Dear Shareholders,

Fiscal year 1998 was highlighted by significant progress for Epitope. Your company has evolved from a research-oriented organization to one with commercially successful operations and the potential for additional growth. When I joined the company as President and Chief Executive Officer in October 1997, I initiated a corporate strategy based on a demanding set of goals – focus our business on profitability, bring new products to market, develop strategic relationships outside of Epitope, leverage the current position of OraSure , and build opportunities in international markets. Today, I am very pleased to report that all of those goals have been accomplished and have established the framework for what we can achieve in the new fiscal year.

In fiscal 1998, our fourth quarter marked the first time in the company's history that we achieved an operating profit and had positive cash flow. For the last three quarters of fiscal 1998, the company had a net cash usage totaling only $0.5 million, a dramatic reduction from our prior cash drain of over $1 million per month. We also reported record revenues of $3.3 million in the fourth quarter, exceeding the prior year period by 120%. Fourth quarter net income was $21,000 versus a net loss from continuing operations of $1.9 million for the same period in the prior year.

The 1998 fiscal year was marked by solid product revenue growth of 21% to $9.8 million, mainly due to the combined impact of the strength of OraSure HIV testing in the public health sector, the addition of new life insurance customers, and strong international sales. The introduction of OraSure to the public health market exceeded initial expectations and quickly gained significant market visibility. During fiscal 1998, our public health sales grew dramatically to over $2 million from only $0.5 million in the prior year. The outstanding skills and successful contribution of our public health sales force, hired from SmithKline Beecham plc in October 1997, have allowed us to make major progress positioning OraSure for HIV testing in this important sector. Our public health representatives have focused on states with high requirements for HIV testing - including California, New York, New Jersey, Florida, Texas and Michigan, with additional sales to many other states. Our goal for 1999 will be to strengthen our position with existing customers and to extend the use of OraSure to a wider base in the public health sector. In the life insurance market, we increased the number of companies using OraSure to 102 from 62 a year ago. Sales in the life insurance segment are expected to accelerate further in 1999 now that we have reduced the excess inventory accumulated by insurance testing laboratories in prior periods.

Epitope's operating costs are now firmly under control as evidenced by the strong fourth quarter results and full year improvements. These results are a testimony to the discipline we have set in place and our hard work over the last 12 months. Noteworthy are the $2.3 million reduction in operating costs and expenses to $12 million, and the gross profit margin improvement from 57% to 62%. Organizational initiatives aimed at improving business performance enabled us to reduce our inventories, improve control of receivables, and expand our core business without the need for significant capital expenditures. Management was also strengthened during the year with the appointment of highly qualified executives in key positions including sales and marketing, operations, quality assurance and finance.

Late in fiscal 1998, we received an FDA warning letter related to procedures required by the agency's newly implemented Quality Systems Regulations. We believe that Epitope has taken the appropriate steps to address the concerns raised in the warning letter and believe that they will be resolved without the need for additional actions. We are also confident that the changes being made by the company will prepare us to operate more efficiently and to the highest standards required by the FDA. It is our belief that none of the FDA's concerns affected the safety or effectiveness of our products.

Other important accomplishments during the year included the completion of the tax-free spin-off to shareholders of our former subsidiary, Agritope, as a one-time $1.60 per share stock dividend in January 1998. This divestiture was an important part of our goal to focus the company on its medical diagnostic business. Epitope was also released from its guarantee on a $6.5 million line of credit to another former subsidiary, Andrew and Williamson Sales, Co. Today, we are operating as a pure medical device company with a clear focus - providing a highly accurate testing platform at a competitive price to our customers.

Building the OraSure Franchise

Although we are pleased with the results of major reforms at the company over the last twelve months, we are even more excited about the future. One essential element of our corporate growth strategy is to build upon the leadership position that we currently hold in oral fluid diagnostic testing. We are taking a number of new steps to enhance our competitive position and accelerate growth.

An integral part of this growth strategy will be to broaden our current OraSure franchise to reach new markets. One of our major efforts in this area has been the development of a set of assays to compete in the $350 million analytical segment of the drugs-of-abuse market where over 36 million tests are performed annually.

Our research partner, STC Technologies, a privately held company that markets and develops clinical diagnostic tests, has received final FDA clearance for four of its NIDA-5 (National Institute Drugs-of-Abuse) tests that use OraSure samples to detect drugs of abuse. The four tests detect cocaine, methamphetamines, cannabinoids (marijuana) and opiates. The FDA confirmed in November 1998 that it will also allow the phencyclidine (PCP) assay, the fifth and final NIDA-5 drugs-of-abuse test, to be sold to selected clinical laboratories for investigational use.

As part of our efforts to ensure commercial success of the NIDA-5 product, we entered an exclusive five-year distribution agreement with STC Technologies. In addition to STC's strong position in the development of testing assays, STC has built an outstanding distribution network that we believe will enable us to capture an important part of this rapidly growing market. Initially, STC will focus on the non-regulated employment testing market. In early 1999, STC will conduct pilot studies with several key customers to gain essential marketplace feedback, and will continue the technical work to refine the product, as required, to ensure that it will be well-positioned for commercial launch. STC will be responsible for all additional research and development work on the NIDA-5 panel of tests and tests for additional drugs of abuse. The distribution agreement also provides for STC to use OraSure on an exclusive basis in testing for drugs of abuse with STC's up-converting phosphor technology, a developing advance in diagnostic testing.

At Epitope, we have focused our research and development efforts to emphasize commercializing products that we can profitably bring to market in a timely fashion.

During 1998, Epitope entered into a research agreement with Analytical Genetic Testing Center to explore the use of OraSure for DNA collection. Results of this research have been positive, showing that OraSure collects a high-quality DNA sample, and we are now developing a beta-site testing program with AGTC to evaluate our product in several key user settings. Because there are limited regulatory requirements in this market, it is anticipated that the commercial launch can be accomplished soon after customer testing is completed.

International Markets: A Foundation for Future Growth

Expansion in the international marketplace has been another key focus. Today, OraSure competes in important markets worldwide, with some examples noted below. After this year's decision by the Japanese government to allow reduced life insurance premiums for non-smokers, combined with years of preparation by Epitope's joint venture in Japan, Epitope KK, the company began selling OraSure in Japan for cotinine (nicotine)

testing in the life insurance market. In Hong Kong, our distributor has launched OraSure into the over-the-counter market during 1998 and our product is currently being sold in over 100 retail outlets. In China, we are working with the Ministry of Health to position our product for sale in that market. Our distributor there is expected to commence clinical trials in fiscal 1999 in mainland China in an effort to commercialize OraSure. Although the growth of OraSure in Asia may be slower than desired due to the ongoing economic turmoil in that region, we are optimistic that opportunities exist to secure additional business in fiscal 1999.

Argentina, one of the largest markets in South America, is now using OraSure to test for hepatitis. Based upon success with the OraSure program to test victims of severe flooding, the Argentine Ministry of Health is currently reviewing the further use of OraSure for testing of pregnant women for both HIV and hepatitis. A decision on this program is expected by the end of calendar year 1998. Brazil, another significant South American market, is considering the use of OraSure for HIV testing.

In Europe, we entered into an important distribution arrangement in September 1998 that should enhance the future growth of OraSure for that market. Epitope signed a five-year exclusive distribution agreement with Altrix Healthcare plc, a UK-based healthcare diagnostic service provider, for the marketing and sale 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 include other European countries.

Additional opportunities exist to develop our business internationally. Epitope is well-positioned today to take advantage of new international markets using OraSure and to optimize distribution in Europe. In the future, we intend to dedicate resources to pursue those markets where Epitope can most effectively leverage its OraSure technology.

OraQuick – An Innovative Rapid Diagnostic Platform

OraQuick® , our one-step oral fluid rapid diagnostic test device, is the next product that we plan to commercialize for both domestic and international markets. This device is expected to be Epitope's next platform technology since it can be used to test for many medical conditions in about 10 minutes. We are in the final stages of preparing prototype OraQuick devices for pre-clinical testing and are refining manufacturing specifications for OraQuick. Epitope has one patent pending on this new platform technology and a second in process. We are also evaluating the regulatory hurdles and clinical trials required to bring this product to market. Based on the results of these evaluations, we expect to have OraQuick in clinical trials in the U.S. by mid-1999 with commercial launch planned for fiscal 1999 internationally and 2000 domestically.

