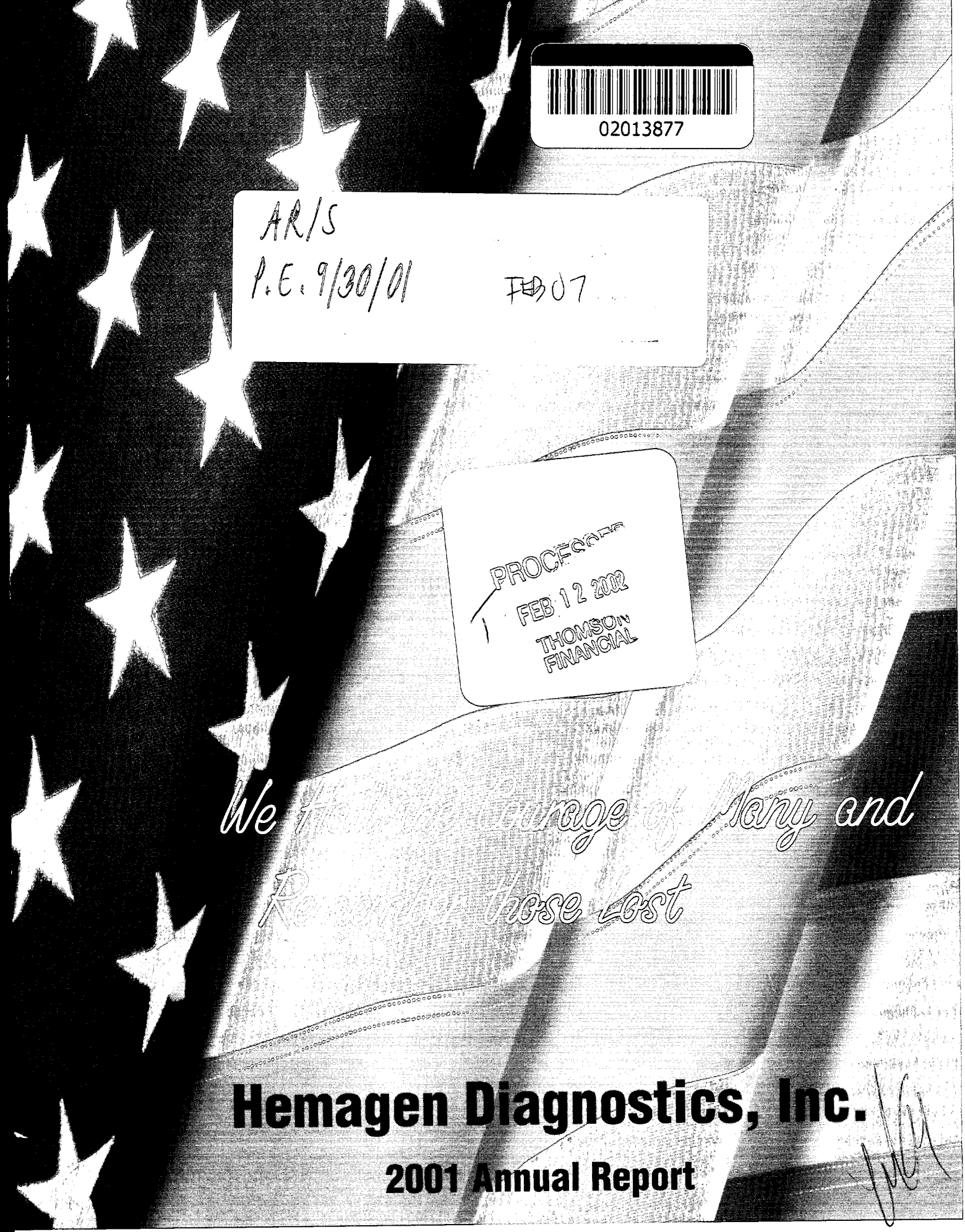


Hemagen Diagnostics, Inc.

2001 Annual Report

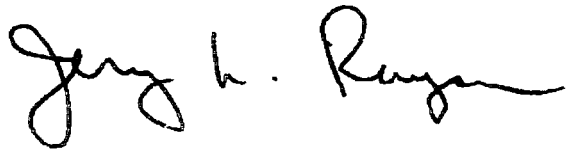
Company for sustained profitability. We remain confident and committed to becoming a major force in our field. Hemagen's products are proven, reliable and used in many of the largest and most reputable laboratories, hospitals and blood banks around the world. Our goals for the upcoming year include:

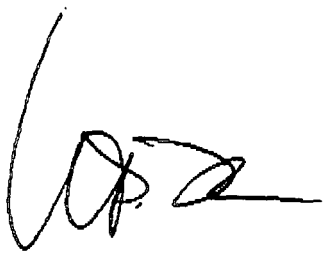
- Increasing sales volumes through our current distribution and expanding our distribution channels. To those ends, we are currently pursuing several significant opportunities and are confident in the Company's ability to succeed in realizing these and other opportunities.
- Expanding our product offering, and
- Evaluating and making strategic acquisitions that improve our product offering, our profitability, and our facilities utilization. Thereby, further increasing our manufacturing efficiencies by driving more business through our current operations.

The achievements of 2001 were the result of a tremendous effort on the part of the entire Hemagen organization. We applaud the efforts and dedication of our employees. We will continue to set goals for the company and will work diligently to achieve them. We look forward with excitement and enthusiasm at the Company's prospects. Most importantly, we appreciate the continued support of our loyal customers and shareholders.

We pray for peace and God's Blessing on America and the world.

Sincerely,





Jerry L. Ruyan
Chairman & CEO

William P. Hales
President & COO

owed to Dade for the purchase of the Analyst® over a two year period with a balloon payment of approximately $134,000 being due on November 15, 2002.

- We focused on improving working capital management by reducing inventories, better managing cash, and exercising tight control over all general expenditures. At September 30, 2001, Hemagen had $672,000 of cash on hand, working capital of $3,937,000 and a current ratio of 3.0 to 1.0. At the prior fiscal year end, the Company had working capital of $3,451,000 and a current ratio of 1.8 to 1.
- We eliminated a significant financial hurdle when we received an unqualified auditor's opinion for the fiscal year ended September 30, 2000. As you may recall, the original independent auditors' report on the September 30, 2000 financial statements contained a "going-concern" opinion. We initiated a re-audit of the September 30, 2000 financial statements that resulted in an "unqualified" opinion in the revised independent auditors' report for the year ended September 30, 2000. The importance of the re-audit was to remove any doubt as to the Company's going concern status and our ability to fund operations internally.

Second, we said we would focus on Sales and Marketing by increasing our core sales, increasing sales to blood banks, exploring the distribution of complementary products through our established distribution channels, and launching our Panels Plus® rotor for use on the Analyst® in the human clinical market. In examining our top line revenues, you will see that we have replaced sales of discontinued low margin products with increased sales of core products. For example, sales to Roche Diagnostics, Inc., pursuant to the December 1999 supply agreement, increased by approximately $800,000 over the previous year. We expect to continue to expand the current product offering under that supply agreement by introducing new products in the upcoming year. As part of our research and development initiatives, we are expanding our product offering to the blood banks. In July 2001, we announced the completion and clearance of our Panels Plus® rotor by the FDA.

Third, we said we would complete a significant product development project by finalizing the development of a diagnostic test kit that identifies an AIDS marker that was identified by one of the co-discoverers of the HIV virus. In addition we set goals to complete clinical trials of new blood bank products, launch our Beta-2 Glycoprotein I test kit, and develop other proprietary tests for use on the Analyst®.

- Hemagen's ability to develop new and innovative products that will significantly impact the health and well being of the general population has brought it together with world-renowned scientists. In May 2001, we completed the development of a diagnostic test kit that identifies an AIDS marker that is believed to identify progressors vs. non-progressors in HIV patients, with one of the co-discoverers of the HIV virus.
- We expect to begin clinical trials on one of our new blood bank products in fiscal 2002, and are in discussions with other organizations for collaborations.
- We expect to launch our Beta–2 Glycoprotein I test shortly, and continue to research other proprietary tests for use on the Analyst®.

Most of the activities of fiscal 2001 were based on improving the profitability of our current sales base, completing the consolidation of operations commenced in fiscal 2000, and focusing on the three initiatives outlined above.

Looking ahead:

Fiscal year 2001 has been a very busy year and one of significant accomplishment for Hemagen. We remain dedicated to our long-term goals of building shareholder value and positioning the

Dear Fellow Shareholders:

We hope this letter finds you well. Fiscal 2001 was certainly a year we will never forget. At 9am on September 11, 2001, the Directors of Hemagen had assembled in a conference room at the Corporate Headquarters in Columbia, Maryland for what we thought would be a normal board meeting. We could never have imagined that by the time that meeting ended, the world, as we knew it had changed forever.

On behalf of all of us at Hemagen, we wish to express our deepest sympathy to those affected by the tragic attacks that took place against our great nation that day. Our heartfelt thoughts and prayers go out to all who have suffered the loss of loved ones and friends. Our genuine thanks and appreciation goes out to the men and women who responded and continue to help in the relief efforts.

On a brighter note, over the past year we have made substantial strides in improving the performance of the Company and in positioning the Company to achieve the goals we have set for it. We are beginning to see the benefits of initiatives commenced and/or completed in our first two years at Hemagen.

Originally, when we launched the consent solicitation in July 1999, it was because we believed that Hemagen's products were superior in both quality and value, and that Hemagen's ability to develop and manufacture new and innovative products gave it a competitive advantage. We also felt that Hemagen was undervalued due to its inability to market its products properly. Our two years at Hemagen have confirmed those beliefs more so than ever. As we begin to develop new market awareness for our products, we will continue to explore the appropriate channels to expose our products more efficiently to create better market awareness.

Since assuming management control of Hemagen on October 1, 1999, we have repeatedly stated our long-term goals of building shareholder value and positioning the company for sustained profitability. These goals continue to guide our every decision and remain our sole focus.

Last Year's Letter to Shareholders:

In last year's letter to shareholders, we stated that Fiscal 2000 was a year of consolidation and expense reduction. It was a year of setting the foundation for the future and executing the completion of several initiatives begun in fiscal 2000. We believe that the fiscal 2001 financial results demonstrate that the foundation is in place for future growth. Last year we identified three critical areas of focus and are pleased to report on them.

First, we said we would improve the financial aspects of the business in order to generate positive cash flow, and continue to reduce costs. We are pleased to report the company's progress in this regard:

- The company's gross margins improved in fiscal 2001 to 31% compared to 13% in fiscal 2000. Much of the improvement in gross margins resulted from the consolidation of operations, and better utilization of inventory.
- In April 2001, the Company completed the closure of its Waltham, Massachusetts's facility and the relocation of its Waltham-based product lines to the Company's Columbia, Maryland headquarters. The savings we experienced during the partial year were offset by the expenses associated with the closure. Going forward, this consolidation is expected to result in significant reductions in rent, warehouse utility and personnel expenses.
- The leverage of the Company improved in fiscal 2001. For example, in November 2000, we renegotiated a note owed to Dade Behring, Inc., that allowed us to pay $397,000 that was

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-KSB
Annual Report Pursuant to Section 13 or 15(d) of

the Securities Exchange Act of 1934

For the fiscal year ended September 30, 2001
Commission file number 1-11700

HEMAGEN DIAGNOSTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	04-2869857
(State or other jurisdiction of incorporation or organization)	(I.R.S. employer identification No.)

9033 Red Branch Rd., Columbia, MD	21045
(Address of principal executive offices)	(Zip Code)

(443) 367-5500
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class on which registered	Name of each exchange on which registered
None	

Securities registered pursuant to Section 12(g) of the Act: Common Stock and Common Stock Warrants expiring April 30, 2002.

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 60 days. Yes X No__.

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-B 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-KSB or any amendment to this Form 10-KSB.

The registrant had revenues of $10,970,558 in its most recent fiscal year. The aggregate market value of the voting stock held by non-affiliates of the registrant on December 20, 2001, was $8,302,542. As of December 20, 2001, 9,883,979 shares Common Stock and 5,197,555 Common Stock Warrants expiring April 30, 2002 were outstanding.

Documents Incorporated by Reference

Portions of the Registrant's Proxy Statement filed with the Commission for its 2002 Annual Meeting as specified are incorporated by reference in Part III as specified.

HEMAGEN DIAGNOSTICS, INC.
INDEX TO ANNUAL REPORT ON FORM 10-KSB

Certain statements contained in this report that are not historical facts constitute forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, and are intended to be covered by the safe harbors created by that Act. Reliance should not be placed on forward-looking statements because they involve known and unknown risks, uncertainties and other factors which may cause actual results, performance or achievements to differ materially from those expressed or implied. Any forward-looking statement speaks only as of the date made. Hemagen undertakes no obligation to update any forward-looking statements to reflect events or circumstances after the date on which they are made.

