HOLOGIC INC
Form 10-K405
December 12, 2001

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended: September 29, 2001

or

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

For the transition period from_____ to _____

Commission File Number: 0-18281

Hologic, Inc.
(Exact Name of Registrant as Specified in Its Charter)

| Delaware | 04-2902449 |
|---|---|
| (State or Other Jurisdiction of Incorporation or Organization) | (IRS Employer Identification No.) |

35 Crosby Drive, Bedford, Massachusetts 01730
(Address of Principal Executive Offices, Including Zip Code)

(781) 999-7300
(Registrant's Telephone Number, Including Area Code)

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

Securities registered pursuant to Section 12(g) of the Act: Common Stock, $.01 par value
Rights to Purchase Common Stock

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

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

The aggregate market value of the registrant's Common Stock held by non-affiliates of the registrant as of December 7, 2001 was $166,348,970 based on the price of the last reported sale on the Nasdaq National Market System on that date.

As of December 7, 2001 there were 15,842,759 shares of the registrant's Common Stock, $.01 par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Proxy Statement for the registrant's annual meeting of stockholders to be filed within 120 days of the end of its fiscal year ended September 29, 2001 (Part III: Items 10, 11, 12 and 13)

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements contained in this report are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These statements involve known and unknown risks, uncertainties and other factors which may cause our or our industry's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to statements regarding:

- our goal of returning to profitability;
- our goal of expanding our market positions;
- the development of new competitive technologies and products;
- regulatory approval and clearances for our products;
- production schedules for our products;
- market acceptance of new products;
- business strategies;
- dependence on significant suppliers;
- dependence on significant distributors and customers;
- the availability of debt and equity financing;
- general economic conditions;
- the impact of our cost-savings initiatives; and
- our financial condition or results of operations.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "could," "would," "expects," "plans," "anticipates," "believes," "estimates," "projects," "predicts," "potential" and similar expressions intended to identify forward-looking statements. These statements are only predictions and involve known and unknown risks, uncertainties, and other factors that may cause our actual results, levels of activity, performance, or achievements to be materially different from any future results, levels of activity, performance, or achievements expressed or implied by such forward-looking statements. Given these uncertainties, you should not place

undue reliance on these forward-looking statements. Also, these forward-looking statements represent our estimates and assumptions only as of the date of this report. We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statement contained in this report to reflect any change in our expectations or any change in events, conditions or circumstances on which any of our forward-looking statements are based. Factors that could cause or contribute to differences in our future financial results include those discussed in the risk factors set forth in Item 7 below as well as those discussed elsewhere in this report. We qualify all of our forward-looking statements by these cautionary statements.



Part I

Item 1. Business

We are a leading developer, manufacturer and supplier of diagnostic and medical imaging systems primarily serving the healthcare needs of women. We focus our resources on developing systems and subsystems offering superior image quality and diagnostic accuracy, which has enabled us to capture significant market shares and customer loyalty, despite the presence of large competitors. Our core women's healthcare business units are focused on bone densitometry, mammography and breast biopsy and on developing a direct-to-digital X-ray mammography system. Our bone densitometry product line and our Lorad line of mammography systems are premier brands in their markets. In addition, we develop, manufacture and supply other X-ray based imaging systems, such as general purpose direct-to-digital X-ray equipment and mini c-arm imaging products. Our customers are hospitals, imaging clinics and private practices and include many of the leading healthcare organizations in the world. Our customers are also major pharmaceutical companies who use our products in conducting clinical trials.

We were founded on and remain committed to the principle of applying superior technology to medical imaging challenges. We achieved our first market and technology position shortly after the first commercial shipment of our initial product targeting bone densitometry in 1987. Our patented technology remains a leading bone densitometry assessment tool, offering superior, cost-effective accuracy and reliability. Starting in 1996, we embarked on an acquisition program intended to expand and diversify our business. In 1996 we acquired Fluoroscan Imaging Systems, a market leader for low intensity, real-time mini c-arm X-ray imaging devices that address the trend towards minimally invasive surgery. We have long identified mammography as an attractive growth opportunity where superior imaging technology could significantly improve diagnosis. With this goal in mind, in June 1999, we acquired Direct Radiography Corporation, or DRC, from Sterling Diagnostics and have continued to invest in the development of their direct-to-digital X-ray technology, DirectRay, targeting mammography as well as general radiography applications. While we originally intended to internally develop mammography systems based on DirectRay, in September 2000 we significantly expedited our entry into the mammography market by acquiring the U.S. assets of Trex Medical Corporation, which included the Lorad product line of mammography and minimally invasive breast biopsy systems used to detect breast cancer. We estimate that we have sold over 9,500 mammography systems worldwide and our products are known within the industry for superior image quality and technological innovation. We plan on integrating our DirectRay technology into the Lorad mammography product line, selling both digital upgrades to our existing installed base and new digital systems to potential customers.

As a result of these acquisitions and our commitment to develop digital radiography, particularly for mammography systems, we generated losses in fiscal

1999, 2000 and 2001. Following the death in June 2001 of S. David Ellenbogen, our co-founder, Chairman and Chief Executive Officer, John W. Cumming was named our Chief Executive Officer and President. In August 2001, we implemented an extensive restructuring plan focused on returning to profitability and strengthening our competitive position in the women's health and emerging digital imaging markets. This restructuring plan included a company-wide cost savings initiative, which we estimate will result in annual cost savings in excess of $10 million. Cost savings initiatives which have been effected include a reduction of the workforce, reduction of operating expenses in each of our four business units and the phase-out of non-core and unprofitable units. The second element of our restructuring plan focuses on long-term revenue growth through new marketing programs, expanded distribution channels, and development of strategic business relationships. Consistent with the plan, we announced in November 2001 that we have entered into a non-exclusive distribution agreement with Siemens Medical Solutions, a unit of Siemens AG, for the sale of our X-ray bone densitometers throughout the United States. We also announced the closure of our conventional X-ray equipment manufacturing facility located in Littleton, Massachusetts, acquired through our acquisition of the U.S. assets of Trex Medical. This business incurred significant losses during fiscal 2001. We intend to relocate some of the Littleton product lines, and sales and service support personnel to our corporate headquarters in Bedford, Massachusetts. Including the reduction in workforce being implemented in connection with the closure of our Littleton facility, since the beginning of fiscal 2001, we will have reduced our workforce by approximately 25%.



We are focused on returning to profitability, expanding our market position in bone densitometry and mammography, and leading the field of digital mammography. We are evaluating new marketing programs designed to expand market share in our core markets, assessing new distribution channels for our product portfolio and pursuing business relationships that would allow us to further leverage our state-of-the-art technology base.

We were incorporated in Massachusetts in October 1985 and reincorporated in Delaware in March 1990. Unless the context otherwise requires, references to us, Hologic or our company refer to Hologic, Inc. and each of its consolidated subsidiaries. We view our operations and manage our business in four principal operating segments: bone assessment products, mini c-arm imaging products, direct-to-digital imaging products, and mammography and general radiography products. We have provided financial information concerning these segments in Note 11 of the Notes to our Consolidated Financial Statements included in this report.

The Hologic logo is one of our service marks. QDR, ACCLAIM, Sahara, EPEX, RADEX, StereoLoc and Lorad are our registered trademarks. Affinity, QDR 4000, QDR 4500, QDR 4500A, QDR 4500SL, QDR 4500W, QDR 4500C, Delphi, Fluoroscan, Premier, OfficeMate, Fluoroscan Imaging Systems, DirectRay, DR1000C, Elite, MultiCare, HTC, Automatic Internal Reference System, Instant Vertebral Assessment, Direct Radiography and Omniflex are other trademarks that we own.

## Our Markets and Products

Our core women's healthcare business units are focused on bone densitometry, mammography and breast biopsy and developing a direct-to-digital X-ray mammography system. In addition, we develop, manufacture and supply general purpose direct-to-digital X-ray equipment, and other X-ray based imaging systems, such as c-arm imaging products.

### Bone Assessment Products

Overview

Bone densitometry is the precise measurement of bone density to assist in the diagnosis and monitoring of osteoporosis and other metabolic bone diseases that can lead to debilitating bone fractures, often of the spine and hip. The National Osteoporosis Foundation estimates that osteoporosis is a major public health threat for approximately 28 million Americans and 250 million people worldwide, the majority of whom are women. Each year osteoporosis contributes to more than 1.5 million new hip, spine and other fractures. In August 2000, the National Institutes of Health estimated that the burden of healthcare costs for osteoporotic and associated fractures were between $10 billion and $15 billion per year. A significant boost for our bone assessment business was the 1995 introduction of drug therapies to treat and prevent osteoporosis. We believe that the introduction of new drug therapies, the aging of the population, and an increased focus on women's health issues and preventive medical practices has created a growing awareness among patients and physicians that osteoporosis is treatable. As a result, more women than ever are seeking bone assessment for osteoporosis. We believe that the demand for our bone densitometry systems will continue to be driven by an increase in the number of available therapies to treat osteoporosis, the increase in the at-risk population, and broader reimbursement coverage for bone density testing. In fiscal 2001, we shipped more than 750-energy dual-energy X-ray bone densitometry systems worldwide which we believe represents at least 50% of the worldwide market in fiscal 2001 for these systems.

We introduced our first product serving the bone densitometry market in 1986, began commercial shipments in 1987, and quickly gained recognition for our superior technology. Our patented dual-energy X-ray technology remains a leading bone densitometry assessment tool, offering superior, cost-effective accuracy and reliability. In 1999, we introduced our next-generation densitometer, Delphi, which incorporates our patented fan beam imaging technology and Instant Vertebral Assessment, or IVA, technology. These dual technologies enable physicians to simultaneously measure bone density and visually assess vertebral status in a clinical setting. The ability to conduct these two diagnostic procedures with one system enables doctors to cost-effectively improve fracture risk assessment and to capture greater reimbursement fees. In May 2001, we received the 2001 Frost & Sullivan Technology Innovation Award in the osteoporosis diagnostics market, given for technical superiority within the industry.



We began commercial shipments of our base models of the Delphi series in March 2000 and introduced more advanced systems, which perform lateral, side-to-side scans of the lower spine without patient repositioning, in November 2000. In our quarter ended September 29, 2001, our high-end Delphi systems represented approximately 70% of our revenue from shipments of X-ray bone densitometry systems, and our bone densitometry revenues in the quarter were the highest for any quarter in the last two fiscal years. Over 500 Delphi systems have been installed to date. In addition to sales of new Delphi systems, we also offer upgrade opportunities to purchasers of many of our earlier generation systems in order to incorporate the technology advantages of Delphi. Worldwide, approximately 3,900 of our previously installed densitometry systems can be upgraded with Delphi capabilities. Through September 29, 2001, over 170 previously installed systems have been upgraded.

Products

Our bone assessment products include a family of QDR X-ray bone densitometers and the Sahara Clinical Bone Sonometer, an ultrasound device that assesses the bone density of the heel.

QDR X-Ray Bone Densitometers. Since our first commercial shipment of a QDR system in October 1987, we have sold more than 8,000 QDR systems. We believe that advantages of our QDR systems include high precision, low patient radiation exposure equivalent to 1/10th of a conventional chest X-ray, a relatively fast scanning time, low operating cost, no radioactive source and the ability to measure bone density of the most important fracture sites, the spine and hip. Our studies and those of independent investigators have demonstrated that the systems can detect a change in spine bone density with a precision error of less than 1%.

All our QDR systems employ our patented Automatic Internal Reference System, which continuously calibrates each patient's bone density measurement to a known standard. This system virtually eliminates errors that might result from manual calibration and saves operators the time-consuming task of calibrating several times a day. The system automatically compensates for drift in the X-ray system, detectors or other electronic components, which ensures long-term measurement stability.

We have invested substantial resources in developing operating and applications software for our systems. The software includes calibration software, automated scan and analysis programs for each scan site, and a patient data base manager that archives all raw data for later retrieval and analysis and allows the operator to review the current image with an earlier image of the same patient.

In November 1999, we introduced our Delphi QDR Series bone densitometer. The Delphi offers physicians the ability to simultaneously assess two of the strongest risk factors for osteoporotic fracture: existing fractures of the spine and low bone density. Using high-resolution fan beam X-ray imaging technology, Delphi's IVA technology enables clinicians to perform a rapid, low-dose evaluation of the spine in a single office visit during a routine bone densitometry exam. The high-resolution, single-energy images obtained with IVA visually reveal spinal fractures, which substantially increase the risk of future fracture, and thereby affect a clinician's therapeutic decisions. Prior to the introduction of Delphi, spine fractures were rarely evaluated in clinical osteoporosis assessment, primarily due to the inconvenience and high radiation dose associated with obtaining conventional X-ray films. Delphi with IVA provides a simple, point of care tool for vertebral assessment, with only 1% of the radiation dose of standard radiographic assessment. The combination of bone mineral density assessment and spine fracture assessment improves the clinician's ability to accurately target therapy to those who can benefit most. In March 2000, we began commercial shipments of Delphi.

In addition to instant vertebral assessment, our Delphi series of bone densitometers offers rapid scanning and high-resolution imaging using our latest fan beam and high density, solid-state multi-detector array technology. These systems are built in modular configurations that allow customers to add new features and capabilities, while protecting their investment in the equipment and patient data. During fiscal 2000, two systems from the Delphi series were



available: the Delphi C and Delphi W. At the November 2000 annual meeting of the Radiological Society of North America, we introduced the more advanced Delphi SL and Delphi A systems.

We also continue to offer our customers four versions of the ACCLAIM QDR Series bone densitometer: the QDR 4500A; the QDR 4500SL; the QDR 4500W; and the QDR 4500C. As with the Delphi, these systems are built in modular configurations that allow customers to add new features and capabilities. These systems do not

offer the instant vertebral assessment capability offered by the Delphi systems.

An important feature of the Delphi A and SL and ACCLAIM A and SL systems is their ability to perform lateral, side-to-side scans of the lower spine, without turning the patient on her side, in addition to back-to-front measurements. The Delphi and ACCLAIM A and SL systems are capable of producing high quality images of the spine, lateral spine, hip and other skeletal sites. The scan arm allows for multiple scan views without patient repositioning. The images produced can be combined with capabilities that enable the dimensions of the spine to be determined. By using either of the A or SL Delphi and ACCLAIM systems, high-quality lateral images of the entire spine can be obtained in as little as ten seconds.

Our QDR 4000 pencil beam bone densitometer combines the reliability and economy of our DXA bone densitometers with a unique package of value-added applications that provide physicians with bone density measurements of the hip, spine and forearm. The QDR 4000 is targeted at the price-sensitive segment of the market.

Ultrasound. In addition to our QDR X-ray bone densitometers, we have developed and sell an enhanced dry ultrasound bone analyzer, called Sahara, that assesses the bone density of the heel. Clinical trials of ultrasound systems have indicated a significant association of low ultrasonic bone measurements of the heel and the risk of fracture. At the time of our introduction of the Sahara, other ultrasound bone analyzers required the patient to place her foot in water. The use of water requires cumbersome plumbing and cleaning mechanisms to be incorporated into the system; our dry Sahara avoids the need for these mechanisms. Advantages of ultrasound examination are the complete absence of radiation and the small size and low cost of the equipment. In addition, since ultrasound devices do not use X-rays in making their measurements, they do not require X-ray licensing or registered operators. However, because ultrasound bone measurements currently are not as precise as X-ray and other measurements, they are less reliable for continued monitoring of small changes in bone density or for assessing the response to therapies. In addition, they are generally limited to measurements at peripheral sites, not the more important spine or hip fracture sites. We believe that our Sahara ultrasound system represents a relatively low cost, compact, easy-to-use, non-ionizing measurement technique to assist in the initial diagnosis of osteoporosis.

Mammography and Other Breast Cancer Detection Products

Overview

According to the American Cancer Society, breast cancer is the second most common cancer among women, and an estimated 192,000 new invasive cases of breast cancer are expected to occur among women in the United States during 2001. Breast cancer ranks as the second leading cause of cancer-related deaths among women, causing an estimated 40,000 deaths in 2001. A leading industry analyst estimates that the mammography imaging equipment market was approximately $293 million in 1999 and expects that it may grow to $567 million by 2007. When we acquired the U.S. assets of Trex Medical in September 2000, we immediately gained a significant market share in the mammography and breast biopsy systems market and a leading market share in the high-end segment of the mammography systems market in which we primarily compete. In fiscal 2001 we shipped 585 mammography systems worldwide.

Products

Our Lorad division offers a broad product line of breast imaging products, including a range of mammography systems and breast biopsy systems. Currently our highest-end Lorad system, the M-IV, is considered a technology leader

in the mammography marketplace. The M-IV incorporates our High Transmission Cellular Imaging System, HTC, recognized by Frost & Sullivan in connection with Lorad's receipt of the 2001 Frost & Sullivan Technology Innovation Award, as one of the most effective contrast improvements in 20 years of breast imaging. The patented HTC technology reduces X-ray scatter in two dimensions, delivering superior contrast and resolution without an increase in radiation dose. Our mid-tier system, the Lorad Elite, can also be configured with our HTC technology. In addition, we recently received marketing clearance from the FDA for our Lorad Affinity mammography system, which is a high-performance screen-film mammography system specifically developed to fill a market need for a cost-effective product, with performance characteristics similar to high-end systems. We expect to begin full commercial production of these systems in the first fiscal quarter of 2002.

We also offer two minimally invasive breast biopsy systems. These systems provide an alternative to open surgical biopsy, which is generally performed under general anesthesia. Minimally invasive biopsies are most often performed on an outpatient basis under local anesthesia and are less expensive than open surgery. The following is a more detailed description of the products sold by our Lorad Division.

Mammography Systems

- Lorad M-IV. The Lorad M-IV was introduced in 1996. Since that introduction, more than 2,400 units have been sold. Features of the Lorad M-IV include a bi-angular X-ray tube, dual filter capability, auto filter mode, three-cell AEC sensor and high image quality. Image quality can be further improved through an HTC Imaging Systems option. Other features of the Lorad M-IV include improved patient management through streamlined patient scheduling, integrated auto film identification, optional bar code reader, and connectivity through a radiology information systems interface. The Lorad M-IV has also been designed to be upgradable to our direct-to-digital full field digital mammography system, currently under development.

- Lorad Elite. The Lorad Elite was introduced in June 1998. The Lorad Elite is designed to combine quality with value. The product provides high image quality through bi-angular X-ray tube technology and the use of our HTC system. The unit offers high reliability, high throughput, cost-effective ownership and upgradabilty. In combination with the Lorad StereoLoc II, the Lorad Elite provides both screening and diagnostic capabilities.

- Lorad Affinity. We received FDA marketing clearance for the Lorad Affinity in October 2001. The Lorad Affinity is a screen-film mammography system developed to fill a market need for a cost-effective, high performance mammography product. The Affinity can be used with other Lorad innovations to improve mammographic image quality, including our HTC technology and our Fully Automatic Self-adjusting Tilt (F.A.S.T.) compression paddle.

Breast Biopsy Systems

We provide clinicians with the flexibility of choosing from either upright or prone systems for breast biopsy. Our minimally invasive breast biopsy systems provide an alternative to open surgical biopsy, which is generally performed under general anesthesia. Minimally invasive biopsies are typically done on an outpatient basis under local anesthesia and are less expensive than open surgery.