New OraSure Product Opportunities

Epitope is also expanding its current technology platform with the development of several new OraSure products for a variety of medical conditions, including infection with hepatitis B and C, and syphilis. Epitope is in discussions with several major companies to collaborate and develop products in these key areas, and to determine manufacturing, marketing and distribution potential for each new product.

Sharing Our Vision with Investors

Over the past fiscal year, we initiated efforts to reposition Epitope in the minds of key investor groups, including institutional holders, portfolio managers, retail brokers, market makers and sell-side analysts. To support that effort, we engaged In-Site Communications, Inc., a New York-based firm specializing in investor relations for the healthcare industry. We have been actively sharing our vision with key Wall Street constituents to communicate the outstanding opportunities that exist for Epitope. We expect In-Site to play an important role in developing our relationships with the investment community over the next several years. We have also retained EGS Securities

Corp., a healthcare investment banker, to act as financial advisor to the company as we enter our next phase of growth. EGS already has been instrumental in helping Epitope identify corporate growth opportunities and initiating relationships with several of the larger investment banking institutions. We look forward to further benefits from this relationship over the coming year.

Our Future Plan for Growth and Progress

Our strategic objectives for Epitope remain consistent. Our initial efforts in repositioning the company have been successful and we intend to continue to work aggressively to build future shareholder value. Listed below are some of our objectives for fiscal 1999:

Strategic Objectives

- Expand existing domestic markets. Build upon our existing OraSure leadership position, ensure outstanding customer service to our customers and manage our customer channels more efficiently.
- Leverage domestic and international opportunities. By continuing to build the network of distributor relationships initiated in 1998, create new strategic partnerships and leverage our sales force, we believe that we have the ability to significantly expand our market presence both domestically and internationally.
- Introduce new products (OraQuick, drugs-of-abuse).
- Build and expand partner relationships (e.g., STC Technologies).

Operating Objectives

- Become profitable and generate positive cash flow.
- Control operating expenses, implement cost improvements and strengthen margins.
- Achieve organizational and operational excellence.
- Finally, our progress would not be possible without the dedicated efforts of our valuable employees. We thank them for their contribution.

John W. Morgan
President and
Chief Executive 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 be quite different. Factors that could affect results include: 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; uncertainties related to customers' and suppliers' ability to achieve Year 2000 compliance; and loss of key personnel. 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, 1998

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. [ ]

State the aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, as of December 1, 1998**:** $ 73,153,540

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of December 1, 1998: Common Stock, no par value, 13,609,961 shares.

Documents Incorporated by Reference:

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

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PART I

ITEM 1. Business.

Epitope, Inc. (Epitope or the Company), is an Oregon corporation incorporated in 1981. Epitope develops and markets oral specimen collection kits and related diagnostic tests primarily for the detection of the Human Immunodeficiency Virus (HIV), the cause of Acquired Immune Deficiency Syndrome (AIDS), and for the detection of other medical conditions and analytes, including drugs of abuse. Epitope's lead product, the patented OraSure® collection device, is used as part of an oral specimen diagnostic system. The Company markets the device in the United States and certain foreign countries for use in screening life insurance applicants and for public health use, and plans to begin marketing for drugs of abuse testing in 1999.

The OraSure device consists of a small, treated cotton-fiber pad on a nylon handle that is placed in the patient'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 testing has several significant advantages over blood or urine-based testing systems for both healthcare professionals and patients.

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 U.S. Food and Drug Administration (FDA) for sale to professional markets in the United States. In 1998, the FDA granted clearance for use of the OraSure device with enzyme immunoassays manufactured by STC Technologies, Inc. (STC) to test for cocaine, methamphetamines, opiates and opiate metabolites, cannabanoids (marijuana), and cotinine (a derivative of nicotine). The FDA has also allowed the commercial sale of OraSure to test for phencyclidine (PCP), while the Company and STC gather more clinical data.

Through December 1997, Agritope, Inc. (Agritope) was a wholly owned subsidiary of Epitope. Agritope is a biotechnology company specializing in the development of new fruit and vegetable plant varieties for sale to the fresh produce industry. Epitope made a dividend distribution of all of its ownership interest in Agritope to Epitope's shareholders (the Agritope Spin-off) on December 30, 1997. Epitope no longer owns or controls any shares of Agritope stock.

Background

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 a new class 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.

Since the early 1980s more than 40 million individuals have contracted HIV, and almost 12 million have died, according to UNAIDS, a program sponsored by the United Nations. In 1997 alone, nearly 6 million people acquired HIV, and some 2.3 million perished from it, including 460,000 children. If the rate of new infections continues at

this pace, nearly 37 million people will be living with AIDS at the end of 1998. In North America, an estimated 860,000 people are infected with HIV. The UNAIDS report estimates that worldwide 1,600 children under 15 years old are infected each day compared to 1,000 per day a year ago.

Based on industry estimates, the Company believes that approximately 100 million HIV tests were performed in the U.S. in 1997, with blood banks accounting for about 25 million. The Company feels that a large proportion of the non-blood bank HIV testing market should be available to OraSure because of the accuracy of the test and the benefits of not having to draw blood. Currently, most HIV tests are performed by testing a patient's 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 a situation 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 from the patient. Healthcare professionals collecting blood risk contracting HIV if accidentally stuck by the needle or lancet used to obtain blood from an infected patient.

Limited Access. Because blood must be collected by trained professionals, its collection is often 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.

Patient Discomfort. Blood tests require the use of needles or lancets that are uncomfortable for patients. In addition, patients 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.

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 proprietary salt solution. The pad, which is mounted on a nylon handle, is placed in the patient's 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 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 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 the screening test for HIV-1 antibodies. 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."

The OraSure oral specimen collection and HIV-1 testing system is easily administered and involves three steps: (i) collection of an oral specimen using the OraSure collection device, (ii) screening of the specimen for HIV antibodies at a laboratory, and (iii) laboratory confirmation of positive screening test results with the FDA-cleared OraSure Western blot kit. A trained healthcare professional then conveys test results and provides appropriate counseling to the patient.

The OraSure HIV-1 testing system 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
Cost	Requires a nurse or other healthcare professional trained in phlebotomy	Eliminates the need for and costs associated with a healthcare professional

OraSure-Drug Testing. The FDA granted clearance in 1998 for use of OraSure with enzyme immunoassays manufactured by STC Technologies, Inc. to test for cocaine, methamphetamines, opiates and opiate metabolites, and cannabanoids (marijuana). In addition, the FDA has also allowed STC to distribute OraSure for use with a PCP test under "For Investigational Use Only" status in order to generate data required for FDA review. Management anticipates final approval for use of the OraSure device to test for PCP in 1999. STC has agreed to act as the exclusive distributor of OraSure for use with STC's drugs-of-abuse assays in the United States and much of Europe.

The OraSure device has also 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. Although cotinine is not currently regulated by the FDA for insurance risk assessment, a 510(k) application for cotinine has been filed in anticipation that the Company will sell OraSure for cotinine testing for non-insurance purposes.

Oral-based and Serum-based Western Blot Confirmatory Tests. In June 1996, the Company received FDA clearance to market an oral-based HIV-1 Western blot confirmatory test. This test uses the original oral specimen 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.

Products Under Development

OraSure. Oral mucosal transudate contains many constituents found in blood serum. The Company therefore believes OraSure is a platform technology with a wide variety of potential applications beyond HIV testing. For example, the OraSure device may be useful for the diagnosis of a variety of infectious diseases in addition to HIV, such as viral hepatitis and a number of childhood 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.

The Company has demonstrated that the OraSure device is effective for the collection of samples which can be tested for the NIDA–5 drugs of abuse and cotinine, a derivative of nicotine. Under an agreement with Epitope, STC Technologies, Inc., has developed enzyme immunoassays for the detection of cocaine, methamphetamine, cannabanoids (THC), opiates, PCP, and cotinine present in oral specimens. Five 510(k) notifications for cocaine, methamphetamines, cannabanoids (THC), opiates, and cotinine have been cleared by the FDA. The FDA has also allowed the Company to distribute OraSure for use with a PCP test under "For Investigational Use Only" status that allows the Company to gather additional samples for submission to the FDA. When all clearances have been received, Epitope plans to market OraSure through STC for drugs of abuse detection and directly to the life insurance industry to test applicants for the presence of drugs of abuse. Although cotinine is not currently regulated by the FDA for risk assessment, a 510(k) application for cotinine has been filed in anticipation that the Company will sell OraSure for cotinine testing for non-insurance purposes at some time in the future.