Statements concerning the establishments of reserves and adjustments for dated and obsolete products, write-offs of goodwill, relocation expenses, expected financial performance, on-going business strategies and possible future action which Hemagen intends to pursue to achieve strategic objectives constitute forward-looking information. The sufficiency of such charges, implementation of strategies and the achievement of financial performance are each subject to numerous conditions, uncertainties and risk factors. Factors which could cause actual performance to differ materially from these forward-looking statements, include, without limitation, management's analysis of Hemagen's assets, liabilities and operations, the failure to sell date-sensitive inventory prior to its expiration, the inability of particular products to support goodwill allocated to them, competition, new product development by competitors which could render particular products obsolete, the inability to develop or acquire and successfully introduce new products or improvements of existing products and the ability to assimilate successfully product acquisitions.

Item 1. Business

Hemagen Diagnostics, Inc. was originally incorporated in 1985 as a Massachusetts corporation and became a Delaware corporation in 1992. Hemagen develops, manufactures and markets proprietary medical diagnostic test kits, or "assays," used to aid in the diagnosis of autoimmune and infectious diseases in general health assessment, and for research purposes. Hemagen also develops, manufactures and markets materials used in the manufacture of diagnostic test kits. Hemagen offers approximately 150 test kits that have been cleared by the United States Food and Drug Administration (FDA) for sale in the United States. Hemagen also manufactures and markets a clinical chemistry analyzer used to measure essential constituents in human and animal blood. Hemagen generally focuses on markets which it believes offer significant growth potential. In addition to the internal development of products, Hemagen has sought to enter growth markets via the acquisition of synergistic companies, products and assets.

In September 1998, Hemagen acquired the Analyst® automated clinical chemistry system from Dade Behring, Inc. This acquisition positioned Hemagen for growth in the physician office laboratory and veterinary diagnostic markets. The Analyst® is a patent protected, low cost, bench-top clinical chemistry instrument and reagent system. The Analyst is cleared by the FDA for marketing in the United States.

Hemagen acquired Reagents Applications, Inc. (RAI) from Kone Holdings, Inc. in 1996. RAI manufactures and markets a complete line of clinical chemistry reagents and diagnostic products for *in vitro* diagnostic use in hospitals, clinics and laboratories. These products are sold directly under the RAICHEM® label and through a network of over 30 distributors located in the United States and throughout the world. RAI also produces private label reagents for domestic and international customers. Most RAI reagents can be used in both automated and manual analyzers. Certain of the reagents used for the Analyst are manufactured by RAI. RAI's leading product lines include blood chemistry assays used to aid the monitoring and measurement of health profiles, such as cholesterol, blood urea nitrogen (BUN), triglycerides, glucose and uric acid. RAI has an exclusive agreement with Roche Diagnostics, Inc. to provide reagents for Roche's COBAS MIRA® instrument in the United States. This agreement was signed in December 1999 and expires in December 2002. This agreement resulted in sales of $1,700,000 to Roche Diagnostics, Inc. in the year ended September 30, 2001.

In July 1995, Hemagen completed the acquisition of a line of diagnostic test kits using immunofluorescence from Schiapparelli Biosystems, Inc. These acquired assays are sold under the registered trademark VIRGO®. Hemagen's VIRGO kits are often used to confirm a diagnosis achieved by other methods of diagnostic testing. In addition to the immunoflurescence based diagnostic test kits, Hemagen manufactures test kits based on two other diagnostic technologies, hemagglutination and enzyme-linked immunosorbence called ELISA or EIA. Hemagen owns a proprietary technique for preserving red blood cells, a key component of Hemagen's hemagglutination assays. This technology enables Hemagen to manufacture products which have a shelf life of up to 24 months (compared to a typical shelf life of 30 to 60 days for traditional hemagglutination processes), provides quick and accurate results, requires no special laboratory equipment to perform the tests and is more reliable than the hemagglutination assays that have traditionally been available. The extended shelf life and improvements in the consistency of these assays substantially eliminates limitations previously encountered in the use of hemagglutination assays.

In February 2001, Hemagen terminated a contract manufacturing agreement with Carter-Wallace, Inc. (C-W) to manufacture approximately 14 diagnostic test kits for the Wampole division of C-W. The test kits were used to aid in the diagnosis of diseases such as rheumatoid arthritis, mononucleosis, strep throat and rubella, as well as to detect pregnancy. Hemagen had begun manufacturing this product for C-W in 1994 and had terminated the agreement in 2001 in conjunction with the closure of Hemagen's Waltham, Massachusetts facility. Sales from the agreement were $435,000 and $932,000 in the years ended September 30, 2001, and 2000, respectively.

Hemagen markets and sells its brand name products worldwide, directly through Hemagen's sales force and through national and international distributors. Hemagen markets its products in South America through its majority owned subsidiary, Hemagen Diagnosticos Comercio, Importacao e Exportacao, Ltd. (HDC), a Brazilian limited liability company. HDC distributes several of Hemagen's products throughout South America. HDC also completes light assembly of certain products.

Recent Developments

New management assumed control of Hemagen following its successful conclusion of the solicitation of shareholder votes to gain control of the Board of Directors on September 30, 1999. New management has taken the following actions in its first two fiscal years:

- Consolidated operations and closed the facility located in Waltham, Massachusetts. Hemagen's administrative operations and certain production were moved to Hemagen's Columbia, Maryland facility during the course of fiscal 2001. Certain unprofitable product lines were discontinued. This consolidation was completed in April 2001 and management believes could result in annual savings in the range of $400,000 to $500,000. It is estimated that approximately $275,000 of potential savings would result from reduced facility costs, rent and utilities, with the remainder of the savings resulting from headcount eliminations.

- Established an in-house marketing and sales force to manage Hemagen, Virgo and Analyst sales. Developed new marketing programs for the Analyst in the veterinary market.

- On November 8, 2000, Hemagen signed an agreement with Dade Behring, Inc., that allowed Hemagen to finance the remainder of the Analyst purchase price over two years and continue to purchase the Analyst tablets from Dade Behring for the next twelve to eighteen months.

- In May 2000, Hemagen raised $6,315,000 in an offering of units consisting of 8% Senior Subordinated Secured Convertible Notes, Common Stock and Warrants. Proceeds of this offering were used to pay off a revolving line of credit and to provide working capital to Hemagen.

- Over the past two fiscal years Hemagen reduced headcount by approximately 34%, from 98 employees as of September 30, 1999, to 68 as of September 30, 2001. Management believes that the reduction in the number of employees has had no impact on our operations.

Technology

The presence and concentration of certain antibodies in human blood can assist physicians in the diagnosis of certain diseases. Hemagen's assays are *in vitro* (outside of a patient's body) diagnostic tests that are used to measure specific substances, either antigens or antibodies, in blood or other body fluids. An antigen is a substance that reacts with a particular antibody in a manner, which, in the proper environment, is detectable either by the naked eye, or with the aid of a laboratory technique, which amplifies the reaction so that it is rendered visible. Hemagen's hemagglutination, ELISA and immunofluorescence assays are three examples of such an amplification. Hemagen's blood chemistry and Analyst system assays are used to aid the monitoring and measurement of health profiles, such as cholesterol, blood urea nitrogen, triglycerides, glucose and uric acid.

Hemagen relies upon proprietary technologies in the manufacture of its kits. These technologies include a lyophilization (freeze drying) technique which substantially extends the shelf life of Hemagen's hemagglutination assays, and proprietary methods to prepare antigens for its ELISA assays. Hemagen acquired a patent protected rotor based technology for use in the Analyst in 1998.

ELISA

ELISA or EIA tests employ small plastic vessels coated with particular antigens. The test process involves introducing the patient's serum into the vessel to allow a reaction to occur. If the antibody being tested for is present, it will bind to the antigens on the inner surface of the vessel. After the vessel is rinsed, the specifically bound antibody will remain while any non-specific antibodies will be washed away. To detect the quantity of the specific antibody, other compounds are added which will cause a color change in the vessel, the intensity of which is proportionate to the quantity of the specific antibody bound. If no color is noted, this indicates that the patient's serum did not contain detectable quantities of the specific antibody.

Immunofluorescence

Hemagen's immunofluorescence tests utilize a fluorescent microscope. Mammalian cells grown on microscope slides are treated with disease-producing organisms (viral or bacterial). Serum from a patient is placed in contact with the infected cells. If a patient has antibodies to the organism causing the disease, the antibodies will bind to the organism. A chemical is added to the slide which binds to the organism and the antibody, if present. When the slide is illuminated with light at a specific wavelength in the microscope, the chemically-treated cells will appear fluorescent, indicating a positive test result. If the patient did not have the appropriate antibody, no fluorescence will appear producing a negative test result.

Clinical Chemistries

Hemagen produces a line of general clinical chemistry reagents utilizing colorimetric, turbidometric and enzymatic procedures. These chemistry reagents are those most commonly performed in clinical laboratories as general health screening tests and in the identifications of diseases. These tests can be performed using a broad range of automated and semi-automated instruments typically used by clinical laboratories.

Hemagglutination

Hemagglutination is the agglutination or "clumping" of red blood cells (RBCs). Many substances, including certain antibodies, when placed in contact with RBCs, will cause agglutination.

Under the appropriate conditions, human RBCs may be modified or sensitized by binding specific foreign antigens to their surface. These sensitized RBCs will agglutinate to the foreign antigen when placed in contact with a specific antibody. The presence of certain antibodies in an individual's serum (blood from which clotted RBCs have been removed) can indicate certain diseases. By sensitizing RBCs with an antigen that specifically reacts with a particular antibody, the simple visible observation of the agglutination reaction will indicate the presence of the disease-produced antibody. The use of RBCs instead of other particles can allow for simple visual observation of the agglutination reaction in the proper environment, and reduces the non-specific reactions seen in artificial systems such as those that utilize latex particles.

To perform Hemagen's hemagglutination test, a technician combines Hemagen's sensitized RBCs with a patient's serum in a small well with a V-shaped bottom according to directions included with Hemagen's test kits. If no agglutination takes place, the RBCs will settle to the bottom of the well, resulting in a clearly visible red dot which indicates that the test is negative.

In contrast, if the particular antibody is present in the patient's blood, the RBCs will agglutinate, which prevents the RBCs from settling to the bottom of the well. Instead of the small red dot, the substance will appear a diffuse red, which indicates a positive reaction.

Analyst Instrument System

The Analyst is a bench-top centrifugal clinical chemistry analyzer. The Analyst uses as a consumable a small rotor that contains dry prepackaged reagents. The Analyst spins the rotor, mixing the patient sample with the dry reagents, producing a result in approximately ten minutes. Five types of rotors providing a variety of clinical chemistry tests, all cleared for marketing by the FDA, are currently on the market. The Analyst instrument has been designated by the FDA as a moderately complex system, and is therefore suitable for the physician and veterinary office laboratories.

Acute Phase Reactants and Apolipoproteins

Hemagen has developed an application for its ELISA technology to detect cardiovascular risk factors (apolipoproteins) and inflammatory signals (acute phase reactants), the latter of which are present in a patient's blood prior to the clinical manifestation of infection or inflammation. If successful, these technologies could lead to earlier detection and prevention of cardiovascular disease, the imminent rejection of transplanted organs or the onset of infections, than is possible with techniques now commercially available. Such earlier detection could enable physicians to better plan appropriate treatment of patients with these conditions. Hemagen currently markets two test kits to detect inflammatory signals.

Current Products

ELISA Assays

Hemagen develops and markets ELISA tests for the detection of disease markers. As with corresponding hemagglutination tests produced by Hemagen, most of Hemagen's ELISA assays test for elevated levels of antibodies, which are useful indicators of certain diseases. ELISA tests are widely used by large laboratories because these tests adapt easily to automated diagnostic testing equipment. Hemagen's FDA cleared ELISA test kits aid in the diagnosis of the following diseases:

SLE (lupus)
mixed connective tissue disease
Sjögren's syndrome
scleroderma (systemic sclerosis)
cytomegalovirus infections
rheumatoid arthritis
polymyositis
dermatomyositis
connective tissue diseases
primary biliary Cirrhosis
Chagas' disease
Wegener's disease

Certain of Hemagen's ELISA tests are also used to monitor the acute phase response to infection and inflammation in diseases such as lupus and rheumatoid arthritis. Several of Hemagen's ELISA tests are now available in both lyophilized and all liquid formats.

Hemagen's ELISA and hemagglutination kits (see below) include screening tests in which up to six different diagnostic indices are monitored at the same time, which is useful in the rapid initial screening of patients. If the screen test is positive, individual kits are available to identify which of these six indices is present.

