

Edgar Filing: CARESIDE INC - Form 10-K/A

CARESIDE INC  
Form 10-K/A  
September 13, 2001

-----  
-----  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

-----  
FORM 10-K/A

Amendment No. 2

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

For the fiscal year ended: December 31, 2000

Commission file number: 001-15051

-----  
Careside, Inc.  
(Exact name of registrant as specified in its charter)

Delaware

23-2863507

(State or other jurisdiction of incorporation or organization) (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 [ ]

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

## Edgar Filing: CARESIDE INC - Form 10-K/A

statements incorporated by reference in Part III of this Form 10-K/A or any amendment to this Form 10-K/A. [ ]

On March 19, 2001, the aggregate market value of the Registrant's Common Equity, par value \$.01 per share, held by non-affiliates of the Registrant was approximately \$17 million, based upon the closing sale price reported for such date on the American Stock Exchange. For purposes of this disclosure, shares of 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 19, 2001, 11,262,352 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 24, 2001 are incorporated by reference into Part III of this Form 10-K/A.

### EXPLANATORY NOTE

This Form 10-K/A (Amendment No. 1) is being filed to amend Items 1, 8, 13 and 14 of the Annual Report on Form 10-K for the fiscal year ended December 31, 2000 (the "Original Form 10-K") which was filed on March 29, 2001.

-----  
-----

### PART I

The Company's forward-looking statements in this Annual Report on Form 10-K/A 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

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. We plan to offer

## Edgar Filing: CARESIDE INC - Form 10-K/A

immunochemistry tests for the Careside system later in 2001. Tests in these five 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 five 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 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. We released the Careside Connect for sale in 2000.

The FDA has granted pre-market clearance for the Careside Analyzer and the H-2000, and pre-market clearance or exemption for 41 blood tests performed by the Analyzer and a 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 2001.

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 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

1

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:

## Edgar Filing: CARESIDE INC - Form 10-K/A

- . 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 system has clearance or approval for 59 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 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. As with any new technology, it involves an expenditure of cash and some learning time by physicians and other healthcare providers. 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

Edgar Filing: CARESIDE INC - Form 10-K/A

effective.

Product Development and Regulatory Status

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,
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 Laboratory and POC Use -----	Planned 2001-2 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	Lactate Direct LDL-cholesterol Direct HDL-cholesterol	Fuji Photo Film Co.

Edgar Filing: CARESIDE INC - Form 10-K/A

	AST ALT/AST Ratio Amylase		
Electrochemistry	Chloride Potassium Sodium	Ionized Calcium	Fuji Photo Film Co.
Coagulation	PT*	APTT Fibrinogen Thrombin Time	Third Party Supplier
Immunochemistry		Theophylline Phenytoin Digoxin Phenobarbital T4 T3 Uptake Carbamazepine	Third Party Supplier

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

3

Product Development and Regulatory Status

Hematology -----	Status of Development -----	Technology Partner/Supplier -----
Careside H-2000 18 parameter, 3 part differential	FDA Cleared; offered for sale to customers	Third Party Manufacturer
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

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

Edgar Filing: CARESIDE INC - Form 10-K/A

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 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 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

## Edgar Filing: CARESIDE INC - Form 10-K/A

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 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

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



## Edgar Filing: CARESIDE INC - Form 10-K/A

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 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 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.

## Edgar Filing: CARESIDE INC - Form 10-K/A

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 (l) 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. In December 1999, we acquired Texas International Laboratories (TIL) in an all-stock acquisition. TIL had developed a new hematology analyzer, the Hematil-2000 which it introduced in April 1999 as a high quality, low cost hematology analyzer that was designed for both human and animal testing. When we acquired TIL, we renamed the device the H-2000. Its hematology tests are equally applicable in the 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 operate with a number of different reagent brands, giving it a high level of flexibility. The H-2000

## Edgar Filing: CARESIDE INC - Form 10-K/A

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 Reiger. We will have exclusive rights to use the Careside Connect in the point-of-care market for laboratory testing services.

7

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 sent to a central location, either a commercial or hospital laboratory, for processing. Commercial laboratories provide approximately 27% of all in vitro diagnostic testing services, hospital laboratories provide approximately 63%, and the balance, about 10%, is currently provided in physicians' offices.

Commercial Laboratories. Commercial laboratories have been the low cost

## Edgar Filing: CARESIDE INC - Form 10-K/A

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.

8

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

## Edgar Filing: CARESIDE INC - Form 10-K/A

ordering the test, but the laboratories are responding with making only single analyte 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.

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 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

9

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 24 hour basis, they require specially trained personnel to be

## Edgar Filing: CARESIDE INC - Form 10-K/A

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 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

Careside has hired a small sales force to launch and train customers on its products in the United States. We will 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. In 2001, we expect to have distribution partners in the United States and in more than fifteen international countries for distribution of the Careside system.

In the U.S., our focus is 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 at the end of 2000 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.

#### 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. Discussions are currently underway for distribution agreements in certain European countries and in the Middle East and South Africa. In addition, the acquisition of TIL has brought distribution opportunities with companies in China, Mexico, Turkey, and certain South America 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 2000, 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 is responsible for compliance with all local or import regulations. These distributors are also responsible for customer support.

In 1997, we entered into a distribution arrangement with Smith Kline Beecham Clinical Laboratories, Inc. (SBCL) which gave SBCL an exclusive right to use and domestically distribute the Careside Analyzer within the commercial laboratory industry and the non-exclusive rights to sell the Careside Analyzer

## Edgar Filing: CARESIDE INC - Form 10-K/A

to hospitals and healthcare systems, other health care providers, managed care organizations and insurers. In June 2000, after Quest Diagnostics, Inc. purchased SBCL, Quest terminated this agreement.

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 because we could use other distributors in each of the countries where we currently use distributors.

