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CARESIDE INC
Form 10-K
March 28, 2002

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended: December 31, 2001

Commission file number: 001-15051

Careside, Inc.
(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

Delaware
(State or other jurisdiction
of incorporation or organization)

23-2863507
(IRS Employer Identification No.)

6100 Bristol Parkway, Culver City, CA 90230
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (310) 338-6767

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

Common Stock, par value \$.01 per share
and
Redeemable Common Stock Purchase Warrants
(Title of Class)

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

None

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

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

On March 22, 2002, the aggregate market value of the Registrant's Common Equity, par value \$.01 per share, held by non-affiliates of the Registrant was approximately \$3.6 million, based upon the closing sale price reported for such date on the American Stock Exchange. For purposes of this disclosure, shares of

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Common Stock held by persons who hold more than 5% of the outstanding shares of Common Stock and shares held by officers and directors of the registrant have been excluded because

such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily conclusive for other purposes.

On March 22, 2002, 19,066,335 shares of the Registrant's Common Stock, par value \$.01 per share, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Proxy Statement to be filed with the Commission in connection with the Annual Meeting of Shareholders scheduled to be held on May 15, 2002 are incorporated by reference into Part III of this Form 10-K.

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PART I

The Company's forward-looking statements in this Annual Report on Form 10-K and those that may be made in the future by or on behalf of Careside, Inc., including statements about the market and opportunity for the Company's products, revenue growth and profitability potential, regulatory approvals, competition, the ability to control expenses and international expansion, are based on assumptions about many important factors. Several important factors may cause the Company's actual results to differ materially from those contemplated by these forward-looking statements. These factors include the Company's limited operating history, and lack of profitability, its need for additional financing, the acceptance of the Company's products by the medical community, product development risks, the level of third party reimbursement for medical tests, reliance on third party manufacturers, suppliers and distributors, retention of key personnel, competitive risks, protection of the Company's proprietary technology, and government regulation.

Item 1. Business

General

We have developed and sell a proprietary blood testing system. It is designed to decentralize laboratory operations. The system provides cost-effective, accurate test results within 10 to 15 minutes at the point-of-care, for a comprehensive menu of routine blood tests. Because it provides rapid test results, the Careside system can also perform blood tests required for critical care testing. The Careside system performs chemistry, electrochemistry, coagulation and hematology tests. Tests in these different test categories comprise the vast majority of blood tests ordered. No other point-of-care product currently in the market offers as broad a menu of tests or combines these test categories. Our goal is to make the Careside system the standard for routine and critical care blood testing. If we are successful, diagnostic information will travel more rapidly and healthcare costs for physicians, providers and payers will be reduced.

The Careside system consists of the Careside Analyzer and disposable test cartridges, the H-2000 and the Careside Connect. The Careside Analyzer is easy to use and can be operated by a non-technical person with appropriate training in connection with use of the device. Its software will enable the user to capture all data required to comply with the Clinical Laboratory Improvement Amendments of 1988. This law, commonly called CLIA, governs quality assurance and quality control processes and reporting for healthcare providers. The H-2000

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is our hematology testing device. The Careside Connect is a data interface, which will link the Analyzer with the H-2000 and any other testing device. It also enables the electronic transmission of blood test results to our customers' information systems.

The FDA has granted pre-market clearance for the Careside Analyzer and the H-2000, and pre-market clearance or exemption for 42 blood tests performed by the Analyzer and an 18-parameter hematology test for the H-2000, including tests for professional laboratory use. We have received FDA approval for point-of-care testing for the Careside Analyzer, thereby enabling non-technical personnel with appropriate training to use it. Similar approvals will be sought for the H-2000 in 2002.

Our concept and technology originated with SmithKline Beecham Clinical Laboratories, Inc. (SBCL). In 1993, SBCL conducted extensive surveys of the point-of-care market. As a result, in 1994, SBCL started our predecessor business to develop the technology we use today. In November 1996, we acquired the assets and contracts used in the predecessor business, including intellectual property, equipment and other assets to continue the development of point-of-care diagnostic technology and to create a commercial product. Several senior members of our management team worked on this point-of-care project at SBCL, including W. Vickery Stoughton, our Chief Executive

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Officer, and Thomas H. Grove, Executive Vice President--Chief Technology Officer. Quest Diagnostics Incorporated later acquired SBCL.

Careside's Strategy

Our goal is to make point-of-care testing with the Careside system the standard of care for routine and critical care blood testing. If we are successful, diagnostic information will travel more rapidly and reduce healthcare costs for physicians, providers and payers. Most point-of-care companies have focused solely on the critical care testing market with a limited number of tests. In contrast, we have developed the Careside system to replace large analyzers and decentralize testing to the point-of-care, reducing reliance on centralized testing services.

Careside's Technology and Products

We designed the Careside system as a platform for solving the limitations of central blood testing laboratories and a means for healthcare providers not currently conducting blood tests to start providing this service. The advantages of our system can be summarized as follows:

- .. Cost-Effective Results-- The Careside system is designed to provide test results that are cost competitive with commercial laboratories.
- .. Rapid Test Results--The Careside system furnishes test results within 10-15 minutes from the time blood is drawn from the patient. The Careside system can test from one to six cartridges in this time period. By comparison, 24 hours or more may elapse before a healthcare provider has in hand the results of blood tests performed at commercial laboratories, and four to five hours may elapse before results are in the provider's hands for a blood test performed at a hospital laboratory.
- .. Comprehensive Test Menu--The Careside system offers a broad menu of the most commonly ordered blood tests, including critical care tests. The Careside system is designed to perform hematology, chemistry, electrochemistry, coagulation and immunochemistry tests. Our Careside

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system has clearance or approval for 60 tests, including 18 hematology tests. This, we believe, substantially exceeds the capabilities of any point-of-care system currently on the market.

- .. Ease of Use--The Careside system can be easily operated and maintained by non-technical personnel with appropriate training in connection with use of the device. The test process does not require separate centrifuging or sample splitting, and automatically doses and mixes the patient's blood sample with reagents within the cartridges or with the reagents in the H-2000. Data transfer is easily accomplished using the Careside Connect product to connect data into local area networks or through the Internet.
- .. Industry Standard Technology--The Careside system uses many test methods that are the same as those used in hospital and commercial laboratories. The Careside system's technology is a miniaturization of the state-of-the-art technology in larger testing devices utilized by centralized laboratories.
- .. Embedded Quality Assurance and Quality Control--The Careside Analyzer and the H-2000 have operating software designed to assist in meeting the quality assurance and quality control documentation requirements of the Clinical Laboratory Improvement Amendments of 1988.
- .. Ability for Practice Enhancement-- The Careside system's rapid test results enable a provider to make clinical decisions more quickly, see more patients, eliminate time spent reviewing records and

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making follow-up telephone calls, and improve patient satisfaction and quality of care. Healthcare providers can also increase their revenue by performing and billing for tests themselves. Currently it is the laboratory, not the physician, which gets paid for performing blood tests.

The disadvantages of our system stem from the fact that it is a new way of providing laboratory testing services, so we cannot predict with certainty how fast or whether the market will adopt it. We have spent more than \$60 million through 2001 and we will need one or more further financings before the Company will be profitable. As with any new technology, it involves an expenditure of cash and some learning time by physicians and other healthcare providers. Furthermore, our system does not perform all in vitro tests. More complex tests that are not supported by our decentralized testing system, such as microbiology, genetic and other less common tests will still be referred to commercial laboratories or to a core laboratory supporting multiple hospitals. Centralized laboratories that continue to provide such complex testing should, with routine tests handled elsewhere, be able to streamline procedures. We think this will lower the cost of complex testing. With lower costs of centralized testing and the Careside system for decentralized testing, we expect that the entire testing process will become more efficient and cost effective.

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PRODUCT DEVELOPMENT AND REGULATORY STATUS

The following chart summarizes the status of development of each of our products.

PRODUCT DEVELOPMENT AND REGULATORY STATUS

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| PRODUCT | REGULATORY/DEVELOPMENT STATUS | | TECHNOLOGY PARTNER/.SUPPLIER |
|----------------------------|---|---|------------------------------|
| Careside Analyzer | Cleared under Section 510(k) of the Food, Drug and Cosmetic Act for use in licensed laboratories and for Point-of Care (POC). The Analyzer is offered for sale to customers. | | UMM Electronics, Inc. |
| Disposable Test Cartridges | Chemistry, electrochemistry and coagulation cartridges have been developed and are offered for sale to customers. The immunochemistry test cartridge is in development. | | Battelle |
| Test Category | Cleared/exempt for | Planned 2002-3 | |
| | Laboratory and POC Use | Submissions | |
| Chemistry | Glucose BUN (Urea Nitrogen) Creatinine BUN/Creatinine Ratio Albumin A/G Ratio (calc.) Globulin (calc.) Creatine Kinase Creatine Kinase MB % CKMB (calc.) Total Cholesterol HDL-Cholesterol* LDL-Cholesterol (calc.) Cholesterol/HDL Chol Ratio GGT ALT Cholinesterase* Total Bilirubin Phosphorus Total Protein Total Calcium Uric Acid Triglycerides LDH Bilirubin, Direct Bilirubin, Indirect (calc.) Ammonia* Carbon Dioxide, Total Anion Gap (CO2+Echem) Magnesium Osmolality Hemoglobin* Hematocrit (calc.) Alkaline Phosphatase AST ALT/AST Ratio Amylase | Lactate Direct LDL-cholesterol Direct HDL-cholesterol | Fuji Photo Film Co., |
| Electrochemistry | Chloride Potassium Sodium | Ionized Calcium | Fuji Photo Film Co., |

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| | | | |
|-------------|-------------|-----------------------------|-----------------------|
| Coagulation | PT* APTT | Fibrinogen Thrombin Time | Third party suppliers |
|-------------|-------------|-----------------------------|-----------------------|

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| PRODUCT | REGULATORY/DEVELOPMENT STATUS | TECHNOLOGY PARTNER/.SUPPLIER |
|-----------------|---|------------------------------|
| Immunochemistry | Theophylline Phenytoin Digoxin Phenobarbital T4 T3 Uptake Carbamazepine | Third party suppliers |

* Requires separate clearance or exemption for point-of-care.

Product Development and Regulatory Status

| HEMATOLOGY | STATUS OF DEVELOPMENT | TECHNOLOGY PARTNER/SUPPLIER |
|--|---|------------------------------------|
| CARESIDE H-2000 18 parameter, 3 part differential | FDA Cleared; orrered for sale to customers | Third Party Manufacturer Tjhior |
| Hematology Tests WBC RBC Platelet count Lymphocyte % Lymphocyte Monocyte % Monocyte Granulocytes % Granulocytes Hematocrit Hemoglobin MCV MCH MCHC RDW MPV PCT** PDW** | All hematology tests have been FDA cleared under Section 510(k) | Aqua Solutions |

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** For diagnostic use outside U.S., for quality control use within U.S.

| COMMUNICATION PRODUCT | STATUS OF DEVELOPMENT | TECHNOLOGY PARTNER |
|---|-------------------------------|--------------------------|
| CARESIDE CONNECT provides an electronic link between the Careside Analyzer and the Careside H-2000 testing device | Offered for sale to customers | Third Party Manufacturer |

The Careside System

The Careside system currently consists of two desktop testing instruments, called the Careside Analyzer and the Careside H-2000, and patented disposable test cartridges. The Careside Analyzer combines chemistry, electrochemistry, coagulation and, in the future, immunochemistry testing in a single testing instrument. Careside's H-2000 is a hematology testing device. We are not aware of any point-of-care blood testing system on the market that has this combined capability. We have also developed a data

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interface, called the Careside Connect, which allows the electronic transmission of blood test results in a standard data format.

The Careside Analyzer

The Careside Analyzer is approximately 14 inches tall by 12 inches wide and 11 inches deep and weighs about 24 pounds. The exterior is made of high impact resin plastic. The top of the Careside Analyzer consists primarily of a touch screen, on an ergonomic angle, on which the user inputs patient, physician and billing information, the tests to be conducted and any desired commentary. We believe that the Careside Analyzer's user interface software is a significant strategic advantage. For example, its quality assurance and quality control capabilities are equal to those required of central laboratories. The quality assurance and quality control software stores and interprets the quality control data generated using the embedded electronic quality control system in the Careside Analyzer as well as the traditional wet testing quality control approach for test cartridges. After testing, quality control data is flagged when out of limits and plotted on graphs for easy review. A set of five re-usable and proprietary quality control test cartridges will be provided with each instrument which allow the user to perform automated, electronic quality control for all electrochemistry, chemistry and coagulation tests. These reusable quality control test cartridges will replace traditional quality control which involved running multiple levels of commercial plasma specimens for all the tests on the system. The software utilized by the Careside Analyzer is designed to govern testing of one patient at a time, perform quality assurance and quality control documentation and conduct the test ordering processes. It also contains a security system that is compliant with the Clinical Laboratory Improvement Amendments of 1988. The user interface system can be customized for each particular customer.

The Careside system can be operated by non-technical personnel with

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appropriate training in connection with the use of the device. The operator will first select one or more test cartridges from inventory depending on the tests ordered by the attending healthcare provider. Most cartridges will contain one test, but some cartridges will contain two or three tests. Up to six cartridges of a single patient's blood can be tested at the same time. The Careside system is currently capable of conducting a maximum of eight tests per patient in a single 10 to 15 minute test cycle. To prepare a cartridge, the operator will place a small amount of the patient's drawn blood into the test cartridge with a pipette or other standard transfer device. The operator will then simply load the test cartridges into the instrument. Any combination of cartridges can be loaded in any order, thus enabling the operator flexibility to perform individual tests or customized panels. This flexibility is designed to minimize waste by allowing the operator to run only the tests ordered by the provider rather than traditional pre-set panels that may contain unnecessary tests. This feature is particularly responsive to the current and expected future requirements of third-party payers.

After the operator inputs patient information and test orders, the instrument will automatically perform the tests and record and display or print the results. To perform the tests, the Careside Analyzer undertakes cycles for heating, centrifuging and several types of reading. The cycle time from the moment the cartridge is dosed with whole blood and placed into the Careside Analyzer to final test result is approximately 10 to 15 minutes for chemistry, electrochemistry, immunochemistry or coagulation tests, or any combination of these tests. A standard Chem 7 panel, comprised of sodium, potassium, chloride, carbon dioxide, glucose, creatinine and urea nitrogen tests, can be performed in approximately ten minutes and will utilize five cartridges. Sodium, potassium and chloride tests are on one cartridge as they are always ordered in combination. At the conclusion of the test, the Careside Analyzer ejects the cartridges into a waste container for later disposal in appropriate biohazard vessels.

The Careside Analyzer provides test results to the healthcare professional in several ways. A self-adhesive label can be printed with test results for direct transfer to the patient's chart. Each Careside Analyzer also incorporates a floppy disk drive so that information can be downloaded from the instrument for analysis. An additional electronic output method is through use of the rs-232 port on the rear of the

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machine. Our data interface, called the Careside Connect, allows the electronic transmission of blood test results in a standard data format.

The Analyzer's Disposable Test Cartridges

Each test cartridge is designed to perform one test and may only be used once. Each test cartridge is designed to facilitate the flow of the blood, serum or plasma specimen onto chemicals packaged in the cartridge. These chemicals, which are called reagents, react with the specimen and change. The changes are then read by the Careside Analyzer to yield the test result. Its various channels and pools assure proper reagent and specimen temperature equilibration, sample separation, sample metering, sample dispensing, test incubation and facilitate result detection. Each cartridge contains all reagents necessary to perform a reagent measurement on a serum, plasma or whole blood sample for a particular test. The proprietary cartridges are each approximately 2.5 inches long and 1.5 inches wide and are comprised of layers of molded plastic with channels for application of the sample to the reagent. When stored in refrigerators, the cartridges are expected to have a 9 to 18 month shelf life. The cartridges are placed in the Careside Analyzer directly from the refrigerator after sample dosing. The first four minutes of the test cycle warms the test cartridges to the appropriate test temperature. If necessary, the

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Careside Analyzer then spins the cartridges using centrifugal force to push the sample through small channels, separating it into serum or plasma. Excess sample is deposited in an overflow well. A measured amount of sample remains in the metering passage and is dispensed onto the reagent film or mixed with wet reagent pushed from an interior pouch. Each test cartridge is designed to be airtight to prevent ventilation spoilage of the specimen sample.

The three basic types of measurements that will be made are spectral transmittance, reflectance and electrochemical. Chemistry tests are used to assess general health status as well as to diagnose and monitor diseases of the major organ systems such as the heart, liver, kidney, blood, pancreas, endocrine and bone. The film chemistry cartridges contain dry chemistry reagents which are stacked as required for the test. The Careside Analyzer's platter spins the cartridge containing the dry film, which will turn color from reaction with the blood element, over LED/photodiode pairs. The LED lights reflect the colors of the reagent. Multiple reflectance measurements are performed to yield a result. In the case of coagulation and immunochemistry tests, the cartridge is spun over the same LED/photodiode pairs which shine through a small rectangular hollowed prism, called a prismatic cuvette, built into the cartridge. The light transmission is then read by the Careside Analyzer.

Electrochemistry Tests. Like chemistry tests, electrochemistry tests are used to assess general health status and to diagnose and monitor diseases of the major organ systems such as the heart, liver, kidney, blood, pancreas, endocrine and bone. The electrochemistry cartridge contains an ion specific electrode slide. When the slide reacts with the sample, which in this case is whole blood, it generates values that correlate to the concentration of sodium, potassium and chloride in the sample. The test compares an electrochemical signal generated from a reference solution to a similar signal generated from the patient's blood. The reference solution is a liquid contained in a pre-filled pouch embedded in the cartridge. One side of an ion specific electrode slide is exposed to a reference solution during the testing sequence and the other side is exposed to the patient's whole blood. The Careside Analyzer reads the difference between the two, thereby generating the test result.

Coagulation Tests. Coagulation testing assesses the ability of a patient's blood to coagulate. Coagulation is the series of events that leads to the formation of a blood clot. Tests of prothrombin time, or PT, and activated partial thromboplastin time, or aPTT, are the primary coagulation tests used by both physicians and hospitals. Reagents from the coagulation test cartridge are contained inside a small hollowed prism, called a prismatic cuvette, and in a pouch. Plasma is delivered to the cuvette by pressurization of the membrane on the cartridge. A second reagent, such as a buffer or calcium chloride, is added via the pouch. Light is then transmitted through the cuvette. The coagulation reaction causes a

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change in the cloudiness, or turbidity, of the plasma that is detected optically by the Careside Analyzer. The time it takes for this optical change to occur is reported out as the coagulation time.

Immunochemistry Tests. Immunochemistry tests are used for the diagnosis of drug effectiveness for heart, thyroid analysis and for other purposes. To date, immunochemistry systems have had limited penetration in the point-of-care market. Generally, they are difficult to use, involve expense instrumentation and costly reagents and have long assay times. We are in the process of developing an immunochemistry test cartridge.

The immunochemistry test cartridge is identical in form and function to the coagulation test cartridge except that a much smaller sample size is

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delivered to the prismatic cuvette. The reagents in the cuvette and pouch are different for each immunochemistry test. The Careside Analyzer measures a rate of change or endpoint in cloudiness depending on the test. The rate of change or endpoint is converted from calibration information coded in the Analyzer and on the test cartridge, generating a test result.

The disposable test cartridges have a number of key features that we believe contribute to the Careside system's reliability, speed, low cost and accuracy of analysis:

- .. Unique Cartridge Design. Specimen preparation, calibration and test performance are incorporated in an inexpensive plastic cartridge. Where necessary, the cartridge stores and measures delivery of reagents and electrolytes for mixing with the patient's sample prior to analysis. Cartridges are loaded into the instrument manually and are designed so that they can be inserted in only one direction to avoid error.
- .. Ease of Sampling. Sampling is automatic and requires small volumes using approximately 75 to 150 microliters (ul) of whole blood, as compared to current approaches requiring much larger amounts. The dosing process requires the tester to fill the cartridge well to a point indicated on the cartridge. No precise measurement of the blood sample is required by the tester, as the cartridges' channels measure how much sample is applied to the reagent.
- .. Built-in Centrifuge. Separation of plasma from whole blood, as required for many tests, is accomplished in the cartridge after placement in the Careside Analyzer, so that a separate centrifugation step is unnecessary.
- .. Flexibility in Testing. One, two or three tests may be contained in each cartridge. Single test cartridges and a three test cartridge have been designed, manufactured and used in testing. Two test cartridges have been designed, but have not yet been manufactured or used in testing. The added cost and complications of using test panels containing unnecessary tests is avoided.
- .. Quality Assurance and Quality Control Features. All test cartridges are bar-coded for test identification. The bar codes identify the type of test contained in cartridge, as well as a lot number, expiration date and self-calibration information, which are all CLIA requirements. The data from the cartridge's bar code is read and stored in the Careside Analyzer. As each test is completed, it becomes part of the CLIA documentation. Because each cartridge contains an identifying bar code which is read by the instrument, the order in which the cartridges are loaded is immaterial. The Careside system will check that the ordered tests and the cartridges entered in the device match.

