DEAR SHAREHOLDERS,

In bringing new and innovative medical technologies to the commercial market, Epitope is advancing along a multi-stage course toward our ultimate goal of becoming a strong commercial entity.

Stage 1 saw the development of our oral fluid technology and the process of achieving Food and Drug Administration (FDA) approval for HIV testing, which was accomplished in June 1996 with clearance of the OraSure® Western blot confirmatory test. Fiscal 1999 brought Epitope to the end of Stage 2, in which we established oral fluid testing as an accurate and well-accepted means of testing for HIV and attained a critical mass of customers in key markets. These first two stages required heavy investment, and position the Company for strong growth in the future.

With much of the development work and initial market penetration behind us, the Company is poised to enter a stage in which our efforts begin to achieve financial rewards. Stage 3 objectives will be to achieve profitability while expanding beyond the current scope of product and market coverage. We plan to add more tests to the OraSure platform, introduce the rapid-assay OraQuick technology, and leverage relationships with customers and partners to increase revenues. One of the keys to Epitope's success in this next stage will be the continuation of our teaming with carefully selected companies offering complementary skills that can accelerate the expansion of our business.

The Company plans to enter this stage by introducing OraSure technology into the $725 million analytical portion of the drugs-of-abuse testing market early in calendar year 2000 under the trade name Intercept Drugs of Abuse. Here we expect the significant efforts and investment by Epitope, STC Technologies, Inc. (a private company that develops and markets clinical diagnostic tests), and LabOne, Inc. to convince customers to switch from urine testing to the proven oral fluid alternative.

In addition, Epitope will be starting clinical trials for our rapid assay OraQuick HIV to prepare for introduction of this product into U.S. and international markets. In the near future we will begin projects to expand both the OraSure laboratory-based platform and the OraQuick rapid testing platform into testing for other diseases and conditions. While widening the scope of our product offering, the Company will place a new emphasis on developing and solidifying distribution relationships needed to succeed in international markets.

FISCAL 1999 FINANCIAL REVIEW

While revenues for fiscal 1999 were up modestly to $10.1 million, compared with $9.8 million in the prior year, these results do not show the solid underlying growth in Epitope's two key markets. Use of OraSure by the U.S. life insurance industry continued to post solid gains with a second year of 25% annual increases in testing. Prior-year inventory imbalances, which occurred in the first years of development of this market, have been resolved and Epitope's shipments of product to this segment are now tracking closely with growing end-user requirements.

In the public health market, customers are adopting OraSure testing at an increasing rate after only two years of direct selling by the Company. Although actual OraSure usage within this market increased by about 15% this past year, recorded revenue for the segment was flat because several major customers changed from a once-a-year ordering pattern to multiple smaller shipments. Now that this change has been reflected in a full fiscal year of results, revenue growth for this segment should begin to track in line with the customer usage.

For the full year, the net loss was $3.2 million, or $0.23 per share, compared with a net loss of $1.9 million, or $0.14 per share, for fiscal year 1998. Overall gross profit margins remained strong, continuing at prior-year levels of 62%, and are expected to improve in fiscal 2000 because of cost reduction programs. The mix of product

offerings may also affect gross margins. Collaborative arrangements that allow Epitope to sell laboratory testing services bundled with the sale of the OraSure device result in much higher per unit revenue and gross profit dollars but somewhat lower percentage margins. This type of program will be expanded to the extent possible because of the positive effect on overall Company profitability.

Expense levels for fiscal year 1999 were inflated by several short-term requirements. Heavier spending resulted from OraQuick development work to prepare for clinical trials, preparations for the launch into the drugs-of-abuse market, comprehensive changes in our quality control and quality assurance systems to ensure compliance with new FDA requirements, and the accrual of expenses associated with the search for a new CEO.

REVIEW OF OPERATIONS AND CURRENT PLANS

U.S. LIFE INSURANCE

For the past three years, the U.S. life insurance market has been using OraSure to test for HIV-1, cotinine and cocaine, and has become a cornerstone market for the Company. To date we have sold more than 8 million OraSure devices to customers in this market. Life insurance companies relying on OraSure now number over 150, including seven of the top 10, compared with 102 companies last year and 62 the year before. Life insurance customers currently represent about one-half of Epitope's total revenues, and their use of OraSure is growing at about 25% annually. In recent months, many insurance companies began implementation of programs to significantly expand their use of OraSure after having tested our product in pilot studies. We expect this trend to continue and we see substantial room for growth in this market.

U.S. PUBLIC HEALTH

U.S. public health customers have been expanding their use of OraSure because it allows them more easily to accomplish one of their main objectives - to test a larger number of people for HIV infection. Oral fluid testing has been shown to foster greater participation than blood testing for HIV because it largely resolves problems associated with patient's fear of needles and the dangers of needle-stick injuries for healthcare workers. In addition, it is both accurate and highly portable.

Epitope is pleased to have participated in a number of public health initiatives during the year, and has supplied our OraSure oral specimen collection device for use during several HIV awareness campaigns. These included the Harlem Health Expo, a free education program that took place in New York City, and World AIDS Day events in various U.S. cities. We have also joined Bristol-Myers Squibb – a manufacturer of AIDS therapy drugs - in several innovative, grassroots efforts to increase HIV awareness and testing.

DRUGS OF ABUSE

One of the more significant and exciting expansions of our product line will take place early in calendar year 2000. The $725 million analytical portion of the U.S. drugs-of-abuse testing market will be a prime focus of the Company during the next few years. Oral fluid testing for drugs of abuse offers significant advantages over the current standard of urine testing. Our OraSure-based test will be easy to use, accurate and difficult (if not impossible) to adulterate. It will also solve many of the chain-of-custody problems with the current methods.

OraSure is approved by the FDA for the testing of cocaine, methamphetamines, cannabinoids (marijuana) and opiates, four of the NIDA-5 panel of drugs of abuse. The FDA has cleared OraSure for sale for investigational

use to test for the fifth drug, phencyclidine, or PCP. In addition, our colleagues in this initiative, STC Technologies and LabOne, have developed a highly accurate laboratory confirmatory test for our oral fluid sample using the same basic techniques that have become standard in testing of urine samples. Recent pilot studies with potential customers have shown that OraSure-based testing for drugs of abuse will be a welcome alternative to current urine-based testing.

INTERNATIONAL

International markets will receive a renewed emphasis and a modified approach starting early in fiscal year 2000. We recently welcomed Paul D. Slowey, Ph.D. as our new, highly experienced Director of International Sales. Dr. Slowey will facilitate our intensified focus on the large potential of the worldwide market. Under his guidance, we are conducting a comprehensive review to determine which additions or modifications to our products will best assist in various non-U.S. markets. It is already clear that the capabilities of our new OraQuick device for HIV testing are in high demand in many of these markets.

Specific requirements for registration and approval of new tests vary considerably from country to country. We believe that, after approval and usage in several countries, the growing body of clinical data on the performance of our products will make the process easier in new markets.

In Argentina, a substantial number of OraSure devices were used in fiscal 1998 for hepatitis testing; that government is now considering a much larger program using OraSure to test for HIV, Chagas and Hepatitis. Although several Argentine cities have conducted their own studies using OraSure, final government approval was delayed this past year by presidential elections and the related transfer of political power. The review process for OraSure appears to be back on track, although it is difficult to predict the timing of a final review.

In Greece, the government has approved the use of OraSure for large-scale HIV testing in that country. The final decision and ordering process is still proceeding. A number of other countries have expressed interest in HIV testing with OraSure in recent months, and discussions are already underway with potential strong distributors for large markets.

ORAQUICK

OraQuick is a rapid-assay technology, much like a home pregnancy test, but one that uses oral fluid. Epitope's development efforts for OraQuick have focused on HIV, with excellent results at this stage. There are many other potential diseases and conditions that could be detected with this technology, which is why we believe that this will become an added platform technology for the Company.

The market for rapid HIV tests is growing because of a realization by public health officials that a large percentage of people who are tested for HIV using current laboratory tests never return to clinics to receive their results. An accurate rapid test would allow clinics to perform screening, to counsel individuals on the basis of the screening result and then to confirm preliminary results with a laboratory test. We expect that the OraQuick HIV device will be in international clinical trials in early calendar year 2000 with a target of an international commercial launch later in the year. U.S. clinical trials are scheduled to begin by mid-calendar year 2000. Pre-production OraQuick devices have already been shipped to the Centers for Disease Control and Prevention (CDC) for use in studies in Africa.

ORASURE PLATFORM EXPANSION

Now that OraSure technology has been proven in the challenging HIV testing arena, the Company plans to begin leveraging our reputation and benefits of oral fluid testing to other markets.

The versatility of oral fluid testing using OraSure was demonstrated with the recent approval of a significant SBIR grant awarded Epitope to develop a test for syphilis using OraSure. The two-part, fast-track NIH grant could total $1.1 million. The Company has already performed much of the research work to establish the technical feasibility of producing a system for both screening and confirmatory tests for syphilis using an oral fluid sample. It is estimated that approximately 36 million syphilis tests are performed each year in the U.S. The number of tests performed is expected to increase, however, as the CDC continues a nationwide program for the elimination of syphilis started in October 1999. This multi-year program will require an increased testing effort to identify new cases of syphilis and begin treatment before transmission can occur. Once cleared by the FDA, the assays under development will for the first time permit the use of oral fluid samples to test for syphilis.

Our research has shown that many other diseases can be accurately detected using an OraSure sample. We are in the process of determining which of these will be given top priority for our near-term development efforts.

OUTLOOK

The future for oral fluid testing is bright. At Epitope, we intend to further solidify our role as the leading player in this important field. New projects will be carefully reviewed for their potential contribution to our financial results, and the management team will stay clearly focused on those tasks that will bring the best return to our shareholders.

Beyond the scope of oral fluid testing, the Company will also move into partnerships or products that fit with our markets or expertise and either improve our financial results or allow faster growth of our product lines. The management team at Epitope, augmented this past year with executives bringing experience and fresh perspectives, is committed to performing together to achieve the goal of building a strong commercial entity.

We wish to express our appreciation to the exceptional dedication of our employees and our partners. Without them, our progress would not be possible.

Charles E. Bergeron, Interim President and Chief Financial Officer

Roger L. Pringle, Chairman of the Board

Statements above regarding future events or performance are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. The Company's actual results could differ materially from such forward-looking statements. Factors that could affect results include: loss of key personnel; failure to comply with regulations of the FDA or other regulatory agencies; obstacles to international marketing of the Company's products; loss or impairment of sources of capital; ability of the Company to develop product distribution channels;ability of the Company to develop new products; development of competing products; market acceptance of oral testing products; changes in federal or state law or regulations; and uncertainties related to customers' and suppliers' ability to achieve Year 2000 compliance. Although forward-looking statements help to provide complete information about the Company, readers should keep in mind that forward-looking statements are much less reliable than historical information.

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark one)

[X] Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended September 30, 1999

OR

[ ] Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the transition period from _____ to _____

Commission File No. 1-10492

EPITOPE, INC.

(Exact name of registrant as specified in its charter)

Oregon	93-0779127
(State or other jurisdiction of incorporation or organization)	(I.R.S. employer identification no.)
8505 S.W. Creekside Place Beaverton, Oregon	97008
(Address of principal executive offices)	(Zip code)

(503) 641-6115
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act: None
Securities registered pursuant to Section 12 (g) of the Act:

Common Stock, no par value
(Title of Class)

Preferred Stock Purchase Rights
(Title of Class)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X] No [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [X]

State the aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, as of December 1, 1999**:** $ 74,793,338

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of December 1, 1999: Common Stock, no par value, 14,246,350 shares.

Documents Incorporated by Reference:

Definitive Proxy Statement for 1999 Annual Shareholders' Meeting: Part III

Table of Contents

PART I

PART II

PART III

PART IV

PART I

ITEM 1. Business.

Epitope, Inc. (Epitope or the Company) develops, manufactures and markets oral specimen collection devices and diagnostic products using its proprietary oral fluid technologies. These products are sold to public and private-sector clients in the United States and certain foreign countries. The Company's primary focus is on the detection of antibodies to the Human Immunodeficiency Virus (HIV), the cause of Acquired Immune Deficiency Syndrome (AIDS). The Company's technology is also being used to test for drugs-of-abuse and other analytes. Commercial distribution of the Company's oral specimen collection device as part of a test for five major drugs-of-abuse is scheduled to begin in calendar year 2000.

Epitope's lead product, the patented OraSure® collection device, is used in conjunction with screening and confirmatory tests approved by the U.S. Food and Drug Administration (FDA) to test for HIV-1 antibodies and other conditions. The Company markets the device for use in screening life insurance applicants and for public health use. The OraSure device consists of a small, treated cotton-fiber pad on a nylon handle that is placed in a person's mouth for two minutes. The device collects oral mucosal transudate (OMT), a serum-derived fluid that contains higher concentrations of antibodies than saliva, including HIV antibodies in people infected with the virus. As a result, OMT testing is a highly accurate method for detecting HIV infection. Because OraSure uses a noninvasive, needle-free collection method without need for privacy during the collection process, the Company believes that oral fluid HIV testing has several significant advantages over blood or urine-based testing systems for both healthcare professionals and individuals being tested.

Epitope also markets HIV-1 Western blot confirmatory test kits used to confirm positive results of initial screening tests for HIV-1 infection. Its OraSure HIV-1 Western blot confirmatory test kit is used in conjunction with oral-specimen based screening tests, while its EPIblot® HIV-1 Western blot confirmatory test kit is used in conjunction with blood-based screening tests. The kits are distributed worldwide under an exclusive agreement with Organon Teknika Corporation (Organon Teknika), a member of the Akzo Pharma group of Akzo Nobel, NV., an international chemical and pharmaceutical manufacturer based in Arnhem, The Netherlands.

The OraSure HIV-1 Oral Specimen Collection device and the OraSure HIV-1 Western blot and EPIblot confirmatory tests have all received clearance from the FDA for sale to professional markets in the United States. The FDA granted clearance in 1998 for use of OraSure with enzyme immunoassays manufactured by STC Technologies, Inc. (STC). In 1998, STC agreed to act as the exclusive distributor of the OraSure device, using STC's trade name Intercept Drugs of Abuse, for use with STC's substance abuse assays in the United States and much of Europe. See "Products" and "Marketing and Customers."

Background

HIV Disease. HIV attacks the immune system, slowly weakening the body's ability to ward off infection and certain forms of cancer. When these complications develop, the HIV infection has progressed to clinically diagnosed AIDS. HIV is spread through sexual contact, blood transfusions, the sharing of intravenous needles, accidental needle sticks, or contact between a mother and her child during gestation, childbirth, or breast-feeding. There is currently no known cure for HIV/AIDS. However, the introduction of anti-HIV drugs called protease inhibitors, when used in combination with nucleoside analogs (e.g., AZT), has shown promising results in slowing progress of the disease. Clinical studies have demonstrated that the early detection and treatment of HIV can help to curb the effects of the disease and significantly prolong the life of the patient. Other studies have shown that treatment with AZT of an HIV-infected pregnant woman may prevent the transmission of HIV from the mother to her child.