11

### 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.

#### H-2000s

We acquired the H-2000 from Texas International Laboratories, Inc. in December 1999. 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. We do not expect our H-2000 sales into the veterinary market to continue at the same levels due to our 2001 focus on the human market. By focusing on the human market, we expect our sales efforts for Analyzers to benefit our H-2000 sales as well, because each device will be marketable to the same customers. The backlog of our H-2000 sales was not material. It was also not material at the end of 1999.

#### Careside Connect



## Edgar Filing: CARESIDE INC - Form 10-K/A

We had no sales of the Careside Connect in 2000 as it was under development until early 2001.

### Significant Customers

In 2000, the Company had sales to three customers that were individually greater than 10 percent of net sales. Combined, these three customers amounted to 38 percent of net sales and 25 percent of accounts receivable at December 31, 2000. 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. markets.

### 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.

12

We continue to pursue development work with other contract partners, including further development of cartridge design with Battelle, coagulation reagent technology with International Technidyne Corporation and software development services of AdMIT for interfaces between the Careside Analyzer and other medical devices and information systems.

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 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 entered into an agreement with UMM Electronics, Inc. for the manufacture of the Careside Analyzer at UMM Electronics' facility in Indianapolis. The contract with UMM covers both development services and manufacturing after development is completed. The development services component of our UMM contract is almost 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.

Our inventories of Analyzers was sufficient in 2000 for internal validation and sales to customers. In 2001, 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

## Edgar Filing: CARESIDE INC - Form 10-K/A

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.

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.

13

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

We have executed a long-term supply agreement 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.

## Edgar Filing: CARESIDE INC - Form 10-K/A

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 2001, 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. 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.

We keep inventories of H-2000's and reagent solutions to support our sales in hematology testing. Our inventories are maintained at levels which are determined by our experience. In 2001, we expect to start using software which captures data about order and utilization patterns among our hematology customers. This data will help us to determine the inventory levels which we will need to keep in the future.

### 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.

### 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

14

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

## Edgar Filing: CARESIDE INC - Form 10-K/A

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 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. A 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.

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.

15

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

## Edgar Filing: CARESIDE INC - Form 10-K/A

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

16

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 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. We expect to receive UL certification for the H-2000 during 2001.

### Clinical Laboratory Improvement Amendments of 1988

All medical testing in the United States is regulated by the Health Care Financing Administration 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

## Edgar Filing: CARESIDE INC - Form 10-K/A

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 HCFA or an organization to whom HCFA 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 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.

17

### 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.

### 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

## Edgar Filing: CARESIDE INC - Form 10-K/A

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.

### Employees

We had 64 employees as of December 31, 2000. Since our initial public offering in June 1999, a number of senior managers have been added with expertise in marketing and sales, information resources, materials management and product development. In addition, the acquisition of TIL has enabled us to move into the veterinary market with experienced management.

### ITEM 8. FINANCIAL STATEMENTS

The Company's consolidated financial statements appear at pages F-1 through F-20, as set forth in Item 14.

### 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. In addition, we continued in 2000 to utilize the software development services of Advanced Medical Information Technologies, Inc., also known as AdMit. AdMit is a company in which our Chief Information Officer, Dennis Reiger, has an equity interest. We paid AdMit \$276,000 in 2000. In addition, we paid an entity owned in part by Mr. Reiger's brother approximately \$275,000 for programming services during 2000. These services were at what we believed were below market rates for comparable services.

In June 2000, S.R. One, Limited agreed to extend the maturity date of the note we owe them to November 2001. The original principal amount of the note is \$2 million. It is the remaining obligation we have from the loan S.R. One made to us in December 1998, a third of which was converted to Series A Preferred Stock, which

was in turn converted to common equity in July 2000. 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. We also issued a



## Edgar Filing: CARESIDE INC - Form 10-K/A

bridge warrant to S.R. One in connection with the bridge financing. The bridge warrant is exercisable for 235,294 shares of common stock at an exercise price of \$6.37 and will expire on July 16, 2004. S.R. One is a venture capital affiliate of GlaxoSmithKline, which owns more than 5% of our outstanding common stock.

On November 29, 2000, December 21, 2000 and January 24, 2001, Careside engaged in three closings of a private placement of common stock and warrants to purchase common stock. Each purchaser in the private placement is an entity controlled by Peter Friedli, who owns more than 5% of our outstanding common stock.

On October 27, 2000, RoyCap, Inc. converted 20 shares of Series B Convertible Preferred Stock at an exercise price of \$2.2625 per share into 44,459 shares of Careside's common stock. On November 2, 2000, RoyCap exercised a warrant to purchase 200 shares of Series B preferred. In addition, on November 13, 2000, RoyCap converted 40 shares of Series B preferred at an exercise price of \$2.4063 per share into 83,800 shares of Careside's common stock. RoyCap, Inc. is an investor that beneficially owns more than 5% of our common stock.

19

### 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/A, commencing on page F-1.

##### (2) 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

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

## Edgar Filing: CARESIDE INC - Form 10-K/A

- 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
- 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.