The H-2000 Hematology Testing Device

Hematology testing determines various attributes of a patient's blood, such as how many platelets, monocytes or lymphocytes it has. The H-2000 is a high quality, low cost hematology analyzer that was designed for both human and animal testing. Its hematology tests are equally applicable in the

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veterinary and human markets. The H-2000 weighs 37 lbs. and measures only slightly larger than a cubic foot. It can provide 18 hematology diagnostic tests in approximately 2 minutes from the time whole blood is drawn from a patient. The H-2000 uses fluid reagents that can be purchased from us or other manufacturers. The architecture is an open system that allows the H-2000 to

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operate with a number of different reagent brands, giving it a high level of flexibility. The H-2000 is automatic and self-cleaning. It is designed to flag suspected abnormalities in various cell populations.

The H-2000 is easy to operate. A few drops of blood are drawn into the H-2000 through an aperture from either a normal test tube or a capillary tube used in a finger prick. The blood is automatically distributed into counting chambers. Reagents are mixed or used in counting chambers in combination with both optical and electronic counting methods which perform up to four cross-referenced measurements per sample, thereby ensuring accurate counts. The reagents and cleaning fluids are flushed into a disposal bottle for standard blood sample disposal.

The Careside Connect

We have partnered with Advanced Medical Information Technologies, Inc., also known as AdMIT, to develop a link between the Careside Analyzer and the H-2000 and between the Careside system and other medical devices and information systems. This cabled interface will enable users of the Careside Analyzer to connect hematology devices (including the H-2000) and other diagnostic test devices into the Careside Analyzer, thereby allowing the users to further avail themselves of the Careside Analyzer's extensive ordering, data storage, clinical records and quality assurance and quality control capabilities. AdMIT is controlled by our Chief Information Officer, Dennis Rieger. We will have exclusive rights to use the Careside Connect in the point-of-care market for laboratory testing services.

In addition to linking the Careside Analyzer and the H-2000 or other diagnostic testing devices, Careside Connect can be connected directly into laboratory or clinical information systems, physician practice management systems or other information systems, either directly through a local area network or via the Internet.

The Laboratory Testing Market

General

The annual U.S. market for laboratory testing services is about \$30 to \$35 billion according to industry research. Clinical Laboratory Improvement Amendments (CLIA) data and Washington G-2 reports show that hospitals do 60-65% of this testing, physician offices 7-8% and independent commercial labs 25-30%. The lab services market can be divided into three primary segments: routine clinical testing (blood or urine testing), anatomic pathology (tissue) and complex testing (DNA and genetic testing). All three comprise in vitro testing, which means the testing is done on a sample outside the body. In vivo testing is done in the body. Annual expenditures for routine in vitro testing are over \$25 billion in the U.S. and it is this segment that is served by the Careside system. Routine in vitro tests are semi-automated on our system and can be conducted by non-technical personnel. Therefore, our market opportunity is virtually wherever blood is drawn from patients for standardized blood tests. Based on industry data and estimates, we believe the worldwide market for our blood tests is expected to be over \$7 billion.

Most routine blood tests are currently sent to a central location, either a commercial or hospital laboratory, for processing, although some physicians do the testing in their offices.

Commercial Laboratories. Commercial laboratories have been the low cost

provider of in vitro blood testing services due primarily to economies of scale in testing multiple samples in large analyzers. Commercial laboratories' testing expenditures relate predominantly to labor intensive functions such as

distribution, customer service, general administration, communication technology and preparation of the blood sample. There are numerous steps involved in obtaining test results from commercial laboratories. Blood samples are collected throughout the day from a variety of sources including hospitals, physicians' offices, nursing homes and home care agencies. The samples are transported to the laboratory, usually with special care in packaging to preserve sample integrity. After the samples arrive at the laboratory, several administrative tasks are necessary as thousands of samples are processed daily. Each sample is split into tubes that are then sorted for testing in multiple large analyzers. The high throughput analyzers require the attention of highly skilled technicians to prepare reagents, prime multiple pumps, calibrate, prepare and load blood samples, conduct centrifuge operations, process measurement data and report results. This complex process must be tightly controlled at each step to ensure both administrative and analytical accuracy. Tests are generally run overnight and results are sent back to the healthcare provider the following day. This factory-like process limits the ability to provide test results in less than 24 hours. If results are required sooner, certain laboratory operations must be interrupted, resulting in significantly increased costs.

Hospital Laboratories. The process in hospital laboratories is very

similar. Blood samples are typically collected in the early morning with tests performed late morning and early afternoon. Results are generally returned within four to five hours. However, in many instances, hospitals must respond to critical patient conditions and conduct tests on an immediate basis in order to support the healthcare provider when a patient's condition is life threatening. A hospital must be able to process these critical care tests 24 hours a day. This requires the hospital laboratory to remain open whether or not any tests are being conducted. With insufficient testing volume to absorb laboratory operating expenses and capital costs, tests performed in hospital laboratories are more expensive.

Physicians' Offices. Many physicians' offices currently outsource their

testing to commercial or hospital laboratories. This practice is largely the result of the enactment of the Clinical Laboratory Improvement Amendments in 1988. CLIA was an attempt to ensure the quality and reliability of laboratory test results by placing more stringent administrative and regulatory burdens on testing conducted in the physician's office. Under CLIA, technicians conducting complex tests must meet detailed proficiency requirements and must have established well-defined quality assurance and quality control programs. As a result, for most individual physicians, diagnostic testing became too burdensome and costly to justify being done in the office.

Managed Care's Impact on Blood Testing

Managed care has put substantial pressure on healthcare providers to reduce costs and to treat patients using clinical treatment protocols for many chronic and acute illnesses. These protocols frequently contain diagnostic tests that are used to help avoid the occurrence of acute episodes of illness. Diagnostic blood and urine testing are two of the major tools used in these protocols for early detection and ongoing evaluation of treatment efficacy. On the one hand, these pressures should increase testing volume. On the other hand, managed care providers and other payers are becoming more stringent by only reimbursing tests for which there is a clear medical need. Medicare and other third party insurance reimbursement for diagnostic tests flow directly to the laboratories performing the testing, not the healthcare professional ordering the test, but the laboratories are responding with making only single analyte

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and approved panel testing available to providers. We expect these pressures to continue to cause healthcare providers to order individual diagnostic tests instead of "panels," or pre-determined groups, of tests performed at one time. Managed care providers and payers will reimburse all tests in a panel only if there is a clear medical need for each. As managed care pressures mount to perform only medically necessary tests, reimbursement rates for individual tests have decreased, requiring the healthcare provider and the testing laboratory to be even more cost-effective. Designed with these phenomena in mind, the Careside system performs single reagent testing and offers packages of tests that are based on third-party payer approved panels.

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Many managed care entities dictate to their member physicians which laboratories they must use for blood testing. Physicians have the opportunity to utilize exceptions to these mandates to conduct in-office testing. The Careside system enables physicians to offer laboratory testing services and take advantage of these exceptions to the managed care organizations' policies. We expect to facilitate this by working closely with the physicians and the managed care organizations to demonstrate cost effectiveness and cost reduction from use of our system.

Even with the focus on managed care, a very significant portion (approximately 70%) of all testing is reimbursed on a fee for service basis. Industry experts expect this number to increase further as commercial laboratories renew managed care contracts. Previously, managed care companies pushed for capitated testing services. Many commercial labs lost money on these contracts, and, as the contracts come up for renewal, will push to convert them to fee for service contracts, pay higher capitation amounts or not renew them. We expect these factors to contribute significantly to making the Careside system a desired alternative to central lab testing.

Marketing Strategy

Our marketing strategy is to position the Careside system as the blood testing system of choice by demonstrating to hospitals the benefits of decentralized blood testing, and by providing other healthcare providers, such as physicians/physician groups and nursing homes, with a profitable and cost-effective alternative to central laboratory testing.

Our key targeted market segments are as follows:

Physicians and Physician Groups. There are over 400,000 physicians and -----
more than 27,000 physician groups in the United States. 21,000 of these groups have three to ten doctors and over 3,500 have more than 35 physicians. Physicians usually obtain their laboratory testing services from the hospital laboratories with which the physicians are affiliated or from a commercial laboratory. In either case, patient samples are collected from the physician's office and sent via courier to the applicable laboratory, with results delivered to the physician, either electronically, by fax or by telephone. For physician group practices, the Careside system will offer improvements in daily office routine, greater convenience, enhanced patient satisfaction and new revenue opportunities.

Hospitals. There are over 5,000 acute care hospitals in the United States. -----
Laboratory testing services required by hospitals are usually provided by a central hospital laboratory, which services all of the hospital's testing needs as well as the testing service needs of hospital physician groups. Hospital laboratories are expensive to maintain because they have to be maintained on a

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24 hour basis, they require specially trained personnel to be present at all times to operate high volume analyzers and they demand significant amounts of capital to equip and maintain. Furthermore, hospitals are often reimbursed by institutional payers for patient admissions based on specific diagnoses reflecting the complexity of the care needed and a predetermined payment for such care. While laboratory testing services are an essential part of diagnosis and monitoring the beneficial results of treatment, they also represent a cost to the hospital as it seeks to generate a profit by completing the care and treatment of patients before their costs exceed the level of reimbursement. The Careside system provides hospitals with the opportunity to decentralize laboratory testing to the patient floors and bedside, as routine and stat tests can be conducted at the time the patient is being evaluated by providers. Consequently, the Careside system is expected to enable some hospitals to eliminate their central laboratories or replace certain costly analyzers and outsource non-routine testing not done on the Careside Analyzer to a centralized laboratory.

Nursing Homes. There are approximately 15,000 nursing homes in the United States comprising more than 1.6 million licensed beds. Occupancy rates average over 90%. Common diagnostic tests ordered for nursing home patients are complete blood counts, Chem 7 panels, electrolytes, blood glucose, prostate specific antigen, therapeutic drug monitoring and urinalysis. Nursing homes generally obtain

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their testing services from commercial laboratories and encounter the same delays and reimbursement issues as physicians. The Careside system provides a profit opportunity to the nursing home by allowing it to conduct and bill for laboratory services, while simultaneously enhancing the nursing home's ability to provide better care.

Home Care. In the 1990s, the number of home care agencies nearly doubled and home care visits increased dramatically to over 300 million annually. Industry experts expect the increase to continue. On average, 30% of home care patients visited each week require laboratory testing. There are currently over 20,000 home care agencies in the United States, with approximately 9,600 Medicare certified. Common laboratory tests ordered for home care include, among others, Chem 7 panels, iron, blood glucose, magnesium, prothrombin time and immunochemistry tests for monitoring phenobarbital, phenytoin and digoxin. Patient samples are drawn from the patient, gathered from the home care providers and delivered via courier to a commercial laboratory for testing. Test results are made available the next day or on a premium price basis by fax, telephone or written report delivered four or five hours later. The Careside Analyzer is expected to enable the home healthcare provider to draw the patient's sample, run the test and deliver the results without having the sample delivered via courier to a commercial laboratory. Home care agencies would benefit from increased revenue opportunities and client service by using the Careside system to conduct blood testing in their base offices.

Other Market Opportunities. Field military hospitals, ships, employee health clinics, drop-in clinics, surgi-centers, dialysis units and other alternate sites where blood is drawn and routine tests are ordered are all potential customer opportunities for Careside.

Sales Strategy

Domestic

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Careside has hired a small sales force to launch and train customers on its products in the United States. We supplement our domestic sales force with distributors. Our sales force is compensated on a base plus commission basis. The commission increases with volume sold. We sell to distributors at a discounted purchase price. We have created a distribution network with more than 1000 distributor reps under contract working through our distribution partners in the United States, including 750 distributor reps who joined the distribution force in the last quarter of 2001.

Our focus is currently the US market and on selling decentralized lab operations and not just testing devices. The Clinical Laboratory Improvement Amendments (CLIA) require all providers who provide testing services to demonstrate quality control (QC) and quality assurance (QA) processes that are standard to the industry. Prior to CLIA, only commercial and hospital labs had demonstrated these standards. CLIA added both cost and administrative difficulty to those labs that did not meet these operating requirements. Our products are easy to use and address the regulatory issues required by CLIA. They also greatly lower the cost of QA/QC processes by automatically providing documentation required by CLIA. We are selling a lab that can be operated at the point of care and our sales force has been trained to prepare our customers to operate a lab using our products. This means calibration of each test at the customer site, initial documentation for QA/QC data files, and other preparation work that is related to lab operations. We have trained our sales force with the knowledge needed to sell and install cost-effective lab systems in our customer sites. These sites include hospitals, large physician group practices, managed care organizations, home care agencies and nursing homes, either directly or through institutional pharmaceutical service organizations which serve them.

We focused our domestic sales strategy during 2001 on sales of Analyzers and H-2000s in the human blood testing market. This represents a shift away from international and veterinary sales for the H-2000.

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International

International markets are not affected by the same regulatory requirements as in the U.S. market. Because we have received FDA clearance and UL certification for the Careside Analyzer, the Careside system is ready to be sold in almost all international markets once the appropriate documentation has been made available to country authorities. We are in discussions with potential distributors for a number of foreign territories. Our strategy is to pick distributors that are selling products into the health care market, but not competitive products. Further, we are in discussions with country specific distributors as opposed to distributors that are more international. Fuji Photo Film Co., Ltd. has a right of first refusal to be our Analyzer distributor on an exclusive basis in Japan and a non-exclusive basis in other Asian countries. The current agreement with Fuji expires in 2003 and permits automatic annual renewals thereafter subject to cancellation by either party. Careside has distribution partners for its hematology product in the Middle East and in China, Mexico, Turkey, and certain South American countries. We are analyzing the possibility of adding the entire Careside system to these distribution agreements.

Distribution Partners

We supplement our own sales force with distribution agreements. In 2001, we had sales through distributors in three different countries. All distributor sales were on a discounted purchase price basis with no price protections or rights of return. Each of our distributors can sell only in its own country and

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is responsible for compliance with all local or import regulations. These distributors are also responsible for customer support.

Except for Fuji's right to distribute Analyzers in Japan on an exclusive basis, none of our distribution agreements represents an exclusive arrangement and all are terminable by us or the distributor upon giving appropriate notice. The cancellation or termination of any one distribution agreement would not be material to our future operations, with the exception of the time it would take to train distribution staff, because we could use other distributors in each of the countries where we currently use distributors.

Sales

Careside Analyzers

In December 1999 through the beginning of 2000, we initiated a number of Analyzer installations in pilot sites. These pilots involved assessing both the economic opportunity provided to the customer from the use of the Careside system, refining an instruction manual which is intended to provide customers with the information they need to operate a lab using the Careside system, reviewing user interface software and making changes, and working out bugs. Careside also used this time to improve mechanical components and manufacturing processes. One pilot was started at a small group practice that had never run a lab. Another was with a larger group that has been operating a lab prior to becoming a pilot site. Other pilots were initiated in a hospital emergency room and in larger health care systems.

Careside sold four Analyzers during the first nine months of 2000. During the second quarter of 2000, Careside was experiencing issues in both the software and hardware of the Careside Analyzer that made it question the reliability of the device in the field. It also experienced technical problems with electrochemistry tests. As a result, Careside pulled back from the market and corrected the issues that gave rise to the reliability concerns. Careside did not lose any customers and it did not have to repurchase any devices as a result of these technical difficulties. Rather, it worked with the customers to ensure the reliability of the test results each customer received from its Analyzer. We completed the revisions to the electrochemistry tests and modifications to the Analyzer by November 2000. Devices in inventory were corrected before being sold, placed in the field or becoming demonstration units. As a result of these events, our backlog of Analyzer orders was immaterial. After the re-launch of the Analyzer, three additional units were sold in 2000.

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Careside began to expand its customer base in 2001. Careside installed its products in 44 beta sites in the first four months of 2001. During the following six months we worked closely with these customers and responded to their observations by making further software improvements and some mechanical changes to the Careside Analyzer. In the last quarter of 2001, we began to aggressively expand our distribution force and signed up more than 750 additional distributor reps half of which were trained by mid December 2001. Careside also began selling its products both directly and through our distributors in the last two months of 2001 so that it ended the year with 57 Careside Analyzers sold and purchases orders for another 8 units.

H-2000s

In 2000, all of our H-2000 sales were into the veterinary market. Approximately, 81% of these sales were sales into foreign countries. 64% of our international sales were to distributors in China. In 2001, our focus on the

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human market meant reduced sales into the veterinary market. We expect these reduced levels to continue in the future. In order to be competitive in the human market, Careside began to upgrade the software, electronics and certain other features of the H-2000 during fiscal 2001. These changes will improve the performance of the H-2000, decrease the cost of manufacturing and better position the product in a very competitive market. As a result of the loss of the key employee important to the hematology business in October 2001, the Company determined that it would no longer focus additional efforts toward the development and sale of the H-2000. The Company intends to cease production of the H-2000 use the sales force and customer base in place to sell the remaining H-2000 units on hand. It is uncertain if the Company will devote resources to the ongoing development and sales of the H-2000 in future periods. The Company will continue to produce and sell the reagents necessary to support the H-2000 units currently in the marketplace.

Careside Connect

We had no sales of the Careside Connect in 2001 as it was under development until late 2001.

Significant Customers

In 2001, the Company had no sales to customers that were individually greater than 10 percent of net sales. The loss of any one of our customers would not be material to our results of operations. We expect our future revenues to be derived predominantly from the sale of Analyzers and cartridges in the U.S. market through distributors. As a result, we may develop concentration with these distributors in the future.

Research and Development

In addition to our own research and development employees, we have entered into a series of research and development agreements with third parties relating to the Analyzer and its disposable test cartridges. As is customary in the industry, these agreements are short term and provide for termination for any reason by either party on relatively short notice. Battelle Memorial Institute, a leader in developing industrial technology, has designed the disposable testing cartridge according to specifications which we provided. All applicable patent rights under this contract have been assigned to us.

We continue to pursue development work with other contract partners, including further development of cartridge design with Battelle and software development services of AdMIT for interfaces between the Careside Analyzer and other medical devices and information systems. This work will continue throughout much of 2002.

Each of our ongoing development agreements provides for payment to our development partners at market or below market rates. Each is terminable upon notice to the other party and in the event of

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breach. We are not aware of any intention of any of our contract partners to terminate their agreements with us. In each case, we believe the cancellation of any one of our development agreements would not be material to us.

Manufacturing and Supply

Analyzers

We have a contract with UMM Electronics, Inc. for the manufacture of the

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Careside Analyzer at UMM Electronics' facility in Indianapolis, Indiana. The contract with UMM covers both development services and manufacturing after development is completed. The development services component of our UMM contract is complete. To date, UMM has manufactured all of our Analyzers pursuant to this contract. The agreement provides for pricing to be renegotiated annually, has a term of four years from market introduction and is terminable by either party upon one year's notice. We own or have the perpetual right to use all intellectual property necessary to manufacture Analyzers in the event of termination of the UMM contract. In 2001, we renegotiated our pricing under the UMM contract. We also took steps toward achieving a second supply source, which are continuing in 2002.

Our inventories of Analyzers were sufficient in 2001 for internal validation and sales to customers. In 2002, as sales are expected to increase, we expect to start using software to track ordering and utilization patterns for Analyzers and cartridges which will assist us in determining proper inventory levels. Pending the data gathering, we are inventorying those Analyzers and cartridges and components used to make cartridges which our management estimates, based on their knowledge of the healthcare field, will be ordered by providers.