Physicians may also find the OraSure device useful for monitoring level of 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 currently developing OraQuick®, a one-step, rapid-format oral specimen testing system designed to provide test results within ten minutes. The Company believes that OraQuick has significant potential as a rapid test for professional use, and possibly as an OTC home-based test. Like OraSure, OraQuick is a platform technology with a variety of potential applications in addition to HIV testing. Prototype OraQuick devices, to be used for pre-clinical 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 platform 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.

Modifications of the basic OraQuick technology may allow use of this approach for detection of antibodies against the ulcer-causing bacterium *Helicobacter pylori*, as well as for a variety of infectious diseases such as syphilis, viral hepatitis, and childhood infections. The application of this technology to drugs of abuse testing appears possible and is a high priority within the Epitope development group, although some drugs are expected to present technical difficulty to achieve desired results. 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, 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. Because there are limited regulatory requirements in this market, it is anticipated that if the results of research continue to be promising the commercial launch of OraSure for DNA collection can be accomplished soon after customer testing is 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 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 OraSure sample 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 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. Over the next several years insurance companies and testing laboratories expect the market for oral fluid testing of applicants to grow by at least 50 percent.

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 availability of an over-the-counter (OTC) 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, the use of OraSure may allow insurance companies to reduce their exposure to losses from anti-selection and thereby to lower overall claims costs.

Insurance companies have also begun using the same OraSure specimen collected for HIV 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 testing system in Canada and in the Bahamas from 1992 to 1995. The life insurance company reported that OraSure sample collection by agents had significantly reduced its testing costs per policy. During the four-year study period, the insurer found that it saved $1.7 million by using OraSure for HIV and cocaine testing. In addition, the life insurance company determined that 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 this same Academy, Crown Life of Canada reported that the five year savings from OraSure testing for cocaine, cotinine and HIV were approximately $1.4 million.

Japanese Insurance Market. The Japanese life insurance market in 1996 was served by 44 companies which sold approximately 35 million policies, of which about one-third were new ordinary life policies, the type for which 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.

Physician and Public Health Clinical Market. The physician market consists primarily of individual doctors' offices which are supplied through the physician's 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 as the product is currently available to physicians through various physician supply channels. The Company is exploring the feasibility of implementing a direct telemarketing program to 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, prison systems 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 testing to combat the spread of AIDS. The OraSure device has received a warm welcome in the public health market because of its ease of use and reliability.

The cost of OraSure had been an obstacle to its adoption by some providers in the public health market. The small size of some public health organizations or their decisions to begin OraSure testing on a small scale made volume discounts for OraSure or related tests unavailable, so that the cost of OraSure testing was higher than blood-based testing. In order to avoid having cost be a major obstacle to growth in volume and adoption of this new testing

format, Epitope has revised its volume pricing policy. In addition, both to decrease the cost of testing and to provide fast turnaround with accurate test methods, Epitope has entered into an agreement with Lab*One*, Inc. (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 being sold directly to public health customers by the Epitope sales force.

International. In light of the worldwide scope of the HIV epidemic, Epitope believes there are significant opportunities for sale of OraSure 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.

Drugs of Abuse Market. The analytic portion of the United States drugs-of-abuse testing market, outside of the criminal justice system, is estimated to be over $350 million, with approximately 36 million tests performed in 1997. The testing is concentrated on a set of commonly abused drugs called the NIDA-5, consisting of cocaine, methamphetimines, opiates, marijuana and PCP.

This market is currently based primarily on urine testing, which is susceptible to adulteration of samples unless precautions are taken in the collection process. The Company believes that oral fluid testing will succeed in this market 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 FDA has approved tests for cocaine, opiates, methamphetimines and marijuana with an OraSure sample. In addition, the FDA is allowing the Company to distribute OraSure for use with a PCP test under "For Investigational Use Only" status in order to generate data required for FDA review. Epitope has teamed with STC to distribute products to this market. See "Marketing and Customers."

OTC Market. The over-the-counter market for HIV testing currently is served by only one test, distributed by Home Access Health Care, 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 has significantly reduced the attention and resources it was devoting to preparation for the OTC market because of the smaller than anticipated market size and the high cost of setting up the required systems, support, and clinical trials needed for FDA approval. The Company has shifted instead to the public health markets, including colleges and corrections facilities. The Company has not ruled out an eventual move into the OTC market, but it is not a high priority at this time.

Marketing and Customers

Life Insurance Industry. Epitope currently markets the OraSure device for use in screening life insurance applicants for HIV, cocaine, and cotinine (a derivative of nicotine). The Company maintains a direct sales force that markets OraSure directly to insurance companies. Insurance companies then make their own decision regarding which insurance reference laboratory to use to supply their devices and testing service. The major laboratories currently using the OraSure device include Lab*One*, Inc., Osborn Laboratories, Clinical Reference Laboratory and Heritage Laboratories. As of November 1998, 30 of the top 100, and 5 of the top 10 life insurance companies were using OraSure to varying degrees for testing applicants for life insurance. As of that date there were 102 insurance companies using OraSure. Because the 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. The Company's sales focus is on converting additional insurance companies to the use of OraSure, and extending its use within the companies already using OraSure.

Physician and Public Health Clinical Market. Through September 1997, SmithKline Beecham, plc (SB) marketed Epitope's oral HIV testing system to the physician, hospital and other professional healthcare provider markets. The Company resumed responsibility for servicing these markets in October 1997. Epitope hired some of SB's sales personnel that had been focused on the public health market, and began selling its products directly to these customers. To better serve this market, Epitope entered into an agreement with Lab*One* to provide a prepackaged OraSure test kit, with prepaid specimen shipping costs and laboratory testing included. The Lab*One* OraSure test kit

is one of the primary products sold into this market and represented nearly half of all the Company's sales to this segment in 1998.

International. Epitope markets to international customers primarily through carefully chosen 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 in each country. Epitope is currently marketing OraSure directly to customers in Canada and through distributors in the United Kingdom (UK), Ireland, Thailand, Argentina, Brazil, South Africa, Greece, the Philippines, Taiwan, Mexico and Colombia.

The Company entered into a distribution agreement with Altrix Healthcare plc (Altrix), 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.

Epitope participates in a joint venture in Japan which markets both the OraSure device and STC's cotinine test to the Japanese 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. In addition, OraSure is now being used for Hepatitis testing in Argentina and the Company is 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 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 OraSure devices to STC for a per-unit price. Epitope will receive a percentage of STC's gross revenue from the resale of OraSure devices and STC oral fluid drugs-of-abuse test sales. 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.

Epitope and STC will participate jointly in marketing activities and obtaining required international regulatory approvals. The two companies plan to begin evaluation of drugs-of-abuse testing products in selected test markets in early 1999. Feedback from these early users, along with the results of additional laboratory testing, will help determine whether modifications in the OraSure device or the STC tests might be needed for optimal performance in the market.

Western Blot Distribution. Epitope has entered into supply and distribution agreements with Organon Teknika Corporation. 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. Epitope and Organon Teknika recently extended the expiration dates for the supply and distribution agreements to March 31, 2000.

Customer Concentration. In fiscal 1998, the Company's sales to Lab*One*, Inc., Osborn Laboratories, Clinical Reference Laboratory and Organon Teknika accounted for over 62 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 emerging market for HIV testing is intense and is expected to increase. The Company believes that the principal competition will come from existing blood-based HIV assays and from urine-based testing assays. 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 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 has approved home collection kits for HIV blood testing developed by Direct Access Diagnostics (Johnson & Johnson) and by Home Access Health Corp. In July 1997, Johnson & Johnson withdrew its HIV home-test from the market, citing weak sales.

Cambridge Biotech Corporation, 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.

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 testing. See "Government Regulation."

The FDA has approved an HIV screening test for use with a urine sample. In June 1998, the FDA notified Cambridge Biotech Corp 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 patient or life insurance applicant, 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. Many of Epitope's proposed and existing diagnostic products are subject to regulation by the FDA, other federal, state, and local agencies, and comparable bodies in foreign countries. Such regulation governs almost all aspects of development and marketing, including the introduction, advertising, promotion, manufacturing practices, labeling, distribution, and record keeping for the products. In the United States, different types of diagnostic products are regulated differently by the FDA, as discussed below. As part of the FDA clearance process, Epitope often must demonstrate that its products are both safe and effective for a particular indication or application.