We offer the StereoLoc II upright biopsy system, which is used in conjunction with our mammography systems. In addition, for physicians that perform a significant number of biopsies, we offer a dedicated, prone biopsy system called the Lorad MultiCare Breast Biopsy System (formerly called the StereoGuide). This system is used with our digital "spot" mammography system, which enables a doctor to position the sampling device at the site of the suspicious lesion. When performing a biopsy with any of our systems, a doctor has a choice of tissue-sampling devices, which are not manufactured by us.



Direct-to-Digital Imaging Products

Overview

We have made a strategic commitment to digital radiography. We believe that the advantages of digital radiography over conventional film technology create a market with significant growth potential in general and in our core mammography systems market in particular. Digital image capture offers speed, eliminates film storage issues and provides for almost instantaneous image preview, modification and re-take when required. Diagnostic images captured in an outpatient setting can be delivered electronically for interpretation throughout a provider's computer network and can enable hospitals to share patient data and allow radiologists to confer more easily regarding diagnoses. In spite of their high acquisition cost, we believe that digital radiography systems are cost effective in the long-term when considering increased throughput, savings in film-related expenses, image storage and transfer costs as well as the benefits of enhanced diagnostic convenience.

We believe that a significant factor in the market's acceptance of digital technology is the current transition within the healthcare industry from conventional X-ray film archiving to Picture, Archive and Communication Systems, known as PACS, to store X-ray images electronically. We believe that only a limited number of hospitals have adopted the PACS environment to date. We expect this adoption rate to accelerate over the next several years as hospitals realize the value and cost savings of a filmless infrastructure. Industry analysts estimate that the worldwide replacement market for installed X-ray units is approximately 11,000 systems per year, and, while not all facilities in which X-ray units are installed will migrate to digital technology, we believe many large facilities will, particularly those in the U.S. where PACS is an important initiative.

According to an industry analyst, in 2000 there were approximately 300,000 general radiographic X-ray units installed worldwide. Although the market for general radiography products is mature, we expect the market for digital X-ray systems to grow substantially over the next several years. By 2005, a leading industry analyst projects that the market for digital radiography products will reach $1.0 billion annually.

Digital radiography can be implemented with a number of technologies, involving the direct or indirect conversion of X-ray energy captured by a detector into electronic signals. The different digital technologies are principally differentiated by their image resolution, X-ray dosage requirement, cost and field of view. First-generation digital radiography systems use indirect-conversion detectors where the X-ray energy is first converted into light, through the use of a fluorescent screen or other device, and then into electronic signals. Second-generation systems utilize a direct conversion method wherein the X-rays are absorbed and the electric signals are created in one step. We believe that amorphous selenium is currently the only commercially available direct conversion technology.

Selenium is particularly well-suited for high-quality digital imaging because it has high X-ray absorption efficiency, very high intrinsic resolution and low noise. We believe that amorphous selenium technology results in the highest quality digital image across a wide range of general radiographic applications and is particularly valuable for mammography which has high resolution requirements.

We have developed two digital technologies. Our first-generation digital technology, developed by Lorad, is an indirect conversion technology involving charged coupled devices, or CCDs, to detect the light emitted by a fluorescent screen. Our second-generation digital technology is DirectRay, developed by DRC, which is a selenium-based direct-conversion technology. While we have no exclusivity on the use of amorphous selenium in detector plates, we hold 34 patents related to our DirectRay technology, and we believe that our amorphous selenium development efforts are the most advanced in the industry. As the only commercially available, FDA-cleared, direct-conversion selenium detector, we believe that our DirectRay technology has the potential to gain industry acceptance as a standard for direct-to-digital conversion technology.



Products

We currently offer the DirectRay digital technology in several forms for general radiographic applications, including as fully integrated radiographic systems, such as our EPEX and RADEX systems and our Digital Chest imaging systems, as an image capture upgrade to existing X-ray equipment, and as a digital component for OEMs to incorporate into their own equipment. As of the close of our fourth quarter of 2001, we had a record backlog of 26 systems, or greater than $8.0 million, due to increasing orders for our EPEX, RADEX and Digital Chest imaging systems. We supply our amorphous selenium flat panels to Agfa Corporation for non-destructive imaging applications as well as to Analogic Corporation, which incorporates our panels into systems, which it supplies to Eastman Kodak.

Integrated Products. Our Direct Radiography integrated product line offers high quality imaging, ease-of-use, a full range of motion for easy patient positioning in multiple planes, and full DICOM compliance, which is the standard protocol for communicating with a hospital's Picture, Archive and Communication Systems.

- EPEX and RADEX. We have developed two integrated direct-to-digital general radiography systems. The EPEX system is a high-end system that permits a full range of general radiography examinations. The RADEX system is a simpler general radiography system designed with need for flexibility as required by outpatient departments. Commercial shipments of the RADEX began in May 2000 and shipments of the EPEX began in July 2000.

- DR1000C. The DR1000C is a dedicated chest radiography system. The system is configured to provide a wide range of vertical motion, allowing upright chest radiography of most patients, ranging from a small child to a large adult.

- Inverse Topography. Inverse Topography is a software application that we introduced at the annual meeting of the Radiological Society of North America in November 2000. This application capitalizes on the dynamic range of the digital detector and enables our direct radiography products to enhance the appearance of soft tissue and bone in one image display.

Digital Upgrade Products. Our Digital Upgrade products offer customers an option to convert existing conventional film-based X-ray equipment to DirectRay technology. This customized offering includes a replacement bucky assembly specifically designed for the DirectRay detector, and related control equipment. This product is installed in place of the existing bucky mechanism in the examination table, enabling the conversion to a direct-to-digital system. This upgrade opportunity varies depending on the different specifications on the wide variety of X-ray systems installed worldwide. This upgrade is currently available for some of General Electric Medical System's conventional X-ray systems.

OEM Products. We offer our DirectRay panel for sale to select original equipment manufacturers that desire to incorporate direct-to-digital technology into their product offerings. Our current OEM customers include Agfa, Analogic (a supplier to Eastman Kodak) and E-Com Technology.

Digital Mammography Products under Development

We expect digital technology to bring particularly important benefits to mammography. In addition to speed and convenience, digital technology and high-resolution detector plates have the potential for greater image accuracy than conventional films, a critical factor in mammography. While digital mammography systems are presently several times more expensive than conventional systems, we believe they can provide long-term savings as they eliminate the recurring film costs and reduce the cost of image manipulation.

We have pursued digital mammography with both our CCD-based and our DirectRay technologies. In October 2001, we received an approvable letter from the FDA for our Lorad Full Field Digital Mammography system. The Lorad Full Field Digital Mammography system utilizes our first-generation CCD-based technology. Final marketing clearance



for the Lorad Full Field Digital Mammography System is subject to labeling discussions, the agreement on criteria on the use of the product and successful completion of a Good Manufacturing Practices audit by the FDA of our manufacturing facilities in Bedford, Massachusetts and Danbury, Connecticut. We are also in the advanced stages of development of a second-generation digital mammography system that incorporates our proprietary amorphous selenium DirectRay direct-to-digital technology. This system will require regulatory review by the FDA. We are currently collecting clinical data for this system as part of a premarket approval application which we expect to submit to the FDA in the first half of 2002. To our knowledge, as of the date of this report, no other company has filed a premarket approval application for a direct-to-digital mammography system. We believe our DirectRay technology to be superior to currently available technologies and expect that the experience gained through our CCD development will enhance our ability to transition to the selenium technology and to gain FDA approval for use of DirectRay in mammography.

We expect that our DirectRay direct-to-digital mammography product line under development, if and when approved by the FDA, will position us to expand our share of the mammography market. With the improved imaging of our direct-to-digital amorphous selenium technology, we believe our Lorad mammography systems will offer women one of the most advanced tools available for early detection of breast cancer.

General Electric Medical Systems and Fischer Imaging received FDA approval to commercialize their own indirect conversion digital mammography systems in January 2000 and September 2001, respectively. In the short time since these

systems became available, we believe that approximately 250 full field digital mammography systems have been installed worldwide. We believe that growth of the digital mammography market will accelerate as product offerings improve image quality over existing systems. We believe that, when and if approved, our DirectRay product line could be the first direct-to-digital FDA approved mammography system. We believe that it will provide excellent image quality, offering women one of the most advanced tools available for early detection of breast cancer, and therefore will receive market acceptance. We intend to offer DirectRay to our existing customer base through upgrades or replacement systems. We estimate that we have sold over 9,500 mammography systems worldwide. We will also seek to expand our market beyond our historic customer base with expansion of our sales force or co-distribution arrangements.

We recently entered into a letter of intent with Siemens AG to enter into a strategic alliance focused on the development of direct-to-digital mammography systems. Through this alliance we intend to combine our proprietary amorphous selenium direct-to-digital technology with Siemens' proprietary software for a dedicated physician's workstation to bring to market direct-to-digital mammography systems. The launch of this strategic alliance is subject to several conditions, including the negotiation and execution of definitive agreements, which we expect will occur over the next several months. We cannot assure that any definitive agreement with Siemens will be reached.

Mini C-arm Imaging Products

Overview

We manufacture and distribute the Fluoroscan Imaging System, a low intensity, real-time mini c-arm X-ray imaging device which provides high resolution images at radiation levels and at a cost well below those of conventional X-ray and fluoroscopic equipment. These mini c-arm systems are used primarily by orthopedic surgeons to perform minimally invasive surgical procedures on a patient's extremities, such as the hand, wrist, knee, foot and ankle.

Products

Premier. We introduced the Premier mini c-arm system in August 1998. The Premier's .045 mm focal spot X-ray tube, currently the smallest in the mini c-arm industry, provides clear resolution and detailed images on a six-inch field of view. The Premier's mini c-arm is designed to rotate 360 degrees easily. The Premier also features dual video channels that allow a surgeon to display different views of the anatomy for side-by-side comparison; four image buffer memories for instant recall of previous images; and built-in video and Ethernet connections that allow the user to output



images to a printer or workstation, send to or receive from remote work stations, or record, review and archive images using existing Windows NT or hospital PACS.

We believe that the combination of advanced technical features and ease-of-use has made the Premier attractive to hospitals, surgery centers, orthopedic group practices and private physician offices.

OfficeMate. We introduced the OfficeMate imaging system in fiscal 1997. This system was designed specifically to meet the needs of the physician office. The OfficeMate features efficient, user-friendly operation, high resolution real-time and freeze frame images, and the choice of three or four inch field-of-view. Due to its compact size and portability, we believe the OfficeMate is

well suited for the in-office extremity imaging requirements of hand and orthopedic surgeons.

Conventional General Radiography Products

On November 13, 2001 we announced that we are closing our conventional X-ray equipment manufacturing facility in Littleton, Massachusetts, and that we will relocate some of the Littleton product lines and sales and service support personnel to our corporate headquarters in Bedford, Massachusetts. This consolidation is a part of our previously announced plan to phase-out non-core and unprofitable product lines. In addition to continuing to provide sales and service for our discontinued product lines, we intend to continue to manufacture and supply the following general radiography products:

- Omniflex, a ceiling mounted X-ray tube support system
- Digital Chest Tube Stand, a floor mounted X-ray tube support system for dedicated chest X-ray rooms

Marketing and Sales

Recently, we have restructured our sales channels, which included the addition of centralized sales management for all of our businesses. We believe that this restructuring positions us to capitalize on our well-developed distribution network including Trex Medical's distribution channels, which we have integrated with our own. In addition, because some of our biggest competitors do not sell their products through distributors, we believe that we have one of the broadest and most attractive product lines for distributors in the diagnostic and imaging systems market. We believe that our bone densitometry and mammography systems are particularly attractive to distributors because they often represent the high-end of the medical imaging marketplace and, consequently, often enjoy premium-pricing consideration. Physician Sales & Service, Inc. and its affiliates, our largest distributor network in the United States, accounted for approximately 20% of our product sales for fiscal 2001.

We have also recently entered into a number of agreements which have strengthened the sales and distribution channels for our core product lines in the United States, as follows:

- We entered into a non-exclusive distribution agreement with Siemens Medical Solutions, a unit of Siemens AG, for the sale of our X-ray bone densitometers throughout the United States. Siemens is a global leader in medical imaging technologies. With the Siemens relationship, we hope to increase sales of our bone densitometry line to the Siemens customer base and increase our presence in the hospital market.

- We entered into an agreement with Ethicon Endo-Surgery for non-exclusive distribution rights in the United States to Ethicon's minimally invasive breast biopsy device, the Mammotome ST, for purchase with Lorad's MultiCare and StereoLoc II stereotactic breast biopsy systems.

- We expanded our relationships with group purchasing organizations with contracts entered into during or after the fourth quarter of fiscal 2001 as follows:



  - We entered into an exclusive two-year contract, with options to renew for an additional two years, with Broadlane Inc., a leader in providing supply chain management services to the healthcare industry, for the sale of Lorad mammography systems. Broadlane customers include leading healthcare providers such as Kaiser

Permanente, Tenet Healthcare Corporation and Universal Health Services.

- We have extended our existing agreement with HealthTrust Purchasing Group for the sale of Lorad mammography systems.

- We entered into a three year agreement with Novation for purchase and sale of our digital radiographic systems. The agreement takes effect January 15, 2002. The agreement covers our EPEX and RADEX direct-to-digital systems for general radiographic applications, and also designates us as one of only two providers of digital chest X-ray systems.

We complement our U.S. distribution channel with a direct sales force, which as of November 30, 2001 was comprised of over 40 people. In addition, we have two national account managers focused on obtaining purchasing contracts from large purchasing entities, such as managed care organizations and government healthcare facilities. The rise of these large purchasing organizations has significantly altered the way we organize ourselves. We believe that our success in capturing managed care accounts will have a significant impact on our growth. We currently believe that we have made excellent progress penetrating these key accounts as evidenced by contracts obtained from Consorta, Catholic Resource Partners, Broadlane, Heath Trust Purchasing Group, Novation and the U.S. Department of Veterans Affairs.

We sell our systems in international markets through a network of independent distributors, as well as a direct sales force in the Benelux countries. In addition to the restructuring of our domestic sales channel, we have recently restructured our operations in Europe. Since the end of fiscal 2001, we entered into strategic alliances, which include exclusive distribution rights, with Stephanix, one of the leading French manufacturers of medical X-ray equipment, and Radiologia, S.A., the oldest X-ray equipment manufacturer in Spain, for sales of our product lines in France, Spain and Portugal. We offer our broad range of products in Latin America, including Argentina, Brazil and Chile, and into Pacific Rim countries, including Japan, Australia, The Peoples Republic of China, South Korea and Taiwan, by working with local sales representatives and distributors or entering into strategic marketing alliances in those territories. In fiscal 1999, 2000 and 2001, foreign sales accounted for approximately 37%, 33% and 28% of our product sales, respectively. See Note 11 of Notes to Consolidated Financial Statements for geographical information concerning those sales.

Competition

The healthcare industry in general, and the market for imaging and bone assessment products in particular, is highly competitive and characterized by continual change and improvement in technology, and multiple technologies that have been or are under development. A number of companies have developed, or are expected to develop, products that compete or will compete with our products. Many of these competitors offer a range of products in areas other than those in which we compete, which may make such competitors more attractive to hospitals, radiology clients, general purchasing organizations and other potential customers. In addition, many of our competitors and potential competitors are larger and have greater financial resources than we do and offer a range of products broader than our products. Some of the companies with which we now compete or may compete in the future have or may have more extensive research, marketing and manufacturing capabilities and significantly greater technical and personnel resources than we do, and may be better positioned to continue to improve their technology in order to compete in an evolving industry. Some of the companies in this industry that have significantly greater resources and product breadth than we do include General Electric Medical Systems (GE), Siemens, Philips and Toshiba. Competitors may develop superior products or

products of similar quality for sale at the same or lower prices. Moreover, our products could be rendered obsolete by new industry standards or changing technology. We cannot assure that we will be able to compete successfully with existing or new competitors.

The primary competitor for our bone assessment products is GE, which manufactures a competing line of dual-energy X-ray and other bone assessment products to measure bone density of the hip and spine. Other companies have developed



competing products as well, including lower priced X-ray based and other systems that assess bone status of peripheral sites, such as the heel, hand or wrist. We believe that competition in the field of dual-energy X-ray bone densitometry is based upon product versatility and features, price, precision, speed of measurement, reputation, cost and ease of operation, product reliability and quality of service. While we are generally not the lowest cost provider of dual-energy X-ray systems, we believe that we have been able to compete effectively because of our advanced technology and product features. We offer our Sahara ultrasound bone analyzer for the more price sensitive segment of the bone assessment market. We believe that competition in the field of ultrasound systems is based on price, precision, speed of measurement, cost and ease of operation, reputation, product reliability and quality of service. We believe that advantages of our Sahara ultrasound bone analyzer system include the system's dry operation, simple single-button operation, and a compact and self-contained design that does not require the use of a separate computer. We believe that ultrasound systems also compete with dual-energy X-ray systems in the diagnostic market for initial screening of patients. However, we believe that because ultrasound systems can only measure peripheral skeletal sites and do not have the precision of dual-energy X-ray systems, dual-energy X-ray systems will continue to be the predominant means of monitoring bone density for patients being treated for or at high risk for osteoporosis.

Our direct-to-digital imaging products compete with traditional X-ray systems as well as indirect-conversion systems, such as computed radiography systems, which are less expensive than our products. Many of these competitors have established relationships with hospitals and other of our potential customers in our targeted markets. The larger competitors in these markets include GE, Siemens, Kodak, Canon and Varian. GE and Kodak have received FDA clearance to market a digital general radiography X-ray system. The Kodak system currently incorporates our DirectRay detector. We have only recently introduced our direct-to-digital imaging products, and have had only limited sales of these products. As a result, the markets for these products are unproven. There is a significant installed base of conventional X-ray imaging products in hospitals and radiological practices. The use of our direct-to-digital X-ray imaging products would require these potential customers to either modify or replace their existing X-ray imaging equipment. Because of the early stage of the markets for these products, it is likely that our evaluation of the potential markets for these products will materially vary with time. We cannot assure that any significant market will develop for our direct-to-digital imaging products.

Our mammography systems compete with products offered by a number of competitors, including GE, Siemens, Instrumentarium and Fischer Imaging. GE and Fischer Imaging received FDA approval to commercialize their own indirect conversion digital mammography systems in January 2000 and September 2001, respectively. While we offer a broad product line of breast imaging products, we compete most effectively in the high-end segment of the mammography market. We attribute this success in large part to our patented HTC technology that enables our products incorporating that technology to deliver high contrast and resolution. We believe that our continued success will depend upon our ability

to improve and enhance our technology, including our ability to obtain FDA approval for our direct-to-digital mammography product currently under development. We believe that our mammography products compete primarily on the basis of image quality, product features, cost and ease of operation, price, reputation, product reliability and quality of service. Our minimally invasive breast biopsy systems compete with products offered by GE, Philips and Fischer Imaging and with conventional surgical biopsy procedures. We believe that competition for our mammography and breast biopsy products is based largely on image quality, product features, product reliability and reputation as well as price and service.