Cartridges

We designed and outfitted a building in Culver City, California, of approximately 16,000 square feet in December 1996 as our development facility and offices. The building contains space for our automated assembly system which Battelle Memorial Institute has designed. The assembly system will mount the reagents in the test cartridges, and package and label the cartridges. This facility has been set up to comply with all applicable state and federal regulatory requirements, including registration with the state and federal governments in accordance with applicable laws governing medical devices prior to commercial distribution. The facility is subject to periodic FDA inspection to determine whether our manufacturing processes comply with federal GMP regulations for medical devices. In the fall of 2001 Careside underwent its first FDA inspection and passed the inspection.

We assemble and package at our Culver City facility all cartridges used by the Analyzer. The cartridges are assembled in two main stages. Initially, those components which are not sensitive to humidity, such as plastic parts, are assembled in a normal humidity environment. The second stage of the cartridge assembly process involves the mounting of dry film chemistry strips or pouched reagents in the cartridges, which must be done in a low humidity environment to preserve the film. This step will be performed in an automated assembly line at our facility. We have purchased the equipment necessary for this process. In addition, during the cartridge manufacturing process, our equipment must test the pressure of the ultrasonic seal between the base plate and the upper plates of the test cartridges. Our equipment allows for several inspection steps during the assembly process. Battelle has assisted us in developing the fully automated assembly line for the cartridges with these steps built in. The production capacity of the pilot cartridge production line for chemistry and immunochemistry is approximately 1,800 units per hour or 13,000 units per shift. Depending on the specific tests ordered, our current facility, with additional equipment, will support between \$40 and \$60 million of test cartridge sales annually. The automated production line utilizes proprietary process technology, designed by Battelle and owned by us, that is scalable to meet increasing demand.

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We outsource the manufacturing of the plastic components of our cartridges. We use a third party to manufacture these components using injection

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molding processes.

We have a long-term supply contract with Fuji Photo Film Co., Ltd. for the use of its dry film chemistry reagent technology. Although in dry form, the film uses the same technology as the wet reagent technology used in high volume commercial analyzers. The agreement replaces an earlier agreement with Fuji that was applicable only during the development stage of the Careside system. The new agreement continues to provide us with an exclusive supply of Fuji's dry film chemistry reagents for use in our point-of-care system for more than 30 chemistry tests. We have agreed to purchase our dry chemistry reagents exclusively from Fuji. Fuji is also developing additional chemistry tests at its expense. Any additional tests that Fuji develops may be available to us over the period of the existing agreement, which runs through 2003 and thereafter is automatically renewed on an annual basis.

We purchase other chemistry, electrochemistry, coagulation and immunochemistry reagents from International Technidyne Corporation and Diagnostic Reagents, Inc. We pay for these on a per order basis in accordance with pricing which is periodically revised by the supplier.

Providers will order test cartridges based on the tests they expect to require for patient care. This will vary with the type of provider. At present, we maintain inventories based on management's estimate of the tests that providers will order. In 2002, we expect to start using software which will capture provider's utilization patterns by type of provider. With this data, we expect to be able to refine the level of inventories which we will need to maintain.

H-2000s

Our hematology testing device, the H-2000, is manufactured by Ysebaert pursuant to a contract which we assumed when we acquired Texas International Laboratories, Inc. (TIL) in 1999. Typical of many contracts with European manufacturers, this contract does not contain material terms other than pricing. We believe the pricing available to us from Ysebaert to be competitive. Pricing is periodically renegotiated with Ysebaert. We own or have the right to use all intellectual property rights necessary to manufacture the H-2000 in the event the Ysebaert contract is terminated.

The reagent solutions used with the H-2000 are currently supplied to us by Aqua Solutions, Inc. We do not have commitments to purchase any minimum quantities of solutions from them. Rather, we submit purchase orders on an as needed basis.

As a result of the loss of the key employee important to the hematology business in October 2001, the Company determined that it would no longer focus additional efforts toward the development and sale of the H-2000. The Company intends to cease production of the H-2000 use the sales force and customer base in place to sell the remaining H-2000 units on hand. It is uncertain if the Company will devote resources to the ongoing development and sales of the H-2000 in future periods. The Company will continue to produce and sell the reagents necessary to support the H-2000 units currently in the marketplace.

Careside Connect

The Connect is a cabled interface that does not require any significant manufacturing components as it is primarily software that interfaces between the Analyzer and H-2000 or either of those devices and providers' information systems.

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Competition

We principally compete with manufacturers of traditional diagnostic testing equipment used by centralized laboratories and current point-of-care diagnostic companies whose products perform testing for patients in critical condition. Historically, most clinical testing has been performed in a centralized laboratory setting. These laboratories provide analyses similar to those to be conducted by our system and have traditionally been effective at processing large panels of tests using skilled technicians and complex equipment. While the Careside Analyzer is not designed to provide the same range of tests, we believe that our products offer several advantages over centralized laboratories, including lower costs, mobility, faster results, simplified specimen preparation, reduced opportunity for error through decreased specimen handling, ease of regulatory compliance and increased patient satisfaction.

The lack of timely test results from central laboratories has given rise to a growing market for point-of-care tests. The initial products in the market have targeted point-of-care tests for use in emergency rooms or critical care units and have focused on the testing for critical care patients or tests that are disease specific. Examples of disease specific tests are glucose and digoxin which measure blood sugar levels in diabetic patients or heart complications. In all cases, these companies perform a limited number of tests and their systems are not designed to have their test menus increase. While immediate test results benefit the patient and the healthcare provider, current point-of-care testing devices have added costs to the system as the hospitals must continue to operate a central laboratory using equipment that conducts the same critical care tests as well as a much broader menu of tests required for routine care. Furthermore, current point-of-care devices have not attempted to provide customers with the quality assurance and quality control data storage and retrieval capabilities necessary for CLIA requirements.

We believe that our system offers distinct competitive advantages over these products, including the ability to conduct tests in multiple test categories in a single device, internal centrifugation, convenience and ease of use. Several companies, including i-STAT Corporation, Abaxis, Inc., Diametrics Medical, Inc. and PharmaNetics, Inc., are currently making or developing products that will compete with our tests although not with our system. Some of these companies also provide disease specific tests which we expect will be added later to our test menu.

Some large pharmaceutical companies also have point-of-care blood testing devices and could, given their resources, develop systems which compete with the Careside system. Abbott Laboratories, Inc., Clinical Diagnostic Systems (a division of Johnson & Johnson) and Roche Diagnostic Systems, Inc. all have products which perform point-of-care testing. To date, we believe that none has developed a point-of-care testing system comparable to our system.

Patents and Proprietary Rights

Our policy is to seek patent protection, both in the United States and abroad, for each of the areas of invention embodied in our products. To date, we have filed nine patent applications on various components of our technology with the U.S. Patent and Trademark Office. We have also sought international patent protection with respect to certain of these U.S. patents and patent applications. One patent was filed with International Technidyne Corp. and covers a coagulation reagent that was discovered jointly. The other eight patents cover the technology that is built into the Careside Analyzer and the test cartridges. To date we have been issued three U.S. patents. These patents as well as those still pending form a very strong portfolio that protects our development investment. One patent issued covers our invention of the spectrophotometric analytical cartridge, which allows our product to perform

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light transmission based tests, such as coagulation and immunochemistry in the Careside Analyzer. Another patent covers the fundamental analytical reagent cartridge invention that underlies all of our cartridge technology. The third patent covers our electrochemistry cartridge. Four of the patent applications cover inventions that are components of the Careside Analyzer, and one covers an additional discovery in another type of cartridge.

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Our agreements with UMM, Battelle Memorial Institute and International Technidyne Corporation, assign to us certain proprietary rights that result from the research conducted under the agreements. The Fuji agreement gives us non-exclusive rights to use Fuji's proprietary technology in the Careside system outside of Japan. Only Fuji will sell our system in Japan. The other agreements provide that the technology used in the Careside system is owned either by us or jointly by us and our partner. These agreements do not restrict us, if we choose, from seeking other suppliers of competitive technologies. We will seek to protect any such proprietary rights assigned to us by our technology partners. Battelle and International Technidyne have agreed to share expenses or otherwise assist us in prosecuting patent applications.

In addition to patent protection, if any, we will rely upon trade secrets, know-how and continuing technological innovation. All of our employees are bound by confidentiality/non-disclosure policies or agreements. We have also protected our name by trademarking "Careside" and the name "Careside Analyzer."

Government Regulation

The FDA regulates the development, manufacture, and marketing of medical devices including diagnostic tests. The FDA requires testing of the Careside system in accordance with regulatory requirements in the laboratory and, as appropriate, in clinical settings to establish product performance before marketing. FDA clearance must be obtained before making certain types of product changes. The Careside Analyzer and tests have received marketing clearance for point-of-care and physician office laboratory use.

The FDA has regulations that set varying requirements for medical devices according to potential risk class. Class I devices represent the lowest potential risk devices and are therefore subject only to the general controls that include establishment registration, product listing, the prohibition of mislabeling or adulteration, and a requirement to comply with federal Good Manufacturing Practices regulations. Pre-market notification is required for some Class I clinical diagnostic devices. Class II devices present greater risk than Class I devices and are subject to special controls, such as guidelines or performance standards, as well as the same general controls that are applicable to Class I devices. Class II devices require pre-market clearance to demonstrate that the FDA accepts the manufacturer's claims that the device is substantially equivalent to other legally marketed devices, and meets generally accepted performance criteria that may be required to demonstrate that the device is safe and effective. Class III devices present a higher level of risk and are additionally subject to rigorous demonstration of safety and effectiveness through the pre-market approval process.

For some Class I and most Class II devices, a pre-market notification must be submitted to the FDA. Usually within 90 days of the receipt of this notification, the FDA makes the determination whether the device submitted is substantially equivalent to a legally marketed device. A legally marketed device is one which was marketed prior to the passage of the Medical Device Amendments of 1976, or a post-1976 device that has been determined by the FDA to be substantially equivalent to previously cleared devices. A determination of substantial equivalence requires several FDA findings: first, that the device

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has the same intended use as the legally marketed device; and second, either that the device has the same technological characteristics as the legally marketed device or, if it does not, that the device is as safe and effective as the legally marketed device and does not present different questions about safety and effectiveness. Class III devices require extensive clinical testing to prove safety and effectiveness, and submission of the resulting data to the FDA as a pre-market approval application. The FDA ordinarily will refer a new device pre-market approval application to an advisory panel of outside experts for a recommendation on whether to approve the application or to request additional testing.

The Careside Analyzer and all 42 tests, along with the 18-parameter hematology test performed by the Careside H-2000, are already cleared or exempt by the FDA and have been classified in Class II.

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Certain future tests, such as prostate specific antigen, are expected to require pre-market approval. Only the H-2000 is used for in vitro animal testing. We are not required to be licensed as a veterinarian and are not subjected to any additional regulation by reason of our veterinary sales.

Where a pre-market approval application is required, FDA regulations require the demonstration of safety and effectiveness, typically based upon extensive clinical trials. Fulfilling the requirements of the pre-market approval application are costly and both the preparation and review are time consuming, commonly taking from one to several years. Before granting pre-market approval, the FDA must inspect and find acceptable the proposed manufacturing procedures and facilities. The pre-market approval regulations also require FDA approval of most changes made after the tests have been approved.

Manufacturing Regulation

For products either cleared through the pre-market notification process or approved through the pre-market approval process, our manufacturing facility must also be and is registered with the FDA. The manufacture of products subject to Section 510(k) of the Federal Food, Drug, and Cosmetic Act or to Section 515 pre-market approval requirements must be in accordance with quality system regulations and current federal Good Manufacturing Practices regulations. We are also subject to various post-marketing requirements, such as complaint handling and reporting of adverse events. Pre-market approval products are also subject to annual reports. The FDA typically inspects manufacturing facilities every two years. We intend to seek and maintain ISO 9001 certification. As a result, inspections by notified bodies may be more frequent.

The Careside Analyzer is being manufactured by UMM Electronics, Inc. UMM is an FDA registered and inspected facility. UMM is also ISO 9001 certified. In adherence to FDA and ISO 9001 requirements, UMM follows a structured design control process. The H-2000 is being manufactured for Careside by Ysebaert in France though Careside is the designated manufacturer under FDA regulation. The Ysebaert facility is ISO 9002 certified.

Third-Party Safety

Third-party safety certification is not required for FDA marketing permission, but will be required by our customers and to enter markets in other countries. In this regard, in 2000, we obtained an Underwriters Laboratories, or UL, listing for the instrument Careside Analyzer. UL has reviewed the Careside Analyzer according to UL 3101-1 that is equivalent to the international standard IEC 1010. The Careside Analyzer is also being designed to comply with requirements that ultimately will facilitate marketing of the product in Europe

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and Japan. These requirements include the Low Voltage Directive (73/23/EEC), the Electromagnetic Compatibility Directive (89/336/EEC), and the In Vitro Diagnostic Medical Device Directive (98/79/EC). The H-2000 is in the process of UL review.

Clinical Laboratory Improvement Amendments of 1988

All medical testing in the United States is regulated by the Centers for Medicare & Medicaid Services (CMS) according to the complexity of the testing as specified under the Clinical Laboratory Improvement Amendments of 1988. CLIA regulations establish three categories of laboratory tests, for which regulatory requirements become increasingly stringent as the complexity of the test rises: (1) tests that require little or no operator skill, which allows for a certificated waiver of the regulations; (2) tests of moderate complexity; and (3) high complexity tests which require significant operator skill or training. CLIA regulatory requirements apply to facilities such as clinical laboratories, hospitals, and physician offices which perform laboratory tests. All laboratories are subject to periodic inspection. In addition, all laboratories performing tests of moderate or high complexity must register with CMS or an organization to whom CMS has delegated such authority. They also must meet requirements relating to personnel qualifications, proficiency testing, quality assurance, and quality control. Both the Careside Analyzer and

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the H-2000 were categorized as test systems of moderate complexity. In practical terms, performing a test of moderate complexity means that the individual supervising the test, i.e., the physician, pathologist or laboratory director, must be appropriately educated and trained, whereas the individual who operates the Careside Analyzer requires either formal laboratory education or a high-school education and training in the skills required to perform testing with the Careside Analyzer, such as specimen collection and quality control.

State Regulation

We and our products are subject to a variety of state laws and regulations in those states where our products are marketed, sold or used. Thirteen states currently restrict or control, to varying degrees, the use of medical devices such as the Careside system outside the clinical laboratory by persons other than doctors or licensed technicians. For example, California, New York and Florida all have unique requirements that define which steps in the testing process can be performed by physicians, nursing or other personnel who are not licensed technicians. We have designed our testing system to comply with these requirements, while minimizing the need for higher cost labor to run the test process. However, these restrictions may add labor costs to the customer, and such costs may hinder our ability to market our products in these locations. Although we plan to seek interpretations, rulings or changes in relevant laws and regulations to remove or ameliorate these restrictions, there can be no assurance that we will be successful.

International Regulation

In addition to the United States market, we intend to pursue markets in Asia and Europe through select strategic alliances. The recently published European Community In Vitro Diagnostic Directive places our products within a category that has a low regulatory burden. Manufacturers are allowed entry into the market based upon self-certification that they complied with published directives, similar to existing United States requirements, containing performance, labeling, and other quality requirements. Japan has its own requirements for in vitro diagnostics.

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Product Liability and Property Insurance

Sale of our products entails risk of product liability claims. The medical testing industry has historically been litigious, and we face financial exposure to product liability claims in the event that use of our products results in personal injury. We also face the possibility that defects in the design or manufacture of our products might necessitate a product recall. There can be no assurance that we will not experience losses due to product liability claims or recalls in the future. We have purchased product liability insurance in reasonable and customary amounts. Such insurance can be expensive, difficult to obtain and may not be available in the future on acceptable terms, or at all. No assurance can be given that product liability insurance can be maintained in the future at a reasonable cost or in sufficient amounts to protect us against losses due to liability. An inability to maintain insurance at an acceptable cost or to otherwise protect against potential product liability could prevent or inhibit the commercialization of our products. We believe that our insurance coverage is adequate for the risks we face. However, a product liability claim in excess of relevant insurance coverage or product recall could have a material adverse effect on our business, financial condition and results of operations.

We have liability insurance covering our property and operations with coverage and deductible amounts and exclusions that we believe are customary for companies of our size and adequate for our industry. There can be no assurance that our current insurance coverage is adequate or that we will be able to maintain insurance at an acceptable cost or otherwise to protect against liability.

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Employees

We had 72 employees as of December 31, 2001. Sales and Marketing staff totaled 24 people, 29 people worked in manufacturing, quality assurance/regulatory or distribution activities, 9 people in product development, 6 in information technology and 4 in administration/general management.

Item 2. Properties

We lease approximately 16,000 square feet of space in Culver City, California for the research and development, validation, manufacture and assembly of disposable test cartridges and for product development. This lease has a term of seven years and expires in August 2005. It has a current monthly rent of \$19,228, gradually increasing to \$23,233 per month in the final lease year. We have an option to renew the lease for one additional five-year term at 95% of the fair market rental value. We believe that the Culver City facility is suitable to expand to \$40 million in test cartridge revenues and will adequately serve our needs for the immediate future.

We also lease approximately 6,200 square feet of space in Culver City, California for use as our executive offices. This lease has a term of seven years and expires in April 2007. It has a current monthly rent of \$9,288, gradually increasing to \$11,000 per month in the final lease year. We have an option to renew the lease for one additional five-year term at 95% of the fair market rental value.

We also lease approximately 1,500 square feet of office space in Houston, Texas which is used solely to support our activities in the veterinary market. This lease has a term of two years and expires in January 2003. It has a current monthly rent of \$877. In February 2002, this office was closed and the Company is in the process of terminating this lease.

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Item 3. Legal Proceedings

We are not a party to any material legal proceedings.

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

No matters were submitted to the vote of security holders during the fourth quarter of 2001.

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PART II

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

We completed our initial public offering of units on June 16, 1999. Each unit consisted of a share of common stock and a warrant to purchase a share of common stock. Since July 17, 1999, when each unit was split into a share of common stock and a warrant to purchase a share of common stock, our common stock has traded on the American Stock Exchange under the symbol "CSA" and our warrants have traded on the American Stock Exchange under the symbol "CSA.WA."

The following table sets forth, for the fiscal quarters indicated, the high and low closing sales prices per share for our common stock and our warrants, as reported on the American Stock Exchange:

| | Common Stock | | Warrants | |
|----------------|--------------|---------|----------|---------|
| | High | Low | High | Low |
| Fiscal 2001 | | | | |
| ----- | ----- | ----- | ----- | ----- |
| First Quarter | \$ 3.75 | \$ 2.04 | \$ 0.63 | \$ 0.18 |
| Second Quarter | \$ 2.70 | \$ 2.00 | \$ 0.60 | \$ 0.22 |
| Third Quarter | \$ 4.10 | \$ 2.15 | \$ 0.59 | \$ 0.25 |
| Fourth Quarter | \$ 2.65 | \$ 0.70 | \$ 0.40 | \$ 0.06 |
| Fiscal 2000 | | | | |
| ----- | ----- | ----- | ----- | ----- |
| First Quarter | \$13.56 | \$ 8.81 | \$ 4.50 | \$ 2.56 |
| Second Quarter | \$11.00 | \$ 4.88 | \$ 2.69 | \$ 1.25 |
| Third Quarter | \$ 5.63 | \$ 3.38 | \$ 1.63 | \$ 0.80 |
| Fourth Quarter | \$ 3.50 | \$ 1.81 | \$ 0.81 | \$ 0.19 |
| Fiscal 1999 | | | | |
| ----- | ----- | ----- | ----- | ----- |
| Third Quarter | \$ 6.06 | \$ 4.88 | \$ 3.00 | \$ 0.94 |
| Fourth Quarter | \$ 9.75 | \$ 4.94 | \$ 2.00 | \$ 1.00 |

As of March 22, 2002, there were 385 holders of record of our common stock and an estimated number of beneficial owners of our common stock of approximately 2,086.

We have not declared or paid any cash dividends or distributions on our capital stock. We currently intend to retain any future earnings to fund operations and the continued development of our business and, therefore, do not

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anticipate paying any cash dividends on our common equity in the foreseeable future. Future cash dividends, if any, will be determined by our Board of Directors, and will be based upon our earnings, capital requirements, financial condition and other factors deemed relevant by the Board of Directors.

