substance and then cut and tested. BioCurex's Histo-RECAF™ is designed to accommodate paraffin-embedded or fresh tissues, and the Company's Cryo-RECAF™ product uses frozen tissues.

### Blood Tests

In addition to its prevalence on the surface of and within cancer cells in tissue, RECAF™ can also be detected in the bloodstream as diseased cells in the body shed the molecule. As such, BioCurex has developed the RECAF™ technology to be incorporated into a basic blood test that could screen patients and assist with diagnosis, as well as be used as a personalized test to monitor treated patients for disease progression or recurrence.

RECAF™ technology has also shown that it can aid in the determination of whether a tumor is benign or malignant. BioCurex believes that this capability could enable the use of RECAF™ with another common cancer marker, PSA, which is not as accurate at signaling malignancy. As described on pages 16-17 under Limitations of Current Cancer Markers, only 25% to 30% of men that express higher-than-normal amounts of PSA in the blood actually have prostate cancer. The rest have benign prostate conditions. BioCurex anticipates that using RECAF™ with PSA could create a test that is highly specific for a prostate condition (via the PSA marker) and yet also able to better distinguish between a benign and a malignant tumor (via the RECAF™ marker). The advantage for BioCurex is that PSA is already an established marker, and the Company may be able to capitalize on its use to help create a general market for RECAF™.

BioCurex has created a blood test based on RECAF™ technology, called Serum-RECAF™. The Company's license agreements related to this aspect of RECAF™ technology are further detailed on pages 9-10, and Serum-RECAF™ is highlighted on page 33. A separate blood test product, a Rapid Test for point-of-care cancer detection, is also in development.

### Genetic Testing

Recent scientific advances are enabling researchers to use **genetic testing** as a method of identifying a patient's predisposition for developing cancer or other diseases, such as degenerative disease. Genetic tests typically entail obtaining the patient's blood sample and subjecting it to laboratory analysis that studies the DNA. For example, women may be tested for the inherited alterations in their **breast cancer 1** or **breast cancer 2** (BRCA1 or BRCA2) genes. Women with mutated BRCA1 or BRCA2 genes have a higher risk of developing breast and ovarian cancers. Approximately 5% to 10% of women with breast cancer have an inherited form of the disease (Source: NCI).

With current technologies, genetic testing can be costly, ranging from \$100 to over \$2,000 per test, and can take anywhere from a few weeks to several months to receive results (Source: Genetics Home Reference, a service of the U.S. National Library of Medicine). BioCurex believes that, as genetic testing technologies improve in specificity and frequency, its RECAF™ technology may also be used more often in patients that are identified as being at high risk for developing cancer.

### Personalized Testing

If an individual's RECAF™ level is fairly consistent over time, a routine RECAF™ test could detect even a small change in personal levels of the marker, which may indicate the early stages of cancer. The Company estimates that performing a RECAF™ test every three to six months could identify cancers shortly after they manifest. When used in this fashion, RECAF™ testing may be able to more accurately monitor each patient's particular RECAF™ expression, creating a personalized early detection test. BioCurex is conducting further research in this area to determine the constancy of RECAF™ levels.

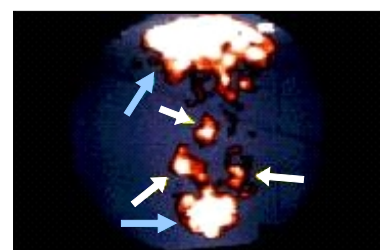
RECAF™ technology may also present a possible preventative measure for cancer patients. If physicians use BioCurex's diagnostic techniques on a regular basis in patients that have recently undergone cancer treatment, the technology may also be able to detect any recurring cancer very early.

### Tumor Imaging

Imaging entails viewing the body's interior and often utilizes radioactive compounds to do so. After diagnosis, oncologists can determine the extent of the cancer by targeting the RECAF™ molecule with radioactive compounds administered to the patient and then observing the highlighted sites using standard imaging equipment.

For example, the white arrows in Figure 2 point to three breast cancer metastases detected with BioCurex's RECAF™ technology. These metastases are located on the lumbar vertebrae and the hip bone. Illuminated at the top and bottom of Figure 2 (marked with light blue arrows) are the liver and the bladder, normal sites of radioactivity accumulation for processing and elimination.

Figure 2  
BioCurex, Inc.  
BREAST CANCER METASTASES  
DETECTED WITH RECAF™ TECHNOLOGY



Source: BioCurex, Inc.

### Therapeutics

Due to its capability to differentiate between a cancer cell presenting the RECAF™ marker and a healthy cell lacking the marker, RECAF™ may enable targeted treatments to impede cancer growth without damaging healthy cells. Early laboratory results in animal models illustrate that BioCurex's technology can shrink tumors, deliberately killing cancer cells. This ability could have implications for a wide variety of cancers, since many current treatments (e.g., chemotherapy and radiation) do not selectively target only cancer cells. To this effect, because the Company's anti-RECAF™ antibodies are designed to bind specifically to the RECAF™ receptor on the cancer cell, therapeutic agents could likely be conjoined with the anti-RECAF™ antibodies and delivered directly to the cancer cell, possibly eliminating many side effects that patients experience with treatments that attack all rapidly growing cells, cancerous or healthy.

Another therapeutic use of RECAF™ technology may include cancer vaccines and immunotherapy. Preliminary data have shown that animals injected with cancer cells and treated with anti-RECAF™ antibodies do not develop tumors, whereas control animals do. BioCurex expects to focus more aggressively on therapy in the future, as the Company has initially pursued diagnostic interests.

### **Summary of Research Results with RECAF™ Technology**

Based on BioCurex's research to date, RECAF™ appears to be a virtually universal marker for multiple tissue types. It is expressed on over 90% of the breast cancer samples that BioCurex has studied thus far, as well as on lung, stomach, colon, ovarian, and prostate cancer samples, among others. Altogether, every cancerous tissue that the Company has tested has expressed RECAF™. Moreover, to BioCurex's knowledge, there is no other cancer marker that has the same wide-ranging presence of RECAF™. As such, BioCurex believes that RECAF™ could replace many currently available cancer markers that are targeted to only one type of cancer, as well as offer a useful diagnostic tool for cancers where there is not yet thought to be an effective marker, such as lung and breast cancer.

#### *Immunohistology*

Early studies illustrated that immunohistological staining with **murine** MAbs to RECAF™ could correctly identify human **mammary** carcinomas as well as benign adenomas. In June 2001, BioCurex received results from independent researchers that its Histo-RECAF™ cancer detection kit positively identified as cancerous 100% of malignant breast tissue and only 4% of benign breast tissue. Further studies found positive RECAF™ staining in 21/23 mammary carcinomas, 14/15 lung cancers, 8/8 colon carcinomas, and several *in situ* (early stage) cancers. Additionally, between May 2003 and April 2004, an independent group of Japanese researchers tested cancer tissue with Histo-RECAF™ and found that the kit accurately and clearly stained approximately 83% of cancerous tissue. These researchers operated on a voluntary basis, without charge to BioCurex. While this collective data validated the Company's Histo-RECAF™ product, it also confirmed the detection capabilities of the RECAF™ technology as a whole.

#### Gastric Cancer

During October 2006, BioCurex reported details of an independent confirmation of RECAF™ technology's ability to identify normal, benign, and malignant stomach tissue. Using a variation of the Histo-RECAF™ kit, scientists from the Shigei Medical Research Hospital (Japan) found that RECAF™ was expressed in 34/47 cancerous tissue samples, but not present in 59/61 normal or benign samples (Source: *Tumor Biology* 2006). Other institutions involved in this study included the Okayama University Graduate School of Medicine, Dentistry and Pharmaceutical Sciences; the Okayama Citizen's Hospital; and the Oota Memorial Hospital.

#### *Blood (Serum) Tests*

Since 2004, BioCurex has performed over 120,000 tests on more than 4,000 serum samples. Collective results of these studies have shown that the Company's serum-based assay, Serum-RECAF™, has between a 80% and 90% sensitivity for a variety of cancers, with a 95% specificity for lung, breast, stomach, and ovarian cancers. Moreover, these tests have demonstrated that RECAF™ technology has improved performance over competing technologies at detecting prostate cancers and at discriminating between malignant and benign lesions.

#### Radioimmunoassay (RIA) Format

The data presented on the accompanying pages were obtained using BioCurex's first-generation blood test, which was a radioimmunoassay (RIA). RIAs have been successfully used for over 50 years. Yet, while the RIA can detect one particular substance (e.g., RECAF™) from among hundreds of different molecules in a serum sample by utilizing minute amounts of measurable radioactivity, it is not the most ideal assay format. RIAs are subject to a short lifespan due to radioactive decay as well as heavy government regulation regarding use and shipment. At the start of 2006, BioCurex began researching an alternative assay format—a colorimetric (or chemiluminescence) blood test. Data related to the performance of the colorimetric assay in breast and prostate cancers is provided on pages 26-27. Page 32, under Blood and Serum Tests, more fully details the Company's transition away from an RIA test.

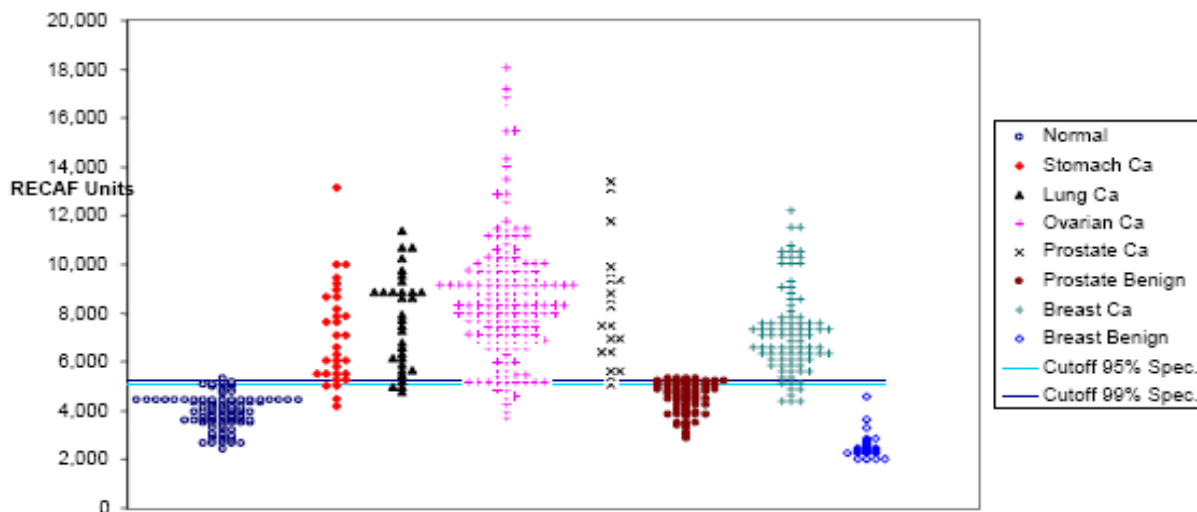
As presented at the NCI's 3<sup>rd</sup> Annual Early Detection Research Network (EDRN) Scientific Workshop (Boston, Massachusetts) and at the International Society of Oncodevelopmental Biology and Medicine (ISOBM) annual meeting (Helsinki, Finland) in 2004, these results found that RECAF™ had an 80% to 90% sensitivity for a variety of cancers, with a 95% specificity for lung, breast, stomach, and ovarian cancers in particular. Sensitivity is a measure of how well a test correctly diagnoses a condition, for instance, the proportion of truly diseased persons in a screened population who are identified as being diseased by the test. Specificity is a measure of the probability of correctly identifying a non-diseased person (or sample).