Drugs and Biological Products. Generally, drugs and biological products require FDA approval before marketing. The steps required before a drug or biological product may be marketed in the United States include: (1) preclinical laboratory and animal tests; (2) submission of an application for an investigational new drug or biological product, which must become effective before human clinical trials may commence; (3) human clinical trials; (4) submission of a Product License Application (PLA) for the biological product or a New Drug Application (NDA) for most other new drug products; and (5) approval of the PLA or NDA.

Preclinical safety and initial efficacy testing is usually undertaken in animals. Results of such preclinical and other laboratory tests are submitted to the FDA before human clinical trials can begin. Clinical trials are typically conducted in three phases. Phase I uses human subjects to determine safety and tolerance. Phase II uses a limited patient population to determine effectiveness and dosage and to identify side effects. Compounds found effective and safe in Phase II are further tested in Phase III with an expanded patient population at geographically dispersed clinical study sites. Each phase may last from one to two years or more.

Most products are not approved because of the failure to demonstrate safety, effectiveness, or both. The FDA may suspend clinical trials at any time if it is felt that subjects or patients are being exposed to an unacceptable health risk. Obtaining FDA approval requires substantial time and effort. There can be no assurance that any approval will be granted to Epitope on a timely basis, if at all. As part of the approval process, the FDA may require the Company to initiate post-approval marketing studies.

Medical Devices. Medical devices are classified either in Class I, Class II, or Class III. Class I devices are subject only to general control provisions of the Federal Food, Drug, and Cosmetic Act, as amended (the FDC Act). These provisions include requirements that a device not be adulterated or misbranded. Class II devices are those for which general controls are insufficient to provide a reasonable assurance of safety and efficacy and for which a "generic" performance standard or other special controls are appropriate. Devices that do not meet the criteria for Class I or II are placed in Class III. Class I and II devices, those Class III devices initially marketed prior to passage of the Medical Device Amendments of 1976 (MDA) for which premarket approval applications (PMAs) are not yet required, and devices substantially equivalent to such devices, may be marketed upon FDA clearance of a Premarket Notification (a 510(k) Notice). Other Class III devices may be commercially marketed only after FDA approval of a PMA. Generally, the process for obtaining FDA approval of a PMA is similar to that for obtaining approval of a biological or other drug product.

Based upon the information provided in a 510(k) Notice regarding the device's intended use and technological features, the FDA will determine whether the device is "substantially equivalent" to a predicate device, i.e., a device legally marketed which did not require a PMA. If a device is found to be substantially equivalent to a predicate device, it may be freely marketed in the United States so long as the device is otherwise in compliance with the FDC Act. If it is not so found, it will be considered a Class III device requiring a PMA. Substantial equivalence means that the FDA has found that the device has the same intended use as the predicate device, and either has the same technological characteristics or has different characteristics, but there is information in the 510(k) Notice that shows the device is as safe and effective as the predicate and does not present different questions of safety and effectiveness.

OraSure Collection Device. Use of the OraSure collection device for applications involving the detection of antibodies to HIV is regulated by the FDA as use of a Class III medical device requiring a PMA. In December 1994, the FDA approved Epitope's PMA for use of the OraSure device in HIV screening. Post-approval marketing studies were completed and a final report submitted to the FDA on August 28, 1997. In June 1996, the FDA approved the PMA for use of the OraSure oral specimen-based Western blot confirmatory test kit for HIV-1 diagnosis. A second generation HIV-1 antibody EIA test for OraSure samples is currently under review by the FDA.

Western Blot Test Kits. Epitope's HIV-1 Western blot serum-based confirmatory test kits are used to confirm whether individuals are infected with HIV-1. They are regulated by the FDA as biological products, unlike most other diagnostic tests which are regulated as medical devices. In March 1991, the FDA cleared the EPIblot HIV-1 serum-based confirmatory test kit for commercial distribution. As noted above, a PMA seeking permission to market the OraSure oral specimen-based Western blot confirmatory test kit for HIV-1 diagnosis was approved by the FDA in June 1996.

Manufacturing Regulations. Every company that manufactures drugs, biological products, or medical devices distributed in the United States is subject to inspections by the FDA and must comply with the FDA's Quality Systems Regulations. These regulations govern, among other matters, manufacture, testing, release, packaging, distribution, documentation, purchasing and design control.

FDA Warning Letter. Epitope received a warning letter from the FDA in June 1998, noting that the Company had not fully adhered to the FDA's new Quality Systems Regulations. These new regulations, which went into effect on June 1, 1997, are part of the FDA's stepwise approach to international harmonization of quality standards and include some new requirements such as design controls. The inspections under these new regulations are part of an industry-wide standard that the FDA has adopted to optimize compliance through more rigorous and detailed inspection of companies operating in biologics industries. The items cited in the warning letter mainly address incidents relating to failure to strictly adhere to standard operating procedures in the production and evaluation of products manufactured by Epitope.

Epitope is cooperating fully with the FDA to address all of the instances cited, has already replied to each of the FDA's questions, and is aggressively making changes in procedures and retraining personnel. It is the Company's belief that none of the FDA's concerns affected the safety or effectiveness of its products, and that the cost of compliance to make the required changes will not be material.

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. Epitope is also subject to foreign regulations governing, for example, human clinical trials and marketing with respect to products distributed outside the United States. 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.

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 ends March 31, 2000. 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 operations are widely available from a variety of sources.

Grants and Contracts

Epitope has received funding in the past from the National Institute of Allergy and Infectious Diseases (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 or 17 years from issuance, whichever is longer.

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.

The Company believes that patent and trade secret protection is important to its business. However, 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

At September 30, 1998, the Company had 85 full-time employees, including 17 persons in research and product development, 27 in administration and marketing, 31 in manufacturing and production, and 10 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 5 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 also 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 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 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 or Impairment of Sources of Capital. Although the Company has made significant progress in the last fiscal year toward controlling expenses, increasing product revenue, and achieving profitability, 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. In particular, the fact that the Company's common stock has recently traded at historically low levels may make it difficult for the Company to raise necessary funds through the sale of common stock or other equity securities.

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 a reliable, effective test system. 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 Systems Regulations, 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.

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.

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. Each lease calls for fixed monthly payments over its term. The Company also entered into a three-year lease, effective October 1, 1996, for 2,265 square feet of warehouse space used to store inventory and equipment. The total amount of the Company's lease obligation through the term of the lease is $456,348.

ITEM 3. Legal Proceedings.

On April 7, 1998, the Company's former subsidiary A&W instituted a lawsuit against two former officers of the Company and an officer of Agritope in connection with events surrounding the recission of the A&W acquisition (U.S. District Court for the Southern District of California, Case No. 98 CV 0666 TW (CGA)). The defendants were not served with notice of the lawsuit until October 1, 1998. A&W alleges improper acts by the officers, and seeks damages claimed to be in excess of $5.7 million, an amount that corresponds to the liquidation value of the preferred stock issued by A&W to the Company at the time the acquisition was rescinded. The Company is defending the officers and believes the lawsuit to be frivolous, without merit, and counter to a settlement agreement signed by A&W at the time of the recission. The defendants have moved for dismissal and will pursue the matter vigorously. The Company has filed an action in Oregon state court (Multnomah County Circuit Court Civ. No. 9810-07537) against A&W for breaching the settlement agreement and is seeking as damages the Company's costs of defending the California action.

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. Prior to January 2, 1997 the Company's Common Stock was listed for trading on the American Stock Exchange (AMEX) under the symbol EPT. High and low sales prices reported by NASDAQ and AMEX during the periods indicated are shown below.

