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MEDSTONE INTERNATIONAL INC/
Form 10-K
March 30, 2001

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2000

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

For the transition period from _____ to _____

Commission File Number: 0-16752

MEDSTONE INTERNATIONAL, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation or organization)

66-0439440
(I.R.S. Employer
Identification No.)

100 Columbia, Suite 100, Aliso Viejo, California
(Address of principal executive offices)

92656
(Zip code)

Registrant's telephone number, including area code: (949) 448-7700

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

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

Common Stock, \$.004 par value
(Title of Class)

Indicate by check mark whether the registrant (1) has filed all reports
required to be filed by Section 13 or 15(d) of the Securities Exchange Act of
1934 during the preceding 12 months (or for such shorter period that the
registrant was required to file such reports), and (2) has been subject to
such filing requirements for the past 90 days. Yes 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 registrant's knowledge, in definitive proxy or information statements

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

The number of shares of the Common Stock of the registrant outstanding as of March 2, 2001 was 4,273,220. The number of shares of voting and non-voting Common Stock held by non-affiliates on such date was 4,175,140 with an approximate aggregate market value of \$25,311,786.

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(i)

PART I

Item 1. BUSINESS

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Introduction

Medstone International, Inc., (the "Company" or "Medstone"), a Delaware corporation formed in October 1984, manufactures, markets and maintains lithotripters. The Company, as a manufacturer of capital medical devices, has vertically integrated by offering its medical devices directly to providers on a fee-per-procedure basis. Medstone currently offers lithotripsy services both in the United States and internationally on a fee-per-procedure basis in both the fixed and mobile environment. Medstone intends to expand efforts to grow this medical service side of its business and has expanded its product offerings to include several durable medical equipment products marketed to the urology market. The Company's consolidated revenues during fiscal 2000 came primarily from Medstone's lithotripsy business.

One continuing element of the Company's strategic plan is the incubation, financing and staffing of new medical businesses. If and when a new business proves viable, the Company is then in a position to spin-out separate public companies as dividends to the Company's stockholders.

The Company's first spin out was Cardiac Science, Inc. ("Cardiac Science") (trade symbol: DFIB), which occurred in 1991. Cardiac Science designs, manufactures and sells a line of external defibrillation devices for the hospital cardiac care market. During 2000, the Company sold 304,667 shares of its holdings of Cardiac Science for a gain of approximately \$1,855,000. In January 2001, the Company sold an additional 73,000 shares of Cardiac Science for a gain of approximately \$358,000. At March 2, 2001, when the market price of the Cardiac Science stock was \$4.00, the Company held 114,000 shares of Cardiac Science with a balance sheet value of \$0 and a market value of approximately \$456,000. (See Item 13. "Certain Relationships and Investments" and "Note 9. Related Party Transactions" and "Note 13. Subsequent Events" in the Notes to Consolidated Financial Statements.)

In early 1996, the Company spun off two additional subsidiaries, Endocare, Inc. ("Endocare") (trade symbol: ENDO) and Urogen Corp. ("Urogen") (trade symbol: UROG), to the Company's stockholders of record at December 29, 1995. Endocare manufactures equipment and devices to treat urologic soft tissue diseases. Urogen is a development stage biotechnology company currently developing gene therapy products for the treatment of hemophilia A and prostate cancer. During 2000, Urogen changed its name to Genstar Therapeutics Corp. ("Genstar") (trade symbol: GNT). At March 2, 2001, when the market price of the Genstar stock was \$5.45 per share, the Company held 95,000 shares of Genstar with a balance sheet value of \$0 and a market value of approximately \$518,000. (See Note 9. "Related Party Transactions" in the Notes to Consolidated Financial Statements.)

In June 1996 the Company purchased, for \$1.35 million cash, a 60% interest in Northern Nevada Lithotripsy Associates, LLC ("Northern Nevada"), an operator of lithotripsy services. In March 1997, the Company purchased, for \$2.3 million cash, a 60% interest in Southern Idaho Lithotripsy Associates, LLC ("Southern Idaho"), another operator of lithotripsy services. At March 2, 2001, the Company continued to own a majority interest in each of these companies. These companies' revenues are derived from invoicing patients or insurers. (See Note 3. "Acquisitions and Investments in Joint Ventures" in the Notes to Consolidated Financial Statements.)

United Physicians Resources, Inc. ("UPR") was incorporated as a majority-owned subsidiary of the Company in June 1996, to expand the Company's service orientation to the urologist practitioners. UPR provides billing, practice management and consulting services as an additional service line once the initial physician relationship has been established. At March 2, 2001, the Company continued to own a majority interest in UPR. UPR purchased the operations of Integrated Healthcare Systems, Inc. in July 1996 for \$30,000.

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In September 1998, the Company was party to the formation of k.Biotech, an Indian biotechnology company. k.Biotech is a development stage enterprise which has purchased license agreements for four

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compounds developed by the International Centre of Genetic Engineering and Biotechnology of the United Nations ("ICGEB"). The four licensed ICGEB compounds, Hepatitis B Vaccine, Interferon, Erythropoietin and GCSF, may be marketed in ICGEB member countries, primarily in lower Asia and Africa. The Hepatitis B Vaccine is currently in clinical trials in India, with a target of 2002 for the commercialization of this and the Interferon compounds. At March 2, 2001, the Company had invested a total of \$325,000 in k.Biotech, giving the Company then a 21% ownership share. (See Item 13. "Certain Relationships and Investments" and Note 3. "Acquisitions and Investments in Joint Ventures" and Note 9. "Related Party Transactions" in the Notes to Consolidated Financial Statements.)

On April 16, 1999, a wholly-owned subsidiary of the Company, Medstone International, Ltd., ("Ltd") purchased certain assets of Creos Ltd., a former supplier of the Company, from its liquidator for \$165,000 in cash. Upon purchase, the subsidiary, located in Fife, Scotland, commenced manufacturing operations. (See Note 3. "Acquisitions and Investments in Joint Ventures" in the Notes to Consolidated Financial Statements.)

On October 11, 1999, Medstone International Ltd. purchased all outstanding shares of Zenith Medical Systems, Ltd. ("Zenith"), a distributor of durable medical equipment located in Manchester, England, for \$870,000 in cash less \$284,000 of acquired cash for a net cost of \$586,000. (See Note 3. "Acquisitions and Investments in Joint Ventures" in the Notes to Consolidated Financial Statements.)

On April 20, 2000, the Company purchased common stock representing a 46% interest in Medicredit.com, Inc. ("MediCredit") for \$1 million in cash. MediCredit, a California based company, funds and services loans to physicians to finance elective surgeries in the cosmetic and cash paying sector of healthcare. Along with the cash investment in MediCredit, the Company also agreed to a line of credit of up to \$2 million at prime rate. At March 2, 2001, the full \$2 million credit line was outstanding to MediCredit and the Company retained its 46% ownership interest. (See Item 13. "Certain Relationships and Investments" and Note 9. "Related Party Transactions" in the Notes to Consolidated Financial Statements.)

Markets

The Company's current products and planned future products are targeted at the urology, radiology and imaging table markets.

The Company's most important current market is the kidney stone treatment market. In the United States, it is estimated that over 1,500,000 persons per year suffer from kidney stones and an estimated 375,000 patients per year are hospitalized with a primary kidney stone. Historically, approximately 180,000 of these patients have been treated with extra corporeal shockwave lithotripsy each year. With an estimated installed base of 450 lithotripters in the United States, there is a sufficient number of lithotripters to respond to this market.

Outside the United States the incidence of kidney stones varies from country to country. The installed base of extra corporeal shockwave lithotripters is not as extensive as in the United States. Medstone has sold

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systems into Japan, Egypt, Russia, Israel, Saudi Arabia, U.A.E., Hong Kong and China.

The share of its markets that the Company will obtain will be dependent on successful development of new products, obtaining appropriate regulatory agency approvals, market acceptance of the products, the Company's ability to market, the alternative sources of equivalent products and future developments.

An estimated 25 million Americans have gallstones resulting in approximately 500,000 surgeries each year. This compares to an estimated 1.5 million Americans with kidney stones resulting in approximately 200,000 extracorporeal shockwave lithotripsy procedures each year. As approved, the combination of Medstone's lithotripter with a pharmaceutical dissolution is indicated for use in fragmenting and eliminating symptomatic, radiolucent, non-calcified gallstones less than 20 mm in maximum diameter in certain patients with a functioning gallbladder.

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Products

Lithotripsy Equipment

The Medstone STS and STS-T lithotripter systems (the "Systems") are presently being used to treat kidney stones, without invasive surgery, in the U.S. and foreign locations. The Company received a pre-market approval ("PMA") for the STS System from the U.S. Food and Drug Administration ("FDA") in 1988 authorizing commercial use of the device for treating patients with kidney stones. A PMA supplement covering the STS-T System was approved by the FDA in 1998.

In the STS System ("STS"), a series of shockwaves are created outside the patient's body and focused to travel through water-based fluids until they enter the body and disintegrate the stone. Each successive shockwave serves to further break apart the kidney stone into smaller particles until they are small enough to be passed in the patient's urine. A treatment typically requires 1200-1600 shockwaves in a procedure which lasts 45 to 60 minutes.

In addition to the shockwave generator, the STS's components include a customized X-ray table on which the patient lies horizontally with his or her kidney positioned above the shockwave generator, a computer, an X-ray system, an ultrasound system, and an electrocardiogram ("ECG") monitor. The computer generates information regarding the treatment and monitors the patient's condition. The X-ray/ultrasound system produces images that are converted and analyzed by the computer and then used by the physician for proper positioning and to determine when the kidney stone has been sufficiently disintegrated to terminate the treatment. The ECG monitor supplies the data that allows the computer to synchronize the shockwaves with phases of the patient's heartbeat.

The Company has developed and copyrighted all the software that controls the STS. This software, an integral part of the system and therefore subject to review by regulatory agencies, is licensed for use on a per procedure basis.

On September 6, 2000, the Company was notified by the FDA that its PMA application for treatment of gallstones with the STS, in conjunction with the drug Actigall, was approved for commercialization. This places the STS in the position as the only dual-modality lithotripter available in the United States, thereby enhancing the equipment's appeal to hospitals and surgery centers.

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The Medstone STS-T ("STS-T"), is a transportable lithotripter for treatment of kidney stones. The STS-T contains components similar to the STS, except for the ultrasound unit, with all components built to be modular, allowing the STS-T to be moved in and out of a hospital surgical suite. This "in operating room" technology, the current industry direction, allows hospitals and clinics to set up the lithotripter for patient treatment in existing surgical operating rooms and, once complete, the lithotripter can be moved to an equipment holding area or loaded on to a truck for transportation to another facility. This transportability allows hospitals and clinics the flexibility of full-time access to a lithotripter without dedication of a surgical suite to a fixed unit installation.

The STS-T has been commercially distributed for treatment of kidney stones since the Company's PMA supplement was approved by the FDA in 1998. The STS-T currently has ETL, ISO 9001 and EN46001 certifications and the Company is currently undergoing testing for CE mark registration of the STS-T.

The Company also has developed and manufactures its own disposable components for use with the STS and STS-T. Electrodes manufactured by the Company are used to produce electrical sparks in the shockwave generator part of the device. A disposable coupling bag containing fluid for transmission of the shockwave is placed between the shockwave generator and the patient's back or stomach during the treatment. One complete set of the supplies is normally used in each patient procedure.

The Company, as a vertically integrated manufacturer, also offers fee-for-service lithotripsy in the continental United States. It contracts with hospitals, clinics, and ambulatory surgery centers to provide the

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equipment necessary to treat kidney stones, usually on an outpatient basis. It intends to expand the geographic coverage of this service, both domestically and, in future years, to foreign markets.

The Company moves some of its fee-for-service Systems from place to place either in mobile trailers for the STS where treatments are performed or in small trucks for the STS-T. This allows small and mid-size facilities in wide ranging geographic locations to access on a part-time basis equipment and technology that otherwise would only be economically viable in larger population centers. There are currently over 80 sites in the United States that are active sites on the Company's mobile trailer and transmobile routes.

During 1999, the Company developed a business plan which calls for the widespread "permanent" distribution of the STS-T in fee-for-service arrangements. The program gives the hospital, clinic or surgery center full-time access to the intuitive, easy to operate lithotripter and the convenience of a fee-for-service payment plan where fees are incurred only if the equipment is used.

The execution of this business strategy started in the fourth quarter of 1999 and the Company continues its implementation.

The fee-for-service procedures are currently provided by the Company using 15 STS Systems housed in mobile trailers, two STS Systems located at fixed sites and 20 STS-T Systems which are located in "permanent" sites or moved to different locations in small trucks.

Urotable

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With its network of physicians and facilities that utilize lithotripsy products, the Company has begun using that same contact base to market fixed and mobile urological treatment tables, the Medstone "UTS-Series". These urological tables, which are used for various urological procedures, are used both as in-office devices for physicians and as in-facility devices in hospital or clinic settings. The Company is an integrator of products available on the market and will use the "UTS-Series" for bundling of urological tables along with lithotripsy products, and will also sell the "UTS-Series" as a stand-alone product.

The Company's entry in this market was achieved by \$30,000 of development funding to the Swedish manufacturer, Arcoma AB, to develop the mobile urological treatment table. The product was successfully introduced in the fourth quarter of 1999 and the Company continues to expand its distribution.

The Company is also completing development of a state of the art fixed urology table to be introduced in early 2001. This table, also developed by Arcoma for a contract of \$250,000, has multi-plane movement for enhanced patient positioning capability along with physician preference settings programmable into a multifunction touch screen control panel which will control all table, imaging and exposure functions. During 1999 and 2000, the Company has paid a total of \$230,000 to Arcoma for development costs with a balance due of \$20,000 upon deliver of final documentation.

X-Ray Generators

Since commencing operations in 1999, Medstone International, Ltd. has manufactured and marketed a family of compact, high frequency X-ray generators which are used in medical imaging. The compact design allows installation in a very space efficient manner. Its modular design makes repairs in the field time efficient as components can be replaced at the customer's site. Ltd. supplies the equipment used in the STS-T imaging system and the Urotable. The majority of its third party customers are in member countries of the European Union.

Pain Management Tables

Drawing from the Company's relationships with the radiology market and knowledge from the UTS-Series tables, the Company successfully introduced in 2000 the Pro-2000 series of pain management and vascular

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tables. These portable, multi-position tables are used by pain management clinics for imaging and vascular studies in a cost-efficient office or clinic setting. The tables can also be used as portable imaging tables without requiring complete rooms strictly for imaging. The Company currently offers several models of the tables, including fixed height or multi-plane adjustable types.

Kidney Stones and Treatment

A kidney stone develops when the salt and mineral substances in urine form crystals that stick together and grow in size. In most cases, these crystals are removed from the body by the flow of urine, but they sometimes stick to the lining of the kidney or settle in places where the urine flow fails to carry them away. These crystals may gather and grow into a stone ranging in size from that of a grain of sand to a golf ball. Most stones start to form in the kidney. Some may travel to other parts of the urinary system, such as the ureter or bladder, and grow there.

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Stones vary in size, composition and the ease with which they can be dissolved. In some cases, certain medications may be used to lower the amount of acidity or alkalinity in the urine, thereby dissolving the stones. At present, stones that contain calcium cannot be dissolved. Most stones can be treated with conservative methods. This includes increased fluid intake, changes in diet, and medications. About 90 percent of stones that leave the kidney will pass through the ureter within three to six weeks. Stones that do not pass through the ureter may be removed with the aid of a grasping device (basket). The device is passed through a telescopic instrument (cystoscope) that the doctor inserts into the bladder or ureter (urethroscope). In some cases, the stones are removed whole, but sometimes they must be broken into smaller pieces with ultrasound before they can be removed with the basket.

The Medstone STS and STS-T provide a non-invasive nonsurgical treatment for stones in the kidney and ureter called extra corporeal shockwave lithotripsy. In this method, X-rays are used to target the stone, and then high energy shockwaves are used to break down the stones into gravel which passes out with urine within a few weeks.

Although most stones can be treated with nonsurgical methods, certain stones still require conventional surgery, particularly when there is internal scarring and obstruction. With conventional surgery, an incision is made over the stone site. The hospital stay and recovery period are several weeks longer than when more conservative techniques are used. Therefore, stones are treated with non-invasive methods when possible.