Immunofluorescence or "IFA" Products

Hemagen's immunofluorescence products consist primarily of diagnostic assays for infectious diseases. Immunofluorescence kits are used as primary or confirmatory tests in many large clinical laboratories in the United States. There are currently 15 kits sold in the immunofluorescence format.

Hemagen's immunofluorescence products are used to aid in the diagnosis of the following:

cytomegalovirus infections
SLE (lupus)
connective tissue diseases
primary bilary Cirrhosis
toxoplasmosis
syphilis
primary RSV infections
Herpes simplex
german measles
chicken pox
infections with Epstein-Barr virus
chlamydial infections
measles
mumps infections
autoimmune diseases

Hemagglutination Assays

Hemagen believes that it manufactures and markets the only commercially available hemagglutination kits which test for antibodies to antigens present in the nucleus of a cell referred to as extractable nuclear antigens, or ENAs, which are markers of certain autoimmune diseases. Each of Hemagen's hemagglutination assays is based on Hemagen's proprietary technique to lyophilize, or "freeze dry," the RBCs which form the central component of a hemagglutination assay. Hemagen's proprietary lyophilization technique for the preservation of RBCs permits the production of standardized, easy-to-use and accurate hemagglutination tests with an extended shelf-life, most of which are attributes previously unavailable using hemagglutination assays. The shelf-life of the lyophilized RBCs before reconstitution may be up to 24 months. A technician reconstitutes the powdered cells in a water-based solution prior to introducing the patient's serum.

Each hemagglutination test also requires a specific formula to sensitize the RBCs prior to lyophilization such that they will react to a specific antibody. For each of its tests, Hemagen uses a proprietary formula to combine antigens and other reagents with RBCs in a manner that allows for standard, sensitive and specific agglutination reactions. Results from Hemagen's test kits are generally available within two hours. Hemagen's hemagglutination test kits aid in the diagnosis of the following diseases:

SLE (lupus)	dermatomyositis
mixed connective tissue disease	polymyositis
Sjögren's syndrome	rheumatoid arthritis
scleroderma (systemic sclerosis)	Chagas' disease
	cytomegalovirus infections

RAI Products

Hemagen's general chemistry products, sold under the trade name RAICHEM® consist of a broad range of assays used on automated and semi-automated clinical chemistry analysis systems. Many of the RAICHEM assays are used in profiling general health conditions and as specific indications of possible disease states. The most widely recognized general chemistry tests made by Hemagen include those for blood levels of glucose, cholesterol, triglycerides, uric acid, urea nitrogen and total protein. In all, more than 70 of Hemagen's clinical chemistry products have been cleared by the FDA for sale in the United States.

Analyst® System Products

Hemagen currently markets four FDA approved rotor types for use on the Analyst clinical chemistry analyzer, two general chemistry rotors, a glucose test and a lipid screen test. In addition, Hemagen sells a general chemistry rotor specifically designed for the veterinary marketplace called the VET-16.

South American Activities

In 1991, Hemagen began to market its product line in South America through HDC. In 1994, HDC began light manufacturing of test kits in South America.

Today, Hemagen markets its full product line to the South American market, including three proprietary assays for Chagas' disease. Chagas' disease (American Trypanosomiasis) is an insect and blood transfusion transmitted parasitic infection which eventually attacks the victim's cardiovascular system. Due to poor sanitation and other factors, insects have transmitted Chagas' disease widely throughout Central and South America, with substantial encroachment into Mexico. In response to the need for efficient and accurate testing for Chagas' disease, Hemagen has developed three diagnostic tests: an instrument-free hemagglutination assay, an ELISA assay and a hemagglutination assay prepared specifically for use with certain automated blood-typing instruments. The ELISA assay has received FDA clearance for sale in the United States.

Our office in Sao Paulo is staffed by five full-time salespeople administrators who receive and process orders, and four employees who handle production, shipping and technical support. In addition, Dr. de Oliveira,

Hemagen's Director and Vice President of Research and Development, spends time in Brazil attending to the business of HDC. In fiscal 2001 and 2000, Hemagen derived product sales through HDC of $855,000 and $1,043,000, respectively. See "Item 2 - Description of Property."

Distribution and Marketing

General

In the United States, Hemagen sells its products directly to clinical laboratories and blood banks and on a private-label basis through multinational distributors of medical diagnostics. Internationally, Hemagen sells its products primarily through distributors. Hemagen grants non-exclusive distributorships, which generally cover limited geographic areas and specific test kits. Hemagen has relationships with approximately 35 distributors and its products have been sold in over 20 countries.

In December 1999, Hemagen's RAI division signed a supply agreement with Roche Diagnostics, Inc. to supply reagents to be used with Roche's COBAS MIRA® instrument. The initial term of this agreement is three years, expiring in December 2002. The agreement provides that RAI will be the exclusive supplier of reagents for the COBAS MIRA in the United States. In fiscal 2001 and 2000, sales to Roche were approximately $1,700,000 and $838,000, respectively.

In fiscal 2001 and 2000, Hemagen manufactured products on a private-label basis for Carter-Wallace pursuant to a supply agreement and Carter-Wallace distributed the Analyst product line for physician office laboratories in the United States. Carter-Wallace accounted for approximately 14% of Hemagen's revenue for the fiscal years ended September 30, 2001 and 2000. In February 2001, Hemagen and Carter-Wallace agreed to terminate the private-label supply agreement. This supply agreement accounted for sales of $435,000 and $932,000 for the fiscal years 2001 and 2000, respectively. Hemagen terminated the private-label supply agreement because of the high production costs incurred by Hemagen in producing this product. At this time, management believes the distribution agreement for the Analyst, which is currently a non-exclusive agreement, will continue.

From 1989 to January 1999, Hemagen had an agreement to provide test kits to detect CMV antibodies for use with the Olympus' PK Series Pre-Transfusion instruments, the world's most widely used automated blood-typing instruments in blood banks and large commercial laboratories. Today, Hemagen offers the same product under the Hemagen brand name. In fiscal 2001 and 2000, these sales amounted to approximately $264,000 and $297,000, respectively.

Hemagen's South American Distribution and Marketing activities are described in the section entitled "Business: South American Activities."

Products Under Development

Hemagen is presently developing new products in the areas described below. Hemagen spent approximately $387,000 and $526,000 on research and development for the fiscal years ended September 30, 2001, and 2000, respectively.

Elisa Kits

Hemagen completed the development of an Elisa diagnostic test kit to identify individuals that have an antibody that appears to neutralize the HIV virus and prevents the virus from progressing into AIDS. The test is based on a discovery by Professor Jean-Claude Chermann, Chief Scientific Officer of URRMA Biopharma, Inc.

Analyst

In July 2001, Hemagen received FDA clearance to market the Panels+ rotor for the physician office laboratory marketplace. This product is intended to ease reimbursement procedures and provide more complete information for both the doctor and patient.

Clinical Chemistry Reagents

Hemagen continues to develop additional assays and reagents to fill in its clinical chemistry reagent product line sold under the RAICHEM label. Almost all of the powdered clinical chemistry assays are now available in liquid format, making RAICHEM one of the most complete clinical chemistry lines offered worldwide.

New Acquisition

On December 10, 2001, Hemagen acquired substantially all of the assets of Kalisto Biologicals, Inc. from Advanced Magnetics, Inc., in conjunction with a Voluntary Repossession and Collateral Disposition Agreement between Advanced Magnetics, Inc. and Kalisto. Kalisto manufactures and markets a clinical chemistry analyzer, called the Endochek™, that is used to measure essential constituents in animal blood. This instrument, like Hemagen's Analyst, is sold in the veterinary market and will be used to expand Hemagen's product offerings in that distribution channel.

Manufacturing and Sources of Supply

Hemagen manufactures its ELISA test kits, hemagglutination test kits and its immunofluorescence technology products at its facility in Columbia, Maryland. Clinical chemistry products are produced at Hemagen's facility in San Diego, California. Hemagen purchases red blood cells and many of the antigens and other reagents used in the kits from outside vendors. Some reagents used in Hemagen's test kits are manufactured at Hemagen's facilities. Hemagen uses lyophilization equipment to preserve sensitized red blood cells for its hemagglutination test kits.

All components used in Hemagen's products are available from multiple sources, except for an antigen called SSA, which Hemagen uses in two of its ELISA and two of its hemagglutination test kits. Hemagen believes that the supplier of this antigen produces this antigen for many customers. Management believes that if necessary, Hemagen could produce sufficient quantities of this antigen itself. Therefore, if the supply of this antigen were to cease, Hemagen believes it would not have a long-term material adverse impact on Hemagen's business taken as a whole.

Government Regulation

Hemagen's manufacturing, distribution, and marketing of diagnostic test kits are subject to a number of both domestic and international regulatory controls. In the United States, Hemagen's production and marketing activities are subject to regulation by the FDA, under the authority of the Federal Food Drug, and Cosmetic Act, as amended.

These regulations require that Hemagen must formally notify the FDA of its intentions to market *in vitro* diagnostic devices through a regulatory submissions process, either the 510(k) process or the Premarket Approval (PMA) process. When a 510(k) process is used Hemagen is required to demonstrate that the product

equivalency letter. Currently, the majority of products that are reviewed by the 510(k) process are cleared within 90 days. In certain cases, specifically for Class III devices, Hemagen must follow the PMA process which involves a lengthier and more burdensome process.

Hemagen is required to register with the FDA as a device manufacturer and to disclose its devices. Accordingly, Hemagen is subject to inspection on a routine basis for compliance with the FDA's Quality System Regulations. These regulations require that Hemagen manufacture its products and maintain its documents in a prescribed manner with respect to design, manufacturing, testing, process control and distribution activities. In addition, Hemagen is required to comply with various FDA requirements for labeling, pursuant to the applicable regulations. Finally, the FDA prohibits an approved device from being marketed for unapproved applications. Hemagen believes it is in conformity with all such regulations.

The regulatory controls being imposed upon Hemagen with respect to the international distribution and marketing of *in vitro* diagnostic devices are increasing. Specifically, member nations of the European Community are developing a standardized quality system similar to QSR called EN 29000 that is anticipated to be effective throughout the European Community once enacted. Companies will be allowed a grace period to conform to the directive. Hemagen will be required to conform to the EN 29000 regulations for any product sold in the European Community. The European Community has adopted the IVD Directive. All *in vitro* devices must bear the CE Marking of Conformity by 2003. Hemagen received the CE Marking for the Analyst instrument in December 1999.

Competition

The clinical diagnostic industry is highly competitive. There are many companies, both public and private, engaged in diagnostics-related research and development, including a number of well-known pharmaceutical and chemical companies. Competition is based primarily on product reliability, customer service and price. Many of these companies have substantially greater capital resources and have marketing and business organizations of substantially greater size than Hemagen. Many companies have been working on immunodiagnostic reagents and products, including some products believed to be similar to those currently marketed or under development by Hemagen, for a longer period of time than has Hemagen. Hemagen believes that its primary competitors in the diagnostics market include Abbott Laboratories, Sigma Diagnostics, Trace-America, Inc., Meridian Bioscience, Inc., INOVA, Sanofi Diagnostics Pasteur, Inc., Diamedix Corporation, IDEXX and Abaxis, Inc. Hemagen expects competition within this industry to intensify.

Product Liability

The testing, marketing and sale of clinical diagnostic products entail an inherent risk of allegations of product liability, and there can be no assurance that product liability claims will not be asserted against Hemagen. Hemagen may incur product liability due to product failure or improper use of products by the user. Inaccurate detection may result in the failure to administer necessary therapeutic drugs or administration of unnecessary and potentially toxic drugs. Even with proper use of a product, there may be specific instances in which the results obtained from Hemagen's test kits could lead a physician to predict the inappropriate therapy for a particular patient. Hemagen maintains product liability insurance in the amount of up to $5,000,000 per incident and in the aggregate which, based on Hemagen's experience and industry practice, Hemagen believes to be adequate for its present operations. No assurance can be given that Hemagen's insurance coverage is sufficient to fully insure against claims which may be made against Hemagen.

Patents and Proprietary Rights

Hemagen protects its technology primarily as trade secrets rather than relying on patents, either because patent protection is not possible or, in management's opinion, would be less effective than maintaining secrecy. In addition, Hemagen relies upon confidentiality agreements with its employees. To the extent that it relies on confidentiality agreements and trade secret protection, there can be no assurance that Hemagen's efforts to maintain secrecy will be successful or that third parties will not be able to develop the technology independently. Hemagen may in the future apply for patent protection for certain of its technology when management believes such protection would be beneficial to Hemagen. The protection afforded by patents

depends upon a variety of factors which may severely limit the value of the patent protection, particularly in foreign countries, and no assurance can be given that patents, if granted, will provide meaningful protection for Hemagen's technology.