In 1998 UNAIDS, a program sponsored by the United Nations, estimated that since the beginning of the HIV/AIDS epidemic, more than 47 million individuals had contracted HIV. The death toll for HIV/AIDS in that same time span includes over 11 million adults and 3.2 million children. In 1998 alone, nearly 6 million people became infected with HIV, and nearly 2 million adults and 510,000 children perished from it. HIV/AIDS continues to be one of the leading causes of death in the world today with underdeveloped countries having the highest occurrence. In North America, an estimated 890,000 people are living with HIV as of December 1998.

According to reports from the Centers for Disease Control and Prevention (CDC) in August 1999, AIDS is now the leading cause of death in African Americans aged 25 to 44, affecting 1 in 50 African American males and 1 in 160 African American females in that age group. A growing number of women in the United States are also living with HIV/AIDS. In just over a decade, the proportion of all AIDS cases reported in women has tripled, accounting for 23 percent of the total new cases as of December 1998. The Global Strategic Business Report titled "HIV and AIDS Testing" published in May 1999, estimated that in the United States $232 million would be spent on HIV/AIDS screening and confirmatory tests in 1999. By 2003, this figure is estimated to increase to over $445 million.

Currently, most HIV tests are performed by testing blood. There are a number of blood tests for HIV, the most common of which is the enzyme immunoassay (EIA). In order to reduce the possibility that an individual without HIV will be diagnosed as having the virus (a false positive), most industrialized countries require the re-testing of the blood sample using a second, more specific test to confirm an initial positive test result. The most commonly used confirmatory test is the Western blot.

The Company believes that blood-based testing, in situations other than blood donation, has a number of disadvantages which increase healthcare costs and patient inconvenience, pose a risk of infection to healthcare professionals and make testing uneconomic or unavailable in certain applications or settings, and that the OraSure product overcomes these problems. The disadvantages of blood testing include:

Risk of HIV Infection. Blood tests involve the use of needles or lancets to obtain blood. Healthcare professionals collecting blood risk contracting HIV if accidentally stuck by the needle or lancet used to obtain blood from an infected individual.

Limited Access. Because blood must be collected by trained professionals, collection can be difficult or prohibitively expensive in certain settings. For example, community-based outreach programs, homeless shelters, rural communities, and other remote settings often lack healthcare professionals trained in blood collection. As a result, blood testing may not be readily available in some of these settings.

Higher Overall Cost. The cost of collecting a blood specimen represents a significant component of the total cost of HIV testing. Furthermore, when a healthcare professional must travel to the subject's office or home to collect a blood sample, as is often the case with life insurance applicant testing, the cost of collecting the blood specimen is substantially increased.

Discomfort. Blood tests require the use of needles or lancets that are uncomfortable for the individual being tested. In addition, individuals with small or damaged veins, such as intravenous drug users, the elderly and young children, may require multiple needle sticks in order to obtain an adequate blood sample.

Substance Abuse. Although HIV disease and drug abuse are distinct illnesses, each profoundly affects the other. According to the CDC, drug abuse is now the leading factor in the spread of HIV infection in the United States with half of all new infections in 1996 occurring among injecting drug users. According to the National Institute on Drug Abuse (NIDA), many public health agencies concerned about the spread of HIV are testing for both HIV and drugs-of-abuse. With the development of OraSure and Intercept Drugs of Abuse, both HIV and substance abuse testing may be done with a needleless, noninvasive orally collected sample.

Currently, the most common means to test for substance abuse involves collecting urine or blood samples, each of which may be considered either invasive or inconvenient. Urine testing is susceptible to adulteration of samples unless precautions are taken in the collection process.

The Company believes that oral fluid collection will be popular for substance abuse testing because of its non-invasive nature and ease of maintaining a chain of custody without embarrassment to the person being tested, as well as the lack of requirement for specially prepared collection facilities. The availability of an oral fluid test is intended to allow workplace administrators to test for impairment on demand, eliminate scheduling costs, and streamline the testing process.

Epitope Oral Specimen Collection Technology

In order to address the significant drawbacks associated with blood-based tests, Epitope developed and patented a device to collect an oral specimen instead of blood. The OraSure device, shaped like a small toothbrush, consists of a cotton-fiber pad treated with a patented salt solution. The pad, which is mounted on a nylon handle, is placed in the mouth between the lower cheek and gum for two minutes. The pad collects oral mucosal transudate, a serum-derived fluid that contains higher concentrations of antibodies than does saliva. The OraSure sample contains approximately four times the amount of antibodies found in saliva expectorated into a cup.

Following collection, the pad is sealed in a specimen vial containing a proprietary non-toxic preservative solution. The treated pad enhances the collection, and the preservative solution enhances the stabilization, of antibodies and other analytes originating from the oral mucosae. The specimen in the vial is stable for three weeks at room temperature, although in most cases laboratory testing takes place within one to three days.

Products

OraSure-HIV. In December 1994, the Company received clearance from the FDA to sell OraSure to professional markets for use with a laboratory-based EIA screening test for HIV-1 antibody detection. The device is marketed by the Company for use by the life insurance industry and public health programs in the United States and a number of other countries. See "Marketing and Customers."

HIV-1 antibody detection using the OraSure oral specimen collection device involves three steps: (i) collection of an oral specimen using OraSure, (ii) screening of the specimen for HIV-1 antibodies at a laboratory with an EIA screening test, and (iii) laboratory confirmation of any positive screening test results with the FDA-approved OraSure Western blot kit. A trained healthcare professional then conveys test results and provides appropriate counseling to the individual who was tested.

The OraSure HIV-1 test represents a highly accurate alternative to traditional blood-based tests. In clinical trials, OraSure provided the correct result or triggered appropriate follow-up testing in 3,569 out of 3,570 cases (99.97 percent). The Company believes OraSure has several advantages over blood-based tests, as outlined in the following table.

Feature	Blood Collection	OraSure
Safety	Poses risk of HIV infection through accidental needle sticks	Eliminates risk of needle-stick accidents
Invasiveness	Requires use of a needle or lancet	Uses noninvasive collection technique
Ease of use	Requires blood collection by a trained healthcare professional	Sample collection requires minimal training
Portability	Generally performed in a physician's office or other healthcare setting	Can be used rapidly and efficiently in almost any setting
Professional Cost	Requires a nurse or other healthcare professional trained in phlebotomy	Eliminates the need for and costs associated with a healthcare professional

In July 1999, an article was published by the Florida Bureau of HIV/AIDS titled “OraSure Uncovers Higher Seroprevalence in Some Florida Counties.” Florida began providing testing programs throughout the state with the OraSure device in February 1998. The testing programs were primarily for use in outreach settings, to reach high-risk persons (e.g., homeless persons, drug abusers, youth, and rural residents) who are less likely to access health care systems and less accepting of conventional testing methods.

Between February 1, 1998 and May 31, 1999, 30,328 OraSure tests were administered in Florida. 650 of which were returned positive (2.1 percent). Of the twenty-nine counties conducting tests during this period, fifteen found higher relative positivity rates with OraSure as compared to blood-based tests. Although OraSure tests accounted for less than 10 percent of the HIV testing in Florida at the time the article was written, the use of OraSure as an outreach tool was demonstrated in several counties. According to the article, anecdotal evidence from the field suggested that the availability of OraSure has resulted in increased test acceptance in a variety of outreach settings, including jails, homeless shelters, and high risk youth programs. For some of those tested, OraSure represents the opportunity to be tested safely and privately in situations where a needle mark could result in suspicion of drug use or domestic violence. Health care workers in Florida also appreciated the convenience, flexibility, and safety of using OraSure in outreach settings.

OraSure Drugs-of-Abuse Testing. The FDA granted clearances in 1998 for use of OraSure with enzyme immunoassays manufactured by STC Technologies, Inc. to test for cannabanoids (marijuana), amphetamines and methamphetamines, opiates, and cocaine. In addition, the FDA has allowed the use of OraSure to test for phencyclidine (PCP) under a "For Investigational Use Only" status in order to collect clinical samples and generate data required for FDA review.

In May 1999, STC contracted with Lab*One*, Inc. (Lab*One*) to market and provide oral fluid analysis for the Intercept Drugs Of Abuse product line in North America for work-site drug testing. Product trials are expected to be completed by December 1999 with product launch expected early in calendar year 2000.

The OraSure device has been approved in Japan for cotinine testing of life insurance applicants. Cotinine is a derivative of nicotine that indicates whether the tested subject is a smoker. The Finance Ministry of Japan announced in February 1998 that life insurance companies could reduce premiums on new nonsmoker policies by as much as thirty percent, effectively creating a larger market for cotinine testing of life insurance applicants in Japan. The Company also sells OraSure for cotinine testing of life insurance applicants in the United States. Cotinine is not currently regulated by the FDA for insurance risk assessment.

Oral-based and Serum-based Western Blot Confirmatory Tests. The Company markets an oral-based HIV-1 Western blot confirmatory test that received FDA clearance in 1996. This test uses the original specimen collected with the OraSure oral specimen collection device to confirm positive results of initial OraSure HIV-1 screening tests. The Company also markets EPIblot, a serum-based Western blot HIV-1 confirmatory test kit. The kit is used to confirm the positive results of initial blood-based screening tests for HIV-1 infection. Both Western blot products are marketed under an exclusive arrangement with Organon Teknika.

Products Under Development

OraSure. Oral mucosal transudate contains many constituents found in blood serum, although in lower concentrations. The Company therefore believes OraSure is a platform technology with a wide variety of potential applications beyond HIV-1 and drugs-of-abuse testing. For example, the OraSure device may be useful for the diagnosis of a variety of infectious diseases in addition to HIV-1, such as viral hepatitis, syphilis, prostate specific antigen (PSA) and a number of other diseases. In addition, the Company believes that the use of oral specimens may allow physicians to diagnose diseases more readily in children without subjecting them to the discomfort of drawing a blood sample, thereby increasing the frequency of testing for diseases.

Physicians may also find the OraSure device useful for monitoring the level of certain drugs and hormones that must be maintained within narrow therapeutic ranges. Monitoring of these substances currently requires frequent blood tests to determine drug concentration. The Company believes that oral specimen testing would eliminate the discomfort and inconvenience associated with this frequent blood testing.

OraQuick. Epitope is developing OraQuick®, a rapid-format oral specimen test designed to provide results within fifteen minutes. The Company believes that OraQuick has significant potential as a rapid test for professional use, and possibly as an over-the-counter home-based test. Prototype OraQuick devices, to be used for pre-clinical HIV testing, are in the final stages of development and the Company is establishing manufacturing specifications for the device. One patent is pending on this new technology and a second patent is in process. The Company is also evaluating the regulatory hurdles and clinical trials required to bring this product to market.

Like OraSure, OraQuick provides a platform technology that can be modified for detection of a variety of infectious diseases in addition to HIV, such as viral hepatitis, syphilis, childhood infections and a number of other diseases. The application of this technology to drugs-of-abuse testing appears promising and is currently under investigation within the Epitope development group. The Company will carefully analyze each application to determine the cost of development and regulatory approval compared to the potential benefits of each market and will focus its efforts on those with the best business return.

DNA Forensic Testing. During 1998, the Company entered into a research agreement with Analytical Genetic Testing Center (AGTC) to explore the use of OraSure for DNA collection. Results of this research have been positive, demonstrating that OraSure collects a high quality DNA sample. This sample is in addition to the antibody sample that is used to test for HIV-1, making it possible to test for antibodies and produce a DNA "fingerprint" with a single OraSure collection. The Company is now developing a beta-site testing program with AGTC to evaluate the use of OraSure in several key user settings. There are limited regulatory requirements in this market. If the results of research continue to be promising, a commercial launch of OraSure for DNA collection could be accomplished soon after field testing and development are completed.

Markets

Life Insurance Industry. Epitope believes there is a significant need in the life insurance industry for an easy-to-administer, noninvasive and cost-effective HIV-1 testing system such as OraSure. In the United States, approximately 7 million HIV tests were administered in 1997 by the life insurance industry in connection with the issuance of about 11 million new policies. In addition, data from the American Council of Life Insurance and the Health Insurance Association of America indicate that approximately $1 billion in AIDS-related death benefits were paid in 1997. The organizations also cautioned that, due to difficulty in identifying all AIDS-related claims, the data may significantly understate the financial impact of AIDS on the insurance industry.

Traditional HIV testing of life insurance applicants involves the use of a paramedic or other trained healthcare professional to obtain a blood sample. The cost to the insurance company for an HIV test includes the cost of the paramedic as well as the cost of the collection kit and laboratory testing services. The cost of collecting and processing a blood sample is approximately $70 per test versus a cost of $15 for an agent-collected OraSure test. As a result of the higher cost of collecting blood samples, insurance companies have generally limited HIV testing to policies with face amounts of $100,000 or more. Based on industry statistics, Epitope estimates that in 1997 approximately 8.9 million policies were issued for face amounts of less than $100,000, representing 80 percent of all policies issued. The Company believes that the use of OraSure can significantly reduce the cost of HIV-1 testing to the insurance industry because collection of an oral fluid specimen can be performed by insurance agents or other persons without professional medical training, eliminating the cost of the paramedic and making testing at policy levels below $100,000 a cost-effective practice. Insurance companies and testing laboratories expect the market for oral fluid testing of applicants to grow by at least 50 percent over the next several years .

Epitope also believes that the use of OraSure will allow the insurance industry to address "anti-selection." Anti-selection occurs when an individual who knows that he or she is infected with HIV intentionally applies for one or more life insurance policies that do not entail HIV testing. The Company believes that the adoption of OraSure by a number of insurance companies, and the current availability of an over-the-counter HIV blood test, may increase the incidence of anti-selection. By allowing insurance companies to lower the policy level at which HIV testing is cost-effective, using OraSure may allow insurance companies to reduce their exposure to losses from anti-selection and thereby lower overall claims costs.

Insurance companies have also been using the same OraSure specimen collected for HIV-1 testing to identify smokers and users of cocaine. Cotinine, a metabolite of nicotine, and cocaine can be detected using OraSure. In a presentation at the 105th annual meeting of The American Academy of Insurance Medicine in 1997, a major life insurance company reported results of the use of the OraSure device for tests in Canada and the Bahamas from 1992 to 1995. The life insurance company reported that OraSure sample collection by agents significantly reduced its testing costs per policy. During the four-year study period, the insurer found it saved $1.7 million using OraSure for HIV-1 and cocaine testing. In addition, the life insurance company determined it realized $1.6 million in increased

premiums as a result of identifying smokers who claimed on their applications that they were nonsmokers. In another study presented to the same Academy, Crown Life of Canada reported five-year savings from OraSure testing for cocaine, cotinine and HIV-1 of approximately $1.4 million.