In closings held on November 29, 2000, December 21, 2000, and January 24, 2001, we privately placed with Venturetec, Inc. and Pine, Inc., an affiliate of Venturetec, an aggregate of 1,742,951 shares of Common Stock at an average purchase price of \$2.49 per share under Regulation S of the Securities Act of 1933. Gross proceeds to the Company from this transaction were \$4,334,879. Friedli Corporate Finance received a cash commission of \$368,465 for its role as advisor in the transaction. The proceeds from this transaction were used for general corporate purposes. In connection with this transaction, warrants to purchase common stock were granted to Pine, Inc., an affiliate of Venturetec, totaling 87,148 shares, 41,324 of which have an exercise price of \$2.75 per share and expire November 2004, 25,000 of

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which have an exercise price of \$2.25 per share and expire December 2004, and 20,824 of which have an exercise price of \$2.25 per share and expire January 2005.

In March and May 2001, the Company sold 517,371 shares of Series C Convertible Preferred stock to various investors in a private placement, in which Dougherty & Company, LLC served as placement agent, for \$1.94 per share, which was 80 percent of fair market value at the March closing date. This financing resulted in net proceeds to us of \$9.0 million, after \$1.0 million of cash offering costs. In conjunction with the placement, warrants to purchase an aggregate of 5,173,716 shares of common stock were issued with an average exercise price of \$2.55. The placement agent received warrants to purchase 517,371 shares of Careside's common stock at \$1.94 per share. The proceeds from this transaction were used for general corporate purposes. The shares of Series C preferred stock were exchanged for 5,173,716 shares of common stock in October 2001. These shares of Common Stock were registered for resale on a Form S-3 registration statement which became effective in December 2001.

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Item 6. Selected Financial Data

The following table presents our summary consolidated financial information.

| | Careside, Inc. (in thousands except share and per share amounts) | | |
|-------------------------|---|--------------|-------------------------------|
| Operating Results Data: | 1997 ---- | 1998 ---- | Years End Dec 1999 ---- |
| Net Sales | \$ - | \$ - | \$ 61 |
| Cost of Sales | - | - | 31 |
| Gross profit (loss) | ----- | ----- | ----- |
| Operating Expenses | - | - | 30 |

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| | | | |
|--|------------|------------|-------------|
| Research and Development -products | 5,896 | 8,298 | 8,252 |
| Research and Development-software | - | - | 313 |
| Sales and Marketing | 85 | 249 | 1,204 |
| General and Administrative | 555 | 601 | 1,135 |
| Impairment of goodwill | - | - | - |
| Amortization of Goodwill | - | - | 37 |
| | ----- | ----- | ----- |
| Operating loss | (6,536) | (9,148) | (10,911) |
| Interest Income | 213 | 234 | 291 |
| Interest Expense | (8) | (22) | (971) |
| | ----- | ----- | ----- |
| Net loss | (6,331) | (8,936) | (11,591) |
| Preferred stock dividends | - | - | (55) |
| Accreted dividend on Preferred Stock | - | - | - |
| Beneficial conversion feature on Preferred Stock | - | - | - |
| | ----- | ----- | ----- |
| Net Loss available to common stockholders | \$ (6,331) | \$ (8,936) | \$ (11,646) |
| Basic and diluted Net Loss per Common Share | \$ (2.04) | \$ (1.93) | \$ (1.88) |
| Shares used in computing Basic and Diluted Net Loss per Common Share | 3,098,980 | 4,629,916 | 6,210,496 |

| Balance Sheet Data: | 1997 | 1998 | Years End Dec 1999 |
|---|----------|----------|--------------------|
| | ---- | ---- | ---- |
| Cash and cash equivalents | \$ 1,237 | \$ 3,927 | \$ 4,905 |
| Total assets | 3,140 | 7,911 | 14,389 |
| Total current liabilities | 703 | 1,717 | 4,214 |
| Long-term debt, net of current portion | - | 2,045 | 1,060 |
| Mandatorily Redeemable Series B Convertible Preferred Stock | - | - | - |
| Accumulated deficit | (7,969) | (16,905) | (28,496) |
| Total stockholders' equity | 2,438 | 4,149 | 9,079 |

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The following table presents our summary consolidated quarterly financial information.

| | 2000 | | | | | |
|---|-----------|-----------|-----------|-----------|-----------|-----|
| | Q1 | Q2 | Q3 | Q4 | Q1 | |
| | -- | -- | -- | -- | -- | |
| Net Sales | \$ 283 | \$ 245 | \$ 108 | \$ 105 | \$ 184 | \$ |
| Gross profit (loss) | 140 | 136 | 49 | (585) | (818) | |
| Net loss | (4,200) | (3,832) | (4,102) | (4,569) | (3,325) | (3) |
| Net loss available to common stockholders | (4,226) | (3,858) | (4,103) | (4,752) | (3,372) | (8) |
| Net loss per share | \$ (0.54) | \$ (0.44) | \$ (0.46) | \$ (0.48) | \$ (0.30) | \$ |

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| | | | | | | |
|---|-------|-------|-------|-------|--------|----|
| Shares used in computing basic and diluted net loss per share | 7,867 | 8,798 | 8,988 | 9,535 | 11,092 | 11 |
|---|-------|-------|-------|-------|--------|----|

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

.. Overview

Since our inception, we have devoted substantially all of our resources to research and development activities, establishment of a sales force and the administrative structures necessary to support operations. We have incurred losses since inception and generated minimal revenues. As of December 31, 2001, the aggregate loss incurred was approximately \$60.9 million. In 1998, 1999 and for the first nine months of 2000, Careside was considered a development stage enterprise. In the fourth quarter of 2000, Careside had substantially completed the development efforts of the Company's core product and began generating sales and increasing its focus on marketing efforts. Careside anticipates incurring additional losses over at least the next year.

In 2001, the Company began to aggressively pursue both the hospital and physician office markets. It became clear that the time to close sales in the hospital market was lengthy due to the number of committees and individuals involved in the qualification and approval process. It also became clear that to pursue the physician office market, it would be necessary to distribute our products with large distribution partners who were already calling these customers. In the first half of 2001, we signed agreements with a number of regional distributors and one national distributor. During the third quarter, we invested significant time and effort training the representatives of these distributors. In the late third quarter, we signed a distribution agreement with Physicians Sales & Service (PSS), the largest physician office distribution organization in the United States. During the fourth quarter of 2001, we began training their 750 distributor reps and had trained approximately half by year end. With these additional reps, at the close of 2001, we had more than 1,000 distributor reps.

.. Results of Operations

.. Years Ended December 31, 2001 and 2000

Sales and Cost of Sales. Sales increased to \$1.0 million in 2001 compared to \$741,000 in 2000. The sales in the last two quarters were predominately sales of Careside Analyzers. Orders for H-2000's decreased from quarter to quarter in 2001, reflecting Careside's shift in focus from the H-2000 to the Careside Analyzer and from the veterinary to the human market. This aligns our H-2000 sales efforts with the marketing efforts of our sales staff which is directed to consumers who might use all of our products. Hence, Careside does not interpret the decreasing sales of H-2000s as decreasing market interest in Careside products. The cost of sales for fiscal 2001 represents the cost of instruments and reagents sold. In the fourth quarter of 2000, the company exited the development stage. Cost of sales in 2001 includes a full year's expense of certain fixed costs that were recorded as development expense in the first three quarters of 2000. This results in additional expense of \$2.7 million compared to prior year.

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Research and Development Expenses - Product. Research and development expenses decreased to \$2.9 million for the year ended December 31, 2001. This compared to approximately \$9.1 million in the same period in 2000. This reduction was due to the completion of development activities in 2000 prior to the launch of the Careside Analyzer and to the effect of a full year allocation of certain costs to cost of sales in 2001 which were recorded as development expense for three quarters in 2000.

Research and Development Expenses - Software. Research and development expenses related to software increased to \$1.2 million for 2001 compared to \$898,000 in the same period in 2000. This increase reflects the increase in staff costs.

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Selling and Marketing Expenses. Selling and marketing expenses increased to \$3.9 million for 2001 compared to \$3.7 million in the same period in 2000. This increase reflects increased travel expense in 2001, and expenses associated with training distributor representatives to augment Careside's sales force efforts.

General and Administrative Expenses. General and administrative expenses remained the same at \$2.1 million for 2001 compared to \$2.1 million in the same period in 2000. This reflects reduced travel, insurance and consulting expenses partially offset by increased legal and accounting fees.

Goodwill. Goodwill amortization was \$520,000 in 2001 compared to \$567,000 in 2000. The decrease is due to the reduction in the carrying amount of goodwill that resulted from the impairment charge recorded in the fourth quarter of 2001. As a result of the loss of the key employee important to the hematology business in October 2001 and the resulting impact on the financial performance of Careside Hematology, the goodwill was reviewed for future recovery. This review resulted in a \$1.7 million impairment charge in 2001.

Net Interest Income (Expense). Interest income was \$65,000 for the year ended December 31, 2001 as compared to \$372,000 for the same period in 2000. This reflects lower average levels of cash and cash equivalents available for investment. Interest expense was \$401,000 for 2001 compared to \$495,000 for 2000. This decrease is due to lower remaining balances on Careside's existing equipment leases.

Net Loss. The net loss increased to approximately \$20.4 million for the twelve months ended December 31, 2001 compared to \$16.9 million for the same period in 2000. This increase reflects non-cash charges of approximately 4.8 million associated with beneficial conversion features and accrued dividend expense associated with financings completed or converted in 2001. These non-cash charges obscure the decrease of \$1.1 million in net loss from operations to \$15.6 million in 2001 compared to a net loss from operations of \$16.7 million in 2000.

.. Years Ended December 31, 2000 and 1999

Sales and Cost of Sales. Sales increased to \$741,000 in 2000 compared to \$61,000 in 1999. The sales were predominately sales of Careside H-2000s, a product of the Company we acquired in December 1999. Sales of the Careside H-2000 were primarily related to orders for the international markets. These orders tend to fluctuate from quarter to quarter depending upon timing of distributor orders. Orders decreased from quarter to quarter in 2000, reflecting Careside's shift in focus from the H-2000 to the Careside Analyzer and from the veterinary to the human market in order to align our H-2000 sales efforts with

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the marketing efforts of our sales staff which is directed to consumers who might use all of our products. Hence, Careside does not interpret the decreasing sales of H-2000s as decreasing market interest in Careside products. The cost of sales for fiscal 2000 represents the cost of instruments and reagents sold and the establishment of a reserve of \$628,000 for excess film and cartridge inventory and old analyzers.

Research and Development Expenses - Product. Research and development expenses increased to \$9.1 million for the year ended December 31, 2000 from \$8.3 million in the same period in 1999. The increased expenditure was related to changes in some of the mechanical components of the Careside Analyzer and the software that controls the operation of these components. These changes were the result of the outcome of the testing process in customer sites prior to market launch.

Research and Development Expenses - Software. Research and development expenses related to software increased to \$898,000 for 2000 compared to \$313,000 in the same period in 1999. This increase reflected the increase in staff of approximately \$300,000 and expenditures, approximately \$280,000 in expenditures related to development of the Careside Connect, a new product developed by Careside to provide interfaces with customer information systems and the Careside Analyzer and H-2000. The

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Company also expanded its facilities to a second location adjacent to its primary facility and this resulted in the need to modify the internal computer systems and the network information system between the two sites.

Selling and Marketing Expenses. Selling and marketing expenses increased to \$3.7 million for 2000 compared to \$1.2 million in the same period in 1999. This increase reflected the preparations for the launch of the Careside system in 2000, including the full year effect of sales force salaries.

General and Administrative Expenses. General and administrative expenses increased to \$2.1 million for 2000 compared to \$1.1 million in the same period in 1999. This increase reflected staff additions, of approximately \$110,000, additional office space of approximately \$80,000, liability insurance increases of approximately \$75,000, legal expenses of approximately \$135,000 and investor relations, of approximately \$65,000.

Goodwill. Goodwill amortization of \$567,000 was recorded in 2000 associated with goodwill recorded related to the December 1999 acquisition of TIL. This compared with amortization of \$37,000 which was recorded for part of December in 1999. This decrease was due to a one time interest charge in 1999 in connection with the modification of the S.R. One Bridge Warrant in the amount of \$290,000 and amortization of the discount on the S.R. One Bridge Note in the amount of \$309,000 that only was incurred in 1999. These decreases were offset by increases due to additional borrowings under our equipment facility and an increase in the interest rate on the S.R. One Bridge Note.

Net Interest Income (Expense). Interest income was \$372,000 for the year ended December 31, 2000 as compared to \$291,000 for the same period in 1999. This reflected slightly higher average levels of cash and cash equivalents available for investment. Interest expense was \$495,000 for 2000 compared to \$971,000 for 1999. This decrease was due to a one time interest charge in 1999 in connection with the modification of the S.R. One Bridge Warrant in the amount of \$290,000 and amortization of the discount on the S.R. One Bridge Note in the amount of \$309,000 that only was incurred in 1999. These decreases were offset by increases due to additional borrowings under our equipment facility and an increase in the interest rate on the S.R. One Bridge Note.

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Net Loss. The net loss increased to approximately \$16.7 million for the twelve months ended December 31, 2000 compared to \$11.6 million for the same period in 1999. This increase reflected the increase in cost of sales due to the inventory reserve, increases in selling and marketing, goodwill amortization and administrative expenses partially offset by a decrease in interest expense associated with the S.R. One bridge loan.

.. Liquidity and Capital Resources

We have financed our operations since inception primarily through the net proceeds generated from the issuance of common and preferred stock, long-term debt and certain short-term borrowings that were subsequently converted into equity securities. From inception through December 31, 2001, we have received net proceeds aggregating approximately \$60.8 million from equity transactions.

Net cash used in operating activities for the year ended December 31, 2001 was approximately \$11.1 million. For the period ended December 31, 2001, cash used in operating activities primarily represents the net loss for the period, offset by depreciation and amortization, increases in accounts payable, accrued expenses and accrued interest and decreases in inventory. These were offset by increases in accounts receivable and prepaid expenses. Net cash used in operating activities was approximately \$15.7 million for the year ended December 31, 2000. This represents the net loss for the period offset by depreciation and amortization and increases in accounts payable and accrued interest and partially offset by increases in inventory and prepaid expenses and decreases in accrued expenses. We provide reserves for doubtful accounts based on our specific review of aged accounts receivable.

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Cash used in investing activities for the purchase of property and equipment was approximately \$191,000 and \$2.1 million for the twelve months ended December 31, 2001 and 2000, respectively. The cash used in 2000 and 2001 was primarily for the acquisition of manufacturing equipment and laboratory equipment used in research and development.

Cash provided by financing activities was approximately \$9.5 million for the twelve months ended December 31, 2001, net of payments made on long term debt obligations. Net cash provided by financing in 2001 was a result of closing a private placement of our Series C Preferred stock in the first half of 2001. Cash provided by financing activities was approximately \$14.6 million for the twelve months ended December 31, 2000.

In December 1998, we entered into an agreement with an equipment lease financing company regarding a \$2.5 million facility secured by specific equipment. Each draw was a separate loan under the facility. We drew the remaining amount in early 2000 secured by manufacturing equipment for the cartridge assembly lines that we had previously purchased. Each equipment loan has a 48-month term and bears an interest rate of approximately 14%-15% per annum adjusted for an index rate based on four-year U.S. Treasury Notes at the time of borrowing.

We entered into an agreement for bridge financing with S.R. One, Limited in December 1998. Under this agreement, we borrowed \$3 million, of which \$1 million was first converted to Series A preferred stock and later converted to 179,696 shares of common stock and warrants to purchase 179,696 shares of common stock. As a result of various extensions, the remaining \$2.0 million of the loan matures May 31, 2002. At that time, we expect either to repay the \$2.0 million balance on the bridge financing with the proceeds of a new loan, to negotiate to extend the term or convert the balance of it into preferred or common equity.

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The annual interest rate on the remaining \$2.0 million is 10%. S. R. One has the option to convert all or any portion of the remaining loan, plus accrued interest thereon, into shares of Series A Convertible Preferred Stock. This Series A Convertible Preferred Stock would be issued to S.R. One on the same basis as the Series A Convertible Preferred Stock that was issued to S. R. One in connection with the \$1.0 million conversion discussed above. In connection with the bridge financing, we issued a bridge warrant to S.R. One. As currently in effect, the bridge warrant is exercisable for 235,294 shares of Common Stock, at \$6.375 per share. It will expire on June 16, 2004.

Prior to the end of the second quarter of 2001, the Company sold 517,3716 shares of Series C Preferred Stock in a series of closings. As part of this private placement, the Company also sold five-year warrants to purchase 5,173,716 shares of Common Stock at an exercise price of \$2.55 per common share. The gross proceeds of this private placement were \$10,037,000. The placement agent in the transaction earned warrants to purchase 517,371 shares of Common Stock at an exercise price per share of \$1.94 in connection with the three closings.

Proceeds from the sale of Series C Preferred and related warrants were used to fund our working capital needs and in particular our increasing sales and marketing efforts.

At December 31, 2001 cash on hand was \$39,000. Our current liquidity and sales revenue expected in 2002 are projected to be sufficient to fund our operating expenses and capital requirements for at least the first quarter of 2002. We will need additional funds to sustain our activities. There can be no assurance that we will be able to meet our capital requirements for this period as a result of certain factors set forth under "Risk Factors--Additional Funding May Not Be Available" and elsewhere in our registration statement on Form S-3 on file with the SEC dated December 2001. We will need to raise additional capital to expand our sales and marketing efforts, to scale-up manufacturing activities and to fund our research and development activities. Our future liquidity and capital funding requirements will depend on numerous factors, including the extent to which our products gain market acceptance, the exercise of outstanding warrants to purchase common stock, the timing of regulatory actions regarding our products, the costs and timing of expansions of sales, marketing and manufacturing activities,

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procurement and enforcement of patents important to our business, and the impact of competitors' products. There can be no assurance that such additional capital will be available to us or that the terms of it will be acceptable to us. Furthermore, any additional equity financing and exercise of existing warrants will likely be very dilutive to stockholders, and debt financing, if available, may include restrictive covenants. If adequate funds are not available, we may be forced to curtail or even cease our operations significantly or to obtain funds through entering into collaborative agreements or other arrangements on unfavorable terms. If we do not raise a substantial amount of capital, we will not be able to sustain operations. If we are able to raise capital, the terms of such capital could have a material adverse effect on our business, financial condition or results of operations and our ability to continue as a going concern. Subsequent to year-end, the Company obtained \$1,040,000 through the issuance of bridge notes. The Company continues to seek additional funding, however, as stated above, there is no assurance that the Company will be able to successfully raise such funds. The Company's auditors have included an explanatory paragraph in their Report of Independent Public Accountants included in the Company's annual report on Form 10K for each of the last three years in the period ended December 31, 2001 to the effect that the Company's losses from operations for the year ended December 31, 2001, and the working capital deficit

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and the accumulated deficit at December 31, 2001 raise substantial doubt about the Company's ability to continue as a going concern.

.. Income Taxes

As of December 31, 2001, we had approximately \$48.6 million and \$1,167,000 of net operating loss and research and development credit carryforwards, respectively, for federal income tax purposes, which expire on various dates between 2011 and 2014. These amounts reflect different treatment of expenses for tax reporting than are used for financial reporting. The Tax Reform Act of 1986 contains certain provisions that may limit our ability to utilize net operating loss and tax credit carryforwards in any given year. We experienced a change in ownership interest in excess of 50% as defined under the Tax Reform Act upon the first closing of our 1997 equity financing and by means of the private placements in 2000 and 2001. We do not believe that these changes in ownership will have any significant impact on our ability to utilize our net operating loss and tax credit carryforwards. There can be no assurance that ownership changes in future periods will not significantly limit our use of existing or future net operating loss and tax credit carryforwards.

.. Significant Accounting Pronouncements

Statements of Financial Accounting Standards No. 141, Business Combinations, and No. 142, Goodwill and Other Intangible Assets, were recently issued. The Company plans to adopt the standards effective January 1, 2002. The statements, among other things, require the use of purchase accounting for business combinations, discontinues amortization of goodwill, and requires an annual assessment of goodwill for impairment. The statements require amortization of goodwill recorded in connection with previous business combinations to cease upon adoption of the statements by calendar year companies on January 1, 2002. The Company does not expect these standards will have a material impact on our financial position or results of operations.