Additional data from studies during 2004 documented that RECAF™ technology could detect 92% of cervical cancer serum samples with a 95.7% specificity. There were 25 cervical cancer samples and 69 normal samples involved. Conversely, the Pap test, which is widely used to detect cervical abnormalities, has an estimated sensitivity for high-grade lesions of only 55% to 80% (Source: NCI). Further, BioCurex compared 73 colon cancer samples to 352 normal samples and discovered that its RECAF™ blood test had a sensitivity of 74% with a 95% specificity. When the specificity was improved to 100%, the test was still able to identify over 71% of the colon cancers.

In June 2005, BioCurex published an article in *IVD Technology*, a trade journal designed exclusively for manufacturers of *in vitro* diagnostic products, containing scientific data relating to the RECAF™ marker. Figure 3, as was published in *IVD Technology*, illustrates the distribution of RECAF™ values in a variety of normal, cancer, and benign tumor samples. This Figure highlights the variations in RECAF™ expression (RECAF™ units) that enable the identification of “normal” versus “cancer” or “benign.” The horizontal lines represent the cutoff values for 95% and 99% specificity. At the 99% cutoff, only 1% of normal samples fall above the line, whereas at the 95% cutoff, 5% of normal samples are above the line.

Figure 3  
BioCurex, Inc.

RECAF™ DISTRIBUTION IN SEVERAL COMMON CANCERS



Sources: *IVD Technology* (2005) and BioCurex, Inc.

Likewise, Table 7 summarizes the sensitivity of RECAF™ detection in these same cancer samples for each of the specificity values. Each cancer type in Table 7 was compared against 103 normal samples. This data suggests a total sensitivity for RECAF™ of 94% across all cancers when the specificity is 95%, and 91% when the specificity is increased to 99%.

Table 7  
BioCurex, Inc.  
SENSITIVITY AND SPECIFICITY WITH RECAF™ IN SEVERAL COMMON CANCERS

Cancer Type	Sensitivity with 95% Specificity (%)	Sensitivity with 99% Specificity (%)	Number
Ovarian	96	92	162
Stomach	90	87	31
Lung	91	87	32
Breast	93	90	88
Prostate versus Normal	99	95	20
<b>Total</b>	<b>94</b>	<b>91</b>	<b>333</b>
Breast benign*	0	0	22
Prostate benign*	25	5	77

\*At the 95% cutoff value, a small percentage of benign breast and prostate samples were positive. Increasing the cutoff value to include 99% of normal individuals reduces the percentage of false positives, at the expense of a slight decrease in sensitivity.

Sources: IVD Technology (2005) and BioCurex, Inc.

## Colorimetric Format

### Breast Cancer

In early 2006, further tests for RECAF™ in early stage breast cancers found that the marker was able to detect even the initial stages of cancers with a high degree of accuracy. These studies were blinded, indicating that BioCurex's researchers were unaware of the status of each sample (e.g., cancerous or normal) until after the tests were performed. As listed in Table 8, RECAF™ technology detected 90% to 93% of all the Stage I and Stage II breast cancer samples. In addition, the marker did not return any false positives. The Company believes that mammograms, a current standard for detecting breast cancer, only have a sensitivity of approximately 65% to 75%, with a 90% specificity. Yet Medicare reimburses for mammograms at an estimated rate of \$135 for digital and \$85 for film. If breast cancer can be caught and treated at its earliest stages, patients have five-year survival rates between 81% and 100% versus only 20% by Stage IV (Source: MedlinePlus).

Table 8  
BioCurex, Inc.  
DETECTION OF EARLY STAGE BREAST CANCERS USING RECAF™

Cancer Stage	Sensitivity	Specificity	Number of Samples
Stage I	90%	100%	42
Stage II	93%	100%	45

Source: BioCurex, Inc.

### Prostate Cancer

- In May 2006, BioCurex announced results from tests using RECAF™ technology to detect early stage prostate cancers. The Company performed two types of studies on RECAF™ for prostate cancer: (1) the marker's ability to differentiate between a patient with prostate cancer and a healthy individual; and (2) the marker's ability to discriminate between a cancerous prostate condition and a benign condition. Table 9 (page 27) summarizes the results for each prostate cancer stage tested.

Table 9  
BioCurex, Inc.  
DETECTION OF EARLY STAGE PROSTATE CANCERS USING RECAF™

Prostate Cancer Patient versus a Healthy Patient			
Cancer Stage	Sensitivity	Specificity	Number of Samples
Stage I and Stage II	75%	100%	84
Stage III	85%	100%	20
Stage IV	86%	100%	28

Prostate Cancer versus a Benign Prostate Condition			
Cancer Stage	Sensitivity	Specificity	Number of Samples
Stage I and Stage II	68%	97%	84
Stage III	80%	97%	20
Stage IV	68%	97%	28

Source: BioCurex, Inc.

Whereas currently only 25% to 30% of men with a positive PSA test are actually found to have prostate cancer, BioCurex's results demonstrate between a 97% and 100% specificity (little to no false positives) when detecting prostate cancer with RECAF™. In addition, the Company is able to identify the cancer even in early stages (Stage I and Stage II), when chances for survival are greatest. The five-year survival rate for prostate cancer caught early is nearly 100% versus only approximately 30% to 34% once the cancer has spread.

- In July 2006, BioCurex presented further results of its RECAF™ test at the American Association for Clinical Chemistry's (AACC) Annual Meeting. These data illustrated that the Company's serum test was able to better discriminate between malignant and benign prostate conditions than both the standard PSA test and the enhanced **Free PSA** test. In a study of 130 serum samples, composed of 100 known cancer sections and 30 benign lesions, RECAF™ technology produced a sensitivity of 90% and specificity of 84%. When normal samples were included in addition to the cancer and benign samples, the sensitivity and specificity of the RECAF™ test was nearly 100%.

Comparatively, in the Company's studies, the standard PSA test had a sensitivity of only 48% and a specificity of 60%. The 48% sensitivity indicates that the standard PSA test did not detect 52% of the cancers; the 60% specificity indicates that it returned false positives in 40% of the samples, which would have subjected those patients to unnecessary biopsies. Using the Free PSA test improved specificity to 70%, but also doubled the cost of the test.

- By October 2006, BioCurex was able to present data demonstrating that its RECAF™-based colorimetric assay detected more than twice as many prostate cancers as did the PSA test. The Company sampled 68 Stage I or II prostate cancers, with a 71% sensitivity and an 87% specificity. Yet, only 27% of the samples that RECAF™ correctly identified as cancerous had PSA values above 4 ng/ml, which is the traditional cut-off level used with the PSA test to distinguish between a normal sample (<4 ng/ml) and a cancer sample (>4 ng/ml). Accordingly, the Company believes that a standard PSA test would not have detected many of these early cancers. When the study was expanded to include 28 more advanced cancer samples, the RECAF™ test had an 86% sensitivity and a 95% specificity.

Additional data on RECAF™ can be found on pages 32-35 for both the Serum-RECAF™ product candidate and the Company's potential Rapid Test for point-of-care cancer detection.

**PRODUCT PIPELINE**

All of BioCurex’s product candidates are based on the RECAF™ technology, which is also semi-exclusively licensed to Abbott and Inverness (detailed on pages 9-10). At present, the Company’s pipeline includes product candidates for histology and cytology, blood and serum tests, tumor imaging, and leukemia therapy. Within these areas, BioCurex has developed Histo-RECAF™ and Cryo-RECAF™ product kits for histology and cytology and is working toward the establishment of the Serum-RECAF™ blood test and a Rapid Test for point-of-care cancer detection. Product areas and candidates are summarized in Table 10 and described thereafter.

Table 10  
BioCurex, Inc.  
PRODUCT PIPELINE

<b>Histology and Cytology</b>	
<i>Histo-RECAF™</i>	a histological cancer detection kit for staining RECAF™ in tissue cells; approved as a Class 1 Medical Device in the U.S.
<i>Cryo-RECAF™</i>	a diagnostic kit to identify malignant versus benign cells during surgery; approved for research use only
<b>Blood and Serum Tests</b>	
<i>Serum-RECAF™</i>	a serum-based cancer screening assay to detect multiple cancers from a blood or serum sample
<i>Rapid Test</i>	a blood test for point-of-care cancer detection
<b>Tumor Imaging</b>	
<b>Leukemia (Therapeutic Application)</b>	

*Sources: BioCurex, Inc. and Crystal Research Associates, LLC.*

**Histology and Cytology**

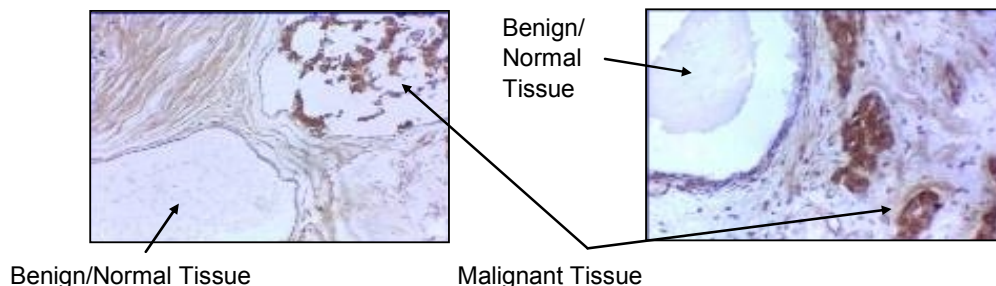
For histology (study of tissues) and cytology (study of cells), BioCurex has developed a cancer detection kit and a diagnostic kit, called Histo-RECAF™ and Cryo-RECAF™, respectively. Due to the high costs associated with manufacturing and marketing these kits, the Company intends to license both Histo-RECAF™ and Cryo-RECAF™ technology to third parties. The U.S. Food and Drug Administration (FDA) has already granted Histo-RECAF™ Class I Medical Device status. For Cryo-RECAF™, BioCurex hopes to outlicense the technology to a third party that can complete the research and clinical studies required for FDA (or other regulatory agency) clearance for commercial sale. If submitted for clearance, the Company anticipates that Cryo-RECAF™ could also be classified as a Class I Medical Device.

**Histo-RECAF™**

BioCurex’s Histo-RECAF™ is a histological cancer detection kit for staining RECAF™ in tissue cells. This kit stains malignant and regenerating cells brown, which distinguishes the diseased cells from other normal, healthy cells that may also be present in the tissue (as illustrated in Figure 4 [page 29]).

Figure 4  
BioCurex, Inc.

RECAF™ DETECTION OF MALIGNANT AND BENIGN/NORMAL CELLS IN THE SAME BREAST TISSUE



Source: BioCurex, Inc.

