BIOTRACES, INC.

Highly Sensitive Detectors for Biomedical and Environmental Diagnostics

A technology that can detect minute traces of biomolecules — pesticides, bacteria in water, organic toxins like botulin — much better than conventional detectors would be extremely useful in a number of fields. Medicine, for instance, has obvious need for highly sensitive methods of detecting viruses. Such a technology would also be applicable in a broad range of environmental areas, where early detection of chemicals or other substances could trigger corrective action early enough to head off disaster. Detecting traces of toxic materials in a municipal water supply, for example, might lead to the elimination of their source before they poison the city's population. A highly sensitive detection technology could also be useful for the optimized control of semiconductor fabrication.

COMPOSITE PERFORMANCE SCORE
(Based on a four star rating.)
★ ★

Detecting Minute Amounts of Unwanted Molecules

This ATP project created such a technology through the efforts of BioTraces, a small company founded in 1989 to develop, manufacture, and market instruments for detecting microtraces of various materials. During its ATP project, the company developed a highly sensitive biomolecule detection method based on an improved radioactive tracer detection system originally developed for cosmology. Instruments of this types use radioactive isotopes that are chemically bound to the target molecules or atoms. Photon or electron detectors that register radiation decay particles are used to spot the "tagged" targets. Sensitivity is limited by background radiation — 10 to 100 counts per minute for conventional commercial instruments in typical applications. BioTraces beats this limitation with a sophisticated multiphoton detector (MPD) that registers only counts that match the multiple-photon decay pattern of the isotopes used as tags. In contrast to conventional methods, background levels for BioTraces detectors are a few counts per day.

Safer Analyses for Patients and the Environment

The BioTraces technology uses different isotopes to tag different types of molecules in the sample. This allows several different molecule types to be measured simultaneously, greatly speeding complex analysis tasks such as those used in clinical screening (for example, to detect contaminants in blood supplies). Since background interference is so low, the minimum amount of isotope needed for an analysis can be as much as 1000 times less than that used in conventional radioisotope analysis, making the BioTraces system considerably safer for patients and the environment.

Detecting traces of toxic materials in a municipal water supply, for example, might lead to the elimination of their source before they poison the city's population.

The company met most of the project's technical goals. Its researchers developed prototype MPD instrumentation hardware and software that is much more sensitive than current state-of-the-art equipment. They also developed biomedical applications of the technology for enhanced immunoassay, chromatography and nucleic acid analysis.

First Fruits of Commercialization

At the start of the ATP project, BioTraces planned to do only the instrumentation work and to leave specific applications to partner companies. But lack of success in finding suitable partners led BioTraces to change its approach to commercialization. It is now finishing development work on the MPD technology and hopes to begin offering its own commercial products widely in the near future.

PROJECT HIGHLIGHTS

PROJECT:
To develop instrumentation based on multiphoton detection (MPD), high-speed/high-sensitivity sensors and proprietary software, one that can detect minute concentrations of chemicals in gas, liquid or solid matrices — a technology that would be extremely useful in environmental monitoring and biomedical research.

Duration: 1/1/1994 — 12/31/1996

ATP Number: 93-01-0250

FUNDING (in thousands):

ATP	$1,718	69%
Company	773	31%
Total	$2,491	

ACCOMPLISHMENTS:
BioTraces developed MPD instrumentation, both hardware and software, as well as biomedical applications of the technology for enhanced immunoassay, chromatography and nucleic acid analysis. The company:

- applied for two patents on technology developed during the ATP project: "Enhanced Chromatography Using Multiphoton Detection" and "Ultralow Background Multiple Photon Detection;"
- negotiated with the French company Pasteur-Merieux Connaught an agreement under which BioTraces developed an MPD-enhanced quantitative polymerase chain reaction assay for measuring tiny amounts of DNA and RNA;
- negotiated a $1.78 million agreement in July 1996 with a newly-formed company, PetroTraces, granting it an exclusive license for commercial applications of the new technology in the petroleum industry — a deal that so far has generated $585,000 in revenues for PetroTraces and $560,000 in license fees for BioTraces;
- arranged in June 1997 for Genetics Institute, Inc., to evaluate the MPD technology as a pharmaceutical R&D tool; if successful, the test could lead to a license allowing Genetics Institute, Inc. to use the technology in its drug discovery program;
- created a clinical diagnostics device, the ssMPD™ (sequential sample MPD), which received market clearance from the U.S. Food and Drug Administration and entered the market on a limited basis in 1997;
- has received since the start of the ATP project $1 million in equity investment to support commercialization of the new technology; and
- entered into discussions with two venture capital firms about securing an additional $4 million in equity funding in 1998 or 1999.

COMMERCIALIZATION STATUS:
Commercialization is in progress. Applications of the technology are underway in the petrochemical field via PetroTraces. BioTraces' first commercial product for medical applications, ssMPD™, has entered the market on a limited basis and is expected to be more widely available in 1998 or 1999.

OUTLOOK:
Once BioTraces works out a strategy for protecting its intellectual property, the new technology is expected to be disseminated more aggressively. Given its potential use in detecting viruses, bacteria, toxins and pollutants, the ATP-funded technology stands to generate substantial benefits to the economy. If, for example, it were used to detect a toxin in a water supply, preventing a whole town or region from becoming ill, the benefits would be enormous.

Composite Performance Score: ★ ★

COMPANY:
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Number of Employees: 3 at project start, 14 at the end of 1997

The company has made enough progress to license the technology exclusively to a new company, PetroTraces, for petrochemical applications. PetroTraces uses it to tag and trace different liquids and gases that are transported in pipelines so it can supply customers with data for auditing and other applications.

BioTraces expects to launch wide-scale sales of the ssMPD™ in late 1998 or early 1999 . . .

BioTraces' own initial commercial product, the ssMPD (sequential sample MPD) is used for super-sensitive measurement in extremely small samples — up to a few milliliters. The ssMPD received market clearance from the U.S. Food and Drug Administration for sale as a clinical diagnostics device and entered the market in 1997 on a limited basis for use in research. BioTraces expects to launch wide-scale sales of the ssMPD in late 1998 or early 1999, after enhancing protection for its proprietary software and establishing a strategic alliance with a major clinical diagnostics company.

The new MPD technology has great potential as an advanced biomedical diagnostic tool and for other uses where detection of minute traces of biomolecules is critical. BioTraces entered an agreement with Pasteur-Merieux Connaught, a French company, under which it developed an MPD-enhanced quantitative polymerase chain reaction assay for measuring tiny amounts of deoxyribonucleic acid (DNA) and ribonucleic acid (RNA). And in June 1997, it arranged for Genetics Institute, Inc., to evaluate the MPD

technology as a pharmaceutical research and development tool. If the test is successful, it could lead to a license allowing Genetics Institute, Inc., to use the technology in its drug discovery program.

ATP Gives a Big Boost to a Small Startup

BioTraces is a very small company, having only three employees when it started the ATP project. Since then, the company has received $1 million in equity investment to support commercialization of the new technology. It has also entered into discussions with two venture capital firms about securing an additional $4 million in equity funding in 1998.

Company officials report that the ATP award enabled BioTraces to achieve its research results two to three years sooner than it otherwise would have been able to do. The funds also helped it develop research alliances and improved its ability to raise investor capital.