Accounting for Asset Retirement Obligations - Statement of Financial Accounting Standards (SFAS) No. 143 was issued in June 2001. SFAS No. 143 establishes accounting standards for recognition and measurement of a liability for an asset retirement obligation and the associated asset retirement cost. This statement is effective for financial statements issued for fiscal years beginning after June 15, 2002. The company plans to adopt this standard on January 1, 2003. As the Company currently does not have any legal obligations associated with the retirement of long-lived assets within the scope of SFAS No. 143, the potential future impact statements is not known.

Accounting for the Impairment of Disposal of Long-Lived Assets - SFAS No. 144, was issued in August 2001. This statement addresses financial accounting and reporting of long-lived assets and for long-lived

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assets to be disposed of. The provisions of this statement are effective for financial statements issued for fiscal years beginning after December 15, 2001, and interim periods within those fiscal years. The Company will adopt this statement on January 1, 2002. The Company is currently evaluating the impact of SFAS No. 144.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

The Company does not believe that it is subject to significant market risk exposure. Its debt instruments carry fixed interest rates and its investments are in cash equivalent instruments that deliver fixed rates of return. The Company also believes that the effects of inflation have not had a significant

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impact on its results of operations.

Item 8. Financial Statements

The Company's consolidated financial statements appear at pages F-1 through F-24, as set forth in Item 14.

Item 9. Changes in and Disagreements With Accountants On Accounting and

Financial Disclosure

None.

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PART III

Item 10. Directors and Executive Officers of the Registrant

The following table sets forth certain information concerning the individuals who serve as our directors, executive officers and key employees:

| NAME ---- | AGE --- | POSITION ----- |
|-----------------------------------|------------|---|
| Directors and Executive Officers: | | |
| W. Vickery Stoughton | 55 | Chairman of the Board of Directors and Chief Executive Officer |
| Thomas H. Grove..... | 52 | Chief Technology Officer, Executive Vice President, Secretary |
| James R. Koch..... | 47 | Chief Financial Officer, Executive Vice President, Treasurer |
| Dennis E. Rieger..... | 56 | Senior Vice President, Information Technology and Chief Information Officer |
| Sandra P. Twyon..... | 63 | Vice President Operations |
| Anthony P. Brenner (1)... | 44 | Director |
| William F. Flatley (2)(3) | 60 | Director |
| Kenneth N. Kermes (2)(3). | 66 | Director |
| C. Alan MacDonald (2)(3). | 68 | Director |
| Diana Mackie (1)..... | 54 | Director |
| Bruce C. Vladeck | 52 | Director |
| Key Employees: | | |
| Kenneth Asarch..... | 44 | Vice President--Quality Systems and Regulatory Affairs |
| David Crais | 38 | Vice President--Sales |
| Grant Frazier..... | 40 | Vice President--Marketing |
| George M. Saiz..... | 48 | Vice President--Manufacturing |

- (1) Member of Compensation Committee
- (2) Member of Audit Committee
- (3) Member of Nominating Committee

Directors and Executive Officers

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W. Vickery Stoughton, Chairman of the Board of Directors and Chief Executive Officer. Mr. Stoughton has served as our Chairman of the Board of Directors and the Chief Executive Officer since our formation in July 1996. Prior to that, he served as President of SmithKline Beecham Diagnostics Systems Co. (SBDS), a diagnostic services and product company, from October 1995 to July 1996, and was President of SmithKline Beecham Clinical Laboratories, Inc. (SBCL), a provider of diagnostic laboratory services, from August 1992 to September 1995. As President of SBDS, Mr. Stoughton had responsibility for SBCL, SmithKline Beecham Clinical Laboratories International and SBDS's genetic testing and point-of-care testing projects. In addition, Mr. Stoughton served as Chief Executive Officer and Vice Chancellor for Health Affairs of Duke University Hospital from 1991 to 1992, Chief Executive Officer of Toronto Hospital in Toronto, Canada from 1981 to 1991, Chief Operating Officer of Brigham and Women's Hospital in Boston from 1980 to 1981 and Chief Executive Officer of Peter Bent Brigham Hospital in Boston from 1978 to 1980. Mr. Stoughton holds a B.S. in Chemistry from St. Louis University and a M.B.A. from the University of Chicago. He is currently a director of Sun Life Assurance Company of Canada, a financial services company, and Biomira, Inc., a pharmaceutical company.

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Thomas H. Grove, Executive Vice President--chief Technology Officer, Secretary. Dr. Grove has served as our Executive Vice President--Chief Technology Officer, Secretary and as one of our directors since our formation in July 1996 until January 2001. From April 1984 to July 1996, he served in a number of management positions at SmithKline Beecham Clinical Laboratories, Inc. involving research and development activities, including the position of Vice President of Scientific Affairs from January 1991 to July 1996, where, among other things, he was in charge of National Quality Control and Quality Assurance for SBCL. Dr. Grove has received a number of awards, including a NATO Science Fellowship to attend Oxford University from 1978 to 1979. He was also named Young Investigator of the Year in 1980 by the American Association for Clinical Chemistry and was elected to the National Academy of Clinical Biochemistry in 1977. Dr. Grove holds a B.S. in Biology from SUNY-Albany and a Ph.D. in Biochemistry from Syracuse University.

James R. Koch, Chief Financial Officer, Executive Vice President, Treasurer. Mr. Koch has served as our Chief Financial Officer, Treasurer, Executive Vice President since July 1998 and as one of our directors From July 1998 until January 2001. Prior to joining us, Mr. Koch served as Vice President and Chief Financial Officer of ILEX Oncology, Inc., a company which develops oncology drugs, from August 1996 to July 1998. In addition, Mr. Koch served as Vice President, Finance and Chief Financial Officer for two start-up specialty pharmaceutical companies, Symphony Pharmaceuticals, Inc., from September 1993 to August 1996, and Neose Pharmaceuticals, Inc., currently Neose Technologies, Inc., from September 1991 to September 1993. His prior experience also includes ten years in senior financial management positions with G.D. Searle Pharmaceutical, a manufacturer of pharmaceutical products. Mr. Koch holds a B.S. in Mechanical Engineering from General Motors Institute and a M.S. from the Krannert School of Management at Purdue University.

Dennis E. Rieger, Senior Vice President Information Technology and Chief Information Officer. Mr. Rieger joined us in December 1999. Mr. Rieger's professional experience includes over 29 years in the high technology products industry. Mr. Rieger is also serving as President and CEO of Advanced Medical Information Technologies (AdMIT), a company he founded in 1992 that developed a mobile, bedside clinical information system, and a new universal medical and laboratory device data acquisition system. Prior to AdMIT, Mr. Rieger served as President and Chief Operating Officer of Compare Data Systems, an insurance and

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telecommunications software company, from 1987 to 1992; President of TRG, Inc., a technology based consulting and venture funding firm, from 1981 to 1987; and held several management positions in research and development, strategic planning and marketing at Apple Computer, Hewlett Packard and Procter and Gamble from 1971 to 1981. Mr. Rieger has a B.Sc. in Computer Information Science, with honors, from California State University at Sacramento, and served with the U.S. NAVY. Mr. Rieger is also serving on the board of directors of two companies, an embedded software products company and a publishing company, and is one of the Industry Advisory Board members for the new Biomedical Engineering Interdepartmental program at the UCLA School of Engineering and Applied Science.

Sandra P. Twyon - Vice President Operations. Ms. Twyon joined us in January 2000. Prior to that she held positions as Vice President for Patient Services with the Mercy Health System in Pittsburgh, PA (1994-1999); Vice President for Nursing at the Toronto Hospital in Toronto, Canada (1989-1993) and Chairman of Nursing at Tufts New England Medical Center in Boston, MA (1977-1989). In addition she was President and founder of the Center for Case Management (1989-1992), an original developer of critical pathways which consulted widely throughout the U.S. and Canada. Ms. Twyon received a B.S. Degree from the College of Saint Rose and holds a M.S. from Boston College.

Anthony P. Brenner, Director. Mr. Brenner has served as one of our directors since November 1996. Since January 1998, he has served as a Managing Director with Crosslink Capital (formerly Omega Ventures), a venture capital firm, where he oversees investment activities in the information and business services industries. Prior to that, Mr. Brenner served as Senior Managing Director of Advanta Partners LP, a private equity investment partnership, and as a member of the Board of Directors of Advanta

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Corporation, a financial services company, from 1992 to 1996. In addition, since 1989 Mr. Brenner has served as President of Cedar Point Partners, a private equity investment partnership. Mr. Brenner earned a B.A. from Yale University and a M.B.A. from Stanford University. In addition, Mr. Brenner is currently a director of Eloquent, Inc.

William F. Flatley, Director. Mr. Flatley has served as one of our directors since November 1996. Since July 1997, he has served as the President and Chief Executive Officer of Executive Health Group, a provider of preventive healthcare services to corporations. From 1980 to December 1994, he held a number of senior management positions with Bristol-Myers Squibb Corporation, a pharmaceutical company, including President of a multi-division medical device business, the Health Care Group, and President of the Drackett Company, a household product manufacturer. Mr. Flatley retired from Bristol-Myers Squibb at the end of 1994 but continued to provide the company with certain consulting services after his retirement. Mr. Flatley obtained a B.S. from Villanova University and a M.B.A. from the Wharton School of the University of Pennsylvania.

Kenneth N. Kermes, Director. Mr. Kermes has served as one of our directors since February 1997. Since June 2001 he has served as Chairman of the Board of BNS Co., a NASDAQ listed company, which was the successor to Brown & Sharpe Manufacturing Company after the sale of substantially all of its assets in April 2001. BNS Co. is engaged in the development and marketing of CAD-CAM Software Systems and the management of several pieces of real estate. From April 2000 until May 2001, Mr. Kermes has served as President, Chief Executive Officer of Brown & Sharpe Manufacturing Company, a NYSE listed manufacturer of measuring systems used in the automotive, aircraft manufacturing and industrial equipment industries. He also continues as a partner in Sea View Capital, LLC, a Providence, RI based private equity investment company. Prior to that, he served

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as a principal of Riparian Partners Limited and Bay View Equity Partners, two related investment banking and private equity investment partnerships. He served as Vice President of Business and Finance for the University of Rhode Island from December 1994 to June 1998 and as Chief Financial Officer for SmithKline Beecham Corporation from October 1986 to July 1989 and as Senior Vice President and Group Director of Corporate Development from July 1989 to 1991. From 1991 to 1994, Mr. Kermes was a consultant and an investor in the venture capital industry. Mr. Kermes obtained a B.A. from Amherst College and attended the New York University Graduate School of Business and the Harvard Business School Advanced Management Program. In addition to Careside, Mr. Kermes serves as director of four private, closely held manufacturing companies in the Northeast and as a director of BNS Company.

C. Alan Macdonald, Director. Mr. MacDonald has served as one of our directors since November 1996. Mr. MacDonald is the principle of CAM Consulting where he has been since his retirement in 1991 from Stouffer/Nestle where he was the President and CEO of Stouffer Foods and later Nestle Foods from 1971. Mr. MacDonald has also served as a Managing Director of Directorship, Inc., a consulting firm specializing in corporate governance issues from 1997 to 2000. Mr. MacDonald holds a B.S. in Hotel Administration from Cornell. In addition to Careside, Mr. MacDonald also serves on the boards of Lord Abbett & Co., Seix Investments, J.B. Williams Co., Lincoln Snacks Co., and Fountainhead Bottled Water Co.

Diana J. Mackie, Director. Ms. Mackie has served as one of our directors since February 1997. From January 24 until December 27, 2000, Ms. Mackie accepted a special assignment to co-lead the merger integration process for GlaxoSmithKline (GSK). She is now Vice President Switch and New Innovations at GSK. From June 1999 to January 2000, she held the position of Vice President and Director, Category Management, Dermatologicals, Phytomedicines and Vitamins at SmithKline Beecham Consumer Healthcare (SBCH). From November 1996 to May 1999, she held various positions of Vice President at SmithKline Beecham Healthcare Services where her responsibilities included developing business plans, long-range strategy and negotiating external alliances and investments. From March 1996 to November 1996, she was General Manager of Diversified Prescription Delivery, a pharmaceutical mail services company and a wholly owned subsidiary of Diversified Pharmaceutical Services, a

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pharmaceutical benefit management group. Prior to March 1996, she served as Vice President in a variety of strategy or corporate development positions for SmithKline Beecham. Ms. Mackie holds a B.S. in Chemistry from the University of Illinois, a M.B.A. from The Massachusetts Institute of Technology Sloan School of Management and a M.S. in Polymer and Fiber Engineering from The Massachusetts Institute of Technology.

Bruce C. Vladeck, Director. Dr. Vladeck is Senior Vice President for Policy of Mount Sinai NYU Health as well as Director of the Institute for Medicare Practice and Professor of Health Policy and Geriatrics at the Mount Sinai School of Medicine. He also serves as a director of a number of non-profit and for-profit organizations. From 1993 through September 1997, Dr. Vladeck was Administrator of the Health Care Financing Administration (now CMS) of the U.S. Department of Health and Human Services. Before joining the federal government, Dr. Vladeck served ten years as President of the United Hospital Fund of New York. He has also held positions on the faculty of Columbia University, at the Robert Wood Johnson Foundation, and, from 1979 through 1982, as Assistant Commissioner for Health Planning and Resources Development of the New Jersey State Department of Health. At the Institute of Medicine of the National Academy of Sciences, to which he was elected in 1986, Dr. Vladeck chaired the Committee on Health Care for Homeless People. He received his BA, magna cum laude, from

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Harvard College, and an MA and Ph.D. in Political Science from the University of Michigan.

Other Key Employees

Kenneth Asarch, Vice President--quality Systems and Regulatory Affairs. Dr. Asarch has served as our Vice President--Quality Systems and Regulatory Affairs since November 1996. From June 1995 to October 1996, Dr. Asarch served as Director of Regulatory Affairs for SmithKline Beecham Clinical Laboratories, Inc. and SmithKline Beecham Diagnostics Systems Co. Prior to that, he served as Director of Regulatory Affairs, Quality Assurance and Clinical Affairs with Diagnostic Products Corporation, an immuno-diagnostic testing company, from 1987 to 1995, where his duties included overseeing the FDA regulatory clearance and approval process for approximately 150 blood testing products. Dr. Asarch holds a B.S. in Biochemistry from the University of California at Los Angeles and doctoral degrees in both Clinical Pharmacy (Pharm.D.) and Pharmaceutical Sciences (Ph.D.) from the University of Southern California.

David Crais, Vice President - Sales. Mr. Crais joined Careside in September 1999 as a Regional Sales Director and was promoted to Vice President in September 2001. Prior to joining Careside, Mr. Crais was a Strategic Sales Representative for I-STAT Corporation from 1993 to 1999. Previously he had started an import/export company, and a marketing consulting company. Mr. Crais has served as an appointee for the State of Louisiana Imports and Exports Authority. He has a combined BA/BS degree from Loyola University, New Orleans, LA and has done graduate studies at Universidad Iberoamericana in Mexico City.

Grant Frazier, Vice President-marketing. Mr. Frazier has served as our Vice President-Marketing since November 1999. Prior to joining us, Mr. Frazier served as Vice President-Marketing & Business Development at Mobile Technology Inc., a provider of magnetic resonance imaging, lithotripsy and cancer therapy services. Mr. Frazier joined MTI in December 1991 and was responsible for developing the first mobile radiation therapy cancer care service deployed within the United States. He led this strategic business unit until August 1998 before assuming his corporate marketing and business development responsibilities. Mr. Frazier holds a B.S. in Industrial Engineering from Stanford University and a M.B.A. from UCLA's Anderson School of Management.

George M. Saiz, Vice President - Manufacturing. Mr. Saiz has served as our Vice President-Manufacturing since January 2001. Prior to joining us, Mr. Saiz served from 1998 as Vice President & General Manager for Micro Motors, a private label supplier of powered and electronic devices for the specialty surgical and dental markets. From 1988 to 1998, he held general and operations management

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positions with the Shutt Medical Technologies division of Linvatec and the Hall Surgical division of Zimmer, both Bristol-Myers Squibb companies. His manufacturing experience at these companies included implants, power and hand equipment, electronic controllers and disposables. Mr. Saiz has a BS Business Administration from West Coast University and a MBA from University of La Verne.

Classified Board of Directors

The Board of Directors is divided into three classes. In 2001, two classes contained two directors and one class contained three directors. Directors within each class are elected to serve three-year terms and approximately one-third of the directors sit for election at each annual meeting of our stockholders. Mr. Stoughton, and Mr. MacDonald serve in the class whose term expires in 2002, and Mr. Brenner and Mr. Kermes serve in the class whose term expires in 2003. Mr. Flatley and Ms. Mackie serve in the class whose term

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expires in 2004. Mr. Vladeck joined the Board of Directors in July 2001, filling the vacancy created by the departure of Mr. Smith, a member of the class of directors whose term expires in 2003. Mr. Vladeck's term thus expires in 2003. A classified board of directors may have the effect of deterring or delaying any attempt by any group to obtain control of us by a proxy contest since such third party would be required to have its nominees elected at two separate annual meetings of our Board of Directors in order to elect a majority of the members of our Board of Directors.

Information under the caption "Section 16(a) Beneficial Ownership Reporting Compliance" in the Proxy Statement is incorporated herein by reference in response to this Item 10.

Item 11. Executive Compensation

The information contained in the section titled "Executive Compensation" in the Proxy Statement, with respect to executive compensation, and the information contained in the section entitled "Director Compensation" in the Proxy Statement, with respect to director compensation, is incorporated herein by reference in response to this Item 11.

Item 12. Security Ownership of Certain Beneficial Owners and Management

The information contained in the section titled "Security Ownership of Certain Beneficial Owners" in the Proxy Statement, with respect to security ownership of certain beneficial owners and management, is incorporated herein by reference in response to this Item 12.

PART III

Item 13. Certain Relationships and Related Transactions

The information contained in the section titled "Certain Relationships and Transactions" in the Proxy Statement, with respect to certain relationships and related transactions, is incorporated herein by reference in response to this Item 13.

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PART IV

Item 14. Exhibits, Financial Statement Schedules and Reports On Form 8-K

(a) (1) Financial Statements

The financial statements listed in the accompanying Index to Consolidated Financial Statements are filed as part of this Form 10-K, commencing on page F-1.

1. Financial Statement Schedules - none applicable

Other financial statement schedules are not included because they are not required or the information is otherwise shown in the financial statements or notes thereto.