With staining, pathologists are able to more easily identify cancer cells under a conventional microscope and subsequently make a diagnosis. Microscopic examination of Histo-RECAF™-stained tissue can also indicate the density and **morphology** of malignant cells. When combined with a conventional Pap smear, it is believed that Histo-RECAF™ has the potential to significantly reduce false positive readings due to its degree of sensitivity. In addition, if it is used in an automated system that employs vision recognition, Histo-RECAF™ may be able to considerably reduce computer processing time, as the system only needs to examine the spots (cells) on the slide that are stained brown. With tests such as Pap smears that are routinely executed approximately 180 million times each year (worldwide), reduced computer time could be particularly beneficial.

The FDA has classified Histo-RECAF™ as a Class I medical device exempt from **premarket notification**. Accordingly, these kits can be sold in the U.S. as a staining test for AFP receptors (RECAF™) in tissues. However, this product is not yet approved as a **510(k)** diagnostic device; therefore, it may only be marketed as an adjunct to standard light microscopy staining methods in order to aid in the identification of cancer in breast and axillary (armpit) node tissue.

*Kit Components*

Figure 5 depicts the components of the Histo-RECAF™ kit, which includes 100 ml of Wash Buffer, 1.5 ml of Reagent A, 1.5 ml of Negative Control, 30 ml of Diluent, 0.6 ml of Diaminobenzidine (DAB) Reagent, 15 ml of Peroxide Reagent, and Positive Controls. Each kit includes enough reagents for 60 tests, including negative controls.

Figure 5  
BioCurex, Inc.  
HISTO-RECAF™



Source: BioCurex, Inc.

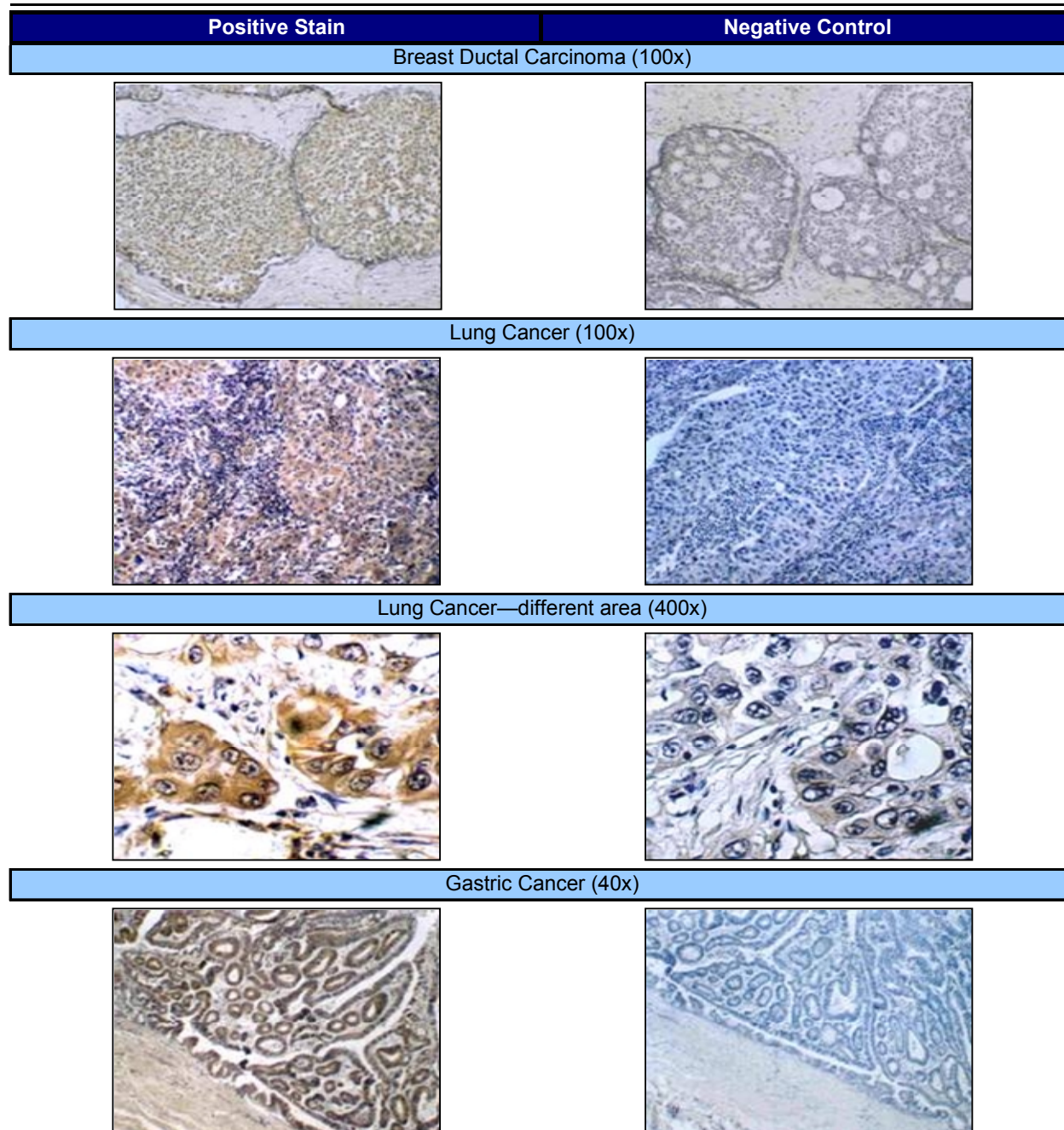
*Histo-RECAF™ Procedure*

The Histo-RECAF™ procedure entails incubating tissue slides with Diluent and Reagent A, which binds to RECAF™ on the cell surface and cytoplasm (the substance between the cell membrane and nucleus). Then, to stain brown the cells that express RECAF™, the tissues sections are **incubated** with a mixture of DAB and hydrogen peroxide. At the same time, a parallel section of tissue is incubated with the Negative Control (instead of Reagent A) to provide a negative baseline for the color reaction. Figure 6 depicts several Histo-RECAF™-produced stains versus the negative controls for common cancers. Malignant cells are stained brown, with the exception of the cell nuclei, which is typically negative.

Figure 6

BioCurex, Inc.

STAINING FOR RECAF™ TO IDENTIFY MALIGNANT CELLS, VARYING MAGNIFICATIONS



Sources: BioCurex, Inc. and Crystal Research Associates, LLC.

**Cryo-RECAF™**

As shown in Figure 7, BioCurex has also created Cryo-RECAF™, a diagnostic kit for use by pathologists during surgery. Each kit is designed for use on a single patient. Although it is fully developed, the Company has not yet applied to regulatory authorities in the U.S., Canada, or elsewhere for permission to market Cryo-RECAF™ as BioCurex seeks a partner to aid the commercialization process.

Figure 7  
BioCurex, Inc.  
CRYO-RECAF™

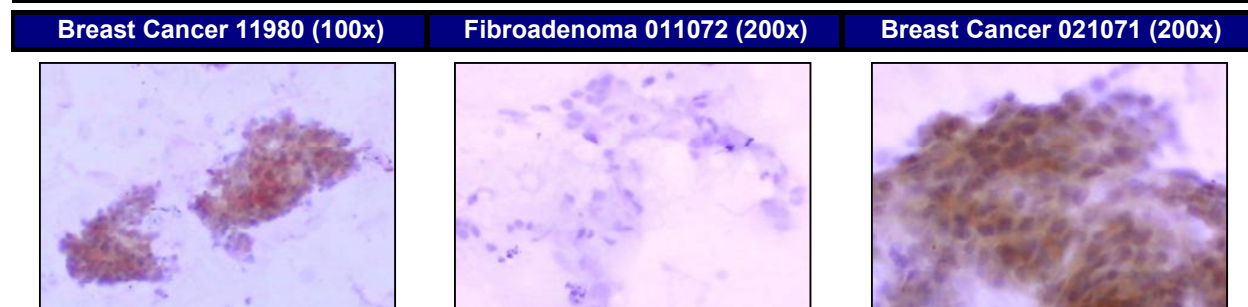


Source: BioCurex, Inc.

Often, it is still unclear by the time of surgery whether cells are benign or malignant. Cryo-RECAF™ is designed to allow surgeons and pathologists to excise, freeze, slice, stain, and examine tissue while the patient remains under anesthesia. While not as comprehensive as the Histo-RECAF™ kit, Cryo-RECAF™ can return results within 15 minutes, which enables surgeons to quickly decide on the proper surgical procedure. Figure 8 depicts breast tissues stained with a modified Cryo-RECAF™ kit.

Figure 8  
BioCurex, Inc.

NEEDLE BIOPSY STAINING WITH MODIFIED CRYO-RECAF™ (100 AND 200 TIMES MAGNIFICATION)



Source: BioCurex, Inc.

### ***Blood and Serum Tests***

In addition to presenting the RECAF™ molecule on the cell surface or cytoplasm, cancer cells shed the marker into the body's blood stream or other bodily fluids. As a result, BioCurex can detect the marker using either its tissue- and cell-based stains or a blood (serum) test. The Company has been working toward the commercialization of a screening assay that can detect multiple cancers from a blood sample since March 2002.

#### *Radioimmunoassay (RIA) Format*

Originally, BioCurex had designed a RECAF™ blood test that employed low doses of radioactivity, called an RIA. RIAs are very sensitive, specific laboratory assays that use radiolabeled substances in an immunological (e.g., antibody-antigen) reaction. The Company still retains all rights to its original prototype radiolabeled format, but now intends to commercialize this RIA directly to clinical laboratories for use in production of the laboratories' own tests rather than as a license option for large biopharmaceutical companies. For outlicensing to other companies, BioCurex has designed a new colorimetric test.

#### Manual Testing with an Analyte Specific Reagent (ASR)

For potential commercialization to clinical laboratories, the Company seeks to classify its test as an **Analyte Specific Reagent (ASR)**. ASRs are composed of chemicals or antibodies that can be considered the active ingredients of laboratory-developed tests and thereby purchased from manufacturers under this label. Once the base ingredients are purchased, an ASR manufacturer essentially reassembles the components into a manual test, versus an automated test used by the high-throughput diagnostic machines employed in large clinical laboratories. The majority of ASRs are exempt from FDA approval or clearance, but consequently, ASR manufacturers are prohibited from making claims of analytical or clinical performance (Source: College of American Pathologists). By commercializing an ASR, BioCurex anticipates that laboratories could produce independent RECAF™ tests based on the Company's test without requiring a lengthy FDA approval process or costly automated diagnostic instruments.

#### *Colorimetric Format*

Based on input from potential licensees of the first-generation, radiolabeled blood test, BioCurex opted to redesign its assay in a colorimetric (or chemiluminescence) format. Most of today's high-throughput automated diagnostic systems use colorimetric assays. This type of test is expected to have a longer shelf-life as well as be easier to use and easier to ship to laboratories, all of which could encourage more licensees to adopt the test. The new assay is easier to ship partly because BioCurex is now able to freeze-dry the reagents, a development that arose as part of the research into the test's redesign.

BioCurex spent all of 2006 and early 2007 converting its blood test. While doing so, the Company discovered that the new format improves detection of smaller, earlier stage tumors and magnifies the measured difference in RECAF™ serum values between cancer and normal patients. This progress is exemplified by the Company's 2006 studies of breast and prostate cancers (detailed on pages 26-27), which found that the new RECAF™ blood test can detect over 90% of Stage I and II breast cancers and 75% of Stage I and II prostate cancers. Moreover, the greater discrimination between cancer and normal patients enabled by the colorimetric test also allowed BioCurex to begin development of a Rapid Test for point-of-care cancer detection.