Our mini c-arm products compete directly with mini c-arms manufactured and sold by a limited number of companies including GE and XiTec. We also compete with manufacturers of conventional c-arm image intensifiers including Philips, Siemens, GE, Fischer Imaging and Picker International. We believe that competition for our mini c-arm systems is based largely on price, quality, reputation, service and production capabilities. We believe that advantages of our mini c-arm systems include low levels of radiation, low costs, mobility, quality and durability.

Manufacturing

Following the closing of our Littleton facility, we will manufacture all of our systems, other than our mammography and breast biopsy systems, at our headquarters in Bedford, Massachusetts. We manufacture our



mammography and breast biopsy systems at our manufacturing facilities in Danbury, Connecticut. Manufacturing operations for our systems consist primarily of assembly, test, burn-in and quality control. We purchase a major portion of the parts and peripheral components for these products, and manufacture some subsystems, such as high-voltage X-ray power supply, from raw materials. Parts and materials for these systems are generally readily available from several supply sources. However, we rely on one supplier for the HTC grid, an important component for our more advanced mammography systems. In addition, several key components of our mini c-arm systems are manufactured by only one or a small number of suppliers, including the X-ray tube, image intensifier, video camera and fiberoptic taper.

We manufacture our direct radiography plates at our manufacturing facility in Newark, Delaware and our EPEX and RADEX systems at our facility in Bedford, Massachusetts. Our manufacture of DirectRay plates consists primarily of vapor deposition in clean rooms, assembly, test, burn-in and quality control. We rely on one or only a limited number of suppliers for key components or subassemblies for our plates. In particular we have only one source of supply for our transistor plates and only one source of supply for the coating of those plates. The supplier for the plate coating is Analogic Corporation, which is also a customer as well as a potential competitor. The manufacture of our direct radiography detectors is highly complex and requires precise high quality manufacturing that is difficult to achieve. We have experienced difficulties manufacturing these detectors. Following our recent development of an improved design for our transistor plates, we experienced unacceptably high levels of defects for the newly designed plates. While the manufacturer has resolved the problem, and is now producing the plates to our satisfaction, we could again encounter production problems with future shipments. Moreover, further changes in design for our direct radiography detectors, including for our mammography detectors under development, could result in other unanticipated production problems. Our initial difficulties led to a delay in our ability to ship our new digital radiography systems. Our manufacture of the EPEX and RADEX systems differ from the process for manufacture of the plate, and consists primarily of

assembly, test, burn-in and quality control. Parts and materials for these systems are generally readily available from several supply sources.

Obtaining alternative sources of supply of components or systems that are available from only one or a limited number of suppliers could involve significant delays and other costs, and these supplies may not be available to us on reasonable terms, if at all.

Backlog

Our backlog as of November 30, 2001 totaled $40.5 million and as of November 30, 2000 totaled $39.5 million. Backlog consists of purchase orders for which a delivery schedule within the next twelve months has been specified by the customer. Orders included in backlog may be canceled or rescheduled by customers without significant penalty. Backlog as of any particular date should not be relied upon as indicative of our net revenues for any future period.

Research and Development

Our research and development efforts are focused on enhancing our existing products and developing new products. Our current emphasis is development of digital plates, including a new mammography digital plate, the engineering and system design of new end-use digital radiography products, and software improvements for our existing products. This research and development includes refining and continuing Trex Medical's research on the full field digital mammography system. Our research and development personnel also are involved in establishing protocols, monitoring, and interpreting and submitting test data to the FDA and other regulatory agencies to obtain the requisite clearances and approvals for our products. Our research and product development expenses, without consideration of purchased in-process research and development, were approximately $23.3 million in fiscal 2001, $17.2 million in fiscal 2000, and $12.7 million in fiscal 1999.



Patents and Proprietary Rights

We rely primarily on a combination of trade secrets, patents, copyright and trademark laws, and confidentiality procedures to protect our technology. Due to the rapid technological change that characterizes the medical device industry, we believe that the improvement of existing products, reliance upon trade secrets and unpatented proprietary know-how and the development of new products are generally as important as patent protection in establishing and maintaining a competitive advantage. Nevertheless, we have obtained patents and will continue to make efforts to obtain patents, when available, in connection with our product development program.

As of November 30, 2001, we have obtained 46 United States patents relating to our densitometry technology, 34 patents relating to our direct radiography technology, four patents relating to our mini c-arm technology, and 21 patents relating to the Lorad mammography business which we acquired from Trex Medical. These patents have expiration dates ranging from 2003 to 2017. In addition, we have applied for an additional 48 U.S. patents on these technologies. Also, we license patents from others on a variety of terms and hold approximately 57 additional U. S. patents acquired from Trex Medical relating to other matters. We have obtained or applied for corresponding patents and patent applications for some of our patents in selected foreign countries. Two of our ultrasound patents, one owned and one licensed, are being challenged in connection with a lawsuit that we brought against McCue PLC and Norland Medical Systems, its distributor, for infringement of those patents.

In January 2000, in connection with the merger of Vivid Technologies, Inc. with and into PerkinElmer, Inc., Vivid paid us $2.0 million for a fully-paid up exclusive license to our existing patents and technology for the development, manufacture and sale of X-ray screening security systems for explosives, drugs, currency and other contraband. All other licenses and arrangements between Vivid and us were terminated upon completion of the merger.

We had been involved in extensive patent litigation with Lunar Corporation, which has since been acquired by GE. This litigation was settled by agreement dated November 22, 1995. The agreement provides that neither party will engage the other party in patent litigation for a period of ten years following the date of the agreement, regardless of the infringement claimed and regardless of whether the technology in question currently exists or is developed or acquired by the other party in the future. Neither party is required to disclose to the other any of its technology during this ten year period or otherwise.

In connection with our acquisition of the U.S. assets of Trex Medical, we assumed liability for a lawsuit filed by Fischer Imaging against Trex Medical alleging that the Lorad prone biopsy system infringes upon two Fischer Imaging patents, subject to indemnification from Trex Medical and its parent, Thermo Electron Corporation, for any damages and related costs, including attorneys' fees, up to our adjusted purchase price for the Trex Medical assets. In connection with this arrangement, Trex Medical is continuing to defend this lawsuit. Recently, Fischer Imaging filed a lawsuit against us in the United States in connection with our sales of this product. We have also become aware that Fischer Imaging may be contemplating similar action in Europe. The lawsuits filed by Fischer in the United States seek to enjoin Trex Medical and us from further violation of Fischer Imaging's patents, unspecified damages of up to three times the amount found or assessed, and attorneys' fees. Trex Medical and Thermo Electron have agreed to indemnify us, and to defend the recently filed United States lawsuit on the same basis as the previously existing lawsuit. If Trex Medical is unsuccessful in defending these lawsuits, we may be prohibited from manufacturing and selling the existing prone breast biopsy system without a license from Fischer Imaging and Fischer Imaging could be awarded significant damages. If required, a license from Fischer Imaging to manufacture or sell the existing prone breast biopsy system may not be available, or may not be available on commercially reasonable terms. Moreover, if Fischer Imaging were awarded damages, indemnification from Trex Medical and Thermo Electron, if any, may be insufficient to cover the award. A significant award above the indemnification amount actually received could harm our business and prospects.



There has been substantial litigation regarding patent and other intellectual property rights in the medical device and related industries. We have been, and may be in the future, notified that we may be infringing intellectual property rights possessed by other third parties. If any such claims are asserted against us or our products, we may seek to enter into royalty or licensing arrangements. There is a risk in these situations that no license will be available or that a license will not be available on reasonable terms. Alternatively, we may decide to litigate such claims or to design around the patented technology. These actions could be costly and would divert the efforts and attention of our management and technical personnel. As a result, any infringement claims by third parties or other claims for indemnification by customers resulting from infringement claims, whether or not proven to be true, may harm our business and prospects.

Regulation

The medical devices manufactured and marketed by us are subject to

regulation by the FDA and, in many instances, by foreign governments. Under the Federal Food, Drug and Cosmetic Act, known as the FD & C Act, manufacturers of medical devices must comply with certain regulations governing the design, testing, manufacturing, packaging and marketing of medical devices. Our products are also subject to the Radiation Control for Health and Safety Act, administered by the FDA, which imposes performance standards and record keeping, reporting, product testing and product labeling requirements for devices using radiation, such as X-rays.

The FDA generally must clear the commercial sale of new medical devices. Commercial sales of our medical devices within the United States must be preceded by either a premarket notification filing pursuant to Section 510(k) of the FDA Act or the granting of a premarket approval. The 510(k) notification filing must contain information that establishes that the device is substantially equivalent to an existing device that has been continuously marketed since May 28, 1976.

The premarket approval procedure involves a more complex and lengthy testing and review process by the FDA than the 510(k) premarket notification procedure and often requires at least several years to obtain. We must first obtain an investigational device exemption, known as an IDE, for the product to conduct extensive clinical testing of the device to obtain the necessary clinical data for submission to the FDA. The FDA will thereafter only grant premarket approval if, after evaluating this clinical data, it finds that the safety and efficacy of the product has been sufficiently demonstrated. This approval may restrict the number of devices distributed or require additional patient follow-up for an indefinite period of time. We believe that the direct-to-digital mammography system that our Lorad division is developing will require the more rigorous premarket approval. We anticipate filing this submission in the first half of 2002.

Our systems are also subject to approval by certain foreign regulatory and safety agencies. Some of our technology, including that used in some of our Fluoroscan Systems, is governed by the International Traffic in Arms Regulations of the United States Department of State. As a result, the export of Fluoroscan Systems to some countries may be limited or prohibited.

We cannot assure that the FDA or foreign regulatory agencies will give the requisite approvals or clearances for any of our medical devices under development on a timely basis, if at all. Moreover, after clearance is given, these agencies can later withdraw the clearance or require us to change the device or its manufacturing process or labeling, to supply additional proof of its safety and effectiveness, or to recall, repair, replace or refund the cost of the medical device, if it is shown to be hazardous or defective. The process of obtaining clearance to market products is costly and time-consuming and can delay the marketing and sale of our products.

As a manufacturer of medical devices, we are subject to additional FDA regulations, including the Radiation Control for Health and Safety Act of 1968, which specifically regulates radiation-emitting products. In addition, our manufacturing processes and facilities are subject to continuing review by the FDA. Most states and many other foreign countries monitor and require licensing of X-ray devices. Federal, state and foreign regulations regarding the manufacture and sale of medical devices are subject to future change. We cannot predict what impact, if any, such changes might have on our business.



Reimbursement

In the United States, the Health Care Finance Administration, known as

HCFA, establishes guidelines for the reimbursement of healthcare providers treating Medicare and Medicaid patients. Under current HCFA guidelines, varying reimbursement levels have been established for bone density assessment, mammography and other imaging and diagnostic procedures performed by our products. The actual reimbursement amounts are determined by individual state Medicare carriers and, for non-Medicare and Medicaid patients, private insurance carriers. There are often delays between the reimbursement approvals by HCFA and by a state Medicare carrier and private insurance carriers. Moreover, states as well as private insurance carriers may choose not to follow the HCFA reimbursement guidelines. The use of our products outside the United States are similarly affected by reimbursement policies adopted by foreign regulatory and insurance carriers.

Employees

As of November 30, 2001, we had 780 full-time employees, including 367 in manufacturing operations, 33 in research and development, 264 in marketing, sales and support services, and 116 in finance and administration. In connection with our planned closure of our Littleton manufacturing facility we are eliminating approximately 80 employees. None of our employees are represented by a union.

Item 2. Properties

We own and lease the real property identified below. We believe that we have adequate space for our anticipated needs and that suitable additional space will be available at commercially reasonable prices as needed.

Owned Real Property

We own our headquarters and manufacturing facility located in Bedford, Massachusetts. The facility has approximately 200,000 square feet of space. We lease approximately 40,000 square feet of the facility to three tenants, Tech Online, Enmed, and Phonetic Systems, Inc. under leases which expire in May 2005, July 2003, and July 2002, respectively.

In connection with the acquisition of DRC, we purchased a 168,000 square foot research and development, manufacturing and administrative site in Newark, Delaware at which DRC conducts its research and development and plate manufacture. We currently occupy approximately 63,000 square feet of this building, which houses our plate manufacturing facility, including both a class 1 and a class 2 clean room. We lease approximately 45,000 square feet of the facility to Agfa under a lease which expires in April 2005. The remaining space in the facility, approximately 60,000 square feet, is leased to Dade Behring under a lease which expires in July 2010. The property is subject to a mortgage to Foothill Capital Corporation.

In connection with the acquisition of the U.S. assets of Trex Medical, we acquired a 62,500 square foot office and Lorad manufacturing facility in Danbury, Connecticut. As part of the purchase price for the medical imaging assets of Trex Medical we issued a note in the principal amount of $25 million. This note is secured by a mortgage on the property we own in Danbury, Connecticut and in Bedford, Massachusetts.

Leased Real Property

During our third fiscal quarter we relocated our Fluoroscan operations from a leased facility in Northbrook, Illinois to our corporate headquarters in Bedford, Massachusetts, and therefore, we no longer lease the Illinois facility. We maintain a leased sales and service office in Belgium and a leased support office in France.

In connection with our acquisition of the U.S. assets of Trex Medical, we also acquired a lease to a 156,000 square foot office and manufacturing facility in Littleton, Massachusetts and a lease to a 60,000 square foot office and manufacturing facility in Danbury, Connecticut. These leases expire in May 2010 and November 2006, respectively. We have announced the closure of the Littleton facility and have negotiated the termination of that lease, effective April 2003.

Item 3. Legal Proceedings

Fischer Imaging Corporation.

On April 2, 1992, Fischer Imaging filed a lawsuit in the United States District Court, District of Colorado, against Trex Medical, alleging that Lorad's prone breast biopsy system infringes a Fischer Imaging patent on a precision mammographic needle-biopsy system. On April 7, 1998, Fischer Imaging filed a second lawsuit in the United States District Court, District of Colorado, against Trex Medical, alleging that Lorad's manufacture of breast-imaging equipment and breast biopsy system equipment infringes on a second Fischer Imaging patent which was issued April 7, 1998. These two lawsuits were consolidated into a single lawsuit. The lawsuit seeks to enjoin further violation of Fischer Imaging's patents, unspecified damages of up to three times the amount found or assessed, and attorneys' fees. In connection with our Trex Medical acquisition, we assumed liability for this lawsuit subject to indemnification from Trex Medical and its parent, Thermo Electron Corporation, for any damages, including attorneys' fees, up to our adjusted purchase price for the Trex Medical assets. In connection with this arrangement, Trex Medical is continuing to defend this lawsuit. On November 13, 2001, Fischer Imaging filed a lawsuit against us in the United States District Court, District of Massachusetts. The complaint alleges that our Lorad MultiCare Stereotactic Breast Biopsy System infringes a Fischer Imaging patent. The lawsuit seeks to enjoin us from further violation of Fischer Imaging's patent, unspecified damages of up to three times the amount found or assessed, and attorneys' fees. This lawsuit is effectively an extension of the ongoing lawsuit by Fischer Imaging against Trex Medical in the United States District Court, District of Colorado. Trex Medical has agreed to defend this new lawsuit and provide us with indemnification for this lawsuit as an extension of the Colorado lawsuit. We believe, and Trex Medical has advised us that they believe, that they have meritorious defenses to Fischer Imaging's claims.

Fleet Business Credit, LLC Settlement.

On August 9, 2001 we reached a settlement agreement with Fleet Business Credit, LLC (Fleet), concerning rights and obligations under a Master Product Financing Agreement entered into in September 1996. This Settlement Agreement ends a two-year dispute relating to our Strategic Alliance Program under which Fleet (formerly Sanwa Business Credit Corp.) acquired our bone densitometry systems to lease to physicians on a fee-per-scan basis throughout the United States. Prior to this settlement the matter was pending before the Chancery Division of the Circuit Court of Cook County, Illinois.

Under the Strategic Alliance Program, which was discontinued in February 1999, we sold approximately $61 million of bone densitometers to Fleet. In mid-1999, Fleet advised us that it had incurred substantial losses under the program and sought to shift losses that Fleet faced to us. We filed suit in September 1999 regarding Fleet's failure to fulfill its contractual obligations, and Fleet subsequently counter-sued us in October 1999.

The settlement agreement provides for all claims to be dismissed with prejudice, and for us to repay Fleet $3.1 million, comprised of $1.5 million cash and a note of $1.6 million payable in three years. In addition, we will continue to be entitled to certain amounts collected over time from customers, such as scan overages and excess pool deposits. These amounts will be credited directly against the note payable.

Other Litigation.

We are the subject of additional lawsuits, none of which we believe to be material to our business or financial condition.



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

None.



Part II

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

Market Information. Our common stock is traded on the Nasdaq National Market under the symbol "HOLX." The following table sets forth, for the periods indicated, the high and low sales prices per share of our common stock, as reported by the Nasdaq National Market.

| Fiscal Year Ended September 30, 2000 | High | Low |
|---|---|---|
| First Quarter | $6.75 | $3.06 |
| Second Quarter | 9.81 | 5.69 |
| Third Quarter | 7.81 | 5.56 |
| Fourth Quarter | 8.88 | 6.88 |

| Fiscal Year Ended September 29, 2001 | High | Low |
|---|---|---|
| First Quarter | $7.06 | $4.66 |
| Second Quarter | 7.19 | 4.00 |
| Third Quarter | 6.80 | 4.00 |
| Fourth Quarter | 6.60 | 4.62 |

Number of Holders. As of December 7, 2001, there were approximately 1,852 holders of record of our common stock, including multiple beneficial holders at depositaries, banks and brokers listed as a single holder in the street name of each respective depositary, bank or broker.

Dividend Policy. We have never declared or paid cash dividends on our capital stock and do not plan to pay any cash dividends in the foreseeable future. Our current policy is to retain all of our earnings to finance future

growth. In addition, our existing credit facility with Foothill Capital Corporation prohibits us from declaring or paying any dividends.

Recent Sales of Unregistered Securities. On November 9, 2000, we granted 6,000 shares of our common stock each to four executive officers. These shares were granted in connection with the performance of services. We did not register these securities under the Securities Act of 1933, as amended, in reliance upon the exemptions from registration set fourth in Sections 3(b) and 4(2) of that act, relating to offers and sales by an issuer not involving any public offering. None of these transactions, either individually or in the aggregate, involved a public offering.



Item 6. Selected Financial Data.