Royalty Obligations

Hemagen is required to pay royalties to third parties on sales of some of its products. Hemagen has a license agreement with Dade Behring, Inc. for the license of technical information relating to the Analyst® product line. The license was signed in conjunction with the Analyst acquisition and terminates on August 2004. Hemagen also has a license agreement with Elf Acquitaine for the use of technology involved in the manufacture and sale of the Analyst product line. This license agreement terminates upon the expiration of the last patent associated with the applicable technology, which is February 2007.

Employees

As of September 30, 2001, Hemagen had 68 full-time employees, of which three are executive officers, 25 are employed in sales, marketing, general and administrative activities and 40 are involved in production and research and development. As of September 30, 2001, Hemagen had two part-time employees.

None of Hemagen's employees are represented by a labor organization and Hemagen is not a party to any collective bargaining agreement. Hemagen has never experienced any strike or work stoppage and considers its relationship with its employees to be excellent.

Item 2. Description of Property.

Hemagen maintains its principal administrative office, laboratory and production operations in a 27,400 square foot leased facility in Columbia, Maryland. Under the Columbia lease, which extends through July 30, 2007, Hemagen pays approximately $144,000 per year in rent. Hemagen also leases 20,100 square feet in San Diego, California, where it manufactures the RAICHEM products. Under the San Diego lease, which extends through September 30, 2002, Hemagen will pay approximately $217,000 in the next year. Hemagen believes that its facilities are adequate for its present and foreseeable needs.

Hemagen's 51%-owned subsidiary, Hemagen Diagnosticos Comercio, Importacao e Exportacao, Ltd, leases approximately 1,800 square feet of flexible office space in Sao Paulo, Brazil pursuant to a lease that expires on June 30, 2006. This subsidiary pays approximately $32,400 per year in rent for this space. Hemagen believes that its facilities in Sao Paulo are adequate for its present and foreseeable needs.

It is management's opinion that all of the properties are adequately insured.

Item 3. Legal Proceedings.

Hemagen is not presently involved in any material pending litigation.

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

None.

Part II

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

Hemagen's Common Stock has been traded on the over-the-counter market through the National Association of Securities Dealers Automated Quotation System ("NASDAQ") since February 4, 1993. On December 20, 2001 the closing bid and ask price for the Common Stock as reported by NASDAQ were $ 0.84 and $0.88 per share, respectively.

For the periods indicated, the following table sets for the range of high and low bid prices for the Common Stock as reported by NASDAQ during Fiscal 2000 and 2001. These prices reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not represent actual transactions.

	High	Low
2000		
First Quarter..... .	$1.437	$0.81
Second Quarter.....	$6.00	$0.81
Third Quarter.....	$3.50	$1.38
Fourth Quarter.....	$1.97	$1.09
2001		
First Quarter.....	$1.53	$0.38
Second Quarter.....	$0.97	$0.44
Third Quarter.....	$1.70	$0.60
Fourth Quarter.....	$1.24	$0.57
2002		
First Quarter (through December)	$0.95	$0.73

As of December 17, 2001, there were 171 holders of record of Hemagen's Common Stock which Hemagen believes represents 3,217 beneficial owners.

For the periods indicated, the following table sets for the range of high and low bid prices for the Common Stock Warrants expiring April 30, 2002, that are traded under the symbol - HMGNW, as reported by NASDAQ during Fiscal 2000 and 2001. These prices reflect inter-dealer prices, without retail mark-up, mark-down or commission, and may not represent actual transactions.

	High	Low
2000		
First Quarter	$0.25	$0.06
Second Quarter	$3.00	$0.13
Third Quarter.....	$1.13	$0.25
Fourth Quarter.....	$0.53	$0.13
2001		
First Quarter.....	$0.22	$0.03
Second Quarter.....	$0.37	$0.02
Third Quarter.....	$0.50	$0.10
Fourth Quarter.....	$0.26	$0.09
2002		
First Quarter (through December)	$0.06	$0.02

As of December 17, 2001, there were 88 holders of record of Hemagen's Common Stock Warrants expiring April 30, 2002.

Dividends

Hemagen has never paid cash dividends. Hemagen currently intends to retain all future earnings, if any, for use in its business and does not anticipate paying any cash dividends in the foreseeable future.

Item 6. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Overview

Historically, Hemagen has concentrated its efforts on developing, manufacturing and marketing medical diagnostic test kits used to aid in the diagnosis of certain diseases and the profiling of general health conditions. Hemagen has concentrated its expansion efforts on synergistic acquisitions of companies, product lines and assets. Hemagen has approximately 150 different test kits available that have received FDA clearance for sale in the United States.

Fiscal year 2001 represents the second year of Hemagen operations under a new management team. On October 1, 1999, a new management team assumed control of Hemagen as a result of a shareholder consent solicitation. While the primary goal of management during fiscal 2000 was to cure the default of the revolving line of credit, management has been working over the past two fiscal years to reorganize the Company to achieve sustained profitability. In order to achieve those goals management sought to:

- Improve the leverage of the Company
- Better manage working capital
- Reduce expenses; and
- Improve sales and marketing, increase profitable sales and eliminate unprofitable product lines.

In order to achieve these goals Hemagen took the following actions during fiscal 2001:

- **Restructured Subordinated Note Payable In November 2000**

  On November 9, 2000, management signed an agreement with Dade Behring, Inc. ("Dade") in connection with a $1,050,000 subordinated note payable and $158,000 worth of trade payables owed by Hemagen to Dade on September 30, 2000. This agreement with Dade required Hemagen to pay $800,000 on November 9, 2000, and sign a new subordinated note for the net remaining amount owed of $397,000. The new note provides for interest to accrue at the rate of 10% per annum, 24 monthly payments of $12,810 and a final payment of $134,112 due on November 15, 2002. In conjunction with this agreement, Hemagen issued Dade 100,000 shares of Hemagen common stock with an estimated market value of $100,000. In addition to re-negotiating the terms of the financing with Dade, the agreement included a supply agreement for the manufacture of tablets for the Analyst® product-line for a period of twelve to eighteen months.

- **Working Capital Management**

  Hemagen has worked to better manage working capital by reducing raw material and finished goods inventories and by better managing cash receipts and disbursements. At September 30, 2001, Hemagen's working capital was approximately $3,937,000 compared to approximately $3,451,000 at September 30, 2000.

- **Reduction of Expenses**

  Hemagen has instituted an overall plan to reduce expenses and better utilize its resources. This plan centers on consolidating facilities, reducing duplicative functions and focusing Research and Development activities. In the second fiscal quarter of 2001, the Waltham, Massachusetts facility was closed and all operations previously carried on in Waltham were relocated to Hemagen's new headquarters in Columbia, Maryland. Additionally, in April 2001, Hemagen was released from its lease obligation in Waltham and sold its leasehold improvements and excess equipment that were located in Waltham. Hemagen provided for the closure and related termination costs in the fourth quarter of fiscal 2000. This consolidation is expected to result in significant reductions in rent, warehouse, utility and personnel expenses. On an annual basis, management believes these savings could amount to $400,000 - $500,000.

  Hemagen has sought to exercise tighter control over expenditures, including Research and Development spending. In fiscal 2001, Hemagen spent approximately $387,000 on Research and Development. While our

Research and Development spending declined in fiscal 2001, Hemagen remains actively engaged in several commercially significant Research and Development projects and committed to the development of new products as discussed in Part 1, "Products Under Development." The majority of our cost savings come from the elimination of duplicate efforts and facilities as recognized when we closed our Waltham facility. Management is planning to continue to reduce Hemagen's operating expenses in this area.

- **Improvement in Sales and Marketing**

In fiscal 2000, Hemagen hired several industry professionals to fill various sales and marketing positions. Hemagen signed supply agreements with Roche Diagnostics, Inc. and Quest Diagnostics, Inc., and replaced some of its blood banking business that had been previously lost.

In fiscal 2001, Hemagen began to focus its sales and marketing efforts on products that could provide the highest profit margin to Hemagen. As a result of this focus, some high cost sales were terminated and more profitable sales have been added. In February 2001, Hemagen terminated a contract manufacturing agreement with Carter-Wallace because of its high cost of production. Sales under this agreement were approximately $435,000 in fiscal 2001 and will be zero in future fiscal years.

Offsetting the reduction in Carter-Wallace sales, Hemagen grew its sales to Roche Diagnostics, Inc. in conjunction with a supply agreement signed in December 1999. Sales to Roche in conjunction with this agreement were approximately $1,700,000 and $838,000 in fiscal years 2001 and 2000, respectively. Hemagen will continue to work with Roche to expand product offerings and continue to grow the annual sales resulting from this supply agreement.

There can be no assurance that any of the above, and other actions management is taking will achieve the desired results. Management believes that as a direct result of these actions, operating efficiency and cash flow from operations have improved; and together with this improvement, Hemagen believes that cash flow from operations and cash on hand at September 30, 2001 will be sufficient to finance its operations for fiscal 2002. Additionally, over the next twelve months Hemagen may attempt to secure a traditional working capital revolving line of credit for up to $1 million. The Senior Secured Subordinated Convertible Notes provide for such financing by allowing the lender to obtain a first lien on all assets of Hemagen ahead of the Note holders in an amount not to exceed $1 million. Hemagen can give no assurance that it will be able to obtain such financing or, if obtained, that such financing terms will be favorable to the Company.

Results of Operations

Fiscal Year Ended September 30, 2001 Compared to Fiscal Year Ended September 30, 2000

Revenues for fiscal 2001 decreased $25,000 (0.2%) to approximately $10,971,000 from approximately $10,996,000 for fiscal 2000. Sales under the Carter-Wallace contract manufacturing agreement terminated in February 2001 were $496,000 lower than the prior year. HDC and Hemagen's Analyst® product-line sales decreased $188,000 and $115,000, respectively. These sales reductions were partially offset by an increase of $604,000 at Hemagen's Raichem division, due primarily to increased sales to Roche.

Cost of product sales decreased approximately $2,061,000 (21%) to approximately $7,557,000 from approximately $9,619,000 in fiscal 2000 due to cost savings and more efficient operations. Cost of product sales as a percentage of sales decreased to 69% in fiscal year 2001 from 88% in fiscal year 2000. This decrease is attributed to savings realized in connection with the closure of the Waltham, Massachusetts facility in April 2001, and the better utilization of inventory. In fiscal 2000, the cost of product sales was burdened with the cost of relocating and setting up the Analyst product-line in Columbia, Maryland which resulted in higher scrap and low yield rates.

Research and development expenses for fiscal 2001 decreased approximately $139,000 (26%) to approximately $387,000 primarily due to the elimination of outside consulting and service fees in fiscal 2001.

Selling, general and administrative expenses for fiscal 2001 decreased approximately $930,000 (22%) to

approximately $3,289,000 primarily due to reduced salary expense, consulting and legal expenses, royalty expenses associated with Analyst® product-line, and reduced office rent expense.

There were no other operating expenses in fiscal 2001 as compared to $879,000 of miscellaneous operating expenses in fiscal 2000. Fiscal 2000 charges represented the cost of closing Hemagen's Waltham, Massachusetts facility.

Net other expense decreased to approximately $805,000 from approximately $882,000 due to a decrease in interest expense. Net interest expense for fiscal 2001 was $773,000 as compared to $880,000 in fiscal 2000. This decrease is mainly attributed to a $100,000 finance charge related to the restructuring of the subordinated note payable with Dade Behring that was recorded in fiscal 2000. That charge was paid in Hemagen common stock in fiscal 2001.

Net loss before the cumulative effect of a change in accounting principle for fiscal 2001 decreased to approximately $1,068,000 compared to a net loss of approximately $5,130,000 the previous year primarily due to the reduction of cost of product sales and selling, general and administrative expenses.

In the first quarter of fiscal 2001, Hemagen recorded a cumulative effect of a change in accounting principle that resulted in a one-time non-cash charge of $1,130,000. This change in accounting principle was recognized as a result of a new accounting pronouncement regarding the accounting for the senior subordinated secured convertible notes issued in conjunction with the private placement offering completed in May 2000.

Liquidity and Capital Resources

At September 30, 2001, Hemagen had $672,000 of unrestricted cash, working capital of $3,937,000 and a current ratio of 3.0 to 1. In fiscal 2001, Hemagen had capital expenditures of $84,000 and has capital expenditures of approximately $100,000 planned for fiscal 2002.

In fiscal 2001, Hemagen used cash of approximately $788,000. This usage of cash mainly resulted from the repayment of approximately $916,000 to Dade Behring, Inc. in conjunction with the restructuring of a subordinated note payable in November 2000. Offsetting the usage of cash was approximately $128,000 of cash generated from operations and net disposals of property and equipment.