To date, BioCurex is progressing two product candidates based on its blood testing technology: (1) Serum-RECAF™; and (2) the Rapid Test.

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## Serum-RECAF™

The Company anticipates that Serum-RECAF™ can be easily used to initially screen patients who present symptoms of cancer as well as to monitor patients who have already been treated for cancer. BioCurex believes that its Serum-RECAF™ assay performs better than many current technologies at detecting prostate cancer as well as at discriminating between malignant and benign tumors. Accordingly, Serum-RECAF™ may have the potential to become a standardized blood test widely available in clinical laboratories due to its detection capabilities and ease of use. If successfully developed and submitted to the FDA for clearance, the Company believes that Serum-RECAF™ may be considered a **Class II Medical Device**. Future variations of this product could include the ability to test saliva and urine for RECAF™ as well as serum.

### *Recent Serum-RECAF™ Results*

In September 2007, BioCurex and Abbott submitted results to the ISOBM of two RECAF™ studies completed under a joint initiative with BioCurex, Abbott, and the University of Munich. The ISOBM accepted the results for presentations at international cancer congresses. Each presentation provides additional support for the efficacy of RECAF™ technology and is summarized below.

- The first presentation was titled *cHEMILUMINEsCENT aSSAY (CIA) FOR THE rECEPTOR OF aLPHA fETOPROTEIN (recaf) to separate cancer from normal SERA*. Study results documented in this presentation demonstrated the ability of the RECAF™ cancer marker to identify cancerous cells versus non-cancerous cells. Using several different automated assay instruments, which included Abbott's Architect® diagnostic platform, researchers compared 68 breast, gastric, and other cancers to 52 normal samples. The reported area under curve (AUC) was 0.954. A score of 1.0 would indicate perfect discrimination between cancer and non-cancer samples. Additional studies with prostate cancer samples at Abbott's facilities reported similar results. (Abbott's Architect® platform is an integrated immunoassay and clinical chemistry system that is widely used in major clinical laboratories.)

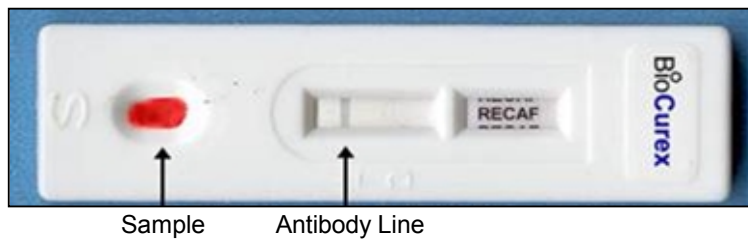
To determine the AUC, BioCurex utilized a statistical test called **Receiver Operating Characteristic (ROC)**. An ROC curve plots the fraction of true positives versus the fraction of false positives. ROC analysis is widely used in medicine, radiology, psychology, and diagnostics.

- The second RECAF™ study sought to determine the best type of specimen-collecting tube for RECAF™ testing in a clinical laboratory environment. As not all collection tubes are compatible with certain assays, BioCurex believes that it is necessary to delineate the chemically compatible tubes prior to commercializing a serum test. For example, one type of collection device, a vacuum tube, utilizes different chemical combinations to accelerate or prevent clotting as well as separate the clot from the serum. Results of this study indicated that the RECAF™ assay can be compatible with the most commonly used serum collection tube types.

### **Rapid Test**

BioCurex is also developing a Rapid Test for initial point-of-care cancer detection in physicians' offices, third-world countries, or areas with large rural populations, such as China and India. In these locales, which may have limited access to large clinical laboratories, a Rapid Test must be able to provide a significant discrimination between cancer cells and normal cells in order to accurately display either "yes" or "no" to cancer in the form of a colored antibody line (shown in Figure 9 [page 34]).

Figure 9  
BioCurex, Inc.  
PRELIMINARY RAPID TEST CARTRIDGE

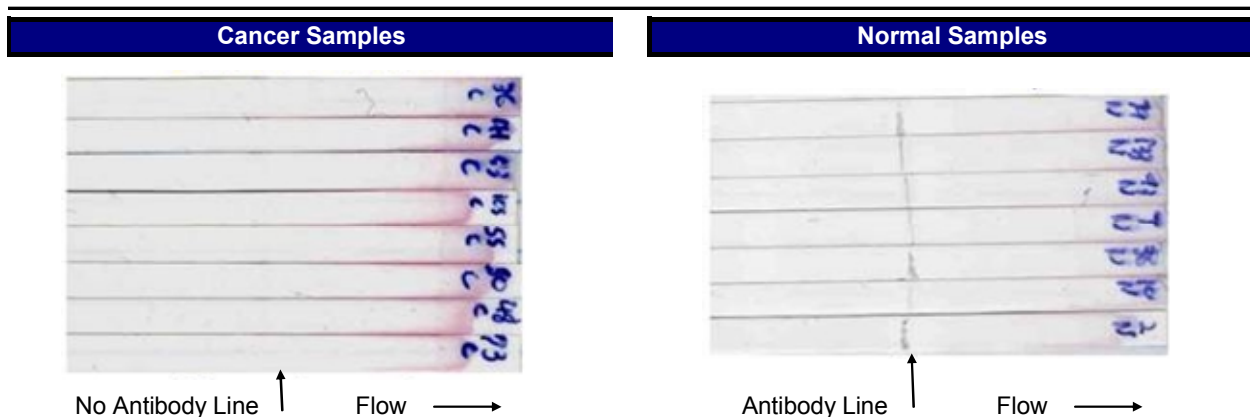


Source: BioCurex, Inc.

In essence, BioCurex’s point-of-care test device is similar to a common pregnancy test kit. The Rapid Test cartridge contains a small strip that is coated with dried, colored RECAF™ on one end (the left side of Figure 9, where a patient would deposit a blood sample) and anti-RECAF™ antibody in the middle. The far right side of the strip consists of an absorbent pad. After the patient’s blood sample is placed on the strip, it reacts with the existing colored RECAF™. If the sample contains little to no RECAF™ (indicative of a normal sample with no cancer cells), the colored RECAF™ migrates via **capillary action** toward the strip’s anti-RECAF™ antibody. The anti-RECAF™ antibody then retains the colored RECAF™ in the middle of the strip, where it appears as a thin line called the antibody line. Alternatively, a blood sample that contains RECAF™ competes with the strip’s existing RECAF™, as both attempt to bind to the anti-RECAF™ antibody. The antibody becomes saturated and the colored RECAF™ cannot bind to it, thereby resulting in no antibody line.

Consequently, when the Rapid Test is administered, the appearance of the antibody line indicates that the patient likely does not have cancer; if no line appears, the patient may have cancer and would be referred for additional diagnostic testing. Figure 10 shows images of strips obtained during BioCurex’s preliminary studies with its Rapid Test, clearly delineating between a cancerous blood sample and a normal sample based on the presence of the antibody line.

Figure 10  
BioCurex, Inc.  
PRELIMINARY RAPID TEST RESULTS



Source: BioCurex, Inc.

An added component—a small, portable instrument such as that used for monitoring blood sugar—may also be needed to accompany the Rapid Test. This instrument would likely be used for reading the intensity of the color of the test’s antibody line. BioCurex is still researching the necessity of this element.

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When a patient enters a physician's office with a specific symptom or concern where cancer is suspected, the physician could administer the Rapid Test to receive an immediate yes or no cancer reading. The Company anticipates that such a cancer test could be used in the future as easily and as routinely as a blood sugar or cholesterol reading is now requested as part of a blood test. For verification of the Rapid Test, BioCurex expects to use the more detailed Serum-RECAF™ laboratory test. Ideally, the two tests could function in concert, with the Rapid Test serving to expand the use of Serum-RECAF™.

#### *Recent Results Using the Rapid Test*

BioCurex has recently presented preliminary results with its Rapid Test to an international cancer congress. Data indicated solid discrimination between cancer and healthy cells and correlated with results from the Company's Serum-RECAF™.

With the N.N. Blokhin Cancer Research Center (Moscow, Russia), BioCurex studied RECAF™ as a Rapid Test for ambulatory cancer detection. Results found that RECAF™ could detect 80.4% of ovarian cancers in Stages I to III with an 88% specificity. This study tested 64 normal, non-cancerous samples and 51 ovarian cancer serum samples, which included 25 Stage I or II cancers and 26 Stage III cancers. BioCurex believes that these results signify a potential breakthrough that could simplify cancer detection.

Outcomes also illustrated that a rapid lateral flow **chromatography** test based on RECAF™ can discriminate between cancer and normal samples. Moreover, when applied to early stage ovarian cancer, the Rapid Test demonstrated better performance than a CA-125 blood test, a tumor marker often found in higher-than-normal amounts in the blood of women with ovarian cancer.

#### *Tumor Imaging*

In addition to aiding cancer detection, BioCurex's RECAF™ technology benefits patients and physicians by selectively identifying cancer cells. Radioactive compounds can be targeted to the RECAF™ cancer marker and corresponding cancer cell. Tumor locations can then be imaged using standard equipment to determine the cancer's location and size. The Company has obtained preliminary results in humans illustrating the effectiveness of RECAF™ for imaging tumors as small as 1.5 cm. In mice, BioCurex has imaged breast tumors as small as 4 mm. Unlike many antibodies used in this manner, RECAF™ is a **homologous** protein, and as such, does not need to be **humanized** before use. Humanizing antibodies is often employed to prevent a patient's immune system from rejecting the agent.

#### *Leukemia (Potential Therapeutic Application)*

As RECAF™ technology can detect blood cancers in addition to tissue-based cancers, the Company is also able to identify and mark leukemia cells. When only the infected blood cells are isolated, there is a potential for targeted treatment. If anti-RECAF™ antibodies could be used to clean patients' bone marrow *in vitro*, the cleansed marrow might then be able to be used in autografts (removed from the patient to be transplanted into another site on the same patient) following whole body radiation or chemotherapy.

Further, BioCurex believes that its technology could enable physicians to detect recurrences of blood cancers at an early stage using currently available equipment. With a technique called **cytofluorometry** (analyzing cells using florescent markers), leukemia patients under treatment could be consistently monitored for the reappearance of a small yet significant number of malignant cells in the blood stream. Theoretically, cytofluorometry can detect one cancer cell in a group of 100,000 to 1 million normal cells. The sensitivity of cytofluorometry is believed to be higher than that of conventional blood smear microscopy, which could enable increased therapy efficiencies and aid physicians in making treatment (chemotherapy) decisions for leukemia patients.

## Competition

BioCurex may compete with a variety of companies, most notably the diagnostic product divisions or subsidiaries of large pharmaceutical and medical companies that market cancer detection kits, instruments, and reagents used in clinical laboratories to measure levels of serum cancer markers. In addition, potential competition may include smaller companies that seek to discover improved cancer markers or that are developing new diagnostics. However, to BioCurex's knowledge, there are no other cancer markers either being developed or that have been referenced in scientific literature that can detect nearly all cancer types, reliably detect over 90% of breast and lung cancers, or be used to image the location of most cancers. Table 11 is not an exhaustive listing, but it is indicative of the type of competition the Company faces.