Sales prices per share

Year ended September 30	**1998**		**1997**	
	High	**Low**	**High**	**Low**
First Quarter	$ 8.125	$ 4.25	$ 16.375	$ 10.875
Second Quarter	7.1875	4.75	17.375	9.75
Third Quarter	6.875	4.5625	11.125	6.25
Fourth Quarter	7.00	2.875	8.625	4.625

On December 1, 1998, there were 923 holders of record of the Common Stock, and the closing price of the Common Stock was $5.375. 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, 1998 and 1997 and the operating results data for the years ended September 30, 1998, 1997 and 1996 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, 1996, 1995, and 1994 and operating results data for the years ended September 30, 1995 and 1994 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	**1998**	**1997**	**1996**	**1995**	**1994**
Operating Results					
Revenues.	$ 9,792	$ 9,360	$ 5,594	$ 2,856	$ 2,605
Operating costs and expenses	12,042	14,323	10,881	14,464	8,890
Other income, net	322	882	6,388(1)	1,157	456
(Loss) income from continuing operations.	(1,928)	(4,081)	1,101	(10,451)	(5,829)
Discontinued operations.	-	(18,359)	(2,501)	(8,045)	(9,804)
Net loss	(1,928)	(22,440)	(1,400)	(18,496)	(15,633)
(Loss) income per share from continuing operations	(0.14)	(.30)	.08(2)	(.88)	(.58)
Net loss per share.	(0.14)	(1.67)	(.11)	(1.56)	(1.56)
Shares used in per share calculations.	13,529	13,404	12,661(2)	11,886	10,050
Balance Sheet Data					
Working capital	$ 6,510	$ 9,538	$ 24,793	$ 20,686	$ 16,766
Total assets	10,357	17,012	29,784	26,142	19,993
Accumulated deficit	(103,046)	(95,426)	(72,985)	(71,585)	(53,090)
Shareholders' equity	8,274	15,014	27,967	22,347	18,470

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

(2) 13,440,000 shares used in calculation of profit 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 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; uncertainties related to customers' and suppliers' ability to achieve year 2000 compliance; and loss of key personnel. 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.

Discontinued Operations

Agritope. On December 30, 1997, Epitope distributed all of its ownership interest in Agritope, Inc. (Agritope) to Epitope's shareholders through a stock dividend (the Agritope Spin-off). Epitope no longer owns or controls any shares of Agritope stock.

Agritope's results of operations are presented as discontinued operations in the Consolidated Financial Statements included in this Annual Report on Form 10-K through the date of the spin-off. Agritope's net assets are presented in the September 30, 1997 balance sheet as net assets of discontinued operations. All intercompany loans from Epitope to Agritope have been reflected as capital contributions to Agritope consistent with the separation agreement between Agritope and Epitope dated December 1, 1997.

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 producer and wholesale distributor of fresh and frozen fruits and vegetables based in San Diego, California. Under the terms of the merger, the Company issued 520,000 shares of Epitope common stock in exchange for all of the outstanding common stock of A&W. On May 27, 1997, in accordance with the terms of a rescission agreement, the former shareholders of A&W returned the 520,000 shares of Epitope common stock they received, and Epitope returned all of the outstanding shares of A&W common stock. Epitope also received A&W preferred stock in satisfaction of intercompany loans made to A&W between December 12, 1996 and March 19, 1997. This A&W preferred stock carries a $5.7 million liquidation preference, dividend preferences, and various redemption features and carries no value on the accompanying balance sheet based upon management's estimate of fair value on the date it was received. In addition, the Company had provided a guarantee to Wells Fargo Bank for a credit facility provided to A&W. On June 16, 1998, the Company was released from any contingent liability with regard to the guarantee.

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	**1998**		**1997**		**1996**	
Product Sales						
Oral specimen collection devices.	$7,195	74%	$6,279	67%	$3,311	59%
Western blot HIV confirmatory tests	2,370	24	1,791	19	1,540	28
Other product sales	214	2	14	-	14	-
	9,779	100%	8,084	86%	4,865	87%
Grants and contracts	13	0	1,276	14	729	13
	$9,792	100%	$9,360	100%	$5,594	100%

Revenues. Product sales increased by $1.7 million or 21 percent from 1997 to 1998 and by $3.2 million or 66 percent from 1996 to 1997 primarily as a result of expanded sales volume of Epitope's lead product, the OraSure oral specimen collection device. Approximately 34 percent of 1998 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 following the approval by the FDA in June 1997 and the reduction of inventories built up beyond pilot programs. This inventory build-up resulted in reduced OraSure device sales in the second half of 1997 and the first half of 1998 as insurance customers reduced their inventory levels. In addition, the Company's continued expansion into the public health markets in 1998 contributed to the increase in sales.

OraSure device sales into the public health markets in 1998 totaled $2.5 million or 25 percent of total product sales. The life insurance testing market contributed $4.2 million or approximately 44 percent of total 1998 product sales. OraSure device sales into the international market totaled $420,000 or 4 percent in 1998. The Company's total product sales into foreign markets, including cotinine test devices and product components, represented 10 percent of total sales in 1998.

Fiscal year sales are anticipated to continue rising in 1999. However, sales may be affected by seasonality of 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 increased by $579,000 or 32 percent from 1997 to 1998 and increased by $251,000 or 16 percent from 1996 to 1997. Sales in 1997 were negatively affected by a reduction in orders from the Company's exclusive distributor for this product as the distributor lowered inventory levels. In addition, 1998 sales of the Western blot HIV confirmatory test have increased as a result of increased use of the related oral specimen collection devices and screening tests.

As of September 30, 1998, the Company had firm orders and contractual commitments for delivery within 90 days of OraSure devices and Western blot HIV confirmatory tests totaling approximately $940,000 and $570,000, respectively, as compared to firm orders for delivery within 90 days of $900,000 and $450,000, respectively, as of September 30, 1997.

Grant and contract revenues decreased by $1.3 million or nearly 100 percent from 1997 to 1998 and increased $547,000 or 75 percent from 1996 to 1997. The decrease in 1998 was due to the termination of the Company's development, license and supply agreement with Smithkline Beecham, plc (SB) in July 1997. R&D activities related to the SB agreement accounted for the increase in 1997. Discussions are under way with other potential partners who may provide R&D funding to the Company. Grant applications for additional funding are also being considered.

Gross Margin on product sales was 62 percent in 1998, 57 percent in 1997, and 45 percent in 1996. The improvement in gross margins is attributable to increased sales and production volumes for the OraSure device which resulted in lower per unit costs and to the shift in product mix towards the OraSure device which carries a higher gross margin than does the Western blot HIV confirmatory test. The gross margin in the fourth quarter of 1998 was 65 percent as a result of increased product sales volume.

Research and Development Expenses. Research and development expenses decreased by $1.2 million or 30 percent from 1997 to 1998 and increased by $991,000 or 31 percent from 1996 to 1997. The decrease in 1998 was primarily the result of decreased levels of research and clinical studies activity conducted the under SB agreement. R&D expenses for 1999 should be near the 1998 level, unless funding for additional R&D projects is forthcoming from potential new partners or from research grants.

Selling, General and Administrative Expenses. Selling, general and administrative expenses decreased by $1.2 million or 18 percent from 1997 to 1998 and expenses increased by $1.6 million or 32 percent from 1996 to 1997. The decrease in 1998 was primarily a result of cost containment measures and a reduction in compensation expense. The increase in 1997 was primarily attributable to higher corporate and marketing expenses as the Company expanded its direct sales efforts. 1999 sales expenses are expected to increase as a result of increased advertising and

promotion to support expansion in all markets.

Selling, general and administrative expenses have been reduced by $1.4 million and $1.1 million in 1997 and 1996, respectively, for amounts allocated to Agritope (see "Discontinued Operations").

Other Income (Expense), Net. Other income for 1996 included $5.0 million related to license fees received from SB as a result of FDA approval of an extension of dating for the OraSure device. Interest income decreased in 1998, primarily due to lower levels of invested funds.

Year 2000 Readiness. Epitope is aware of the issues associated with the programming code in existing computer systems and other electronic equipment as the year 2000 (Y2K) approaches. The "year 2000 problem" is pervasive and complex. Virtually every computer system and many electronic controlled devices will be affected in some way by the rollover of the two-digit year value to 00. The issue is whether these systems and devices will properly recognize date-sensitive information when the year changes to 2000. Systems and devices that do not properly recognize such information could generate erroneous data or cause the system or device to fail.

The Company's management has conducted a review of Epitope's exposure to the Y2K problem, including the development of a plan of identifying systems and devices that are non-compliant and a systematic approach to replacing or upgrading those systems and devices that are compliant. In addition, Epitope is in the process of contacting all vendors, suppliers, and customers, the interruption of whose businesses would have a material effect on the Company. All non-Y2K compliant internal systems or devices, including those that affect technology, products or service functions, will be replaced or upgraded in the ordinary course of business (as part of a regular ongoing upgrade program) during fiscal 1999. The Company is also working with computer and electronic device hardware and software vendors to ensure that the replacement products are Y2K compliant. The Company has not incurred any material costs to date and does not anticipate incurring any material costs to resolve issues relating to the Y2K problem internally. Such costs will be funded by cash flows from operations or available cash and cash equivalents.