Japanese Insurance Market. The Japanese life insurance market is served by 44 companies which sold approximately 35 million policies in 1996, of which about one-third were new ordinary life policies. Whole life policy applicants are most likely to be tested for smoking and other risk factors. While non-smoker policies have been available in the U.S. insurance market since the mid-1960s, it was only in early 1998 that Japanese regulators allowed premium reductions for non-smokers. Some insurance companies have begun the process of applying for new premium schedules and are using OraSure to test for evidence of smoking for these policies. Although many of the insurance companies in Japan are currently experiencing financial difficulties, the number of companies using OraSure has increased in the past year from five to eight. Epitope will continue to service this market, but does not anticipate any significant increases in sales for the next year.

Physician and Public Health Clinical Market. The physician market consists primarily of individual doctors' offices, which are supplied through the physicians' supply house network. Selling to this market requires a substantial sales force to call on the many offices throughout the country, each making its own purchasing decisions. Epitope has chosen not to focus on this market at this time because of the high cost of selling to these customers. The product is currently available to this customer base through various physicians' office supply channels. The Company has begun a pilot program to determine the feasibility of implementing a direct telemarketing program to further serve this market.

The public health market is more concentrated than the physician market, with typically more purchasing power in each decision maker. The customers consist of a broad range of clinics and laboratories and includes states, counties, colleges and universities, correctional facilities and the military. There are also a number of smaller organizations in the public health market such as AIDS Service Organizations and various community-based organizations set up for the primary purpose of encouraging and enabling HIV-1 testing to combat the spread of AIDS. The OraSure device has received a warm welcome in the public health market because of its accuracy, ease of use, reliability, and non-invasive nature.

International. In light of the worldwide scope of the HIV epidemic, Epitope believes there are significant opportunities for sale of OraSure and OraQuick in international markets. The Company believes that the ease of use, portability, and increased safety of OraSure, and aversion to blood draw in certain cultures will provide significant advantages for oral fluid testing over blood tests in international markets.

During the second quarter of fiscal 1999 the Company received approval for the sale of the OraSure HIV-1 device in Europe. Approval to use the CE mark, which is required to sell the OraSure device in all fifteen countries of the European Economic Community, was received following an inspection of Epitope's facilities and processes by representatives of the European Notified Body. The OraSure collection device has been registered under European regulations as a Class III medical device, the classification requiring the highest degree of scrutiny for CE mark approval. Epitope distributors are actively marketing the device in England, Ireland and Greece. The Company expects to begin product shipments to Europe under the new CE mark approval in fiscal 2000.

Drugs-of-Abuse Market. The analytical testing portion of the United States drugs-of-abuse testing market is estimated to be over $725 million, with approximately 42 million tests performed in 1998. Testing is concentrated on a set of commonly abused drugs called the NIDA-5, consisting of cocaine, methamphetamines, opiates, marijuana and PCP.

According to an Office of National Drug Control Policy report on drug abuse in America, October 1999, the social cost of illicit drug abuse is nearly $110 billion each year. There are more than one million drug arrests each year and half of all those arrested test positive for illicit drug use.

Results from the 1994 and 1997 National Household Survey on Drug Abuse released by the Substance Abuse and Mental Health Services Administration (SAMHSA) showed that the percent of workers who reported that their workplaces had any type of drug testing program increased significantly between 1994 and 1997 (from 44 percent to 49 percent). The study found that 70 percent of illicit drug users, age 18-49, are employed full-time. Among full-

time workers, there were 6.3 million illicit drug users and 6.2 million heavy alcohol users. The study further revealed that 1.6 million of these workers were both heavy alcohol and illicit drug users. The overall rate of current illicit drug use among full time employees had fallen from 17.5 percent in 1985 to 7.4 percent in 1992, but had risen to 7.7 percent by 1997.

Comprehensive workplace programs that combine drug testing, access to treatment, and employee education have proven to increase workplace safety and productivity, reduce absenteeism and theft, and reduce the human and economic effects of substance abuse. See "Marketing and Customers."

OTC Market. The over-the-counter (OTC) market for HIV testing currently is served by only one product, distributed by Home Access Health Corp., which uses a dried blood spot to provide the patient's sample. This sample is then sent to a laboratory for testing and test results are communicated to the customer via an 800 number. In July 1997, citing lower sales than expected and lower market estimates, Johnson & Johnson dropped its Confide HIV test from the OTC market. Epitope is not currently pursuing this market, but has not ruled out doing so in the future.

Marketing and Customers

Life Insurance Industry. Epitope currently markets the OraSure device for use in screening life insurance applicants to test for three of the most important underwriting risk factors: HIV-1, cocaine, and cotinine (a derivative of nicotine). Epitope sells the devices to insurance testing laboratories, which in turn provide the devices to insurance companies, usually in combination with testing services. The Company maintains a direct sales force that promotes use of OraSure directly to insurance companies. Insurance companies then make their own decision regarding which laboratory to use to supply their collection devices and testing services. The major laboratories currently using the OraSure device include Lab*One*, Inc., Osborn Group, Inc., Clinical Reference Laboratory, and Heritage Labs International, LLC (Heritage Labs).

As of August 1999, more than 150 U.S. ordinary life insurance companies were using OraSure to varying degrees for testing applicants for life insurance. These 150 companies included seven of the top ten U.S. life insurance companies; the ten accounted for 21 percent of ordinary life insurance policies issued in the U.S. in 1998. According to Best's Review (July 1999), the top 100 companies represented 79 percent of newly issued business and 81 percent of in-force business. In 1998, ordinary life insurance issued climbed 8.5 percent to $1.48 trillion, while ordinary life insurance in force grew by 12.8 percent industry-wide to $12.9 trillion.

Because insurance companies are in various stages of their adoption of OraSure, there exists a wide range of policy limits where the product is being applied. Some insurance companies have chosen to extend their testing to lower policy limits where they did not test at all before, while others have used OraSure to replace some of their blood-based testing. Epitope's sales force continues to encourage additional insurance companies to use OraSure and to extend the use of the product by existing customers. Several companies have expanded use of OraSure in "Preferred" products in addition to the $1 million and higher dollar policy amounts. This expansion is attributable to several factors, including increasing comfort with oral fluid testing following its successful use, the low cost of oral fluid testing relative to blood tests, and the ease of use of OraSure.

Physician and Public Health Clinical Market. As explained above under "Markets," Epitope is not currently focusing sales efforts on the physician market because of the high cost of selling to the large number of independent entities involved in making purchasing decisions. OraSure is currently available to the physician market through various physicians' office supply channels. The Company has begun a pilot program to determine the feasibility of implementing a direct telemarketing program to further serve this market.

Epitope sales personnel sell its products directly to customers in the public health market. To better serve this market, Epitope entered into agreements with Lab*One* and Heritage Labs to provide prepackaged OraSure test kits, with prepaid laboratory testing and specimen shipping costs included. These OraSure test kits represented nearly half of the Company's revenues from this market in 1999.

Federal Supply Schedule Contract. Epitope received approval to be listed in the General Services Administration (GSA) Federal Supply Schedule during the second quarter of fiscal 1999. Government agencies are encouraged to purchase from the Federal Supply Schedule, which offers the best pricing for approved products. This schedule applies to various federal agencies, including the Veteran's Administration, the military, the Federal Bureau of Prisons, Job Corp, the Federal Aviation Administration, the National Institutes of Health, and many others. Market studies indicate that the number of HIV tests associated with GSA contracts is currently about 2 million per year. The Company reorganized its public health field sales force during fourth quarter 1999 to place more emphasis on selling to the large customers represented by this market.

International. Epitope markets to international customers primarily through distributors with knowledge of their local market. The distributor's expertise is supplemented by Epitope's contacts with testing companies to assist in registering the necessary tests in each country, and Epitope's assistance with training and support materials. Epitope's international marketing program features direct assistance to distributors in establishing OraSure programs that include laboratory services, cooperation from screening test manufacturers, and provision of Western blot confirmatory kits when necessary. Epitope has marketed OraSure in the United Kingdom (UK), Ireland, Thailand, Argentina, Brazil, South Africa, Greece, the Philippines, Taiwan, Mexico and Colombia. Canadian insurance customers are served primarily through their United States-based affiliated insurance testing laboratories. The recent addition of a new Director of International Sales and Marketing will greatly improve the Company's ability to expand its international sales of OraSure. See "Personnel."

The Company entered into a distribution agreement in September 1998 with Altrix Healthcare, plc, a UK-based health diagnostic service provider, for the sale and distribution of OraSure to the life insurance, public health, and laboratory markets in the UK and Ireland. The agreement contemplates optional expansion of the relationship to other European countries.

In September 1999, Epitope signed an exclusive distribution arrangement with Medical Products, Ltd., a Greece-based medical products distributor selected to replace the Company's former distributor in that country. The Company's former distributor has protested the termination of its agreement and attempted to disrupt the sales process in Greece. Epitope has responded and will take legal action, if necessary, to preserve its rights in establishing a new distributor. OraSure has been recently selected by the Greek government for a planned multi-year program for widespread HIV testing of the Greek population. The Company will begin shipping product when the Greek government gives all required approvals and issues a purchase order.

Epitope participates in a joint venture in Japan which markets both the OraSure device and STC's cotinine test to the Japanese life insurance market. Epitope holds exclusive distribution rights in Japan for STC's laboratory-based test for cotinine, sold for use in insurance risk assessment. Epitope has the option to expand its exclusive distribution rights for the cotinine test worldwide, excluding the U.S.

The Argentinean Society of AIDS organized an HIV virus and detection campaign called "Seven Days of Life" in Rosario, Argentina during late November 1999. This campaign was presented to stimulate and facilitate the testing of the general population using Epitope's OraSure device. In addition, the Company is actively pursuing a clinical trial supported by Argentina's Ministry of Health; however, recent government elections in that country have slowed that process. In 1998, OraSure was used to test patients for Hepatitis in Argentina. The Company is also exploring opportunities to distribute OraSure in Brazil.

Drugs-of-abuse Market. In November 1998, the Company entered a supply and distribution agreement with STC, its research partner in the drugs-of-abuse market. Under the terms of the agreement, Epitope will act as the exclusive supplier of oral fluid collection devices using STC's trade name Intercept Drugs of Abuse for use with STC's laboratory-based, NIDA-5 drugs-of-abuse tests in the U.S. and Europe, excluding the U.K. and Ireland. STC will act as the exclusive distributor of the OraSure device for drugs-of-abuse testing in the same territory. The agreement provides for Epitope to sell oral fluid collection devices to STC for a per-unit price plus a royalty based on STC's gross revenue from the sale of the devices and STC's oral fluid drugs-of-abuse test. The agreement also covers any additional laboratory-based drugs-of-abuse tests that STC may market, including those STC is now developing using up-converting phosphor technology. The agreement will remain in effect for a minimum term of five years. STC has contracted with Lab*One* to provide oral fluid laboratory analysis for STC's drugs-of-abuse product line in the North American work-site testing market.

Western Blot Distribution. Epitope has exclusive supply and distribution agreements with Organon Teknika Corporation for Epitope's Western blot products. The supply agreement provides that Organon Teknika will supply the HIV-1 antigen used to manufacture Western blot confirmatory test kits. The distribution agreement grants Organon Teknika the exclusive right to purchase Western blot confirmatory test kits from Epitope and to market them worldwide. The supply and distribution agreements between Epitope and Organon Teknika were recently extended to March 31, 2001.

Customer Concentration. In fiscal 1999, the Company's sales to Lab*One*, Inc., Osborn Group, Inc., Clinical Reference Laboratory, Heritage Labs and Organon Teknika accounted for over 70 percent of product revenues. The Company believes that its relationship with each of these customers is strong and believes that they will purchase comparable or increasing volumes of the Company's products for the foreseeable future. There can be no assurance, however, that sales to these customers will not decrease or that these customers will not choose to replace the Company's products with those of competitors. The loss of any of these customers or a significant decrease in the volume of products purchased by them would have a material adverse effect on the Company.

Competition

Competition in the market for HIV testing is intense and is expected to increase. The Company believes that the principal competition will come from existing laboratory-based blood tests, point-of-care whole blood rapid tests, urine-based assays, or other oral fluid-based tests that may be developed. Epitope's competitors include specialized biotechnology firms as well as pharmaceutical companies with biotechnology divisions and medical diagnostic companies, many of which have considerably greater financial, technical, and marketing resources than Epitope. Competition may intensify as technological advances are made and become more widely known and as products reach the market in greater numbers. Furthermore, new testing methodologies could be developed in the future that render Epitope's oral-based HIV-1 test impractical, uneconomical or obsolete. There can be no assurance that Epitope's competitors will not succeed in developing or marketing technologies and products that are more effective than those developed by Epitope or that would render its technologies or products obsolete or otherwise commercially unattractive. In addition, there can be no assurance that competitors will not succeed in obtaining regulatory approval for these products, or in introducing or commercializing them before Epitope. Such developments could have a material adverse effect on the Company's business, financial condition and results of operations.

Three companies have submitted applications to the FDA for OTC HIV blood testing: Direct Access Diagnostics, Home Access Health Corp., and ChemTrak Incorporated. The FDA approved home collection kits for HIV blood testing developed by Direct Access Diagnostics (a division of Johnson & Johnson) and by Home Access Health Corp. In July 1997, Direct Access Diagnostics withdrew its HIV home-test from the market, citing weak sales. Direct Access and ChemTrak are no longer in business, leaving only Home Access active in this market.

Calypte, Inc., BioRad Laboratories, Inc. and Genetic Systems Corp. manufacture HIV Western blot confirmatory tests, and Waldheim Pharmazeutika manufactures immunofluorescent HIV confirmatory tests, which compete with Epitope's EPIblot HIV-1 Western blot serum-based confirmatory test kits. Calypte, Inc. acquired the Western blot manufacturing facilities and rights of Cambridge Biotech Corporation in December 1998.

Several other companies market or have announced plans to market oral specimen collection devices and tests outside the United States and have announced plans to seek FDA approval of such tests in the United States. Epitope expects the number of devices competing with its OraSure device to increase as the benefits of oral specimen-based testing become more widely accepted. The Company expects that FDA approval of the OraSure device will also encourage potential competitors to develop oral diagnostic products. No such devices have yet been approved by the FDA for HIV-1 testing. See "Government Regulation."

The FDA has approved an HIV-1 screening test for use with a urine sample. In June 1998, the FDA notified Cambridge Biotech Corp. (acquired by Calypte**,** Inc. in December 1998) that it had approved the use of its HIV-1 Western Blot confirmatory test for use with urine samples. Although the sensitivity and specificity are less than blood-based or oral fluid tests, urine testing will compete in the same markets as the Company's products. The

Company believes that urine collection can be logistically more difficult, inconvenient and potentially embarrassing for the individual being tested, and that privacy and chain-of-custody issues are further impediments to routine use of urine-based HIV tests. The Company cannot predict the impact of the availability of urine-based tests on the HIV testing market or on sales of the Company's products.