Table 11  
BioCurex, Inc.  
COMPETITION

Company Name	Symbol (Exchange)	Last Trade (04/08/08)	52-week Range	Avg Vol (3 month)	P/E	Market Cap
F. Hoffmann-La Roche Ltd.*	ROG-VTX	182.10	182.20 - 237.80	3,197,940	N/A	N/A
Dako A/S	private	N/A	N/A	N/A	N/A	N/A
DIANON Systems, Inc., part of Lab. Corp. of America Holdings	LH-NYSE	73.54	65.13 - 82.32	1,267,540	18.86	8.19B
Miraculins Inc.**	MOM-TSX.V	0.20	0.10 - 0.69	13,021	N/A	N/A
Ortho-Clinical Diagnostics, Inc., part of Johnson & Johnson Co.	JNJ-NYSE	66.23	59.72 - 68.85	13,360,300	18.22	187.63B

Organization Name	Mission
National Cancer Institute (NCI)	Created by the 1971 National Cancer Act, the NCI fosters cancer research, including in the areas of discovering new, more effective cancer biomarkers.
*Amounts in Swiss Francs.	**Amounts in Canadian Dollars.

Sources: Crystal Research Associates, LLC, Yahoo! Finance, and the National Cancer Institute.

### Roche Diagnostics

For more than 100 years, F. Hoffmann-La Roche has focused on the discovery, development, manufacture, and marketing of healthcare solutions. It is presently divided into two operating units: pharmaceuticals and diagnostics. Roche Diagnostics offers products and services for all fields of medical testing and is a leader in *in vitro* diagnostics, which tests bodily fluids and tissues for disease. Its products range from at-home blood glucose monitoring devices and point-of-care testing devices to high-throughput laboratory systems and state-of-the-art instruments for genetic research. The company's hemo FEC<sup>®</sup> test offers preventive screening for intestinal cancer that can obtain results within 30 seconds. During 2006, the company launched 10 new major products created by the Diagnostics Division, and its proteomics research has recently identified several new biomarker candidates for colorectal, lung, and breast cancer. Additionally, Roche is developing the AmpliChip p53 Test, which seeks to identify mutations of the p53 gene that allow cancer cells to proliferate. Mutations of this gene are thought to exist in most tumor types. Roche believes that, in the future, this test could assist the assessment of cancer patients and help select the therapies best suited to their needs.

### Dako A/S

Founded in Denmark in 1966, Dako is a closely held company that develops and markets cell-based cancer diagnostics, aiming to improve tissue-based diagnostics by focusing on facilitating workflow in the pathology laboratory. The company sells instruments, reagents, and software that reduce the time from biopsy to diagnosis while seeking to increase quality and reliability as well. As of December 2006, Dako had 1,300 employees. Its current products include pharmDx<sup>™</sup>, a collection of tests to determine cancer

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types and measure the effectiveness of the associated treatments. For example, Dako's epidermal growth factor receptor (EGFR) pharmDx™ Kit aids the identification of colorectal cancer patients who are eligible for treatment with ImClone Systems Inc.'s (IMCL-NASDAQ) Erbitux® (cetuximab) or Amgen, Inc.'s (AMGN-NASDAQ) Vectibix™ (panitumumab). In addition, the company markets a wide variety of antibodies and reagents to stain tissue for diseases, including Hodgkin's lymphoma, small-cell carcinoma, and mesothelioma.

#### *DIANON Systems, Inc.*

DIANON is a company of Laboratory Corp. of America Holdings. Its mission is to provide physicians with comprehensive anatomic and clinical pathology services, patient information, and business solutions for their practices. DIANON specializes in uropathology, dermatopathology, gastrointestinal pathology, hematopathology, and breast and Ob/Gyn pathology. The company uses cytogenetic and molecular testing methods to help predict the course of certain diseases and guide therapy choices. In addition, DIANON maintains a portfolio of serum tumor markers that aid the detection of disease and monitor therapy. For instance, DIANON's TriView Pro IHC Stain combines the p63, CK903, and p504s immunostains on one slide to improve diagnosis of prostate cancer beyond that achieved with individual stains. The p63 and CK903 stain benign and high-grade prostatic intraepithelial neoplasia (PIN) cells brown, while the p504s stains them red.

#### *Miraculins Inc.*

Incorporated in 1998, Miraculins is a biotechnology company focused on finding and validating cancer biomarkers for use in developing diagnostic tools and therapeutic products. To aid early cancer detection and diagnosis, the company uses a proprietary B.E.S.T. Platform™ to screen and identify target proteins and peptides related to diseases. Miraculins is developing five cancer diagnostic programs—one each for prostate, colorectal, pancreatic, gastric, and breast cancers. The prostate cancer diagnostic is a urine-based test that Miraculins believes has a sensitivity and specificity greater than the PSA test. On November 29, 2007, Miraculins filed a pre-Investigational Device Exemption (IDE) submission with the FDA in preparation for a planned clinical study for the P2V™ prostate cancer diagnostic test. The company's additional tests are serum based instead of urine based, and are in either the discovery or validation stages. In addition, Miraculins anticipates that its potential colorectal cancer diagnostic could have a sensitivity and specificity greater than the fecal occult blood test, which is used for initial colorectal screening. The company does not yet have any products in commercial use.

#### *Ortho-Clinical Diagnostics, Inc.*

Ortho-Clinical, a Johnson & Johnson company, supplies diagnostic products and services for the global healthcare community that screen, diagnose, monitor, and confirm diseases. Its focus areas include screening donated blood, ensuring patient-donor compatibility in blood transfusions, creating enhanced technologies for *in vitro* diagnostic testing and other clinical chemistry applications, and furthering immunodiagnosics through chemiluminescence and immunoassays for oncology and infectious diseases, thyroid function, reproductive endocrinology, cardiology, anemia, and metabolism. Ortho-Clinical is headquartered in Raritan, New Jersey, with research headquarters in Rochester, New York, and facilities in Canada, the UK, France, Germany, Italy, Spain, Japan, Singapore, and Australia.

#### *National Cancer Institute (NCI)*

The NCI applies many of its resources to the research and development of biomarkers to diagnose and treat cancer. In October 2006, the organization launched the Biomarkers Consortium, a major public-private biomedical research partnership with the goal of validating biological markers for a variety of diseases, including cancer. Over \$1.2 million has been committed by the consortium's funding members to support operations. The consortium's current projects include the evaluation of an imaging agent (fluorodeoxyglucose-positron emission tomography [FDG-PET]) that can detect an increase in cell metabolism characteristic of tumor growth. The NCI is conducting trials in lung cancer and non-Hodgkin's lymphoma using FDG-PET to monitor tumors for cell growth or cell death and investigate whether FDG-PET results can predict treatment response in the first two to six weeks after treatment.

## Potential Milestones

Within the next 12 months, BioCurex intends to continue working toward the following milestones:

- Entering into agreements with clinical laboratories relating to the blood test using analyte specific reagents (ASRs);
- Licensing Serum-RECAF™ to major biopharmaceutical companies;
- Licensing the Histo-RECAF™ technology to third parties;
- Researching imagery applications through the Company's collaborations;
- Expanding research into the therapeutic uses of RECAF™ technology; and
- Raising capital through the sale of Common Stock or securities convertible into Common Stock, if needed, to fund the Company's operations and R&D.

## Key Points to Consider

- BioCurex is a biotechnology company developing products based on a patented and proprietary technology for improved cancer diagnosis, imaging, and therapy. The Company's technology uses a novel cancer marker called RECAF™ that is present on malignant cells of many cancer types but absent from most normal or benign cells. With RECAF™ technology, BioCurex seeks to reduce human suffering through the early detection of cancer or cancer recurrences.
- BioCurex reports that RECAF™ successfully detects over 90% of cancer in blood and tissue samples, which the Company views as a significant improvement over present cancer markers. Preliminary studies indicate that diagnostic tests using RECAF™ have a high level of clinical sensitivity and specificity in many common cancers, including leukemia, and prostate, breast, colorectal, and lung cancers.
- Since 2004, BioCurex has performed over 120,000 tests on more than 4,000 serum samples. Collective results of these studies have shown that the Company's serum-based assay, Serum-RECAF™, has between a 80% and 90% sensitivity for a variety of cancers, with a 95% specificity for lung, breast, stomach, and ovarian cancers.
  - Thus far, every type of cancer tissue that BioCurex has tested has expressed RECAF™. The Company believes that this finding is significant, as a major limitation of many currently available cancer markers is their inability to successfully detect more than one type of cancer and their lack of sensitivity.
  - BioCurex estimates that, when used on a regular basis (such as every three to six months), a RECAF™ test could be an important preventative measure for the early detection of cancer or the recurrence of cancer after treatment. If an individual's measured RECAF™ level is fairly consistent over time, a routine RECAF™ test could detect even a small change in personal levels of the marker, which may indicate the early stages of cancer. When used in this fashion, RECAF™ testing may be able to more accurately monitor each patient's particular RECAF™ expression, creating a personalized detection test.
  - Preliminary laboratory results in animal models illustrate that BioCurex's technology can shrink tumors, deliberately killing cancer cells.
- In September 2007, BioCurex, the University of Munich, and Abbott Laboratories released results of two RECAF™ tests that studied the method of blood collection and demonstrated the RECAF™ cancer marker's ability to discriminate between cancerous and non-cancerous cells. Researchers compared 68 breast, gastric, and other cancers to 52 normal samples. The reported area under curve (AUC) was 0.954. A score of 1.0 would indicate perfect discrimination between cancer and non-cancer samples.
  - In BioCurex's studies, RECAF™ technology has detected 90% to 93% of all Stage I and Stage II (early stage) breast cancer samples, without returning any false positives (100% specificity). The Company believes that mammograms, a current standard for detecting breast cancer, only have a sensitivity of approximately 65% to 75%, with a 90% specificity.
  - BioCurex has shown that its RECAF™-based colorimetric assay can detect more than twice as many prostate cancers as the prostate-specific antigen (PSA) test. Currently, only 25% to 30% of men with a positive PSA test actually have prostate cancer.
- BioCurex's product portfolio targets the following RECAF™ applications: (1) histology and cytology, with the Company's fully developed Histo-RECAF™ and Cryo-RECAF™ products; (2) blood and serum tests, with the Serum-RECAF™ cancer screening assay and a Rapid Test for point-of-care cancer detection; (3) leukemia; and (4) tumor imaging.