Gallstones and Treatment

Gallstones are hard deposits, of which approximately 85% are cholesterol and approximately 15% are calcified, which form in the gallbladder and occasionally may migrate into the common bile duct. Gallstones commonly grow to an inch or more in diameter and two or more stones may be present in the gallbladder and common bile duct at the same time. As the stones grow over time, severe pain can result from inflammation of the gallbladder because of blockage of the natural flow of bile from the liver in and out of the gallbladder, from passage of stones through the common bile duct and from inflammation of the pancreas if the pancreatic duct is blocked. The incidence of gallstones is almost three times greater in women than in men, increases with age and obesity, and is doubled in women who take estrogen and oral contraceptives as these agents increase the body's secretion of cholesterol.

Surgery in which the gallbladder is removed either via laparoscopic or open surgery historically has been the accepted method for treatment of patients with gallstones. Although mortality rates for this type of surgery are low in the U.S. because of the quality of medical care, health care costs associated with hospital stays are substantial and a patient may be a poor surgical candidate or may choose a course of treatment not involving surgery. Oral administration of bile acids have been one method of non-surgical treatment, but this may involve a lengthy period of treatment.

Under the recent approval from the FDA, gallstone disease patients fitting certain criteria established in the Company's gallstone PMA may be treated with non-surgical shockwave lithotripsy using the Company's STS and the drug Actigall. The treatment is similar to the treatment described above for kidney stones. In the treatment for gallstones, ultrasound images are used to target the stone and the same type of high energy shock waves are used to fragment the stone. The stone fragments are ejected from the gallbladder into the digestive tract.

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Production

The Company's Aliso Viejo, California facility, first occupied in 1994, is certified by the FDA under its mandated Good Manufacturing Practices ("GMP"). It also has ISO 9001 and EN 46001 certifications to produce the STS-T. The Company currently has several testing requirements to complete its CE mark registration for the STS-T and has current CE mark registrations for the portable urology and pain management table product lines. Ltd.'s plant in Scotland also has GMP certification from the FDA, along with CE mark, EN46001 and ISO 9001 certifications, for the Company's x-ray generator products. The Company has existing capacity in its plants to produce sufficient quantities of its shockwave lithotripters, urotables, pain management tables and X-ray generators to support its commercial needs for the foreseeable future.

Product Development

The Company research in 2000 concentrated on the development of the UroPro 2000 urology table and several variations of the UroPro 2000T pain table. The Company also has continued expenditures for refinements to the STS-T and its user interfaces. During the year, the Company tested several prototypes of the UroPro 2000 and, late in 2000, took delivery of the first two production units. Development expenses for 2001 will be for the costs associated with refinements, options and new applications of the basic UroPro-2000 urology system. The Company will continue its development program alliance with Arcoma AB and has discussed a possible purchase of a minority interest in Arcoma AB. During the years ended December 31, 1998, 1999, and 2000, the Company's expenditures for research and development totaled \$1,078,792, \$1,455,429 and \$1,180,409, respectively.

Sales and Marketing

The Company's current products and planned future products are targeted at the urology, radiology and imaging table markets. Medstone has a direct sales force covering the continental United States. Outside the United States, the Company uses a network of distributors and direct sales efforts in the United Kingdom through the Ltd. and Zenith subsidiaries.

The Company generates revenue from the sale of equipment, and also from the sale of software licenses, disposable supplies, procedure fees and service contracts to hospitals, physicians, and other health care providers.

The Company offers to hospitals, surgery centers and physician groups lithotripsy services on a fee basis. In the current cost conscious healthcare environment, many facilities do not have the patient flow to justify owning, or the available capital to purchase, a lithotripsy machine. These facilities are candidates for fee-for-service. In a fee-for-service arrangement the customer will sign a contract for a period of time, typically one to three years, and will pay a fixed fee for each patient treated on the lithotripter or a flat monthly equipment charge. Most often this service is provided by a lithotripter that is in a mobile van so a single machine can provide service over a wide geographic area. For facilities with adequate patient flow, fee-for-service can be provided with a fixed unit installed in these facilities.

Marketing for the Company's products is accomplished through advertisement in medical journals, direct mail, direct physician contact, company participation in various associations, product exhibition and telephonic marketing.

Product Liability and Insurance

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The Company currently has in force commercial liability insurance, with coverage limits of \$1 million per incident, and \$2 million on an annual aggregate basis. It also has general umbrella liability insurance with a coverage limit of \$4 million per incident for a total aggregate coverage amount of \$5 million per incident. The Company has product liability and directors and officers liability insurance with a \$10 million coverage limit per incident. The Company's insurance policies provide coverage on a claims-made basis and are all subject to annual renewals.

Government Regulation

Governmental regulations in the United States and other countries are a significant factor affecting the research and development, manufacture and marketing of the Company's products. In the United States, the FDA has broad authority under the Federal Food, Drug and Cosmetic Act and the Public Health Service Act to regulate the distribution, manufacture and sale of drugs, including biologics, and medical devices. Foreign sales of drugs and medical devices are subject to foreign governmental regulation and restrictions which vary from country to country.

Medical devices intended for human use in the United States are classified into three categories, depending upon the degree of regulatory control to which they will be subject. Such devices are classified by regulation into either class I (general controls), class II (performance standards) or class III (pre-market approval) depending upon the level of regulatory control required to provide reasonable assurance of the safety and effectiveness of the devices. A class III product, such as the Medstone STS and STS-T, generally require initial Investigational Device Exemption ("IDE") approval by the FDA. An IDE permits limited clinical evaluation of the product under controlled conditions. Extensive reporting and monitoring of patient treatments made pursuant to the IDE are required. After the PMA is obtained, the product may be marketed to an unrestricted number of users in the United States, but general medical device regulations regarding FDA inspection of facilities, Good Manufacturing Practices, labeling, maintenance of records and filings with the FDA continue to be applicable.

A subset of medical devices, including "old" devices commercially distributed before March 28, 1976 or substantially equivalent to devices that were in commercial distribution before that date, may be marketed under a "510(k) exemption." Section 510(k) section of the Federal Food, Drug and Cosmetic Act provides an exemption from the pre-market approval requirement for such devices. The Medstone UTS-Series is sold under a 510(k) exemption received by the original manufacturer of the components used in the equipment.

In September 2000, kidney stone lithotripters were classified from Class III to Class II devices and became eligible for 510(k) exemptions, but the Company's STS lithotripter still falls under Class III due to its gallstone PMA certification.

Medstone has obtained from the California Department of Health Services a license to manufacture medical devices and is subject to periodic inspections and other regulation by that agency.

Certificate of Need ("CON") laws and regulations are in effect in many states. Under such laws, a CON issued by a governmental agency is generally required before the introduction of certain new health care services or before a hospital or other provider can acquire certain new medical equipment or facilities having values exceeding specified amounts. Failure to obtain a required CON may prohibit the purchase of desired equipment or cause the denial of Medicare or other governmental reimbursements or payments for patient treatments. In recent years several states have repealed their CON

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laws and many other states have made or are considering possible amendments to the laws. Most of the revisions involve raising the thresholds for review, eliminating certain types of facilities or services from review or streamlining the review process.

On January 4, 2001, the Health Care Finance Administration ("HCFA") published final "Stark II" regulations regarding various inpatient and outpatient services, including lithotripsy facilities, and physician ownership of such equipment. Under these regulations, the physician ownership of lithotripsy equipment is not

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expressly forbidden, but must, instead, meet strict guidelines in which any compensation arrangement based on "per use" charges must be at "fair market value". These regulations apply to the patients covered under Medicare, Medicaid and Champus health care. Compliance with these regulations will become effective January 4, 2002, allowing current ownership and contractual arrangements time to be restructured as necessary. The Company believes that its contractual arrangements with its customers are or will be in compliance with the new regulations by the implementation date.

Patents, Copyrights, Trade Secrets and Licenses

The Company's policy is to secure and protect intellectual property rights relating to its technology. While Medstone believes that the protection of patents or licenses is important to its business, it also relies on trade secrets, know-how and continuing technological innovation to maintain its competitive position. The Company has received or filed for certain patents or copyrights for its lithotripter operating systems and utilizes a licensing agreement for certain technology incorporated in its X-ray generators.

The Company seeks to preserve the confidentiality of its technology by entering into confidentiality agreements with its employees, consultants, customers, and key vendors and by other means. No assurance can be given, however, that these measures will prevent the unauthorized disclosure or use of such technology.

Competition

The Company's products currently marketed and under development will be competing with many existing products and therapies for market share. The Company competes with fully integrated device companies, many of which have substantially more experience, financial and other resources and superior expertise in research and development, manufacturing, testing, obtaining regulatory approvals, marketing and distribution.

Future products of the Company are expected to address the urological market. The Company's competition will be determined in part by the particular urological disease to which the Company's potential products relate. An important factor in competition may be the timing of market introduction of its or competitive products. Accordingly, the relative speed with which Medstone can develop products, complete the clinical trials and approval processes and supply commercial quantities of the products to the market are expected to be important competitive factors. The Company expects that competition among products approved for sale will be based on, among other things, product efficacy, safety, reliability, availability, price, patent position and sales, marketing and distribution capabilities.

The Company's competitive position also depends upon its ability to attract and retain qualified personnel, obtain patent protection or otherwise develop

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proprietary products or processes and secure sufficient capital resources for the often substantial period between technological conception and commercial sales.

Shockwave Lithotripters

The Company's two principal competitors in kidney stone shockwave lithotripsy are Dornier, a subsidiary of a Singapore-based conglomerate, and Siemens GmbH, a German electronic company. In addition, a number of other companies, both in the U.S. and foreign countries, have PMAs or 510(k) exemptions to sell their lithotripters for the treatment of kidney stones in the U.S. or are applying for 510(k) device exemptions for the use of their lithotripters for the treatment of kidney stones.

The Company believes that, in addition to the obtaining of FDA and other governmental approvals, important competitive factors in the markets for shockwave lithotripters include the reliability, effectiveness in treating patients and pricing of particular systems. The Company believes the Medstone Systems compare favorably with other lithotripters presently being offered by competitors with respect to the precision of their imaging systems, their ease of patient handling, their simplicity of operation design, their safety features and their success rate in treating patients.

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Fee-For-Services

In the fee-for-service business segment, the Company competes with a number of service-oriented medical businesses, in a fragmented and highly competitive industry, both nationally and locally. Moreover, certain of the Company's current and potential competitors have substantially greater financial resources than the Company and may compete with the Company for acquisitions and development of operations in markets targeted by the Company. The Company has experienced competition in the acquisition of existing lithotripsy facilities and the development of relationships with treating physicians. The Company has experienced competition from hospitals or treating physicians who have opened their own lithotripsy facilities. Such competition could intensify in the event of a decrease in the purchase price of lithotripters or if the supply of new or used lithotripters increases over time.

The Company's main competitors in the fee-for-service business are Prime Medical Services, Inc., a Texas-based mobile lithotripsy provider, the lithotripsy business of Integrated Health Services, Inc., a Maryland based healthcare concern, of which one operating entity owns lithotripsy provider partnerships, and other smaller regional and local providers.

Tables and X-ray Generators

The Company's main competitors in the urological table business are Liebel Flarsheim Co., an Ohio-based division of Mallinkrodt which manufactures urology products, and OEC Medical Systems, Inc., a Utah-based division of GE Medical Systems, which provides imaging and related products.

The Company's x-ray generators compete in a market which has been highly competitive and price sensitive. This market includes hospital radiology, oncology and orthopedic departments as well as clinics and surgery centers. Most equipment is sold as replacements of existing equipment that has ceased operating or fails performance criteria.

Competition in the x-ray and imaging equipment market is widespread, with GE Medical Systems, a subsidiary of General Electric, a world wide

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conglomerate, and Siemens Medical Systems, a subsidiary of Siemens GmbH, a German conglomerate, and numerous smaller manufacturers, both domestic and foreign.

Backlog--Shockwave Lithotripsy

The Company's lithotripsy equipment sale backlog for the STS-T was \$0 for the STS-T as of March 1, 2001 and \$375,000 as of March 1, 2000. Due to the high per unit price of the Medstone Systems, equipment backlog can vary significantly from period to period based upon the number of systems on order. Backlog consists only of orders evidenced by signed contracts for equipment scheduled for delivery and installation within 12 months and does not include revenues for maintenance and per procedure charges, or management services contracts.

Backlog for radiology equipment (urology tables, pain tables and oncology tables) totaled \$1,156,000 as of March 1, 2001 with no comparable amount in the prior year due to these products' introduction during 2000.

With the maturity of Medstone's lithotripsy business, recurring revenues from fee for service and procedure fees and maintenance services have become a major source of Medstone's revenue stream. Maintenance services are generally provided under annual service contracts, and procedure and fee for service fees are earned based upon usage of the System.

Human Resources

As of February 15, 2001, Medstone had 100 employees. Of the 100 employees, 5 are engaged directly in research and development activities, 27 are engaged in manufacturing, 22 are engaged in mobile operations, 20 are engaged in field service, 11 are engaged in sales and marketing and 15 are employed in general and administrative positions.

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Although Medstone conducts most of its research and development using its own employees, the Company has funded, and plans to continue to fund, research using consultants. Consultants provide services under written agreements and are paid based on the amount of time spent on Company matters. Under their consulting agreements, Medstone's consultants are required to disclose and assign to the Company any ideas, discoveries and inventions developed by them in the course of providing consulting services.

Item 2. PROPERTIES

In March 1994, the Company took occupancy of 20,600 square feet of office, manufacturing, engineering, and warehouse space, and research and development laboratories, located in Aliso Viejo, California. In April 2000, the Company signed a new 64-month lease on the present facility with an average monthly rent of \$19,449 for the term. The initial term will expire November 30, 2005, with an option to renew for five years at a rental rate to be negotiated in the future based on the market rates.

Medstone International, Ltd. leases a 5,000 square foot facility in Fife, Scotland, for manufacturing, warehouse and administrative operations for approximately \$2,900 per month with a term through October 2005.

Zenith owns a 6,107 square foot building in Manchester, England which it uses to house administration, warehouse and equipment staging.

United Physicians Resources leases a 1,417 square foot office in Phoenix,

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Arizona with a monthly rental expense of \$2,150 under an operating lease which expires in October 2002.

Item 3. LEGAL PROCEEDINGS

The Company carries director and officer liability insurance, and has indemnification agreements with its officers and directors.

From time to time, the Company is subject to legal actions and claims for personal injuries or property damage related to patients who use its products. The Company has obtained a liability insurance policy providing coverage for product liability and other claims. Management does not believe that the resolution of any current proceedings will have a material financial impact on the Company or the consolidated financial statements.

Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

The Company's annual meeting of shareholders was held on June 21, 2000. At the meeting Frank R. Pope, David V. Radlinski, Donald Regan and Michael C. Tibbitts were elected directors of the Company.

EXECUTIVE OFFICERS OF THE REGISTRANT

Information regarding the Company's executive officers is included in Item 10 of Part III.

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PART II

Item 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

The Company's common stock is traded on the NASDAQ Stock Market under the symbol MEDS. The following table sets forth the high and low sales prices of the Company's common stock for the two years ended December 31, 2000 and December 31, 1999 as reported in the NASDAQ National Market System for the quarter indicated.

| | High | Low |
|------------------------------|---------|---------|
| | ---- | --- |
| Year ended December 31, 2000 | | |
| ----- | | |
| First quarter..... | \$8 | \$4 3/4 |
| Second quarter..... | 6 3/4 | 5 1/32 |
| Third quarter..... | 9 | 5 19/64 |
| Fourth quarter..... | 7 17/16 | 5 5/16 |
| Year ended December 31, 1999 | | |
| ----- | | |
| First quarter..... | \$8 1/2 | \$6 1/8 |
| Second quarter..... | 8 9/16 | 6 1/2 |
| Third quarter..... | 7 5/32 | 6 |
| Fourth quarter..... | 6 17/32 | 4 3/8 |

The stock markets have experienced extreme price and volume fluctuations during certain periods. These broad market fluctuations and other factors may adversely affect the market price of the Company's Common Stock. Any shortfall

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in revenue or earnings from levels expected by securities analysts could have an immediate and significant adverse effect on the trading price of the Company's common stock in any given period. Additionally, the Company may not learn of such shortfalls until late in the fiscal quarter, which could result in an even more immediate and adverse effect on the trading price of the Company's stock. Finally, the Company participates in a highly dynamic industry, which often results in significant volatility of the Company's common stock price.

At March 2, 2001, there were 233 stockholders of record and approximately 2,200 beneficial owners of the Company's Common Stock.