In 1999, we acquired Direct Radiography Corp. and in 2000 we acquired the U.S. assets of Trex Medical. The purchase accounting method under APB No. 16 was used for both of these transactions. Included in the fiscal 2000 financial data are acquisition related pre-tax charges of $13.3 million related to the Trex Medical acquisition. Included in the fiscal 2001 financial data are (i) a $2.5 million reduction in expenses as a result of the settlement of the final purchase price and reassessment of reserves from the Trex Medical acquisition, (ii) the recognition of $2.1 million of other revenue previously deferred and a $500,000 reduction to cost of product sales due to excess warranty reserves related to the settlement of the litigation with Fleet Business Credit, LLC, (iii) restructuring charges of approximately $1.0 million for severance related expenses resulting from reductions in our workforce and (iv) a $500,000 nonrecurring charge from the relocation of the Fluoroscan mini c-arm manufacturing facility from Illinois to Massachusetts.

| | Fiscal Years Ended | | |
|---|---|---|---|
| | September 27, 1997 | September 26, 1998 | September 25, 1999 |
| Consolidated Statement of Operations Data | | | (In thous |
| Revenues: | | | |
| Product sales | $102,781 | $111,498 | $ 81,737 |
| Other revenue | 3,908 | 4,066 | 2,403 |
| | 106,689 | 115,564 | 84,140 |
| Costs and Expenses: | | | |
| Cost of product sales | 47,492 | 55,891 | 50,333 |
| Research and development | 8,527 | 9,778 | 12,664 |
| Selling and marketing | 19,448 | 28,589 | 19,658 |
| General and administrative | 8,827 | 10,452 | 10,963 |
| Nonrecurring and restructuring charges | --- | --- | --- |
| | 84,294 | 104,710 | 93,618 |
| Income (loss) from operations | 22,395 | 10,854 | (9,478) |
| Interest income | 5,346 | 5,998 | 4,204 |
| Interest/other expense | (172) | (664) | (548) |

| | | | |
|---|---|---|---|
| Income (loss) before income taxes | 27,569 | 16,188 | (5,822) |
| Provision (benefit) for income taxes | 9,840 | 5,800 | (2,075) |
| Net income (loss) | $ 17,729 | $ 10,388 | $ (3,747) |
| Net income (loss) per common share: | | | |
| Basic | $ 1.37 | $ .78 | $ (.27) |
| Diluted | $ 1.30 | $ .75 | $ (.27) |
| Weighted average number of common shares outstanding: | | | |
| Basic | 12,986 | 13,259 | 13,950 |
| Diluted | 13,672 | 13,766 | 13,950 |
| Consolidated Balance Sheet Data | | | |
| Working capital | $112,869 | $ 99,633 | $ 89,823 |
| Total assets | 144,667 | 172,597 | 175,770 |
| Long-term debt | --- | --- | --- |
| Total stockholders' equity | 126,767 | 140,382 | 150,422 |



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

The following discussion and analysis should be read in conjunction with the "Selected Consolidated Financial Data" and the Consolidated Financial Statements included elsewhere in this report and the information described under the caption "Risk Factors" below.

Overview

We are engaged in the development, manufacture and distribution of proprietary X-ray, digital X-ray and other medical imaging systems. We view our operations as four business segments: Bone Assessment products; Mammography/General Radiography products; Digital Imaging products; and Mini c-arm products.

Our Bone Assessment products primarily consist of dual X-ray bone densitometry systems and, to a lesser extent, an ultrasound based bone assessment product. Bone densitometry is the precise measurement of bone density to assist in the diagnosis and monitoring of osteoporosis and other metabolic bone diseases that can lead to debilitating bone fractures. Our Mammography/General Radiography products include a broad product line of breast imaging products, including mammography systems and breast biopsy systems, as well as basic general radiography X-ray systems used by hospitals and clinics. We recently announced, as set forth in further detail below, that we were discontinuing the manufacture, but continuing the service and support, of most of our general radiography X-ray product lines. Our Digital Imaging products include general radiographic systems and a digital component for original equipment manufacturers to incorporate into their own equipment. Our Mini c-arm products are low intensity, real-time mini c-arm X-ray systems used primarily for minimally invasive surgery on a patient's extremities.

Acquisitions, Recent Developments and Restructuring and Nonrecurring Charges

Direct Radiography Corp. Acquisition. In June 1999, we acquired Direct Radiography Corp. and the land and buildings at which it conducted its business for approximately $20 million. Direct Radiography Corp. was a development stage manufacturer of digital X-ray systems for medical imaging and non-destructive testing applications. During fiscal 2000 we introduced two new general radiography digital systems, EPEX and RADEX. We began shipping these systems in the second half of fiscal 2000. We also sell a digital chest system and digital upgrade package for conventional X-ray systems. In fiscal 2000 and 2001, we continued to invest heavily in the research and development of the digital plates and the engineering and system design of new end-use digital radiography products. Sales of Direct Radiography Corp. digital products and services accounted for approximately 6% and 7% of our total revenues in fiscal 2000 and fiscal 2001, respectively.

Trex Medical Acquisition. On September 15, 2000, we acquired the U.S. business assets of Trex Medical in exchange for approximately $30.0 million in cash and a note in the amount of $25.0 million. The cash portion of the purchase price was subject to adjustment based upon the working capital of Trex Medical as of the closing. Following the acquisition, we disagreed with Trex Medical's calculation of its working capital as reflected on its closing balance sheet. In accordance with the dispute resolution procedures set forth in the purchase agreement, we and Thermo Electron Corporation, sole shareholder of Trex Medical, jointly sought the assistance of an independent arbitrator to determine the closing working capital.

In June 2001, the independent arbitrator determined that adjustments of approximately $2.8 million, in addition to $119,000 of adjustments agreed to by Thermo Electron Corporation before submission to arbitration, were required to the closing balance sheet submitted by Trex Medical. This resulted in a payment of approximately $932,000 to us as an adjustment to the cash portion of the purchase price.

In addition, we finalized the plan to close the Hologic Systems Division manufacturing facility located in Littleton, Massachusetts that we had acquired as part of the Trex Medical acquisition. In connection with the closure of the Littleton facility, we expect to eliminate approximately 80 employment positions and incur a restructuring charge, primarily related to severance costs, of approximately $1.0 million, in the first quarter of fiscal 2002. In addition, we expect to



incur continuing losses from our conventional general radiography business through at least the first half of fiscal 2002, as we wind down our manufacturing operations. Our Littleton operations reported significant losses during fiscal 2001.

As a result of the arbitration, assessment of acquired assets and accruals and finalization of the exit strategy for Littleton, we have assessed the original purchase price allocation as follows:

| | |
|---|---|
| Current assets | $ 49,484 |
| Property plant and equipment | 8,098 |
| In-process research and development | 5,000 |
| Cost in excess of net assets acquired | 15,732 |
| Liabilities assumed | (23,246) |

| | |
|---|---|
| | $ 55,068 |

Also, as a result of the arbitration settlement, we evaluated the components of the $2.8 million of adjustments and determined that approximately $2.1 million of reserves and accruals provided for through charges to earnings in the fourth quarter of fiscal 2000 should be recorded in our allocation of the purchase price for this acquisition. Included in our results for the twelve month period ended September 29, 2001 are expense reductions totaling $2.5 million related to the purchase price reallocation as follows:

- $1.7 million cost of product sales reduction for warranty accrual and for performance upgrades on prior sales;
- $376,000 selling expense reduction for accrued sales commissions; and
- $428,000 general and administrative expense reduction for various expense accruals and bad debt expense.

Fleet Business Credit, LLC Litigation Settlement. In August 2001, we settled our two-year dispute with Fleet Business Credit, LLC relating to our Strategic Alliance Program under which Fleet, formerly Sanwa Business Credit Corp., acquired our bone densitometry systems to lease to physicians on a fee-per-scan basis throughout the United States. This litigation is more fully described under Part II, Item 1 of this report.

Under the settlement agreement, the parties dismissed their claims and entered mutual releases. In addition, we paid Fleet $1.5 million in cash and executed a $1.6 million unsecured note payable. The note bears interest at Fleet's prime rate plus 1% with the full amount of principal to be paid on August 10, 2004. We further agreed to continue to assist Fleet in remarketing returned systems, as requested by Fleet, based on separately negotiated market rate terms on a prepaid basis. We also continue to be entitled to benefit from excess lease and other payments made to Fleet under the program, which will offset amounts due under the note payable.

Under the terms of the original agreement with Fleet's predecessor, Sanwa, we were contingently liable for a certain amount per system sold under the agreement. We recorded the amount for which we were contingently liable as deferred revenue. Based on the settlement, we reduced deferred revenue for the $1.5 million cash payment and reflected $1.6 million as a long term note payable in our consolidated balance sheet as of September 29, 2001. We have also recognized as revenue the remaining deferred revenue amounts of $2.1 million. In addition, we reversed $500,000 of related warranty reserves, which were no longer necessary as a result of the settlement, through a reduction of cost of product sales, for a total positive impact on earnings relating to the Fleet settlement of approximately $2.6 million.

Restructuring and Nonrecurring Charges. In addition to the adjustments and charges described above, our results for the year ended September 29, 2001 include the following restructuring and nonrecurring charges:

- On August 13, 2001 we announced a restructuring plan focusing primarily on a company-wide cost savings initiative which includes a planned reduction of the workforce by 10%, or approximately eighty employees, and otherwise trimming operating expenses in each of our business units. As a result of the plan, once completed, we



expect to realize annual cost savings of approximately $10 million. We incurred a restructuring charge, primarily related to severance costs, of approximately $1.0 million in fiscal 2001.

. We incurred approximately $500,000 of expenses related to the move of the Fluoroscan mini c-arm product line to the corporate headquarters in Bedford, Massachusetts including approximately $200,000 of moving costs, $100,000 of severance costs, $100,000 to vacate the facility and $100,000 of other costs.

Results of Operations

The following table sets forth, for the periods indicated, the percentage of revenues represented by items as shown in our consolidated statements of operations.

| | Fiscal Years Ended | | |
|---|---|---|---|
| | September 25, 1999 | September 30, 2000 | September 29 2001 |
| Revenues: | | | |
| Product sales | 97.1% | 96.9% | 98.6% |
| Other revenue | 2.9 | 3.1 | 1.4 |
| | 100.0 | 100.0 | 100.0 |
| Cost and expenses: | | | |
| Cost of product sales | 59.8 | 67.8 | 65.1 |
| Research and development | 15.1 | 23.7 | 13.1 |
| Selling and marketing | 23.4 | 25.5 | 19.8 |
| General and administrative | 13.0 | 17.5 | 11.7 |
| Nonrecurring and restructuring charges | -- | -- | 0.9 |
| | 111.3 | 134.5 | 110.6 |
| Loss from operations | (11.3) | (34.5) | (10.6) |
| Interest income | 5.0 | 3.8 | 0.6 |
| Interest/other expense | (0.7) | (0.2) | (1.6) |
| Loss before income taxes | (7.0) | (30.9) | (11.6) |
| (Benefit) provision for income taxes | (2.5) | (11.1) | 0.1 |
| Net loss | (4.5)% | (19.8)% | (11.7)% |

Fiscal Year Ended September 29, 2001 Compared to Fiscal Year Ended September 30, 2000

Revenues. Total revenues increased 90.4% to $178.5 million in fiscal 2001 from $93.7 million in fiscal 2000. This increase was primarily due to the addition of revenues of $86.5 million from sales of mammography and general radiography products acquired in connection with the Trex Medical acquisition in September 2000.

Total revenues for our historic businesses, bone assessment, mini c-arm imaging and digital imaging, increased 3.8% to $92.0 million in fiscal 2001 from

$88.7 million in fiscal 2000. This increase was primarily due to an increase in the number of digital imaging products sold and an increase in service revenues. Mini c-arm revenues remained substantially unchanged and bone assessment revenues decreased slightly to $65.7 million in fiscal 2001 from $66.3 million in fiscal 2000. The decrease in bone assessment revenues was primarily due to a decrease in Sahara ultrasound product unit sales in the United States which were partially offset by an increase in service revenues and an increase in revenues from our sales of dual-energy X-ray bone densitometers, principally our newly introduced Delphi product line. Total digital imaging revenues for fiscal 2001 increased 48% to $11.7 million from $7.9 million in fiscal 2000. This increase was primarily due to an increase in the number of digital imaging systems sold, primarily in the United States.



Total revenues for the fourth quarter of fiscal 2001 increased 66.9% to $45.3 million compared to the $27.1 million for the fourth quarter of fiscal 2000. This increase was primarily attributable to the addition of $15.5 million of revenues from the Lorad mammography and conventional general radiography businesses acquired in the Trex Medical acquisition at the end of fiscal 2000. Total revenues for the fourth quarter of fiscal 2001 increased slightly compared to the $44.9 million in the immediately preceding quarter. The third quarter of fiscal 2001 revenues included $2.1 million recognized in connection with the Fleet Business Credit, LLC settlement. Revenues generated from operations in the third quarter of fiscal 2001, excluding this amount, were $42.8 million. The increase in our revenues over the immediately preceding quarter, after excluding the effect of the Fleet settlement, was primarily attributable to increased unit sales of our bone assessment, mammography and digital radiography products.

In November 2001, we announced that we were closing our conventional X-ray equipment manufacturing facility and relocating some product lines and our sales and support personnel to our corporate headquarters. Approximately $27.2 million of revenues in fiscal 2001 and $5.3 million of revenues in the fourth quarter of fiscal 2001 related to this operation. These revenues included service revenues of approximately $6.5 million during the year and $1.5 million in the fourth quarter. We plan to continue to support all our products, including those that will be discontinued.

In fiscal 2000 and 2001, other revenue consisted primarily of royalty revenues from our licensing of technology to Vivid Technologies, Inc. for explosives detection screening, and additional revenues generated from our strategic alliance program on a fee-per-scan basis. In fiscal 2001, other revenue included $2.1 million of revenue attributable to our settlement of the Fleet Business Credit, LLC litigation. In fiscal 2000, other revenue included the $2.0 million of royalty revenue we recognized relating to the buy-out by Vivid Technologies, Inc. of our baggage equipment license. These revenues for both periods were included in our bone assessment segment revenues. We do not expect to have significant other revenue in fiscal 2002.

In fiscal 2001, approximately 72% of product sales were generated in the United States, 14% in Europe and 14% in other international markets. In fiscal 2000, approximately 67% of product sales were generated in the United States, 21% in Europe and 12% in other international markets. We expect that foreign sales will continue to account for a significant portion of product sales. We believe that in fiscal 2001, our European sales were adversely affected by the strength of the dollar in relation to the Euro and other European currencies, which resulted in increased prices of our products denominated in those currencies. Additionally, continued economic and currency related uncertainty in a number of foreign countries, especially in Asia and Latin America, could reduce our future sales to these markets.

Cost of Product Sales. The cost of product sales decreased as a percentage of product sales to 66% in fiscal 2001 from 70% in fiscal 2000. In fiscal 2001, these costs were reduced by $2.2 million related to the final purchase price adjustment of the Trex Medical acquisition and the settlement of the Fleet Business Credit, LLC litigation. Excluding the effects of these reductions, in fiscal 2001, cost of product sales as a percentage of product revenue would have been 67% in fiscal 2001. Included in the cost of product sales for Lorad and the Trex Medical general radiography products in fiscal 2000 was approximately $5.6 million of acquisition related charges. Excluding the effects of these charges, our costs of product sales as a percentage of product sales would have been 64% in fiscal 2000.

In fiscal 2001, improvements in margins in the bone assessment and digital imaging businesses were offset by our increased sales of mammography and general radiography products acquired from Trex Medical and of digital radiography products. Margins from our digital imaging products improved in the current year as compared to the prior year as a result of increased volume. However, margins on these products continued to be negative reflecting the under absorption of our manufacturing overhead, as a result of our limited sales of those products, and inefficiencies relating to new product introduction. Our cost of product sales as a percentage of product sales for our bone assessment, mini c-arm and digital imaging businesses increased to 65% in fiscal 2001 from 64% in fiscal 2000. This increase was primarily due to increased manufacturing and service costs related to digital imaging, which has significant fixed manufacturing costs and is operating significantly below manufacturing capacity.



Research and Development Expenses. Research and development expenses increased 5.2% to $23.3 million, 13% of total revenues, in fiscal 2001 from $22.2 million, 24% of total revenues, in fiscal 2000. The increase, in absolute dollars, was primarily due to the acquisition of Trex Medical which added approximately $4.2 million of research and development expenses in fiscal 2001. Partially offsetting these increases was a reduction in research and development spending primarily related to our bone densitometry products, following our introduction of the Delphi product line. In fiscal 2001, approximately $9.8 million of our research and development expenses related to our development of new digital radiography systems and detectors, compared to approximately $10.2 million of such expenses in fiscal 2000. In addition, in fiscal 2000, our research and development expense included a $5.0 million charge related to purchased in-process research and development acquired in connection with the acquisition of the assets of Trex Medical. As part of the purchase price allocation, all intangible assets that are a part of the acquisition were identified and valued. It was determined that technology assets, certain tradename and assembled workforce had value. As a result of this identification and valuation process, we allocated approximately $5.0 million of the purchase price to in-process research and development projects. This allocation represented the estimated fair value based on risk-adjusted cash flows related to the incomplete research and development projects. At the date of acquisition, the development of these projects had not yet reached technological feasibility, and the research and development in progress had no alternative future uses. Accordingly, these costs were expensed as of the acquisition date. We expect to continue our significant research and development spending in fiscal 2002.

Selling and Marketing Expenses. Selling and marketing expenses increased 48.3% to $35.4 million, 20% of product sales, in fiscal 2001 from $23.9 million, 26% of product sales, in fiscal 2000. The increase, in absolute dollars, was primarily due to incremental selling and marketing expenses of $13.0 million related to the mammography and general radiography products acquired from Trex Medical in fiscal 2001, partially offset by a decrease in sales commissions in our other businesses. The reduced sales commissions were primarily attributable

to the lower sales volume in the primary care market in the United States, where we generally have higher commission expenses. In fiscal 2001, selling and marketing expenses were also decreased by approximately $400,000 as a result of the Trex Medical purchase price settlement, as compared to fiscal 2000 which included approximately $400,000 of acquisition related charges.

General and Administrative Expenses. General and administrative expenses increased 26.8% to $20.9 million, 12% of total revenues, in fiscal 2001 from $16.4 million, 18% of total revenues, in fiscal 2000. The increase, in absolute dollars, was primarily due to the addition of approximately $7.1 million of general and administrative expenses related to the acquired Trex Medical businesses in the current year. Fiscal 2000 results included approximately $2.2 million of general and administrative expenses relating to the acquired Trex Medical businesses. In fiscal 2001, we had a reduction of approximately $400,000 to our general and administrative expenses relating to the Trex Medical acquisition to reflect the arbitrated purchase price adjustment. Our increases in general administrative expenses associated with the Trex Medical acquisition were partially offset by a decrease in general and administrative expenses in our historic businesses, primarily due to a reduction in payroll and payroll related expenses and bad debt expense compared to fiscal 2000.

Restructuring and Nonrecurring Charges. Restructuring and nonrecurring costs in fiscal 2001 were primarily the result of our ongoing efforts to streamline operations. In fiscal 2001, as a result of a reduction in our workforce, we incurred restructuring charges of approximately $1.0 million, primarily related to severance related expenses. In the third quarter of fiscal 2001 we moved our Fluoroscan operations from a facility in Northbrook, Illinois to our corporate headquarters in Bedford, Massachusetts. We incurred approximately $500,000 of expenses in connection with this move. Longer term, we believe that the move will result in operating efficiencies and reduced overhead for the Fluoroscan operations. In November 2001 we announced that we are closing our Littleton manufacturing facility acquired from Trex Medical. In connection with the closure of that facility, we expect to eliminate approximately 80 employment positions and incur a restructuring charge, primarily related to severance costs, of approximately $1.0 million, in the first quarter of fiscal 2002. We also expect to incur continuing losses from our conventional general radiography business through at least the first half of fiscal 2002, as we wind down our manufacturing operations for that business.