- The U.S. Food and Drug Administration (FDA) has classified Histo-RECAF™ as a Class I medical device that can be sold in the U.S. as an adjunct to standard light microscopy staining methods in order to aid in the identification of cancer in breast and axillary (armpit) node tissue.
- Due to its ability to differentiate between cancer and normal cells, RECAF™ may also enable the future development of targeted cancer treatments that do not damage healthy tissue.
- BioCurex is developing Serum-RECAF™ in a colorimetric format that can be used by high-throughput automated instruments. A colorimetric test is expected to have a longer shelf-life as well as be easier to use and easier to ship to laboratories—all of which could encourage more licensees and laboratories to adopt the test.
- In March 2005, BioCurex and Abbott entered into a worldwide, semi-exclusive licensing agreement (which was amended in principle in March 2008) to commercialize products using RECAF™ technology. Through collaborative research, Abbott has found a high sensitivity and specificity with RECAF™ for cancer detection.
- In January 2008, BioCurex entered into a second semi-exclusive, worldwide licensing agreement with Inverness Medical Innovations, Inc. for use of the RECAF™ technology to commercialize products.
- BioCurex retains the rights to enter into additional licenses for applications of RECAF™ technology. The Company also maintains partnerships with Pacific BioSciences Research Centre and Moscow's N.N. Blokhin Cancer Research Center, Russian Academy of Medical Sciences.
- It is estimated that there were over 12.3 million new cancer diagnoses worldwide and 7.6 million deaths in 2007, of which nearly 40% were in developed nations. Over the next 20 years, the global incidence of cancer is projected to increase by 50% (Source: World Health Organization [WHO]).
- Current cancer marker tests are limited by the following factors: (1) Currently available markers are not 100% specific to a particular type of cancer, indicating that other, non-cancerous conditions can also cause an increase in certain cancer markers; (2) Many markers are restricted to only certain cancers; (3) The same marker is not always expressed on every patient's cancer, even if it is related to the same organ; and (4) The detection of "normal" levels of a cancer marker can occasionally be ambiguous.
- According to PharmaLive.com/Engel Publishing Partners, the global oncology market is forecast to grow at an average annual growth rate of 5.49% to \$53.1 billion in 2009, up from \$38.5 billion in 2003. As of 2005, the global market for laboratory-based diagnostic tests exceeded \$25 billion annually, with molecular diagnostic testing growing by approximately 20% each year and forecast to reach more than \$5 billion by 2009 (Source: Caris & Company). Within the diagnostics market, cancer testing is anticipated to experience some of the greatest growth over the next three to five years, having recently exceeded \$2 billion (Source: *Cancer Diagnostic Testing World Markets*).
- BioCurex's patents are registered in 22 countries, with the U.S. patent expiring in 2014, and those in Australia, Russia, and China expiring in 2015. In March 2008, BioCurex's patent claims for RECAF™-based cancer diagnostic serum tests were granted by the European Patent Office (EPO). The Company is working toward the submission of additional patent applications for RECAF™ technology, and also relies on its proprietary know-how related to the technology.
- BioCurex has an experienced management team that has taken a research technology and developed it toward the point of commercialization in a relatively short timeframe, while also negotiating beneficial license agreements. The Company's chief executive officer (CEO), president, and founder, Dr. Ricardo Moro-Vidal, discovered the RECAF™ cancer marker, and the Scientific Advisory Board (SAB) includes leaders in the cancer marker field, such as Dr. Phil Gold, who discovered the carcinoembryonic antigen (CEA) marker, and Dr. Garri Abelev, who found alpha-fetoprotein (AFP).
- At March 1, 2008, BioCurex had cash of approximately \$1.4 million versus over \$2.3 million at September 30, 2007.

## Historical Financial Results

Tables 12, 13, and 14 provide a summary of BioCurex's key historical financial statements: its Statements of Operations, Balance Sheets, and Statements of Cash Flows. Revenues are generated through license fees related to the RECAF™ technology, which, as of June 2007, consisted only of revenue from Abbott. In addition, the Company issued Convertible Notes plus Share Purchase Warrants in exchange for \$3 million in proceeds from two private investors, received at the beginning of July 2007.

	Year ended December 31,		Accumulated During the Development Stage January 1, 2001 to December 31, 2007
	2007	2006	2007
	\$	\$	\$
Revenue	50,000	—	464,456
Operating Expenses			
Amortization	27,896	22,281	136,257
General and administrative	1,260,865	826,779	4,286,862
Professional and consulting fees	313,925	687,053	4,416,035
Research and development	662,944	572,032	3,064,536
Total Operating Expenses	2,265,630	2,108,145	11,903,690
Loss From Operations	(2,215,630)	(2,108,145)	(11,439,234)
Other Income (Expense)			
Accretion of discounts on convertible debt	(791,092)	(65,160)	(132,989)
Amortization of debt issue costs	(107,217)	—	(107,217)
Gain (loss) on issuance of shares	(10,708)	7,886	(36,297)
Gain on extinguishments of convertible debt	—	—	33,584
Gain on sale of equity investment securities	—	95,782	185,315
Interest expense	(242,628)	(30,521)	(1,831,864)
Interest income	12,956	18,865	375,515
Total Other Income (Expense)	(1,138,689)	26,852	(1,513,953)
Net Loss for the Period	(3,354,319)	(2,081,293)	(12,953,187)
Other Comprehensive Loss			
Unrealized loss on investment securities	(115,061)	(131,128)	(42,189)
Total Comprehensive Loss	(3,469,380)	(2,212,421)	(12,995,376)
Net Loss Per Share - Basic and Diluted	(0.08)	(0.06)	
Weighted Average Shares Outstanding	41,127,000	36,856,000	

Source: BioCurex, Inc.

Table 13  
Whispering Oaks International, Inc. (dba BioCurex, Inc.)  
(A Development Stage Company)  
BALANCE SHEETS

	December 31, 2007	December 31, 2006
	\$	\$
<b>ASSETS</b>		
Current Assets		
Cash	1,372,598	590,254
Investment securities	61,366	176,426
Prepaid expenses and other	109,045	76,340
Notes receivable, net	35,497	36,432
Total Current Assets	1,578,506	879,452
Deferred financing costs	536,084	—
Patents	360,812	329,004
Total Assets	2,475,402	1,208,456
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities		
Accounts payable	105,505	117,713
Accrued liabilities	359,854	109,085
Due to related parties	344,355	358,763
Convertible Notes payable	194,828	194,828
Current portion of convertible debt	371,712	—
	1,376,254	780,389
Convertible debt	266,618	—
	1,642,872	780,389
Commitments and Contingencies		
Stockholders' Equity		
Common Stock		
Authorized: 125,000,000 shares, par value \$0.001		
Issued and outstanding: 42,143,275 and 40,425,615, respectively		
	42,143	40,425
Additional paid-in capital	13,899,938	10,027,813
Accumulated other comprehensive income (loss)	(42,189)	72,872
Accumulated deficit	(114,175)	(114,175)
Deficit accumulated during the development stage	(12,953,187)	(9,598,868)
Total Stockholders' Equity	832,530	428,067
Total Liabilities and Stockholders' Equity	2,475,402	1,208,456

Source: BioCurex, Inc.

Table 14  
Whispering Oaks International, Inc. (dba BioCurex, Inc.)  
(A Development Stage Company)  
STATEMENTS OF CASH FLOWS

(Expressed in U.S. dollars)

	Year ended December 31,		Accumulated During the Development Stage January 1, 2001 to December 31,
	2007 \$	2006 \$	2007 \$
<b>Operating Activities:</b>			
Net loss for the period	(3,354,319)	(2,081,293)	(12,953,187)
Adjustments to reconcile net loss to net cash used in operating activities:			
Accretion of discounts on convertible debt	791,092	—	1,527,634
Allowance for uncollectible Notes receivable	—	—	65,298
Amortization	27,895	22,281	136,256
Amortization of debt issue costs	107,217	—	107,217
Gain on extinguishments of debt	—	—	(33,584)
Gain on sale of investment securities	—	(95,782)	(290,389)
Intrinsic value of the embedded conversion options	65,160	132,989	—
Loss (gain) on issuance of shares	10,708	(7,886)	36,297
Stock-based compensation	666,650	792,818	4,157,062
Changes in operating assets and liabilities:			
Notes and interest receivable	—	—	(6,296)
Prepaid expenses and other	5,767	(36,734)	(35,678)
Accounts payable	95,083	288,120	1,119,589
Accrued liabilities	139,968	33,406	249,053
Deferred revenue	—	—	(162,000)
Subscriptions receivable	—	—	(100,682)
<b>Net Cash Used in Operating Activities</b>	<b>(1,509,939)</b>	<b>(1,019,910)</b>	<b>(6,050,421)</b>
<b>Investing Activities:</b>			
Issuance of Notes receivable	—	—	(100,542)
Proceeds from Notes receivable	—	8,273	101,713
Patent costs	(59,704)	(74,483)	(292,601)
Proceeds from sale of investment securities	—	154,228	384,894
<b>Net Cash Provided by (Used in) Investing Activities</b>	<b>(59,704)</b>	<b>88,018</b>	<b>93,464</b>
<b>Financing Activities:</b>			
Due to related parties	(14,408)	(62,056)	410,506
Proceeds from convertible debt	3,000,000	—	3,639,743
Repayment of convertible debt	(300,000)	—	(353,000)
Debt issue costs	(532,500)	—	(532,500)
Proceeds from private placements of Common			
Stock and share subscriptions received	124,750	1,454,500	2,927,522
Proceeds from the exercise of Stock Options and Warrants	85,333	25	1,128,421
Share issuance costs	(11,188)	(122,500)	(133,688)
<b>Net Cash Provided by Financing Activities</b>	<b>2,351,987</b>	<b>1,269,969</b>	<b>7,087,004</b>
<b>Net Increase in Cash</b>	<b>782,344</b>	<b>338,077</b>	<b>1,130,047</b>
Cash - Beginning of Year	590,254	252,177	242,551
<b>Cash - End of Year</b>	<b>1,372,598</b>	<b>590,254</b>	<b>1,372,598</b>
<b>Non-cash Investing and Financing Activities:</b>			
Shares issued to settle debt	118,000	484,738	677,847
Notes payable converted into Common Shares	—	138,545	858,076
<b>Supplemental Disclosures:</b>			
Interest paid	205,133	—	205,912
Income taxes	—	—	—

Source: BioCurex, Inc.

## Risks

Some of the information in this Executive Informational Overview<sup>®</sup> (EIO<sup>®</sup>) relates to future events or future business and financial performance. Such statements can only be predictions and the actual events or results may differ from those discussed due to the risks described in BioCurex's statements on Forms 10-KSB, 10-QSB, and 8-K, as well as other forms filed from time to time. The content of this EIO<sup>®</sup> with respect to BioCurex has been compiled primarily from information available to the public released by the Company through news releases, Annual Reports, and Securities and Exchange Commission (SEC) filings. BioCurex is solely responsible for the accuracy of this information. Information relating to other companies has been prepared from publicly available information and has not been independently verified by the Company. Certain summaries of activities have been condensed to aid the reader in gaining a general understanding. For more complete information about BioCurex, please refer to the Company's website at [www.biocurex.com](http://www.biocurex.com).

Investors should carefully consider the risks and information about BioCurex's business described below. Investors should not interpret the order in which these considerations are presented as an indication of their relative importance. The risks and uncertainties described below are not the only risks that the Company faces. Additional risks and uncertainties not presently known to BioCurex or that BioCurex currently believes to be immaterial may also adversely affect its business. If any of the following risks and uncertainties develops into actual events, the business, financial condition, and results of operations could be materially and adversely affected, and the trading price of the Company's shares could decline.

### **RISKS RELATED TO BIOCUREX**

BioCurex has limited operations, a history of losses, and may never be profitable. It has never earned a profit. As of December 31, 2007, the Company's accumulated losses were (\$12,953,187). BioCurex expects to incur additional losses for an indefinite period. To date, the Company has not received any revenues from the sale of its Histo-RECAF<sup>™</sup> kit or any other products that it is developing. No assurance can be given that BioCurex's products can be manufactured and marketed successfully, or that BioCurex will ever earn a profit.

If BioCurex is unable to raise additional capital, it may be unable to continue operating. To raise additional capital, BioCurex will most likely sell shares of its Common Stock or securities convertible into Common Stock. The issuance of additional shares will have a dilutive impact on other stockholders and could have a negative effect on the market price of BioCurex's Common Stock.