20

Exhibit No. -----	Description -----
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,

## Edgar Filing: CARESIDE INC - Form 10-K/A

Inc. dated as of September 13, 2000 (including Warrant Certificate)

- 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
- 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\*\*\* Registration Rights Agreement dated as of December 4, 1996 by and between Careside, Inc. and Spencer Trask Securities Incorporated
- 10.5\*\*\* Registration Rights Agreement dated as of January 31, 1997 by and among Careside, Inc. and the Investors signatory thereto
- 10.6\*\*\* Stockholders Agreement dated as of December 4, 1996 by and among the Careside, Inc., SmithKline Beecham Corporation, SmithKline Beecham Diagnostic Systems Co., Spencer Trask Securities Incorporated, Exigent Partners, L.P., W. Vickery Stoughton, Thomas H. Grove, Kenneth B. Asarch, William S. Knight, Donald S. Wong, Ashok K. Sawhney, Philip B. Smith and each Investor signatory thereto
- 10.7\*\*\*\* Registration Rights Agreement dated as of December 7, 1999 by and between Careside, Inc. and Yves LeBihan and Jean-Yves LeBihan.
- 10.8+ Registration Rights Agreement dated as of September 13, 2000, by and between RoyCap, Inc., Brighton Capital, Inc. and Careside, Inc.
- 10.9\*\*\* Registration Rights Agreement dated as of March 6, 1998 by and among Careside, Inc. and the Investors signatory thereto
- 10.10\*\*\* Registration Rights Agreement dated as of March 6, 1998 by and between Careside, Inc. and Spencer Trask Securities Incorporated
- 10.11\*\*\* Registration Rights Agreement dated as of December 17, 1998 by and between Careside, Inc. and S.R. One, Limited
- 10.12\*\*\* 1996 Key Executive Stock Option Plan, as amended and restated
- 10.13\*\*\* 1998 Incentive and Non-Qualified Stock Option Plan
- 10.14\*\*\* 1998 Director Stock Option Plan
- 10.15\*\*\* 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.
- 10.16\*\*\* Agreement dated as of August 31, 1996, by and between Fuji Photo Film Co., Ltd. and Careside, Inc.
- 10.18\*\*\* Product Development and Supply Agreement dated as of July 18, 1997, by and between Careside, Inc. and UMM Electronics, Inc.

Edgar Filing: CARESIDE INC - Form 10-K/A

Exhibit No. -----	Description -----
10.20***	Agreement No. CPO32284 Cost Type executed December 5 and 17, 1996 by and between Battelle Memorial Institute and Careside, Inc.
10.21***	Joint Research & Development Agreement dated as of October 28, 1996 by and between Careside, Inc. and International Technidyne Corporation
10.22***	Employment Agreement dated as of March 3, 1997 between Careside, Inc. and W. Vickery Stoughton
10.23***	Employment Agreement dated as of March 3, 1997 between Careside, Inc. and Thomas H. Grove
10.24***	Employment Agreement dated as of July 30, 1998 between Careside, Inc. and James R. Koch
10.37**	Securities Conversion Agreement dated as of June 14, 1999 between S.R. One, Limited and Careside, Inc.
10.38**	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.

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

\*\*\* 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.

(b) Reports on Form 8-K.

A report on Form 8-K was filed on December 7, 1999 reporting the Company's acquisition of Texas International Laboratories, Inc. on December 7, 1999. An amendment to that 8-K was filed on February 22, 2000, reporting Item 7 Financial Information.

A report on Form 8-K was filed on January 28, 2000 reporting that the Company issued a press release announcing a proposed equity private placement.

## Edgar Filing: CARESIDE INC - Form 10-K/A

A report on Form 8-K was filed on April 20, 2000 reporting that the Company issued press releases announcing that it had completed the equity private placement previously discussed on January 28, 2000.

22

### 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 12th day of September, 2001.

CARESIDE, INC.

/s/ W. Vickery Stoughton

By: \_\_\_\_\_

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

23

### REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

To the Shareholders of Careside, Inc.:

We have audited the accompanying consolidated balance sheets of Careside, Inc. (a Delaware corporation) as of December 31, 1999 and 2000, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2000. 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.

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, 1999 and 2000, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2000, 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, the Company has suffered recurring losses from operations and has accumulated a significant deficit

## Edgar Filing: CARESIDE INC - Form 10-K/A

that 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 23, 2001

F-1

### CARESIDE, INC.

#### CONSOLIDATED BALANCE SHEETS--DECEMBER 31, 1999 AND 2000

	1999	2000
<b>ASSETS</b>		
-----		
Current Assets:		
Cash and cash equivalents.....	\$ 4,905,440	\$ 1,789,259
Accounts receivable, net of allowance of \$0 in 1999 and \$53,670 in 2000.....	78,046	104,132
Inventory.....	548,623	2,698,351
Prepaid expenses and other.....	102,615	173,520
	5,634,724	4,765,262
Property and Equipment, net of accumulated depreciation of \$1,846,275 in 1999 and \$4,212,593 in 2000.....	5,939,186	5,643,028
Deferred Offering Costs.....	2,318	--
Deposits and Other.....	15,000	23,974
Goodwill, net of accumulated amortization of \$36,577 in 1999, and \$566,276 in 2000.....	2,798,170	2,231,221
	\$ 14,389,398	\$ 12,663,485
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
-----		
Current Liabilities:		
Current portion of long-term debt.....	\$ 2,316,192	\$ 2,519,946
Current portion of obligation under capital lease.....	11,006	12,650
Accounts payable.....	844,904	1,456,652
Accrued expenses.....	886,260	420,504
Accrued interest.....	156,493	333,918
	4,214,855	4,743,670
Long-Term Debt, net of current portion.....	1,059,876	1,192,418
Obligation Under Capital Lease, net of current		

Edgar Filing: CARESIDE INC - Form 10-K/A

portion.....	35,835	23,185
	-----	-----
Mandatorily Redeemable Series B Convertible Preferred Stock 0 and 290 shares issued and outstanding at December 31, 1999 and 2000, respectively.....	--	1,054,030
Stockholders' Equity:		
Preferred stock, \$.01 par value: 5,000,000 shares authorized--Series A Convertible Preferred 162,914 and 0 shares issued and outstanding at December 31, 1999 and 2000, respectively.....	1,629	--
Common stock, \$.01 par value:		
50,000,000 shares authorized--7,609,581 and 10,590,191 shares issued and outstanding at December 31, 1999 and 2000, respectively.....	76,095	105,901
Additional paid-in capital.....	37,496,984	50,743,642
Accumulated Deficit.....	(28,495,876)	(45,199,361)
	-----	-----
Total stockholders' equity.....	9,078,832	5,650,182
	-----	-----
	\$ 14,389,398	\$ 12,663,485
	=====	=====