The Company has not paid any cash dividends during its two most recent fiscal years. The Company's board of directors does not presently anticipate that any cash dividends will be paid in the foreseeable future.

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Item 6. SELECTED FINANCIAL DATA

| | Year ended December 31, | | | | |
|--|--|----------|----------|----------|----------|
| | 2000 | 1999 | 1998 | 1997 | 1996 |
| | (in thousands, except per share amounts) | | | | |
| Consolidated Statements of Operations Data: | | | | | |
| Revenues: | | | | | |
| Net equipment sales..... | \$ 3,284 | \$ 3,338 | \$ 2,144 | \$ 2,722 | \$ 2,420 |
| Procedure, maintenance, and management fees..... | 18,930 | 19,532 | 21,129 | 18,476 | 14,884 |
| Interest and dividends..... | 608 | 598 | 552 | 536 | 676 |
| | ----- | ----- | ----- | ----- | ----- |
| Total revenues..... | 22,822 | 23,468 | 23,825 | 21,734 | 17,980 |
| Costs and expenses: | | | | | |
| Cost of sales..... | 13,942 | 12,106 | 11,000 | 9,503 | 8,009 |
| Research and development..... | 1,180 | 1,456 | 1,079 | 1,021 | 522 |
| Selling..... | 2,175 | 2,048 | 1,988 | 2,257 | 2,146 |
| General and administrative..... | 2,651 | 2,592 | 2,131 | 2,231 | 1,666 |
| | ----- | ----- | ----- | ----- | ----- |
| Total operating costs..... | 19,948 | 18,202 | 16,198 | 15,012 | 12,343 |
| | ----- | ----- | ----- | ----- | ----- |
| Operating income..... | 2,874 | 5,266 | 7,627 | 6,722 | 5,637 |
| Lawsuit settlement costs..... | -- | -- | -- | -- | 5,500 |
| Other (income) expense..... | (1,773) | (97) | (61) | (39) | 402 |
| Minority interest in subsidiaries income..... | 895 | 603 | 628 | 468 | 143 |
| | ----- | ----- | ----- | ----- | ----- |
| Income (loss) before provision (benefit) for income taxes..... | 3,752 | 4,760 | 7,060 | 6,293 | (408) |
| Provision (benefit) for income taxes..... | 1,663 | 1,919 | 2,718 | 2,329 | (170) |
| | ----- | ----- | ----- | ----- | ----- |
| Net income (loss)..... | \$ 2,089 | \$ 2,841 | \$ 4,342 | \$ 3,964 | \$ (238) |
| | ===== | ===== | ===== | ===== | ===== |
| Net income (loss) per share:(1) | | | | | |
| Basic..... | \$.46 | \$.57 | \$.84 | \$.74 | \$ (.04) |

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| | | | | | |
|--------------|--------|--------|--------|--------|----------|
| Diluted..... | \$.46 | \$.56 | \$.82 | \$.72 | \$ (.04) |
|--------------|--------|--------|--------|--------|----------|

December 31,

| | | | | |
|------|------|------|------|------|
| 2000 | 1999 | 1998 | 1997 | 1996 |
|------|------|------|------|------|

(in thousands)

Consolidated Balance Sheet Data:

| | | | | | |
|---------------------------|----------|----------|----------|----------|----------|
| Working capital..... | \$15,597 | \$17,539 | \$18,432 | \$16,256 | \$14,983 |
| Total assets..... | 29,877 | 30,175 | 29,149 | 27,688 | 25,395 |
| Total liabilities..... | 3,569 | 3,758 | 3,216 | 3,567 | 4,230 |
| Stockholders' equity..... | 26,308 | 26,417 | 25,933 | 24,121 | 21,165 |

(1) Restated in accordance of SFAS Statement No. 128 "Earnings Per Share".

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ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

General

Medstone manufactures, markets and maintains lithotripters, and continues to expand its Fee-for-Service Program to supply lithotripsy equipment to providers on a per procedure basis. The lithotripters manufactured by Medstone is approved to treat both kidney stones and gallstones. The Company is also marketing a urology imaging and treatment table, used for various urological functions, mobile urology and pain management table to serve the mobile treatment market and various radiology room equipment, capitalizing on the relationships that the Company has with radiology equipment manufacturers. To date, the Company's consolidated revenues have come primarily from Medstone's lithotripsy business.

As a manufacturer of medical devices, the Company has been vertically integrating by offering its medical devices directly to providers. It currently offers lithotripsy procedures using 15 mobile systems, two fixed sites and 20 transmobile lithotripters located throughout the United States on a per procedure basis. With the ability to offer quality equipment at reasonable prices, Medstone intends to continue the growth of this manufacturer direct business.

In June 1996, the Company completed the acquisition of a 60% interest in Northern Nevada, a lithotripsy partnership which deals directly with patient and insurers, and also founded UPR as a majority-owned subsidiary of the Company, to expand the Company's service orientation to the urologist practitioner. Both entities signify the Company's emphasis on growth through expansion of relationships and acquisition. In March 1997, the Company completed the acquisition of a 60% interest in Southern Idaho Lithotripsy Associates LLC, another operator of "retail" lithotripsy operations in Southern Idaho, and operating results have been consolidated effective March 1, 1997. In April 1999, the Company purchased certain assets of Creos, Ltd., a manufacturer of high performance x-ray generators and a supplier to the Company. The Company then commenced manufacturing operations in a facility, located in Fife, Scotland, formerly occupied by Creos, Ltd. In October 1999, the Company purchased the outstanding shares of Zenith Medical Systems, Ltd., a distributor of major imaging equipment to the British National Health

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Service, located in Manchester, England. Both 1999 acquisitions' operating results have been consolidated effective with their respective acquisition dates.

Goodwill represents approximately 11% and 12% of the Company's total assets and stockholders' equity, respectively, at December 31, 2000. Goodwill resulted from the excess of the purchase price of Northern Nevada, Southern Idaho and Zenith Medical Systems, Ltd. over the fair value of the net assets acquired. Goodwill is being amortized over periods ranging from 15 to 40 years, the expected period of benefit, using the straight-line method. The Company reviews goodwill and other long-lived assets for impairment whenever changes in circumstances indicate that the carrying value of the asset may not be recoverable. Based upon the Company's analysis, which includes a comparison of the carrying amount of such assets to the Company's historical actual cash flows and estimated future undiscounted cash flows, the Company is not aware of any material portion of goodwill or other long-lived assets which will dissipate over a shorter period than the amortization period used.

From time to time, the Company makes investments in businesses which are accounted for under the equity method. During 2000, the Company made an investment, including loans, in Medicredit.com aggregating \$3 million. During 1998 and 1999, the Company made an aggregate investment in k.Biotech of \$325,000. The Company's share of losses in unconsolidated subsidiaries in 2000, related to Medicredit.com, approximated \$61,000. No earnings or losses in unconsolidated subsidiaries were recognized in 1999 or 1998. The Company does not have additional financial commitments to these unconsolidated subsidiaries. The future performance of the unconsolidated subsidiaries is uncertain and therefore, the Company may recognize earnings or losses in unconsolidated subsidiaries in the future.

The Company began the year with approximately \$9.7 million in cash and short-term investments, no debt, inventories of \$5.8 million, and total assets of \$30.2 million. After the purchase of \$2.7 million of treasury stock, an investment in and lendings to MediCredit totaling \$3.0 million and fixed asset additions of \$1.5 million,

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partially offset by proceeds from the sale of long-term investments of \$1.9 million, the Company ended the year with approximately \$6.2 million in cash and short-term investments, no debt, inventories of \$6.1 million and total assets of \$29.9 million.

Through its research and development, acquisitions and clinical submissions, management believes that it is hiring and retaining the appropriate personnel necessary to continue growth and development of the Company's product lines and brand recognition.

From time to time, the Company is subject to legal actions and claims for personal injuries or property damage related to patients who use its products. The Company has obtained a liability insurance policy providing coverage for product liability and other claims. Management does not believe that the resolution of any current proceedings will have a material financial impact on the Company or the consolidated financial statements.

Results of Operations

Year Ended December 31, 2000 Compared to Year ended December 31, 1999

The Company recorded total revenue of \$22.8 million in 2000, a 3% decrease compared to the \$23.5 million in total revenue recognized for the year ending

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December 31, 1999. Revenues from procedures, maintenance fees and fee-for-service decreased to \$18.9 million in 2000 when compared to the \$19.5 million in revenue in 1999. Pricing pressures continue to force per patient charges lower as competing equipment has saturated the market with low cost, transportable lithotripsy equipment. Patient volume and per patient fees both decreased during 2000 as sites continued to transition to lower cost equipment and more sites are selecting a flat daily or monthly fee in anticipation of the release of final Stark II regulations which occurred on January 4, 2001. Procedure fees from third party equipment decreased by 11%, the second year in a row with decreased fees. Although patient volume increased by 4% in 2000 when compared to 1999 fees per procedure decreased. The Company experienced an increase in volume as STS-T units, which commenced shipment in 1999, reached full utilization and also renewed interest in the Company's lithotripsy products was achieved due to the approval of the gallstone procedure. Revenue from radiographic supplies increased in the current year due to a full year of activity from both the Medstone Ltd., and Zenith operations and additional activity from the expanding product offerings from the Company during 2000.

Equipment revenues decreased by 2% in 2000 when compared to the same period in 1999 as the number of lithotripters sold decreased to 7 in 2000, compared to 10 in 1999 and average sales prices decreased slightly. Offsetting this decrease in lithotripters was the introduction of the imaging tables in 2000, with a total of 29 various units sold in 2000. This equipment included pain management tables, radiology tables and portable urology tables along with the imaging systems associated with several unit sales.

Interest income increased by 1% in the current year when compared to the same period of the prior year due to higher investment yields even though the average invested balance has decreased substantially.

Costs on recurring revenue increased to \$11.7 million, or 62% of recurring revenue in 2000, compared to \$10.2 million, or 52% of recurring revenue in 1999 due to the continuation of the Company's program of placement of a large number of fixed-site fee-for-service lithotripsy units at hospitals and surgery centers. It is expected that these units will drive long-term patient volume growth with the continuous availability of equipment, along with the expectation of additional volume due to the gallstone approval. Costs of providing maintenance increased also due to the higher number of Company-owned units in service.

Cost of equipment sales increased to \$2.3 million in 2000, or 69% of sales in the current year compared to \$1.9 million, or 58%, for the year ended December 31, 1999. This increase is due to the lower margin associated with the sale of radiology equipment when compared to the historical higher margin on lithotripsy equipment. Lithotripsy equipment margins deteriorated slightly due to unabsorbed overhead expenses due to lower actual production levels when compared to plan.

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Research and development costs decreased by 19%, or \$275,000 in the twelve months ending December 31, 2000 when compared to the same period of 1999. This decrease is due to the majority of the development work on the UroPro-2000 urology imaging table occurring earlier in 2000 and reduced staffing after completion in 1999 of the final development of the STS-T.

Selling costs increased by \$126,000, or 6%, for the year ending December 31, 2000 compared to the same period in 1999 due to higher advertising, tradeshow and consulting expenses with the introduction of the new imaging table products. The Company has also increased its efforts to sell into the government contract market and is incurring expenses to establish

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reimbursement guidelines for gallstone lithotripsy.

General and administrative expenses increased by \$59,000 or 2% in the twelve months ended December 31, 2000 compared to the same period in the prior year due to higher consulting expenses for the gallstone post-approval work, higher audit expenses due to the expanded scope of the Company's operations, and a full year's expenses in Medstone Ltd..

Gain on sale of investments was approximately \$1,882,000 in the twelve months ending December 31, 2000 compared to \$244,000 in the same period of 1999. In 2000, the Company sold 304,667 shares of Cardiac Science, Inc. common stock and 5,000 shares of Genstar common stock, while in 1999 the Company sold warrants to purchase 87,500 shares of Cardiac Science common stock. The net book value of these sales was \$0.

Minority interest in subsidiaries income increased by \$292,000 or 48% in the twelve months ended December 31, 2000 when compared to the same period of the prior year due to substantially higher activity in the Northern Nevada and Southern Idaho operations. Also the Company, through its equity investment in Medicredit, recognized a \$61,000 expense for its portion of the operating losses of Medicredit from April 1, 2000 through December 31, 2000.

Provision for income taxes for the year 2000 decreased by \$256,000 as a result of lower taxable income in the current year when compared to the same period of 1999.

Year Ended December 31, 1999 Compared to Year ended December 31, 1998

Total revenue of \$23.5 million in 1999 represented a 1% decrease in revenue when compared to \$23.8 million in 1998, breaking a string of several years of continuous revenue growth. Results were lower in the procedure, maintenance and management fee revenue partially offset by an increase in the equipment revenue generated by 1999's sales activity.

Revenue from procedure, maintenance fees and fee-for-service decreased to \$19.5 million in 1999, an 8% decrease, when compared to the \$21.1 million in revenue in 1998. This decline was due to the market pressures of the widespread availability of transportable lithotripters that caused patient volume to shift as customers purchased lower cost lithotripsy systems and average revenue per patient decreased. With the lower price for transportable technology, some larger patient volume customers chose to purchase equipment from the Company or its competitors and price concessions were instituted for continuing customers. In 1999, procedure revenue from third party owned equipment decreased by 11% compared to the prior year, due to declines in both volume and lower per procedure fees. Maintenance fees decreased by 20% in the current period when compared to 1998 due to lower average contract prices and a lower number of sites under maintenance contracts. The Company also realized revenue of \$604,000 in 1999 from sales of the imaging product lines acquired with the Zenith and Ltd operations.

Net equipment sales in 1999 increased to \$3.3 million, or 56%, from \$2.1 million for the comparable period of the prior year. This was due to the increased shipments of equipment related to the introduction of the STS-T transportable lithotripter in 1999, even though transportable lithotripters carry a lower average unit sales price when compared to the fixed unit models. The activity level of equipment upgrades remained level in the current year compared to the prior year.

Interest income increased by 9%, or \$47,000, in the year ended December 31,

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1999 when compared to the same period of the prior year as average invested cash balances increased even as yields remained level from year to year.

Costs on recurring revenue increased to \$10.2 million in 1999, or a 12% increase when compared to the \$9.0 million in 1998 due to the Company's strategy of placing STS-T equipment in customer sites on a permanent basis, making the technology always available to the customer, rather than a scheduled service program. This approach has a large up-front investment with the results reflected in the patient volume as utilization increases.

Cost of equipment sales decreased to 58% of revenue for the year ended December 31, 1999 compared to 89% of revenue for the year ended December 31, 1998. In absolute dollars the costs remained level from year to year as the Company realized substantial cost savings from the introduction of its transportable lithotripter even as total unit shipments doubled.

Research and development costs increased by \$377,000, or 35% when compared to 1998 levels due to increased spending on the transportable lithotripter and continued development of the "UTS Series" of products.

Selling expenses increased by \$60,000, or 3%, in 1999 when compared to 1998 due to the introductory advertising expenses for the Medstone STS-T transportable lithotripter and the Company's trade show expenses for the medical imaging business.

General and administrative expenses increased by 22% or \$461,000 from 1998 to 1999, due to the increased staffing costs for foreign operations, costs associated with the strategic planning process during 1999 and legal costs associated with actions against the Company.

Other income/expense increased by \$36,000 in 1999 when compared to 1998 due to recognition of gains on sale of Cardiac Science securities partially offset by an investment reserve in 1999 compared to the gain on sales of a joint venture in 1998.

Minority interest expense decreased to \$603,000 in 1999 compared to \$628,000 in 1998 due to a slight decrease in the per patient revenue and the corresponding effect on profitability.

Provision for income taxes decreased due to a lower level of profitability in the current year when compared to the prior year.

Liquidity and Capital Resources

At December 31, 2000, the Company had cash and short-term investments of approximately \$6.2 million. These funds were generated from operating activities.

During 2000, the Company purchased 459,800 shares of treasury stock for approximately \$2,736,000. The Company estimates that the purchase resulted in a 10% increase in basic net income per share.

The Company's long-term capital expenditure requirements will depend upon numerous factors, including the progress of the Company's research and development programs, the time required to obtain regulatory approvals, the resources that the Company devotes to the development of self-funded products, proprietary manufacturing methods and advanced technologies, the cost of acquisition and/or new revenue opportunities, the ability of the Company to obtain additional licensing arrangements and to manufacture products under those arrangements, the demand for its products if and when approved and possible acquisitions of products, technologies and companies.

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The Company believes that its existing working capital and funds anticipated to be generated from operations will be sufficient to meet the cash needs for continuation of its present operations during 2000. See "Safe Harbor Statement under the Private Securities Litigation Reform Act of 1995."