Interest Income. Interest income decreased to $1.0 million in fiscal 2001 from $3.6 million in fiscal 2000. This decrease was due to a lower investment base than in the prior year, primarily due to the use of cash for the Trex Medical



acquisition during fiscal 2000 and our continuing investment in research and development of our digital radiography products.

Interest/Other Expense. We incurred other expense of approximately $2.9 million in fiscal 2001 and $227,000 in fiscal 2000. In fiscal 2001, these expenses were primarily due to interest costs of approximately $2.8 million per year on the $25 million note payable issued in connection with the Trex Medical acquisition. In the first quarter of fiscal 2001, these costs were partially offset by insurance proceeds received in excess of cost related to storm damage at Fluoroscan last year. In fiscal 2000, these expenses primarily included foreign currency transaction losses and interest costs on a bank line of credit used by our European subsidiaries to borrow funds in their local currencies to pay for intercompany sales, thereby reducing the foreign currency exposure on those transactions. To the extent that foreign currency exchange rates fluctuate in the future, we may be exposed to continued financial risk. Although we have

established a borrowing line of credit denominated in the two foreign currencies, the French Franc and the Belgian Franc, in which the subsidiaries currently conduct business to minimize this risk, we cannot assure that we will be successful or can fully hedge our outstanding exposure. In fiscal 2002, our other expense will include interest expense incurred in connection with our new lending arrangements with Foothill Capital Corporation entered into at the end of the fourth quarter of fiscal 2001.

Provision (Benefit) for Income Taxes. In fiscal 2000, we had a benefit for income taxes as a result of the loss during the period. We believe the related deferred tax asset will be realizable in the future. In fiscal 2001, our effective tax rate was impacted by our establishing a valuation allowance for the tax benefit associated with our losses arising during that year. We established valuation allowances in accordance with the provisions of Statement of Financial Accounting Standards No. 109, "Accounting for Income Taxes," under which we can only recognize a deferred tax asset for future benefit of our tax losses to the extent that we determine that is "more likely than not" that this asset will be realized. In determining the realizability of this asset, we considered numerous factors, including historical profitability, estimated future taxable income and the industry in which we operate.

Fiscal Year Ended September 30, 2000 Compared to Fiscal Year Ended September 25, 1999

Revenues. Total revenues increased 11.4% to $93.7 million in fiscal 2000 compared to $84.1 million in fiscal 1999. The increase in revenues was primarily due to the addition of $5.1 million of revenues from the Lorad and Trex Medical general radiography products acquired in September 2000, a $4.9 million increase in revenues from sales of our digital X-ray products from Direct Radiography Corp., an increase in the number of dual X-ray bone densitometer units sold through our direct sales force, primarily in the United States, and increased service revenues. The increase in revenues was partially offset by a decrease in the number of bone densitometer product shipments to the United States primary care market, including strategic alliance sales to a leasing company, and to a lesser extent, a decrease in Sahara ultrasound and mini c-arm product sales.

Other revenue increased 19.9% to $2.9 million in fiscal 2000 compared to $2.4 million in fiscal 1999. Other revenue has historically consisted primarily of revenue relating to medical data management services provided to pharmaceutical companies to assist in the collection and monitoring of clinical trial data, royalty revenues from our licensing of technology to Vivid Technologies, Inc. for explosives detection screening, and additional revenues generated from our strategic alliance program on a fee-per-scan basis. The increase in other revenues in fiscal 2000 was primarily the result of the sale of a fully paid up license to Vivid Technologies, Inc. for $2.0 million in the second quarter of fiscal 2000. This increase was partially offset by the elimination of revenues relating to the medical data management services division, which we sold to Synarc in June 1999.

Total revenues for the fourth quarter of fiscal 2000 increased 34.7% compared to the $20.1 million for fourth quarter of fiscal 1999. The increase over the immediately preceding quarter was primarily attributable to the addition of $5.1 million of revenues from the Lorad and Trex Medical general radiography products acquired in September 2000, increased shipments of the new Delphi bone densitometer and, when compared to the fourth quarter of last year, an increase in revenues from our digital radiography products. Partially offsetting these increases was a decrease in revenues from Sahara and, to a lesser extent, a decrease in mini c-arm revenues.

In fiscal 2000, approximately 67% of product sales were generated in the United States, 21% in Europe, 7% in Asia and 5% in other international markets. In fiscal 1999, approximately 63% of product sales were generated in the United States, 24% in Europe, 7% in Asia and 6% in other international markets.

Costs and Expenses. The cost of product sales increased as a percentage of product sales to 70% in fiscal 2000 from 62% in fiscal 1999. These costs increased as a percentage of product sales primarily due to the addition of approximately $8.9 million related to Lorad and the Trex Medical general radiography products sold in the last two weeks of fiscal 2000 and the increase in manufacturing costs of approximately $6.1 million related to Direct Radiography Corp., which has significant fixed manufacturing costs and was operating significantly below manufacturing capacity. Included in the cost of product sales for Lorad and the Trex Medical general radiography products was approximately $5.6 million of acquisition related charges and the impact of the fair value write-up of acquired inventory on equipment sold. Excluding Direct Radiography Corp., Lorad and Trex Medical general radiography products, cost of product sales as a percentage of product sales would have decreased to approximately 58%. The low sales volume of digital imaging plates resulted in the under absorption of fixed manufacturing costs.

Research and development expenses increased 75.1% to $22.2 million, 24% of total revenues, in fiscal 2000 from $12.7 million, 15% of total revenues, in fiscal 1999. This increase was primarily due to the acquisition of Direct Radiography Corp. in June 1999 and the associated inclusion of a full year of research and development expenses associated with our direct radiography plates and systems in fiscal 2000. In addition, in fiscal 2000, our research and development expense included a $5.0 million charge related to purchased in-process research and development acquired in connection with the acquisition of the assets of Trex Medical.

Selling and marketing expenses increased 21.5% to $23.9 million, 26% of product revenues, in fiscal 2000 from $19.7 million, 24% of product revenues, in fiscal 1999. The increase in selling and marketing expenses in 2000 was primarily due to additional selling and marketing expenses of $2.7 million at Direct Radiography Corp., and approximately $900,000 related to Trex Medical, of which approximately $400,000 were acquisition related charges.

General and administrative expenses increased 50.0% to $16.4 million, 18% of total revenues, in fiscal 2000 from $11.0 million, 13% of total revenues, in fiscal 1999. The increase was primarily due to the addition of $2.2 million of charges associated with our acquisition of Trex Medical to increase reserves to their required levels, the addition of approximately $1.5 million of general and administrative expenses related to Direct Radiography Corp. and, to a lesser extent, an increase in professional service fees and employee benefit expenses.

Interest Income. Interest income decreased to $3.6 million in fiscal 2000 from $4.2 million in fiscal 1999. This decrease was primarily attributable to a lower investment base than in the prior year, as a result of the use of cash for the Direct Radiography Corp. acquisition and building renovations during fiscal 1999.

Other Expense. Other expense decreased to $227,000 in fiscal 2000 from $548,000 in fiscal 1999. These expenses primarily include foreign currency transaction losses and interest costs on a bank line of credit used by our European subsidiaries to borrow funds in their local currencies to pay for all intercompany sales, thereby reducing the foreign currency exposure on those transactions.

Provision for Income Taxes. In fiscal 2000 we had a benefit for income taxes as a result of that year's loss which we believed would be realizable in the future. Our effective tax rate was 35.8%, which was lower than the statutory

tax rates due primarily to the favorable Federal and state tax treatment afforded to our foreign sales corporation and the favorable state tax treatment of a portion of our interest income.

Segment Results of Operations



Our businesses are reported as four segments: bone assessment; mammography/general radiography; digital imaging; and mini c-arm imaging. The accounting policies of the segments are the same as those described in the footnotes to the accompanying consolidated financial statements. We measure segment performance based on total revenues and operating income or loss. Revenues from each of these segments are described above. The discussion that follows is a summary analysis of the primary changes in operating income by segment.

Bone Assessment. Reported operating income for bone assessment was $7.4 million for fiscal 2001 compared to $88,000 in fiscal 2000. The improved operating income for this business segment was primarily due to an improvement in gross margins from an increased percentage of sales of the Delphi DXA system, the $2.6 million of revenue recorded as part of the Fleet Business Credit, LLC settlement and an overall reduction in operating expenses including the reassignment of certain research and development personnel to our digital imaging segment.

Mammography/General Radiography. We acquired this business segment from Trex Medical on September 15, 2000 and therefore the fiscal year ended September 30, 2000 includes revenues and expenses from the acquired Lorad and Trex Medical general radiography businesses for only two weeks. In addition, this fiscal 2000 two week period includes pre-tax charges of $13.3 million in connection with the acquisition. In fiscal 2001, we recognized an operating loss of $5.6 million from this business segment, primarily attributable to operating losses from sales of general radiography products that was partially reduced by operating profits from sales of our mammography products. As a result of the decision to close our Littleton manufacturing facility, we expect to eliminate approximately 80 employees and take a restructuring charge, primarily related to severance costs, of approximately $1.0 million, in the first quarter of fiscal 2002.

Digital Imaging. The digital imaging business operating loss increased 4.9% to $21.3 million in fiscal 2001 from $20.3 million in fiscal 2000. This increase was primarily due to the increase of personnel and related operating expenses for the development of new digital radiography systems and detectors, including development of a mammography detector, a single plate general radiography detector, and improvements to the EPEX and RADEX general radiography systems. Through September 29, 2001, we had only limited sales of our EPEX and RADEX systems. Total costs and expenses related to our digital imaging business totaled approximately $33.0 million in fiscal 2001. We expect to continue to incur significant costs and expenses in our digital imaging business for the foreseeable future as we continue to develop and commerce our digital radiography systems.

Mini C-Arm Imaging. The mini c-arm business reported operating income of $683,000 for fiscal 2001 compared to operating income of $163,000 in fiscal 2000. This improvement was primarily attributable to an increase in gross margins due to a reduction of product material and overhead costs and from an overall reduction in operating expenses, that was partially offset by $500,000 of costs associated with moving our mini c-arm manufacturing facility from Illinois to our corporate headquarters in Massachusetts.

Acquired In-Process Technology

We incurred in-process research and development charges totaling approximately $5.0 million in fiscal 2000. These charges related to our acquisition of Trex Medical. We determined these valuations giving explicit consideration to the Securities and Exchange Commission's views on purchased in-process research and development as set forth in its September 9, 1998 letter to the American Institute of Certified Public Accountants SEC Regulations Committee (the "AICPA Letter"). These valuations were further based upon appraisals prepared by an independent appraiser experienced in evaluating in-process research and development. A description of our valuation methodology used and a comparison of our actual results through September 29, 2001, and assumptions used in those valuations are set forth below.

As part of the purchase price allocation, all intangible assets that were a part of the acquisition were identified and valued. It was determined that technology assets and assembled workforce had value. As result of this identification



and valuation process, we allocated approximately $5.0 million of the purchase price to in-process research and development projects. This allocation represented the estimated fair value based on risk-adjusted cash flows related to the incomplete research and development projects. At the date of acquisition, we believed that the development of these projects had not yet reached technological feasibility and the research and development in progress had no alternative futures uses. Accordingly, these costs were expensed as of the acquisition date.

At the acquisition date, Trex Medical was conducting design, development, engineering and testing activities associated with the completion of several research and development projects related to its Mammography and General Radiography-R/F lines of business. Mammography-related projects included development efforts on a full field digital mammography system, Lorad M-V, the I-650 platform to replace the Lorad Elite, and a second-generation mobile X-ray system. Projects related to the Radiography and R/F division included the next-generation R/F 3000i, second-generation mobile X-ray system, and the TouchView user-interface and System HUB research and development efforts.

At the acquisition date, we estimated that the mammography technologies under development were approximately 46% complete based on engineering man-month data and technological progress. We estimated that the Radiography and R/F projects in progress were approximately 60% complete. Trex Medical had spent approximately $5.7 million on the in-process projects, and expected to spend approximately $5.1 million to complete all phases of the research and development. Anticipated completion dates ranged from six to 18 months, at which times we expected to begin benefiting from the developed technologies.

In making our purchase price allocation, we considered present value calculations of income, an analysis of project accomplishments and remaining outstanding items, an assessment of overall contributions, as well as project risks. The value assigned to purchased in-process technology was determined by estimating the costs to develop the acquired technology into commercially viable products, estimating the resulting net cash flows from the projects, and discounting the net cash flows to their present value. The revenue projection used to value the in-process research and development was based on estimates of relevant market sizes and growth factors, expected trends in technology, and the nature and expected timing of new product introductions by us and our competitors. The resulting net cash flows from such projects were based on our estimates of cost of sales, operating expenses, and income taxes from such projects.

Aggregate revenues for Trex Medical technologies were estimated to grow at a compounded annual growth rate of approximately 17% for the five years following the acquisition, assuming the successful completion and market acceptance of the major acquired research and development programs. The estimated revenues for the in-process projects were expected to peak approximately in fiscal 2006 and then decline as other new products and technologies were expected to enter the market.

The rates utilized to discount the net cash flows to their present value were based on estimated cost of capital calculations. Due to the nature of the forecast and the risks associated with the developmental projects, a discount rate of 25% was used for the in-process research and development. The discount rate utilized was higher than our weighted average cost of capital due to the inherent uncertainties surrounding the successful development of the purchased in-process technology, the useful life of such technology, the profitability levels of such technology, and the uncertainty of technological advances that were unknown at that time.

Since the acquisition, we have used the acquired in-process technology to develop new products, which have or are expected to become part of our product lines when completed. However, we are constantly reviewing the allocation of our research and development resources to respond to the ever changing market and technology developments, as well as developments of our own internally developed and acquired evolving technology portfolio. Also, we have combined acquired research and development projects with other of our development activities, and we have delayed two projects.

As of September 29, 2001 our expenditures incurred and estimates to complete our acquired in-process projects related to the Mammography business were consistent with our initial expectations. If we are not successful in implementing our projects, we may be unable to realize the remaining value assigned to this in-process technology. In



addition, the remaining value of the other acquired intangible assets associated with this technology may also become impaired.

Liquidity and Capital Resources

At September 29, 2001 we had approximately $44.7 million of working capital. At that date our cash and cash equivalents totaled $12.8 million. Our cash, cash equivalents and short-term investments balance decreased approximately $10.0 million during fiscal 2001 primarily due to the use of cash in operating activities. Our cash used in operating activities reflected a net loss of $20.9 million for fiscal 2001 which included non-cash revenues of $3.0 million for the reduction in deferred revenue related to the Fleet Business Credit, LLC settlement and $2.0 million decrease in accrued expenses as a result of the arbitrated purchase price adjustment for the Trex Medical acquisition, that were partially offset by non-cash charges for depreciation and amortization of $8.7 million. Cash flow from operations due to changes in our current assets and liabilities included a decrease in accounts receivable of $7.9 million, an increase in accounts payable of $4.7 million and a decrease in inventories of $2.3 million, that were partially offset by a decrease in accrued expenses of $6.4 million and an increase of prepaid expenses and other current assets of $2.1 million. The decrease in accounts receivable was primarily due to improved collections at the former Trex Medical businesses. The increase in accounts payable was primarily due to the timing of payments. The decrease in inventories was primarily attributable to a decrease in finished goods inventory due to the increase in product sales in the fourth quarter of fiscal 2001 compared to

fiscal 2000. The decrease in accrued expenses and the increase in prepaid expenses and other current assets were primarily due to the timing of payments.

In fiscal 2001, we used $4.7 million of cash in investing activities. This use of cash was primarily attributable to purchases of property and equipment of $4.3 million, which consisted primarily of computer and information systems equipment and building improvements, and an increase of other assets of $1.3 million. These uses were partially offset by the $932,000 we received in connection with the settlement of the Trex Medical acquisition purchase price adjustment.

In fiscal 2001 financing activities provided us with $4.9 million of cash. These cash flows included $2.4 million of borrowings under our term loan with Foothill Capital Corporation and $1.6 million of borrowings under our European lines of credit.

As of September 29, 2001 we had short term borrowings, including the current portion of our long term obligations, of $2.5 million and long term notes payable totaling $28.4 million. The short term borrowings consisted of $2.0 million borrowed under our European line of credit and $0.5 million representing the current portion of our long term notes payable. The long term notes payable consisted of the $25.0 million note payable for the Trex Medical acquisition, the $1.9 million borrowed from Foothill Capital Corporation as the long term portion of our term loan under our credit facility, and the $1.5 million balance due on the note to Fleet Business Credit, LLC.



We maintain an unsecured line of credit with a European bank for the equivalent of $3.0 million, which bears interest at the Europe Interbank Offered Rate (3.79% at September 29, 2001) plus 1.5%. The borrowings under this line are primarily used by our European subsidiaries to settle intercompany sales and are denominated in the respective local currencies of its European subsidiaries. The line of credit may be canceled by the bank with 30 days notice.

The Trex Medical note bears interest at 11.5% per year, with accrued interest first payable on September 13, 2001 and semi-annually thereafter. The entire principal balance is due on September 13, 2003. The note is secured by our real property in Danbury, Connecticut and Bedford, Massachusetts.

In September 2001 we obtained a secured loan from Foothill Capital Corporation. The loan agreement with Foothill Capital Corporation provides for a term loan of approximately $2.4 million, which we borrowed at signing, and a revolving line of credit facility. The maximum amount we can borrow under the loan agreement is $25 million with an option for us to increase this amount to $30 million during the term of the Agreement, if certain conditions are met. The loan agreement contains financial and other covenants and the actual amount which we can borrow under the line of credit at any time is based upon a formula tied to the amount of our qualifying accounts receivable and inventory. In December 2001 we amended this loan agreement primarily to change financial covenants to reflect restructuring charges we incurred in the fourth quarter of fiscal 2001 and the additional charges we expect to incur in connection with our decision to close our Littleton facility. Also, as a result of this amendment, our loan availability is limited to a maximum of $15.0 million until we have received at least $10.0 million in net proceeds from the sale of our common stock or other qualifying transaction, and may be further limited based upon other financial covenants and formulas. Our existing availability under the revolving line of credit facility as of September 29, 2001 was $19.5 million. The term loan accrues interest at prime plus 1.25% for five years. The line of credit advances accrue interest at prime plus 0.5%. The line of credit expires in September 2004.

In August 2001, we entered into a settlement agreement with Fleet Business Credit, LLC relating to a dispute that arose in connection with our strategic alliance fee-for-scan program. As part of the settlement agreement, we executed a $1.6 million unsecured note to Fleet. The note bears interest at Fleet's prime rate plus 1% with the full amount of principal to be paid on August 10, 2004. We continue to be entitled to benefit from excess lease and other payments made to Fleet under the program, which will offset amounts due under the note. As of September 29, 2001, the outstanding principal balance of the note was reduced to $1.53 million, as a result of application of these excess payments.