Government Regulation

General. Most of Epitope's existing and proposed diagnostic products are regulated by the FDA, other state and local agencies, and comparable bodies in other countries. This regulation governs almost all aspects of development, production, and marketing, including product testing, authorizations to market, labeling, promotion, manufacturing, and recordkeeping. All of Epitope's FDA-regulated products require some form of action by the FDA before they can be marketed in the United States, and, after approval, Epitope must continue to comply with other FDA requirements applicable to marketed products. Both before and after approval, failure to comply with the FDA's requirements can lead to significant penalties.

Product Approvals. Most of Epitope's diagnostic products are regulated as medical devices. The Western blot confirmatory test is regulated as a biologic product.

There are two review procedures by which medical devices can receive FDA clearance or approval. Some products may qualify for clearance under a Section 510(k) procedure, in which the manufacturer provides a premarket notification that it intends to begin marketing the product, and shows that the product is substantially equivalent to another legally marketed product (i.e., that is has the same intended use and is as safe and effective as a legally marketed device and does not raise different questions of safety and effectiveness). In some cases, the submission must include data from human clinical studies. Marketing may commence when the FDA issues a clearance letter finding such substantial equivalence.

If the medical device does not qualify for the 510(k) procedure (either because it is not substantially equivalent to a legally marketed device or because it is a Class III device required by the statute and the FDA's implementing regulations to have an approved application for premarket approval), the FDA must approve a premarket approval application (PMA) before marketing can begin. PMAs must demonstrate, among other matters, that the medical device is safe and effective. A PMA is typically a complex submission, including the results of preclinical and clinical studies. Preparing a PMA is a detailed and time-consuming process. Once a PMA has been submitted, the FDA's review may be lengthy and may include requests for additional data.

Biologic products must be the subject of an approved biologics license application (BLA) before they can be marketed. The FDA approval process for a biologic is similar to the PMA approval process, involving a demonstration of the product's safety and effectiveness based in part on both preclinical and clinical studies.

Epitope has received several FDA approvals and clearances. The first approval, in March 1991, was a BLA for the EPIblot HIV-1 serum-based confirmatory Western blot confirmatory test. Since then, Epitope's approvals have involved oral specimen-based diagnostic tests. In 1994, the FDA approved Epitope's PMA for use of the OraSure device in HIV-1 screening. The FDA also has issued several 510(k) clearances for non-HIV uses of the OraSure device. In June 1996, the FDA approved Epitope's PMA for use of the OraSure and oral-specimen-based Western blot confirmatory test for HIV-1 diagnosis.

Obtaining FDA approval for either medical devices or biologic products requires substantial time, effort, and expense. Epitope cannot assure that it will be able to obtain any additional approvals or clearances on a timely basis, or at all. Approvals and clearances limit the indications for which a product may be marketed; accordingly, Epitope may market its existing and future approved products only for the indications that the FDA has approved or cleared. Even after approvals are obtained, the FDA may suspend or revoke approvals if problems are identified.

Manufacturing Requirements. Every company that manufactures biological products or medical devices distributed in the United States must comply with the FDA's Good Manufacturing Practices ("GMP") Regulations. These regulations govern the manufacturing process, including design, manufacture, testing, release, packaging, distribution, documentation, and purchasing. Compliance with GMPs is generally required before the FDA will approve a PMA or BLA, and these requirements also apply to marketed products.

Postapproval Requirements. Companies are also subject to other post-market and general requirements, including compliance with restrictions imposed on marketed products, compliance with promotional standards, recordkeeping, and reporting of certain adverse reactions. The FDA regularly inspects companies to determine compliance with GMPs and other post-approval requirements. Failure to comply with statutory requirements and the FDA's regulations can lead to substantial penalties, including monetary penalties, injunctions, product recalls, seizure of products, and criminal prosecution.

Warning Letter. Epitope received a warning letter from the FDA in June 1998, asserting that the Company has not fully adhered to FDA's Good Manufacturing Practice Regulations. The FDA made similar observations during an inspection in January 1999. It is the Company's belief that none of the FDA's observations affected the safety or effectiveness of its products. Epitope has cooperated with the FDA to address the issues identified, has aggressively implemented enhanced quality control procedures, and has retrained personnel. The Company has also hired a new Vice President of Quality Assurance and Regulatory Affairs- to assist in bringing the Company's systems into compliance. See "Personnel."

International. Epitope is also subject to regulations in foreign countries governing products, human clinical trials and marketing. Approval processes vary from country to country, and the length of time required for approval or to obtain other clearances may in some cases be longer than that required for U.S. governmental approvals. The extent of potentially adverse governmental regulation affecting Epitope that might arise from future legislative or administrative action cannot be predicted. Epitope will pursue approval only in those countries that have a significant market opportunity.

In the second quarter of fiscal 1999 Epitope received approval to use the CE mark which is required to sell the OraSure device in all fifteen countries of the European Economic Community. The Company received approval to sell OraSure as a Class III medical device, the classification requiring the highest degree of scrutiny for the CE mark, following an inspection of Epitope's facilities and processes by representatives of the European Notified Body. Epitope distributors are actively marketing the device in England, Ireland and Greece. The Company has begun shipments to Europe under the new CE mark approval.

Other. Epitope is also subject to regulation by the Occupational Safety and Health Administration and may be subject to regulation by the U.S. Environmental Protection Agency (EPA) under the Toxic Substances Control Act (TSCA), the Resource Conservation and Recovery Act, and other legislation.

Supplies

The HIV-1 antigen needed to manufacture Epitope's Western blot HIV confirmatory test kits is available from only a limited number of sources. Organon Teknika, the exclusive distributor of the test kits, is required to supply Epitope's requirements for antigen for the term of its distribution agreement with Epitope, which has recently been extended to March 31, 2001. If for any reason Organon Teknika should no longer be able to supply the Company's antigen needs, management believes Epitope would be able to obtain its own supply of antigen at a competitive cost, although a change in the antigen would require FDA approval. Epitope has obtained a license from the National Technical Information Service which is required for the production of the HIV-1 antigen currently used in the Company's Western blot test kits. It is unlikely that Epitope would choose to manufacture its own antigen because of its availability from other suppliers. Other materials used by Epitope in manufacturing, production, and research and development are widely available from a variety of sources.

Grants and Contracts

In September 1999, the National Institutes of Health (NIH) and the National Institute of Allergy and Infectious Diseases (NIAID) approved a grant to Epitope under the Small Business Innovation Research Program Fast-Track Initiative for the development of syphilis assays based on an oral fluid sample. Under the Fast-Track Initiative, both Phase I and Phase II requests were reviewed and approved. This approval means that if agreed-upon benchmarks are met at the end of Phase I work, the award of the Phase II funding can be made based on the recommendation of the project's steering committee. Phase I funding amounting to $117,674 has already been approved and an additional

$992,373 has been requested for Phase II.

Epitope has received funding in the past from the NIAID, for work in developing a rapid test to detect HIV antibodies in oral fluid specimens, and from the National Cancer Institute (NCI), to fund research for the treatment of cancer by exploiting a deficiency of certain compounds in cancer cells. The Company regularly makes applications for new grants, but there is no assurance that additional grant support can be obtained.

Patents and Proprietary Information

Epitope has obtained patents in the United States and certain foreign countries for the OraSure device and related technology. Epitope has applied for additional patents, both in the United States and in certain foreign countries, on the OraSure collection device and a number of other technologies and products. The Company anticipates filing patent applications for protection on future products and technology. United States patents generally have a maximum term of 20 years from the date an application is filed.

Much of the technology developed by the Company is subject to trade secret protection. To reduce the risk of loss of trade secret protection through disclosure, the Company requires its employees and consultants to enter into confidentiality agreements.

Although important, the issuance of a patent or existence of trade secret protection does not in itself ensure the Company's success. Competitors may be able to produce products competing with a patented Company product without infringing on the Company's patent rights. Issuance of a patent in one country generally does not prevent manufacture or sale of the patented product in other countries. The issuance of a patent to the Company or to a licensor is not conclusive as to validity or as to the enforceable scope of the patent. The validity or enforceability of a patent can be challenged by litigation after its issuance, and, if the outcome of such litigation is adverse to the owner of the patent, the owner's rights could be diminished or withdrawn. Trade secret protection does not prevent independent discovery and exploitation of the secret product or technique.

Personnel

William D. Block was named Vice President of Sales and Marketing on May 16, 1999. Mr. Block was hired following a nationwide search to replace Edward V. Collom, Jr., who resigned in March 1999 for health reasons. Prior to accepting the position at Epitope, Mr. Block held a variety of sales and management positions with companies in the medical field, including McKesson Automated Pharmacy Solutions (a division of McKesson HBOC, Inc.), Allegiance Healthcare Corp., Baxter Healthcare Corp., and Biotronics Enterprises, Inc.

Rob Ngungu was named to the newly created position of Vice President of Quality Assurance and Regulatory Affairs on October 25, 1999. Mr. Ngungu has more than 17 years of quality assurance and regulatory affairs experience with medical companies such as Baxter Diagnostics (a former division of Baxter Healthcare Corp.) and Johnson & Johnson Ultrasound (a former division of Johnson & Johnson, Inc.). He was most recently employed by McGhan Medical Corporation, a Santa Barbara, California- based medical device company, where he was Vice President, Quality Systems and was responsible for overseeing five departments within the regulatory and compliance sector.

Paul D. Slowey, Ph.D. was appointed Director of International Sales and Marketing on October 1, 1999. Dr. Slowey has over 16 years experience in medical products and diagnostics and was most recently Vice President, Sales and Marketing and Chief Operating Officer of Saliva Diagnostics Systems, Inc., a Vancouver, Washington-based maker of rapid saliva and blood tests for HIV and H. Pylori. Before joining Saliva Diagnostics, he worked six years at Incstar Corporation, a Minneapolis-based medical systems and diagnostics subsidiary of American Standard Companies. While there, Dr. Slowey became Director, International Sales, where he managed a $22 million unit, appointing international distributors and establishing strategic partnerships.

On September 30, 1999, John W. Morgan notified the Company of his resignation as President and Chief Executive Officer. Mr. Morgan remains a member of the Epitope board of directors. Charles E. Bergeron, Chief Financial Officer, is serving as Interim President until a new Chief Executive Officer is hired. The Company has retained an industry-focused executive search firm to assist in the search for a permanent Chief Executive Officer. A committee

of the board of directors is overseeing the search.

At September 30, 1999, the Company had 83 full-time employees, including 16 persons in research and product development, 28 in administration and marketing, 30 in manufacturing and production, and 9 in regulatory affairs and quality assurance. The Company considers its relations with its employees to be excellent. None of its employees are represented by labor unions.

The Company employs 6 persons holding Ph.D. degrees with specialties in the following disciplines: virology/molecular biology, biochemistry, microbial physiology, microbiology and organic chemistry. From time to time, the Company also engages the services of scientists as consultants to augment the skills of its scientific staff.

Scientific Advisory Board

The Company utilizes the services of a Scientific Advisory Board. The Scientific Advisory Board meets periodically to review the Company's research and development efforts and to apprise the Company of scientific developments pertinent to the Company's business. The Scientific Advisory Board comprises chair Daniel Malamud, Ph.D., Professor and Chair, Department of Biochemistry, University of Pennsylvania School of Dental Medicine; J. Richard George, Ph.D., Chief Scientific Officer of Epitope; James I. Mullins, Ph.D., Professor of Microbiology and Medicine, University of Washington; Wayne R. Wecksler, Ph.D., General Manager, Esoteric Testing Center, SmithKline Beecham Clinical Laboratories, Van Nuys, CA; and John V. Parry, Ph.D., Deputy Director, Hepatitis and Retrovirology Laboratory, Central Public Health Laboratory, Virus Reference Division, London, England.

Forward-Looking Statements; Risk Factors

Statements in this report regarding future events or performance are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. The Company's actual results could be quite different from those expressed or implied by the forward-looking statements. Factors that could affect results include the risk factors discussed below, those discussed in Item 7, and those described elsewhere in this Annual Report on Form 10-K. Although forward-looking statements help to provide complete information about the Company, readers should keep in mind that forward-looking statements are much less reliable than historical information. Readers are cautioned not to place undue reliance on the forward-looking statements.

Loss of Key Personnel. The Company depends to a large extent on the abilities and continued participation of its executive officers and scientific personnel. The loss of key personnel could have a material adverse effect on the Company's business, financial condition, and results of operations. Competition for management and scientific staff in the medical products field is intense. No assurance can be given that the Company will be able to continue to attract and retain personnel with sufficient experience and expertise to satisfy the Company's needs.

Regulatory Compliance. The Company can manufacture and sell the OraSure device and other regulated products, both in the U.S. and in some cases abroad, only if it complies with regulations of government agencies such as the FDA. The Company has implemented quality assurance and other systems that are intended to comply with applicable regulations. The FDA has issued warning letters, to which the Company has responded, stating that the Company is not in compliance with the FDA's regulations. Although the Company believes that it has satisfactorily addressed the points raised by the FDA, the FDA could force the Company to stop manufacturing products if the FDA concludes that the Company is out of compliance with applicable regulations. In addition, until the FDA agrees that the Company has resolved all points raised in the warning letters, the Company may not be able to obtain regulatory clearance certificates needed in certain foreign countries.

International Marketing Obstacles. The Company is devoting significant resources to international sales of its products. In addition to economic and political issues, a number of factors can slow or prevent international sales. In the past, Epitope has had little direct experience with the governmental regulatory agencies in many countries that control sale of the Company's products. The Company's new Director of International Sales and Marketing, however, has substantial experience dealing with these agencies. See "Personnel." The Company's recent experience with extended delays in obtaining approvals to make sales in Argentina demonstrates that compliance

with foreign regulatory requirements can be difficult and can impede international marketing efforts. Epitope must rely on the cooperation of distributors to market its products in foreign countries and to register and provide technical support for the laboratory tests which may be used with OraSure. Changes in distributor relationships can interfere with the sales process because registrations may be in the name of the former distributor.

Loss or Impairment of Sources of Capital. Although the Company has made significant progress in the last two fiscal years toward controlling expenses and increasing product revenue, the Company has historically depended to a substantial degree on capital raised through the sale of equity securities to fund its operations. The Company's future liquidity and capital requirements will depend on numerous factors, including the costs and timing of expansion of manufacturing capacity, the success of product development efforts, the costs and timing of expansion of sales and marketing activities, the extent to which existing and new products gain market acceptance, competing technological and market developments, and the scope and timing of strategic acquisitions. If additional financing is needed, the Company may seek to raise funds through the sale of equity securities. There can be no assurance that financing through the sale of equity securities, or otherwise, will be available on satisfactory terms, if at all.

Ability of the Company to Develop Product Distribution Channels. The Company has marketed most of its products by collaborating with pharmaceutical and diagnostic companies and distributors. For example, the Company's EPIblot and OraSure Western blot confirmatory tests are distributed through Organon Teknika, the OraSure collection device is distributed to the insurance industry through major insurance testing laboratories, and the Company has entered an agreement with STC to distribute the OraSure device for drugs-of-abuse testing. Except in the public health market, the Company does not maintain a substantial sales or marketing force. Accordingly, the Company's sales depend to a substantial degree on its ability to develop product distribution channels and on the marketing abilities of the companies with which it collaborates.