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Safe Harbor Statement Under the Private Securities Litigation Reform Act of 1995

Forward-looking statements in this report, including without limitation, statements relating to the Company's plans, strategies, objectives, expectations, intentions and adequacy of resources, are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Investors are cautioned that such forward-looking statements involve risks and uncertainties including without limitation the following: (i) the Company's plans, strategies, objectives, expectations and intentions are subject to change at any time at the discretion of the Company, (ii) the Company's plans and results of operations will be affected by the Company's ability to manage its growth; (iii) the Company's businesses are highly competitive and the entrance of new competitors into or the expansion of the operations by existing competitors in the Company's markets and other changes could adversely affect the Company's plans and results of operations; and (iv) other risks and uncertainties indicated from time to time in the Company's filings with the Securities and Exchange Commission.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The Company has no financial instruments which are subject to market risk. Although the Company's earnings and cash flows are subject to fluctuations due to changes in the interest rates on its investments, a hypothetical 10% adverse decrease in the interest rates would not have a material adverse effect on the results of operations because the majority of the Company's investments are short-term treasury bills. A 10% reduction in interest rates would reduce interest income by approximately \$50,000 annually. Due to the short period to maturity, the Company believes that the impact of a 10% reduction in interest rates would not have a material effect on the carrying value of its securities.

The Company's earnings and cash flows at Medstone International, Ltd., a Scottish subsidiary are subject to fluctuations due to changes in foreign currency rates. The Company believes that changes in the foreign currency exchange rate would not have a material adverse effect on its results of operations as the majority of its foreign transactions are delineated in Medstone International, Ltd.'s functional currency, the British Pound.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

See Item 14. "Exhibits, Financial Statement Schedules, and Reports on Form 8-K."

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

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PART III

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Item 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

Directors

The following are the directors of the Company:

| Name ---- | Age --- | Principal Occupation ----- |
|--------------------------|------------|--|
| David V. Radlinski..... | 56 | Chairman of the Board and Chief Executive Officer of the Company |
| Frank R. Pope..... | 51 | Executive Managing Director The Global Financial Group |
| Donald J. Regan..... | 66 | Chairman of the Board Advanced Biocatalytics Corporation |
| Michael C. Tibbitts..... | 53 | Executive Vice President Quality System Solutions |
| David A. Reed..... | 68 | Consultant DAR Consulting Group |

Mr. Radlinski has been the Chairman of the Board and Chief Executive Officer of the Company since September 1995. He had been the President of the Company's subsidiary, Medstone International, Inc., and Chief Financial Officer and Secretary of the Company from January 1991 to September 1995. From July 1987 to January 1991, he was the Company's Executive Vice President of Finance, Chief Financial Officer and Secretary. From 1984 to 1987, he was Vice President of Finance and Chief Financial Officer of Printronix, Inc., a publicly-owned company which manufactured computer printers.

Mr. Pope has been the Executive Managing Director of The Global Financial Group, a private fund management firm since April 2000. He is also Managing Director of Verdigris Capital, a private investment firm. From April 1981 to October 1996, Mr. Pope was a General Partner with Technology Funding, a venture capital investment firm. He is also the Executive Vice President, Chief Financial Officer and a director of Technology Funding Inc. Mr. Pope is also a director of Thermatrix, Inc., Breadcrumbs.com, and a director and officer of Advanced BioCatalytics Corp. Mr. Pope is a C.P.A. and a member of the California Bar. He has been a director of the Company since January 1991.

Mr. Regan, an attorney, is currently the Chairman of the Board of Advanced Biocatalytics Corporation, a private biotech company and a founder and director of Breadcrumbs, Inc., developer of a new search engine, and is a consultant to Kinsell, Newcomb & De Dios, Inc., a municipal securities investment banking firm. Mr. Regan has practiced securities, municipal finance, nonprofit corporation, real estate, and business transactions law for over thirty years. He has published several articles on securities law and served as a lecturer for the Practicing Law Institute. He has been a director of the Company since September 1995.

Mr. Tibbitts is currently Executive Vice President of Quality System Solutions, a medical software company. From May 1991 to May 1999, he was Vice President of Gulf South Medical Supply, Inc., a medical supply distributor. Prior to joining that corporation, he was employed for 19 years by Johnson & Johnson in two divisions: Sterile Design (which manufactured and marketed kit packages) and Surgikos (which manufactured and marketed surgical supplies). He has been a director of the Company since May 1996.

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Mr. Reed is now retired, was formerly president and chief executive officer of St. Joseph Health System in Orange, California. He is the former Board Chairman of Mission Hospital Regional Medical Center in Mission Viejo, California. He also serves as a Board Chairman of PacifiCare Health Systems, a publicly traded company. He has been a director of the Company since August 1999.

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Executive Officers

The names, ages and positions of all the executive officers of the Company as of March 2000 are listed below, followed by a brief account of their business experience during the past five years. Officers are normally appointed annually by the Board of Directors at a meeting of the directors immediately following the Annual Meeting of Shareholders. There are no family relationships among these officers nor any arrangements or understandings between any officer and any other person pursuant to which an officer was selected. None of these officers has been involved in any court or administrative proceeding within the past five years adversely reflecting on his or her ability or integrity.

| Name ---- | Age --- | Position ----- |
|-------------------------|------------|--|
| David V. Radlinski..... | 56 | Chief Executive Officer and Chairman of the Board |
| Mark Selawski..... | 45 | Vice President of Finance, Chief Financial Officer and Secretary |
| Eva Novotny..... | 43 | Executive Vice President of Sales and Marketing |

Mr. Radlinski has been the Chairman and Chief Executive Officer of the Company since September 1995. He had been the President of the Company's subsidiary, Medstone International, Inc., and Chief Financial Officer and Secretary of the Company from January 1991 to September 1995. From July 1987 to January 1991, he was the Company's Executive Vice President of Finance, Chief Financial Officer and Secretary. From 1984 to 1987, he was Vice President of Finance and Chief Financial Officer of Printronix, Inc., a publicly-owned company which manufactured computer printers.

Mr. Selawski has been the Chief Financial Officer, Vice President of Finance and Secretary of the Company since September 1995. He had previously served as the Company's Manager of Planning and Analysis since joining the Company in 1988. Prior to joining the Company he held various finance management positions with several high-tech manufacturing companies.

Ms. Novotny has been Executive Vice President of Sales and Marketing of the Company since October 1997. Prior to joining the Company, she was Director of Marketing for Imagyn Medical, formerly UroHealth, from June 1995 to October 1997. From 1985 to 1995, she was employed by Mentor Corporation, manufacturer of aesthetic and general surgery products, as a Marketing Manager and later as Director of Marketing for Mentor Urology.

Section 16(a) Beneficial Ownership Reporting Compliance

The Company is not aware of any director, officer or 10% shareholder who

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during 2000 failed to file on a timely basis any report regarding the Company's securities required by Section 16(a) of the Securities Exchange Act of 1934.

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Item 11. EXECUTIVE COMPENSATION

Executive Compensation

The following table sets forth certain information regarding compensation paid by the Company during each of the Company's last three fiscal years to the Company's Chief Executive Officer and to each of the Company's other executive officers during fiscal 2000.

SUMMARY OF COMPENSATION TABLE

| Name and Principal Position | Fiscal Year | Annual Compensation | | | Long Term Compensation | | | All Other Compensation (\$) |
|---|-------------|---------------------|------------|--------------------------------|--------------------------------|---------------------------|---------|-----------------------------|
| | | Salary (\$)(1) | Bonus (\$) | Other Annual Compensation (\$) | Awards | | Payouts | |
| | | | | | Restricted Stock Award(s) (\$) | Underlying Options (#)(2) | | |
| David V. Radlinski..... Chairman of the Board and Chief Executive Officer | 2000 | 250,000 | -- | 2,224 | -- | -- | -- | -- |
| | 1999 | 250,000 | -- | 2,426 | -- | -- | -- | -- |
| | 1998 | 219,135 | -- | 2,426 | -- | 350,000 | -- | -- |
| Mark Selawski..... Chief Financial Officer, Vice President of Finance and Secretary | 2000 | 101,667 | 5,500 | -- | -- | -- | -- | -- |
| | 1999 | 105,625 | 500 | -- | -- | -- | -- | -- |
| | 1998 | 99,038 | 300 | -- | -- | 80,000 | -- | -- |
| Eva Novotny..... Executive Vice President of Sales and Marketing | 2000 | 120,000 | 5,500 | -- | -- | -- | -- | -- |
| | 1999 | 120,000 | 500 | -- | -- | -- | -- | -- |
| | 1998 | 120,000 | 300 | -- | -- | 70,000 | -- | -- |

(1) In addition to the cash compensation shown in the table, executive officers of the Company may receive indirect compensation in the form of perquisites and other personal benefits. For each of the named executive officers, the amount of this indirect compensation in 2000, 1999 and 1998 did not exceed the lesser of \$50,000 or 10% of the executive officer's total salary and bonus for that year.

(2) Options to acquire shares of Common Stock granted or repriced.

Employment Agreements

Mr. Radlinski - On August 13, 1998, the Company entered into an employment agreement with Mr. Radlinski to assure his continued service to the Company. The agreement runs for a term of five years, expiring on August 13, 2003. The agreement provides for a base salary of not less than \$250,000 per year, subject to adjustments as authorized by the Board of Directors.

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Mr. Radlinski is also eligible for bonuses based on performance of the Company's Common Stock. The Common Stock's closing price must attain and remain at or above various levels, ranging from \$11 to \$21, for a period of 90 consecutive days. If these breakpoint prices are achieved within a set number of months, the longest which is 48 months, from the commencement of the contract, a cash bonus will be paid following the achievement period. Each breakpoint bonus can be earned separately if achieved within the stated achievement period, but each bonus can only be awarded once.

Concurrent with the commencement of this agreement, the exercise prices of Mr. Radlinski's existing stock options to purchase up to 350,000 shares of the Company's Common Stock from \$7.13 to \$10.63 were reduced to equal \$6.375 per share, the closing price per share of the Company's Common Stock on the commencement date as reported on the NASDAQ National Market System. Such option agreements were amended to provide that they shall become fully exercisable, regardless of any otherwise applicable vesting requirements, i) concurrently with any termination of Mr. Radlinski's employment by the Company without "Good Cause" (as defined), or ii) if there is an acquisition of substantially all of the Company's assets or business while he is still employed by the Company and he does not immediately enter into an employment agreement with a buying or surviving party in the transaction (a "change in control").

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If he is terminated without "Good Cause" or a change of control occurs within the first three years of the agreement, a severance payment of five times his then current base salary will be due and payable. If he is terminated without "Good Cause" or such a change of control occurs within the fourth year of the agreement, a severance payment of four times his then current base salary will be due and payable. If he is terminated without "Good Cause" or a change of control occurs within the fifth year of the agreement, a severance payment of three times his then current base salary will be due and payable.

In addition to the preceding paragraph, if Mr. Radlinski is terminated without Good Cause in the first three years of this agreement, he will become a consultant to the Company for a period of five years following termination at a monthly compensation of \$16,500 per month. If he is terminated without Good Cause in the fourth year of this agreement, he will become a consultant to the Company for a period of four years following termination at the same monthly compensation. If he is terminated without Good Cause in the fifth year of this agreement, he will become a consultant to the Company for a period of three years following termination at the same monthly compensation. The Company, during the consulting contract, shall provide term life insurance equivalent to the unpaid amount of the consulting fees as established above, payable to the beneficiary of his designation.

Mr. Selawski and Ms. Novotny - On August 13, 1998, the Company entered into employment agreements with both Mr. Selawski and Ms. Novotny to assure their continued service to the Company. The agreements run for a term of three years, expiring on August 13, 2001. The agreements provide for a base salary of not less than \$100,000 per year for Mr. Selawski and \$120,000 per year for Ms. Novotny, subject to adjustments as authorized by the Board of Directors.

Concurrent with the commencement of these agreements, the exercise prices of Mr. Selawski's existing stock options to purchase up to 80,000 shares of the Company's Common Stock at from \$7.13 to \$9.68 were reduced to equal \$6.375 per share, the closing price per share of the Company's Common Stock on the commencement date as reported on the NASDAQ National Market System. Ms.

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Novotny's existing stock options to purchase up to 70,000 shares of the Company's Common Stock at from \$9.68 to \$10.68 were reduced to equal \$6.375 per share, the closing price per share of the Company's Common Stock on the commencement date as reported on the NASDAQ National Market System. Each such option agreement was amended to provide that it shall become fully exercisable, regardless of any otherwise applicable vesting requirements, i) concurrently with any termination of the officer's employment by the Company without Good Cause, or ii) if there is an acquisition of substantially all of the Company's assets or business while such officer is still employed by the Company and he or she does not immediately enter into an employment agreement with a buying or surviving party in the transaction. If the officer is terminated without "Good Cause" or such a change of control occurs within the term of the agreement, a severance payment of two times his or her then current base salary will be due and payable.

Stock Option Grants During 2000

No options were granted during 2000.

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Stock Options Held at End of Fiscal Year

The following table provides information related to options exercised during 2000 and options held by the named executive officers at December 31, 2000.

| Name | Shares Acquired on Exercise (#) | Value Realized (\$)(1) | Number of Securities Underlying Unexercised Options at FY-End (#) | Value of Unexercised In-the-Money Options at FY-End |
|-------------------------|---------------------------------|------------------------|---|---|
| David V. Radlinski..... | -- | -- | 295,000/55,000 | ----/- |
| Mark Selawski..... | -- | -- | 62,333/17,667 | ----/- |
| Eva Novotny..... | -- | -- | 42,334/27,666 | ----/- |

(1) The value is calculated based on the difference between the option exercise price and the market price for the Company's Common Stock on the exercise date, multiplied by the number of shares purchased. For this purpose, the surrender or withholding of shares to pay the exercise price is not taken into account.

(2) The closing price for the Company's Common Stock as reported by the National Association of Securities Dealers (NASD) on December 31, 2000 was \$5.875. Value is calculated on the basis of the difference between the option exercise price and \$5.875, multiplied by the number of shares of Common Stock underlying the option.

Compensation Committee Interlocks and Insider Participation

During 2000 Donald J. Regan and Frank R. Pope served as the members of the Company's Compensation Committee. Neither such individual is a current or former officer or employee of the Company or any of its subsidiaries. During 2000 there were no compensation committee interlocks between the Company and other entities involving Medstone executive officers serving as directors or members of compensation or similar committees of such other entities.

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Compensation of Directors

The Company currently compensates its outside directors, Messrs. Regan, Tibbitts, Pope and Reed, a \$10,000 annual retainer, paid quarterly, and \$1,000 per Board meeting for their services, and reimburses all directors for expenses incurred by them in connection with the Company's business.

Under the Nonemployee Director Stock Option Plan which expired in June 1999, each new nonemployee director was automatically granted an option to purchase up to 5,000 shares as of the effective date of his or her first appointment to the Board or first election to the Board by the shareholders, whichever is earlier. Subject to acceleration of the option exercises in the event of certain events specified in the plan, including certain changes in control based on altered makeup of the Company's Board or stockholders, each such option becomes exercisable with respect to 1/60 of the shares issuable for each elapsed full month during the five-year period after its grant date during which the optionee remains on the Company's board. The exercise price of each option equals the fair market value of the underlying Common Stock on the date the option was granted. Each option will expire six years after its grant, except that the expiration will be extended until one year after the optionee's death if it occurs less than one year before the option's expiration date. An option granted under the plan is not transferrable during the grantee's lifetime and must be exercised within one year following his or her death, or within 90 days after the grantee ceases to be a member of the Board for any other reason, and will only be exercisable to the extent it is exercisable on the date the grantee leaves the Board. Under this plan, Mr. Regan was granted 5,000 shares in September 1995 and Mr. Tibbitts was granted 5,000 shares in May 1996. Both grants have exercise prices of \$6.375 after repricing of the options on August 13, 1998.

Options to purchase 15,000 shares of Common Stock were issued to Messrs. Pope, Regan and Tibbitts in November 1996 and have exercise prices of \$6.375 after repricing of the options on August 13, 1998. The options are exercisable, after six months following their grant dates, in incremental amounts equal to 1/48 of the

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underlying shares for each elapsed calendar month during which the director remains on the Company's Board. The terms of the options are five years, subject to earlier termination related to the director no longer serving on the Board. Additionally, each such director was granted options under the Company's 1997 Stock Incentive Plan, on August 13, 1998 and June 24, 1999, for 4,000 shares at an exercise price of \$6.375 and \$7.375, respectively. These options are exercisable, after six months following their grant dates, in incremental amounts equal to 1/36 of the underlying shares for each elapsed calendar month during which the director remains on the Company's Board. The term of the options are four years, subject to early termination related to the director no longer serving on the Board.