(3) Exhibits

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| Exhibit No. ----- | Description ----- |
|----------------------|---|
| 2.1* | Agreement and Plan of Merger dated as of December 7, 1999 by and among Careside, Inc., Careside Hematology, Inc., Texas International Laboratories, Inc., Yves LeBihan and Jean-Yves LeBihan. |
| 3.1** | Amended and Restated Certificate of Incorporation of Careside, Inc. |
| 3.2** | Certificate of Designations of Series A Convertible Preferred Stock |
| 3.3** | Amended and Restated Bylaws of Careside, Inc. |
| 3.4+ | Certificate of Designations of Series B Convertible Preferred Stock |
| 3.5++ | Certificate of Designations of Series C Convertible Preferred Stock |
| 4.1*** | Specimen Stock Certificate |
| 4.1a** | Specimen Warrant Certificate |
| 4.1b** | Specimen Unit Certificate |
| 4.2*** | Placement Agent Warrant Agreement dated as of January 31, 1997 by and between Careside, Inc. and Spencer Trask Securities Incorporated (including Form of Warrant) |
| 4.3*** | Placement Agent Warrant Agreement dated as of March 6, 1998 by and between Careside, Inc. and Spencer Trask Securities Incorporated (including Form of Warrant) |
| 4.4*** | Securities Purchase Agreement dated as of December 17, 1998 by and between S.R. One, Limited and Careside, Inc. (including Form of Note) (as amended) |
| 4.5*** | Warrant Issued to S.R. One, Limited on December 17, 1998 |

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| Exhibit No. ----- | Description ----- |
|----------------------|--|
| 4.6** | Warrant Agreement dated June 21, 2000, by and between Careside, Inc. and Paulson Investment Company, Inc. |
| 4.7** | Warrant Agreement dated June 21, 2000, by and between Careside, Inc. and American Stock Transfer & Trust Company, as Warrant Agent |
| 4.8** | Warrant issued to S.R. One, Limited dated June 21, 1999 |
| 4.9** | New Note issued to S.R. One, Limited dated as of June 21, 1999 |
| 4.11*** | Securities Purchase and Subscription Agreement dated as of March 8, 2000 by and between Careside, Inc. and Purchasers |
| 4.12*** | Warrant Agreement dated as of March 8, 2000 by and between Careside, Inc. and H. C. Wainwright & Co., Inc. (including Warrant certificate) |
| 4.13*** | Contingent Warrant Agreement dated as of March 8, 2000 by and between Careside, Inc. and Purchasers (including Form of Warrant) |
| 4.14 + | Securities Purchase Agreement dated as of September 13, 2000 by and between RoyCap, Inc. and Careside, Inc. |
| 4.15 + | Series B Convertible Preferred Warrant issued to RoyCap, Inc. on September 13, 2000 |
| 4.16 + | Warrant Agreement by and between RoyCap, Inc. and Careside, Inc. dated as of September 13, 2000 (including Warrant Certificate) |
| 4.17 + | Common Stock Purchase issued to RoyCap, Inc. on September 13, 2000 |
| 4.18 + | Warrant Agreement By and between Brighton Capital, Ltd. and Careside, Inc. dated as of September 13, 2000 |

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(including Warrant Certificate)

4.19 ++ Form of Securities Purchase and Subscription Agreement dated as of March 29, 2001 by and between Careside, Inc. and Purchasers

4.20 ++ Form of Warrant dated as of March 29, 2001 executed by Careside, Inc. and addressed to Purchasers (including Warrant Certificates)

10.1*** Registration Rights Agreement dated as of November 7, 1996 by and among SmithKline Beecham Diagnostic Systems Co., SmithKline Beecham Corporation and Careside, Inc.

10.2*** Registration Rights Agreement dated as of December 4, 1996 by and among Careside, Inc., Exigent Partners, L.P., W. Vickery Stoughton, Thomas H. Grove, Kenneth B. Asarch, William S. Knight, Donald S. Wong, Ashok K. Sawhney and Philip B. Smith

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| Exhibit No. ----- | Description ----- |
|----------------------|---|
| 10.3*** | Amendment No. 1 to Registration Rights Agreement dated as of January 31, 1997 by and among Careside, Inc. Exigent Partners, L.P., W. Vickery Stoughton, Thomas H. Grove, Kenneth B. Asarch, William S. Knight, Donald S. Wong, Ashok K. Sawhney and Philip B. Smith |
| 10.4*** | 1996 Key Executive Stock Option Plan, as amended and restated |
| 10.5*** | 1998 Incentive and Non-Qualified Stock Option Plan |
| 10.6*** | 1998 Director Stock Option Plan |
| 10.7*** | Standard Industrial/Commercial Single-Tenant Lease - NET dated as of October 14, 1996, by and between Fox Hills Business Park, a California limited partnership and Careside, Inc. |
| 10.8*** | Agreement dated as of August 31, 1996, by and between Fuji Photo Film Co., Ltd. and Careside, Inc. |
| 10.9*** | Product Development and Supply Agreement dated as of July 18, 1997, by and between Careside, Inc. and UMM Electronics, Inc. |
| 10.10*** | Agreement Number CPO 32284 Cost Type executed December 5 and 17, 1996 by and between Battelle Memorial Institute and Careside, Inc. |
| 10.11*** | Joint Research & Development Agreement dated as of October 28, 1996 by and between Careside, Inc. and International Technidyne Corporation. |
| 10.12*** | Employment Agreement dated as of March 3, 1997 between Careside, Inc. and W. Vickery Stoughton. |
| 10.13*** | Employment Agreement dated as of March 3, 1997 between Careside, Inc. and Thomas H. Grove |
| 10.14*** | Employment Agreement dated as of July 30, 1998 between Careside, Inc. and James R. Koch |
| 10.15*** | Securities Conversion Agreement dated as of June 14, 1999 between S.R. One, Limited and Careside, Inc. |
| 10.16*** | Form of Amended and Restated Registration Rights Agreement dated as of June 21, 1999 between S.R. One, Limited and Careside, Inc. |
| 23.1 | Consent of Arthur Andersen LLP, Independent Auditors |
| 99.1 | Letter of Arthur Andersen LLP Representation |

* Incorporated herein by reference to Careside's current report on Form 8-K

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filed on December 22, 1999.

** Incorporated herein by reference to Careside's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 1999 filed on August 13, 1999.

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*** Incorporated herein by reference to the Registration Statement on Form S-1 of Careside, Inc., as amended. Registration No. 333-69207.

**** Incorporated herein by reference to Careside's Annual Report on Form 10-K filed on March 31, 2000.

+ Incorporated herein by reference to the Registration Statement on Form S-3 of Careside, Inc. filed on September 27, 2000. Registration No. 333-46746.

++ Incorporated herein by reference to Careside's Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2001 filed on May 15, 2001 (SEC File Number 001-15051).

(b) Reports on Form 8-K.

None.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report to be signed on its behalf by the undersigned, thereunto duly authorized, in Culver City, California, on the 28th day of March, 2002.

CARESIDE, INC.

By: /s/ W. Vickery Stoughton

W. Vickery Stoughton
Chairman of the Board of Directors
and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this Report has been signed by the following persons in the capacities and on the dates indicated.

| Signature ----- | Title ----- | Date ---- |
|---|--|----------------|
| /s/ W. Vickery Stoughton ----- W. Vickery Stoughton | Chairman of the Board of Directors, Chief Executive Officer and Director (principal executive officer) | March 28, 2002 |

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| | | |
|---|---|---------------|
| /s/ James R. Koch ----- James R. Koch | Chief Financial Officer, Treasurer, Executive Vice President (principal financial and accounting officer) | March 28, 200 |
| /s/ Anthony P. Brenner ----- Anthony P. Brenner | Director | March 28, 200 |
| /s/ William F. Flatley ----- William F. Flatley | Director | March 28, 200 |
| /s/ Kenneth N. Kermes ----- Kenneth N. Kermes | Director | March 28, 200 |
| /s/ C. Alan MacDonald ----- C. Alan MacDonald | Director | March 28, 200 |
| /s/ Diana J. Mackie ----- Diana J. Mackie | Director | March 28, 200 |
| /s/ Bruce C. Vladeck ----- Bruce C. Vladek | Director | March 28, 200 |

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REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

To Careside, Inc.:

We have audited the accompanying consolidated balance sheets of Careside, Inc. (a Delaware corporation) as of December 31, 2000 and 2001, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2001. 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. 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.

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In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Careside, Inc. as of December 31, 2000 and 2001, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, for the year ended December 31, 2001, the Company incurred a loss from operations of \$15,669,000 and at December 31, 2001, the Company had a working capital deficit of \$2,468,000 and an accumulated deficit of \$60,868,000 which raises substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments relating to the recoverability and classification of asset carrying amounts or the amount and classification of liabilities that might result should the Company be unable to continue as a going concern.

ARTHUR ANDERSEN LLP

Los Angeles, California
March 7, 2002

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CARESIDE, INC.
CONSOLIDATED BALANCE SHEETS
December 31, 2000 and 2001
(in thousands except share and per share amounts)

| | Assets | 2000 |
|--|--------|-----------------------------|
| | ----- | ----- |
| Current Assets: | | |
| Cash and cash equivalents | | \$ 1,789 |
| Accounts receivable, net of allowance of \$54 in 2000 and \$27 in 2001 | | 104 |
| Inventories | | 2,698 |
| Prepaid expenses and other | | 174 |
| Total current assets | | ----- 4,765 |
| Property and Equipment, net of accumulated depreciation and amortization of \$4,213 in 2000 and \$6,186 in 2001 | | 5,643 |
| Deposits and Other | | 24 |
| Goodwill, net of accumulated amortization of \$603 in 2000, and none in 2001 | | 2,231 |
| | | ----- \$ 12,663 ===== |
| Liabilities and Stockholders' Equity | | |
| Current Liabilities: | | |
| Current portion of long-term debt | | \$ 2,520 |
| Current portion of obligation under capital lease | | 13 |
| Accounts payable | | 1,456 |
| Accrued expenses | | 421 |
| Accrued interest | | 334 |

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| | |
|---|-----------|
| Total current liabilities | 4,744 |
| Deferred Warranty Revenue | - |
| Long-Term Debt, net of current portion | 1,192 |
| Obligation Under Capital Lease, net of current portion | 23 |
| Manditorily Redeemable Series B Convertible Preferred Stock 290 and 0 shares issued and outstanding at December 31, 2000 and 2001, respectively | 1,054 |
| Stockholders' Equity: | |
| Preferred stock, \$.01 par value: 5,000,000 shares authorized- 0 shares issued and outstanding | - |
| Common stock, \$.01 par value: | |
| 50,000,000 shares authorized- | |
| 10,590,191 and 16,904,193 shares issued and outstanding at December 31, 2000 and 2001, respectively | 106 |
| Additional paid-in capital | 50,743 |
| Accumulated Deficit | (45,199) |
| Total stockholders' equity | 5,650 |
| | \$ 12,663 |
| | ===== |

The accompanying notes are an integral part of these consolidated statements.

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CARESIDE, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands except share and per share amounts)

| | For the Years Ended December 31, | | |
|-------------------------------------|----------------------------------|----------|---------|
| | 1999 | 2000 | 2001 |
| | ----- | ----- | ----- |
| Sales | \$ 61 | \$ 741 | \$ 1,02 |
| Cost of Sales | 31 | 1,001 | 4,08 |
| Gross Profit (Loss) | 30 | (260) | (3,06) |
| Operating Expenses: | | | |
| Research and development - products | 8,252 | 9,074 | 2,87 |
| Research and development - software | 313 | 898 | 1,16 |
| Selling and marketing | 1,204 | 3,657 | 3,91 |
| General and administrative | 1,135 | 2,124 | 2,13 |
| Impairment of goodwill | - | - | 1,66 |
| Goodwill amortization | 37 | 567 | 52 |
| Operating Loss | (10,911) | (16,580) | (15,33) |

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| | | | |
|---|-------------|-------------|------------|
| Other income (expense): | | | |
| Interest Income | 291 | 372 | 6 |
| Interest Expense | (971) | (495) | (40) |
| | ----- | ----- | ----- |
| Net Loss | (11,591) | (16,703) | (15,66) |
| Preferred stock dividends | (55) | (69) | (2) |
| Accreted dividend on Preferred Stock | - | (83) | (91) |
| Beneficial conversion feature on Preferred Stock | - | (84) | (3,79) |
| | ----- | ----- | ----- |
| Net loss available to common stockholders | \$ (11,646) | \$ (16,939) | \$ (20,40) |
| | ===== | ===== | ===== |
| Basic and Diluted Net Loss per Common Share | \$ (1.88) | \$ (1.92) | \$ (1.6) |
| | ===== | ===== | ===== |
| Shares used in Computing Basic and Diluted Net Loss per Common Share | 6,210,496 | 8,800,171 | 12,423,43 |
| | ===== | ===== | ===== |

The accompanying notes are an integral part of these consolidated statements.

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CARESIDE, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

| | Common Stock | | Preferred Stock | |
|--|--------------|--------|-----------------|--------|
| | Shares | Amount | Shares | Amount |
| | ----- | ----- | ----- | ----- |
| Balance, December 31, 1998 | 5,084,340 | \$ 51 | - | \$ - |
| Shares issued in connection with initial public offering, net | 2,000,000 | 20 | - | - |
| Shares issued in connection with issuance of preferred stock in exchange for bridge debt | - | - | 162,914 | 2 |
| Issuance of warrant with bridge conversion | - | - | - | - |
| Series A Preferred dividend | - | - | - | - |
| Shares issued in connection with acquisition of Texas International Laboratories, Inc. | 521,739 | 5 | - | - |
| Shares issued in connection with ESPP | 3,502 | 0 | - | - |
| Net loss | - | - | - | - |
| | ----- | ----- | ----- | ----- |
| Balance, December 31, 1999 | 7,609,581 | 76 | 162,914 | 2 |
| Shares issued in connection with private placement, net | 2,510,570 | 25 | - | - |
| Shares issued in connection with exercise of stock option | 1,154 | 0 | - | - |
| Accrued Series A Preferred dividend | - | - | - | - |
| Accrued Series B Preferred dividend | - | - | - | - |
| Shares issued in connection with ESPP | 30,454 | 0 | - | - |
| Conversion of the Series A Preferred | 179,696 | 2 | (162,914) | (2) |
| Accreted Series B Preferred Stock dividend | - | - | - | - |
| Issuance of warrants in connection with Series B Preferred Stock | - | - | - | - |

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| | | | | |
|--|------------|--------|-------|---------|
| Shares issued in connection with the conversion of the Series B Preferred | 128,259 | 1 | - | - |
| Shares issued in connection with exercise of stock warrant | 385 | 1 | - | - |
| Shares issued in connection with exercise of contingent stock warrants | 130,092 | 1 | - | - |
| Net loss | - | - | - | - |
| <hr/> | | | | |
| Balance, December 31, 2000 | 10,590,191 | 106 | - | - |
| Shares issued in connection with private placement, net | 416,472 | 4 | - | - |
| Shares issued in connection with the conversion of the Series B Preferred | 654,327 | 7 | - | - |
| Shares and warrants issued in connection with the issuance of the Series C Preferred | - | - | 517 | 2,902 |
| Accreted Series C Preferred dividend | - | - | - | 897 |
| Shares issued in connection with the conversion of the Series C Preferred | 5,173,716 | 52 | (517) | (3,799) |
| Shares issued in connection with callable warrant exercise, net | 11,190 | - | - | - |
| Accrued Series B Preferred dividend | - | - | - | - |
| Accreted Series B Preferred dividend | - | - | - | - |
| Shares issued in connection with ESPP | 58,297 | - | - | - |
| Net loss | - | - | - | - |
| <hr/> | | | | |
| Balance, December 31, 2001 | 16,904,193 | \$ 169 | - | \$ - |
| <hr/> | | | | |

The accompanying notes are an integral part of these consolidated statements.

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CARESIDE, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

| | 1999 | 2000 | 2001 |
|---|-------------|-------------|-------------|
| | <hr/> | <hr/> | <hr/> |
| Cash Flows from Operating Activities: | | | |
| Net loss | \$ (11,591) | \$ (16,703) | \$ (15,660) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | |
| Depreciation and amortization | 1,357 | 2,933 | 2,490 |
| Impairment of goodwill | - | - | 1,660 |
| Amortization of debt discount | 309 | - | - |
| Noncash interest expense | 290 | - | - |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | (73) | (26) | (50) |
| Inventory | (472) | (2,150) | 90 |
| Prepaid expenses and other | (20) | (71) | (30) |
| Deposits and other | 3 | (9) | - |
| Accounts payable | (73) | 612 | 250 |
| Accrued expenses | 671 | (425) | 200 |
| Accrued interest | 195 | 177 | 220 |

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| | | | |
|--|----------|----------|--------|
| Net cash used in operating activities | (9,404) | (15,662) | (11,09 |
| Net Cash Used in Investing Activities: | | | |
| Purchases of property and equipment | (3,821) | (2,070) | (19 |
| Cash Flows from Financing Activities: | | | |
| Proceeds from borrowings under long-term debt | 2,059 | 795 | - |
| Payments on long-term debt | (224) | (459) | (47 |
| Payments on capital lease obligation | (6) | (11) | (1 |
| Deferred offering costs | (2) | 2 | - |
| Net proceeds from exercise of callable warrants | - | - | 3 |
| Net Proceeds from the issuance of preferred and common stock | 12,377 | 14,289 | 9,98 |
| Net cash provided by financing activities | 14,204 | 14,616 | 9,53 |
| Net Increase (Decrease) in Cash and Cash Equivalents | 979 | (3,116) | (1,75 |
| Cash and Cash Equivalents, beginning of period | 3,926 | 4,905 | 1,78 |
| Cash and Cash Equivalents, end of period | \$ 4,905 | \$ 1,789 | \$ 3 |

The accompanying notes are an integral part of these consolidated statements.

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CARESIDE, INC.

Notes to Consolidated Financial Statements

December 31, 2001

1. Background

Careside, Inc. ("Careside" or "the Company") is focused on designing products intended to perform routine diagnostic blood tests in doctors' offices, hospital rooms, patient homes or anywhere a patient is receiving medical attention. Careside's first product is a compact portable device with related disposables that performs chemistry, electrochemistry, immunochemistry and coagulation testing.

In December 1999, Careside completed an acquisition of Texas International Laboratories, Inc. ("TIL") and merged TIL into a newly formed, wholly-owned subsidiary, Careside Hematology.

Risks and Liquidity/Going Concern

Careside was incorporated in July 1996 to acquire an ongoing, point-of-care ("POC") testing, development-stage product from SmithKline Beecham Corporation and its affiliates ("SmithKline") and to complete the development of

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and to manufacture, market and distribute POC diagnostic products. In the fourth quarter of 2000, Careside had substantially completed the initial development efforts of the Company's core product and began generating sales and increasing its focus on marketing efforts. In 1998, 1999 and for the nine months ended September 30, 2000, Careside was considered a development stage enterprise. Since its inception, Careside has generated minimal revenues and incurred significant losses. Careside anticipates incurring additional losses over at least the next year, and such losses are expected to increase as Careside expands its marketing activities. The accompanying consolidated financial statements have been prepared in conformity with principles of accounting applicable to a going concern. These principles contemplate the realization of assets and the satisfaction of liabilities in the normal course of business. As shown in the accompanying consolidated financial statements for the year ended December 31, 2001, the Company incurred a net loss of \$15.7 million, has used cash in operating activities of \$11.1 million at December 31, 2001, the Company had a working capital deficit of \$2.5 million and an accumulated deficit of \$60.9 million. These factors raise substantial doubt about the ability of the Company to continue as a going concern. Additional financing will be needed by Careside to fund its operations. Subsequent to year-end, the Company obtained \$1,040,000 through the issuance of several bridge notes (see Note 16). The Company is currently working to raise additional funding through bridge loans, long-term debt financing and permanent equity financing. Further, the Company plans to reduce portions of its fixed overhead expenses. In addition, the ability of Careside to commercialize its products will depend on, among other things, the relative cost to the customer of Careside's products compared to alternative products, its ability to obtain necessary regulatory approvals and to manufacture the products in accordance with Good Manufacturing Practices, and its ability to market and distribute its products. The Company's failure to raise additional capital on acceptable terms could have a material adverse effect on its business, financial condition or results of operations. There can be no assurance that Careside's future product enhancements will receive regulatory clearance, that the Company will be able to obtain additional financing, be profitable in the marketplace, or will be able to repay its current debt obligations. The failure of the Company to successfully achieve one or all of the above items will have a material impact on the Company's financial position and results of operations.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of Careside and Careside Hematology. Intercompany accounts and transactions are eliminated in consolidation.

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Use of Estimates

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

Cash and Cash Equivalents

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All highly liquid investments with an original maturity of three months or less are presented as cash equivalents in the accompanying consolidated financial statements.

Inventories

Inventories are stated at the lower of cost or market with cost determined on a first-in, first-out basis, and are summarized as follows (in thousands):

| | December 31, | |
|-------------------------------------|--------------|----------|
| | 2000 | 2001 |
| Raw materials | \$ 1,164 | \$ 932 |
| Work in process | 126 | 123 |
| Finished goods | 2,036 | 1,967 |
| Reserve for excess and obsolescence | (628) | (524) |
| | ----- | ----- |
| | \$ 2,698 | \$ 2,498 |
| | ===== | ===== |

Allowance for Doubtful Accounts

Allowances for doubtful accounts are estimates and are established based on the specific circumstances of each customer.

Property and Equipment

Property and equipment are stated at cost. Property and equipment capitalized under capital leases are recorded at the present value of the minimum lease payments due over the lease term. Depreciation and amortization are provided using the straight-line method over the estimated useful lives of the related assets or the lease term, whichever is shorter. The Company uses lives of two to nine years for laboratory equipment and manufacturing equipment and three to ten years for computer and office equipment. Leasehold improvements generally are amortized over the remaining life of the lease.