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

F-2

CARESIDE, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Year Ended December 31,		
	1998	1999	2000
	-----	-----	-----
Net Sales.....	\$ --	\$ 60,956	\$ 741,039
Cost of Sales.....	--	30,566	1,001,097
	-----	-----	-----
Gross Profit (Loss).....	--	30,390	(260,058)
Operating Expenses:			
Research and development--			
products.....	8,297,974	8,252,081	9,073,391
Research and development--			
software.....	--	313,400	898,256
Selling and marketing.....	249,000	1,204,548	3,657,072
General and administrative.....	601,129	1,134,900	2,124,264
Goodwill amortization.....	--	36,577	566,949
	-----	-----	-----
Operating Loss.....	(9,148,103)	(10,911,116)	(16,579,990)
Other income(expense):			
Interest Income.....	234,089	291,008	371,781
Interest Expense.....	(22,275)	(970,525)	(495,276)
	-----	-----	-----
Net Loss.....	(8,936,289)	(11,590,633)	(16,703,485)
Preferred stock dividends on Series A & B.....	--	(55,201)	(68,684)

Edgar Filing: CARESIDE INC - Form 10-K/A

Accreted dividend on Series B.....	--	--	(83,028)
Beneficial conversion feature on Series B.....	--	--	(84,044)
Net loss available to common stockholders.....	\$ (8,936,289)	\$ (11,645,834)	\$ (16,939,241)
Basic and Diluted Net Loss per Common Share.....	\$ (1.93)	\$ (1.88)	\$ (1.92)
Shares used in Computing Basic and Diluted Net Loss per Common Share...	4,629,916	6,210,496	8,800,171

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

F-3

CARESIDE, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock		Preferred Stock		Additional	Accumulated	T
	Shares	Amount	Shares	Amount	Paid-in Capital	Deficit	Stock Eq
Balance, December 31, 1997.....	3,365,400	\$ 33,654	--	\$ --	\$10,372,907	\$ (7,968,954)	\$ 2,
Shares issued in connection with private placement, net.....	1,701,225	17,012	--	--	10,180,959	--	10,
Shares issued in connection with exercise of stock options.....	17,715	177	--	--	119,565	--	
Issuance of warrants in conjunction with bridge financing.....	--	--	--	--	330,114	--	
Net loss.....	--	--	--	--	--	(8,936,289)	(8,
Balance, December 31, 1998.....	5,084,340	50,843	--	--	21,003,545	(16,905,243)	4,
Shares issued in connection with initial public offering, net...	2,000,000	20,000	--	--	12,340,788	--	12,
Issuance of Series A Preferred stock in exchange for bridge debt.....	--	--	162,914	1,629	1,036,946	--	1,
Issuance of warrant with bridge conversion.....	--	--	--	--	289,801	--	
Accrued Series A Preferred dividend.....	--	--	--	--	(55,201)	--	
Shares issued in connection with acquisition of Texas							



Edgar Filing: CARESIDE INC - Form 10-K/A

International Laboratories, Inc. ....	521,739	5,217	--	--	2,864,348	--	2,
Shares issued in connection with ESPP...	3,502	35	--	--	16,757	--	
Net loss.....	--	--	--	--	--	(11,590,633)	(11,
Balance, December 31, 1999.....	7,609,581	76,095	162,914	1,629	37,496,984	(28,495,876)	9,
Shares issued in connection with private placements, net.....	2,510,570	25,105	--	--	12,603,565	--	12,
Shares issued in connection with exercise of stock options.....	1,154	12	--	--	48	--	
Accrued Series A Preferred dividend.....	--	--	--	--	(51,787)	--	
Accrued Series B Preferred dividend.....	--	--	--	--	(16,897)	--	
Accreted Series B Preferred dividend.....	--	--	--	--	(83,028)	--	
Shares issued in connection with ESPP...	30,454	305	--	--	102,963	--	
Conversion of Series A Preferred and accrued and unpaid dividends...	179,696	1,797	(162,914)	(1,629)	106,820	--	
Issuance of warrants in connection with Series B Preferred Stock.....	--	--	--	--	530,986	--	
Shares issued in connection with the conversion of the Series B Preferred.....	128,259	1,283	--	--	53,992	--	
Shares issued in connection with cashless exercise of stock warrant.....	385	4	--	--	(4)	--	
Shares issued in connection with exercise of contingent stock warrants.....	130,092	1,300	--	--	--	--	
Net loss.....	--	--	--	--	--	(16,703,485)	(16,
Balance, December 31, 2000.....	10,590,191	\$105,901	--	\$ --	\$50,743,642	\$ (45,199,361)	\$ 5,