We financed some sales to Latin America over a two-to-three year time-frame. At September 29, 2001, we had total accounts receivable outstanding of approximately $3.3 million relating to these sales, of which approximately $425,000 were long-term and included in other assets. As of September 29, 2001, we had not experienced any significant write-offs of these receivables, however, the economic and currency related uncertainties in these countries may increase the likelihood of non-payment.

In connection with our acquisition of the U.S. assets of Trex Medical, we assumed liability for a lawsuit filed by Fischer Imaging against Trex Medical alleging that the Lorad prone biopsy system infringes upon two Fischer Imaging patents, subject to indemnification from Trex Medical and its parent, Thermo Electron Corporation, for any damages and related costs, including attorneys' fees, up to our adjusted purchase price for the Trex Medical assets. In connection with this arrangement, Trex Medical is continuing to defend this lawsuit. Recently, Fischer Imaging filed a lawsuit against us in the United States in connection with our sales of this product. We have also become aware that Fischer Imaging may be contemplating similar action in Europe. The lawsuits filed by Fischer Imaging in the United States seek to enjoin Trex Medical and us from further violation of Fischer Imaging's patents, unspecified damages of up to three times the amount found or assessed, and attorneys' fees. Trex Medical and Thermo Electron have agreed to indemnify us, and to defend the recently filed United States lawsuit on the same basis as the previously existing lawsuit. If Trex Medical is unsuccessful in defending these lawsuits, we may be prohibited from manufacturing and selling the existing prone breast biopsy system without a license from Fischer Imaging and Fischer Imaging could be awarded significant damages. If required, a license from Fischer Imaging to manufacture or sell the existing prone breast biopsy system may not be available, or may not be available on commercially reasonable terms. Moreover, if Fischer Imaging were awarded damages, indemnification from Trex Medical and Thermo Electron, if any, may be insufficient to cover the award. A significant award above the indemnification amount actually received could harm our business and prospects.



Except as set forth above, we do not have any significant capital commitments. We are working on several projects, with an emphasis on direct radiography plates and systems. We believe that we will require additional funds in order to complete the development, conduct clinical trials and achieve regulatory approvals of our direct radiography and other products under development over the next several years. Moreover, we may require additional funds for the working capital to commence the manufacture and marketing of these new products in commercial quantities, if and when approved or cleared by the regulatory authorities. As a result, we anticipate that we will be required to reduce our losses and obtain additional funding to support these efforts. We are reviewing various alternatives to obtain additional funding, including a proposed public offering of our common stock for which a registration statement on Form S-3 has been filed with the Securities and Exchange Commission, the sale

and lease-back of one of our owned facilities and possible strategic alliances to help support our ongoing research and development costs. We cannot assure that additional funds will be available through the proposed public offering, or otherwise, on favorable terms, if at all, as more fully set forth in the risk factors set forth below.

Recent Accounting Pronouncements

Staff Accounting Bulletin (SAB) No. 101, Revenue Recognition, was issued in December 1999. On March 24, 2000, the SEC deferred implementation of SAB 101 until the second calendar quarter of 2000, and on June 26, 2000, implementation was further deferred until the fourth quarter of calendar 2000. We were required to adopt this new accounting principle through a cumulative charge to the statement of operations, in accordance with Accounting Principles Board Opinion No. 20, Accounting Changes, no later than the fourth quarter of fiscal 2001. The adoption of this principle did not have a material effect on our results of operations, financial position or cash flows.

In July 2001, the FASB issued SFAS No, 141, Business Combinations. SFAS No. 141 requires all business combinations initiated after June 30, 2001 to be accounted for using the purchase method. This statement is effective for all business combinations initiated after June 30, 2001.

In July 2001, the FASB issued SFAS No. 142, Goodwill and Other Intangible Assets. This statement applies to goodwill and intangible assets acquired after June 30, 2001, as well as goodwill and intangible assets previously acquired. Under this statement, goodwill will no longer be amortized, instead goodwill will be reviewed for impairment annually, at a minimum, by applying a fair-value-based test. We will adopt this statement early, effective the first quarter in the fiscal year ended September 2002. Accordingly, we will reclassify the net book value of assembled workforce to goodwill and cease amortization. We expect this will reduce annual amortization expense by approximately $700. Management is currently evaluating the impact that this statement will have on our financial statements in reviewing goodwill for impairment when applying a fair-value-based test.

In August 2001, the FASB issued SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. This statement supercedes SFAS No. 121, Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of, and the accounting and reporting provisions of Accounting Principles Board (APB) Opinion No. 30, Reporting the Results of Operations - Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions. Under this statement it is required that one accounting model be used for long-lived assets to be disposed of by sale, whether previously held and used or newly acquired, and it broadens the presentation of discontinued operations to include more disposal transactions. The provisions of this statement are effective for financial statements issued for fiscal years beginning after December 15, 2001, and interim periods within those fiscal years, with early adoption permitted. We are currently evaluating the ultimate impact of this statement on its results of operations or financial position until such time as its provisions are applied.

Risk Factors

This report contains forward looking statements that involve risks and uncertainties, such as statements of our objectives, expectations and intentions. The cautionary statements made in this report should be read as applicable to all forward-looking statements wherever they appear in this report. Our actual results could differ materially from those discussed herein. Factors that could cause or contribute to such differences include those discussed below, as well as those discussed elsewhere in this report.

We are incurring significant losses and cannot assure that we will become profitable.

We incurred net losses of $18.6 million in fiscal 2000 and $20.9 million in fiscal 2001. In fiscal 2000, these losses were primarily attributable to the operations of Direct Radiography Corp. and charges incurred in connection with our acquisition of substantially all of the U.S. assets of Trex Medical in September 2000. Similarly, in fiscal 2001, these losses were primarily attributable to the operations of Direct Radiography Corp. and general radiography operations of the acquired Trex Medical businesses. Direct Radiography Corp. has had only limited sales of its products. We intend to incur significant expenses in connection with the further development and commercialization of our direct radiography plates and systems. We cannot assure that we will become profitable or that we can maintain profitability if we attain it.

Our failure to reduce our losses or obtain additional funding could result in the delay or limitation of our research and development activities or otherwise harm our business and prospects.

We are working on the research and development of several long-term projects, with an emphasis on direct radiography plates and systems. We believe that we will require significant additional funds in order to complete the development, conduct clinical trials and achieve regulatory approvals of our direct radiography and other products under development over the next several years. Moreover, we may require additional funds for the working capital to commence the manufacture and marketing of these new products in commercial quantities, if and when approved or cleared by the regulatory authorities. If our capital requirements vary materially from those currently planned, we may require additional financing sooner than anticipated. As a result, we anticipate that we will be required to reduce our losses or obtain additional funding to support these efforts. We will need to raise additional capital through additional equity or debt financings, asset sales, collaborative arrangements or from other sources. This additional financing may not be available to us on a timely basis, if at all, or, may not be available on terms acceptable to us. If we fail to obtain acceptable additional financing, we may be required to reduce our planned expenditures, including our ongoing research and development expenditures. Such a reduction could result in the delay or limitation of our ongoing research and development projects and otherwise harm our business and prospects. Moreover, additional equity financing may cause dilution to existing stockholders.

If we are unable to satisfy our financial covenants under our loan agreement our loan availability may be limited or we may have to obtain alternative sources of financing.

Our loan agreement with Foothill Capital Corporation contains financial and other covenants. As a result of recent events, including the restructuring charges we incurred in the fourth quarter of fiscal 2001 and the additional charges we expect to incur in connection with our decision to close our Littleton facility, we were required to modify some of these covenants. Our loan availability is also limited to a maximum of $15.0 million until we have received at least $10.0 million in net proceeds from the sale of our common stock or other qualifying transaction, and may be further limited based upon other financial covenants and formulas. If we do not comply with our covenants, our availability under our loan agreement could be reduced or our lender could declare a default. In the event of a loan default or a substantial reduction of loan availability, we would be required to obtain alternative financing, which

could be more expensive than our current arrangement, be dilutive to existing stockholders and divert management's time and attention. Moreover, we cannot assure that we would be able to obtain alternative financing on favorable terms and on a timely basis, if at all. At September 29, 2001 we had borrowed approximately $2.4 million under our loan agreement. Our failure to meet any of our covenants under our loan agreement could significantly harm our liquidity and financial position.

The markets for our direct radiography products are unproven.

In 1998, our subsidiary, Direct Radiography Corp., was the first company to introduce direct-to-digital X-ray imaging products in the United States. Since that introduction, Direct Radiography Corp. has had only limited sales of its products. Moreover, the markets for these products are relatively new and remain unproven. There is a significant



installed base of conventional X-ray imaging products in hospitals and radiological practices. The use of our direct-to-digital X-ray imaging products in many cases would require these potential customers to either modify or replace their existing X-ray imaging equipment. Moreover, we believe that a major factor in the market's acceptance of direct-to-digital X-ray technology is the trend toward transition by the healthcare industry from conventional film archiving systems to hospital Picture, Archive and Communication Systems, known as PACS, to store X-ray images electronically. Because the benefits of our direct-to-digital technology may not be fully realized by customers until they install a PACS platform, a large potential market for these products may not develop until PACS environments are more widely used. Because of the early stage of the markets for these products, it is likely that our evaluation of the potential markets for these products will materially vary with time. We cannot assure that any significant market will develop for our direct radiography products.

If we fail to achieve and maintain the high manufacturing standards that our direct radiography products require, we will not be successful in developing and marketing those products.

The manufacture of our direct radiography detectors is highly complex and requires precise high quality manufacturing that is difficult to achieve. We have experienced difficulties manufacturing these detectors.

We obtain transistor plates for our direct radiography detectors from a sole contract manufacturer. Following our recent development of an improved design for our transistor plates, we experienced unacceptably high levels of defects for the newly designed plates. While the manufacturer has resolved the problem, and is now producing the plates to our satisfaction, we could again encounter production problems with future shipments. Moreover, further changes in design for our direct radiography detectors, including for our mammography detectors under development, could result in other unanticipated production problems. Our initial difficulties have led to a delay in our ability to ship our new direct radiography systems and adversely affected our anticipated revenues and results of operations from sales of those systems. Our failure, including the failure of our contract manufacturers, to achieve and maintain the required high manufacturing standards could result in further delays or failures in product testing or delivery, cost overruns, product recalls or withdrawals, or other problems that could harm our business and prospects.

Our success depends on new product development.

We have a continuing research and development program designed to develop

new products and to enhance and improve our products. We are expending significant resources on the development of digital X-ray imaging products, including a digital mammography product. The successful development of our products and product enhancements are subject to numerous risks, both known and unknown, including:

- unanticipated delays;
- access to capital;
- budget overruns;
- technical problems; and
- other difficulties that could result in the abandonment or substantial change in the design, development and commercialization of these new products, including, for example, changes requested by the FDA in connection with pre-market approval applications for our products or 510(k) notification.

Given the uncertainties inherent with product development and introduction, we cannot assure that any of our product development efforts will be successful on a timely basis or within budget, if at all. Our failure to develop new products and product enhancements on a timely basis or within budget could harm our business and prospects.



We are undergoing a management transition, which if not successfully implemented could harm our business and prospects.

On June 21, 2001, S. David Ellenbogen, our co-founder, Chairman and Chief Executive Officer, unexpectedly passed away. On July 31, 2001, our Board of Directors named John W. Cumming, as our Chief Executive Officer, President and a director. Mr. Cumming joined Hologic in August 2000 as Senior Vice President and President of Lorad, one of our divisions. Steve L. Nakashige, our former President, Chief Operating Officer and a director, left us in July 2001, and Thomas Umbel, our former Vice President, Business Development, left us in September 2001. In addition, Glenn P. Muir, an Executive Vice President and our Chief Financial Officer, has also been appointed as a director. The management transition is occurring at a challenging time, given our recent acquisitions, ongoing development activities and losses, and involves numerous other risks and uncertainties, including:

- the diversion of management's attention;
- the ability of continuing and new management to work together effectively;
- the ability of new management to handle its new responsibilities and to quickly understand and develop and successfully implement effective strategies for the business; and
- the potential loss of key employees.

The management transition, if not successful, could harm our business and prospects.

Our business could be harmed if our products contain undetected errors or defects or do not meet customer specifications.

We are continuously developing new products and improving our existing products. Newly introduced products can contain undetected errors or defects. In addition, these products may not meet their performance specifications under all conditions or for all applications. If, despite our internal testing and testing by our customers, any of our products contains errors or defects or any of our products fails to meet customer specifications, then we may be required to enhance or improve those products or technologies. We may not be able to do so on a timely basis, if at all, and may only be able to do so at considerable expense. In addition, any significant reliability problems could result in adverse customer reaction, negative publicity or legal claims and could harm our business and prospects.

The general radiography digital market is a new market which is continuing to develop and our new products for this market may not meet the needs of this market as it continues to develop.

The general radiography digital market is a new market which is continuing to develop and for which customer requirements have not been fully specified. For example, our initial specification for the first two digital products for general radiography, the EPEX and RADEX, did not fulfill all the needs of some potential customers for these systems. We have addressed these additional customer requirements through the development and release of new software for these systems. Our introduction of our EPEX and RADEX systems has also resulted in challenges to our direct sales force, which had only limited experience in marketing general radiography products. We cannot assure that we will be able to develop a successful strategy for addressing the general radiography market as it continues to develop. Our failure to do so could harm our business and prospects.



Our reliance on one or only a limited number of suppliers for some key components or subassemblies for our products could harm our business and prospects.

We rely on one or only a limited number of suppliers for some key components or subassemblies for our products. In particular we have only one source of supply for each of the panel and the coating of that panel for our direct radiography products. The supplier for the panel coating is Analogic Corporation, which is also a customer as well as a potential competitor. In addition we have only limited sources of supply for some key components used in our mini c-arm systems. Obtaining alternative sources of supply of these components could involve significant delays and other costs, and may not be available to us on reasonable terms, if at all. The failure of a component supplier or contract assembler to provide acceptable quality and timely components or assembly service at an acceptable price, or an interruption of supplies from such a supplier could harm our business and prospects. Any disruption of supplies of key components could delay or reduce shipments which could result in lost or deferred sales.

Our reliance on a customer for a significant portion of our revenues could harm our business and prospects.

Physician Sales & Service, Inc. and its affiliates, known as PSS, serve as independent distributors in the United States for many of our product lines. These distributors owed us a total of approximately $7.0 million as of September 29, 2001 and accounted for approximately 20% of our product sales for fiscal 2001. We do not have a long term agreement with PSS obligating them to purchase products from us. A reduction or delay in orders from PSS or a delay or default in the payment of their accounts receivable could harm our business and prospects.

We may not be able to compete successfully.

A number of companies have developed, or are expected to develop, products that compete or will compete with our products. Many of these competitors offer a range of products in areas other than those in which we compete, which may make such competitors more attractive to hospitals, radiology clients, general purchasing organizations and other potential customers. In addition, many of our competitors and potential competitors are larger and have greater financial resources than we do and offer a range of products broader than our products. Some of the companies with which we now compete or may compete in the future have or may have more extensive research, marketing and manufacturing capabilities and significantly greater technical and personnel resources than we do, and may be better positioned to continue to improve their technology in order to compete in an evolving industry. Our failure to compete successfully could harm our business and prospects.

The primary competitor for our bone densitometry products is General Electric Medical Systems (GE). Our direct-to-digital imaging products compete with traditional X-ray systems as well as computed radiography systems, which are less expensive than our products, and other direct-to-digital systems. The larger competitors in these markets include GE, Siemens, Kodak, Canon and Varian. General Electric has received FDA approval to market a digital general radiography X-ray system. Another company, Fischer Imaging, recently received FDA marketing approval for its general radiography digital X-ray system. Our mammography systems compete with products offered by GE, Siemens, Instrumentarium and Fischer Imaging. Our minimally invasive breast biopsy systems compete with products offered by Fischer Imaging and with conventional surgical biopsy procedures. Our mini c-arm products compete directly with mini c-arms manufactured and sold by a limited number of companies including GE. We also compete indirectly with manufacturers of conventional c-arm image intensifiers including Siemens and GE.

Our success depends upon our ability to adapt to rapid changes in technology and customer requirements.

The market for our products has been characterized by rapid technological change, frequent product introductions and evolving customer requirements. We believe that these trends will continue into the foreseeable future. Our success will depend, in part, upon our ability to enhance our existing products, successfully develop new products that meet



increasing customer requirements and gain market acceptance. If we fail to do so our products may be rendered obsolete or uncompetitive by new industry standards or changing technology.

We may be unable to successfully integrate the operations of our acquisitions.

We acquired the United States business of Trex Medical in September 2000 and Direct Radiography Corp. in June 1999. Both of these acquisitions involve numerous risks generally associated with acquisitions, including:

- the diversion of management's attention;
- the assimilation of operations, personnel and products of the acquired businesses;
- the ability to manage geographically remote units; and

- the potential loss of key employees of the acquired businesses.

We may not be able to successfully integrate the operations of Trex Medical or Direct Radiography Corp. Failure to do so would harm our business and prospects.

Our failure to manage current or future alliances or joint ventures effectively may harm our business and prospects.

We are exploring potential alliances, joint ventures or other business relationships to expand our distribution channels, raise cash or share ongoing research and development costs. As a result of these efforts we have entered into a distribution agreement with Siemens for our bone densitometry products and a letter of intent with respect to the research and development of digital mammography products. Siemens is a competitor or potential competitor to us in some of our business segments, as well as a competitor or potential competitor to some of our customers or potential customers. Our alliance with Siemens or any other person could enhance their business to our detriment or make it more difficult for us to enter into advantageous business transactions or relationships with others. Moreover, we may not be able to:

- identify appropriate candidates for alliances or joint ventures;
- assure that any alliance or joint venture candidate will provide us with the support anticipated;
- successfully negotiate an alliance or joint venture on terms that are advantageous to us; or
- successfully manage any alliance or joint venture.

Furthermore, any alliance or joint venture may divert management time and resources. Our entering into a disadvantageous alliance or joint venture or failure to manage an alliance or joint venture effectively could harm our business and prospects.

The uncertainty of healthcare reform could harm our business and prospects.

In recent years, the healthcare industry has undergone significant change driven by various efforts to reduce costs, including efforts at national healthcare reform, trends toward managed care, cuts in Medicare, consolidation of healthcare distribution companies and collective purchasing arrangements by office-based healthcare practitioners. Healthcare reform proposals and medical cost containment measures in the United States and in many foreign countries could:



- limit the use of our products;
- reduce reimbursement available for such use; or
- adversely affect the use of new therapies for which our products may be targeted.

These reforms or cost containment measures, including the uncertainty in the medical community regarding their nature and effect, could harm our business and prospects and make it difficult for us to raise additional capital on advantageous terms, if at all.

We depend on third party reimbursement to our customers for market acceptance of

our products. Failure of third party payors to provide appropriate levels of reimbursement for use of our products could harm our business and prospects.