Hemagen believes that cash flow from operations and cash on hand at September 30, 2001 will be sufficient to finance its operations and capital expenditures for fiscal 2002, but Hemagen can give no assurance that it will have sufficient cash flow to finance operations. Additionally, over the next twelve months Hemagen will attempt to secure a traditional working capital revolving line of credit for up to $1 million. The Senior Secured Subordinated Convertible Notes provide for Hemagen to secure such financing by allowing the lender to obtain a first lien on all assets of Hemagen ahead of the Note holders in an amount not to exceed $1 million. Hemagen can give no assurance that it will be able to obtain such financing or, if obtained, that such terms will be favorable to the company.

Fiscal 2001 compared to Fiscal 2000

Cash generated from operating activities increased to $60,000 in fiscal 2001 from using $1,943,000 in cash in fiscal 2000. This increase in cash generated is attributed to a decrease in the net loss after adjusting for non-cash charges of $4,010,000 offset by changes in working capital items in fiscal 2001 as compared to fiscal 2000. Such changes in working capital include a reduction in the cash generated by lowering inventory levels of $1,238,000, and an increase in the cash used to fund accounts payable, accrued expenses and customer deposits of approximately $1,115,000 offset by $375,000 of cash generated from lower accounts receivable.

Cash provided by investing activities totaled $67,000 in fiscal 2001 as compared to $357,000 of cash used in fiscal 2000. This increase in cash generated is attributed to the proceeds from sales of property and equipment associated with the closure of the Waltham, Massachusetts facility, and a reduction in our capital spending.

Cash used by financing activities totaled $916,000 in fiscal 2001 as compared to $3,469,000 provided in fiscal 2000. This increase in cash used is attributed to the payments required for the subordinated note payable to Dade Behring, Inc. in fiscal 2001 offset by the net proceeds of private placement offering completed in fiscal 2000.

New Accounting Pronouncements

In June 1998, the Financial Accounting Standards Board issued FSAS No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("SFAS No. 133"). SFAS No. 133 requires companies to recognize all derivative contracts as either assets or liabilities in the balance sheet and to measure them at their fair values. If certain conditions are met, a derivative may be specifically designed as a hedge, the objective of which is to match the timing of gain or loss recognition on the hedging derivative with the recognition of (i) the changes in the fair value of the hedged assets or liability or (ii) the earnings effect of the hedged forecasted transaction. For a derivative not designated as a hedging instrument, the gain or loss is recognized in income in the period of change. SFAS No. 133, as amended by SFAS No. 137, is effective for all fiscal quarters of fiscal years beginning after June 15, 2000. Historically, Hemagen has not entered into derivative contracts either to hedge existing risks or for speculative purposes. Accordingly, Hemagen does not expect adoption of this standard to affect its financial statements.

On July 20, 2001, the FASB issued SFAS No. 141, Business Combinations, and SFAS 142, Goodwill and Intangible Assets. SFAS 141 is effective for all business combinations completed after June 30, 2001. SFAS 142 is effective for fiscal years beginning after December 15, 2001; however, certain provisions of this Statement apply to goodwill and other intangible assets acquired between July 1, 2001, and the effective date of SFAS 142. Major provisions of these accounting pronouncements and their effective dates for Hemagen are as follows:

- All business combinations initiated after June 30, 2001, must use the purchase method of accounting. The pooling of interest method of accounting is prohibited except for transactions initiated before July 1, 2001.

- Intangible assets acquired in a business combination must be recorded separately from goodwill if they arise from contractual or other legal rights or are separable from the acquired entity and can be sold, transferred, licensed, rented, or exchanged, either individually or as part of a related contract, asset or liability.

- Goodwill, as well as intangible assets with indefinite lives, acquired after June 30, 2001, will not be amortized. Effective April 1, 2002, all previously recognized goodwill and intangible assets with indefinite lives will no longer be amortized.

- Effective January 1, 2002, goodwill and intangible assets with indefinite lives will be tested for impairment annually and whenever there is an impairment indicator. All acquired goodwill must be assigned to reporting units for purposes of impairment testing and segment reporting.

Although it is still reviewing the provisions of these Statements, management's preliminary assessment is that these accounting pronouncements will not have a material impact on Hemagen's financial position or results of operations.

Item 7. Financial Statements and Supplementary Data.

See Item 13 below and the Index therein for a listing of the financial statements and supplementary data filed as part of this report.

Item 8. Changes in and Disagreements with Accountants on Accounting and Financial Disclosures

On March 23, 2001, Hemagen dismissed BDO Seidman, LLP as its independent public accountants. The report of BDO Seidman, LLP for the last fiscal years was qualified as to substantial doubt as to Hemagen's ability to continue as a going concern.

The decision to change accountants was approved by Hemagen's Board of Directors.

During Hemagen's two most recent fiscal years, and the interim period in fiscal 2001 to the time of termination, there were no disagreements with BDO Seidman, LLP on any matters of accounting principles or practices, financial statement disclosure or auditing scope of procedure. Hemagen has authorized BDO Seidman, LLP to respond fully to any inquiries of its successor accountants.

During Hemagen's two most recent fiscal years and the subsequent interim period fiscal 2001 to the date of the dismissal of BDO Seidman, LLP, did not advise Hemagen of any reportable conditions relating to weaknesses in internal controls.

On March 28, 2001, Hemagen engaged Grant Thornton, LLP as the principal accountant to audit its financial statements.

During Hemagen's two most recent fiscal years and the interim period in fiscal 2001 until the engagement of Grant Thornton, LLP, Hemagen did not consult Grant Thornton, LLP, concerning the application of accounting principles to any specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on Hemagen's financial statements in circumstances in which a written report was provided or oral advice was provided that Grant Thornton concluded was an important factor considered by Hemagen in reaching a decision as to the particular issue.

PART III

Items 9 through 12 are incorporated by reference to the Registrant's Proxy Statement regarding its 2002 Annual Shareholders Meeting to be filed with the Commission pursuant to Regulation 14A.

Item 13. Exhibits and Reports on Form 8-K.

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

(a)(3) **Exhibit List.**

Exhibit No.	Description of Exhibit	Filing Status
3.1	Certificate of Incorporation.	A
3.2	Bylaws.	A
4.1	Specimen Stock Certificate.	A
4.2	Rights Agreement dated January 27, 1999.	A
4.3	First Amendment to the Rights Agreement dated September 30, 1999.	H
10.5	Financial Assistance Agreement between Hemagen and Hemagen Diagnosticos, Comercio, Importacao e Exportacao Ltd., dated July 31, 1991.	A
10.6*	1992 Stock Option Plan.	A
10.11	Lease between Hemagen and Philip Pagliazzo and Rose Pagliazzo, dated May 15, 1992.	A
10.13*	Revised Employment Agreement between Hemagen and Dr. de Oliveira.	A
10.14*	Revised Employment Agreement between Hemagen and Dr. Franzblau.	A
10.15	Description of Hemagen's lease for certain premises located in Waltham, Massachusetts.	A
10.16	Lease for office space of Hemagen Diagnosticos, Comercio, Importaceo e Exportaceo, Ltd. ("HDC") in Sao Paulo, Brazil.	A
10.17	Description of the Lease for office space of HDC in Sao Paulo, Brazil.	A
10.23	Agreement between Hemagen and Carter-Wallace, Inc. dated December 22, 1994.	D
10.24	License Assignment and License Agreement between Hemagen and Aberlyn Capital Management Limited Partnership dated December 30, 1994.	D
10.25	Settlement Agreement dated September 30, 1999.	E
10.27	Distribution Agreement between the Company and Phoenix Diagnostics, Inc.	E
10.28	Form of Warrant expiring April 30, 2002.	G
10.29	Form of 8% Senior Subordinated Secured Convertible Note.	G
10.30	Second Amendment to the Lease between the Company and 9033 Red Branch Road, L.L.C. dated June 9,2000.	H
10.31	Consulting agreement between the Company and Thomas A. Donelan	H

	Thomas A. Donelan and Christopher P. Hendy, dated October 1, 1999.	
10.32	Second Restructuring Agreement between the Company and Dade Behring, Inc. dated November 9, 2000.	F
10.33	Termination Agreement between the Company and Carter-Wallace, Inc. dated February 26, 2001.	J
10.34	Conditional Lease Termination Agreement between the Company and Philip and Rose M. Pagliazzo dated March 30, 2001.	F
10.35*	2001 Stock Option Plan.	I
16	BDO Seidman, LLP letter dated March 28, 2001 regarding the Form 8-K filed by Hemagen on March 29, 2001 reporting on Item 4, Changes in Registrant's Certifying Accountant.	K
23	Consent of Independent Certified Public Accountants.	F
28	Prospectus Sale Letter Dated July 28, 2000.	G

*Management compensatory contracts.

A. Incorporated by reference to Registration Statement No. 33-52686-B.
B. Incorporated by reference to Hemagen's Form 10-QSB for the quarter ended March 30, 1993.
C. Incorporated by reference to Hemagen's Form 10-KSB for the fiscal year ended September 30, 1994.
D. Incorporated by reference to Hemagen's Form 10-QSB for the quarter ended December 31, 1994.
E. Incorporated by reference to Hemagen's Form 8-K filed on October 7, 1999.
F. Filed herewith.
G. Incorporated by reference to Hemagen's Form S-3 filed on July 21, 2000.
H. Incorporated by reference to Hemagen's Form 10-KSB for the fiscal year ended September 30, 2000.
I. Incorporated by reference to Hemagen's Form S-8, Registration Statement No. 333-57080, filed with the SEC on March 15, 2001.
J. Incorporated by reference to Hemagen's 10-QSB for the quarter ended March 31, 2001.
K. Incorporated by reference to Hemagen's Form 8-K filed on March 23, 2001.

(b) Reports on Form 8-K. None.

Hemagen Diagnostics, Inc. and Subsidiaries

Index to Consolidated Financial Statements

Report of Independent Certified Public Accountants

To the Board of Directors and Stockholders of
Hemagen Diagnostics, Inc.

We have audited the accompanying consolidated balance sheets of Hemagen Diagnostics, Inc. and subsidiaries as of September 30, 2001 and 2000, and the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended. 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 in accordance with auditing standards generally accepted in the United States of America. Those standards 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. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Hemagen Diagnostics, Inc. and subsidiaries at September 30, 2001 and 2000, and the consolidated results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 9 to the consolidated financial statements, the Company changed its method of accounting for its subordinated secured convertible notes beneficial feature in accordance with EIFT 00-27 "Application of Issue 98-5 to Certain Convertible Instruments."

Grant Thornton LLP
Baltimore, Maryland
November 21, 2001

Hemagen Diagnostics, Inc. and Subsidiaries

Consolidated Balance Sheets

September 30,	**2001**	2000
Assets		
Current:		
Cash and cash equivalents	**$ 672,378**	$ 1,460,446
Accounts receivable, less allowance for doubtful accounts of $611,000 and $598,000 at September 30, 2001 and 2000, respectively	**1,299,616**	1,704,481
Inventories	**3,774,346**	4,188,162
Prepaid expenses and other current assets	**113,226**	177,376
Total current assets	**5,859,566**	7,530,465
Property and equipment, net of accumulated depreciation and amortization	**2,226,093**	3,079,470
Other assets, net	**297,849**	321,212
Total Assets	**$ 8,383,508**	$ 10,931,147

See accompanying notes to consolidated financial statements.

Hemagen Diagnostics, Inc. and Subsidiaries

Consolidated Balance Sheets

September 30,	2001	2000
Liabilities and Stockholders' Equity		
Current liabilities:		
Subordinated note payable, current portion	$ 136,256	$ 1,050,000
Accounts payable and accrued expenses	1,654,430	2,826,573
Deferred revenue	132,322	122,069
Customer deposits	--	81,239
Total current liabilities	1,923,008	4,079,881
Subordinated note payable, less current portion	145,070	--
Senior subordinated secured convertible notes, net of unamortized discount of $ 4,542,376 and $5,046,697 at September 30, 2001 and 2000, respectively	1,547,624	1,268,303
Total subordinated debt	1,692,694	1,268,303
Commitments	--	--
Stockholders' equity:		
Preferred stock, $0.01 par value - 1,000,000 shares authorized; none issued	-	-
Common stock, $0.01 par value - 30,000,000 shares authorized; and 9,962,422 and 9,697,790 shares issued at September 30, 2001 and 2000, respectively	99,623	96,978
Additional paid-in capital	20,693,055	19,230,767
Accumulated deficit	(15,853,966)	(13,655,145)
Accumulated other comprehensive loss - foreign currency translation loss	(81,269)	--
Less treasury stock at cost; 100,000 shares at September 30, 2001 and 2000, respectively	(89,637)	(89,637)
Total stockholders' equity	4,767,806	5,582,963
Total liabilities and stockholders equity	$8,383,508	$10,931,147

See accompanying notes to consolidated financial statements.