Ability of the Company to Develop New Products. The Company's OraSure collection device is becoming recognized in the insurance and public health markets as part of a reliable, effective testing alternative. The Company's long-term strategy is based on continued expansion of markets for OraSure and the development of new products. OraQuick and other planned products are in various stages of development. In some cases, the Company will be required to achieve difficult scientific or technical objectives before the commercial or technological feasibility of new products can be demonstrated. There can be no assurance that products under development will perform in accordance with expectations, that necessary regulatory approvals will be obtained, or that the products can be successfully and profitably manufactured, distributed, and sold.

Development of Competing Products. Competition in the medical products business is intense and will likely increase. The Company believes that the principal competition for OraSure will come from blood-based and urine-based assays, and could also come from other oral-fluid testing systems. New testing methods could be developed in the future that render the Company's products uneconomical or obsolete. Most of the Company's competitors have significantly greater financial, manufacturing, technical, research, marketing, sales, distribution and other resources than those of the Company. There can be no assurance that the Company will not experience competitive pressures, particularly with respect to pricing, that could have a material adverse effect on the Company's business, results of operations and financial condition. See "Competition" above for additional information.

Market Acceptance of Oral Testing Products. The Company has made significant progress in gaining acceptance of oral testing for HIV in the insurance and public health markets. The Company also expects that oral testing for drugs-of-abuse will be accepted in employment testing. Other markets, particularly the physician market, may resist the adoption of oral testing as a replacement for other testing methods in use today. There can be no assurance that the Company will be able to expand use of its oral testing products in these markets.

Changes in Federal or State Law or Regulations. As described more fully above under "Government Regulation," many of the Company's proposed and existing products are subject to regulation by the FDA and other governmental agencies. The process of obtaining required approvals from these agencies varies according to the nature of and uses for the product and can involve lengthy and detailed laboratory and clinical testing, sampling activities, and other costly and time-consuming procedures. Changes in government regulations could require the Company to undergo additional trials or procedures, or could make it impractical or impossible for the Company to market its products for certain uses, in certain markets, or at all. Other changes in government regulations, such as the adoption of the FDA's Quality System Regulation, may not affect the Company's products directly but may

nonetheless adversely affect the Company's financial condition and results of operations by requiring that the Company incur the expense of changing or implementing new manufacturing and control procedures.

The previous discussion of the Company's business should be read in conjunction with the Consolidated Financial Statements and accompanying notes included in Item 14 of this Annual Report on Form 10-K.

ITEM 2. Properties.

The Company leases approximately 35,600 square feet of office, manufacturing, and laboratory space in Beaverton, Oregon, under two leases that terminate January 31, 2000. The lease for the Company's primary office, manufacturing and laboratory space of 30,500 square feet has been renewed through January 31, 2005. The remaining lease for 5,100 square feet of excess office space will not be renewed at expiration. The Company also leases 2,265 square feet of warehouse space to store inventory and equipment under a lease expiring September 30, 2002. Each lease calls for fixed monthly payments over its term plus an allocation of common area charges and taxes. The total amount of the Company's base lease obligation through the term of these leases is $2,030,025.

ITEM 3. Legal Proceedings.

Not applicable.

ITEM 4. Submission of Matters to a Vote of Security Holders.

No matters were submitted to a vote of security holders during the fourth quarter of the fiscal year covered by this report.

PART II

ITEM 5. Market for Registrant's Common Equity and Related Stockholder Matters.

The Company's Common Stock is listed for trading on the National Market tier of The Nasdaq Stock Market (NASDAQ) under the symbol EPTO. High and low sales prices reported by NASDAQ during the periods indicated are shown below.

Sales prices per share

Year ended September 30	**1999**		**1998**	
	High	**Low**	**High**	**Low**
First Quarter	$ 6.500	$ 2.500	$ 8.125	$ 4.250
Second Quarter	8.375	4.500	7.188	4.750
Third Quarter	6.125	3.688	6.875	4.563
Fourth Quarter	7.500	4.875	7.000	2.875

On December 1, 1999, there were 873 holders of record of the Common Stock, and the closing price of the Common Stock was $5.25. The Company has never paid any cash dividends, and the Board of Directors does not anticipate paying cash dividends in the foreseeable future. The Company intends to retain any future earnings to provide funds for the operation and expansion of its business.

ITEM 6. Selected Financial Data.

The following table sets forth selected consolidated operating results and balance sheet data of Epitope, Inc. and its subsidiaries. The balance sheet data at September 30, 1999 and 1998 and the operating results data for the years ended September 30, 1999, 1998 and 1997 have been derived from audited Consolidated Financial Statements and notes thereto included in this Annual Report on Form 10-K. The balance sheet data at September 30, 1997, 1996, and 1995 and operating results data for the years ended September 30, 1996 and 1995 have been derived from audited Consolidated Financial Statements and notes thereto not included in this Annual Report on Form 10-K. This information should be read in conjunction with the Consolidated Financial Statements and notes thereto included in Item 14 and Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Comparative Financial Data
(In thousands, except per share data)

Year ended September 30,	**1999**	**1998**	**1997**	**1996**	**1995**
Operating Results					
Revenues.	$ 10,073	$ 9,792	$ 9,360	$ 5,594	$ 2,856
Operating costs and expenses	13,555	12,042	14,323	10,881	14,464
Other income, net	276	322	882	6,388(1)	1,157
(Loss) income from continuing operations.	(3,206)	(1,928)	(4,081)	1,101	(10,451)
Discontinued operations.	-	-	(18,359)	(2,501)	(8,045)
Net loss	(3,206)	(1,928)	(22,440)	(1,400)	(18,496)
(Loss) income per share from continuing operations	(0.23)	(0.14)	(.30)	.08(2)	(.88)
Net loss per share..	(0.23)	(0.14)	(1.67)	(.11)	(1.56)
Shares used in per share calculations.	13,957	13,529	13,404	12,661(2)	11,886
Balance Sheet Data					
Working capital	$ 6,887	$ 6,510	$ 9,538	$ 24,793	$ 20,686
Total assets	10,694	10,357	17,012	29,784	26,142
Accumulated deficit	(106,251)	(103,046)	(95,426)	(72,985)	(71,585)
Shareholders' equity	8,576	8,274	15,014	27,967	22,347

(1) Includes one-time licensing fee of $5.0 million.

(2) 13,440,000 shares used in calculation of income per share from continuing operations due to common stock equivalents.

ITEM 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Statements below regarding future events or performance are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. The Company's actual results could be quite different from those expressed or implied by the forward-looking statements. Factors that could affect results include: loss of key personnel; failure to comply with regulations of the FDA or other regulatory agencies; obstacles to international marketing of the Company's products; loss or impairment of sources of capital; ability of the Company to develop product distribution channels; ability of the Company to develop new products; development of competing products; market acceptance of oral testing products; changes in federal or state law or regulations; and uncertainties related to customers' and suppliers' ability to achieve year 2000 compliance. These factors are discussed more fully under "Forward-Looking Statements; Risk Factors" in Item 1, under "Year 2000 Readiness" in this Item 7, and elsewhere in this Annual Report on Form 10-K. Although forward-looking statements help to provide complete information about the Company, readers should keep in mind that forward-looking statements are much less reliable than historical information. Readers are cautioned not to place undue reliance on the forward-looking statements.

Results of Operations

The table below shows the amount (in thousands) and percentage of Epitope's total revenue contributed by each of its principal products and by grants and contracts.

Fiscal Year	**1999**		**1998**		**1997**	
Product Sales						
Oral specimen collection devices.	$7,762	77%	$7,195	74%	$6,279	67%
Western blot HIV confirmatory tests.....	2,133	21	2,370	24	1,791	19
Other product sales.....	178	2	214	2	14	-
	10,073	100%	9,779	100%	8,084	86%
Grants and contracts.....	-	-	13	-	1,276	14
	$10,073	100%	$9,792	100%	$9,360	100%

Revenues. Product sales increased by $294,000 or 3 percent from 1998 to 1999 and by $1.7 million or 21 percent from 1997 to 1998 primarily as a result of expanded sales volume of Epitope's lead product, the OraSure oral specimen collection device. Approximately 30 percent of 1999 sales were attributable to shipments in the fourth quarter. The increase in sales volume of the OraSure device is primarily due to increased purchases of the device by the Company's distributors for the life insurance testing market.

Sales of the Company's OraSure device increased by $567,000 or 8 percent from 1998 to 1999 and increased by $916,000 or 14.6 percent from 1997 to 1998. OraSure device sales into the international market decreased $314,000 or 68 percent in 1999 reflecting the economic problems of many countries after increasing $438,000 or 246 percent in 1998. The Company's total product sales into foreign markets, including cotinine test devices and product components, represented 3 percent, 6 percent and 2 percent of total sales in 1999, 1998 and 1997, respectively.

OraSure device sales into the public health markets in 1999 totaled $2.5 million or 25 percent of total product sales which was the same as 1998. The life insurance testing market contributed $5.1 million or approximately 51 percent of total 1999 product sales, an increase of $884,000 or 21 percent over 1998.

Although sales are anticipated to continue rising in fiscal 2000, they may be affected by seasonality and ordering patterns of customers in certain market segments such as insurance. Expectations for future sales are based primarily on forecasts provided to the Company by individual customers rather than firm orders, as many of the customers in the public health market do not have contractual arrangements with the Company.

Sales of the Company's Western blot HIV confirmatory test decreased by $237,000 or 10 percent from 1998 to 1999 and increased by $579,000 or 32 percent from 1997 to 1998. Sales in 1999 were negatively affected by a reduction in orders from the Company's exclusive distributor for this product as the distributor began to experience both an overall decline in the demand for Western blot products and increased price competition.

As of September 30, 1999, the Company had firm orders and contractual commitments for delivery within 90 days of OraSure devices and Western blot HIV confirmatory tests totaling approximately $715,000 and $362,000, respectively, as compared to firm orders for delivery within 90 days of $940,000 and $570,000, respectively, as of September 30, 1998.

Grant and contract revenues decreased by $13,000 or 100 percent from 1998 to 1999 and decreased $1.3 million or 99 percent from 1997 to 1998. The decrease in 1998 was due to the termination of the Company's development, license and supply agreement with Smithkline Beecham, plc in July 1997. The Company received two grants for the development of an oral fluid test for syphilis, as described in Part I, the majority of which is anticipated to be received in fiscal 2000. Grant applications for additional funding are also being considered.

Gross Margin. The gross margin on product sales was 62 percent in 1999, 62 percent in 1998, and 57 percent in 1997. Although gross margin on the OraSure device improved in 1999, it was offset by a decline in the gross margin of Western blot products due to declining production volumes.

Research and Development Expenses. Research and development expenses increased by $1.1 million or 36 percent from 1998 to 1999 and decreased by $1.2 million or 30 percent from 1997 to 1998. The increase in 1999 was primarily the result of continued work on the OraQuick device, process improvements for OraSure, Intercept Drugs of Abuse development, obtaining the European CE mark, and FDA regulatory compliance. R&D expenses for 2000 are expected to exceed the 1999 level as funding for the syphilis test and clinical trials for OraQuick are planned.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased by $296,000 or 5 percent from 1998 to 1999 and decreased by $1.2 million or 18 percent from 1997 to 1998. The increase in 1999 was primarily a result an accrual for costs related to the search for a new CEO and increased costs in the development of international markets. The decrease in 1998 was primarily attributable to cost containment and a reduction in compensation expense. 2000 sales and marketing expenses are expected to increase over 1999 as a result of additional advertising and promotion to support expansion in all markets and an increase in direct sales efforts in the international area. Selling, general and administrative expenses were reduced by $1.4 million in 1997 for amounts allocated to Agritope, Inc. See Note 3 to the Consolidated Financial Statements under Item 14.

Other Income (Expense), Net. Interest income decreased in 1999, primarily due to lower levels of invested funds.

Year 2000 Readiness

The Company has completed its planned systems upgrades and replacements, as part of a regular ongoing upgrade program, during fiscal 1999. Upgraded or replacement systems have all been certified Year 2000 (Y2K) compliant. Responses to inquiries or other sources of information regarding Y2K compliance have been received from substantially all vendors, suppliers, and customers, the interruption of whose businesses would have a material effect on the Company. A contingency plan has been completed and testing of the plan has been completed to the extent possible. The Company has incurred $133,000 in costs to date for Y2K compliance and does not anticipate incurring any other material costs to resolve issues relating to the Y2K problem internally. Such costs were funded by available cash and cash equivalents.

At the current time, the Company believes that all essential products and internal systems and equipment are now Y2K compliant. This belief is based on the representations made by vendors and, where possible, by testing. In addition, Epitope has not investigated Y2K compliance of third parties that are either not critical or significant to the Company's operations or are not currently vendors, suppliers, or customers of the Company. Any failure of the Company or its vendors, suppliers, customers, or any third party governmental or business entities to be Y2K compliant could materially affect the business, results of operations, financial conditions and prospects of Epitope, the impact of which cannot be quantified at this time.

This section captioned "Year 2000 Readiness" is a "Year 2000 Readiness Disclosure" pursuant to the Year 2000 Information and Readiness Disclosure Act.

Liquidity and Capital Resources

(In thousands)	9/30/99	9/30/98
Cash and cash equivalents	$1,076	$1,164
Marketable securities	4,533	4,455
Working capital	6,887	6,510

Net cash flows used in operating activities increased by $867,000 from 1998 to 1999. Cash and cash equivalents had a net decline of $88,000 from 1998 to 1999. The decline would have been much greater without the exercise of options to purchase common stock which represented the primary sources of funds for meeting the Company's requirements for operations, working capital and business expansion in 1999. The Company received proceeds of $3.2 million, $448,000, and $1,668,000 from the exercise of options to purchase common stock in 1999, 1998 and 1997, respectively.

Research grant funding from strategic partners was $0, $13,000, and $1.3 million in 1999, 1998 and 1997, respectively. The acquisition of capital equipment for manufacturing, research and development, and computer system upgrades used $646,000, $141,000, and $197,000 in 1999, 1998 and 1997, respectively. In 1998 and 1997 the funding of the Company's discontinued operations, required $2.1 million and $7.7 million, respectively. See Note 3 to the Consolidated Financial Statements under Item 14.

The Company anticipates that it will continue to need funds to support ongoing research and development projects as well as to provide additional manufacturing capacity and related increases in working capital to support growth. The Company believes that its operating liquidity requirements for the foreseeable future can be met by existing resources, including marketable securities and cash generated by operations. The Company may also receive funds through the exercise of outstanding stock options and warrants as well as research grants. There can be no assurances however that such funds will be available.

ITEM 7A. Quantitative and Qualitative Disclosures About Market Risk.