At the current time, the Company anticipates that all essential products and internal systems and equipment are now or will be timely made Y2K compliant in all material respects. This belief is based on the progress to date and the assessed degree of difficulty associated with the remaining phases to achieve Y2K readiness, the representations made by vendors and, where possible, by testing. Significant uncertainty exists, however concerning the effects of the Y2K problem, primarily with regards to assurances made by the Company's key or significant vendors, suppliers, and customers. 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.

Contingency plans are under development at this time and the Company anticipates that acceptable alternatives will be available in the event that a contingency arises. These contingency plans anticipate using alternative vendors and suppliers of goods and services. It is impossible, however, for the Company to fully assess the likelihood or magnitude of consequences of Y2K issues, should representations of vendors, suppliers, and customers prove to be inaccurate.

This section captioned "Year 2000 Readiness" as well as other statements herein relating to Y2K issues are "Year 2000 Readiness Disclosures" pursuant to the Year 2000 Information and Readiness Disclosure Act.

Liquidity and Capital Resources

(In thousands)	**9/30/98**	**9/30/97**
Cash and cash equivalents	$1,164	$ 1,934
Marketable securities	4,455	7,142
Working capital	6,510	9,532

Net cash flows used in operating activities decreased by $745,000 and the total net decrease in cash and cash equivalents declined $2,995,000 from 1997 to 1998 as a result of improved operating results, no longer having the need to fund the operations of subsidiaries, and continued control of expenses.

Proceeds from current assets, primarily the sale of marketable securities, represented the primary sources of funds for meeting the Company's requirements for operations, working capital and business expansion in 1998. The Company received proceeds of $448,000, $1,668,000 and $5.9 million from the exercise of warrants and options to purchase common stock in 1998, 1997 and 1996, respectively. Research grant funding from strategic partners was $13,000, $1.3 million and $729,000 in 1998, 1997 and 1996, respectively. Funding of the Company's discontinued operations, Agritope and A&W, required $2.1 million, $13.9 million and $3.2 million in 1998, 1997 and 1996, respectively.

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.

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, 1998 and 1997. 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, 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 net loss per share	(.07)	(.05)	(.02)	0.00	(0.14)
Diluted net loss per share	(.07)	(.05)	(.02)	0.00	(0.14)
Year ended September 30, 1997					
Revenues	2,640	2,336	2,884	1,500	9,360
Operating costs and expenses	3,250	3,574	4,005	3,494	14,323
Other income, net	319	274	173	116	882
Loss from continuing operations	(291)	(964)	(948)	(1,878)	(4,081)
Discontinued operations	(4,093)	(9,202)	(1,366)	(3,698)	(18,359)
Net loss	(4,384)	(10,166)	(2,314)	(5,576)	(22,440)
Basic loss per share from continuing operations	(.02)	(.07)	(.07)	(.14)	(.30)
Diluted loss per share from continuing operations	(.02)	(.07)	(.07)	(.14)	(.30)
Basic and diluted net loss per share	(.34)	(.74)	(.17)	(.42)	(1.67)

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

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, 1998 and 1997, and the results of their operations and their cash flows for each of the three years in the period ended September 30, 1998, in conformity with generally accepted accounting principles. 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 generally accepted auditing standards 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, 1998

Epitope, Inc.
Consolidated Balance Sheets

September 30	**1998**	**1997**
Assets		
Current assets		
Cash and cash equivalents	$ 1,164,275	$ 1,934,480
Marketable securities	4,455,044	7,141,640
Trade accounts receivable, net (Note 2)	1,519,652	928,047
Other accounts receivable	47,818	128,949
Inventories (Note 2)	1,092,577	1,324,647
Prepaid expenses	313,941	78,240
Total current assets	8,593,307	11,536,003
Property and equipment, net (Note 4)	819,095	1,200,988
Patents and proprietary technology, net (Note 2)	596,169	657,487
Other assets and deposits	348,733	55,099
Net assets of discontinued operations (Note 3)	-	3,562,726
	$ 10,357,304	$ 17,012,303
Liabilities and Shareholders' Equity		
Current liabilities		
Accounts payable	$ 566,894	$ 110,285
Salaries, benefits and other accrued liabilities	1,516,395	1,887,825
Total current liabilities	2,083,289	1,998,110
Commitments and contingencies (Notes 8 and 11)	-	-
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; 13,577,319 and 13,454,330 shares issued and outstanding, respectively	111,319,573	110,439,726
Accumulated deficit	(103,045,558)	(95,425,533)
	8,274,015	15,014,193
	$ 10,357,304	$ 17,012,303

The accompanying notes are an integral part of these statements.

Epitope, Inc.
Consolidated Statements of Operations
For the Year Ended September 30

	1998	1997	1996
Revenues			
Product sales	$ 9,778,930	$ 8,083,606	$ 4,864,378
Grants and contracts	12,652	1,276,454	729,271
	9,791,582	9,360,060	5,593,649
Costs and expenses			
Product costs	3,684,702	3,512,054	2,681,429
Research and development costs	2,917,742	4,156,996	3,165,838
Selling, general and administrative expenses	5,439,743	6,654,553	5,033,491
	12,042,187	14,323,603	10,880,758
Loss from operations	(2,250,605)	(4,963,543)	(5,287,109)
Other income (expense), net			
Interest income	362,694	885,583	1,386,968
Interest expense	(8,868)	(8,165)	-
License fee	-	-	5,000,000
Other, net	(31,229)	4,861	1,493
	322,597	882,279	6,388,461
Net income (loss) from continuing operations	(1,928,008)	(4,081,264)	1,101,352
Discontinued operations (Note 3)			
Loss from discontinued operations; Agritope	-	(9,890,599)	(2,501,268)
Income from discontinued operations; A&W	-	170,646	-
Estimated loss on disposal of A&W	-	(8,639,054)	-
	-	(18,359,007)	(2,501,268)
Net loss	$ (1,928,008)	$(22,440,271)	$ (1,399,916)
Basic (loss) income per share from continuing operations	$ (.14)	$ (.30)	$ .09
Diluted (loss) income per share from continuing operations	$ (.14)	$ (.30)	$ .08
Basic loss per share	$ (.14)	$ (1.67)	$ (.11)
Diluted loss per share	$ (.14)	$ (1.67)	$ (.11)
Weighted average number of shares outstanding	13,528,596	13,404,402	12,661,420*

*Diluted income per share from continuing operations calculated using 13,440,396 weighted average shares outstanding due to common stock equivalents.

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, 1995	12,485,130	$ 93,931,947	$(71,585,346)	$ 22,346,601
Common stock issued upon exercise of options	386,550	4,886,118	-	4,886,118
Common stock issued as compensation	19,353	263,586	-	263,586
Compensation expense for stock option grants	-	1,044,183	-	1,044,183
Common stock issued upon exercise of warrants	46,350	826,600	-	826,600
Equity issuance costs	-	(152)	-	(152)
Net loss for the year	-	-	(1,399,916)	(1,399,916)
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 for 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, Inc.	-	-	(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

The accompanying notes are an integral part of these statements.