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

F-4

CARESIDE, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

For the Year Ended December 31,

-----  
1998                      1999                      2000

Edgar Filing: CARESIDE INC - Form 10-K/A

	-----	-----	-----
Operating Activities:			
Net loss.....	\$ (8,936,289)	\$ (11,590,633)	\$ (16,703,485)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization.....	367,231	1,357,488	2,933,268
Amortization of debt discount.....	20,960	309,154	--
Noncash interest expense.....	--	289,801	--
Changes in operating assets and liabilities:			
Accounts receivable.....	--	(73,446)	(26,086)
Inventory.....	--	(472,123)	(2,149,728)
Prepaid expenses and other.....	(25,118)	(20,442)	(70,905)
Deposits and other.....	80,067	2,700	(8,974)
Accounts payable.....	876,904	(72,942)	611,748
Accrued expenses.....	(49,192)	670,621	(425,220)
Accrued interest.....	--	195,068	177,425
	-----	-----	-----
Net cash used in operating activities.....	(7,665,437)	(9,404,754)	(15,661,957)
	-----	-----	-----
Investing Activities:			
Purchases of property and equipment.....	(2,005,463)	(3,820,634)	(2,070,160)
Cash acquired in purchase of Texas International Laboratories, Inc....	--	118	--
	-----	-----	-----
Net cash used in investing activities.....	(2,005,463)	(3,820,516)	(2,070,160)
	-----	-----	-----
Financing Activities:			
Proceeds from borrowings under long-term debt.....	2,541,084	2,058,831	795,456
Payments on long-term debt.....	--	(223,847)	(459,160)
Payments on capital lease obligation.....	--	(6,139)	(11,006)
Deferred offering costs.....	(498,443)	(2,318)	2,318
Net Proceeds from the issuance of preferred and common stock.....	10,317,713	12,377,580	14,288,328
	-----	-----	-----
Net cash provided by financing activities.....	12,360,354	14,204,107	14,615,936
Net Increase (Decrease) in Cash and Cash Equivalents.....	2,689,454	978,837	(3,116,181)
Cash and Cash Equivalents, beginning of period.....	1,237,149	3,926,603	4,905,440
	-----	-----	-----
Cash and Cash Equivalents, end of period.....	\$ 3,926,603	\$ 4,905,440	\$ 1,789,259
	=====	=====	=====

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

F-5

CARESIDE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

## Edgar Filing: CARESIDE INC - Form 10-K/A

### 1. Careside

#### 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 Instrument Laboratories, Inc. ("TIL") and merged TIL into a newly formed, wholly-owned subsidiary, Careside Hematology. TIL manufactured hematology products used primarily in veterinary applications.

#### Risks and Liquidity

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 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, 2000, the Company incurred a net loss of \$16,703,485, has used cash for operating activities of \$15,661,957 and has an accumulated a deficit of \$45,199,361. 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. 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 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.

### 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.

#### Use of Estimates

## Edgar Filing: CARESIDE INC - Form 10-K/A

The preparation of financial statements in conformity with generally accepted accounting principles 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.

F-6

CARESIDE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

### Cash and Cash Equivalents

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

### Inventory

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:

	December 31,	
	1999	2000
Raw materials.....	\$369,937	\$1,163,593
Work in process.....	48,620	126,111
Finished goods.....	130,066	2,036,265
Reserve for excess and obsolescence.....	--	(627,618)
	<u>\$548,623</u>	<u>\$2,698,351</u>

### 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 office equipment. Leasehold improvements generally are amortized over the remaining life of the lease.

### Goodwill

Goodwill represents the excess of the purchase price and related costs over the value assigned to the tangible net assets of TIL. Goodwill is being

## Edgar Filing: CARESIDE INC - Form 10-K/A

amortized on a straight line basis over 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. In management's opinion, no impairment exists at December 31, 2000.

### 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. The Company has not recorded an impairment loss in any period presented.

F-7

CARESIDE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

### 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 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's distributors do not have rights of return or cancellation and price protection provisions. Revenue from distributors that does not meet all of the requirements of SAB 101 are deferred and recognized upon the sale 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.

### Warranty

The Company outsources the manufacture of its Analyzer to a third party who

## Edgar Filing: CARESIDE INC - Form 10-K/A

warrantees the Analyzers for 30 months from the date of shipment to the Company. Careside offers a 24 month warranty to the customer. Procedures have been put in place to assure no system will be shipped with less than a remaining 24 month warranty. As such, no provision for warranty has been recorded for the years ended December 31, 1998, 1999 and 2000.

### 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 Statement of Financial Accounting Standards (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, 1999 or December 31, 2000.

### Income Taxes

The Company follows Statement of Financial Accounting Standards ("SFAS") No. 109, "Accounting for Income Taxes." Under SFAS No. 109, the liability method is used in accounting for income taxes. Under this

F-8

CARESIDE, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

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.

### 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

## Edgar Filing: CARESIDE INC - Form 10-K/A

per share amounts have been retroactively restated to reflect the reverse stock split.

### Reclassifications

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

### Recently Issued Pronouncements

In June 1999, the FASB issued SFAS No. 133 "Accounting for Derivative Instruments and Hedging Activities". SFAS No. 133 establishes accounting and reporting standards for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities. SFAS No. 133, as amended by SFAS No. 137, is effective for all fiscal quarters of fiscal years beginning after June 15, 2000. The Company does not believe that implementation of SFAS No. 133 and SFAS No. 137 will have a material impact.

### 3. Concentration of Risk

In 2000, the Company had sales to three customers that were individually greater than 10 percent of net sales. Combined, these three customers amounted to 38 percent of net sales and 25 percent of accounts receivable at December 31, 2000. The Company's geographic sales data is as follows:

	1999	2000
	-----	-----
Domestic.....	\$ 5,067	\$281,823
Asia Pacific.....	48,355	428,436
Europe.....	--	18,580
Latin America.....	7,534	12,200
	-----	-----
	\$60,956	\$741,039
	=====	=====

F-9

CARESIDE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

### 4. Property and Equipment

	December 31,	
	-----	-----
	1999	2000
	-----	-----
Laboratory equipment.....	\$ 3,865,507	\$ 4,607,144
Manufacturing equipment.....	3,233,301	4,357,105
Computer and office equipment.....	315,414	513,258

Edgar Filing: CARESIDE INC - Form 10-K/A

Leasehold improvements.....	371,239	378,114
	-----	-----
	7,785,461	9,855,621
Less--Accumulated depreciation and amortization...	(1,846,275)	(4,212,593)
	-----	-----
	\$ 5,939,186	\$ 5,643,028
	=====	=====

At December 31, 2000, Careside had analyzers with a cost of \$1,056,000 and a net book value of \$425,400 included in laboratory equipment and computer and office equipment. 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, 1998, 1999 and 2000, was \$367,231, \$1,357,488 and \$2,933,268, 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, 2000, the Company had net operating loss carryforwards for federal income tax purposes of approximately \$33,634,347. In addition, the Company has federal research and development credit carryforwards of approximately \$1,047,937. The net operating loss carryforwards expire beginning in 2011 through 2020. The research and development credit carryforward expire 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 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 and 2000 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.