The Company does not hold material amounts of derivative financial instruments, other financial instruments, or derivative commodity instruments, and accordingly has no material market risk to report under this item. See Note 2 to the Consolidated Financial Statements included under Item 14.

ITEM 8. Financial Statements and Supplementary Data.

Information with respect to this item is (i) set forth below and (ii) contained in the Company's Consolidated Financial Statements included in Item 14 of this Annual Report on Form 10-K.

QUARTERLY RESULTS OF OPERATIONS (UNAUDITED)
(In thousands, except (loss) income per share)

The following table presents summarized quarterly results of operations for each of the fiscal quarters in the Company's fiscal years ended September 30, 1999 and 1998. These quarterly results are unaudited, but, in the opinion of management, have been prepared on the same basis as the Company's audited financial information and include all adjustments (consisting only of normal recurring adjustments) necessary for a fair presentation of the information set forth therein. The data should be read in conjunction with the Consolidated Financial Statements and related notes thereto included in Item 14 of this Annual Report on Form 10-K.

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
Year ended September 30, 1999					
Revenues	$ 2,244	$ 2,073	$ 2,688	$ 3,068	$ 10,073
Operating costs and expenses	3,003	2,976	3,517	4,059	13,555
Other income, net	59	70	65	82	276
Net loss	(700)	(833)	(764)	(909)	(3,206)
Basic and diluted net loss per share	(.05)	(.06)	(.05)	(.07)	(.23)
Year ended September 30, 1998					
Revenues	1,603	2,103	2,783	3,303	9,792
Operating costs and expenses	2,653	2,921	3,109	3,360	12,043
Other income, net	95	84	66	78	323
Net income (loss)	(955)	(734)	(260)	21	(1,928)
Basic and diluted net loss per share	(.07)	(.05)	(.02)	0.00	(0.14)

ITEM 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

PART III

The Company has omitted from Part III the information that will appear in the Company's definitive proxy statement for its 1999 annual meeting of shareholders (the Proxy Statement), which will be filed within 120 days after the end of the Company's fiscal year pursuant to Regulation 14A.

ITEM 10. Directors and Executive Officers of the Registrant.

The information required by this item is incorporated by reference to the information under the captions “Election of Directors,” “Executive Officers,” “Compensation Committee Interlocks and Insider Participation,” and “Section 16(a) Beneficial Ownership Reporting Compliance” in the Proxy Statement.

ITEM 11. Executive Compensation.

The information required by this item is incorporated by reference to the information under the caption "Executive Compensation" in the Proxy Statement.

ITEM 12. Security Ownership of Certain Beneficial Owners and Management.

The information required by this item is incorporated by reference to the information under the caption "Principal Shareholders" in the Proxy Statement.

ITEM 13. Certain Relationships and Related Transactions.

None.

PART IV

ITEM 14. Exhibits, Financial Statement Schedules, and Reports on Form 8-K.

(a)(1) and (a)(2) Consolidated Financial Statements and Schedules.

Index to Financial Statements Page

No schedules have been presented because they are either not required or the information is in the consolidated financial statements.

Report of Independent Accountants

To the Board of Directors and Shareholders of Epitope, Inc.

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of changes in shareholders' equity and of cash flows present fairly, in all material respects, the financial position of Epitope, Inc. and its subsidiaries at September 30, 1999 and 1998, and the results of their operations and their cash flows for each of the three years in the period ended September 30, 1999, in conformity with accounting principles generally accepted in the United States. These financial statements are the responsibility of the Company's management; our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with auditing standards generally accepted in the United States which require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for the opinion expressed above.

PRICEWATERHOUSECOOPERS LLP

Portland, Oregon

November 12, 1999

Epitope, Inc.
Consolidated Balance Sheets

September 30	**1999**	**1998**
Assets		
Current assets		
Cash and cash equivalents	$ 1,075,898	$ 1,164,275
Marketable securities	4,532,594	4,455,044
Trade accounts receivable, net (Note 2)	1,489,884	1,519,652
Other accounts receivable	73,356	47,818
Inventories (Note 2)	1,504,050	1,092,577
Prepaid expenses	329,958	313,941
Total current assets	9,005,740	8,593,307
Property and equipment, net (Note 4)	1,030,595	819,095
Patents and proprietary technology, net (Note 2)	487,085	596,169
Other assets and deposits	170,895	348,733
	$ 10,694,315	$ 10,357,304
Liabilities and Shareholders' Equity		
Current liabilities		
Accounts payable	$ 474,713	$ 566,894
Salaries, benefits and other accrued liabilities	1,643,573	1,516,395
Total current liabilities	2,118,286	2,083,289
Commitments and contingencies (Note 9)	-	-
Shareholders' equity (Note 5)		
Preferred stock, no par value - 1,000,000 shares authorized; no shares outstanding	-	-
Common stock, no par value - 30,000,000 shares authorized; 14,245,097 and 13,577,319 shares issued and outstanding, respectively	114,827,231	111,319,573
Accumulated deficit	(106,251,202)	(103,045,558)
	8,576,029	8,274,015
	$ 10,694,315	$ 10,357,304

The accompanying notes are an integral part of these statements.

Epitope, Inc.
Consolidated Statements of Operations

For the Year Ended September 30	1999	1998	1997
Revenues			
Product sales	$ 10,072,961	$ 9,778,930	$ 8,083,606
Grants and contracts	59	12,652	1,276,454
	10,073,020	9,791,582	9,360,060
Costs and expenses			
Product costs	3,847,444	3,684,702	3,512,054
Research and development costs	3,972,096	2,917,742	4,156,996
Selling, general and administrative expenses	5,735,408	5,439,743	6,654,553
	13,554,948	12,042,187	14,323,603
Loss from operations	(3,481,928)	(2,250,605)	(4,963,543)
Other income (expense), net			
Interest income	278,889	362,694	885,583
Interest expense	(989)	(8,868)	(8,165)
Other, net	(1,616)	(31,229)	4,861
	276,284	322,597	882,279
Net loss from continuing operations	(3,205,644)	(1,928,008)	(4,081,264)
Discontinued operations (Note 3)			
Loss from discontinued operations; Agritope	-	-	(9,890,599)
Income from discontinued operations; A&W	-	-	170,646
Estimated loss on disposal of A&W	-	-	(8,639,054)
	-	-	(18,359,007)
Net loss	$ (3,205,644)	$ (1,928,008)	$(22,440,271)
Basic and diluted loss per share from continuing operations	$ (0.23)	$ (.14)	$ (.30)
Basic and diluted loss per share	$ (0.23)	$ (.14)	$ (1.67)
Weighted average number of shares outstanding	13,956,512	13,528,596	13,404,402

The accompanying notes are an integral part of these statements.

Epitope, Inc.
Consolidated Statements of Changes in Shareholders' Equity

	Common Stock		Accumulated	
	Shares	**Dollars**	**Deficit**	**Total**
Balances at September 30, 1996	12,937,383	$100,952,282	$(72,985,262)	$27,967,020
Common stock issued upon exercise of options	16,124	168,211	-	168,211
Common stock issued as compensation	41,088	323,938	-	323,938
Compensation expense for stock option grants	-	489,668	-	489,668
Common stock issued upon exchange of convertible notes (Note 3)	250,367	4,529,009	-	4,529,009
Equity issuance costs	-	(86,134)	-	(86,134)
Capital contributed in rescission (Note 3)	-	1,820,000	-	1,820,000
Common stock issued for cash	209,368	1,500,000	-	1,500,000
Minority interest investment in Vinifera	-	742,752	-	742,752
Net loss for the year	-	-	(22,440,271)	(22,440,271)
Balances at September 30, 1997	13,454,330	110,439,726	(95,425,533)	15,014,193
Common stock issued upon exercise of options	91,278	411,052	-	411,052
Common stock issued under the Employee Stock Purchase Plan	14,451	54,814	-	54,814
Common stock issued as matching savings plan contributions	17,260	80,740	-	80,740
Compensation expense for stock option grants	-	333,241	-	333,241
Spin-off of Agritope	-	-	(5,692,017)	(5,692,017)
Net loss for the year	-	-	(1,928,008)	(1,928,008)
Balances at September 30, 1998	13,577,319	111,319,573	(103,045,558)	8,274,015
Common stock issued upon exercise of options	632,580	3,028,576		3,028,576
Common stock issued as compensation	6,233	29,996		29,996
Common stock issued under the Employee Stock Purchase Plan	16,002	59,697		59,697
Common stock issued as matching savings plan contributions	12,963	75,475		75,475
Compensation expense for stock option grants	-	313,914		313,914
Net loss for the year	-	-	(3,205,644)	(3,205,644)
Balances at September 30, 1999	14,245,097	$114,827,231	$(106,251,202)	$ 8,576,029

The accompanying notes are an integral part of these statements.

Epitope, Inc.
Consolidated Statements of Cash Flows

For the Year Ended September 30	1999	1998	1997
Cash flows from operating activities			
Net loss	$ (3,205,644)	$ (1,928,008)	$(22,440,271)
Adjustments to reconcile net loss to net cash used in operating activities:			
Loss from discontinued operations	-	-	18,359,007
Depreciation and amortization	663,388	669,839	729,970
Loss on disposition of property	7,081	31,290	17,888
Decrease (increase) in receivables	4,230	(510,474)	264,686
(Increase) decrease in inventories	(411,473)	232,070	(166,717)
(Decrease) increase in prepaid expenses	(16,017)	(235,701)	11,278
Increase (decrease) in other assets and deposits	195,273	(292,544)	(32,340)
Increase in accounts payable and accrued liabilities	34,997	85,179	180,773
Common stock issued as compensation for services	29,996	-	323,938
Compensation expense for stock option grants and deferred salary increases	313,914	431,482	489,668
Net cash used in operating activities	(2,384,255)	(1,516,867)	(2,262,120)
Cash flows from investing activities			
Investment in marketable securities	(11,173,092)	(13,524,782)	(20,106,837)
Proceeds from sale of marketable securities	11,095,542	16,213,797	31,783,317
Additions to property and equipment	(645,508)	(140,903)	(196,910)
Proceeds from sale of property	-	37,629	-
Expenditures for patents and proprietary technology	(127,377)	(157,063)	(265,435)
Investment in affiliated companies	(17,435)	(1,090)	(6,702,299)
Net cash (used in) provided by investing activities	(867,870)	2,427,588	4,511,836
Cash flows from financing activities			
Proceeds from issuance of common stock	3,163,748	448,365	1,668,211
Cash to Agritope (Note 3)	-	(2,129,291)	(7,682,710)
Net cash provided by (used in) financing activities	3,163,748	(1,680,926)	(6,014,499)
Net decrease in cash and cash equivalents	(88,377)	(770,205)	(3,764,783)
Cash and cash equivalents at beginning of year	1,164,275	1,934,480	5,699,263
Cash and cash equivalents at end of year	$ 1,075,898	$ 1,164,275	$ 1,934,480

The accompanying notes are an integral part of these statements.

Notes to Consolidated Financial Statements

Note 1 The Company

Epitope, Inc. (Epitope or the Company) develops, manufactures and markets oral specimen collection devices and diagnostic products using its proprietary oral fluid technologies. These products are sold to public and private-sector clients in the United States and certain foreign countries. The Company's primary focus is on the detection of antibodies to the Human Immunodeficiency Virus (HIV), the cause of Acquired Immune Deficiency Syndrome (AIDS). The Company's technology is also being used to test for drugs-of-abuse and other analytes. Commercial distribution of the Company's oral specimen collection device as part of a test for five major drugs-of-abuse is scheduled to begin in calendar year 2000.

See Note 3, Discontinued Operations, below.

Note 2 Summary of Significant Accounting Policies

Basis of Presentation. The accompanying consolidated financial statements include the accounts of the Company and its wholly and majority owned subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

Cash and Cash Equivalents; Marketable Securities. The Company considers all highly liquid investments with maturities at time of purchase of three months or less to be cash equivalents. At September 30, 1999, marketable securities consisted of commercial paper and U.S. Treasury securities with an original maturity period greater than three months, but generally less than 12 months. The Company's policy is to invest its excess cash in securities that maximize (a) safety of principal, (b) liquidity for operating needs, and (c) after-tax yields.

Pursuant to Statement of Financial Accounting Standards No. 115, "Accounting for Certain Investments in Debt and Equity Securities," the Company has categorized all of its investments as available-for-sale securities and, accordingly, unrealized gains and losses on such investments, if material, are carried as a separate component of comprehensive income. Such unrealized gains and losses were immaterial as of September 30, 1999 and 1998.

Trade Accounts Receivable. Accounts receivable are stated net of an allowance for doubtful accounts of $50,000 and $49,513, respectively, at September 30, 1999 and 1998.

Inventories. Inventories are recorded at the lower of standard cost (which approximates actual cost on a first-in, first-out basis) or market. Inventory components are summarized as follows:

September 30	**1999**	**1998**
Raw materials	$ 360,806	$ 238,916
Work-in-process	441,952	627,503
Finished goods	701,292	211,703
Supplies	-	14,455
	$ 1,504,050	$ 1,092,577

Depreciation and Capitalization Policies. Property and equipment are stated at cost less accumulated depreciation. Expenditures for repairs and maintenance are charged to operating expense as incurred. Expenditures for renewals and betterments are capitalized.

Depreciation and amortization of property and equipment are calculated using the straight-line method over the estimated lives of the related assets (three to seven years). Leasehold improvements are generally amortized over the shorter of estimated useful lives or the terms of the related leases. When assets are sold or otherwise disposed of, cost and the related accumulated depreciation or amortization are removed from the accounts and any resulting gain or loss is included in operations.

Patents and Proprietary Technology. Direct costs associated with patent submissions and acquired technology are capitalized and amortized over their minimum estimated economic useful lives, generally five years.

Amortization and accumulated amortization are summarized as follows:

	1999	1998	1997
Amortization expense for the year ended September 30 ..	$ 236,463	$ 218,381	$ 209,180
Accumulated amortization at September 30	1,285,134	1,048,671	830,290

Fair Value of Financial Instruments. The carrying amounts for cash equivalents, accounts receivable, and accounts payable approximate fair value because of the immediate or short-term maturity of these financial instruments.

Revenue Recognition. Product revenues are generally derived from the sale of products and are recognized as revenue when the related products are shipped. Grant and contract revenues include funds received under research and development agreements with various entities. Such revenues are recognized in accordance with the contract terms.

Research and Development. Research and development expenditures are comprised of those costs associated with the Company's own ongoing research and development activities including the costs to prepare for, obtain and compile clinical studies and other information to support product license applications. Expenditures for research and development also include costs incurred under contracts to develop certain products, including those contracts resulting in grant and contract revenues. All research and development costs are expensed as incurred.

Shared Services. For the year ended September 30, 1997 certain corporate overhead services were provided by Epitope on a centralized basis for the benefit of the Company's subsidiaries (Shared Services). The related subsidiaries' operating results are included in discontinued operations. See Note 3, Discontinued Operations. Selling, general and administrative expenses have been reduced by the cost of Shared Services allocated to the discontinued operations of $1,402,895 for the year ended September 30, 1997.