Hemagen Diagnostics, Inc. and Subsidiaries

Consolidated Statements of Operations

Years ended September 30,	2001	2000
Net sales	$10,970,558	$10,995,604
Costs and expenses:		
Costs of product sales	7,557,394	9,618,713
Research and development	387,345	526,281
Selling, general and administrative	3,289,439	4,219,679
Other operating costs	--	878,906
Total costs and expenses	11,234,178	15,243,579
Operating loss	(263,620)	(4,247,975)
Other income (expenses):		
Interest income	66,067	10,340
Interest expense	(839,197)	(890,714)
Other expense	(31,687)	(1,787)
Total other income (expense)	(804,817)	(882,161)
Net loss before cumulative effect of a change in accounting principle	(1,068,437)	(5,130,136)
Cumulative effect of a change in accounting principle for beneficial conversion feature of debt	(1,130,384)	--
Net loss	$(2,198,821)	$(5,130,136)
Net loss per share - Basic and Undiluted		
Loss from continuing operations	$(0.11)	$(0.53)
Cumulative effect of change in accounting principle for beneficial conversion feature of debt	$(0.12)	-
	$(0.23)	$(0.53)
Weighted average common shares used in calculation	9,751,462	8,587,739

See accompanying notes to consolidated financial statements.

Hemagen Diagnostics, Inc. and Subsidiaries

Consolidated Statements of Stockholders' Equity

Years ended September 30, 2001 and 2000	Common Stock Shares	Common Stock Par Value	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Treasury Stock Shares	Treasury Stock Cost	Total Stockholders' Equity
Balance at September 30, 1999	7,851,890	$78,519	$13,434,947	$(8,525,009)	-	(100,000)	$(89,637)	$4,898,820
Exercise of common stock purchase warrants	99,500	995	271,635	-	-	-	-	72,630
Exercise of stock options	226,700	2,267	338,524-	-	-	-	-	340,791
Issuance of common stock settled in lieu of cash payments	259,700	2,597	297,540	-	-	-	-	300,137
Issuance of common stock in a private placement offering, net of fees paid	1,260,000	12,600	1,587,916	-	-	-	-	1,600,516
Issuance of common stock warrants in a private placement offering	-		3,486,412	-	-	-	-	3,486,412
Warrants granted for issuance costs	-	-	(186,207)	-		-	-	(186,207)
Net loss	-	-	-	(5,130,136)	-	-	-	(5,130,136)
Balance at September 30, 2000	9,697,790	$96,978	$19,230,767	$(13,655,145)	-	(100,000)	$(89,637)	$5,582,963
Issuance of common stock related to the settlement with Dade Behring	100,000	1,000	99,000	-	-	-	-	100,000
Cumulative effect of a change in accounting principle for beneficial conversion feature of debt	-	-	1,130,384	-	-	-	-	1,130,384
Issuance of common stock related to the conversion of debt	110,000	1,100	48,948	-	-	-	-	50,048
Issuance of stock options to employees	-	-	142,501	-	-	-	-	142,501
Issuance of common stock in lieu of cash payments	54,632	545	41,455	-	-	-	-	42,000
Net loss	-	-	-	(2,198,821)	-	-	-	(2,198,821)
Foreign exchange loss	-	-	-		(81,269)	-	-	(81,269)
Balance at September 30, 2001	**9,962,422**	**$99,623**	**$20,693,055**	**$(15,853,966)**	**$(81,269)**	**(100,000)**	**$(89,637)**	**$4,767,806**

See accompanying notes to consolidated financial statements

Hemagen Diagnostics, Inc. and Subsidiaries

Consolidated Statements of Cash Flows

Years ended September 30,	**2001**	2000
Cash flows from operating activities:		
Net loss	$(2,198,821)	$ (5,130,136)
Adjustments to reconcile net loss to net cash (used) provided by operating activities:		
Depreciation and amortization	853,320	1,111,678
Amortization of debt discount	329,370	224,789
Cumulative effect of a change in accounting principle	1,130,384	-
Provision for inventory obsolescence	-	(174,623)
Foreign exchange loss	(81,269)	3,993
Loss on sale of property and equipment	13,175	-
Changes in operating assets and liabilities		
Accounts receivable	347,947	(27,465)
Inventories	413,816	1,651,367
Prepaid expenses and other current assets	64,150	94,633
Checks issued against future deposits	-	(411,140)
Accounts payable and accrued expenses	(740,603)	901,241
Customer deposits	(81,239)	(225,013)
Deferred revenue	10,253	37,695
Net cash provided by (used in) operating activities	60,483	(1,942,981)
Cash flows from investing activities:		
Purchase of property and equipment	(84,211)	(356,659)
Proceeds from sales of property and equipment	151,374	-
Net cash provided by (used in) investing activities	67,163	(356,659)
Cash flows from financing activities:		
Net repayments under revolving line of credit	-	(3,169,589)
Net repayments of subordinated note payable	(915,714)	-
Net proceeds from issuance of common stock in a private placement offering	-	1,600,516
Net proceeds from issuance of warrants in a private placement offering	-	3,486,412
Net proceeds from issuance of debt in a private placement offering	-	938,596
Exercise of stock options and warrants	-	613,421
Net cash (used in) provided by financing activities	(915,714)	3,469,356
Effect of exchange rates on cash and cash equivalents	-	1,410
Net increase in cash and cash equivalents	(788,068)	1,171,126
Cash and cash equivalents, beginning of year	1,460,446	289,320
Cash and cash equivalents, end of year	$ 672,378	$ 1,460,446

See accompanying notes to consolidated financial statements.

1. Nature of Business

Hemagen Diagnostics, Inc. (the "Company") is a biotechnology company that develops, manufactures, and markets medical diagnostic test kits used to aid in the diagnosis of certain autoimmune and infectious diseases. In the United States, the Company sells its products directly to physicians, veterinarians, clinical laboratories and blood banks and on a private-label basis through multinational distributors of medical supplies. Internationally, the Company sells its products primarily through distributors. The Company also manufactures and sells an FDA-cleared clinical chemistry analyzer ("The Analyst") used to measure important constituents in human and animal blood. The Company sells The Analyst through distributors servicing both the physician's office laboratory and veterinary markets.

2. Significant Accounting Policies

Estimates and Assumptions

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America,requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company, its wholly-owned subsidiary, Reagents Applications, Inc. ("RAI") and its majority owned subsidiary, and Hemagen Diagnostics Commercio, Importaco & Exporataco, Ltd. ("HDC"). All significant intercompany balances and transactions have been eliminated in consolidation.

The Company has a 51% interest in HDC. All losses of HDC in excess of the minority shareholders' investment have been allocated to the Company.

2. **Significant Accounting Policies** (Continued)

Foreign Currency Translation

The financial position and results of operations of HDC are measured using HDC's local currency as the functional currency. Revenues and expenses of HDC have been translated into U.S. dollars at average exchange rates prevailing during the year. Assets and liabilities have been translated at the rates of exchange on the balance sheet date. The resulting translation gain and loss adjustments are recorded directly as a separate component of shareholders' equity.

Cash Equivalents

The Company considers all investments with original maturities of three months or less to be cash equivalents.

Inventories

Inventories are stated at the lower of cost, determined on a first-in, first-out basis, or market.

Long-lived Assets

The Company reviews the carrying values of its long-lived assets, including goodwill, for possible impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. Should the review indicate that long-lived assets, including goodwill, are not recoverable (i.e., the carrying amount is less than the future projected undiscounted cash flows). This carrying amount would be reduced to fair value.

Property and Equipment

Property and equipment are stated at cost. Depreciation is provided on a straight-line basis over the estimated useful lives of the related assets which range from 4 to 10 years. Expenditures for repairs and maintenance are expensed as incurred.

Other Assets

Other assets, net consists primarily of goodwill resulting from the acquisition of RAI and is being amortized on a straight-line basis over 5 years.

2. **Significant Accounting Policies** (Continued)

Income Taxes

The Company follows the liability method of accounting for income taxes. Under this method, deferred tax liabilities and assets are recognized for the expected future tax consequences of temporary differences between the carrying amount and the tax basis of assets and liabilities at each year-end based on enacted tax laws and statutory tax rates applicable to the periods in which the differences are expected to affect taxable income. A valuation allowance is established when necessary to reduce deferred tax assets to the amount expected to be realized.

Revenue Recognition

Revenues from the sale of products are recognized upon product shipment. Revenues from contracts to conduct research and development are recognized using the percentage-of-completion method. Revenues from product service contracts are recognized ratably over the terms of the contracts. Losses are provided for at the time that management determines that contract costs will exceed related revenues. The portion of contract billings related to research and development and product service contracts not complete at the balance sheet date is included in deferred revenue.

Stock- Based Compensation

The Company accounts for stock-based employee compensation arrangements in accordance with the provisions of Accounting Principles Bases Board Opinion No. 25 (APB 25) Accounting for Stock Issued to Employees, and complies with the disclosure provisions of Statement of Financial Accounting Standard No. 123 (SFAS No. 123), Accounting for Stock-Based Compensation. Under APB 25, compensation expense is based on the difference, if any, on the date of grant, between the market value of the Company's stock and the exercise value of the option granted.

Net Loss Per Share of Common Stock

The Company follows Statement of Financial Accounting Standards No. 128 (SFAS No. 128), Earnings per Share. Under SFAS No. 128, basic earnings per share excludes the effect of any dilutive options, warrants or convertible securities and is computed by dividing the net income (loss) available to common shareholders by the weighted average number of common shares outstanding for the period. Diluted earnings per share is computed by dividing the net income (loss) available to common shareholders by the sum of the weighted average number of common shares and common share equivalents computed using the average market price for the period under the treasury stock method.

2. Significant Accounting Policies (Continued)

Weighted-average common share equivalents outstanding at September 30, 2001 and 2000 totaling 10,819,000 and 10,011,000 shares, respectively for currently outstanding stock options, warrants and convertible debt were not included in the denominator for diluted income per share as their effect was anti-dilutive.

Research and Development Costs

All costs incurred to research, design and develop products are considered research and development costs and are charged to expense as incurred.

Reclassifications

Certain reclassifications have been made to the 2000 financial statements to conform to the 2001 presentation.

New Accounting Pronouncements

In June 1998, the Financial Accounting Standards Board issued SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities" ("SFAS No. 133"). SFAS No. 133 requires companies to recognize all derivative contracts as either assets or liabilities in the balance sheet and to measure them at their fair values. If certain conditions are met, a derivative may be specifically designated as a hedge, the objective of which is to match the timing of gain or loss recognition on the hedging derivative with the recognition of (i) the changes in the fair value of the hedged assets or liability or (ii) the earnings effect of the hedged forecasted transaction. For a derivative not designated as a hedging instrument, the gain or loss is recognized in income in the period of change. SFAS No. 133, as amended by SFAS No. 137, is effective for all fiscal quarters of fiscal years beginning after June 15, 2000. Historically, the Company has not entered into derivative contracts either to hedge existing risks or for speculative purposes. Accordingly, the Company does not expect adoption of the new standard to affect its financial statements.

2. Significant Accounting Policies (Continued)

New Accounting Pronouncments (Continued)

In July 2001, the Financial Accounting Standards Board (FASB) issued SFAS 141, Business Combinations, and SFAS 142, Goodwill and Intangible Assets. SFAS 141 is effective for all business combinations completed after June 30, 2001. SFAS 142 is effective for fiscal years beginning after December 15, 2001; however, certain provisions of this Statement apply to goodwill and other intangible assets acquired between July 1, 2001, and the effective date of SFAS 142. Major provisions of these Statements and their effective dates for the Company are as follows:

- All business combinations initiated after June 30, 2001, must use the purchase method of accounting. The pooling of interest method of accounting is prohibited except for transactions initiated before July 1, 2001.

- Intangible assets acquired in a business combination must be recorded separately from goodwill if they arise from contractual or other legal rights or are separable from the acquired entity and can be sold, transferred, licensed, rented, or exchanged, either individually or as part of a related contract, asset or liability.

- Goodwill, as well as intangible assets with indefinite lives, acquired after June 30, 2001, will not be amortized.

- Effective January 1, 2002, goodwill and intangible assets with indefinite lives will be tested for impairment annually and whenever there is an impairment indicator. All acquired goodwill must be assigned to reporting units for purposes of impairment testing and segment reporting.