F-10

CARESIDE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

The components of the deferred income tax assets are as follows:

	December 31,
	-----
	1999                      2000



Edgar Filing: CARESIDE INC - Form 10-K/A

Net operating loss carryforwards.....	\$ 7,612,306	\$ 14,408,954
Research and development credit carryforwards...	1,115,120	1,403,593
Capitalized research and development.....	2,152,254	1,840,084
Start-up costs.....	1,570,460	1,358,515
Accruals.....	18,569	124,389
Depreciation and amortization.....	783,964	1,219,365
Deferred rent.....	31,365	53,619
Inventory reserve.....	--	304,389
State tax benefit.....	(319,686)	(343,803)
Valuation allowance.....	(12,964,352)	(20,369,105)
	\$ --	\$ --

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 March 1997, Careside completed a private placement (the "1997 Private Placement") of 1,923,090 shares of its common stock at \$5.20 per share. The 1997 Private Placement raised approximately \$8.7 million, net of the placement agent's commission and offering costs. In connection with the 1997 Private Placement, the placement agent and its affiliates received warrants to purchase 384,615 shares of Careside's Common stock at \$5.20 per share. The estimated fair value of these warrants, computed using the Black-Scholes option pricing model, was \$763,527. This amount was offset against the proceeds and credited to additional paid-in capital. These warrants are currently exercisable and expire seven years from the date of issuance.

In June 1998, Careside completed a private placement (the "1998 Private Placement") of 1,701,225 shares of its common stock at \$6.76 per share, which generated net proceeds of approximately \$10.2 million. In connection with the 1998 Private Placement, the placement agent and its affiliates received warrants to purchase 340,237 shares of Careside's common stock at \$6.76 per share. The estimated fair value of these warrants, computed using the Black-Scholes option pricing model, was \$827,178. This amount was offset against the proceeds and credited to additional paid-in capital. These warrants are currently exercisable and expire seven years from the date of issuance. In connection with providing financial consulting services for the 1998 Private Placement, Careside granted an option to purchase 1,154 shares of common stock at \$.05 per share to an entity owned by a director of Careside. The estimated fair value of these warrants using the Black-Scholes option pricing model, was \$7,762 and was offset against the proceeds and credited to additional paid-in capital.

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 share and warrant 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 \$9,544,488,

## Edgar Filing: CARESIDE INC - Form 10-K/A

net of \$840,000 of cash offering costs. The \$8.77 per share was at

F-11

CARESIDE, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

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 and expired on December 15, 2000. 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. The estimated fair value of the 101,305 and the 154,246 warrants, computed using the Black-Scholes option pricing model were \$971,804 and \$1,996,697 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 \$3,084,203, net of \$313,624 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 \$2.56. The estimated fair value of these warrants, computed using the Black-Scholes option pricing model was \$101,638. This amount was offset against the proceeds and credited to additional paid-in capital.

#### 7. Preferred Stock

In June 1999, the Company exchanged \$1,038,575 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 162,914 and its accrued, unpaid dividends in the amount of 16,782 shares 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 \$615,030, net of expenses of \$134,970. 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.

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

## Edgar Filing: CARESIDE INC - Form 10-K/A

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 has a stated value equal to \$5,000 per share and is entitled to an annual five percent (5%) dividend payable, as declared by the board of directors, payable in cash, additional shares of Series B Preferred, or any combination of the two. Accrued and unpaid dividends were \$66,451 at December 31, 2000. The Series B Preferred has a liquidation preference over the Common Stock, but ranks junior to the Series A Convertible Preferred Stock with respect to rights on liquidation, dissolution or winding

F-12

CARESIDE, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

up. The liquidation preference is equal to the stated value of the Series B Preferred Stock, plus all accrued and unpaid dividends. The Series B Preferred Stock has the right to vote as a separate class pursuant to applicable law and on any action limiting the preferences or rights of the Series B Preferred Stock, reclassifying the Common Stock or any other capital stock ranking junior to the Series B Preferred Stock into any class of security ranking senior to or the same as the Series B Preferred Stock, or increasing the authorized number of shares of Series B Preferred Stock.

Each share of Series B Preferred Stock is convertible at the option of the holder at any time before September 13, 2002 into a number of shares of Common Stock equal to the stated value of \$5,000 (plus all accrued and unpaid dividends thereon) divided by the lower of (a) the average of the lowest ten closing sales prices within the last thirty days prior to the date the holder delivers a notice exercising his or her right to convert and (b) \$5.48. In October and November 2000, 60 shares of Series B Preferred Stock, plus accrued and unpaid dividends totaling \$2,233 were converted to 128,259 shares of common stock. The holder may only convert a number of shares of Series B Preferred Stock such that the aggregate number of shares of Common Stock issued to the holder after such conversion of the Series B Preferred Stock and as a result of all prior conversions of Series B Preferred Stock, do not, when aggregated with the number of shares of Common Stock previously issued, or then issuable pursuant to an exercise notice received, upon exercise of the warrant to purchase up to 4,000,000 shares of common stock discussed above, exceed 1,797,631 shares of Common Stock (which number will be adjusted for stock splits and similar events) in violation of Section 713 of the Listing Standards of the American Stock Exchange, unless and until the shareholders of Careside have approved such aggregate issuance of Common Shares in excess of 1,797,631.