Upon his becoming a director in July 1999, Mr. Reed was granted an option under the 1997 Stock Incentive Plan to purchase up to 5,000 shares of Common Stock at an exercise price of \$6.56 per share. Subject to acceleration of the option exercise in the event of certain events specified in the option agreement, including certain changes in control based on altered makeup of the Company's Board or shareholders, the option becomes exercisable, after six months following its grant date, with respect to 1/60 of the shares issuable for each elapsed full month during the five-year period after its grant date during which Mr. Reed remains on the Company's Board. The option term is six years, subject to early termination related to Mr. Reed no longer serving on

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the Board, but the option will be extended one year after his death if it occurs less than one year before the expiration date.

Subject to certain exceptions set forth in the applicable plan or agreement provisions, the exercisability of the outstanding options held by the nonemployee directors will be accelerated, and the options will thereafter terminate, if there is a reorganization, merger or consolidation as a result of which the Company is not the surviving corporation or the Company's outstanding shares are changed into or exchanged for cash, property or securities not of the Company's issue, or if there is a sale of all or substantially all of the Company's assets. Such accelerations will not apply if appropriate provision is made in the transaction for the assumption of such options by, or the substitution of new options for such options covering the stock of, the surviving, successor or purchasing corporation or its affiliate.

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Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth the number of shares of the Company's Common Stock known to the Company to be beneficially owned as of March 2, 2001 by each person who owns beneficially more than 5 percent of the outstanding shares of Common Stock, by each of the present directors, by each of the executive officers named in the Executive Compensation in Item 11 and by all executive officers and directors of the Company as a group, and the percentage of the total outstanding shares of Common Stock such shares represented as of March 2, 2001.

| Name and Address of Beneficial Owner ----- | Number of Shares Beneficially Owned(1) ----- | Percentage of Ownership ----- |
|--|---|-------------------------------------|
| FMR Corp. 82 Devonshire Street Boston, MA 02109 | 561,200 | 13.1% |
| Hathaway & Associates, Ltd. 119 Rowayton Avenue Rowayton, CT 06853 | 500,000 | 11.7% |
| David V. Radlinski (2) (3) 100 Columbia, Suite 100 Aliso Viejo, CA 92656 | 390,833 (4) | 8.5% |
| Dimensional Fund Advisors, Inc..... 1299 Ocean Ave., 11th Floor Santa Monica, CA 90401 | 363,700 | 8.5% |
| Mark Selawski (3)..... 100 Columbia, Suite 100 Aliso Viejo, CA 92656 | 70,513 (5) | 1.6% |
| Eva Novotny (3)..... 100 Columbia, Suite 100 Aliso Viejo, CA 92656 | 47,800 (6) | (11) |
| Donald J. Regan (2)..... 462 Stevens Avenue, Suite 308 | 32,600 (7) | (11) |

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Solana Beach, CA 92075

| | | |
|---|-----------|-------|
| Michael C. Tibbitts(2) | 27,917(8) | (11) |
| 27001 La Paz Road, Suite 448B Mission Viejo, CA 92691 | | |
| Frank R. Pope(2)..... | 23,000(9) | (11) |
| 3460 Baker St. San Francisco, CA 94123 | | |
| David A. Reed(2)..... | 1,750(10) | (11) |
| 24681 La Plaza, Suite 240 Dana Point, CA 92629 | | |
| All executive officers and directors as a group (7 persons)(12)..... | 592,663 | 12.4% |

(1) All such shares were held of record with sole voting and investment power, subject to applicable community property laws, by the named individual and/or by his wife, except as indicated in the following footnotes.

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- (2) Director of the Company.
- (3) Executive officer of the Company.
- (4) Includes 308,333 shares issuable upon exercise of presently outstanding stock options.
- (5) Includes 66,333 shares issuable upon exercise of presently outstanding stock options.
- (6) Includes 47,000 shares issuable upon exercise of presently outstanding stock options.
- (7) Includes 26,000 shares issuable upon exercise of presently outstanding stock options.
- (8) Includes 25,917 shares issuable upon exercise of presently outstanding stock options.
- (9) Includes 21,000 shares issuable upon exercise of presently outstanding stock options.
- (10) Includes 1,750 shares issuable upon exercise of presently outstanding stock options.
- (11) Percentage information is omitted because the beneficially owned shares represent less than 1% of the outstanding shares of the Company's Common Stock
- (12) Includes 496,333 shares issuable upon exercise of presently outstanding stock options.

Item 13. CERTAIN RELATIONSHIPS AND INVESTMENTS

Cardiac Science, Inc.

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During 1991, the Company was a party to the formation of Cardiac Science, Inc., for which the Company purchased 5,353,031 (pre-split) shares of common stock, for a cash payment of \$.0016 per share. This purchase represented 77.3% of the outstanding stock. As of July 8, 1991, the Company distributed, as a dividend to its stockholders of record on that date, one share of Cardiac Science, Inc. stock for each share of Medstone stock held. The Company retained 629,768 (pre-split) shares of common stock of Cardiac Science, Inc.

From 1991 through 1996, the Company performed various financings for Cardiac Science and received warrants to purchase Cardiac Science common stock. Due to exercise of warrants, common stock issued in lieu of interest and unsecured advances, the Company received 5,619,054 (pre-split) shares of Cardiac Science.

In April 1997, Cardiac Science effectuated a 1 for 11.42857142 reverse stock split, reducing the Company's holdings to 546,772 shares.

Since mid-1999, the Company has been actively selling its position in Cardiac Science, selling 55,105 shares for a gain of approximately \$244,000 in 1999 and selling 304,667 shares for a gain of approximately \$1,855,000 in 2000 and selling 73,000 shares for a gain of approximately \$358,000 in January 2001. As of March 2, 2001, the Company held 114,000 shares of Cardiac Science common stock.

Also during 1999, the Company, which held unexpired warrants to purchase 87,500 shares at \$.011 each, sold these warrants for a cash price of \$3.00 per share, resulting in a gain of approximately \$262,000.

Digital Imaging Systems, Inc.

In 1998, the Company entered into a supply agreement with Digital Imaging Systems, Inc. ("DIS") for components integral in the Company's STS-T. The Company has purchased \$300,000, or 300,000 shares, of DIS preferred stock, which represented a 14% ownership interest. DIS commenced shipments of the components to the Company as of January 1999. In 1999, the Company recorded an investment writedown of \$300,000 for impairment as a result of its review of the realizable value of its investment in DIS shares.

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k. Biotech

In 1998, the Company was made aware of an opportunity to invest in a developmental biotech drug company catering to the members of the International Centre for Genetic Engineering and Biotechnology ("ICGEB"), a United Nations sponsored institute. k. Biotech purchased license agreements for formulas, developed by the ICGEB, for commercialization purposes in the Indian sub-continent as its primary market. The Company has purchased \$325,000 of preferred stock to assist k. Biotech in establishing itself as a viable business entity. Two of the Company's directors, Mssrs. Pope and Regan, are investors in k. Biotech and Mr. Regan serves as k. Biotech's President. Additional funding from international sources is currently being evaluated.

Chinese Joint Venture

The Company, along with Acuity International ("Acuity") and Phenix Optical Ltd ("Phenix"), a Chinese company, created a joint venture, in March 1998, to provide lithotripsy services to inland Chinese areas. Each entity was a 1/3 owner of the joint venture. The Company recognized a gain of \$105,000 on its contribution of equipment to the joint venture in the first quarter of 1998, and recorded its investment of \$92,000 as other assets. In December 1998,

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documents were drawn to turn ownership over to Phenix in return for delivery of optical products to both Acuity and the Company. In 1999, the Company received optical products in release of its share in the joint venture and final release documents were processed. The Company is carrying the value of the optical products at the remaining estimated fair value, based on the value established in the joint venture, for the quantity remaining from the remarketing efforts of the Company.

Medicredit .com, Inc.

In April 2000, the Company purchased common stock representing a 46% interest in Medicredit.com, Inc. ("Medicredit") for \$1 million in cash. Medicredit, a California-based company, funds and service loans to physicians to finance elective surgeries in the cosmetic and cash paying sector of healthcare. Mssrs. Radlinski and Selawski serve on the Medicredit Board of Directors. Along with the cash investment in Medicredit, the Company also agreed to a line of credit of up to \$2 million at the prime interest rate. As of March 2, 2001, the full \$2 million credit line was outstanding to Medicredit and is reflected as long-term receivable from unconsolidated subsidiary in the Consolidated Balance Sheets of the Company.

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PART IV

Item 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

(a) Index to Consolidated Financial Statements

| | Page |
|---|------|
| | ---- |
| 1. Consolidated Financial Statements | |
| Report of Independent Auditors..... | 29 |
| Consolidated Balance Sheets at December 31, 2000 and 1999..... | 30 |
| Consolidated Statements of Income for the years ended December 31, 2000, 1999 and 1998..... | 31 |
| Consolidated Statements of Stockholders' Equity for the years ended December 31, 2000, 1999 and 1998..... | 32 |
| Consolidated Statements of Cash Flows for the years ended December 31, 2000, 1999 and 1998..... | 33 |
| Notes to Consolidated Financial Statements..... | 34 |
| 2. Schedule to Consolidated Financial Statements | |
| Schedule II--Valuation and Qualifying Accounts..... | 47 |

All other schedules are omitted because they are not applicable or the required information is included in the consolidated financial statements or notes thereto.

(b) Reports on Form 8-K

There were no reports on Form 8-K filed with the Commission during the quarter ended December 31, 2000.

(c) Exhibits

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Exhibit

| No. | Description |
|-------|---|
| 3.1 | Certificate of Incorporation of the Company, as amended (1) |
| 3.2 | Restated and Amended Bylaws of the Company (2) |
| 4.2 | Specimen Certificate of the Company's Common Stock (3) |
| 10.26 | 1989 Stock Incentive Plan (4) (5) |
| 10.27 | Non-employee Director Stock Option Plan (4) (5) |
| 10.29 | 1997 Stock Incentive Plan (5) (6) |
| 10.30 | Employment Agreement with David Radlinski (5) (7) |
| 10.31 | Employment Agreement with Mark Selawski (5) (7) |
| 10.32 | Employment Agreement with Eva Novotny (5) (7) |
| 10.33 | Amended Lease for Aliso Viejo Property (8) |
| 21 | Subsidiaries |
| 23.1 | Consent of Independent Auditors |
| 28.2 | Form of Cytocare, Inc. Information Statement--Distribution to Shareholders of Stock of Cardiac Science, Inc. (9) |
| 28.3 | Form of Medstone International, Inc. Information Statement--Distribution to Shareholders of Stock of Endocare, Inc. and Urogen Corp. (10) |

(1) Previously filed with the same exhibit number with the Company's Registration Statement on Form S-1 under the Securities Act of 1933, Reg. No. 33-16340 and with the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 1998 and incorporated herein by reference.

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(2) Previously filed with the same exhibit number with the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 1999, and incorporated herein by reference.

(3) Previously filed with the same exhibit number with the Company's Registration Statement on Form S-1 under the Securities Act of 1933, Reg. No. 33-16340 and incorporated herein by reference.

(4) Previously filed with the same exhibit number with the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 1989, and incorporated herein by reference.

(5) Compensatory plan or arrangement.

(6) Previously filed with the same exhibit number with the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 1997.

(7) Previously filed with the same exhibit number with the Company's

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Quarterly Report on Form 10-Q for the quarter ended September 30, 1998.

- (8) Previously filed with the same exhibit number with the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2000.
- (9) Previously filed with the same exhibit number with the Company's current report on Form 8-K dated June 26, 1991, and incorporated herein by reference.
- (10) Previously filed with the Company's current report on Form 8-K dated February 9, 1996, and incorporated herein by reference.

The Company will furnish to a requesting beneficial owner of its securities a copy of any such exhibits upon payment of a fee equal to \$.20 per exhibit page.

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REPORT OF INDEPENDENT AUDITORS

Stockholders and Board of Directors
Medstone International, Inc.

We have audited the accompanying consolidated balance sheets of Medstone International, Inc. and subsidiaries (the "Company") as of December 31, 2000 and 1999, and the related consolidated statements of income, stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2000. Our audits also included the financial statement schedule listed in the Index at Item 14(a). These financial statements and schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule 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 consolidated financial position of Medstone International, Inc. and subsidiaries at December 31, 2000 and 1999, and the consolidated results of their operations and their 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. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

Ernst & Young LLP

Orange County, California
February 14, 2001

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MEDSTONE INTERNATIONAL, INC.

CONSOLIDATED BALANCE SHEETS

| | December 31, | |
|--|---------------|--------------|
| | 2000 | 1999 |
| ASSETS | | |
| ----- | | |
| Current assets: | | |
| Cash and cash equivalents..... | \$ 945,610 | \$ 1,061,422 |
| Short-term investments held to maturity..... | 5,223,659 | 8,629,990 |
| Accounts receivable, less allowance for doubtful accounts of \$477,180 and \$571,252 in 2000 and 1999, respectively..... | 4,165,563 | 3,291,372 |
| Inventories, less allowance for inventory obsolescence of \$457,088 and \$307,203 in 2000 and 1999, respectively..... | 6,103,051 | 5,760,887 |
| Deferred tax assets..... | 1,005,814 | 1,273,386 |
| Prepaid expenses and other current assets..... | 526,825 | 366,774 |
| | ----- | ----- |
| Total current assets..... | 17,970,522 | 20,383,831 |
| Buildings, property and equipment, at cost: | | |
| Building..... | 359,324 | 359,324 |
| Lithotripters..... | 12,316,739 | 11,163,744 |
| Equipment..... | 1,835,855 | 1,698,185 |
| Furniture and fixtures..... | 948,362 | 879,458 |
| Leasehold improvements..... | 157,083 | 147,200 |
| | ----- | ----- |
| | 15,617,363 | 14,247,911 |
| Less accumulated depreciation and amortization..... | (10,440,172) | (8,308,841) |
| | ----- | ----- |
| Net property and equipment..... | 5,177,191 | 5,939,070 |
| | ----- | ----- |
| Goodwill, net..... | 3,306,622 | 3,409,916 |
| Investment in unconsolidated subsidiaries..... | 1,263,598 | 325,000 |
| Long-term receivable from unconsolidated subsidiary..... | 2,000,000 | -- |
| Other assets, net..... | 158,914 | 117,195 |
| | ----- | ----- |
| | \$ 29,876,847 | \$30,175,012 |
| | ===== | ===== |

LIABILITIES AND STOCKHOLDERS' EQUITY

| | | |
|--------------------------------|------------|------------|
| ----- | | |
| Current liabilities: | | |
| Accounts payable..... | \$ 657,878 | \$ 611,492 |
| Accrued expenses..... | 580,232 | 716,619 |
| Accrued income taxes..... | 73,314 | 263,058 |
| Accrued payroll expenses..... | 347,034 | 346,262 |
| Customer deposits..... | 58,441 | -- |
| Deferred revenue..... | 656,332 | 907,326 |
| | ----- | ----- |
| Total current liabilities..... | 2,373,231 | 2,844,757 |

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| | | |
|---|---------------|---------------|
| Deferred tax liabilities..... | 562,313 | 628,856 |
| Minority interest..... | 554,292 | 284,350 |
| Deferred rent..... | 78,697 | -- |
| Commitments and contingencies (Notes 7 and 8) | | |
| Stockholders' equity: | | |
| Common stock--\$.004 par value, 20,000,000 shares authorized, 5,742,670 and 5,667,142 shares issued and outstanding at December 31, 2000 and 1999, respectively..... | | |
| | 22,971 | 22,669 |
| Additional paid-in capital..... | 19,646,388 | 19,177,274 |
| Accumulated earnings..... | 16,708,143 | 14,619,507 |
| Accumulated other comprehensive income (loss)..... | 55,395 | (13,942) |
| Treasury stock, at cost, 1,434,450 and 974,650 shares at December 31, 2000 and 1999, respectively..... | (10,124,583) | (7,388,459) |
| | ----- | ----- |
| Total stockholders' equity..... | 26,308,314 | 26,417,049 |
| | ----- | ----- |
| | \$ 29,876,847 | \$ 30,175,012 |
| | ===== | ===== |

See accompanying notes

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MEDSTONE INTERNATIONAL, INC.