Clinical and other studies necessary to obtain approval of BioCurex's products can be time consuming and costly, especially in the U.S., but also in foreign countries. The different steps necessary to obtain regulatory approval, especially that of the FDA, involve significant costs. In addition, BioCurex's estimates of the costs associated with its proposed research, development, and marketing activities may be substantially lower than the actual costs of these activities. The Company will need additional capital in order to fund the costs of future studies, related research, and general and administrative expenses.

BioCurex may be forced to delay or postpone research, development, and marketing expenditures if it is unable to secure adequate sources of funds. BioCurex may not be able to obtain any additional funding that it may require. At present, the Company does not have any agreements or commitments from any source to provide additional capital.

In an audit report on the December 31, 2006, financial statements, BioCurex's auditors expressed substantial doubt as to the Company's ability to continue as a going concern.

Any failure to obtain or any delay in obtaining required regulatory approvals may adversely affect the ability of BioCurex to successfully license its products or any products that it may develop. The FDA, in its device listing database, shows the Histo-RECAF<sup>™</sup> kit as a Class I Medical Device. As such, the Histo-RECAF<sup>™</sup> kits may be sold in the U.S. as a staining test that can be used as an adjunct to standard light microscopy staining methods to aid in the identification of cancer in breast and axillary node tissues. BioCurex has not applied to any regulatory authority for permission to sell the Cryo-RECAF<sup>™</sup> kit on a commercial basis.

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The testing, manufacturing, or marketing of BioCurex's cancer detection kits is subject to regulation by numerous governmental authorities in the U.S. and in other countries, including, but not limited to, the FDA. Among other requirements, FDA approval of the processes and facilities used to manufacture the Company's cancer detection kits will be required before any of these kits may be marketed in the U.S. The process required by European regulatory authorities before BioCurex's cancer detection kits can be marketed in Europe are similar to those in the U.S. As with the FDA review process, there are numerous risks associated with the review of medical devices by foreign regulatory agencies. Additional data may be requested by foreign regulatory agencies to demonstrate the clinical safety and efficacy of a product, or to confirm the comparable performance of materials produced by a changed manufacturing process or at a changed manufacturing site.

BioCurex's R&D efforts have lately focused on the development of a screening assay that can detect multiple cancers from a blood (serum) sample. This serum-based screening assay has not been approved by the FDA. Although FDA approval is only required for the U.S. market, BioCurex believes that FDA approval can add credibility when negotiating with overseas distributors. In order to obtain FDA approval of a product, it must be demonstrated to the satisfaction of the FDA that the product is safe and effective for its intended uses and that the product can be manufactured with procedures that conform to the FDA's regulations, which must be followed at all times. The process of obtaining FDA approvals can be costly, time consuming, and subject to unanticipated delay. Approvals may not be granted for any product developed by BioCurex.

In addition to delays in review and approval of BioCurex's serum-based screening assay (assuming this product can be successfully developed), delays or rejection may also be encountered based upon changes in applicable law or regulatory policy during the period of regulatory review. Any failure to obtain or any delay in obtaining FDA approvals would adversely affect the ability of BioCurex to license its serum-based screening assay. Moreover, even if FDA approval is granted, such approval may include significant limitations on indicated uses for which the product could be marketed.

Both before and after approval is obtained, a product and its manufacturer are subject to comprehensive regulatory oversight. Violations of regulatory requirements at any stage may result in adverse consequences, including the FDA's delay in approving or refusal to approve a product, withdrawal of an approved product from the market, or the imposition of criminal penalties against the manufacturer. In addition, later discovery of previously unknown problems relating to a marketed product may result in restrictions on such product or manufacturer, including withdrawal of the product from the market.

BioCurex may not achieve or maintain a competitive position in its industry and future technological developments may result in the Company's proprietary technologies becoming uneconomical or obsolete. The field in which BioCurex is involved is undergoing rapid and significant technological change. The successful marketing of the Company's cancer detection kits will depend on its ability to be in the technological forefront of this field. There can be no assurance that BioCurex will achieve or maintain such a competitive position or that other technological developments will not cause BioCurex's proprietary technologies to become uneconomical or obsolete.

BioCurex's patents might not protect its technology from competitors. Certain aspects of BioCurex's technologies are covered by a U.S. patent and a number of foreign patents. In addition, the Company has patent applications pending in foreign countries. There is no assurance that the applications still pending or those that may be filed in the future will result in the issuance of any patents. Furthermore, there is no assurance as to the breadth and degree of protection that any issued patents might afford BioCurex. Disputes may arise between the Company and others as to the scope, validity, and ownership rights of these or other patents. Any defense of the patents could prove costly and time consuming, and there can be no assurance that BioCurex will be in a position, or will deem it advisable, to carry on such a defense. Other private and public concerns may have filed applications for, may have been issued, or may expect to obtain additional patents and other proprietary rights to technology potentially useful or necessary to BioCurex. The scope and validity of these patents, if any, are presently unknown.

BioCurex's success is dependent on the continued availability of its officers. The loss of management and scientific personnel could adversely affect the Company. BioCurex does not have any employment agreements with any of its officers. Accordingly, any of these officers, all of whom have medical backgrounds, may resign at any time.

BioCurex is dependent on the continued availability of R&D services provided by Pacific BioSciences, and the loss of these services could adversely affect BioCurex. Pacific BioSciences conducts substantially all research relating to the technology under development by the Company. It is wholly owned by Dr. Ricardo Moro-Vidal, an officer and director of BioCurex. If Pacific BioSciences discontinues these services, the Company may be unable to find another firm with the same expertise in the technology under development, in which case the ability of the Company to develop its technology would be impaired.

Future transactions between BioCurex and its officers and directors may not be on terms as favorable as BioCurex could obtain in similar transactions with persons who do not have any relationship with the Company. BioCurex has in the past issued shares of its Common Stock, as well as Options and Warrants, to its officers and directors. Dr. Moro-Vidal, in his capacities as an officer and director of both BioCurex and Pacific BioSciences, is in a position to both approve the nature of the research conducted by Pacific BioSciences and to control the cost of the research.

In addition, the directors of BioCurex approve their own compensation since decisions regarding compensation to be paid to the officers and directors of BioCurex are made by the directors by resolutions adopted by unanimous written consent. The Company does not have any policy to limit the amount of compensation paid to its officers.

The terms relating to the issuance of the shares, Options, and Warrants, the amounts paid to Pacific Biosciences, and the compensation paid to BioCurex's officers were determined by the officers and directors who control BioCurex and who may have benefited if the terms of these transactions were not as favorable as those that the Company could have obtained from unrelated third parties.

To the extent that BioCurex has future transactions with its officers or directors, it is possible that the terms of any future transactions may be more favorable to the officers or directors than the Company.

The market price of BioCurex's Common Stock, as well as the securities of other biopharmaceutical and biotechnology companies, have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Factors such as fluctuations in BioCurex's operating results, announcements of technological innovations or new products by the Company or its competitors, governmental regulation, developments in patent or other proprietary rights, public concern as to the safety of products developed by BioCurex or other biotechnology and pharmaceutical companies, and general market conditions may have a significant effect on the future market price of BioCurex's Common Stock.

There is, at present, only a limited market for the Company's Common Stock, and there is no assurance that this market will continue. Trades of BioCurex's Common Stock are subject to Rule 15c-9 of the SEC, which imposes certain requirements on broker/dealers who sell securities subject to the rule to persons other than established customers and accredited investors. For transactions covered by the rule, brokers/dealers must make a special suitability determination for purchasers of the securities and receive the purchaser's written agreement to the transaction prior to sale. The SEC also has rules that regulate broker/dealer practices in connection with transactions in "penny stocks." Penny stocks generally are equity securities with a price of less than \$5.00 (other than securities registered on certain national securities exchanges or quoted on the NASDAQ system, provided that current price and volume information with respect to transactions in that security is provided by the exchange or system). The penny stock rules require a broker/dealer, prior to a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document prepared by the SEC that provides information about penny stocks and the nature and level of risks in the penny stock market. The broker/dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker/dealer and its salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer's account. The bid and offer quotations, and the broker/dealer and salesperson compensation information, must be given to the customer orally or in writing prior to effecting the transaction and must be given to the customer in writing before or with the customer's confirmation. These disclosure requirements have the effect of reducing the level of trading activity in the secondary market for BioCurex's Common Stock. As a result of the foregoing, investors may find it difficult to sell their shares.

## Recent Events

**03/25/2008**—BioCurex, Inc. announced that the European Patent Office (EPO) granted the Company's patent claims for cancer diagnostic serum tests based on the RECAF™ marker.

**03/20/2008**—Announced that it reached an agreement in principle to amend its licensing agreement, dated April 2005, with Abbott Laboratories. The proposed amendment relieves Abbott of future due diligence obligations to commercialize or perform further research and development (R&D) on the RECAF™ technology as well as its obligation to pay the annual minimum royalty. BioCurex is continuing development of Serum-RECAF™ in its facilities, and Abbott may resume R&D work and commercialize products incorporating RECAF™ technology, as per the original agreement. In consideration for the modification, BioCurex gained a higher royalty on any RECAF™ products that may be sold by Abbott. BioCurex also obtained the right to terminate the license at any time if Abbott, following notice from BioCurex, does not agree within 90 days to new due diligence obligations for the commercialization of any products using RECAF™ technology.

**01/10/2008**—Detailed the new licensing agreement for its RECAF™ material and technology signed with Inverness Medical Innovations, Inc. This agreement moved BioCurex closer to the commercialization of cancer detection products, and is believed to represent an important step in the Company's development. Under the terms of the license agreement, Inverness obtained semi-exclusive worldwide rights to commercialize products using RECAF™ technology. BioCurex expects to be paid up-front fees, product and development milestones, and royalties on product sales. Inverness is to handle U.S. Food and Drug Administration (FDA) approvals, manufacturing, marketing, and distribution for clinical laboratory testing.

**01/09/2008**—The Company and Inverness announced a licensing agreement for BioCurex's RECAF™ material and technology.

**09/25/2007**—Announced that Dr. Stewart Sell, a member of BioCurex's Scientific Advisory Board (SAB) since October 2005 (biography on page 13), was awarded the International Society for Oncodevelopmental Biology and Medicine (ISOBM)-Abbott award for his lifetime achievements in cancer research, immunology, developmental biology, and stem cell research. Dr. Phil Gold and Dr. Garri Abelev, also members of the Company's SAB (biographies on pages 11-12), are previous recipients of the ISOBM-Abbott award.

The ISOBM is a leading international forum for cancer markers. The ISOBM-Abbott award is presented by Abbott to scientists in the international community who have made a significant contribution to basic or clinical oncology. For more information about the ISOBM-Abbott awards, see [www.isobm.org/awards.htm](http://www.isobm.org/awards.htm).

**09/20/2007**—Announced the acceptance of two presentations that were submitted to the ISOBM. The presentations documented two RECAF™ studies involving joint initiatives with the University of Munich (Germany) and Abbott.

**09/18/2007**—Announced a presentation to the ISOBM. The presentation documented a study conducted by BioCurex in its development of a Rapid Test for ambulatory cancer detection, based on the patented RECAF™ cancer marker. This study was conducted in conjunction with the N.N. Blokhin Cancer Research Center (Moscow, Russia).