The Company has the right to redeem the Series B Preferred Stock, pro rata among all the holders of the Series B Preferred Stock, at any time upon notice to the shareholders for a per share amount equal to \$5,750 plus all accrued and unpaid dividends per share redeemed. The shareholders must be given a minimum of thirty days notice before the date of redemption. During that period, the holders may elect to convert such holder's Series B Preferred stock into Common Shares equal to the Series B Stated Value of \$5,000 plus all accrued and unpaid dividends, divided by the lower of (a) the average of the lowest ten closing sales prices within the last thirty days prior to the date

Edgar Filing: CARESIDE INC - Form 10-K/A

of notice and (b) \$5.475.

At September 13, 2002, any shares of Series B Preferred Stock not converted to common stock must be purchased by the Company at stated value, plus any accrued and unpaid dividends. Due to this mandatory redemption feature, the Series B Preferred Stock is classified as mezzanine financing.

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 value 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 was \$12,626, \$495,601, \$9,327 and \$13,362 respectively. These amounts were offset against the net proceeds of sale and resulted in an allocation of the remaining net proceeds of \$84,044 to the Series B Preferred. Since the Series B Preferred is mandatorily redeemable at the option of the holder, the carrying value of shares not converted to common stock must be accreted 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 accreted dividend recorded through December 31, 2000 was \$83,028.

F-13

CARESIDE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

8. Purchase of Texas Instrument 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 \$2,869,565, 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 \$2,834,747. Goodwill will be amortized over a five-year period. Amortization expense was \$36,577 in 1999 and \$566,949 in 2000.

The following unaudited proforma results of operations for the years ended December 31, 1998 and 1999 have been prepared as if the acquisition of TIL occurred on January 1, 1998:

	Years Ended December 31,	
	----- 1998	1999 -----
	(unaudited)	
Revenue.....	\$ 285,856	\$ 321,823

## Edgar Filing: CARESIDE INC - Form 10-K/A

Net loss.....	(9,532,870)	(12,103,215)
Net loss available to common stockholders.....	(9,532,870)	(12,158,416)
Basic and diluted loss per common share.....	(1.85)	(1.81)

### 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 \$38,575 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 has been incurred and expensed in 2000. 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 of \$76,000 to AdMIT in 2000 for additional research and development expenditures. In addition during 2000, payments of \$275,000 for software programming were made to a consulting firm where the CIO's brother is one of the partners. These payments totaling \$275,000 were for contract programming and were invoiced at rates which management believes are below market cost from similar competitive service providers.

F-14

CARESIDE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

### 10. Debt

Long-term debt consists of the following:

	December 31,	
	1999	2000
Note payable, interest at 10%, due on November 30, 2001.....	\$ 2,000,000	\$ 2,000,000
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.....	854,286	638,945
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.....	521,782	421,929
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.....	--	651,490

Edgar Filing: CARESIDE INC - Form 10-K/A

	-----	-----
	3,376,068	3,712,364
Less--Current Portion.....	(2,316,192)	(2,519,946)
	-----	-----
	\$ 1,059,876	\$ 1,192,418
	=====	=====

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, 2000, approximately \$2.4 million of the facility had been drawn under this facility to finance equipment purchases. Careside recorded interest expense of \$0, \$155,369 and \$283,579 in 1998, 1999 and 2000, respectively related to these borrowings.

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 June 30, 2001. 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 \$330,114 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 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 \$172,138 and will be 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.

F-15

CARESIDE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

Future maturities of debt at December 31, 2000 are as follows:

Edgar Filing: CARESIDE INC - Form 10-K/A

2001.....	\$2,519,946
2002.....	709,306
2003.....	384,973
2004.....	98,139
	-----
	\$3,712,364
	=====

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 1,201,923 shares of common stock to directors, officers, consultants and employees of the Company. At December 31, 2000 603,260 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 1998, 1999, and 2000:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Fair Value of Options Granted During the Year	Number Exercisable	Exercisable Weighted Average Exercise Price
	-----	-----	-----	-----	-----
Outstanding at December 31, 1997.....	317,163	\$5.49		23,051	\$5.28
				=====	=====
Granted.....	111,950	6.76	\$1.83		
			=====		
Exercised.....	(17,715)	6.76			
Cancelled.....	(673)	5.20			
	-----	-----			
Outstanding at December 31, 1998.....	410,725	5.78		198,343	\$5.08
				=====	=====
Granted.....	95,017	6.17	\$2.82		
			=====		
Exercised.....	--	--			
Cancelled.....	(8,365)	6.07			
	-----	-----			
Outstanding at December 31, 1999.....	497,377	5.85		390,278	\$5.76
				=====	=====
Granted.....	148,500	8.62	\$5.10		
			=====		
Exercised.....	(1,154)	0.05			
Cancelled.....	(64,929)	7.42			
	-----	-----			
Outstanding at December 31, 2000.....	579,794	\$6.40		479,857	\$6.05
	=====	=====		=====	=====

Edgar Filing: CARESIDE INC - Form 10-K/A

The table below summarizes information about options outstanding at December 31, 2000:

Range of Exercise Prices	Number Outstanding at December 31, 2000	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price of Options Outstanding	Number Exercisable at December 31, 2000
\$5.00-6.00.....	341,252	6.7 years	\$5.42	335,511
\$6.69-10.00.....	238,542	7.2 years	\$7.79	144,346
	-----	-----	-----	-----
\$5.00-10.00.....	579,794	6.9 years	\$6.40	479,857
	=====	=====	=====	=====

F-16

CARESIDE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

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. In 1998 Careside issued 1,154 options to a consultant. Compensation expense recorded for these options was immaterial.