CONSOLIDATED STATEMENTS OF INCOME

| | For the year ended December 31, | | |
|---|---------------------------------|--------------|--------------|
| | 2000 | 1999 | 1998 |
| | ----- | ----- | ----- |
| Revenue: | | | |
| Procedures, maintenance fees and fee- for-service..... | \$18,930,319 | \$19,532,046 | \$21,128,586 |
| Net equipment sales..... | 3,284,119 | 3,337,650 | 2,144,500 |
| Interest income..... | 607,616 | 598,661 | 551,723 |
| | ----- | ----- | ----- |
| Total revenues..... | 22,822,054 | 23,468,357 | 23,824,809 |
| Costs and expenses: | | | |
| Cost of procedures and maintenance fees..... | 11,678,337 | 10,186,243 | 9,098,822 |
| Cost of equipment sales..... | 2,264,073 | 1,920,117 | 1,900,803 |
| Research and development..... | 1,180,409 | 1,455,429 | 1,078,792 |
| Selling..... | 2,174,592 | 2,048,390 | 1,988,331 |
| General and administrative..... | 2,651,172 | 2,592,308 | 2,131,373 |
| | ----- | ----- | ----- |
| Total costs and expenses..... | 19,948,583 | 18,202,487 | 16,198,121 |
| | ----- | ----- | ----- |
| Operating income..... | 2,873,471 | 5,265,870 | 7,626,688 |
| Other expense (income): | | | |
| Gain on sale of investments..... | (1,882,545) | (244,305) | -- |

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| | | | |
|--|--------------|--------------|--------------|
| Other expense..... | 109,046 | 147,031 | (61,045) |
| | ----- | ----- | ----- |
| Total other expense (income)..... | (1,773,499) | (97,274) | (61,045) |
| Minority interests: | | | |
| Minority interest in subsidiaries income..... | 833,942 | 602,594 | 627,639 |
| Equity loss from unconsolidated subsidiary..... | 61,402 | -- | -- |
| | ----- | ----- | ----- |
| Total minority interest..... | 895,344 | 602,594 | 627,639 |
| Income before provision for income taxes..... | | | |
| | 3,751,626 | 4,760,550 | 7,060,094 |
| Provision for income taxes..... | 1,662,990 | 1,919,400 | 2,718,000 |
| | ----- | ----- | ----- |
| Net income..... | \$ 2,088,636 | \$ 2,841,150 | \$ 4,342,094 |
| | ===== | ===== | ===== |
| Net income per share: | | | |
| Basic..... | \$.46 | \$.57 | \$.84 |
| | ===== | ===== | ===== |
| Diluted..... | \$.46 | \$.56 | \$.82 |
| | ===== | ===== | ===== |
| Number of shares used in the computation of net income per share: | | | |
| Basic..... | 4,504,468 | 4,956,508 | 5,162,112 |
| | ===== | ===== | ===== |
| Diluted..... | 4,511,119 | 5,034,850 | 5,286,967 |
| | ===== | ===== | ===== |

See accompanying notes

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MEDSTONE INTERNATIONAL, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

| | Common Stock | | Additional paid-in capital | Accumulated earnings | Stock Purchase Note Receivable | Accumulated Other Comprehensive income (loss) |
|--|---------------------|----------|----------------------------------|-------------------------|-----------------------------------|--|
| | Number of shares | Amount | | | | |
| | ----- | ----- | ----- | ----- | ----- | ----- |
| Balance at December 31, 1997..... | 5,365,988 | \$22,539 | \$18,998,260 | \$ 7,436,263 | \$ (134,800) | \$ (579) |
| Net income..... | -- | -- | -- | 4,342,094 | -- | -- |
| Other comprehensive income: | | | | | | |
| Unrealized loss on short-term investments..... | -- | -- | -- | -- | -- | (598) |
| Total comprehensive income..... | -- | -- | -- | -- | -- | -- |
| Common stock options | | | | | | |

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| | | | | | | |
|--|-----------|----------|--------------|--------------|---------|-------------|
| exercised..... | 15,717 | 63 | 77,844 | -- | -- | -- |
| Repayment of stock purchase note..... | -- | -- | -- | -- | 134,800 | -- |
| Treasury stock repurchased..... | (318,300) | -- | -- | -- | -- | -- |
| | ----- | ----- | ----- | ----- | ----- | ----- |
| Balance at December 31, 1998..... | 5,063,405 | 22,602 | 19,076,104 | 11,778,357 | -- | (1,177) |
| Net income..... | -- | -- | -- | 2,841,150 | -- | -- |
| Other comprehensive income: | | | | | | |
| Unrealized gain on short-term investments..... | -- | -- | -- | -- | -- | 1,177 |
| Unrealized loss on foreign currency translation..... | -- | -- | -- | -- | -- | (13,942) |
| Total comprehensive income..... | -- | -- | -- | -- | -- | -- |
| Common stock options exercised..... | 16,637 | 67 | 101,170 | -- | -- | -- |
| Treasury stock repurchased..... | (387,550) | -- | -- | -- | -- | -- |
| | ----- | ----- | ----- | ----- | ----- | ----- |
| Balance at December 31, 1999..... | 4,692,492 | \$22,669 | \$19,177,274 | \$14,619,507 | \$ -- | \$ (13,942) |
| Net income..... | -- | -- | -- | 2,088,636 | -- | -- |
| Other comprehensive income: | | | | | | |
| Unrealized gain on foreign currency translation, net.... | -- | -- | -- | -- | -- | 69,337 |
| Total comprehensive income..... | -- | -- | -- | -- | -- | -- |
| Common stock options exercised..... | 75,528 | 302 | 469,114 | -- | -- | -- |
| Treasury stock repurchased..... | (459,800) | -- | -- | -- | -- | -- |
| | ----- | ----- | ----- | ----- | ----- | ----- |
| Balance at December 31, 2000..... | 4,308,220 | \$22,971 | \$19,646,388 | \$16,708,143 | \$ -- | \$ 55,395 |
| | ===== | ===== | ===== | ===== | ===== | ===== |

See accompanying notes

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| | 2000 | 1999 | 1998 |
|---|--------------|--------------|--------------|
| Cash flows from operating activities: | | | |
| Net income..... | \$ 2,088,636 | \$ 2,841,150 | \$ 4,342,094 |
| Adjustments to reconcile net income to net cash provided by operating activities: | | | |
| Depreciation and amortization..... | 2,377,014 | 2,075,884 | 1,946,746 |
| Provision for doubtful accounts..... | -- | 35,000 | 130,000 |
| Writedown of investment..... | -- | 300,000 | -- |
| Minority interest in partnership..... | 833,942 | 602,595 | 627,639 |
| Minority equity in unconsolidated subsidiary..... | 61,402 | -- | -- |
| Provision for inventory obsolescence..... | 277,138 | -- | -- |
| Gain on sale of long-term investments..... | (1,882,545) | (506,805) | -- |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable..... | (874,191) | 309,763 | (544,794) |
| Inventories..... | (619,302) | (1,992,704) | (915,686) |
| Deferred tax assets..... | 201,029 | (219,364) | (183,183) |
| Prepaid expenses and other current assets..... | (160,051) | 374,474 | (263,624) |
| Accounts payable..... | 46,386 | 215,090 | (498,151) |
| Accrued expenses..... | (99,225) | 104,189 | 274,687 |
| Accrued income taxes..... | (226,674) | 69,388 | 816,444 |
| Accrued payroll expenses..... | 772 | 42,575 | 64,183 |
| Deferred revenue..... | (250,994) | (39,756) | (347,010) |
| Customer deposits..... | 58,441 | (86,125) | (46,574) |
| Other, net..... | 70,884 | (4,444) | 124,616 |
| Net cash provided by operating activities..... | 1,902,662 | 4,120,910 | 5,527,387 |
| Cash flows from investing activities: | | | |
| Purchases of short-term investments.... | (12,575,069) | (23,351,435) | (25,798,243) |
| Proceeds from sales of short-term investments..... | 15,981,400 | 25,216,697 | 25,205,077 |
| Proceeds from sale of long-term investments..... | 1,882,545 | 506,805 | -- |
| Investment in unconsolidated subsidiary..... | (1,000,000) | (100,000) | (617,369) |
| Purchase of net assets..... | -- | (751,712) | -- |
| Long-term loan to unconsolidated subsidiary..... | (2,000,000) | -- | -- |
| Distribution of minority interest..... | (564,000) | (638,300) | (676,800) |
| Purchases of property and equipment, net..... | (1,518,177) | (2,718,288) | (1,106,832) |
| Net cash provided by (used in) investing activities..... | 206,699 | (1,836,233) | (2,994,167) |
| Cash flows from financing activities: | | | |
| Proceeds from issuance of common stock..... | 469,416 | 101,237 | 77,907 |
| Proceeds from stock purchase note..... | -- | -- | 134,800 |
| Purchase of treasury stock..... | (2,736,124) | (2,445,250) | (2,742,473) |
| Deferral of rent payments..... | 78,697 | -- | -- |

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| | | | |
|---|--------------|--------------|--------------|
| Loan payments..... | (37,162) | (7,705) | -- |
| | ----- | ----- | ----- |
| Net cash used in financing activities..... | (2,225,173) | (2,351,718) | (2,529,766) |
| Net increase (decrease) in cash and cash equivalents..... | (115,812) | (67,041) | 3,454 |
| Cash and equivalents at beginning of year..... | 1,061,422 | 1,128,463 | 1,125,009 |
| | ----- | ----- | ----- |
| Cash and equivalents at end of year..... | \$ 945,610 | \$ 1,061,422 | \$ 1,128,463 |
| | ===== | ===== | ===== |
| Supplemental cash flow disclosures: | | | |
| Cash paid during the year for: | | | |
| Income taxes..... | \$ 1,694,826 | \$ 1,925,645 | \$ 2,588,819 |
| | ===== | ===== | ===== |
| Supplemental disclosures of non-cash investing activities: | | | |
| Liabilities assumed in connection with the purchase transaction (Note 3)..... | \$ -- | \$ 365,110 | \$ -- |
| | ===== | ===== | ===== |

See accompanying notes

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MEDSTONE INTERNATIONAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

December 31, 2000

1. Organization and Operations of the Company

Medstone International, Inc. ("Medstone" or the "Company") designs, manufactures and markets the Medstone STS(TM) and STS-T Shockwave Therapy Systems (the "System") for the noninvasive disintegration of kidney stones in human patients. The Company also generates revenues from use of the Systems under procedure fees and fee for service arrangements and from repairs and maintenance. The Company's customers are primarily located in the United States.

2. Summary of Significant Accounting Policies

Principles of consolidation

The consolidated financial statements include the accounts of the Company; Medstone International, Ltd., a Scottish subsidiary group; United Physicians Resources, an 80% owned physicians practice management operation incorporated in June 1996; Northern Nevada Lithotripsy Associates, LLC, a 60% owned Nevada Limited Liability Company; Southern Idaho Lithotripsy Associates, LLC, a California Limited Liability Company, also 60% owned (See Note 3); and Medstone Sales Corporation, a 100% owned foreign sales corporation. All majority-owned subsidiaries are consolidated and all material intercompany accounts and transactions are eliminated. Investments in less than 20% owned affiliates are accounted for on the cost method, unless the Company is able to exercise significant influence over the affiliates operating and financial policies, in which case the investments are accounted for on the equity method.

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Reclassifications

Certain prior year balances have been reclassified to conform with the December 31, 2000 presentation.

Use of estimates

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 at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Statement of cash flows

The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents.

Fair Value of Financial Instruments

The fair market value of cash and cash equivalents, short-term investments and accounts receivable approximate cost due to the short period of time to maturity. The carrying value of the long term receivable from unconsolidated subsidiary approximates fair value because the interest rate fluctuates with market conditions.

Short-term Investments

The Company applies the provisions of Statement of Financial Accounting Standards No. 115, "Accounting for Certain Investments in Debt and Equity Securities," to its short-term investments. Under this statement, management determines the appropriate classification of such securities at the time of purchase and reevaluates such classification as of each balance sheet date. Based on its intent, the Company's investments are classified as held-to-maturity and are carried at amortized cost.

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MEDSTONE INTERNATIONAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

December 31, 2000

The amortized cost and market value of investments at December 31, 2000, by contractual maturity, is shown below.

| | Amortized Cost | Market Value |
|------------------------------|-------------------|-----------------|
| | ----- | ----- |
| Due in one year or less..... | \$5,223,659 | \$5,400,953 |

Comprehensive Income

As of January 1, 1998, the Company adopted Statement of Financial

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Accounting Standards No. 130, Reporting Comprehensive Income (SFAS 130). SFAS No. 130 established new rules for the reporting and display of comprehensive income and its components; however, the adoption of this Statement had no impact on the Company's net income. SFAS No. 130 requires unrealized gains or losses on available-for-sale securities and unrealized gains or losses on foreign currency translation, to be included in other comprehensive income. Prior financial statements have been reclassified to conform to the requirements of SFAS No. 130.

The components of accumulated other comprehensive income/(loss) are as follows:

| | Foreign Currency Translation Adjustment | Unrealized Gains on Available- for-Sale Securities | Total |
|--|--|--|------------|
| | ----- | ----- | ----- |
| Balance at December 31, 1998..... | \$ -- | \$ (1,177) | \$ (1,177) |
| Foreign currency translation adjustment... | (13,942) | -- | (13,942) |
| Unrealized gain on available-for-sale securities..... | -- | 1,177 | 1,177 |
| | ----- | ----- | ----- |
| Balance at December 31, 1999..... | (13,942) | -- | (13,942) |
| Foreign currency translation adjustment net of income taxes..... | 69,337 | -- | 69,337 |
| | ----- | ----- | ----- |
| Balance at December 31, 2000..... | \$ 55,395 | \$ -- | \$ 55,395 |
| | ===== | ===== | ===== |

Concentrations of Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents, and short-term investments, which are not federally insured, and accounts receivable. The Company's short-term investments consist principally of U.S. Treasury Bills, U.S. Government Agency Notes and Commercial Paper.

The Company sells its products primarily to hospitals worldwide. Credit is extended based on an evaluation of the customer's financial condition and collateral generally is not required. The Company's ten largest customers accounted for approximately 10% of accounts receivable at December 31, 2000.

Inventories

Inventories are stated at the lower of cost (first-in, first-out) or market and consist of the following:

| | December 31, | |
|----------------------|--------------|-------------|
| | 2000 | 1999 |
| | ----- | ----- |
| Raw materials..... | \$3,888,640 | \$3,699,983 |
| Work in process..... | 231,175 | 427,600 |
| Finished goods..... | 1,983,236 | 1,633,304 |

 \$6,103,051 \$5,760,887
 =====

MEDSTONE INTERNATIONAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

December 31, 2000

Building, Property and Equipment

Building, property and equipment are carried at cost. Depreciation and amortization are computed on the straight-line method over the following estimated useful lives:

| | |
|-----------------------------|---------------|
| Building..... | 50 years |
| Lithotripters..... | 5 years |
| Equipment..... | 5 years |
| Furniture and fixtures..... | 5 years |
| Leasehold improvements..... | Life of lease |

Depreciation expense for the years ended December 31, 2000, 1999 and 1998 was \$2,274,183, \$1,987,000, and \$1,863,000, respectively.

Goodwill

The Company recorded goodwill resulting from the excess of the purchase prices of Northern Nevada, Southern Idaho and Zenith Medical Systems, Ltd. over the fair market value of the net assets acquired. Goodwill is being amortized over periods ranging from fifteen to forty years using the straight-line method. Accumulated amortization at December 31, 2000 and 1999 is \$371,194 and \$269,635, respectively.

Long-Lived Assets

Long-lived assets and certain identifiable intangibles held and used by the Company are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Based upon the Company's analysis, the Company believes no material impairment of the carrying value of its long-lived assets, inclusive of intangible assets, existed at December 31, 2000 and 1999. The Company's analysis was based on a comparison of the carrying amount of such assets to the Company's historical actual cash flows and to an estimate of future undiscounted cash flows.

Earnings Per Share

The Company has adopted SFAS No. 128, "Earnings Per Share," and applied this pronouncement to all periods presented. This statement requires the presentation of both basic and diluted net income per share for financial statement purposes. Basic net income per share is computed by dividing income available to common stockholders by the weighted average number of common shares outstanding. Diluted net income per share includes the effect of the

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potential shares outstanding, including dilutive stock options and warrants using the treasury stock method. All earnings per share amounts for all periods have been restated to conform with the SFAS No. 128 requirements.