**07/08/2007**—BioCurex educated its shareholders regarding the increasingly voluminous material in the cancer diagnostics arena. In recent publications, there has been mention of the possibility of genetic testing for various disease, degenerative, and cancer states. Genetic testing is a process that looks for inherited genetic alterations that may increase the risk of certain cancers. Page 23 addresses the possibility of genetic testing and the impact that it may have on RECAF™ technology.

**06/05/2007**—Announced progress on its initiative to develop point-of-care tests (also called Rapid Tests). The Company reported that preliminary results show that it is possible to make such RECAF™-based rapid tests for cancer detection.

**05/02/2007**—Provided an update of the Company’s activities to its shareholders. BioCurex had been working to expand its technology in the scientific and business arenas, specifically at converting the format of the radiolabeled test for cancer into a colorimetric (or chemiluminescence) test.

**02/13/2007**—Announced that it started development of a point-of-care RECAF™ test that would be available for use at a physician’s office rather than in a laboratory setting.

**12/07/2006**—Announced that it signed a collaboration agreement with the N.N. Blokhin Cancer Research Center for further development and evaluation of the RECAF™ technology.

**11/29/2006**—Announced that an interview with Dr. Ricardo Moro-Vidal, (biography on page 11) chief executive officer (CEO) and president, is available at <http://smallcapdigest.net/archive/listserv/20061129-1.html>.

**11/07/2006**—BioCurex commented on the prostate-specific antigen (PSA) velocity study published on November 1, 2006, in the *Journal of the National Cancer Institute*. In this study, the authors studied the increase of PSA (velocity) in serum samples from 980 men monitored since 1958. The authors evaluated the association between PSA velocity and death from prostate cancer during the period of 10 to 15 years before diagnosis. The authors conclude that PSA velocity provides information early in the disease course that is related to the chance of dying of prostate cancer, before diagnosis, when PSA levels are below 4.0 ng/ml (the current threshold above which cancer is suspected), and at a time when a cure might be still possible with local therapy (surgery or radiation). However, the authors make it clear that this is a possibility and not a fact as they add that they cannot be certain that, if a life-threatening prostate cancer had been identified by PSA velocity earlier in the natural history of the disease, treatment at that point in time would have changed the outcome. Rather, PSA velocity might identify men who are destined to succumb to their disease in spite of curative intervention.

## Glossary

**510(k)**—See *Premarket Notification*.

**Alpha-Fetoprotein (AFP)**—An antigen produced in the liver of a fetus that can appear in certain diseases of adults, such as liver cancer. Its level in amniotic fluid can also be used in the detection of certain fetal abnormalities, including Down syndrome and spina bifida.

**Analyte Specific Reagents (ASRs)**—Antibodies, both polyclonal and monoclonal, specific receptor proteins, ligands, nucleic acid sequences, and similar reagents that, through specific binding or chemical reaction with substances in a specimen, are intended for use in a diagnostic application for identification and quantification of an individual chemical substance or ligand in biological specimens. The majority of ASRs are exempt from FDA approval or clearance, and manufacturers of ASRs are prohibited from making claims of analytical or clinical performance.

**Assay**—A biological test, measurement, or analysis to determine whether compounds have the desired effect either in a living organism, outside an organism, or in an artificial environment.

**Axillary**—Pertaining to the cavity beneath the junction of the arm and the body, also known as the armpit.

**Benign**—Not dangerous to health; not recurrent or progressive, especially as related to a tumor.

**Biopsy**—The removal of a piece of tissue from a living body for diagnostic study.

**Breast Fibroadenoma**—A common, benign growth in the breast that is solid, firm, smooth, and usually painless or only slightly tender. The peak incidence of fibroadenomas are in women 30 to 35 years old.

**Bronchus**—Either of two main branches of the trachea, leading directly to the lungs.

**Capillary Action**—The drawing of a substance along an adherent surface despite the force of gravity. This effect is caused by adhesive and cohesive forces as well as surface tension.

**Carcinoembryonic Antigens (CEAs)**—A glycoprotein in fetal gastrointestinal tissue and in the cells or serum of adults who have certain cancers. It is used clinically to monitor cancer treatment effectiveness.

**Chromatography**—A process used for separating mixtures by virtue of differences in absorbency.

**Class I Medical Device**—Class I devices are subject to the least regulatory control. They present minimal potential for harm to the user and are often simpler in design than Class II or Class III devices. However, Class I devices are subject to several general controls, including listing the medical device with the FDA, manufacturing the device in accordance with Good Manufacturing Practices (GMP), and labeling devices in accordance with labeling regulations. Many Class I devices are exempt from premarket notifications (510(k) registrations). Examples of Class I devices include elastic bandages, examination gloves, and hand-held surgical instruments.

**Class II Medical Device**—Class II devices are those for which general controls alone are insufficient to assure safety and effectiveness, and existing methods are available to provide such assurances. In addition to complying with general controls, Class II devices are also subject to special controls, such as special labeling requirements, mandatory performance standards, and postmarket surveillance. Examples of Class II devices include powered wheelchairs, infusion pumps, and surgical drapes.

**Colorimetric**—Relating to colorimetry, which is quantitative chemical analysis using a device to analyze color by measuring a given color in terms of a standard color, a scale of colors, or primary colors.

**Current Procedural Terminology (CPT®) Codes**—The American Medical Association's (AMA) coding system that is primarily used to identify medical services and procedures. Healthcare professionals use the CPT® to identify services and procedures for which they bill public or private health insurance programs. Decisions regarding the addition, deletion, or revision of CPT® codes are made by the AMA.

**Cytofluorometry**—A technique for separating and analyzing cells or chromosomes that relies on the detection of specific fluorescent markers.

**Cytology**—The study of cells taken as samples during procedures such as a Pap smear.

**Cytotoxic**—A substance that has a toxic effect on certain cells.

**Endometriosis**—The presence of uterine lining in other pelvic organs, such as the ovaries, that is characterized by cyst formation, adhesions, and menstrual pains.

**False Positive**—A test result that is read as positive but is actually negative; a test that shows evidence of a disease when it is not present.

**Free PSA**—PSA exists in two forms in the blood, either bound to protein or unbound (“free”). Measuring both the bound and free forms can better predict risk.

**Genetic Testing**—Analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites in order to detect heritable disease-related genotypes, mutations, phenotypes, or karyotypes.

**Histology**—The study of tissues under a microscope.

**Homologous**—Having the same evolutionary origin but not necessarily the same function. For example, the wing of a bat and the arm of a man are homologous.

**Humanized**—Converted into something human or belonging to man.

**Immunoassay**—A laboratory technique that identifies and quantifies a protein, such as a hormone or an enzyme, based on its ability to act as an antigen or antibody in a chemical reaction. Test results can provide information about a disease that may help in planning treatment (e.g., when estrogen receptors are measured in breast cancer).

**Immunocytochemistry**—A method of detecting cancer in tissues. MAbs are used to stain the tissues and cells before examination under a microscope.

**Immunohistochemistry**—A type of assay where specific antigens are made visible by the use of fluorescent dye or enzyme markers.

**Incubate**—(as it relates to BioCurex’s technology) To maintain a chemical or biochemical system under specific conditions in order to promote a particular reaction.

**Lifetime Risk**—The probability that an individual will develop or die from cancer during their lifetime.

**Malignant**—Dangerous to health; characterized by progressive and uncontrolled growth, especially as related to a tumor.

**Mammary**—Pertaining to the breast.

**Monoclonal Antibodies (MAbs)**—Any of a class of highly specific antibodies produced by the clones of a single hybrid cell formed in the laboratory by the fusion of a B-cell with a tumor cell and widely used in medical and biological research.

**Morphology**—The study of the form and structure of organisms.

**Murine**—Belonging or pertaining to the Muridae, the family of rodents that includes mice and rats.

**Occult**—Indicating a disease or condition that is not clinically apparent.

**Paraffin**—A white or colorless, tasteless, odorless, water-insoluble, solid substance not easily acted upon by reagents. It consists of a mixture of hydrocarbons chiefly of the alkane series, obtained from crude petroleum. Paraffin is used in candles, preservative coatings and seals, and waterproofing.

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**Premarket Notification**—Section 510(k) of the U.S. Food, Drug, and Cosmetic Act requires certain device manufacturers to notify the FDA, at least 90 days in advance, of an intent to market a medical device. This is known as premarket notification or 510(k) submission.

**Prostate-Specific Antigen (PSA)**—A protease secreted by the epithelial cells of the prostate gland. Serum levels, used as a screening test for prostate cancer, are elevated in patients with benign prostatic hyperplasia and prostate cancer.

**Radiolabeled**—Any compound that has been joined with a radioactive substance.

**Receiver Operating Characteristic (ROC)**—A graphical plot that provides an index of accuracy by demonstrating the limits of a test's ability to discriminate between alternative states of health over the complete spectrum of operating conditions. ROC plots are pivotal to assessing and using diagnostic tools. Once the plot is generated, users can perform quantitative ROC analysis and comparisons of tests, revise the probability of disease in individual subjects, select decision thresholds, or incorporate the tool into a clinical strategy.

**Sensitivity**—The proportion of truly diseased persons in a screened population who are identified as being diseased by the test. It is a measure of the probability of correctly diagnosing a condition and is calculated as the number of true positive results divided by the number of true positive and false negative results.

**Serum**—The watery fluid of the blood that resembles plasma but contains fibrinogen.

**Solvents**—Substances, usually a liquid, that are capable of dissolving other substances.

**Specificity**—The proportion of truly non-diseased persons who are so identified by the screening test. It is a measure of the probability of correctly identifying a non-diseased person.

**Stage**—The extent of a cancer within the body. If the cancer has spread, the stage describes how far it has spread from the original site to other parts of the body.

- **Stage I (Breast Cancer)**—Early stage breast cancer where the tumor is less than 2 cm across and has not yet spread beyond the breast.
- **Stage II (Breast Cancer)**—Early stage breast cancer where the tumor meets one of the following characteristics: (1) less than 2 cm across and has spread to nearby lymph nodes (under the arm); (2) between 2 cm and 5 cm and has or has not spread to the lymph nodes; and (3) over 5 cm but has not spread beyond the breast.
- **Stage III (Breast Cancer)**—Locally advanced breast cancer where the tumor meets one of the following characteristics: (1) greater than 5 cm across and has spread to the lymph nodes (under the arm); (2) extensive cancer in the lymph nodes; or (3) the cancer has spread to additional lymph nodes near the breast bone or to other tissues near the breast.
- **Stage IV (Breast Cancer)**—Metastatic breast cancer where the cancer has spread outside the breast to other organs in the body.
- **Stage I (Prostate Cancer)**—Tumor cells are found in less than 5% of removed prostate tissue and the cells are not aggressive in nature.
- **Stage II (Prostate Cancer)**—Tumor cells are found in less than 5% of removed prostate tissue and the cells are more aggressive in nature, or the tumor is larger in size but is confined to the prostate gland.
- **Stage III (Prostate Cancer)**—The tumor has grown through the capsule that surrounds the prostate gland and may involve seminal vesicles.
- **Stage IV (Prostate Cancer)**—The tumor has spread beyond the seminal vesicles to any other organ or structure.



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