The Company is currently reviewing the provisions of these Statements, management's preliminary assessment is that these Statements will not have a material impact on the company's financial position or results of operations.

3. Related Party Transactions

William P. Hales, Redwood Holdings, Inc. and certain of Redwood Holdings, Inc. employees, namely Jerry L. Ruyan, Thomas A. Donelan, and Christopher P. Hendy solicited written consents from shareholders of Hemagen seeking several changes to its Bylaws, the removal of its directors and the election of themselves to the Board of Directors. Following the delivery of consents, the matter was settled pursuant to a settlement agreement executed on September 30, 1999.

3. Related Party Transactions (Continued)

As part of the settlement agreement four of Hemagen's six directors resigned and were replaced by Jerry L. Ruyan, William P. Hales, Thomas A. Donelan, and Christopher P. Hendy. The new Board of Directors then elected Jerry L. Ruyan as Chairman and CEO and William P. Hales as President. Also, the four new directors purchased from the previous management all of their common shares totaling 777,801 at a price approximating market.

On October 1, 1999, the Company entered into a consulting agreement with two outside directors, Thomas A. Donelan and Christopher P. Hendy, for consulting services to be provided to the Company with respect to general corporate or strategic matters for a period of one year ended September 30, 2000. As of September 30, 2000, the Company had incurred $226,500 in consulting fees of which $183,600 was accrued for Thomas A. Donelan and Christopher P. Hendy.

4. Inventories

Inventories consist of the following:

September 30,	**2001**	2000
Raw materials	**$2,404,437**	$2,886,126
Work-in-process	**109,351**	371,845
Finished goods	**2,091,788**	2,128,497
	4,605,576	5,386,468
Less reserves	**(831,230)**	(1,198,306)
	$3,774,346	$4,188,162

5. Property and Equipment

Property and equipment consist of the following:

September 30,	2001	2000
Furniture and equipment	$7,472,998	$7,578,744
Leasehold improvements	158,404	664,241
	7,631,402	8,242,985
Less accumulated depreciation and amortization	5,405,309	5,163,515
	$2,226,093	$3,079,470

Depreciation and amortization expense relating to property and equipment was approximately $773,000 and $1,050,000 for the years ended September 30, 2001, and 2000, respectively.

6. Accounts Payable and Accrued Expenses

Accounts payable and accrued expenses include the following:

September 30,	2001	2000
Accounts payable – trade	$528,497	$862,299
Accrued professional fees	296,042	323,094
Accrued royalties	252,365	242,876
Accrued vacation	134,306	123,785
Accrued closure provision	146,478	878,906
Accrued other	296,742	395,613
	$1,654,430	$2,826,573

7. Development and License Agreements

The Company entered into an agreement under which the Company obtained exclusive proprietary rights to certain patents, licenses and technology to manufacture, market and sell certain products. Under the agreement, the Company is obligated to make quarterly royalty payments based on a percentage of sales of the defined products through August 31, 2004.

In addition, the Company entered into a sublicense agreement whereby two license agreements related to certain Analyst® products were transferred to the Company. These license agreements, which contain provisions for royalty obligations based on production and net sales of certain products, expire in March 2000 and May 2005. Royalty expense recorded under the royalty agreement and the sublicense agreement amounted to approximately $48,000 and $201,000 during the years ended September 30, 2001 and 2000, respectively.

8. Subordinated Note Payable

On November 9, 2000, the Company reached an agreement with Dade Behring, Inc. which provided for the settlement of a $1,250,000 note payable. The $1,250,000 note payable originated from the September 1, 1998 acquisition of the Analyst® product line from Dade Behring. This settlement agreement called for a payment of $800,000 in cash, a reduction of the outstanding balance by $200,000, a new note for $397,000 and 100,000 shares of Hemagen common stock. The note for $397,000 provides for interest to accrue at the rate of 10% per annum, with 24 monthly payments of $12,810 and a final payment of $134,112 due on November 15, 2002. The common shares were estimated to have a value of $100,000 based on the market price on November 9, 2000. The Company recorded the market value of the common shares as additional interest expense in the year ended September 30, 2000. Under this agreement, Dade Behring continues to provide production services to the Company. The balance outstanding of the note at September 30, 2001, is $281,326.

9. Private Placement Offering

On May 24, 2000, the Company completed a private placement offering of senior subordinated secured convertible notes in the amount of $6,315,000 with net proceeds of $6,025,524. The offering consisted of units of senior subordinated convertible notes, common stock and detachable warrants. Each unit was sold for $500,000 and consisted of one $500,000 senior subordinated secured convertible note, 200,000 detachable warrants to purchase common stock and 93,750 shares of common stock.

The senior subordinated secured convertible notes mature on April 17, 2005, with no principal payments required until maturity. The notes provide for quarterly interest payments at the annual rate of 8%. The effective interest rate on these notes was calculated to be approximately 58% and an original issue discount of approximately $5,185,000 is being amortized over the term of the notes. The face value of the notes outstanding at September 30, 2001, is $6,090,000. The unamortized discount on these notes equals $4,542,000 and $5,047,000 at September 30, 2001 and 2000, respectively..

The Company adopted Emerging Issues Task Force ("EITF") Issue 00-27, "Application of EITF 98-5, 'Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios' to Certain Convertible Instruments" during the fourth quarter of 2000. EITF 00-27 requires that a convertible instrument's beneficial conversion feature be measured using an effective conversion price. As a result, the value assigned to the original issue discount on the convertible debt securities issued by the Company in the private placement completed in May 2000, was increased by $1,130,384. In accordance with the EITF, this additional original discount was expensed in the current period and recognized as the cumulative effect of a change in accounting principle.

The senior subordinated secured convertible notes are convertible into shares of the Company's common stock at a conversion price of $2.00 per share. The Company may force the notes to be converted at any time after the common stock has traded above $4.50 for ten consecutive business days. Additionally, the Company may prepay the notes at any time at the full face value of the notes plus accrued and unpaid interest. During the year ended September 30, 2001, the Company issued 110,000 shares of common stock in connection with the conversion of $225,000 of notes payable.

9. Private Placement Offering (Continued)

In conjunction with the sale of the units, 2,526,000 warrants were issued. The warrants issued allow the holder to purchase one share of common stock at an exercise price of $2.75 at any time on or after April 30, 2001, through April 30, 2002. The Company may call the warrants for $0.10 per warrant at any time after April 30, 2001, provided that the closing bid price of the Company's common stock has exceeded $4.25 for ten consecutive business days. Using the Black-Scholes option pricing model the estimated fair value of the warrants was approximately $1.34 each or $3,384,840 in aggregate. An additional 75,800 warrants were issued to the placement agent of the offering at the estimated value of $101,572. The offering provided for the issue of 1,184,072 shares of common stock to the unit holders. These shares were valued at approximately $1.52 per share for a total value of $1,799,789. The placement agent for the offering was also issued 75,800 shares at a value of $115,216. The cost of this offering was allocated between debt and equity.

10. Stockholders' Equity

Preferred Stock

The Company is authorized to issue up to 1,000,000 shares of preferred stock, $.01 par value per share. The preferred stock may be issued in one or more series, the terms of which may be determined at the time of issuance by the Board of Directors and may include voting rights, preferences as to dividends and liquidation, conversion and redemption rights and sinking fund provisions.

Accumulated Comprehensive Income

In 1999, the Company adopted Statement of Financial Accounting Standards No. 130, "Reporting Comprehensive Income" (SFAS No. 130). SFAS No. 130 establishes new rules for the reporting and display of comprehensive income and its components; however, until this year, the adoption of this statement had no impact on the Corporation's net income or shareholders' equity. Accumulated other comprehensive loss consists of foreign currency translation adjustments totaling $81,269 at September 30, 2001.

Common Stock Purchase Warrants

At September 30, 2001, 5,197,555 warrants at an exercise price of $2.75 expiring at April 30, 2002, were outstanding. On February 28, 2001, 2,595,755 warrants at an exercise price of $2.75 expiring at February 28, 2001 were extended and now expire on April 30, 2002.

10. Stockholders' Equity (Continued)

Common Stock Purchase Warrants (Continued)

During the year ended September 30, 2000, warrants for the purchase of 99,500 shares at a purchase price of $2.75 per share were exercised. Also, during the year ended September 30, 2000, warrants for the purchase of an aggregate of 87,000 shares of common stock at prices ranging from $2.00 to $2.50 expired.

Stock Options

On February 27, 2001, at the Company's annual meeting, the shareholders voted to approve the 2001 Stock Option Plan. The 2001 Stock Option Plan provides for the grant of incentive and nonqualified stock options for the purchase of an aggregate of 1,000,000 shares of the Company's common stock by employees, directors and consultants of the Company. The Compensation Committee of the Board of Directors is responsible for the administration of the Plan. The Compensation Committee determines the term of each option, the number of shares for which each option is granted and the rate at which each option is exercisable. The Company may not grant an employee incentive stock options with a fair market value in excess of $100,000 that is exercisable during any one calendar year. The term of incentive stock options granted cannot exceed ten years (five years for options granted to holders of more than 10% of the voting stock of the Company). The exercise price for incentive stock options granted may not be less than 100% of the fair market value per share of the underlying common stock (110% for options granted to holders of more than 10% of the voting stock of the Company).

Prior to the establishment of the 2001 Stock Option Plan, the Company granted certain stock options in accordance with the terms of the 1992 Stock Option Plan. The 1992 Stock Option Plan, as amended, provides for the grant of incentive and nonqualified stock options for the purchase of an aggregate of 1,000,000 shares of the Company's common stock by employees, directors, and consultants of the Company. The Board of Directors is responsible for the administration of the Plan. The terms of the 1992 Stock Option Plan are generally the same as the 2001 Stock Option Plan as described above.

10. Stockholders' Equity (Continued)

Stock Options (Continued)

On September 30, 1999, the Company's Board of Directors awarded options to the Company's President and certain directors to purchase an aggregate of 1,732,014 shares of the Company's common stock at an exercise price of $1.36 per share, which represented the fair value of the common stock at that date. The director's options were granted to Redwood Holdings, Inc. which is a 100% owned subsidiary of an employee stock ownership plan, the beneficial owners of which are Jerry Ruyan (49.9%), Thomas A. Donelan (24.9%), and Christopher P. Hendy (24.9%). The options were granted pursuant to stockholder authorization received during a consent solicitation which resulted in the replacement of certain former members of the Company's senior management and Board of Directors. The options, which were not issued under the Plan, expire on September 30, 2009, and became exercisable on March 31, 2001.

Stock Options (Continued)

Changes in all options outstanding are summarized as follows:

	Shares	Weighted - Average Exercise Price
Balance, September 30, 1999	2,209,189	$1.42
Granted	475,000	1.59
Exercised	(226,700)	1.50
Cancelled or expired	(170,325)	1.53
Balance, September 30, 2000	2,287,164	1.44
Granted	425,000	0.74
Exercised	--	--
Cancelled or expired	(135,304)	1.52
Balance, September 30, 2001	2,576,860	$1.31

As of September 30, 2001, options for 2,236,360 shares were exercisable at prices ranging from $0.63 to $2.19 per share.

10. Stockholders' Equity (Continued)

The following table summarizes information about stock options outstanding at September 30, 2001:

Stock Options (Continued)

	Options Outstanding		
Range of Exercise Prices	Number Outstanding at September 30, 2001	Weighted-Average Remaining Contractual Life (years)	Weighted Average Exercise Price
2.19	58,850	0.6	$2.19
2.00	225,996	2.4	2.00
1.75	8,000	1.0	1.75
1.38	10,000	4.0	1.38
1.36	1,732,014	8.0	1.36
1.25	15,000	4.0	1.25
1.20	74,500	1.3	1.20
1.00	30,000	3.3	1.00
0.97	50,000	3.3	0.97
0.83	10,000	5.0	0.83
0.81	20,000	9.4	0.81
0.75	40,000	5.0	0.75
0.64	30,000	4.6	0.64
0.63	272,500	4.2	0.63
$0.63 to $2.19	2,576,860	6.5	$1.31

	Options Exercisable	
Range of Exercise Prices	Number Exercisable at September 30, 2001	Weighted Average Exercise Price
$2.19	58,850	$2.19
2.00	212,996	2.00
1.75	8,000	1.75
1.36	1,732,014	1.36
1.20	74,500	1.20
0.97	25,000	0.97
0.81	20,000	0.81
0.75	40,000	0.75
0.63	65,000	0.63
$0.63 to $2.19	2,236,360	$1.40

10. Stockholders' Equity (Continued)

Stock Options (Continued)

The Company accounts for its stock-based compensation plan using the intrinsic value method as prescribed in APB 25. Accordingly, no compensation cost has been recognized for its stock option plan. Had compensation costs for the Company's stock option plan been determined based on the fair value at the grant dates for awards under the plan consistent with the method of SFAS No. 123, the Company's net loss and loss per common share would have been adjusted to the pro forma amounts indicated below:

Years ended September 30,		2001	2000
Net loss	As reported	$(2,198,821)	$ (5,130,136)
	Pro forma	$(2,388,878)	$(5,218,792)
Loss per common share:	As reported:		
	Basic	(.23)	(.53)
	Diluted	(.23)	(.53)
	Pro forma:		
	Basic	(.24)	(.54)
	Diluted	(.24)	(.54)

In determining the pro forma amounts above, the Company estimated the fair value of each option granted using the Black-Scholes option pricing model with the following weighted-average assumptions used for grants in 2001 and 2000: dividend yield of 0% for both years and expected volatility of 91% for 2001 and 51% for 2000, risk free rates of 5.4% in both 2001 and 2000, and expected lives of 5 years for both 2001 and 2000. The weighted average fair value of options granted during the years ended September 30, 2001 and 2000 was $0.50 and $0.66 per share, respectively.