Sales of medical products largely depend on the reimbursement of patients' medical expenses by government healthcare programs and private health insurers. The costs of our products are substantial, and market acceptance of our products depends upon our customers' ability to obtain appropriate levels of reimbursement from third-party payors for use of our products. In the United States, the Health Care Finance Administration, known as HCFA, establishes guidelines for the reimbursement of healthcare providers treating Medicare and Medicaid patients. Under current HCFA guidelines, varying reimbursement levels have been established for dual-energy X-ray and ultrasound bone density assessment, mammography and other imaging and diagnostic procedures performed by our products. The actual reimbursement amounts are determined by individual state Medicare carriers and, for non-Medicare and Medicaid patients, private insurance carriers. There are often delays between the reimbursement approvals by HCFA and by a state Medicare carrier and private insurance carriers. Moreover, states as well as private insurance carriers may choose not to follow the HCFA reimbursement guidelines. The use of our products outside the United States is similarly affected by reimbursement policies adopted by foreign regulatory and insurance carriers. A reduction or other adverse change in reimbursement policies for the use of our products could harm our business and prospects.

The future growth of our bone densitometry business depends in large part on the continued development and more widespread acceptance of complementary therapies.

Our bone densitometers and related products are used to assist physicians in diagnosing patients at risk for osteoporosis and other bone disorders, and to monitor the effectiveness of therapies to treat these disorders. As a result, the future growth of the market for these products and of this business will in large part be dependent upon the development and more widespread acceptance of drug therapies to prevent and to treat osteoporosis. Over the last several years, the FDA has approved a number of drug therapies to treat osteoporosis. We also understand that a number of other drug therapies are under development. While sales of our bone densitometry products have benefited from the increased availability and use of these therapies, most patients who are at risk for osteoporosis continue to go untreated. We cannot assure that any therapies under development or in clinical trials will prove to be effective, obtain regulatory approval, or that any approved therapy will gain wide acceptance. Even if these therapies gain widespread acceptance, we cannot assure that this acceptance will increase the sales of our products.

Reductions in revenues could harm our operating results because a high percentage of our operating expenses is relatively fixed.

A high percentage of our operating expenses is relatively fixed. We likely will not be able to reduce spending to compensate for adverse fluctuations in revenues. As a result, shortfalls in revenues are likely to harm our operating results.



Our results of operations are subject to significant quarterly variation and seasonal fluctuation.

Our results of operations have been and may continue to be subject to significant quarterly variation. The results for a particular quarter may vary due to a number of factors, including:

. the overall state of healthcare and cost containment efforts;

- the development status and demand for drug therapies to treat osteoporosis;
- the development status and demand for our direct-to-digital imaging products;
- economic conditions in our markets;
- foreign exchange rates;
- the timing of orders;
- the timing of expenditures in anticipation of future sales;
- the mix of products sold by us;
- the introduction of new products and product enhancements by us or our competitors; and
- pricing and other competitive conditions.

We also believe that our sales may be somewhat seasonal, with reduced orders in the summer months reflecting summer vacation schedules. Customers may also cancel or reschedule shipments. Production difficulties could also delay shipments. Any of these factors also could harm our business and prospects.

Our delay or inability to obtain any necessary United States or foreign regulatory clearances or approvals for our products could harm our business and prospects.

Our products are medical devices that are the subject of a high level of regulatory oversight. Our delay or inability to obtain any necessary United States or foreign regulatory clearances or approvals for our products could harm our business and prospects. The process of obtaining clearances and approvals can be costly and time-consuming. There is a risk that any approvals or clearances, once obtained, may be withdrawn or modified. Medical devices cannot be marketed in the United States without clearance or approval by the FDA. Medical devices sold in the United States must also be manufactured in compliance with FDA Good Manufacturing Practices, which regulate the design, manufacture, packing, storage and installation of medical devices. Moreover, medical devices are required to comply with FDA regulations relating to investigational research and labeling. States may also regulate the manufacture, sale and use of medical devices, particularly those that employ X-ray technology. Our products are also subject to approval and regulation by foreign regulatory and safety agencies.

Fluctuations in the exchange rates of European currencies and the other foreign currencies in which we conduct our business, in relation to the U.S. dollar, have harmed and could continue to harm our business and prospects.

Foreign sales accounted for approximately 33% of our product sales in fiscal 2000 and 28% of our product sales in fiscal 2001. We maintain a sales and service office in Belgium and a support office in France. The expenses and sales of these offices are denominated in local currencies. We anticipate that foreign sales and sales denominated in foreign



currencies will continue to account for a significant portion of our total sales. Fluctuations in the value of local currencies have caused, and are likely

to continue to cause, amounts translated into U.S. dollars to fluctuate in comparison with previous periods. In particular, the strength in value of the U.S. dollar to the Euro and other European currencies has resulted in an increase in price for products denominated in those currencies. We believe that these price increases have harmed our ability to compete in these markets. Conversely, an increase in the value of the local currencies in which we have offices would likely increase our expenses relative to U.S. dollar sales and could also harm our operating results. We have hedged our foreign currency exposure by borrowing funds in local European currencies to pay the expenses of our foreign offices. There is a risk that these hedging activities will not be successful in mitigating our foreign exchange risk exposure.

We conduct our business worldwide, which exposes us to a number of difficulties in coordinating our international activities and dealing with multiple regulatory environments.

We sell our products to customers throughout the world. Our worldwide business may be harmed by:

- difficulties in staffing and managing operations in multiple locations;
- greater difficulties in trade accounts receivable collection;
- possible adverse tax consequences;
- governmental currency controls;
- changes in various regulatory requirements;
- political and economic changes and disruptions;
- export/import controls; and
- tariff regulations.

We have experienced difficulties in collecting accounts receivable in Latin America, which as of September 29, 2001 totaled $3.3 million, including $425,000 of long-term accounts receivable included in other assets.

Our business could be harmed if we are unable to protect our proprietary technology.

We rely primarily on a combination of trade secrets, patents, copyright and trademark laws and confidentiality procedures to protect our technology. Despite these precautions, unauthorized third parties may infringe, copy or reverse engineer portions of our technology. We do not know if current or future patent applications will be issued with the scope of the claims sought, if at all, or whether any patents issued will be challenged or invalidated. In addition, we have obtained or applied for corresponding patents and patent applications in several foreign countries for some of our patents and patent applications. There is a risk that these patent applications will not be granted or that the patent or patent application will not provide significant protection for our products and technology. Our competitors may independently develop similar technology that our patents do not cover. In addition, because patent applications in the United States are not publicly disclosed until the patent is issued, applications may have been filed which relate to our technology. Moreover, there is a risk that foreign intellectual property laws will not protect our intellectual property rights to the same extent as United States intellectual property laws. In the absence of significant patent protection, we may be vulnerable to competitors who attempt to copy our products, processes or

technology.



Our business could be harmed if we infringe upon the intellectual property rights of others.

There has been substantial litigation regarding patent and other intellectual property rights in the medical device and related industries. We have been, and may be in the future, notified that we may be infringing intellectual property rights possessed by third parties. If any such claims are asserted against our intellectual property rights, we may seek to enter into royalty or licensing arrangements. There is a risk in these situations that no license will be available or that a license will not be available on reasonable terms. Alternatively, we may decide to litigate such claims or to design around the patented technology. These actions could be costly and would divert the efforts and attention of our management and technical personnel. As a result, any infringement claims by third parties or claims for indemnification by customers resulting from infringement claims, whether or not proven to be true, may harm our business and prospects.

We may be prohibited from manufacturing and selling our existing Lorad prone breast biopsy system and be required to pay significant damages if Fischer Imaging Corporation succeeds in its lawsuit against Trex Medical and us that alleges that the system infringes two Fischer Imaging patents.

In connection with our acquisition of the U.S. assets of Trex Medical, we assumed liability for a lawsuit filed by Fischer Imaging against Trex Medical alleging that the Lorad prone biopsy system infringes upon two Fischer Imaging patents, subject to indemnification from Trex Medical and its parent, Thermo Electron Corporation, for any damages and related costs, including attorneys' fees, up to our adjusted purchase price for the Trex Medical assets. In connection with this arrangement, Trex Medical is continuing to defend this lawsuit. Recently, Fischer Imaging filed a lawsuit against us in the United States in connection with our sales of this product. We have also become aware that Fischer Imaging may be contemplating similar action in Europe. The lawsuits filed by Fischer Imaging in the United States seek to enjoin Trex Medical and us from further violation of Fischer Imaging's patents, unspecified damages of up to three times the amount found or assessed and attorneys' fees. Trex Medical and Thermo Electron have agreed to indemnify us, and to defend the recently filed United States lawsuit on the same basis as the previously existing lawsuit. If Trex Medical is unsuccessful in defending these lawsuits, we may be prohibited from manufacturing and selling the existing prone breast biopsy system without a license from Fischer Imaging and Fischer Imaging could be awarded significant damages. If required, a license from Fischer Imaging to manufacture or sell the existing prone breast biopsy system may not be available or may not be available on commercially reasonable terms. Moreover, if Fischer Imaging were awarded damages, indemnification from Trex Medical and Thermo Electron, if any, may be insufficient to cover the award. A significant award above the indemnification amount actually received could harm our business and prospects.

Our future success will depend on the continued services of our key personnel.

The loss of any of our key personnel, particularly our key research and development personnel, could harm our business and prospects. Our success will also depend upon our ability to attract and retain other qualified managerial and technical personnel. Competition for such personnel, particularly software engineers and other technical personnel, is intense. We may not be able to

attract and retain personnel necessary for the development of our business. We do not have any key man life insurance for any of our officers or other key personnel.

There is a risk that our insurance will not be sufficient to protect us from product liability claims, or that in the future product liability insurance will not be available to us at a reasonable cost, if at all.

Our business involves the risk of product liability claims inherent to the medical device business. We maintain product liability insurance subject to deductibles and exclusions. There is a risk that our insurance will not be sufficient to protect us from product liability claims, or that product liability insurance will not be available to us at a reasonable cost, if at all. An underinsured or uninsured claim could harm our operating results or financial condition.

We use hazardous materials and products.



Our research and development involves the controlled use of hazardous materials, such as toxic and carcinogenic chemicals and various radioactive compounds. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by federal, state and local regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of this type of accident, we could be held liable for any resulting damages, and any such liability could be extensive. We are also subject to substantial regulation relating to occupational health and safety, environmental protection, hazardous substance control, and waste management and disposal. The failure to comply with such regulations could subject us to, among other things, fines and criminal liability.

Provisions in our Certificate of Incorporation and By-laws and our stockholder rights plan may have the effect of discouraging advantageous offers for our business or common stock and limit the price that investors might be willing to pay in the future for shares of our common stock.

Our Certificate of Incorporation, By-laws and the provisions of Delaware corporate law include provisions that may have the effect of discouraging or preventing a change in control. In addition, we have a stockholder rights plan that may have the effect of discouraging or preventing a change in control. These provisions could limit the price that our stockholders might receive in the future for shares of our common stock.

Our stock price is volatile.

The market price of our common stock has been, and may continue to be, highly volatile. We believe that a variety of factors could cause the price of our common stock to fluctuate, perhaps substantially, including:

- announcements and rumors of developments related to our business, or the industry in which we compete;
- quarterly fluctuations in our actual or anticipated operating results and order levels;
- general conditions in the worldwide economy;

- announcements of technological innovations;
- new products or product enhancements by us or our competitors;
- developments in patents or other intellectual property rights and litigation; and
- developments in our relationships with our customers and suppliers.

In addition, in recent years the stock market in general and the markets for shares of small capitalization and "high-tech" companies in particular, have experienced extreme price fluctuations which have often been unrelated to the operating performance of affected companies. Any such fluctuations in the future could adversely affect the market price of our common stock, and the market price of our common stock may decline.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Financial Instruments, Other Financial Instruments, and Derivative Commodity Instruments. SFAS No. 107, Disclosure of Fair Value of Financial Instruments, requires disclosure about fair value of financial instruments. Financial instruments consist of cash equivalents, short and long-term investments, accounts receivable, accounts payable and debt obligations. The fair value of these financial instruments approximates their carrying amount.

Primary Market Risk Exposures. Our primary market risk exposures are in the areas of interest rate risk and foreign currency exchange rate risk. We incur interest expense on loans made under a European line of credit at the



Europe Interbank Offered Rate. At September 29, 2001, our outstanding borrowings under the line of credit were approximately $2.0 million, at a weighted average interest rate of approximately 6.1%.

Substantially all of our sales outside the United States are conducted in U.S. dollar denominated transactions. We operate two European subsidiaries which incur expenses denominated in local currencies. However, we believe that these operating expenses will not harm our business, results of operations or financial condition.

Item 8. Financial Statements and Supplementary Data.

The consolidated Financial Statements and Supplementary Data of Hologic are listed under Part IV, Item 14, in this report.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable.



PART III

Item 10. Directors and Executive Officers of the Registrant.

The information required by this item is incorporated by reference to the

sections entitled "Election of Directors" and "Executive Officers" in our Definitive Proxy Statement for our annual meeting of stockholders to be filed with the Securities and Exchange Commission within 120 days after the close of our fiscal year.

Item 11. Executive Compensation.

The information required by this item is incorporated by reference to the sections entitled "Executive Compensation" in our Definitive Proxy Statement for our annual meeting of stockholders to be filed with the Securities and Exchange Commission within 120 days after the close of our fiscal year.

Item 12. Security Ownership of Certain Beneficial Owners and Management.

The information required by this item is incorporated by reference to the section entitled "Share Ownership of Directors, Officers and Certain Beneficial Owners" in our Definitive Proxy Statement for its annual meeting of stockholders to be filed with the Securities and Exchange Commission within 120 days after the close of our fiscal year.

Item 13. Certain Relationships and Related Transactions.

Prior to joining us, John Cumming, our Chief Executive Officer, President and director, was the President and Managing Director of Health Care Markets Group, a strategic advisory and investment banking firm which he founded in 1984. During Mr. Cumming's tenure with them, Health Care Markets Group served as our financial advisor in connection with our acquisition of Direct Radiography Corp. and of the U.S. assets of Trex Medical. During each of fiscal 2000 and 1999, we paid Health Care Markets Group $260,000 in advisory fees in connection with those transactions. In addition, in connection with these consulting activities, in June 1999, we granted Mr. Cumming a stock option to acquire 30,000 shares of our common stock at $5.00 per share. Until recently, Mr. Cumming held a 33% equity interest in Health Care Markets Group. He now owns a 25% interest.

In addition, to assist Mr. Cumming in the purchase of a local primary residence in connection with his initial relocation to Danbury, Connecticut to take on the position of Senior Vice President and President of Lorad, we loaned Mr. Cumming the principal amount of $300,000 pursuant to a promissory note. The note bears interest at the rate of 7.0% per year. The principal and interest of the note become payable each quarter commencing on January 10, 2002 until paid in full no later than January 10, 2005. In the event that we undergo a change of control, the balance of the note will be forgiven. In the event Mr. Cumming's employment with us is terminated, either voluntarily or for cause, Mr. Cumming has agreed to repay the balance of the note.

In connection with Mr. Cumming's recent move to our Massachusetts headquarters in order to assume the position of Chief Executive Officer and President, we loaned Mr. Cumming an additional principal amount of $200,000 which has been consolidated with the original loan into one $500,000 promissory note on the same terms. As of the date of this report, an aggregate of $500,000 of principal on this loan remains outstanding.

Additional information required by this Item may be incorporated by reference to the section entitled "Certain Transactions" in our Definitive Proxy Statement for our annual meeting of stockholders to be filed with the Securities and Exchange Commission within 120 days after the close of its fiscal year.



PART IV

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

(a) The following documents are filed as part of this report:

(1) Financial Statements
Report of Independent Public Accountants

Consolidated Balance Sheets as of September 30, 2000 and September 29, 2001

Consolidated Statements of Operations for the years ended September 25, 1999, September 30, 2000 and September 29, 2001

Consolidated Statements of Stockholders' Equity for the years ended September 25, 1999, September 30, 2000 and September 29, 2001

Consolidated Statements of Cash Flows for the years ended September 25, 1999, September 30, 2000 and September 29, 2001

Notes to Consolidated Financial Statements

(2) Financial Statement Schedules

The following financial statement schedules are filed as part of this report and should be read in conjunction with the consolidated financial statements:

| Schedule |
| --- |
| Report of Independent Public Accountants on Schedule II, Valuation and Qualifying Accounts |

All other schedules have been omitted because they are not required or because the required information is given in the Consolidated Financial Statements or Notes thereto.

(3) Listing of Exhibits

| Exhibit Number | |
| --- | --- |
| 2.01 | Securities Purchase Agreement dated April 28, 1999, as amended on June 3, 1999, by and am Hologic, Sterling Diagnostic Imaging, Inc., and SDI Investments, L.L.C. |
| 2.02 | Contract of Sale dated April 28, 1999, as amended on June 3, 1999, by and between Hologic Glasgow Land Company, L.L.C. |
| 2.03 | Asset Purchase and Sale Agreement Among Trex Medical Systems Corporation, Trex Medical Co ThermoTrex Corporation and Thermo Electron Corporation and Hologic, Inc. dated August 13, |
| 3.01 | Certificate of Incorporation of Hologic |
| 3.02 | By-laws of Hologic |
| 4.01 | Specimen certificate for shares of Hologic's Common Stock |
| 4.02 | Description of capital stock (contained in the Certificate of Incorporation of Hologic, f |

| | |
|---|---|
| | Exhibit 3.01). |
| 4.03 | Rights Agreement dated December 22, 1992 |
| 4.04 | Form of Rights Certificate |
| 4.05 | Amendment No. 1 to Rights Agreement, dated as of December 13, 1995 |
| 4.06 | Amendment No. 2 to Rights Agreement, dated as of December 9, 1996 |
| 4.07 | Amendment No. 3 to Rights Agreement, dated as of April 25, 1999 |
| 10.01 | 1986 Combination Stock Option Plan, as amended |
| 10.02 | Amended and Restated 1990 Non-Employee Director Stock Option Plan |
| 10.03 | 1995 Combination Stock Option Plan |
| 10.04 | Amended and Restated 1999 Equity Incentive Plan |
| 10.05 | 2000 Acquisition Equity Incentive Plan |
| 10.06 | Form of Indemnification Agreement for directors and certain officers of Hologic |
| 10.07 | Employment Agreement with an officer of Hologic |
| 10.08 | Severance Agreement with an officer of Hologic |
| 10.09 | Severance Agreement with an officer of Hologic |
| 10.10 | Severance Agreement with an officer of Hologic |
| 10.11 | Severance Agreement with an officer of Hologic |
| 10.12 | Employment Letter to an officer of Hologic |
| 10.13 | Promissory Note to an officer of Hologic |
| 10.14 | Form of Officer Separation Agreement including list of officers to whom provided |
| 10.15 | License Agreement by and between Hologic and Vivid Technologies, Inc. |
| 10.16 | Amendment No.1 to the License Agreement by and between Hologic and Vivid Technologies, Inc |
| 10.17 | Termination Agreement to the License Agreement by and between Hologic and Vivid Technologi |
| 10.18 | Secured Promissory Note |
| 10.19 | Mortgage, Security Agreement and assignment of Leases and Rents (Danbury) |
| 10.20 | Mortgage, Security Agreement and assignment of Leases and Rents (Bedford) |
| 10.21 | Guaranty |
| 10.22 | Supply Agreement |
| 10.23 | Facility Lease (Littleton) |
| 10.24 | Facility Lease (Danbury) |
| 10.25 | Loan and Security Agreement |
| 10.26 | Parent Pledge Agreement |
| 10.27 | Guaranty and Security Agreement |
| 10.28 | Mortgage and Security Agreement |
| 10.29 | First Amendment to the Loan and Security Agreement |
| 21.01 | Subsidiaries of the Company |
| 23.01 | Consent of Arthur Andersen LLP |

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* Management compensation plan or arrangement

A We previously filed this exhibit on January 24, 1990 with the referenced exhibit number as an exhibit to our Registration Statement on Form S-1 (Registration No. 33-33128), and the previously filed exhibit is incorporated herein by reference.