Epitope, Inc.
Consolidated Statements of Cash Flows
For the Year Ended September 30

	1998	1997	1996
Cash flows from operating activities			
Net loss	$ (1,928,008)	$(22,440,271)	$ (1,399,916)
Adjustments to reconcile net loss to net cash used in operating activities:			
Loss from discontinued operations	-	18,359,007	-
Depreciation and amortization	669,839	729,970	1,045,632
Loss (gain) on disposition of property	31,290	17,888	(1,098)
(Increase) decrease in receivables	(510,474)	264,686	125,025
Decrease (increase) in inventories	232,070	(166,717)	(233,929)
(Increase) decrease in prepaid expenses	(235,701)	11,278	69,133
(Increase) decrease in other assets and deposits	(292,544)	(32,340)	20,649
Increase (decrease) in accounts payable and accrued liabilities	85,179	180,773	(1,656,478)
Common stock issued as compensation for services	-	323,938	263,586
Compensation expense for stock option grants and deferred salary increases	431,482	489,668	1,044,183
Net cash used in operating activities	(1,516,867)	(2,262,120)	(723,213)
Cash flows from investing activities			
Investment in marketable securities	(13,524,782)	(20,106,837)	(47,608,270)
Proceeds from sale of marketable securities	16,213,797	31,783,317	45,870,396
Additions to property and equipment	(140,903)	(196,910)	(1,066,758)
Proceeds from sale of property	37,629	-	7,432
Expenditures for patents and proprietary technology	(157,063)	(265,435)	(770,262)
Investment in affiliated companies	(1,090)	(6,702,299)	(331,280)
Minority interest in affiliated companies	-	-	215,407
Net cash provided by (used in) investing activities	2,427,588	4,511,836	(3,683,335)
Cash flows from financing activities			
Principal payments under installment purchase and capital lease obligations	-	-	(39,507)
Proceeds from issuance of common stock	448,365	1,668,211	5,885,573
Cost of common stock issuance	-	-	(152)
Cash to Agritope	(2,129,291)	(7,682,710)	-
Net cash (used in) provided by financing activities	(1,680,926)	(6,014,499)	5,845,914
Net (decrease) increase in cash and cash equivalents	(770,205)	(3,764,783)	1,439,366
Cash and cash equivalents at beginning of year	1,934,480	5,699,263	4,259,897
Cash and cash equivalents at end of year (Note 3)	$ 1,164,275	$ 1,934,480	$ 5,699,263

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), is an Oregon corporation incorporated in 1981. Epitope develops and markets oral specimen collection kits and related diagnostic tests primarily for the detection of the Human Immunodeficiency Virus (HIV), the cause of Acquired Immune Deficiency Syndrome (AIDS), and for the detection of other medical conditions and analytes, including drugs of abuse. Epitope's lead product, the patented OraSure® collection device, is used as part of an oral specimen diagnostic system. The Company markets the device in the United States and certain foreign countries for use in screening life insurance applicants and for public health use, and plans to begin marketing for drugs-of-abuse testing in 1999. Epitope also markets HIV-1 Western blot confirmatory test kits used to confirm positive results of initial screening tests for HIV-1 infection.

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, 1998, 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 shareholders' equity. Such unrealized gains and losses were immaterial as of September 30, 1998 and 1997.

Trade Accounts Receivable. Accounts receivable are stated net of an allowance for doubtful accounts of $49,513 and $32,284, respectively, at September 30, 1998 and 1997.

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	**1998**	**1997**
Raw materials	$ 238,916	$ 296,432
Work-in-process	627,503	343,585
Finished goods.	211,703	670,175
Supplies	14,455	14,455
	$ 1,092,577	$ 1,324,647

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:

	1998	1997	1996
Amortization expense for the year ended September 30.....	$ 218,381	$ 209,180	$ 172,095
Accumulated amortization at September 30.....	1,048,671	830,290	621,110

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.

New Accounting Pronouncements. On June 15, 1997 the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 130, Reporting Comprehensive Income. SFAS No. 130 is effective for all fiscal quarters of all fiscal years beginning after December 15, 1997 (October 1, 1998 for the Company). The Company will adopt this pronouncement subsequent to that date. Also on June 15, 1997 the FASB issued SFAS No. 131, Disclosures about Segments of an Enterprise and Related Information. SFAS No. 131 is effective for all fiscal quarters of all fiscal years beginning after December 15, 1997 (October 1, 1998 for the Company). The Company will adopt this pronouncement subsequent to that date. Both statements require additional disclosures and reclassification of previously issued financial information but will not have a material effect on the results of operations and financial position of the Company. On June 15, 1998, SFAS No. 133 Accounting for Derivative Instruments and Hedging Activities was issued. SFAS No. 133 is effective for all fiscal quarters of all fiscal years beginning after June 15, 1999 (October 1, 1999 for the Company). Management of the Company anticipates that, because the Company does not make use of derivative instruments, the adoption of SFAS No. 133 will not have any effect on the Company's results of operations or its financial position.

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 years ended September 30, 1997 and 1996 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 Shared Services allocated to the discontinued operations of $1,402,895 and $1,069,249 for the years ended September 30, 1997 and 1996, respectively.

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 Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes," (SFAS 109) which requires the use of the asset and liability method for accounting for income taxes. Under SFAS 109, 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.

Stock-Based Compensation. SFAS 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 and diluted income (loss) per share has been computed using the weighted average number of shares of common stock and potential common stock outstanding during the period. 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. Potential common stock is excluded from the computation if its effect is anti-dilutive. Basic and diluted net income (loss) per share are the same for the years ended September 30, 1998, 1997, and 1996. On September 30, 1998, 1997, and 1996, the weighted average shares outstanding were 13,528,596, 13,404,402, and 12,661,420, respectively. Shares of potential common stock on September 30, 1998, 1997, and 1996, respectively of 6,206,279, 4,428,141, and 3,058,555 were not included in the calculation of diluted loss per share as they were antidilutive. At September 30, 1996, 778,878 of potential common shares were included in the calculation of diluted earnings per share.

Statement of Cash Flows. Cash paid for interest approximated interest expense in 1998, 1997, and 1996. No cash was paid for income taxes in 1998, 1997, or 1996. Compensation expense amounted to $431,482, $813,606, and $1,307,769 in 1998, 1997, and 1996, 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.

Reclassifications. Certain reclassifications have been made to prior years' data to conform with the current year's presentation. These reclassifications had no impact on previously reported results of operations or shareholders' equity.

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. From its acquisition in 1987 through December 29, 1997, Agritope was a wholly owned subsidiary of Epitope. Agritope's results of operations and net assets are presented as discontinued operations in the accompanying consolidated financial statements for the periods ended September 30, 1997 and 1996. 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 APB 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 producer and wholesale distributor of fresh and frozen fruits and vegetables based in San Diego, California. Under the terms of the merger, the Company issued 520,000 shares of its common stock in exchange for all of the outstanding common stock of A&W.

On May 27, 1997, in accordance with the terms of a rescission agreement, the former shareholders of A&W returned the 520,000 shares of Epitope common stock they received, and Epitope returned all of the outstanding shares of A&W common stock. Epitope also received A&W preferred stock in satisfaction of intercompany loans made to A&W between December 12, 1996 and March 19, 1997. This A&W preferred stock carries a $5.7 million liquidation preference, dividend preferences, and various redemption features. The A&W preferred stock 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 components of Agritope's net assets are summarized as follows:

September 30	**1997**
Cash	$ 4,384
Trade accounts receivable, net	617,359
Inventories	2,081,295
Other current assets	281,778
Total current assets	2,984,816
Property and equipment, net	2,749,788
Patents and proprietary technology, net	1,276,692
Investment in affiliates	246,962
Other assets	26,797
	7,285,055
Other current liabilities	1,326,008
Long-term liabilities	1,196,321
Accrued losses	1,200,000
Net assets of discontinued operations	$ 3,562,726

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

September 30	**1997**	**1996**
Revenue	$ 1,551,190	$ 585,485
Operating costs and expenses	6,088,883(1)	2,821,397
Other income (expense), net	(4,427,275)	(265,356)
Minority interest in subsidiary net loss	274,369	-
Net loss from operations	$(8,690,599)	$(2,501,268)

(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	**1998**	**1997**
Research and development laboratory equipment	$ 1,014,015	$ 1,096,425
Manufacturing equipment.	1,423,580	1,389,304
Office furniture and equipment	1,753,455	1,772,698
Leasehold improvements	1,102,895	1,102,895
Construction in progress	63,503	109,380
	5,357,448	5,470,702
Less accumulated depreciation and amortization.	(4,538,353)	(4,269,714)
	$ 819,095	$ 1,200,988

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 exerciseable 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% or more of the outstanding shares of common stock. With certain exceptions, if any person becomes the beneficial owner of 15% 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, 1998, the following shares of the Company's common stock were reserved for future issuance, as more fully described below:

Purpose	**Shares**
Outstanding warrants	2,537,307
Outstanding stock options	3,630,727
Employee Stock Purchase Plan subscriptions	38,245
	6,206,279

Common Stock Warrants. As of September 30, 1998, 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		

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 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% 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% 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:

	1998		1997		1996	
	Shares	**Price**	**Shares**	**Price**	**Shares**	**Price**
Outstanding at beginning of period	3,499,865	$3.50 – 20.38	3,365,726	$3.50 – 24.00	3,636,103	$1.09 – 24.00
Granted	4,237,156	1.29 – 18.17	2,801,403	3.50 – 14.81	901,379	9.81 – 18.13
Exercised	(91,278)	2.79 – 5.04	(16,124)	7.25 – 14.81	(386,550)	1.09 – 17.13
Canceled	(4,015,016)	3.50 – 20.38	(2,651,140)	3.50 – 24.00	(785,206)	14.38 – 24.00
Outstanding at end of period	3,630,727	1.29 – 18.17	3,499,865	$3.50 – 20.38	3,365,726	$3.50 – 24.00
Exercisable	2,621,613	1.29 – 18.17	2,474,623	$3.50 – 20.38	2,302,212	$3.50 – 24.00

Exercise Price Range			Number of Shares	Weighted Average Price	Average Remaining Contractual Life
$1.29	-	$4.04	461,950	3.25	8.98
$4.17	-	$4.17	825,000	4.17	7.27
$4.22	-	$4.97	201,150	4.48	23.37
$5.04	-	$5.04	1,876,877	5.04	9.26
$5.75	-	$18.17	265,750	7.84	8.71

Option Repricing. On July 26, 1997, a repricing was approved for all outstanding options held by directors or employees, including executive officers, for which the exercise price was greater than the market value of the underlying stock on that date. The Executive Compensation Committee of the Board of Directors believed that, as a result of a decline in the price of the Common Stock, outstanding options were ineffective to serve the purposes for which they were granted under the 1991 Plan, namely to align the interests of option holders with the long-term interests of the Company's shareholders. The options were repriced using a price equal to fair market value, in order to restore the utility of the options as effective incentives. In addition, the spin-off of Agritope resulted in a price reduction of $2.21 for outstanding options and warrants.

Options exercisable at September 30, 1998 totaled 2,621,613 shares at a weighted average exercise price of $4.88. Options available for grant at September 30, 1998 totaled 892,304.

Pursuant to the 1991 Plan, 2478, 0, and 973 shares of common stock were also awarded to consultants and members of the Company's scientific advisory committees during 1998, 1997 and 1996, respectively.

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 Company's Board of Directors was granted authority to determine 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% 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%.

As of September 30, 1998, 38,245 shares of common stock were subscribed for during 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 $6.00 per share. The subscription prices were adjusted in 1998 as a result of the spin-off of Agritope to $4.78 and $3.79. During the year ended September 30, 1998, 14,451 shares were issued at prices ranging from $4.78 to $3.79 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% 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 1998, 1997 or 1996.

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 1998 and 1997 using the Black-Scholes option pricing model. The weighted average assumptions used for stock option grants for 1998 and 1997 were a risk-free interest rate of 5.7% and 5.9%, respectively, no expected dividend yield, an expected life of 3.9 and 4.3 years, respectively, and an expected volatility of 60% and 53%, respectively. The weighted average assumptions used for 1993 ESPP rights for 1998 and 1997 were a risk-free interest rate of 5.6% and 6.1%, respectively, no expected dividend yield, an expected life of 2 years and 2 years, respectively, and an expected volatility of 69% and 63%, respectively. The weighted-average fair value of ESPP rights granted in 1998 was $55,066 and $248,700 for ESPP rights granted in 1997.

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, 1998 and 1997, the total value of the options granted was computed to be $6,861,799 and $9,096,600, respectively, which would be amortized on the straight-line basis over the vesting period of the options.

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	**1998**		**1997**	
	Net Loss	**Basic and Diluted Net loss per share**	**Net Loss**	**Basic and Diluted Net loss per share**
As reported	$ (1,928,008)	$ (0.14)	$ (22,440,271)	$ (1.67)
Pro forma	$ (4,957,178)	$ (0.37)	(26,958,371)	(2.01)

The effects of applying SFAS 123 in providing pro forma disclosure for 1998 and 1997 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 Income Taxes

As of September 30, 1998, the Company had net operating loss carryforwards to offset federal and state taxable income of approximately $48.6 million and $45.5 million, respectively. Approximately $7.0 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	**1998**	**1997**
Net operating loss carryforwards	$18,532,000	$17,030,000
Deferred compensation	1,829,000	1,707,000
Research and experimentation credit carryforwards	1,026,000	888,000
Accrued expenses	269,000	868,000
Other	779,000	850,000
Gross deferred tax assets	22,435,000	21,343,000
Valuation allowance	(22,435,000)	(21,343,000)
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 $22.4 million, representing a $1.1 million increase since the prior fiscal year end, has been recorded.

The tax benefit of approximately $0.6 million for the year ended September 30, 1998, calculated using the statutory tax rate, has been increased by approximately $0.8 million for the effect of state and local taxes (net of federal impact) and is reduced by approximately $1.1 million for the effect of the increase in valuation allowance and $0.3 million for other permanent differences.

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 EPIblot HIV confirmatory tests (EPIblot) on a worldwide basis. The agreements have been extended to March 31, 2000 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, 1998, 1997 and 1996, respectively, revenues generated from sales of EPIblot to Organon Teknika were $2,371,135, $1,791,290 and $1,539,164, including export sales of $1,250, $15,750 and $62,539.

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 31, 2000, 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, 1998, 1997 and 1996, respectively, revenues generated from product sales to Lab*One* were $2,773,351, $3,194,698, and $1,327,544 including export sales of $402,150, $597,000 and $394,747.

In 1995, SmithKline Beecham plc (SB) and the Company entered an agreement giving SB exclusive rights to market the Company's oral specimen collection device worldwide, except in several foreign countries and to the insurance industry in the U.S., Canada and Japan. In July 1997, SB and the Company terminated the agreement. As a result, the Company acquired marketing rights for OraSure from SB. In 1995, SB made an initial license fee payment of $1 million to the Company and committed an additional license fee of $4 million to be paid upon FDA approval of a pending request to amend the labeling of the Company's oral specimen collection device to indicate a two-year shelf life. In April 1996, the FDA granted the Company's request for extended dating and SB disbursed $4 million plus interest from escrow. Accordingly, the Company recognized income of $5 million in 1996 operating results.

Note 8 Commitments

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

Year Ending September 30	
1999	$ 346,356
2000	109,992
	$ 456,348

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 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 $433,002, $409,970 and $538,665 for the years ended September 30, 1998, 1997 and 1996, respectively.

Note 9 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% of an employee's basic contribution, not to exceed 2.5% of an employee's compensation. The Board of Directors has the authority to increase or decrease the 50% match at any time. During 1998, 1997 and 1996, respectively, the Company contributed $80,741 (17,260 shares), $101,737 (11,459 shares, totaling $101,721 and the remainder in cash) and $73,315 (4,653 shares totaling $73,279 and the remainder in cash). As of September 30, 1998, 33,554 shares of Epitope common stock are held by the plan.

Note 10 Geographic Area Information

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. In 1997 and 1996 product sales to Asia were included in Other. 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.

In thousands

Geographic	**Revenues**			**Operating Loss**			**Identifiable Assets**		
Areas	**1998**	**1997**	**1996**	**1998**	**1997**	**1996**	**1998**	**1997**	**1996**
United States	$8,774	$8,569	$4,903	$(2,264)	$(4,935)	$(5,244)	$10,357	$17,012	$29,784
Canada	415	608	404	-	-	-	-	-	-
Asia	341	130	122	13	(29)	(43)	-	-	-
Latin America	202	4	100	-	-	-	-	-	-
Europe	59	49	65	-	-	-	-	-	-
Other	1	-	-	-	-	-	-	-	-
	$9,792	$9,360	$5,594	$(2,251)	$(4,964)	$(5,287)	$10,357	$17,012	$29,784

Note 11 Contingencies

On April 7, 1998, the Company's former subsidiary A&W instituted a lawsuit against two former officers of the Company and an officer of Agritope in connection with events surrounding the recission of the A&W acquisition (U.S. District Court for the Southern District of California, Case No. 98 CV 0666 TW (CGA)). The defendants were not served with notice of the lawsuit until October 1, 1998. A&W alleges improper acts by the officers, and

seeks damages claimed to be in excess of $5.7 million, an amount that corresponds to the liquidation value of the preferred stock issued by A&W to the Company at the time the acquisition was rescinded. The Company is defending the officers and believes the lawsuit to be frivolous, without merit, and counter to a settlement agreement signed by A&W at the time of the recission. The defendants have moved for dismissal and will pursue the matter vigorously. The Company has filed an action in Oregon state court (Multnomah County Circuit Court Civ. No. 9810-07537) against A&W for breaching the settlement agreement and is seeking as damages the Company's costs of defending the California action.