Goodwill and Impairment Loss

Goodwill represents the excess of the purchase price and related costs over the value assigned to the tangible net assets of TIL. Goodwill has been amortized on a straight line basis with an assigned life of five years. Periodically, the Company reviews the recoverability of goodwill. The measurement of possible impairment is based primarily on the ability to recover the balance of goodwill from expected future operating cash flows on an undiscounted basis. As a result of the loss of the key employee important to the hematology business in October 2001 and the resulting impact on the financial performance of Careside Hematology, the goodwill was reviewed for future recoverability in the fourth quarter of 2001.

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An undiscounted cash flow projection of Careside Hematology products was performed revealing that projected cash flows were not sufficient to recover the carrying amount of the goodwill. As a result, an evaluation of the fair value of

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Careside Hematology was made and the goodwill was written down accordingly. The amount of the writedown was \$1.7 million and was recorded as an expense in the consolidated statement of operations for the year ended December 31, 2001. Included in the consolidated statements of operations were net income/(losses) of Careside Hematology in the amount of \$26,126, (\$978,703) and (\$2,575,781) for 1999, 2000 and 2001 respectively. Included in the consolidated balance sheets were the net assets of Careside Hematology in the amounts of \$2,513,525 and \$261,180 for 2000 and 2001 respectively.

Under the provisions of SFAS No. 142, "Goodwill and other Intangible Assets" the remaining goodwill will no longer be amortized beginning January 1, 2002. The remaining goodwill will be reassessed annually under the provisions of SFAS 142.

Long-Lived Assets

The Company reviews its long-lived assets (including goodwill) for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset or a group of assets may not be recoverable. If an asset is determined to be impaired, the loss is measured as the amount by which the carrying amount of the asset exceeds fair value. If an evaluation is required, the estimated future undiscounted cash flows associated with the asset would be compared to the asset's carrying amount to determine if a write-down to market value or discounted cash flow value is required.

Fair Value of Financial Instruments

Cash equivalents are reflected in the accompanying consolidated financial statements at fair value due to the short-term nature of those instruments. The carrying amount of long-term debt approximates fair value on the balance sheet dates based on borrowing rates currently available to the Company for loans with similar terms and maturities.

Revenue Recognition

The Company applies the provisions of Staff Accounting Bulletin No. 101 (SAB 101) when recognizing revenue. SAB 101 states that the revenue generally is realized or realizable and earned when all of the following criteria are met: a) persuasive evidence of an arrangement exists, b) delivery has occurred or the services have been rendered, c) the seller's price to the buyer is fixed or determinable and d) collectibility is reasonably assured.

The Company recognizes revenue from the sale of analyzers to doctors, hospitals and laboratories upon customer acceptance. The Company recognizes revenue on the sale of test cartridges, supplies and hematology solutions once shipment has occurred and all of the conditions of SAB 101 have been met.

The Company recognizes revenue from sales to distributors according to the terms of the distributor agreements. Revenue from distributors that does not meet all of the requirements of SAB 101 and SFAS No. 48 "Revenue Recognition When a Right of Return Exists" are deferred and recognized upon the sale, or acceptance, if applicable, of the product to the end user.

The Company has entered into sales agreements with leasing companies whereby the Company sells its products directly to the leasing company, who then leases the products to the end user. Sales to the leasing company are on a non-recourse basis and are recognized at the later date of shipment or customer acceptance, when applicable.

Revenues from extended warranty contracts are deferred at the list sales price

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and are recognized over the term of the warranty.

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The Company bills its customers for freight charges related to products sold. Freight revenues are recorded in sales and the related costs are recorded in cost of sales in the accompanying consolidated statements of operations.

Warranty

The Company outsources the manufacture of its Analyzer to a third party who warrants the Analyzers for 18 to 30 months from the date of shipment to the Company. Careside offers a 12 month warranty to the customer. Procedures have been put in place to assure that no Analyzer will be shipped with less than a remaining 12 month warranty. As such, no provision for warranty has been recorded for the years ended December 31, 1999, 2000 and 2001.

Research and Development

Research and development costs are charged to expense as incurred. The company uses both internal and external resources to produce and develop software to run its hardware products. Costs to develop this software are accounted for in accordance with SFAS No. 86, "Accounting for the Costs of Computer Software to be Sold, Leased, or Otherwise Marketed," which requires the Company to capitalize software development costs when "technological feasibility" of the product has been established and future revenues assure recovery of the capitalized amounts. Because of the relatively short time period between "technological feasibility" and product release, the Company has not capitalized any software development costs as of December 31, 2000 or December 31, 2001.

Income Taxes

The Company follows SFAS No. 109, "Accounting for Income Taxes." Under SFAS No. 109, the liability method is used in accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using enacted tax rates that are expected to be in effect when the differences reverse.

Accounting for Stock-Based Compensation

The Company applies Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees," in accounting for its stock options. The Company follows the disclosure requirements of SFAS No. 123, "Accounting for Stock-Based Compensation," which permits pro forma disclosure of the net loss using a fair value-based method of accounting for employee stock option plans (see Note 11).

Net Loss Per Common Share

The Company has presented net loss per common share pursuant to SFAS No. 128, "Earnings per Share." Basic loss per common share was computed by dividing net loss applicable to common shareholders by the weighted average number of shares of common stock outstanding during the period. Dilutive loss per common share has not been presented since the impact on loss per share using the treasury stock method is anti-dilutive due to the Company's losses.

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Recapitalization

In February 1999, Careside's stockholders approved a 1-for-5.2 reverse stock split of Careside's common stock to be effective upon consummation of the initial public offering which took place in June 1999. All references in the accompanying consolidated financial statements to the number of shares and per share amounts have been retroactively restated to reflect the reverse stock split.

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Reclassifications

Certain prior year amounts have been reclassified to conform to the current year presentation.

Recently Issued Pronouncements

Statements of Financial Accounting Standards No. 141, "Business Combinations", and No. 142, "Goodwill and Other Intangible Assets", were recently issued. The Company plans to adopt the standards effective January 1, 2002. The statements, among other things, require the use of purchase accounting for business combinations, discontinues amortization of goodwill, and requires an annual assessment of goodwill for impairment. The statements require amortization of goodwill recorded in connection with previous business combinations to cease upon adoption of the statements by calendar year companies on January 1, 2002. Implementation of SFAS No. 141 and SFAS No. 142 is not expected to have a material impact in 2002 due to the 2001 writedown of goodwill (see note 2).

SFAS No. 143 "Accounting for Asset Retirement Obligations" was issued in June 2001. SFAS No. 143 establishes accounting standards for recognition and measurement of a liability for an asset retirement obligation and the associated asset retirement cost. This statement is effective for financial statements issued for fiscal years beginning after June 15, 2002. The company plans to adopt this standard on January 1, 2003. As the Company currently does not have any legal obligations associated with the retirement of long-lived assets within the scope of SFAS No. 143, the potential future impact statements is not known.

SFAS No. 144 "Accounting for the Impairment of Disposal of Long-Lived Assets" was issued in August 2001. This statement addresses financial accounting and reporting of long-lived assets and for long-lived assets to be disposed of. The provisions of this statement are effective for financial statements issued for fiscal years beginning after December 15, 2001, and interim periods within those fiscal years. The Company will adopt this statement on January 1, 2002. The Company is currently evaluating the impact of SFAS No. 144.

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3. Concentration of Risk

In 1999 and 2001, the Company had no customers who exceeded 10 percent of net sales. In 2000, the Company had sales to three customers that were individually greater than 10 percent of net sales. Combined, these three customers accounted for 38 percent of net sales and 25 percent of accounts receivable at December 31, 2000. The Company's geographic sales data is as follows (in thousands):

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| | 1999 | 2000 | 2001 |
|---------------|-------|--------|----------|
| Domestic | \$ 6 | \$ 282 | \$ 847 |
| Asia Pacific | 47 | 428 | 171 |
| Europe | - | 19 | 7 |
| Latin America | 8 | 12 | - |
| | ----- | ----- | ----- |
| | \$ 61 | \$ 741 | \$ 1,025 |
| | ===== | ===== | ===== |

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4. Property and Equipment (in thousands):

| | December 31, | |
|---|--------------|----------|
| | 2000 | 2001 |
| Laboratory equipment | \$ 1,017 | \$ 1,028 |
| Manufacturing equipment | 7,954 | 8,194 |
| Computer and office equipment | 517 | 560 |
| Leasehold improvements | 368 | 368 |
| | ----- | ----- |
| | 9,856 | 10,150 |
| Less-Accumulated depreciation and amortization | (4,213) | (6,186) |
| | ----- | ----- |
| | \$ 5,643 | \$ 3,964 |
| | ===== | ===== |

Careside had analyzers with a cost of \$1,056,000 and \$1,162,000 and a net book value of \$425,000 and \$98,000 included in laboratory equipment and computer and office equipment at December 31, 2000 and 2001, respectively. These analyzers are used for testing purposes, as design reference units, in research and development activities and for sales and marketing demonstrations.

Depreciation and amortization expense for the years ended December 31, 1999, 2000 and 2001, was \$1,357,000, \$2,933,000, and \$1,973,000, respectively.

5. Income Taxes

Deferred income tax assets or liabilities are computed based on the temporary differences between the financial statement and income tax bases of assets and liabilities using the enacted marginal income tax rate in effect for the year in which the differences are expected to reverse. Realization of the net deferred tax assets is dependent on generating sufficient taxable income during the periods in which temporary differences will reverse. The amount of the net deferred tax assets considered realizable, however, could be adjusted in the near term if estimates of future taxable income during the reversal periods are revised. Deferred income tax expenses or credits are based on the changes in the deferred income tax assets or liabilities from period to period. At December 31, 2001, the Company had net operating loss carryforwards for federal income tax purposes of approximately \$48,560,000. In addition, the Company has federal research and development credit carryforwards of approximately \$1,167,000. The net operating loss carryforwards expire beginning in 2011 through 2020. The research and development credit carryforwards expire beginning in 2012 through 2021. The credits and carryforwards are subject to review and possible adjustment by the Internal Revenue Service. The Tax Reform Act of 1986 contains

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provisions that may limit the net operating loss carryforwards available to be used in any given year in the event of significant changes in ownership interests. The Company experienced such changes in ownership upon the closing of its 1997, 2000 and 2001 private placements. The Company does not believe these changes in ownership will have a material impact on its ability to utilize its net operating loss and tax credit carryforwards. There can be no assurance that ownership changes in future periods will not significantly limit the Company's ability to use existing or future net operating loss or tax credit carryforwards.

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The components of the deferred income tax assets are as follows (in thousands):

| | December 31, | |
|---|--------------|-----------|
| | 2000 | 2001 |
| Net operating loss carryforwards | \$ 14,409 | \$ 18,223 |
| Research and development credit carryforwards | 1,404 | 2,212 |
| Capitalized research and development | 1,840 | 1,528 |
| Start-up costs | 1,359 | 809 |
| Allowance for doubtful accounts | - | 12 |
| Accruals | 124 | 88 |
| Depreciation and amortization | 1,219 | 1,056 |
| Deferred rent | 54 | 63 |
| Inventory reserve | 304 | 224 |
| State tax benefit | (344) | (1,146) |
| Valuation allowance | (20,369) | (23,069) |
| | \$ - | \$ - |
| | ===== | ===== |

Due to the uncertainty surrounding the realization of the deferred tax asset, the Company has provided a valuation allowance against the entire asset.

6. Common Stock Placements

In June 1999, Careside completed an initial public offering of its common stock. The offering totaled 2,000,000 shares of common stock and 2,000,000 tradable warrants exercisable into one share of common stock each. The combined shares and warrants were sold at a price of \$7.50 per unit. The warrants are currently exercisable at a price of \$9.00 per share and expire on the earlier of five years from the date of issuance or if they are called. They are callable at \$0.05 per warrant upon 30 days written notice if the common stock trades for ten consecutive days at a price equal to or exceeding \$14.00 per share.

In March 2000, the Company sold 1,184,091 shares of common stock in a private placement for \$8.77 per share resulting in net proceeds of \$9.5 million, net of \$840,000 of cash offering costs. The \$8.77 per share was at a discount of 20 percent from the average closing price for the twenty days prior to the initial closing date of the sales. The placement agent received warrants to purchase 101,305 shares of Careside's common stock at \$8.77 per share. In connection with the sale, the Company issued the investors and the placement agent contingent warrants for nominal value exercisable into 154,246 shares of the Company's common stock at an exercise price of \$0.01 per share. The contingent warrants were exercisable upon certain conditions. During the third quarter, the conditions triggering the exercisability of these contingent warrants were met. A total of 130,092 warrants were exercised and converted to 130,092 shares of common stock and the remainder expired on December 15, 2000. The estimated fair

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values of the 101,305 and the 154,246 warrants, computed using the Black-Scholes option pricing model were \$972,000 and \$1,997,000 respectively. These amounts were offset against the proceeds of the offering and credited to additional paid-in capital.

In November and December 2000, the Company sold 1,326,479 shares of common stock to an existing investor for an average price of \$2.56 per share, at 90 percent of fair market value, resulting in net proceeds of \$3,084,000, net of \$314,000 of cash offering costs. In conjunction with the placement, warrants to purchase an aggregate of 66,324 shares of common stock were issued with an average exercise price of

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\$2.56. The estimated fair value of these warrants, computed using the Black-Scholes option pricing model was \$102,000. This amount was offset against the proceeds and credited to additional paid-in capital.

In January 2001, the Company sold 416,472 shares of common stock to an existing investor for \$2.25 per share, resulting in net proceeds of \$857,000, net of \$80,000 of cash offering costs and the fair value of warrants issued. In conjunction with the placement, warrants to purchase an aggregate of 20,824 shares of common stock were issued with an average exercise price of \$2.25. The estimated fair-value of the warrant using the Black-Scholes option pricing model was \$31,000 and was offset against the proceeds of the sale.

7. Preferred Stock

In June 1999, the Company exchanged \$1,039,000 of bridge financing and unpaid interest (see Note 9) for 162,914 shares of Series A Convertible Preferred Stock. In July 2000, this Preferred Stock in the amount of \$163,000 and its accrued, unpaid dividends in the amount of \$17,000 were converted into a unit consisting of 179,696 shares of common stock and a warrant to purchase 179,696 additional shares of common stock at \$9.00 per share.

During 2000, the Company sold 150 shares of Series B Convertible Preferred Stock to an investor for net proceeds of \$615,000, net of expenses of \$135,000. In connection with this sale, the Company issued a warrant to the investor to purchase 200 additional shares of Series B Preferred Stock at an exercise price of \$5,000 per share. This warrant was exercised in November 2000 resulting in gross proceeds of \$1,000,000.

The sale of Series B Convertible Preferred Stock also included the placement of callable two year warrants for up to 4,000,000 shares of common stock at an exercise price of \$14.00; however if the warrant is exercised in response to a Company call, then the exercise price will be the lesser of \$14.00 per share or 95% of the average closing price of the stock for the two day period immediately after the date of the notice of the call from the Company. In 2001, callable warrants were exercised for 11,190 shares of common stock.

The sale also included a warrant to the placement agent to purchase 25,000 shares of common stock at an exercise price of \$5.63 per share, or 120% of the closing price on the date prior to the sale. The warrant expires on September 13, 2005.

The placement agent for the Series B Convertible Preferred Stock received a warrant to purchase 50,000 shares of common stock at an exercise price of \$5.63 per share. The warrant expires on September 13, 2005.

The Series B Convertible Preferred Stock was converted into common stock over a

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ten month period which ended July 2001. A total of 782,586 shares were issued as the result of this conversion.

At the date of sale, the conversion feature for the 150 shares was beneficial to the investor because if it was exercised, it could have resulted in proceeds to the investor in excess of the original purchase price of the 150 shares allocated to the Series B Preferred Stock after allocations to warrants. The beneficial conversion feature was recorded as an \$84,044 non-cash charge against the preferred proceeds. This non-cash charge was recorded as a dividend to preferred stockholders in the computation of earnings per share.

The estimated relative fair values of the warrants to purchase 200 shares of Series B Preferred Stock, up to 4,000,000 shares of common stock, 25,000 shares of common stock and 50,000 shares of common stock were \$13,000, \$496,000, \$9,000 and \$13,000 respectively. These amounts were offset against the net proceeds of sale and resulted in an allocation of the remaining net proceeds of \$84,000 to the Series B Preferred. Since the Series B Preferred was mandatorily redeemable at the option of the holder, the carrying value of shares not converted to common stock was accrued as a non-cash dividend to preferred stockholders up to the redemption value of \$5,000 per share on a straight line basis through September 13, 2002. The non-cash accrued dividend recorded at December 31, 2000 was \$83,000 and through December 31, 2001 was \$22,000.

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In March and May 2001, the Company sold 517,371 shares of Series C Convertible Preferred stock in a private placement for \$1.94 per share, at 80 percent of fair market value, resulting in net proceeds of \$9.0 million, net of \$1.0 million of cash offering costs. In conjunction with the placement, warrants to purchase an aggregate of 5,173,716 shares of common stock were issued with an average exercise price of \$2.55. The estimated fair value of these warrants, computed using the Black-Scholes option pricing model was \$5.5 million. This amount was offset against the proceeds and credited to additional paid-in capital. The placement agent received warrants to purchase 517,371 shares of Careside's common stock at \$1.94 per share. The estimated fair value of these warrants, computed using the Black-Scholes option pricing model was \$630,000. This amount was offset against the proceeds and credited to additional paid-in capital.

Prior to the Company's Annual Stockholders' Meeting on May 24, 2001, the Series C Convertible Preferred Stock was mandatorily redeemable at the option of the holders, and its conversion feature had not been approved. As such, the difference between the carrying value and the mandatory redemption amount was accrued over the redemption period and was recorded as a dividend to preferred stockholders. The Company received stockholder approval at its Annual Stockholders' Meeting for the sale and issuance of up to 13,774,130 shares of Common Stock upon the conversion or exercise of the Series C Convertible Preferred, the 5,173,716 investor's warrants and the 517,371 placement agent warrants that had an exercise price below the market price of the Common Stock on the date of issuance. With this approval, the mandatory redemption feature no longer existed. As a result, on May 24, the accretion to redemption value was discontinued. Total accretion recorded in 2001 was \$897,000.

With this approval, the Series C Convertible Preferred Stock also became convertible. At May 24 the conversion feature was beneficial to the investors. The beneficial conversion feature was recorded as a dividend to preferred shareholders in the amount of \$3,799,000 in the consolidated statement of operations.

The Series C Convertible Preferred Stock was exchanged for 5,173,716 placement shares of common stock in October 2001.

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8. Purchase of Texas International Laboratories, Inc. -----

In December 1999, Careside acquired all of the outstanding common stock of TIL in exchange for 521,739 shares of Careside's common stock. TIL was then merged into Careside's newly formed, wholly-owned subsidiary, Careside Hematology. The transaction was accounted for using the purchase method of accounting. Careside acquired substantially all assets of TIL for \$2.9 million, which represented the market value of the 521,739 shares of common stock on the date of acquisition. The excess of the purchase price over the book value of TIL was recorded as goodwill in the amount of \$2,835,000. Goodwill was originally amortized over a five-year period. Amortization expense was \$37,000 in 1999, \$567,000 in 2000 and \$520,000 in 2001. The future value of the goodwill was impaired in the fourth quarter of 2001 and written down in 2001 (see note 2).

The following unaudited proforma results of operations for the year ended December 31, 1999 has been prepared as if the acquisition of TIL occurred on January 1, 1999 (in thousands):

| | |
|---|----------|
| Revenue | \$ 322 |
| Net loss | (12,103) |
| Net loss available to common stockholders | (12,158) |
| Basic and diluted loss per common share | (1.81) |

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9. Related Party Transactions -----

In December 1998, Careside entered into an agreement with an affiliate of SmithKline for up to \$3,000,000 of bridge financing. In 1999, \$1,000,000 of this debt, plus \$39,000 of accrued and unpaid interest was converted to Series A Preferred Stock (see Note 7).