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MEDSTONE INTERNATIONAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

December 31, 2000

The following table sets forth the computation of earnings per share:

| | Year Ended December 31, | | |
|---|-------------------------|-------------|-------------|
| | 2000 | 1999 | 1998 |
| Numerator: Net income..... | \$2,088,636 | \$2,841,150 | \$4,342,094 |
| Denominator for weighted average shares outstanding..... | 4,504,468 | 4,956,508 | 5,162,112 |
| Basic earnings per share..... | \$.46 | \$.57 | \$.84 |
| Effect of dilutive securities: | | | |
| Weighted average shares outstanding..... | 4,504,468 | 4,956,508 | 5,162,112 |
| Stock options..... | 6,651 | 78,342 | 124,855 |
| Denominator for diluted earnings per share..... | 4,511,119 | 5,034,850 | 5,286,967 |
| Diluted earnings per share..... | \$.46 | \$.56 | \$.82 |

Stock Compensation

The Company has elected to follow Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees, (APB 25) and related Interpretations in accounting for its employee stock options because, as discussed below, the alternative fair value accounting provided for under FASB Statement No. 123, Accounting for Stock-Based Compensation, requires the use of option valuation models that were not developed for use in valuing employee stock options. Under APB 25, because the exercise price of the Company's employee stock options equals the market price of the underlying stock on the date of grant, no compensation expense is recognized.

To calculate the pro forma information required by Statement 123, the Company uses the Black-Scholes option pricing model. The Black-Scholes model was developed for use in estimating the fair value of traded options which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because the Company's employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the

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existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

Revenue recognition

Revenues recognized in the fee-for-service segment of the Company's operations are invoiced as the customer uses the equipment in the month that service has been provided. Revenues from equipment sales are recognized in accordance with the underlying contractual terms of each sale. Typically, revenue recognition requires the transfer of title upon shipment, customer acceptance, receipt of specified down payments and performance of all significant contractual obligations.

Service and maintenance contract revenues are deferred and amortized over the terms of the related contracts.

Advertising

The Company expenses advertising costs including promotional literature, brochures and trade shows as incurred. Advertising expense was \$32,000, \$58,000 and \$135,000 for the years ended December 31, 2000, 1999 and 1998, respectively.

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MEDSTONE INTERNATIONAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

December 31, 2000

Business Segments and Geographic Information

The Company applies the provisions of Statement of Financial Accounting Standards No. 131, Disclosures about Segments of an Enterprise and Related Information (SFAS 131). SFAS No. 131 establishes standards for related disclosures about products and services, geographic areas and major customers.

The Company operates in two business segments, equipment sales and fees for procedures, maintenance and management. The equipment sales segment is not significant. The fees for procedures, maintenance and management segment represents recurring revenue from procedure fees and fee for service arrangements for use and the maintenance of lithotripter equipment. The accounting policies of these segments are the same as those described in the summary of significant accounting policies except that certain expenses, such as amortization of certain intangibles and certain corporate expenses, are not allocated to the segments. Asset categories used for allocation to segment reporting include net accounts receivable, net inventory, net property and equipment and net goodwill.

Selected financial information for the Company's reportable segments as of and for the years ended December 31, 2000, 1999 and 1998 follows (in thousands):

| | 2000 | 1999 | 1998 |
|----------|-------|-------|-------|
| | ----- | ----- | ----- |
| Revenue: | | | |

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| | | | |
|--|----------|----------|----------|
| Equipment sales..... | \$ 3,284 | \$ 3,338 | \$ 2,145 |
| Fees for procedures, maintenance and management..... | 18,930 | 19,532 | 21,128 |
| Nonreportable segment..... | 608 | 598 | 552 |
| | ----- | ----- | ----- |
| | \$22,822 | \$23,468 | \$23,825 |
| | ===== | ===== | ===== |
| Operating income (loss): | | | |
| Equipment sales..... | \$ (8) | \$ 678 | \$ (537) |
| Fees for procedures, maintenance and management..... | 2,394 | 4,085 | 7,751 |
| Nonreportable segment..... | 487 | 600 | 474 |
| | ----- | ----- | ----- |
| | \$ 2,873 | \$ 5,363 | \$ 7,688 |
| | ===== | ===== | ===== |
| Assets: | | | |
| Equipment sales..... | \$ 3,642 | \$ 3,228 | \$ 1,764 |
| Fees for procedures, maintenance and management..... | 15,110 | 15,173 | 13,252 |
| | ----- | ----- | ----- |
| | \$18,752 | \$18,401 | \$15,016 |
| | ===== | ===== | ===== |
| Depreciation and amortization: | | | |
| Equipment sales..... | \$ 252 | \$ 206 | \$ 149 |
| Fees for procedures, maintenance and management..... | 2,125 | 1,870 | 1,798 |
| | ----- | ----- | ----- |
| | \$ 2,377 | \$ 2,076 | \$ 1,947 |
| | ===== | ===== | ===== |
| Expenditures for long-lived assets and equity method investments: | | | |
| Equipment sales..... | \$ 1,198 | \$ 1,171 | \$ 473 |
| Fees for procedures, maintenance and management..... | 1,319 | 2,399 | 634 |
| | ----- | ----- | ----- |
| | \$ 2,517 | \$ 3,570 | \$ 1,107 |
| | ===== | ===== | ===== |

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MEDSTONE INTERNATIONAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

December 31, 2000

Selected financial information for the Company's operations by geographic segment is as follows (in thousands):

| | 2000 | 1999 | 1998 |
|-----------------------------|----------|----------|----------|
| | ----- | ----- | ----- |
| Revenue: | | | |
| United States..... | \$21,121 | \$22,733 | \$22,977 |
| Europe and Middle East..... | 1,464 | 459 | 17 |
| Asia Pacific Rim..... | 237 | 276 | 831 |
| | ----- | ----- | ----- |

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| | | | |
|--------------------|----------|----------|----------|
| | \$22,822 | \$23,468 | \$23,825 |
| | ===== | ===== | ===== |
| Long-Lived Assets: | | | |
| United States..... | \$21,699 | \$17,263 | \$14,898 |
| Europe..... | 865 | 820 | -- |
| | ----- | ----- | ----- |
| | \$22,564 | \$18,083 | \$14,898 |
| | ===== | ===== | ===== |

Recently Issued Accounting Pronouncements

In June 1998, the Financial Accounting Standards Board issued Statement of Financial Accounting Standards No. 133, Accounting for Certain Derivatives and Hedging Activities (SFAS 133), as amended, which is required to be adopted effective January 1, 2001. SFAS 133 established new standards for recording derivatives in interim and annual financial reports requiring that all derivative instruments, except those qualifying as a hedge under the criteria set forth in SFAS 133, be recorded on the balance sheet at fair value with adjustments to the fair value through earnings. The Company will adopt the new requirements effective with the filing of its Quarterly Report on Form 10-Q for the quarter ended March 31, 2001. The Company anticipates that the adoption of SFAS No. 133 will not have an impact on its financial position, results of operations, or cash flows.

3. Acquisitions and Investments in Joint Ventures

Equity Investment in Medicredit.com, Inc.

In April 2000, the Company purchased common stock representing a 46% interest in Medicredit.com, Inc. ("Medicredit") for \$1 million in cash. Medicredit, a California-based company, funds and services patient accounts to finance elective surgeries in the cosmetic and cash paying sector of healthcare. The investment in Medicredit is accounted for under the equity method. The investment, net of the Company's share of net losses for the period from April 1, 2000 through December 31, 2000 of \$61,000, is included in Investment in unconsolidated subsidiary.

Along with the cash investments in Medicredit, the Company also provides Medicredit a line of credit of up to \$2 million at the prime interest rate (9.5% at December 31, 2000). Interest payments are due monthly with principal due at maturity on April 20, 2002. As of December 31, 2000, the Company had advanced \$2 million to Medicredit under the line of credit, and has accrued interest of \$21,550 due from Medicredit, which are recorded as a long term receivable from unconsolidated subsidiary and other assets, respectively.

Purchase of Assets of Creos, Ltd.

In April 1999, Medstone International, Ltd., a wholly-owned subsidiary of the Company located in Scotland, purchased certain assets of Creos Ltd. from its liquidator for \$165,600 cash. The acquisition has been accounted for as a purchase and did not generate any goodwill. Medstone International, Ltd. then commenced manufacturing x-ray generator products previously produced by Creos Ltd. The operating results of Medstone International, Ltd. have been included in the consolidated financial statements of the Company since April 1999.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

December 31, 2000

Purchase of Zenith Medical Systems, Ltd.

In October 1999, Medstone International, Ltd. purchased all outstanding shares of Zenith Medical Systems, Ltd., for \$870,000 cash less \$284,000 of acquired cash for a net cost of \$586,000. The acquisition has been accounted for as a purchase and, accordingly, the excess of cost over the fair value of net assets acquired has been recorded as goodwill of approximately \$317,000 and is being amortized over its expected benefit period of 15 years. Zenith Medical Systems Ltd., is a distributor of major medical imaging systems to the British National Health Service located in Manchester, England. The operating results of Zenith Medical Systems, Ltd. are included in the consolidated financial statements of the Company since October 1999.

Investment in Digital Imaging Systems, Inc.

In 1998, the Company entered into a supply agreement with Digital Imaging Systems, Inc. ("DIS") for components integral in the Company's new transportable lithotripsy product. DIS commenced shipments of that product to the Company in January 1999. The Company has purchased 300,000 shares of DIS preferred stock for \$300,000, which represents a 14% ownership interest. In 1999, the Company recorded an investment writedown of \$300,000 as a result of its review of the realizable value of its investment.

Investment in k. Biotech

In 1998, the Company was made aware of an opportunity to invest in a developmental biotech drug company catering to the members of the International Centre for Genetic Engineering and Biotechnology ("ICGEB"), a United Nations sponsored institute. k. Biotech purchased license agreements for formulas, developed by the ICGEB, for commercialization purposes in the Indian sub-continent as its primary market. The Company's investment in k.Biotech preferred stock was \$325,000, representing a 21% ownership interest, and \$225,000, representing a 15.3% ownership interest, at December 31, 1999 and 1998, respectively. The investment in k. Biotech is accounted for under the equity method because the Company has the ability to exercise significant influence over k.Biotech and is included in other assets. k. Biotech is continually seeking additional funding from international sources to finance its required investment in plant and equipment.

Investment in Chinese Joint Venture

The Company, along with Acuity International ("Acuity") and Phenix Optical Ltd ("Phenix"), a Chinese company, created a joint venture in March 1998 to provide lithotripsy services to inland Chinese areas. Each entity was a 1/3 owner of the joint venture. The Company recorded its investment of \$92,000 as other assets. In December 1998, documents were drawn and executed to turn ownership over to Phenix in return for delivery of optical products to both Acuity and the Company. In 1999, the Company received the optical products in release of its share in the joint venture. The Company estimates the resale value of the optical products to approximate the value of the investment established in the joint venture. The Company intends to sell these optical products or distribute them as promotional items.

Unaudited pro forma consolidated results after giving effect to the businesses acquired during fiscal 1999 would not have been materially different from the reported amounts for 1999 and 1998 due to the immateriality of these acquisitions.

MEDSTONE INTERNATIONAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

December 31, 2000

4. Income Taxes

The Company provides for income taxes under the liability method. Accordingly, deferred income tax assets and liabilities are computed for differences between the financial statement and tax bases of assets and liabilities that will result in taxable or deductible amounts in the future based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to amounts which are more likely than not to be realized.

The provision for income taxes consists of the following:

| | Year ended December 31, 2000 | Year ended December 31, 1999 | Year ended December 31, 1998 |
|---------------------------------|------------------------------------|------------------------------------|------------------------------------|
| | ----- | ----- | ----- |
| Current: | | | |
| Federal..... | \$1,125,000 | \$1,653,400 | \$2,270,000 |
| State..... | 336,000 | 486,000 | 631,000 |
| | ----- | ----- | ----- |
| Total current..... | 1,461,000 | 2,139,400 | 2,901,000 |
| | ----- | ----- | ----- |
| Deferred: | | | |
| Federal..... | 171,000 | (168,000) | (153,000) |
| State..... | 31,000 | (52,000) | (30,000) |
| | ----- | ----- | ----- |
| Total deferred..... | 202,000 | (220,000) | (183,000) |
| | ----- | ----- | ----- |
| Provision for income taxes..... | \$1,663,000 | \$1,919,400 | \$2,718,000 |
| | ===== | ===== | ===== |

The following is a reconciliation of the provision for income taxes at the federal statutory rate compared to the Company's effective tax rate:

| | Year ended December 31, 2000 | Year ended December 31, 1999 | Year ended December 31, 1998 |
|--|------------------------------------|------------------------------------|------------------------------------|
| | ----- | ----- | ----- |
| Income tax at the statutory rate.... | \$1,580,000 | \$1,885,000 | \$2,400,000 |
| State income taxes (net of federal benefit)..... | 244,000 | 286,000 | 398,000 |
| Minority interest..... | (284,000) | (195,000) | -- |
| Other..... | 123,000 | (56,600) | (80,000) |

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| | | | |
|---------------------------------|-------------|-------------|-------------|
| Provision for income taxes..... | \$1,663,000 | \$1,919,400 | \$2,718,000 |
| | ===== | ===== | ===== |

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MEDSTONE INTERNATIONAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

December 31, 2000

The tax effect of temporary differences that give rise to significant portions of the deferred tax assets and deferred tax liabilities are as follows:

| | December 31, 2000 | December 31, 1999 |
|--|----------------------|----------------------|
| | ----- | ----- |
| Deferred tax assets (liabilities): | | |
| State taxes..... | \$ 113,000 | \$ 165,000 |
| Cardiac investment reserve..... | 239,000 | 417,000 |
| Inventory reserve..... | 196,000 | 131,000 |
| Bad debt reserve..... | 154,000 | 246,000 |
| Accruals not currently deductible for tax..... | 78,000 | 87,000 |
| Inventory adjustment..... | 97,000 | 66,000 |
| Product reserves..... | 129,000 | 161,000 |
| | ----- | ----- |
| Deferred tax assets..... | 1,006,000 | 1,273,000 |
| | ----- | ----- |
| Depreciation and amortization..... | (562,000) | (629,000) |
| | ----- | ----- |
| Deferred tax liabilities..... | (562,000) | (629,000) |
| | ----- | ----- |
| Net deferred tax assets..... | \$ 444,000 | \$ 644,000 |
| | ===== | ===== |

5. Stock Options

In June 1989, the Company's stockholders approved the 1989 Stock Incentive Plan ("1989 Plan") which provided for the granting of a variety of stock-related securities, including shares of common stock, stock options and stock appreciation rights to employees and other selected individuals. In May 1991, the Company's stockholders amended the 1989 Plan to increase the number of shares issuable to 1,593,783 and eliminated the provision for an automatic increase in the number of shares issuable on January 1 of each year by one percent of the then outstanding shares. In May 1997, the Company terminated the 1989 Plan as to the granting of additional options. As of December 31, 2000 473,201 options for shares of common stock had been granted and remain outstanding under this plan.

In June 1989, the Company's stockholders also approved the Nonemployee Director Stock Option Plan. This plan provides for the issuance of up to 50,000 shares of the Company's common stock upon exercise of options granted under the plan. On June 1, 1999, this plan expired and no additional shares

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may be granted under this plan. Outstanding options shall continue to vest and remain exercisable in accordance with the grants outstanding. As of December 31, 2000, 10,000 options for shares of common stock had been granted and remain outstanding under this Plan.

Options to purchase 15,000 shares of common stock were issued to each member of the Board of Directors in November 1996 and have exercise prices of \$6.375 after repricing of the options on August 31, 1998. The options are exercisable, after six months following their grant dates, in incremental amounts equal to 1/48 of the underlying shares of each elapsed calendar month during which the director remains on the Company's Board. The terms of the options are five years, subject to earlier termination related to the director no longer serving on the Board. As of December 31, 2000, 45,000 options for shares of common stock had been granted and are outstanding.

In May 1997, the Company's stockholders approved the 1997 Stock Incentive Plan which provides for the granting of a variety of stock-related securities, including shares of common stock, stock options and stock appreciation rights to employees and other selected individuals. The Plan allows for the issuance of up to

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MEDSTONE INTERNATIONAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

December 31, 2000

800,000 shares, with increases each January 1 that the Plan is in effect by a number of shares equal to one percent of the total number of outstanding shares of common stock on that date. As of January 1, 2001 the number of shares authorized by the plan increased to 951,234. As of December 31, 2000, 521,950 options for shares of common stock had been granted and are outstanding under this plan.