Income Taxes. The Company accounts for certain revenue and expense items differently for income tax purposes than for financial reporting purposes. The Company accounts for income taxes under the asset and liability method for accounting for income taxes whereby deferred tax assets and liabilities are recognized based on temporary differences between the financial statement and the tax bases of assets and liabilities using enacted tax rates in effect for the year in which the temporary differences are expected to reverse. See Note 8, Income Taxes.

Stock-Based Compensation. Statement of Financial Accounting Standards No. 123, "Accounting for Stock-Based Compensation" (SFAS 123) allows companies which have stock-based compensation arrangements with employees to adopt a fair-value basis of accounting for stock options and other equity instruments or to continue to apply the accounting rules specified in Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" (APB 25), but with additional financial statement disclosure. The Company has elected to continue to account for its stock-based compensation under APB 25. See Note 5, Shareholders' Equity.

Income (Loss) Per Share. Basic income (loss) per share has been computed using the weighted average number of shares of common stock outstanding during the period. Diluted income (loss) per share includes the effect of potential common stock, unless its effect is anti-dilutive. Potential common stock consists of the number of shares issuable upon exercise of outstanding warrants, options and convertible notes less the number of shares assumed to have been purchased for the treasury with the proceeds from such exercise. Basic and diluted net income (loss) per share are the same for the years ended September 30, 1999, 1998 and 1997. On September 30, 1999, 1998 and 1997, the weighted average shares outstanding were 13,956,512, 13,528,596 and 13,404,402, respectively. Shares of potential common stock on September 30, 1999, 1998 and 1997, of 6,075,376, 6,206,279 and 4,428,141, respectively, were not included in the calculation of diluted loss per share as they were anti-dilutive.

Statement of Cash Flows. Cash paid for interest approximated interest expense in 1999, 1998 and 1997. No cash was paid for income taxes in 1999, 1998, or 1997. Compensation expense amounted to $343,910, $431,482 and $813,606 in 1999, 1998 and 1997, respectively, related to the issuance of compensatory equity securities which also represent non-cash transactions.

Management Estimates. The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates relating to assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements as well as the reported amounts of revenues and expenses during the reporting period. Actual results could vary from these estimates.

Comprehensive Income. On June 15, 1997 the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards No. 130, "Reporting Comprehensive Income" (SFAS No. 130). SFAS No. 130 is effective for all fiscal quarters of all fiscal years beginning after December 15, 1997 (October 1, 1998 for the Company). Since the Company adopted this pronouncement there have been no items of other comprehensive income (loss) that are required to be reported.

Note 3 Discontinued Operations

On December 30, 1997, the Company distributed all of its shares of Agritope, Inc. (Agritope) common stock through a stock dividend to Epitope shareholders of record as of December 26, 1997. Epitope no longer owns or controls any shares of Agritope stock. The costs of the spin-off and Agritope's operating losses through December 30, 1997 were estimated and accounted for in fiscal year 1997. Fiscal 1997 also included the loss from discontinued operations of Agritope and Andrew and Williamson Sales, Co. (A&W).

Agritope. Agritope's results of operations are presented as discontinued operations in the accompanying consolidated financial statements for the period ended September 30, 1997. All intercompany loans from Epitope to Agritope were deemed to be terminated and reflected as capital contributions to Agritope as of the spin-off date consistent with the separation agreement between Epitope and Agritope dated December 1, 1997. The 1997 loss from discontinued operations of Agritope includes an accrual of $1.2 million for Agritope's operating losses, from October 1, 1997 to December 1, 1997, and costs of the spin-off of Agritope which occurred on December 30, 1997 in accordance with Accounting Principles Board Opinion No. 30, "Reporting the Effects of Disposal of a Portion or Segment of a Business." This amount is not included in the table below. All net expenses of Agritope subsequent to December 1, 1997, were borne by Agritope.

Andrew and Williamson Sales, Co. On December 12, 1996, a subsidiary of the Company completed a merger with Andrew and Williamson Sales, Co. (A&W), a fruit and vegetable producer and wholesale distributor. The merger was rescinded on May 27, 1997. Epitope received A&W preferred stock in the rescission which carries no value on the accompanying balance sheet based upon management's estimate of fair value on the date it was received. A&W's results of operations for the period from December 13, 1996 through May 27, 1997 and the total estimated loss on disposal are presented in the accompanying financial statements as discontinued operations.

The summarized Statement of Operations for Agritope and subsidiaries is as follows:

September 30	**1997**
Revenue	$ 1,551,190
Operating costs and expenses	6,088,883(1)
Other income (expense), net	(4,427,275)
Minority interest in subsidiary net loss	274,369
Net loss from operations	$(8,690,599)

(1) Does not include $1.2 million of accrued operating losses and spin-off costs for the period of October 1, 1997 to December 1, 1997. Such operating losses and spin-off costs have been reflected in the consolidated statement of operations in 1997.

Note 4 Property and Equipment

Property and equipment are summarized as follows:

September 30	1999	1998
Research and development laboratory equipment	$ 1,117,817	$ 1,014,015
Manufacturing equipment.	1,590,723	1,423,580
Office furniture and equipment	1,785,422	1,753,455
Leasehold improvements	1,155,862	1,102,895
Construction in progress	234,714	63,503
	5,884,538	5,357,448
Less accumulated depreciation and amortization.	(4,853,943)	(4,538,353)
	$ 1,030,595	$ 819,095

Note 5 Shareholders' Equity

Authorized Capital Stock. The Company's amended articles of incorporation authorize 1,000,000 shares of preferred stock and 30,000,000 shares of common stock. The Company's Board of Directors has authority to determine preferences, limitations and relative rights of the preferred stock.

On December 15, 1997, Epitope's Board of Directors approved a Shareholder Rights Plan that would allow the Company to protect shareholders' interests in the event of an attempted takeover of the Company. A dividend distribution of one Right for each outstanding share of common stock was issued to shareholders of record at the close of business on December 26, 1997. Each Right entitles the registered holder to purchase from Epitope 1/1000 of a share of Series A Junior Participating Cumulative Preferred Stock at a price of $60 per share subject to adjustment. The Rights become exercisable in the event a person or group of affiliated or associated persons (other than the Company or its employee benefit plans) acquires or obtains the right to acquire 15 percent or more of the outstanding shares of common stock. With certain exceptions, if any person becomes the beneficial owner of 15 percent or more of the Company's common stock, each of the Rights (other than Rights held by that person and certain of its transferees, all of which will be voided) entitles the holder to acquire shares of the Company's common stock having a value equal to twice the Right's exercise price. The Rights will expire on the earliest of the close of business on December 26, 2007, upon exchange by the Company for common stock, or upon redemption at the option of the Company for $0.01 per Right.

Common Stock Reserved for Future Issuance. As of September 30, 1999, the following shares of the Company's common stock were reserved for future issuance, as more fully described below:

Purpose	Shares
Outstanding stock options	3,448,094
Outstanding warrants	2,537,307
Employee Stock Purchase Plan subscriptions	82,712
	6,068,113

Stock Award Plans. The Company's 1991 Stock Award Plan (the 1991 Plan) was approved by the shareholders during 1991, replacing the Company's Incentive Stock Option Plan (ISOP). The 1991 Plan provides for stock-based awards to employees, outside directors and members of scientific advisory committees or other consultants. Awards which may be granted under the 1991 Plan include qualified incentive stock options, nonqualified stock options, stock appreciation rights, restricted awards, performance awards and other stock-based awards.

Options issued to employees under the ISOP were issued at prices not less than the fair market value of a share of common stock on the date of grant. These options generally expire ten years from the date of grant.

Under the terms of the 1991 Plan, qualified incentive stock options on shares of common stock may be granted to eligible employees, including officers, of the Company at an exercise price not less than the fair market value of the stock on the date of grant. The maximum term during which any incentive option may be exercised is ten years from the date of grant. To date, options have generally been granted with four-year vesting schedules. The options

are generally exercisable after one year from the date of grant at the rate of 25 percent after one year and the balance at 1/36th monthly thereafter.

The 1991 Plan also provides that nonqualified options may be granted at a price not less than 75 percent of the fair market value of a share of common stock on the date of grant. The option term and vesting schedule of such awards may either be unlimited or have a specified period in which to vest and be exercised. For the discounted nonqualified options issued, the Company amortizes, on a straight-line basis over the vesting period of the options, the difference between the exercise price and the fair market value of a share of stock on the date of grant.

SFAS 123 requires the following financial statement disclosure:

Options granted and outstanding under the Company's stock option plans are summarized as follows:

	1999		1998		1997	
	Shares	**Price**	**Shares**	**Price**	**Shares**	**Price**
Outstanding at beginning of period	3,630,727	$1.29 – 18.17	3,499,865	$3.50 – 20.38	3,365,726	$3.50 – 24.00
Granted	650,793	2.41 – 6.84	4,237,156	1.29 – 18.17	2,801,403	3.50 – 14.81
Exercised	(632,580)	3 54 – 6.31	(91,278)	2.79 – 5.04	(16,124)	7.25 – 14.81
Canceled	(200,846)	3.06 – 18.17	(4,015,016)	3.50 – 20.38	(2,651,140)	3.50 – 24.00
Outstanding at end of period	3,448,094	1.29 – 18.17	3,630,727	1.29 – 18.17	3,499,865	$3.50 – 20.38
Exercisable.	2,386,856	1.29 – 18.17	2,621,613	1.29 – 18.17	2,474,623	$3.50 – 20.38

Exercise Price Range	Number of Shares	Weighted Average Price	Average Remaining Contractual Life
$1.29 – $ 4.04	684,706	3.16	8.40
4.17 – 4.17	625,000	4.17	6.27
4.22 – 4.97	318,083	4.48	20.59
5.04 – 5.04	1,413,817	5.04	9.16
5.75 – 18.17	406,489	7.84	9.30

Options exercisable at September 30, 1999 totaled 2,386,856 shares at a weighted average exercise price of $4.97. Options available for grant at September 30, 1999 totaled 379,858.

Pursuant to the 1991 Plan, 2478 shares of common stock were also awarded to consultants and members of the Company's scientific advisory committees during 1998. No shares were awarded in 1999 or 1997.

Common Stock Warrants. As of September 30, 1999, the following warrants to purchase shares of common stock were outstanding:

Date of Issuance	**Shares**	**Exercise Price**	**Expiration Date**
September 26, 1991	159,150	5.91	September 30, 2000
December 23, 1992	988,390	5.91	September 30, 2000
July 20, 1993	375,000	5.91	September 30, 2000
August 1, 1993	200,000	5.91	September 30, 2000
October 17, 1994	50,000	5.91	September 30, 2000
November 22, 1994	228,100	5.91	September 30, 2000
May 15, 1998	416,667	5.91	December 30, 2000
September 30, 1998	120,000	6.13	September 30, 2008
	2,537,307		

Employee Stock Purchase Plan. In 1993, the shareholders approved the Company's adoption of the 1993 Employee Stock Purchase Plan (1993 ESPP). The plan, as subsequently approved and amended by the Company's shareholders, covers a maximum of 500,000 shares of common stock for subscription over established offering periods. The Executive Compensation Committee of the Board of Directors determines the number of offering

periods, the number of shares offered, and the length of each period, provided that no more than three offering periods (other than Special Offering Subscriptions as described below) may be set during each fiscal year of the Company. The purchase price for stock purchased under the 1993 ESPP for each subscription period is the lesser of 85 percent of the fair market value of a share of common stock at the commencement of the subscription period or the fair market value at the close of the subscription period. An employee may also elect to withdraw at any time during the subscription period and receive the amounts paid plus interest at the rate of 6 percent.

As of September 30, 1999, 82,712 shares of common stock were subscribed for through two offerings under the 1993 ESPP. Shares subscribed for under these 1993 ESPP offerings may be purchased over 24 months and had initial subscription prices of $6.99 and $2.74 per share. The subscription prices for the offerings prior to December 30, 1997 were adjusted in fiscal 1998 as a result of the spin-off of Agritope from $6.99 to $4.78 per share. During the year ended September 30, 1999, 16,002 shares were issued at prices ranging from $2.74 to $4.78 under the 1993 ESPP.

The 1993 ESPP was amended to allow the Company, at its discretion, to provide Special Offering Subscriptions whereby an employee's annual increase in compensation could be deferred for a one-year period. At the end of the one-year period, the employee can elect to receive the deferred compensation amount in the form of cash or shares of the Company's common stock. The purchase price for stock issued under a Special Offering Subscription is the lesser of 85 percent of the fair market value of a share of common stock on the first day of the calendar month the employee's increase was effective or the fair market value at the close of the one-year subscription period. No shares were issued under a Special Offering Subscription during 1999, 1998 or 1997.

The Company has elected to account for its stock-based compensation under the provisions of APB 25. However, as required by SFAS No. 123, the Company has computed for pro forma disclosure purposes the value of options granted during 1999, 1998 and 1997 using the Black-Scholes option pricing model. The weighted average assumptions used for stock option grants for 1999, 1998 and 1997 were a risk-free interest rate of 5.1, 5.7 and 5.9 percent, respectively, no expected dividend yield, an expected life of 3.8, 3.9 and 4.3 years, respectively, and an expected volatility of 66, 60 and 53 percent, respectively. Options were assumed to be exercised upon vesting for purposes of this valuation. Adjustments are made for options forfeited prior to vesting. For the years ended September 30, 1999. 1998 and 1997, the total value of the options granted was computed to be $1,705,940, $6,861,799 and $9,096,600, respectively, which would be amortized on the straight-line basis over the vesting period of the options.

The weighted average assumptions used for 1993 ESPP rights for 1999, 1998 and 1997 were a risk-free interest rate of 5.8, 5.6 and 6.1 percent, respectively, no expected dividend yield, an expected life of 1.0, 2.0, and 2.0 years, respectively, and an expected volatility of 69, 69 and 63 percent, respectively. The weighted-average fair value of ESPP rights granted in 1999, 1998 and 1997 were $141,397, $55,066 and $248,700, respectively.

If the Company had accounted for these plans in accordance with SFAS 123, the Company's net loss and pro forma net loss per share would have been reported as follows:

Year Ended September 30	**1999**		**1998**	
	Net Loss	**Basic and Diluted Net loss per share**	**Net Loss**	**Basic and Diluted Net loss per share**
As reported	$(3,205,664)	$(0.23)	$(1,928,008)	$ (0.14)
Pro forma	$(5,467,219)	$(0.39)	$(4,957,178)	$ (0.37)

The effects of applying SFAS 123 in providing pro forma disclosure for 1999 and 1998 are not likely to be representative of the effects on reported net income and earnings per share for future years since options vest over several years and additional awards are made each year.