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:

	1998	1999	2000
Weighted average risk-free interest rate.....	5.56%	5.92%	6.50%
Weighted average expected life.....	7.0 years	4.17 years	4.00 years
Weighted average volatility.....	0%	60%	72.5%
Dividend yield.....	0%	0%	0%

Had the compensation cost of these options been recorded for the years



## Edgar Filing: CARESIDE INC - Form 10-K/A

ended December 31, 1998, 1999 and 2000, the Company's net loss would have been as follows:

	1998	1999	2000
	-----	-----	-----
Net Loss:			
As reported.....	(8,936,289)	(11,645,834)	(16,939,241)
Pro forma.....	(9,279,356)	(12,055,116)	(17,388,486)
Loss per share:			
As reported.....	\$ (1.93)	\$ (1.88)	\$ (1.92)
Pro forma.....	\$ (2.00)	\$ (1.94)	\$ (1.98)

### Stock Warrants

The following table summarizes outstanding warrants at December 31, 2000 issued in connection with private equity financings and the initial public offering (the Offering):

Type of Warrants	Outstanding Warrants	Exercise Price	Issuance Date	Expiration 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.....	179,626	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.....	4,000,000	14.00	September 2000	September 2002
Common Stock.....	66,324	2.56	November and December 2000	November and December 2004
	-----			
	5,581,476			
	=====			

F-17

CARESIDE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

The warrants to purchase 200,000 units were granted to the underwriters of the 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 Offering. The warrants are exercisable for a four year period beginning on the first anniversary of the Offering. (See Notes 6 and 7 for discussion of warrants issued in 2000.)

### 12. Statements of Cash Flows

The Company prepares its statements of cash flows using the indirect method

## Edgar Filing: CARESIDE INC - Form 10-K/A

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:

	1998	1999	2000
	-----	-----	-----
Cash paid for interest.....	\$ --	\$157,653	\$317,851
Cash paid for income taxes.....	--	--	--

### Non-cash Investing and Financing Activities:

	1998	1999	2000
	-----	-----	-----
Conversion of bridge financing to Series A Preferred Stock.....	\$ --	\$1,038,575	\$ --
Acquisition of equipment under capital lease.....	--	52,980	--
Accrued dividends on Series A Preferred stock....	--	55,201	51,787
Accrued dividends on Series B Preferred stock....	--	--	16,897
Accreted dividends on Series B Preferred stock...	--	--	83,028
Beneficial conversion feature on Series B Preferred stock.....	--	--	84,044
Conversion of Series A Preferred stock and unpaid dividends.....	--	--	106,988
Conversion of Series B Preferred stock.....	--	--	55,275
Cashless exercise of common stock warrant.....	--	--	4

In connection with the Company's initial public offering, \$498,433 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:

Additional paid-in capital.....	\$2,869,565
Goodwill.....	2,834,747
Net assets acquired.....	34,818

### 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 1998, 1999 and 2000 was \$156,756, \$174,497 and \$323,168, respectively.

Included in property and equipment is approximately \$52,980 of equipment, at acquisition cost, which is leased under a noncancelable lease accounted for as a capital lease expiring in June 2003. Accumulated depreciation in 1999 and 2000 related to equipment under capital leases was \$4,415 and \$21,287,

## Edgar Filing: CARESIDE INC - Form 10-K/A

respectively.

F-18

CARESIDE, INC.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

At December 31, 2000, the future minimum annual rental payments under lease agreements are as follows:

	Capital Leases	Operating Leases	Total
	-----	-----	-----
December 31:			
2001.....	16,875	339,259	356,134
2002.....	16,875	363,615	380,490
2003.....	9,020	373,229	382,249
2004.....	--	386,107	386,107
2005.....	--	400,008	400,008
Thereafter.....	--	326,983	326,983
	-----	-----	-----
	42,770	\$2,189,201	\$2,231,971
		=====	=====
Less--Amount representing interest at approximately 14 percent.....	(6,935)		
	-----		
Present value of minimum lease payments.....	35,835		
	-----		
Less--Current portion.....	(12,650)		
	-----		
	\$ 23,185		
	=====		

#### 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 Technidyne Corporation for the joint development of coagulation reagents, (iii) UMM Electronics, Inc. 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, Inc. has an agreement with Ysebaert, Inc., the manufacturer of the H-2000. The Company has minimum purchase requirements, as defined in the agreements, with two of its suppliers. Purchase commitment levels were not met for the year ended December 31, 2000. These suppliers have agreed not to enforce the fiscal 2000 requirements.

The Company purchases its dry film based chemistry reagents solely from Fuji Photo Film Co., Ltd. In addition, UMM Electronics, Inc. is the sole

## Edgar Filing: CARESIDE INC - Form 10-K/A

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.

### 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.

### 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, \$34,657, \$47,195 and \$72,913 for the years ended 1998, 1999 and 2000, respectively.

F-19

CARESIDE, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

### 15. Employee Stock Purchase Plan

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 \$16,792. During 2000, 30,454 shares of the Company's stock were sold under the ESPP for \$103,268 and at December 31, 2000, 116,044 shares remained available for sale.

### 16. Subsequent Events

In January 2001, the Company granted 401,500 options to its employees under the 1996 and 1998 stock option Plans with a weighted average exercise price of \$2.69 per share. There were an additional 37,500 options granted to non-employee directors under the 1998 Director Stock Option Plan with a weighted average exercise price of \$2.69 per share.

In January 2001, the Company sold 416,472 shares of common stock in a private placement for \$2.25 per share (at 90 percent of the closing price on that date) resulting in proceeds of \$857,411, net of \$79,650 of offering costs. In connection with the sale, the Company issued a warrant exercisable into 20,824 shares of the Company's common stock at an exercise price of \$2.25 per share. The estimated fair value of the warrant using the Black-Scholes option pricing model was \$31,220 and was offset against the proceeds of the sale.

F-20