Effective August 13, 1998, the Company repriced all outstanding options granted under all plans with exercise prices exceeding the closing market value of the stock on that date. Accordingly, the exercise price of these options was reduced to \$6.375 per share.

A summary of the Company's stock option plans as of the end of 2000, 1999 and 1998 and changes during the years is presented below:

| | December 31, 2000 | | December 31, 1999 | | December 31, 1998 | |
|------------------------|-------------------|------------------------------------|-------------------|------------------------------------|-------------------|------------------------------------|
| | Shares | Weighted-Avg. Exercise Price | Shares | Weighted-Avg. Exercise Price | Shares | Weighted-Avg. Exercise Price |
| Outstanding, beginning | | | | | | |
| of year..... | 1,122,428 | \$6.45 | 1,082,902 | 6.39 | 970,803 | \$8.34 |
| Granted..... | 136,667 | 5.74 | 92,500 | 6.70 | 230,000 | 6.52 |
| Exercised..... | (75,528) | 6.22 | (16,637) | 6.09 | (15,717) | 4.95 |
| Canceled..... | (133,416) | 6.36 | (36,337) | 6.48 | (102,184) | 7.90 |
| | ----- | ----- | ----- | ----- | ----- | ----- |
| Outstanding, end of | | | | | | |
| year..... | 1,050,151 | \$6.38 | 1,122,428 | 6.45 | 1,082,902 | \$6.39 |

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| | ===== | ===== | ===== | ===== | ===== |
|---|---------|--------|---------|-------|---------|
| Available for future grants..... | 406,517 | | 394,585 | | 470,810 |
| Exercisable at end of year..... | 761,534 | | 663,457 | | 474,446 |
| Weighted-average fair value of options granted during the year..... | | \$3.24 | | 3.64 | \$3.56 |

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

| Range of Exercise Prices | Options Outstanding | | |
|--------------------------|--------------------------------|---------------------------------|---------------------------------|
| | Number Outstanding at 12/31/00 | Weighted-average Exercise Price | Weighted-average Remaining Term |
| \$5.30 to \$6.00 | 121,667 | \$5.686 | 5.4 years |
| \$6.01 to \$6.38 | 823,851 | \$6.375 | 1.7 years |
| \$6.56 to \$7.50 | 104,633 | \$7.224 | 4.0 years |
| ===== | ===== | ===== | ===== |
| \$5.30 to \$7.50 | 1,050,151 | \$6.380 | 2.4 years |
| ===== | ===== | ===== | ===== |

In calculating pro forma information regarding net income and net income per share, as required by Financial Accounting Standards Board Statement No. 123, Accounting for Stock-Based Compensation, the fair value was estimated at the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions for the options on the Company's common stock for the years ended December 31, 2000, 1999, and 1998, respectively: risk free interest rates of 6% for all periods; dividend yields of 0% for all periods; volatility of the expected market prices of the Company's common stock of .555, .469 and .542; and expected life of the options of 5.5 years for all periods.

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MEDSTONE INTERNATIONAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

December 31, 2000

For purposes of pro forma disclosures, the estimated fair value of the options is amortized to expense over the options' vesting period. The Company's proforma information for the years ended December 31, 2000, 1999 and 1998 follows (in thousands, except per share information):

Year ended December 31,

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| | 2000 | 1999 | 1998 |
|---|----------|----------|----------|
| Pro forma net income..... | \$ 1,837 | \$ 2,464 | \$ 4,077 |
| Pro forma diluted net income per share..... | \$.41 | \$.50 | \$.77 |

These pro forma amounts do not give effect to options granted prior to January 1, 1995.

6. Stock Repurchase Plan

The Company's Stock Repurchase Programs have authorized repurchase of up to 1,550,000 shares of its common stock. For the year ending December 31, 2000, the Company repurchased a total of 459,800 shares at a cost of \$2,736,124. For the year ending December 31, 1999, the Company repurchased a total of 387,550 shares at a cost of \$2,445,250. For the year ended December 31, 1998 the Company repurchased a total of 318,300 shares at a cost of \$2,742,473. The Company has repurchased a total of 1,434,450 shares since the inception of its Stock Repurchase Programs at a total cost of \$10,124,583 with all amounts recorded as treasury stock. The Company's current repurchase program was active as of December 31, 2000.

7. Commitments

In March 1994, the Company took occupancy of office, manufacturing, engineering and warehouse space, and research and development laboratories under an operating lease with an initial term of two years. The first extended lease on this facility, with a monthly lease rate of \$14,410 expired June 30, 2000. In April 2000, the Company signed a new sixty-four month lease of this facility, with the term running through November 2005. The average monthly rental expense is \$19,449 over the term of the lease. The new lease has the option for one five-year extension at a rate to be negotiated based on then current market rates.

In April 1999, the Company's subsidiary took possession of manufacturing, office and warehouse space under a monthly operating lease until October 2000, at which time it entered into a new sixty-month lease at a monthly rent of \$2,980, commencing October 1, 2000.

The future minimum lease payments under all operating leases are as follows:

| | Minimum Rental |
|-----------|-------------------|
| 2001..... | \$256,000 |
| 2002..... | \$260,000 |
| 2003..... | \$252,000 |
| 2004..... | \$263,000 |
| 2005..... | \$248,000 |

Total net rent expense under all operating leases for the years ended December 31, 2000, 1999 and 1998 was \$204,000, \$227,000 and \$194,000, respectively.

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MEDSTONE INTERNATIONAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

December 31, 2000

8. Contingencies

The Company is involved in legal proceedings incidental to the normal conduct of its business. The Company has obtained various liability insurance policies providing coverage for general liability, product liability and other claims. Management does not believe that the resolution of any current proceedings will have a material financial impact on the Company or its consolidated financial position, results of operations and cash flows.

9. Related Party Transactions

Cardiac Science, Inc.

Cardiac Science, Inc. was formed as a subsidiary of the Company during 1991 and shortly thereafter was spun off as a separate entity with a majority of the common stock of Cardiac Science, Inc. distributed to the Company's stockholders. During 1991 through 1996, the Company performed various financing activities for Cardiac Science in exchange for common stock and warrants.

As of December 31, 2000 and 1999, the Company held approximately 187,000 and 492,000 shares of common stock and 0 and 87,500 warrants to purchase common stock, respectively in Cardiac Science, Inc. The common stock and warrants had a carrying value of zero. At December 31, 2000, the fair market value of the investment in Cardiac Science, Inc. common stock approximates \$795,000.

During 2000 and 1999, the Company sold approximately 305,000 and 55,000 shares for \$1,855,000 and \$244,000 in cash, respectively. During 1999, the Company sold the 87,500 warrants for \$262,000 in cash. All proceeds from these sales of the common stock and warrants were included in other income.

k. Biotech

During 1999, the Company increased its ownership interest in k.Biotech, Inc. by \$100,000 for a total investment of \$325,000 which represents a 21% interest. Two members of the Board of Directors of the Company are also shareholders of k.Biotech, Inc. and one member of the Board of Directors is the President of k.Biotech.

Digital Imaging Systems

During 1998, the Company obtained a 14% ownership interest in Digital Imaging Systems, Inc. ("DIS") for \$300,000 and entered into a supply agreement whereby the Company would purchase equipment up to \$1.1 million from DIS. In 1999, the Company recorded an investment writedown of \$300,000 as a result of its review of the realizable value of this investment. DIS commenced shipments of its products to the Company in January 1999 pursuant to the supply agreement.

Genstar Therapeutics Corporation

Genstar Therapeutics Corp. (formerly Urogen Corp.) was a subsidiary of the

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Company until early 1996 at which time the Company spun off this subsidiary as a separate company. The Company distributed all the stock of Genstar to its stockholders, except for 100,000 shares which the Company retained. During 2000, the Company sold 5,000 shares of Genstar for a gain of approximately \$28,000 and still holds 95,000 shares of Genstar common stock with a book value of \$0 as of December 31, 2000. The market value of the retained Genstar common stock is approximately \$926,000 at December 31, 2000.

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MEDSTONE INTERNATIONAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS--(Continued)

December 31, 2000

Investment in Medicredit.com, Inc.

In April 2000, the Company purchased common stock representing a 46% interest in Medicredit.com. Inc. ("Medicredit") for \$1 million in cash. Medicredit, a California-based company, funds and services loans to physicians to finance elective surgeries in the cosmetic and cash paying sector of healthcare. Along with the cash investment in Medicredit, the Company agreed to a line of credit of up to \$2 million at the prime interest rate. As of December 31, 2000, the full \$2 million credit line was outstanding to Medicredit and is reflected in long-term assets in the Consolidated Balance Sheets of the Company. The Company reflects its equity position of the operating results of Medicredit since its purchase in the Minority Interest section of the Consolidated Statements of Income.

10. Employee Benefit Plan

In January 1990, the Company established a defined contribution profit sharing 401(k) plan for all eligible employees. The plan provides for the deferral of up to 15% of an employee's qualifying compensation under Section 401(k) of the Internal Revenue Code. Contributions by the Company may be made to the plan at the discretion of the Board of Directors. During 1997, the Company's Board of Directors elected to match the employee contributions \$.25 on a dollar, up to a maximum company contribution of \$2,000 per year. In 2000, 1999 and 1998, the Company's contribution totaled \$58,382, \$50,557 and \$44,430, respectively.

11. Major Customers and Foreign Sales

During the three years ended December 31, 2000, 1999 and 1998, no single customer has accounted for 10% or more of total revenues in any one year. The Company derived 7%, 3% and 4% of total revenues from sales to foreign customers in the years ending December 31, 2000, 1999 and 1998, respectively.

12. Selected Quarterly Financial Data (Unaudited)

The tables below set forth selected quarterly financial information for 2000 and 1999 (in thousands, except per share amounts):

| 2000 | 1st Quarter | 2nd Quarter | 3rd Quarter | 4th Quarter |
|----------------|-------------|-------------|-------------|-------------|
| ---- | ----- | ----- | ----- | ----- |
| Net sales..... | \$6,109 | \$5,983 | \$5,443 | \$5,287 |

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| | | | | |
|------------------------------|--------|--------|--------|--------|
| Gross profit..... | 2,487 | 2,455 | 2,011 | 1,927 |
| Net income..... | 922 | 555 | 573 | 39 |
| Basic earnings per share.... | \$.20 | \$.12 | \$.13 | \$.01 |

| | | | | |
|------------------------------|-------------|-------------|-------------|-------------|
| 1999 | 1st Quarter | 2nd Quarter | 3rd Quarter | 4th Quarter |
| ----- | ----- | ----- | ----- | ----- |
| Net sales..... | \$4,904 | \$6,493 | \$6,440 | \$5,632 |
| Gross profit..... | 2,437 | 3,434 | 3,172 | 2,317 |
| Net income..... | 532 | 633 | 1,182 | 494 |
| Basic earnings per share.... | \$.11 | \$.12 | \$.23 | \$.10 |

13. Subsequent Events

In January 2001, the Company sold 73,000 shares of Cardiac Science Common Stock for a gain of approximately \$358,000.

In January 2001, the Company purchased 10,000 shares of its Common Stock for a cost of \$62,475 under its current Stock Repurchase Program.

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MEDSTONE INTERNATIONAL, INC.

SCHEDULE II--VALUATION AND QUALIFYING ACCOUNTS

| Description | Balance at beginning of year | Additions | | Deductions | Balance at end of year |
|--|---------------------------------------|-------------------------------------|---------------------------------|---------------|------------------------------|
| | | Charged to costs and expenses | Charged to other accounts | | |
| For the year ended December 31, 2000: | | | | | |
| Allowance for doubtful accounts..... | \$571,252 | \$ -- | \$ -- | \$ 94,072 (b) | \$477,180 |
| | ===== | ===== | ===== | ===== | ===== |
| Allowance for inventory obsolescence..... | \$307,203 | \$277,138 | \$ -- | \$127,253 (a) | \$457,088 |
| | ===== | ===== | ===== | ===== | ===== |
| For the year ended December 31, 1999: | | | | | |
| Allowance for doubtful accounts..... | \$602,564 | \$ 35,000 | \$ -- | \$ 66,312 (b) | \$571,252 |
| | ===== | ===== | ===== | ===== | ===== |
| Allowance for inventory obsolescence..... | \$337,437 | \$ -- | \$ -- | \$ 30,234 (a) | \$307,203 |
| | ===== | ===== | ===== | ===== | ===== |
| For the year ended December 31, 1998: | | | | | |
| Allowance for doubtful accounts..... | \$534,918 | \$130,000 | \$ -- | \$ 62,354 (b) | \$602,564 |
| | ===== | ===== | ===== | ===== | ===== |
| Allowance for inventory obsolescence..... | \$337,437 | \$ -- | \$ -- | \$ -- | \$337,437 |
| | ===== | ===== | ===== | ===== | ===== |

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=====

- (a) Write-off of inventories
- (b) Write-off of bad debts

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

MEDSTONE INTERNATIONAL, INC.

/s/ David V. Radlinski

By: _____
 David V. Radlinski
 Chief Executive Officer

Dated: March 30, 2001

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities indicated on March 23, 2001.

| Signature ----- | Title ----- | Date ---- |
|--|--|-----------------------|
| <p>/s/ David V. Radlinski _____ David V. Radlinski</p> | <p>Chairman of the Board and Chief Executive Officer and Director (Principal Executive Officer)</p> | <p>March 23, 2001</p> |
| <p>/s/ Mark Selawski _____ Marck Selawski</p> | <p>Chief Financial Officer (Principal Financial and Accounting Officer)</p> | <p>March 23, 2001</p> |
| <p>/s/ Donald J. Regan _____ Donald J. Regan</p> | <p>Director</p> | <p>March 23, 2001</p> |
| <p>/s/ Frank R. Pope _____ Frank R. Pope</p> | <p>Director</p> | <p>March 23, 2001</p> |
| <p>/s/ David A. Reed _____ David A. Reed</p> | <p>Director</p> | <p>March 23, 2001</p> |
| <p>/s/ Michael C. Tibbitts _____ Michael C. Tibbitts</p> | <p>Director</p> | <p>March 23, 2001</p> |

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Exhibit Index

Exhibit No. Description

| Exhibit No. | Description |
|-------------|--|
| 3.1 | Certificate of Incorporation of the Company, as amended (1) |
| 3.2 | Restated and Amended Bylaws of the Company (2) |
| 4.2 | Specimen Certificate of the Company's Common Stock (3) |
| 10.26 | 1989 Stock Incentive Plan (4) (5) |
| 10.27 | Non-employee Director Stock Option Plan (4) (5) |
| 10.28 | Facility Lease on 100 Columbia (6) |
| 10.29 | 1997 Stock Incentive Plan (5) (7) |
| 10.30 | Employment Agreement with David Radlinski (5) |
| 10.31 | Employment Agreement with Mark Selawski (5) |
| 10.32 | Employment Agreement with Eva Novotny (5) |
| 21 | Subsidiaries |
| 23.1 | Consent of Independent Auditors |
| 28.2 | Form of Cytocare, Inc. Information Statement--Distribution to Shareholders of Stock of Cardiac Science, Inc. (8) |
| 28.3 | Form of Medstone International, Inc. Information Statement--Distribution to Shareholders of Stock of Endocare, Inc. and Urogen Corp. (9) |

-
- (1) Previously filed with the same exhibit number with the Company's Registration Statement on Form S-1 under the Securities Act of 1933, Reg. No. 33-16340 and with the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 1998 and incorporated herein by reference.
 - (2) Previously filed with the same exhibit number with the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 1999, and incorporated herein by reference.
 - (3) Previously filed with the same exhibit number with the Company's Registration Statement on Form S-1 under the Securities Act of 1933, Reg. No. 33-16340 and incorporated herein by reference.
 - (4) Previously filed with the same exhibit number with the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 1989, and incorporated herein by reference.
 - (5) Compensatory plan or arrangement.
 - (6) Previously filed with the same exhibit number with the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 1997.

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- (7) Previously filed with the same exhibit number with the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 1998.
- (8) Previously filed with the same exhibit number with the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2000.
- (9) Previously filed with the same exhibit number with the Company's current report on Form 8-K dated June 26, 1991, and incorporated herein by reference.
- (10) Previously filed with the Company's current report on Form 8-K dated February 9, 1996, and incorporated herein by reference.