Note 6 Profit Sharing and Savings Plan

The Company established a profit sharing and deferred salary savings plan in 1986 and restated the plan in 1991. All employees are eligible to participate in the plan. In addition, the plan permits certain voluntary employee contributions to be excluded from the employees' current taxable income under the provisions of Internal Revenue Code Section 401(k) and the regulations thereunder. Effective October 1, 1991, the Company replaced a discretionary profit sharing provision with a matching contribution (either in cash, shares of Epitope common stock, or partly in both forms) equal to 50 percent of an employee's basic contribution, not to exceed 2.5 percent of an employee's compensation. The Board of Directors has the authority to increase or decrease the 50 percent match at any time. During 1999, 1998 and 1997, respectively, the Company contributed $75,475 (12,963 shares), $80,741(17,260 shares) and $101,737 (11,459 shares, totaling $101,721 and the remainder in cash). As of September 30, 1999, 38,325 shares of Epitope common stock are held by the plan.

Note 7 Distribution and Supply Contracts

The Company has entered into several contractual arrangements, including those discussed in the following paragraphs, for distribution of certain of its products to customers.

The Company maintains supply and distribution agreements with Organon Teknika Corporation (Organon Teknika), whereby Organon Teknika supplies the Company's antigen requirements and exclusively distributes the Company's Western blot HIV confirmatory tests on a worldwide basis. The agreements have been extended to March 31, 2001 and continue to renew each year thereafter unless prior notice of cancellation is given by the Company or Organon Teknika. The distribution agreement includes pricing incentives based on volumes purchased by Organon Teknika and penalties for failure to purchase specified minimum quarterly volumes. For the years ended September 30, 1999, 1998 and 1997, respectively, revenues generated from sales of Western blot tests to Organon Teknika were $2,132,920, $2,371,135 and $1,791,290, including export sales of $0, $1,250 and $15,750.

Lab*One*, Inc. (Lab*One*) purchases oral specimen devices from the Company for use in insurance testing in return for non-exclusive distribution rights in the United States and Canada under an agreement which expires on March 13, 2005, with an automatic five-year renewal, unless either party notifies the other of intent not to renew at least 180 days prior to the expiration date. In 1998, the Company entered into an additional agreement with Lab*One* to provide a prepackaged OraSure test kit with prepaid testing and sample shipment to Lab*One* via Airborne Express. This product package is sold directly to the public health customers by the Epitope sales force. For the years ended September 30, 1999, 1998 and 1997, respectively, revenues generated from product sales to Lab*One* were $2,768,971, $2,773,351, and $3,194,698, including export sales of $0, $402,150 and $597,000.

Note 8 Income Taxes

As of September 30, 1999, the Company had net operating loss carryforwards to offset federal and state taxable income of approximately $52.4 million and $49.5 million, respectively. Approximately $8.3 million of the Company's net operating loss carryforwards were generated as a result of deductions related to the exercise of stock options. If utilized, such carryforwards, as tax effected, will be reflected in the Company's financial statements as an increase in shareholders' equity rather than a reduction of the provision for income taxes.
Significant components of Epitope's deferred tax asset were as follows:

September 30	**1999**	**1998**
Net operating loss carryforwards	$20,123,000	$ 18,532,000
Stock compensation	1,945,000	1,829,000
Research and experimentation credit carryforwards	1,121,000	1,026,000
Accrued expenses	350,000	269,000
Other	687,000	779,000
Gross deferred tax assets	24,226,000	22,435,000
Valuation allowance	(24,226,000)	(22,435,000)
Net deferred tax asset	$ -	$ -

No benefit for these assets has been reflected in the accompanying consolidated financial statements as they do not satisfy the recognition criteria set forth in SFAS 109. Accordingly, a valuation allowance of $24.2 million, representing a $1.8 million increase since the prior fiscal year end, has been recorded.

The tax benefit of approximately $1.1 million for the year ended September 30, 1999, calculated using the statutory tax rate, has been increased by approximately $141,000 for the effect of state and local taxes (net of federal impact) and $559,000 for other permanent and temporary differences, and is reduced by approximately $1.8 million for the effect of the increase in the valuation allowance.

Note 9 Commitments and Contingencies

The Company leases office, manufacturing, warehouse and laboratory facilities under operating lease agreements which require minimum annual payments as follows:

Year Ending September 30	
2000	$ 361,423
2001	375,867
2002	388,743
2003	380,628
2004 and after	523,364
	$ 2,030,025

Under the agreements for the lease of its office and laboratory facilities, the Company is obligated to the lessor for its share of certain expenses related to the use, operation, maintenance, taxes and insurance of the property. These expenses, payable monthly in addition to the base rent, are not included in the amounts shown above. Rent expense aggregated $435,569, $433,002 and $409,970 for the years ended September 30, 1999, 1998 and 1997, respectively. There were no items considered as contingencies at September 30, 1999.

Note 10 Segment and Geographic Area Information

The following disclosures are required by the Statement of Financial Accounting Standards No. 131, "Segment Disclosures and Related Information" (SFAS 131):

The Company's products are all included in the medical products industry segment. See Note 1 for a description of the Company's business. The Company's products are sold principally in the United States, Canada, Asia and Latin America. Operating loss represents revenues less operating expenses. No operating income or loss is reflected for geographic areas other than the United States and Asia as all revenues for other geographic areas are exports from the United States. Most sales to Canada are for the life insurance market and have been made through U.S. laboratories since third quarter 1998.

In thousands

Geographic	**Revenues**			**Operating Loss**			**Identifiable Assets**		
Areas	**1999**	**1998**	**1997**	**1999**	**1998**	**1997**	**1999**	**1998**	**1997**
United States	$9,771	$8,774	$8,569	$(3,499)	$(2,264)	$(4,935)	$10,694	$10,357	$17,012
Canada	10	415	608	-	-	-	-	-	-
Asia	251	341	130	17	13	(29)	-	-	-
Latin America	7	202	4	-	-	-	-	-	-
Europe	29	59	49	-	-	-	-	-	-
Other	5	1	-	-	-	-	-	-	-
	$10,073	$9,792	$9,360	$(3,482)	$(2,251)	$(4,964)	$10,694	$10,357	$17,012

In addition to those customers discussed in Note 7, Osborn Group, Inc. and Clinical Reference Laboratory accounted for 11 percent ($1,139,750) and 10 percent ($1,042,375) of the Company's fiscal 1999 sales, respectively. In 1998 and 1997 no customers accounted for more than 10% of the Company's sales except as discussed in Note 7.

No schedules are included with the foregoing financial statements because the required information is inapplicable or is presented in the financial statements or related notes thereto.

(a)(3) Exhibits.

See Index to Exhibits following the signature page of this report.

(b) Reports on Form 8-K.

None.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on December 23, 1999.

EPITOPE, INC.

By * CHARLES E. BERGERON
Charles E. Bergeron
Interim President and Chief Financial Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed on December 23, 1999, by the following persons on behalf of the Registrant and in the capacities indicated.

SIGNATURE	TITLE
/S/ CHARLES E. BERGERON Charles E. Bergeron	Interim President and Chief Financial Officer (Principal Executive Officer and Principal Financial Officer)
/S/ THEODORE R. GWIN Theodore R. Gwin	Controller (Principal Accounting Officer)
*W. CHARLES ARMSTRONG W. Charles Armstrong	Director
*ANDREW S. GOLDSTEIN Andrew S. Goldstein	Senior Vice President and Director
*MARGARET H. JORDAN Margaret H. Jordan	Director
*JOHN W. MORGAN John W. Morgan	Director
*MICHAEL J. PAXTON Michael J. Paxton	Director
*ROGER L. PRINGLE Roger L. Pringle	Director
*G. PATRICK SHEAFFER G. Patrick Sheaffer	Director
*ROBERT J. ZOLLARS Robert J. Zollars	Director

* /S/ CHARLES E. BERGERON
Charles E. Bergeron
(Attorney-in-Fact)

INDEX TO EXHIBITS

Exhibit Number	Exhibit
3.1	Restated Articles of Incorporation, as amended, of Registrant. Incorporated by reference to Exhibit 3 to the Registrant's Registration Statement on Form 8-A filed December 26, 1997 (Registration Statement No. 000-15337).
3.2	Restated Bylaws of Registrant. Incorporated by reference to Exhibit 3.2 to the Registrant's Annual Report on Form 10-K for the year ended September 30, 1997 (the 1997 10-K).
4.1	Stock Purchase Agreement dated November 9, 1990, between certain investors and Registrant. Copies of the agreements with individual investors shall be filed with the Commission upon request pursuant to Instruction 2 of Item 601 of Regulation S-K (Item 601, Instruction 2). Incorporated by reference to Exhibit 4.2 to the Registrant's Annual Report on Form 10-K for the year ended September 30, 1994 (the 1994 10-K).
4.2	Unit Purchase Agreement dated September 1991 between certain investors and Registrant. Copies of the agreements with individual investors shall be filed with the Commission upon request pursuant to Item 601, Instruction 2. Incorporated by reference to Exhibits 4.1 and 4.2 to the Registrant's Current Report on Form 8-K dated September 17, 1991.
4.3	Warrant Purchase Agreement dated as of November 25, 1992, between certain investors and Registrant. Copies of the agreements with individual investors shall be filed with the Commission upon request pursuant to Item 601, Instruction 2. Incorporated by reference to Exhibit 4.5 to the Registrant's Annual Report on Form 10-K for the year ended September 30, 1992 (the 1992 10-K).
4.4	1993 Technology Transfer Warrant Issuance Agreement dated as of June 15, 1993, between certain investors and Registrant. Copies of the agreements with individual investors shall be filed with the Commission upon request pursuant to Item 601, Instruction 2. Incorporated by reference to Exhibit 4.3 to the Registrant's Registration Statement on Form S-3 (No. 33-68510) (Registration Statement No. 33-68510).
4.5	Form of Letter dated August 1, 1993, from Registrant regarding modification of the terms of the 1993 Technology Transfer Warrants. Incorporated by reference to Exhibit 4.5 to Registration Statement No. 33-68510.
4.6	1993 Warrant Purchase Agreement dated as of July 6, 1993, between certain investors and Registrant. Copies of the agreements with individual investors shall be filed with the Commission upon request pursuant to Item 601, Instruction 2. Incorporated by reference to Exhibit 4.6 to Registration Statement No. 33-68510.
4.7	Notice to warrantholders and current form of warrant certificate for warrants issued in September 1991 offering, reflecting extension of expiration date. Incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K dated September 12, 1997.
4.8	Notice to warrantholders and current form of warrant certificate for warrants issued in December 1992 offering, reflecting extension of expiration date. Incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K dated September 12, 1997.
4.9	Notice to warrantholders and current form of warrant certificate for warrants issued in July 1993 offering, reflecting extension of expiration date. Incorporated by reference to Exhibit 4.3 to the Registrant's Current Report on Form 8-K dated September 12, 1997.

4.10	Notice to warrantholders and current form of warrant certificate for warrants issued in August 1993 offering, reflecting extension of expiration date. Incorporated by reference to Exhibit 4.4 to the Registrant's Current Report on Form 8-K dated September 12, 1997.
10.1	Incentive Stock Option Plan of Registrant, as amended. Incorporated by reference to Exhibit 10.1 to the 1994 10-K.*
10.2	Amended and Restated Epitope, Inc., 1991 Stock Award Plan. Incorporated by reference to Exhibit 10.2 to the 1997 10-K.*
10.3	Lease dated July 17, 1990, among Registrant, Koll Woodside Associates, a California general partnership, and Petula Associates, Ltd., an Iowa corporation. Incorporated by reference to Exhibit 10.5 to the 1994 10-K.
10.4	Fourth Amendment dated May 20, 1994, to Lease dated July 17, 1990, among Registrant, Koll Woodside Associates, a California general partnership, and Petula Associates, Ltd., an Iowa corporation. Incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the fiscal quarterly period ended June 30, 1994 (June 1994 10-Q).
10.5	Business Park Lease dated May 5, 1994, among Registrant, Koll Woodside Associates, a California general partnership, and Petula Associates, Ltd., an Iowa corporation. Incorporated by reference to Exhibit 10.2 to the June 1994 10-Q.
10.6	Lease dated October 25, 1999 between PS Business Parks, L.P., a California Limited Partnership, and Registrant.
10.7	Distribution Agreement dated as of April 1, 1994, between Registrant and Organon Teknika Corporation. Incorporated by reference to Exhibit 10.3 to the June 1994 10-Q.
10.8	Supply Agreement dated as of April 1, 1994, between Registrant and Organon Teknika Corporation. Incorporated by reference to Exhibit 10.4 to the June 1994 10-Q.
10.9	Form of Indemnification Agreement for directors and officers. Incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-4 (No. 333-15705).*
10.10	Amended and Restated Employment Agreement dated January 8, 1991, between Andrew S. Goldstein and Registrant. Incorporated by reference to Exhibit 10.28 to the Registrant's Annual Report on Form 10-K for the year ended September 30, 1991.*
10.11	Employment Agreement dated January 19, 1998, between Charles E. Bergeron and Registrant. Incorporated by reference to Exhibit 10.21 to Amendment No. 1 to the 1997 10-K (the 1997 10-K Amendment).*
10.12	Employment Agreement dated January 13, 1998, between J. Richard George, Ph.D. and Registrant. Incorporated by reference to Exhibit 10.22 to the 1997 10-K Amendment.*
10.13	Employment Agreement dated May 16, 1999, between William D. Block and Registrant.
10.14	Form of Business Protection Agreement (BPA) for certain new employees, including officers. Mr. Block has entered into a BPA with Registrant.
10.15	Separation Agreement between Registrant and Agritope, Inc. ("Agritope"), dated December 1, 1997. Incorporated by reference to Exhibit 2.3 to the 1997 10-K.
10.16	Amended and Restated Employee Benefits Agreement between Registrant and Agritope, dated December 19, 1997. Incorporated by reference to Exhibit 10.24 to the 1997 10-K.*

10.17	Transition Services and Facilities Agreement between Registrant and Agritope, dated December 1, 1997. Incorporated by reference to Exhibit 10.25 to the 1997 10-K.
10.18	Tax Allocation Agreement between Registrant and Agritope, dated December 1, 1997. Incorporated by reference to Exhibit 10.26 to the 1997 10-K.
23.	Consent of PricewaterhouseCoopers LLP.
24.	Powers of Attorney.
27.	Financial Data Schedule.

* Management contract or compensatory plan or arrangement

EXHIBIT 23

CONSENT OF INDEPENDENT ACCOUNTANTS

We hereby consent to the incorporation by reference in the Prospectuses constituting part of the Registration Statements on Forms S-3 (Numbers 33-68510, 33-67618, 33-57246, 33-52920, 33-42841, 33-39166, and 33-32673), and in the Registration Statements on Forms S-8 (Numbers 33-63220, 33-63218, 33-41712, 33-13416, 33-21545, 33-82788, 33-63106, 33-60789, 333-73463 and 333-73465) of Epitope, Inc. of our report dated November 12, 1999 appearing in this Form 10-K.

PricewaterhouseCoopers LLP

Portland, Oregon
December 23, 1999

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