In 1999, the Careside entered into an agreement with Advanced Medical Information Technologies, Inc. (AdMIT) to develop software and hardware. During 1999, Careside paid AdMIT \$300,000 which was included in research and development - software expense. In November 1999, one of the owners of AdMIT was hired by Careside to be its Senior Vice President and Chief Information Officer. In May 2000, the Company amended its agreement with AdMIT to commit to an additional expenditure of \$300,000, of which \$200,000 was incurred and expensed in 2000. At December 31, 2001, the remaining \$100,000 has been accrued in the consolidated balance sheet. In connection with the amendment, the Company also received a 15 percent ownership interest in AdMIT. This investment is carried at no value due to uncertainty regarding the long-term realizability of the investment. In addition to commitments under this agreement, Careside made additional payments to AdMIT of \$76,000 in 2000 and \$12,000 in 2001 for additional research and development expenditures. In addition, during 2000 and 2001, payments of \$275,000 and \$506,000 for software programming were made respectively to a consulting firm where the CIO's brother is one of the partners. These payments totaling \$781,000 were for contract programming and were invoiced at rates which management believes are below market cost from similar competitive service providers.

10. Debt -----

Long-term debt consists of the following (in thousands):

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| | December 31, | |
|---|--------------|----------|
| | 2000 | 2001 |
| | ----- | ----- |
| Note payable to SR One, interest at 10%, due on May 31, 2002 | \$ 2,000 | \$ 2,000 |
| Equipment loan due to finance company, interest at 14%, due in monthly, installments of principal and interest of \$26,837, with a final payment of \$133,490 in December 2002 | 639 | |
| Equipment loan due to finance company, interest at 15%, due in monthly installments of principal and interest of \$14,347, with a final payment of \$69,854 in September 2003 | 422 | |
| Equipment loan due to finance company, interest at 15%, due in monthly installments of principal and interest of \$20,696, with a final payment of \$99,432 in January 2004 | 651 | |
| | ----- | ----- |
| | 3,712 | 3,712 |
| Less--Current Portion | (2,520) | (2,520) |
| | ----- | ----- |
| | \$ 1,192 | \$ 1,192 |
| | ===== | ===== |

In December 1998, Careside entered into a \$2,500,000 facility with an equipment financing company. Borrowings under the facility are evidenced as separate loans and are secured by specific equipment assets. Each equipment loan has a 48-month term and bears interest at approximately 14% and 15% per year. As of December 31, 2001, approximately \$1.7 million of the facility had been drawn under this facility to finance equipment purchases. Careside recorded interest expense of \$155,000, \$284,000 and \$201,000 in 1999, 2000 and 2001, respectively related to these borrowings.

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In December 1998, Careside entered into an agreement with an affiliate of SmithKline (S.R. One, Limited) for up to \$3,000,000 of bridge financing, of which \$1,500,000 was drawn on December 28, 1998 and the remaining \$1,500,000 was drawn on January 31, 1999. The extended maturity date is May 31, 2002. Careside issued a warrant (the "Bridge Warrant") in connection with the bridge financing. The Bridge Warrant was originally exercisable into that number of shares of common stock which is equal to \$750,000 divided by 85% of the initial public offering price per share. The Bridge Warrant has an exercise price of \$6.375 per share. The Bridge Warrant became exercisable in December 1999 and expires on June 16, 2004. Using the Black-Scholes pricing model, the estimated fair value of the Bridge Warrant was calculated at \$330,000 and was recorded as a reduction in the carrying amount of the bridge note, with a corresponding increase in stockholders' equity. The discount on the bridge note was amortized over the estimated term of the note as additional interest expense. In June 1999, \$1,000,000 of the bridge financing plus \$38,575 of unpaid interest was converted to Series A Convertible Preferred Stock (see Note 7). In connection with the conversion, the Bridge Warrant was modified such that it will be exercisable into that number of shares of common stock which is equal to \$1,500,000 divided by 85% of the Offering price per share. Using the Black-Scholes pricing model, the estimated fair value of the increase in shares under the Bridge Warrant modification was calculated at \$289,801 and was recorded as interest expense in 1999, with a corresponding increase in stockholders' equity. In November 2000, the bridge note expiration date was extended to June 30, 2001. In conjunction

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with the extension, the bridge warrant expiration date was extended to June 16, 2004. Using the Black-Scholes pricing model the estimated fair value of the bridge warrant modification was calculated to be \$172,000 and is being recorded as non-cash interest expense over the extended period of the loan. S. R. One has the option to convert all or any portion of the remaining loan, plus accrued interest thereon, into shares of Series A Convertible Preferred Stock. This Series A Convertible Preferred Stock would be issued to S.R. One on the same basis as the Series A Convertible Preferred Stock that was issued to S. R. One in connection with the \$1 million conversion discussed above.

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Future maturities of debt at December 31, 2001 are as follows (in thousands):

| | |
|------|---------|
| 2002 | \$2,756 |
| 2003 | 385 |
| 2004 | 98 |
| | ----- |
| | \$3,239 |
| | ===== |

11. Stock Options and Warrants

Stock Options

Careside has adopted various stock option plans, which provide for the granting of options to purchase up to 1,391,923 shares of common stock to directors, officers, consultants and employees of the Company. At December 31, 2001, 333,003 shares were available for future grant under the plans. The number of options to be granted and the option prices are determined by the Board of Directors in accordance with the terms of the plans. Generally, options are not granted at prices below the fair market value at the date of grant. Each option expires on such date as the Board of Directors may determine. Generally options vest from 3 to 5 years.

The table below summarizes the option activity for 1999, 2000, and 2001:

| | Number of Shares ----- | Weighted Average Exercise Price ----- | Weighted Average Fair Value of Options Granted During the Year ----- | Number Exercisable ----- | Exerci Weight Averag Exerci Price ----- |
|-------------------------------------|---------------------------------|---|---|--------------------------------|--|
| Outstanding at December 31, 1998 | 410,725 ===== | \$ 5.78 ===== | | 198,343 ===== | \$ |
| Granted | 95,017 | 6.17 | \$ 2.82 ===== | | |
| Exercised | - | - | | | |
| Cancelled | (8,365) ----- | 6.07 ----- | | | |
| Outstanding at December 31, 1999 | 497,377 ===== | \$ 5.85 ===== | | 390,278 ===== | \$ |
| Granted | 148,500 | 8.62 | \$ 5.10 | | |

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| | | | | |
|-------------------------------------|-----------|---------|---------|---------|
| | | | ===== | |
| Exercised | (1,154) | 0.05 | | |
| Cancelled | (64,929) | 7.42 | | |
| | ----- | ----- | | |
| Outstanding at December 31, 2000 | 579,794 | \$ 6.40 | | 479,857 |
| | ===== | ===== | | ===== |
| Granted | 492,500 | 2.69 | \$ 1.53 | |
| | | | ===== | |
| Exercised | - | - | | |
| Cancelled | (32,243) | 5.91 | | |
| | ----- | ----- | | |
| Outstanding at December 31, 2001 | 1,040,051 | \$ 4.66 | | 778,995 |
| | ===== | ===== | | ===== |

The table below summarizes information about options outstanding at December 31, 2001:

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| Range of Exercise Prices | Number Outstanding at December 31, 2001 | Weighted Avg. Remaining Life (years) | Exercise Price Of Options Outstanding | Number Exercisable at December 31, 2001 |
|--------------------------------|---|--|---|---|
| ----- | ----- | ----- | ----- | ----- |
| \$ 1.75 - 2.50 | 27,000 | 9.7 | \$ 2.17 | 10,250 |
| \$ 2.65 - 3.75 | 456,550 | 8.6 | \$ 2.72 | 247,525 |
| \$ 5.20 - 7.50 | 489,499 | 5.6 | \$ 5.87 | 480,699 |
| \$ 8.01 -10.00 | 67,002 | 7.9 | \$ 9.96 | 40,521 |
| ----- | ----- | ----- | ----- | ----- |
| \$ 1.75 -10.00 | 1,040,051 | 7.2 | \$ 4.66 | 778,995 |
| | ===== | ===== | ===== | ===== |

As permitted by SFAS No. 123 "Accounting for Stock-Based Compensation," the Company continues to apply the accounting rules of APB No. 25 governing the recognition of compensation expense for employee stock options. Such accounting rules measure compensation expense on the first date at which both the exercise price and the number of shares are known. Expense is only recognized in circumstances where the exercise price is less than the fair market value at the measurement date. No such expense has been recorded in the accompanying consolidated statements of operations.

Under the requirements of SFAS No. 123 pro forma disclosure of compensation expense using the fair value method is required to be disclosed if the Company applies APB No. 25. Pro forma compensation has been computed by estimating the fair value of options at the date of grant using the Black-Scholes option pricing model.

The following assumptions were used in estimating the fair value of options:

| | | | |
|--|-------|-------|-------|
| | 1999 | 2000 | 2001 |
| | ----- | ----- | ----- |

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| | | | |
|--|------------|------------|------------|
| Weighted average risk-free interest rate | 5.92% | 6.50% | 4.79% |
| Weighted average expected life | 4.17 years | 4.00 years | 4.00 years |
| Weighted average volatility | 60% | 72.5% | 78.3% |
| Dividend yield | 0% | 0% | 0% |

Had the compensation cost of these options been recorded for the years ended December 31, 1999, 2000 and 2001, the Company's net loss would have been as follows (in thousands, except per share amounts):

| | 1999 | 2000 | 2001 |
|--|-------------|-------------|-------------|
| | ----- | ----- | ----- |
| Net Loss available to common stockholders: | | | |
| As reported | \$ (11,646) | \$ (16,939) | \$ (20,408) |
| Pro forma | \$ (12,055) | \$ (17,388) | \$ (20,914) |
| Loss per share: | | | |
| As reported | \$ (1.88) | \$ (1.92) | \$ (1.64) |
| Pro forma | \$ (1.94) | \$ (1.98) | \$ (1.68) |

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Stock Warrants

The following table summarizes outstanding warrants at December 31, 2001 issued in connection with private equity financings and the initial public offering (the Offering):

| Type of | Outstanding | Exercise | Issuance | Expiration |
|--------------|-------------|----------|-------------------------------|-------------------------------|
| ----- | ----- | ----- | ----- | ----- |
| Warrants | Warrants | Price | Date | Date |
| ----- | ----- | ----- | ----- | ----- |
| Common Stock | 384,615 | \$ 5.20 | February 1997 | February 2004 |
| Common Stock | 339,312 | 6.76 | June 1998 | June 2005 |
| Common Stock | 235,294 | 6.38 | December 1998 | June 2004 |
| Units | 200,000 | 9.00 | June 1999 | June 2004 |
| Common Stock | 101,305 | 8.77 | March 2000 | March 2005 |
| Common Stock | 179,696 | 9.00 | July 2000 | June 2004 |
| Common Stock | 25,000 | 5.63 | September 2000 | September 2005 |
| Common Stock | 50,000 | 5.63 | September 2000 | September 2005 |
| Common Stock | 3,978,330 | 14.00 | September 2000 | September 2002 |
| Common Stock | 66,324 | 2.56 | November and December 2000 | November and December 2004 |
| Common Stock | 20,824 | 2.25 | January 2001 | January 2005 |
| Common Stock | 5,173,716 | 2.55 | May 2001 | May 2005 |
| Common Stock | 517,371 | 1.94 | May 2001 | May 2005 |
| | ----- | | | |
| | 11,271,787 | | | |
| | ===== | | | |

The warrants to purchase 200,000 units were granted to the underwriters of the initial public offering. Each warrant carries an exercise price of \$9.00 and allows the purchase of one share of common stock and a tradable warrant identical to those sold in the initial public offering. The warrants are exercisable for a four year period beginning on the first anniversary of the

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initial public offering. (See Notes 6 and 7 for discussion of warrants issued in 2001.)

12. Statements of Cash Flows

The Company prepares its statements of cash flows using the indirect method as defined under SFAS No. 95. The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. Supplemental cash flows disclosures are as follows (in thousands):

| | 1999 | 2000 | 2001 |
|----------------------------|--------|--------|--------|
| Cash paid for interest | \$ 158 | \$ 318 | \$ 181 |
| Cash paid for income taxes | 1 | 1 | 1 |

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Non-cash Investing and Financing Activities:

| | 1999 | 2000 | 2001 |
|--|---------|------|-------|
| Conversion of bridge financing to Series A Preferred Stock | \$1,039 | \$ - | \$ - |
| Acquisition of equipment under capital lease | 53 | - | - |
| Accrued dividends on Series A Preferred stock | 55 | 52 | - |
| Accrued dividends on Series B Preferred stock | - | 17 | 21 |
| Accrued dividends on Series B Preferred stock | - | 83 | 22 |
| Beneficial conversion feature on Series B Preferred stock | - | 84 | - |
| Conversion of Series A Preferred stock and unpaid dividends | - | 107 | - |
| Conversion of Series B Preferred stock | - | 55 | - |
| Accrued dividends on Series C Preferred stock | - | - | 897 |
| Beneficial conversion feature on Series C Preferred stock | - | - | 3,799 |
| Cashless exercise of common stock warrant | - | - | - |
| Transfer of analyzers from inventory To property and equipment | - | - | 105 |

In connection with the Company's initial public offering, \$498,000 of previously unpaid deferred offering costs were offset against accounts payable in 1999.

In connection with the acquisition of TIL in December 1999, the Company recorded the following non-cash amounts which have been excluded from the consolidated statement of cash flows (in thousands):

| | |
|----------------------------|---------|
| Additional paid-in capital | \$2,869 |
| Goodwill | 2,834 |

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Net assets acquired 35

13. Commitments

Leases

The Company leases office and laboratory facilities under non-cancelable operating leases expiring from August 2000 to April 2007. Rent expense for the years ended 1999, 2000 and 2001 was \$174,000, \$323,000 and \$362,000, respectively.

Included in property and equipment is approximately \$53,000 of equipment, at acquisition cost, which is leased under a noncancellable lease, accounted for as a capital lease expiring in June 2003. Accumulated depreciation in 1999, 2000 and 2001 related to equipment under capital leases was \$4,000, \$21,000 and \$38,000, respectively.

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At December 31, 2001, the future minimum annual rental payments under lease agreements are as follows (in thousands):

| | Capital Leases | Operating Leases | Total |
|---|-------------------|---------------------|----------|
| December 31: | | | |
| 2002 | \$18 | \$ 353 | \$ 371 |
| 2003 | 9 | 372 | 381 |
| 2004 | - | 386 | 386 |
| 2005 | - | 400 | 400 |
| Thereafter | - | 327 | 327 |
| | ----- | ----- | ----- |
| | 27 | \$ 1,838 | \$ 1,865 |
| | | ===== | ===== |
| Less - Amount representing interest at approximately 14 percent | (3) | | |
| | ----- | | |
| Present value of minimum lease payments | 24 | | |
| Less - Current portion | (15) | | |
| | ----- | | |
| | \$ 9 | | |
| | ===== | | |

Collaborative Arrangements

Careside has utilized strategic partners with specific design and technology expertise in order to develop the Careside system rapidly and on a cost-effective basis. Careside has agreements with (i) Fuji Photo Film Co., Ltd. for the supply of its dry film based chemistry reagents, (ii) International

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Technidyne Corporation for the joint development of coagulation reagents, (iii) UMM Electronics, Inc. (UMM) to design and manufacture the Careside Analyzer and (iv) Advanced Medical Information Technologies, Inc. to develop software to link the Careside system and other medical devices, including the hematology device. In addition, Careside contracted with Hauser, Inc. for the design of the Careside system and with Battelle Memorial Institute for the design of the system's disposable test cartridges and their automated assembly manufacturing system. Careside Hematology has an agreement with Ysebaert, Inc., the manufacturer of the H-2000. In 2001, the Company has negotiated the elimination of previous minimum purchase requirements, as defined in the agreements.

During 2001, the Company paid a deposit of \$300,000 to UMM under a purchase order for 200 analyzers. This deposit was still on hand at UMM at December 31, 2001. The Company and UMM began renegotiating the terms of the purchase order prior to December 31, 2001. The renegotiations are still ongoing. In connection therewith, UMM has requested the Company to reimburse UMM for up to \$1.4 million for the purchase of certain component inventories related to the purchase order. The Company does not believe it bears responsibility for the reimbursement of such component inventories. The Company believes that as part of its renegotiations, it will reach agreement with UMM to resolve this difference for a lesser amount approximating the \$300,000 deposit already paid to UMM. Because the renegotiations have not been finalized, the ultimate liability within the range above cannot be estimated. As such, no accrual for this contingency has been provided at December 31, 2001 in excess of the \$300,000 deposit on hand.

The Company purchases its dry film based chemistry reagents solely from Fuji Photo Film Co., Ltd. In addition, UMM is the primary designer and manufacturer of the Careside Analyzer. The loss of these suppliers could impact the Company's ability to obtain and produce these items in the short-term. However, the Company believes that acceptable alternative suppliers are available.

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Legal Matters

The Company is currently named defendant in legal matters arising in the ordinary course of business. Management does not believe that the outcome of these matters will have a material adverse effect on the Company's financial position or results of operations.

Employment Agreements

In 1997 and 1998 the Company entered into three-year renewable employment agreements with three of its executive officers that provide for aggregate annual compensation of approximately \$660,000. These agreements automatically renew annually unless they are terminated.

14. Profit Sharing Plan

The Company maintains a 401(k) profit sharing plan on behalf of its employees. Participation in the plan is voluntary and eligible employees, as defined, may contribute up to 15 percent of their compensation to the plan. The Company matches 50 percent of the employee's contribution up to 4 percent of an employee's compensation. Contributions under the Plan were \$47,000, \$73,000 and \$70,000 for the years ended 1999, 2000 and 2001, respectively.

15. Employee Stock Purchase Plan

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In 1999, the Company's shareholders approved the Employee Stock Purchase Plan ("ESPP"), under which 150,000 shares of the Company's common stock could be sold to employees. Each quarter, an eligible U.S. employee may elect to withhold up to 15 percent of his or her salary to purchase shares of the Company's stock at a price equal to 85 percent of the fair value of the stock as of the first day of the quarter, or the last day of the quarter. The ESPP will terminate at the earlier of the date that all 150,000 shares have been sold or the date as of which the Board of Directors chooses to terminate the plan as provided in the plan provision. In 1999, 3,502 shares of the Company's stock were sold under the ESPP for \$17,000. During 2000, 30,454 shares of the Company's stock were sold under the ESPP for \$103,000 and in 2001 58,297 shares were sold for \$95,000. At December 31, 2001, 57,747 shares remained available for sale.

16. Subsequent Events

In January 2002, the Company granted 123,900 options to its employees under the 1996 and 1998 stock option plans with a weighted average exercise price of \$0.90 per share.

In January 2002, the Company entered into a loan agreement with an investor that provided a bridge loan of \$600,000. The bridge loan is repayable after 90 days. For each 30 day period this bridge loan is outstanding, the lender will receive warrants to purchase 50,000 shares of common stock at a price of \$0.90 per share.

In February 2002, the Company entered into a note and warrant purchase agreement with an investor that provided a bridge loan of \$350,000. The bridge loan is repayable after 75 days or earlier if the Company consummates a financing of at least \$3,000,000. In connection with this bridge loan, for a 90 day period following repayment of the loan, the lender has the right to purchase up to 500,000 shares of common stock at a price of \$.30 per share. For each 30 day period this bridge loan is outstanding, the lender will receive warrants to purchase 35,000 shares of common stock at a price of \$.30 per share.

Also in February 2002, the Company entered into a note a warrant purchase agreement with each of three of its directors. One of these agreements provided a bridge loan of \$50,000 and each of the other two agreements provided a bridge loan of \$20,000. Each of these bridge loans is repayable upon 90 days or earlier if the Company consummates a financing of at least \$3,000,000. In connection with the \$50,000 bridge loan, for a 90 day period following repayment of the Loan, the lender has the right to purchase up to

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20,000 shares of common stock at a price of \$.30 per share. For each of the \$20,000 bridge loans, each lender has the same purchase right, except that it is for up to 8,000 shares of common stock. For each 30 day period that the \$50,000 bridge loan is outstanding, the lender will receive warrants to purchase 5,000 shares of common stock at an exercise price of \$.30 per share. For each 30 day period that each of the \$20,000 bridge loans is outstanding, each lender will receive warrants to purchase 2,000 shares of common stock at an exercise price of \$.30 per share.

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