10. Stockholders' Equity (Continued)

Stock Rights Purchase Agreement

In fiscal year 1999, the Company's Board of Directors implemented a Stock Purchase Rights Agreement (the "Agreement"). Under the Agreement, as amended, the Company declared a dividend of one common share purchase right (a "Right") for each share of the Company's outstanding common stock as of February 10, 1999. Each Right entitles the holder to purchase from the Company $4.00 worth of Company common stock at a per-share price equal to 50 percent of the current market price. The Rights become exercisable only if a person or group, as defined, acquires beneficial ownership of 15 percent or more of the Company's outstanding common stock or announces a tender offer that would result in beneficial ownership of 15 percent or more of the Company's outstanding common stock. Pursuant to a Board of Directors Resolution dated September 30, 1999, William P. Hales, Jerry L. Ruyan, Thomas A. Donelan, Christopher P. Hendy and Redwood Holdings, Inc. are exempt under the Agreement. The Rights, which expire on January 27, 2009, are redeemable in whole, but not in part, at the Company's option at $0.001 per Right at any time prior to the earlier of ten days after public announcement that a person or group has acquired beneficial ownership of 15% or more of the Company's outstanding common stock or the expiration date of the Rights.

Reserved Shares

At September 30, 2001, the Company has reserved 12,492,496 shares of common stock for issuance upon exercise of outstanding common stock options, warrants and rights.

11. Other Operating Costs

Other operating costs consist of the following:

Years ended September 30,	2001	2000
Severance pay related to facility closure	-	$361,361
Other charges related to facility closure	-	517,545
	-	$878,906

On April 19, 2000, the Company announced a plan to consolidate operations and close the Waltham, Massachusetts facility. The facility had served as the corporate office in addition to the manufacturing facility for blood-banking and ELISA products. In conjunction with this plan to close the facility, the Company recorded charges for severance costs, write down of equipment and leasehold improvements, lease obligations and moving costs. A provision of $361,361 was recognized for severance payments required for those Waltham-based employees that were terminated with the closure of the facility. Charges of $517,545 were recognized to provide for the write off of equipment and leasehold improvements and a provision for remaining lease obligations and office closure related costs. The actual costs incurred by the Company were $150,000 less than what was accrued at September 30, 2000, as a result of early release from a lease obligation.

11. Other Operating Costs (Continued)

In connection with the closure of the Waltham facility, management terminated a contract to provide diagnostic kits to a major customer which had an original termination date of December 22, 2004. The customer has agreed to release the Company from its obligations under this contract. In 2000, the Company recorded an inventory reserve of approximately $48,000 related to the sale of the inventory. This adjustment was recorded in the fourth quarter of fiscal 2000.

12. Income Taxes

Domestic and foreign loss before income taxes and minority interest in net income (loss) of consolidated subsidiary are as follows:

Years ended September 30,	2001	2000
Domestic	(1,996,456)	$(5,147,118)
Foreign	(206,577)	16,982
	(2,203,033)	$(5,130,136)

The difference between income taxes provided at the Company's effective tax rate and the Federal statutory rate is as follows:

Years ended September 30,	2001	2000
Federal tax (credit) at statutory rate	(749,031)	$(1,744,247)
Operating loss generating no current tax benefit	749,031	1,744,247
	$ -	$ -

12. Income Taxes (Continued)

Deferred tax assets (liabilities) are comprised of the following:

September 30,	2001	2000
Net operating loss carryforwards	$4,310,000	$ 3,502,000
Inventory reserve	332,000	396,000
Accounts receivable reserve	244,000	-
Closure provision	59,000	247,000
Other	202,000	70,000
Total deferred tax assets	5,147,000	4,321,000
Basis difference in fixed assets	(251,000)	-
Net deferred tax assets	4,896,000	4,321,000
Deferred tax asset valuation allowance	(4,896,000)	(4,321,000)
Net deferred tax assets	$ -	$ -

The Company has provided a valuation allowance equal to 100% of the total net deferred tax asset in recognition of the uncertainty regarding the ultimate amount of the net deferred tax asset that will be realized.

At September 30, 2001, the Company has approximately $12,675,000 and $2,856,000 of federal and state, net operating loss carry-forwards, respectively, available to offset future taxable income, which expire on various dates through 2021. Ownership changes as defined in the Internal Revenue Code may limit the amount of net operating loss and tax credit carryforwards that may be utilized annually.

13. Significant Sales and Concentration of Credit Risk

During the year ended September 30, 2001, the Company derived revenues from two significant customers; $1,700,000 from one customer and $1,482,000 from the other customer, representing 15% and 14% of total sales, respectively. In fiscal 2000, the Company derived revenues from a single customer totaling $1,531,000 or 14% of total sales. Revenues derived from export sales amounted to approximately $3,537,000, or 32% of total sales, in 2001 and $4,492,000, or 41% of total sales, in 2000. Export sales to Europe were approximately $1,991,000, or 18% of total sales, in 2001 and $2,014,000, or 18% of total sales, in 2000. Export sales to South America were approximately $1,013,000, or 9% of total sales, in 2001 and $1,321,000, or 12% of total sales, in 2000.

14. Geographical Information

The Company considers its manufactured kits, tests and instruments as one operating segment, as defined under Statement of Financial Accounting Standards No. 131 "Disclosures about Segments of an Enterprise and Related Information."

The following table sets forth revenue and assets by geographic location.

Origin of revenues	United* States	Brazil	Consolidated
September 30, 2001:			
Revenues	$10,067,897	$902,661	$10,970,558
Long-lived assets	2,379,947	87,077	2,467,024
September 30, 2000:			
Revenues	$9,952,578	$1,043,026	$10,995,604
Long-lived assets	3,325,585	75,097	3,400,682

* Includes export sales to Europe of approximately $1,991,000 and $2,014,000 in 2001 and 2000, respectively.

15. Commitments

The Company leases certain office and manufacturing facilities under noncancelable operating leases expiring through 2007. Future minimum lease commitments under the noncancelable operating leases are as follows:

Leases

Years ending September 30,	2001
2002	$499,664
2003	242,343
2004	228,930
2005	212,633
2006	200,843
Thereafter	133,318
	$1,517,731

Rent expense approximated $564,000 and $585,000 in 2001 and 2000, respectively.

Retirement Plan

The Company maintains a defined contribution retirement plan, which qualifies under Section 401(k) of the Internal Revenue Code, covering substantially all employees. Participant contributions and employer matching contributions are made as defined in the Plan agreement. The Company's contributions to the Plan amounted to approximately $56,000 and $67,000 in fiscal 2001 and 2000, respectively.

15. Commitments (Continued)

Employment Contracts

As of September 30, 2001, the Company has one executive employment agreement in effect. The agreement provides for an aggregate base salary of $144,000 for fiscal 2001 and performance bonuses, as defined. The contract is effective throughout the executive's employment with the Company. The agreement further provides that, in the event the Company terminates the executive for defined reasons, the Company would be obligated to make a one-time severance payment equal to the executive's annual base salary.

16. Supplemental Disclosure of Cash Flows Information

September 30,	2001	2000
Cash paid for interest	$522,124	$402,192
Disclosure of non-cash investing and financing activities:		
Issuance of stock options to employees in satisfaction of amounts previously accrued	142,501	-
Issuance of 100,000 shares of common stock in satisfaction of debt due to Dade Behring	100,000	-
Issuance of 110,000 shares of common stock on the conversion of debt	50,048	-
Issuance of 54,632 shares of common stock in lieu of cash payments	42,000	-
Fair value of warrants issued to non-employees	-	186,207

SIGNATURES

In accordance with Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

HEMAGEN DIAGNOSTICS, INC.

Date: December 20, 2001

By: /s/ William P. Hales
William P. Hales, President

In accordance with the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the date indicated.

Name	Capacity	Date
/s/ Jerry L. Ruyan Jerry L. Ruyan	CEO and Chairman of the Board of Directors	December 20, 2001
/s/ William P. Hales William P. Hales	President and Chief Operating Officer, Director	December 20, 2001
/s/ Ricardo M. de Oliveira Ricardo M. de Oliveira, M.D.	V.P. Research and Development, Director	December 20, 2001
/s/ Alan S. Cohen, M.D. Alan S. Cohen, M.D.	Director	December 20, 2001
/s/ Howard F. Curd Howard F. Curd	Director	December 20, 2001
/s/ Thomas A. Donelan Thomas A. Donelan	Director	December 20, 2001
/s/ Christopher P. Hendy Christopher P. Hendy	Director	December 20, 2001
/s/ James R. LeRoy James R. LeRoy	Director	December 20, 2001
/s/ Deborah F. Ricci Deborah F. Ricci	Principal Financial Officer	December 20, 2001

Exhibit 23

Consent of Independent Certified Public Accountants

Hemagen Diagnostics, Inc.
Columbia, MD

We hereby consent to the incorporation by reference in the Prospectus constituting a part of the Registration Statements on Form S-3 (Nos. 33-80009, 333-06147, 33-40606 and the Registration Statement on Form S-8 file No 333-03718) of our report dated November 21, 2001, relating to the consolidated financial statements of Hemagen Diagnostics, Inc. appearing in Hemagen's Annual Report on Form 10-KSB for the year ended September 30, 2001.

Grant Thornton, LLP
Baltimore, Maryland
December 18, 2001

Executive Officers

Jerry L. Ruyan
Chairman and Chief Executive Officer

William P. Hales
President and Chief Operating Officer

Ricardo M. De Oliveira, M.D.
Vice President, Research & Development

Deborah F. Ricci
Chief Financial Officer

Board of Directors

Jerry L. Ruyan
Chairman and Chief Executive Officer

Alan S. Cohen, M.D.
Professor of Medicine
Boston University School of Medicine

Ricardo M. De Oliveira, M.D.
Vice President, Research & Development

Howard F. Curd
President and Chief Executive Officer
Jesup & Lamont Group Holdings, Inc.

Thomas A. Donelan
Secretary
Member, Redwood Holdings, Inc.

William P. Hales
President and Chief Operating Officer

Christopher P. Hendy
Member, Redwood Holdings, Inc.

James R. LeRoy
General Manager, Cogent Technologies, Ltd.

Corporate Facilities

Hemagen Diagnostics, Inc.
9033 Red Branch Rd.
Columbia, MD 21045
443-367-5500

Reagents Applications, Inc.
8225 Mercury Court
San Diego, CA 92111
858-569-8009

Hemagen Diagnósticos Comércio, Importação e Exportação, Ltd.
Rua Diogo Moreira 222, Pinheiros
São Paulo-SP-CEP-05423-010 Brazil
011 55 1138 195222

Special Counsel

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1400 Provident Tower
One East Fourth Street
Cincinnati, Ohio 45202

Independent Accountants

Grant Thornton, LLP
Suite 700
Two Hopkins Plaza
Baltimore, MD 21201

Transfer Agent & Registrar

Continental Stock Transfer & Trust Co.
17 Battery Place
New York, NY 10004
212-509-4000

Form 10K & Investor Relations

Copies of the Company's 2001 annual report on Form 10-KSB as filed with the Securities and Exchange Commission may be obtained free of charge by writing to:

Hemagen Diagnostics, Inc.
9033 Red Branch Rd.
Columbia, MD 21045
ATTN: Investor Relations

Market for Securities

NASDAQ
Trading Symbol: HMGN

Notice of Annual Meeting of Stockholders

The Annual Meeting of Stockholders will be held February 27, 2002, at 10:00 A.M. at the Columbia Hilton
5485 Twin Knolls Road
Columbia, MD 21045

Hemagen Diagnostics, Inc.
9033 Red Branch Road
Columbia, MD 21045
(443) 367-5510
(800) 436-2436