B We previously filed this exhibit on January 31, 1990 with the referenced exhibit number as an exhibit to our Registration Statement on Form 8-A, and the previously filed exhibit is incorporated herein by reference.

C We previously filed this exhibit on January 29, 1993 with the referenced exhibit number as an exhibit to our Registration Statement on Form 8-A, and the previously filed exhibit is incorporated herein by reference.

D We previously filed this exhibit on December 22, 1993 with the referenced exhibit number as an exhibit to our 1993 Annual Report on Form 10-K (SEC File No. 000-18281) for the fiscal year ended September 25, 1993, and the previously filed exhibit is incorporated herein by reference.

E We previously filed this exhibit on December 22, 1994 with the referenced exhibit number as an exhibit to our 1994 Annual Report on Form 10-K (SEC File No. 000-18281) for the fiscal year ended September 24, 1994, and the previously filed exhibit is incorporated herein by reference.

F We previously filed this exhibit on December 26, 1995, with the referenced exhibit number as an exhibit to our 1995 Annual Report on Form 10-K (SEC File No. 000-18281) for the fiscal year ended September 30, 1995, and the previously filed exhibit is incorporated herein by reference.

G We previously filed this exhibit on December 27, 1996 with the referenced exhibit number as an exhibit to our 1996 Annual Report on Form 10-K (SEC File No. 000-18281) for the fiscal year ended September 28, 1996, and the previously filed exhibit is incorporated herein by reference.

H We previously filed this exhibit on January 17, 1997 with the referenced exhibit number as an exhibit to our Registration Statement on Form 8-A/A, and the previously filed exhibit is incorporated herein by reference.

I We previously filed this exhibit on August 7, 1998 with the referenced exhibit number as an exhibit to our 1998 Third Quarter Report on Form 10-Q (SEC File No. 000-18281) for the quarter ended June 27, 1998, and the previously filed exhibit is incorporated herein by reference.

J We previously filed this exhibit on December 23, 1998 with the referenced exhibit number as an exhibit to our 1998 Annual Report on Form 10-K (SEC File No. 000-18281) for the fiscal year ended September 26, 1998, and the previously filed exhibit is incorporated herein by reference.

K We previously filed this exhibit on May 11, 1999 with the referenced exhibit number as an exhibit to our 1999 Second Quarter Report on Form 10-Q (SEC File No. 000-18281) for the quarter ended March 27, 1999, and the previously filed exhibit is incorporated herein by reference.

L We previously filed this exhibit on May 20, 1999 with the referenced exhibit number as an exhibit to our Registration Statement on Form 8-A/A, and the previously filed exhibit is incorporated herein by reference.

M We previously filed this exhibit on June 18, 1999 with the referenced exhibit number as an exhibit to our Current Report on Form 8-K (SEC File No. 000-18281) dated as of June 3, 1999, and the previously filed exhibit is incorporated herein by reference.

N We previously filed this exhibit on October 1, 1999 with the referenced exhibit number as an exhibit to our Current Report on Form 8-K (SEC File No. 000-18281) dated as of September 29, 1999, and the previously filed exhibit is incorporated herein by reference.

O We previously filed this exhibit on October 2, 2000 with the referenced exhibit number as an exhibit to our Current Report on Form 8-K (SEC File No. 000-18281) dated as of September 15, 2000, and the previously filed exhibit is incorporated herein by reference.

P We previously filed this exhibit on December 23, 1999 with the referenced exhibit number as an exhibit to our Annual Report on Form 10-K (SEC File No. 000-18281) for the fiscal year ended September 25, 1999, and the previously filed exhibit is incorporated by reference.

Q Trex Medical Corporation previously filed this exhibit with the referenced exhibit number as an Exhibit to its Registration Statement on Form S-1

(Reg. No. 333-2926), and the previously filed exhibit is incorporated by reference.

R We previously filed this exhibit on December 22, 2000 with the referenced exhibit number as an exhibit to our Annual Report on Form 10-K (SEC File No. 000-18281) for the fiscal year ended September 30, 2000, and the previously filed exhibit is incorporated by reference.



(b) Reports on Form 8-K.

The following Current Report on Form 8-K was filed by the registrant during the last quarter of the period covered by this report:

Current Report on Form 8-K filed on August 2, 2001 regarding management changes.

(d) Financial Statement Schedules:

The financial statement schedules required are included as part of Item (2) above.



SIGNATURES

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

HOLOGIC, INC.

By: /s/ John W. Cumming
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JOHN W. CUMMING
Chief Executive Officer and President

Dated: December 11, 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 and on the dates indicated.

| Signature | Title | Date |
|---|---|---|
| /s/ John W. Cumming<br>JOHN W. CUMMING | Director, Chief Executive Officer and President (Principal Executive Officer) | December 11, 2001 |
| /s/ Glenn P. Muir<br>GLENN P. MUIR | Director, Executive Vice President Finance and Administration and Treasurer (Principal Financial Officer) | December 11, 2001 |
| /s/ Jay A. Stein | Chairman of the Board and Chief Technical Officer | December 11, 2001 |

| | | |
|---|---|---|
| JAY A. STEIN | | |
| /s/ Robert H. Lavallee<br>ROBERT H. LAVALLEE | Controller<br>(Principal Accounting Officer) | December 11, 2001 |
| /s/ Irwin Jacobs<br>IRWIN JACOBS | Director | December 11, 2001 |
| /s/ William A. Peck<br>WILLIAM A. PECK | Director | December 11, 2001 |
| /s/ Gerald Segel<br>GERALD SEGEL | Director | December 11, 2001 |
| /s/ Elaine Ullian<br>ELAINE ULLIAN | Director | December 11, 2001 |



Hologic, Inc. and Subsidiaries
Index to Consolidated Financial Statements



Report of Independent Public Accountants

To Hologic, Inc.:

We have audited the accompanying consolidated balance sheets of Hologic, Inc. (a Delaware corporation) and subsidiaries as of September 30, 2000 and September 29, 2001, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended September 29, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial

statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Hologic, Inc. and subsidiaries as of September 30, 2000 and September 29, 2001, and the results of their operations and their cash flows for each of the three years in the period ended September 29, 2001, in conformity with accounting principles generally accepted in the United States.

/s/ Arthur Andersen LLP

Boston, Massachusetts
December 8, 2001



HOLOGIC, INC. AND SUBSIDIARIES

Consolidated Balance Sheets

(In Thousands)

Current Assets:
- Cash and cash equivalents
- Accounts receivable, less reserves of $7,923 and $4,668, respectively
- Inventories
- Prepaid expenses and other current assets

Total current assets

Property and Equipment, at cost:
- Land
- Buildings and improvements
- Equipment
- Furniture and fixtures
- Leasehold improvements

| | |
|---|---|
| Less--Accumulated depreciation and amortization | |
| Intangible Assets: | |
| Patented technology, net of accumulated amortization of $2,404 and $3,402, respectively | |
| Developed technology and know-how, net of accumulated amortization of $40 and $991, respectivel | |
| Assembled workforce, net of accumulated amortization of $20 and $504, respectively | |
| Goodwill, net of accumulated amortization of $23 and $88, respectively | |
| Deferred Income Taxes, net | |
| Other Assets, net | |
| Total assets | |
| Current Liabilities: | |
| Lines of credit | |
| Current portion of note payable | |
| Accounts payable | |
| Accrued expenses | |
| Deferred revenue | |
| Total current liabilities | |
| Notes Payable, net of current portion (Note 3b) | |
| Commitments and Contingencies (Notes 9 and 13) | |
| Stockholders' Equity: | |
| Preferred stock, $0.01 par value- | |
| Authorized--1,623 shares | |
| Issued--0 shares | |
| Common stock, $0.01 par value- | |
| Authorized--30,000 shares | |
| Issued--15,417 and 15,670 shares, respectively | |
| Capital in excess of par value | |
| Retained earnings | |
| Accumulated other comprehensive loss | |
| Treasury stock, at cost--45 shares in 2000 and 2001 | |
| Total stockholders' equity | |
| Total liabilities and stockholders' equity | |

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

HOLOGIC, INC. AND SUBSIDIARIES

Consolidated Statements of Operations

(In Thousands, except per share data)

| | Years En September 25, | September |
|---|---|---|
| | 1999 | 2000 |
| Revenues: | | |
| Product sales | $ 81,737 | $ 90,8 |
| Other revenue | 2,403 | 2,8 |
| | 84,140 | 93,7 |
| Costs and Expenses: | | |
| Cost of product sales | 50,333 | 63,6 |
| Research and development | 12,664 | 17,1 |
| In-process research and development | - | 5,0 |
| Selling and marketing | 19,658 | 23,8 |
| General and administrative | 10,963 | 16,4 |
| Restructuring and nonrecurring charges (Note 14) | - | |
| | 93,618 | 126,1 |
| Loss from operations | (9,478) | (32,3 |
| Interest Income | 4,204 | 3,5 |
| Interest/Other Expense | (548) | (2 |
| Loss before (benefit) provision for income taxes | (5,822) | (29,0 |
| (Benefit) Provision for Income Taxes | (2,075) | (10,4 |
| Net loss | $ (3,747) | $(18,6 |
| Net Loss per Common Share: | | |
| Basic and diluted | $ (0.27) | $ (1. |
| Weighted Average Number of Common Shares Outstanding: | | |
| Basic and diluted | 13,950 | 15,3 |

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

HOLOGIC, INC. AND SUBSIDIARIES
Consolidated Statements of Stockholders' Equity
(In Thousands)

| | Common Stock Number of Shares | Common Stock $0.01 Par Value | Capital in Excess of Par Value | R E |
|---|---|---|---|---|
| Balance, September 26, 1998 | 13,376 | $ 134 | $ 95,100 | |
| Exercise of stock options | 30 | - | 131 | |
| Stock issued for employee compensation | 11 | - | 144 | |
| Issuance of common stock under employee stock purchase plan | 27 | - | 163 | |
| Issuance of shares related to acquisition | 1,857 | 19 | 13,910 | |
| Compensation for grants of stock options to nonemployees | - | - | 133 | |
| Tax benefit from stock options exercised | - | - | 43 | |
| Net loss | - | - | - | |
| Translation adjustments | - | - | - | |
| Comprehensive loss | | | | |
| Balance, September 25, 1999 | 15,301 | 153 | 109,624 | |
| Exercise of stock options | 13 | - | 49 | |
| Stock issued for employee compensation | 12 | - | 61 | |
| Issuance of common stock under employee stock purchase plan | 91 | 1 | 499 | |
| Net loss | - | - | - | |
| Translation adjustments | - | - | - | |
| Comprehensive loss | | | | |
| Balance, September 30, 2000 | 15,417 | $ 154 | $110,233 | |
| Exercise of stock options | 128 | 1 | 469 | |
| Stock issued for employee compensation | 25 | 1 | 165 | |
| Issuance of common stock under employee stock purchase plan | 100 | 1 | 433 | |
| Net loss | - | - | - | |
| Translation adjustments | - | - | - | |
| Comprehensive loss | | | | |
| Balance, September 29, 2001 | 15,670 | $ 157 | $111,300 | |

| | Accumulated Other Comprehensive Loss | Total Stockholde Equity |
|---|---|---|
| Balance, September 26, 1998 | $ (575) | $ 140,3 |
| Exercise of stock options | - | 1 |
| Stock issued for employee compensation | - | 1 |

| | | |
|---|---|---|
| Issuance of common stock under employee stock purchase plan | - | 1 |
| Issuance of shares related to acquisition | - | 13,9 |
| Compensation for grants of stock options nonemployees | - | 1 |
| Tax benefit from stock options exercised | - | |
| Net loss | - | (3,7 |
| Translation adjustments | (756) | (7 |
| Comprehensive loss | | |
| Balance, September 25, 1999 | (1,331) | 150,4 |
| Exercise of stock options | - | |
| Stock issued for employee compensation | - | |
| Issuance of common stock under employee stock purchase plan | - | 5 |
| Net loss | - | (18,6 |
| Translation adjustments | (841) | (8 |
| Comprehensive loss | | |
| Balance, September 30, 2000 | $ (2,172) | $ 131,5 |
| Exercise of stock options | - | 4 |
| Stock issued for employee compensation | - | 1 |
| Issuance of common stock under employee stock purchase plan | - | 4 |
| Net loss | - | (20,8 |
| Translation adjustments | 15 | |
| Comprehensive loss | | |
| Balance, September 29, 2001 | $ (2,157) | $ 111,8 |

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



HOLOGIC, INC. AND SUBSIDIARIES

Consolidated Statements of Cash Flows

(In Thousands)

| | September 25, 1999 |
|---|---|
| Cash Flows from Operating Activities: | |
| Net loss | $ (3,747) |
| Adjustments to reconcile net loss to net cash provided by (used in) operating activities- | |
| Depreciation and amortization | 3,474 |

| | |
|---|---|
| Reversal of previously recorded Trex reserves | - |
| Deferred income taxes | (2,128) |
| Acquired in-process research and development | - |
| Compensation expense related to issuance of common stock and stock options | 243 |
| Changes in assets and liabilities, net of impact of businesses acquired in 1999 and 2000, respectively | |
| Accounts receivable | 4,010 |
| Inventories | 6,130 |
| Prepaid expenses and other current assets | (81) |
| Accounts payable | (200) |
| Accrued expenses | (3,006) |
| Deferred revenue | (2,388) |
| Net cash provided by (used in) operating activities | 2,307 |
| Cash Flows from Investing Activities: | |
| Purchases of held-to-maturity investments | (40,848) |
| Proceeds from maturities of investment securities | 46,675 |
| Proceeds from settlement of Trex purchase price | - |
| Purchase of businesses, net of cash acquired | (7,972) |
| Purchase of property and equipment, net | (8,879) |
| Increase in other assets | (107) |
| Net cash used in investing activities | (11,131) |
| Cash Flows from Financing Activities: | |
| Borrowings (repayments) under lines of credit | (2,695) |
| Issuance of note payable | - |
| Repayments of note payable | - |
| Net proceeds from sale of common stock | 294 |
| Tax benefit from stock options exercised | 43 |
| Net cash (used in) provided by financing activities | (2,358) |
| Effect of Exchange Rate Changes on Cash | (733) |
| Net Decrease in Cash and Cash Equivalents | (11,915) |
| Cash and Cash Equivalents, beginning of period | 48,423 |
| Cash and Cash Equivalents, end of period | $ 36,508 |
| Supplemental Disclosure of Cash Flow Information: | |
| Cash paid during the period for income taxes | $ 2,592 |
| Cash paid during the period for interest | $ 229 |
| Supplemental Disclosure of Noncash Financing Activities: | |
| Stock issued for employee compensation | $ 144 |
| Issuance of Note Payable to Fleet Business Credit Corp. for litigation settlement | $ - |

| | |
|---|---|
| Purchase of Businesses, net of cash acquired: | |
| Fair value of assets acquired | $ 23,423 |
| Liabilities assumed | (1,522) |
| Cost in excess of net assets acquired | - |
| In-process research and development cost acquired | - |
| Cash paid | (7,216) |
| Acquisition costs incurred | (756) |
| Fair value of stock/note payable issued | $ 13,929 |

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



HOLOGIC, INC. AND SUBSIDIARIES

Notes to Consolidated Financial Statements

(In Thousands, except per share data)

(1) OPERATIONS

Hologic, Inc. and subsidiaries (the Company or Hologic) is engaged in the development, manufacture and distribution of diagnostic and medical imaging systems primarily serving the healthcare needs of women. The Company's core women's healthcare business units are focused on bone densitometry, mammography and breast biopsy and on developing a direct-to-digital X-ray mammography system.

(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The accompanying consolidated financial statements reflect the application of certain accounting policies as described in this note and elsewhere in the accompanying consolidated financial statements.

(a) Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and all of its wholly owned subsidiaries. All material intercompany accounts and transactions have been eliminated in consolidation.

(b) Fiscal Year

The Company's fiscal year ends on the last Saturday in September. Fiscal 1999, 2000 and 2001 ended on September 25, 1999, September 30, 2000 and September 29, 2001, respectively.

(c) Management's Estimates and Uncertainties

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported

amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

The Company is subject to a number of risks similar to those of other companies of similar size in its industry, including recurring losses, increased debt, rapid technological changes, competition, customer concentration, integration of acquisitions, government regulations, management of international activities and dependence on key suppliers and key individuals.

(d) Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less at the time of acquisition to be cash equivalents. Included in cash equivalents at September 30, 2000 and September 29, 2001 are approximately $2,500 and $541, respectively, of securities purchased under





agreements to resell. The securities purchased under agreements to resell are collateralized by U.S. government securities.

(e) Concentration of Credit Risk

Statement of Financial Accounting Standards (SFAS) No. 105, Disclosure of Information about Financial Instruments with Off-Balance-Sheet Risk and Financial Instruments with Concentrations of Credit Risk, requires disclosure of any significant off-balance-sheet and credit risk concentrations. Financial instruments that subject the Company to credit risk primarily consists of cash, short-term investments, trade accounts receivable and long-term receivables. The Company's credit risk is managed by investing its cash in high-quality money market instruments and securities of the U.S. government and its agencies. The Company has not experienced any material losses related to receivables from individual customers or groups of customers in the X-ray and medical devices industry. Due to these factors, no additional credit risk, beyond amounts provided for, is believed by management to be inherent in the Company's accounts receivable.

The Company utilizes a distributor in the United States for certain product lines. This distributor had amounts due to the Company of approximately $6,969 as of September 29, 2001 and accounted for 20.3% of revenues for fiscal 2001. There were no other customers with balances greater than 10% of accounts receivable as of September 29, 2001 or customers with greater than 10% of the Company's revenues for fiscal 2001. During the years ended September 25, 1999 and September 30, 2000, no individual customers represented greater than 10% of revenue.

The Company finances certain sales to Latin American customers over two to three years. The economic and currency related uncertainties in these countries may increase the likelihood of nonpayment. As a result, the Company increased its bad debt reserve during fiscal 2000;

(In Thousands, except per share data)

no additional amounts were required in fiscal 2001.

The Company had sold its systems to a leasing company, which in turn leased the systems to third parties. The leasing company accounted for 5% of product sales for fiscal 1999. There have been no such sales for any period thereafter (see Notes 10 and 13).

(f) Disclosure of Fair Value of Financial Instruments

The Company's financial instruments mainly consist of cash, accounts receivable, lines of credit, accounts payable and notes payable. The carrying amounts of the Company's cash, accounts receivable, lines of credit and accounts payable approximate fair value due to the short-term nature of these instruments. The note payable to Trex Medical Corporation has a fixed rate of interest and will be subject to fluctuations in fair value during its term. The notes payable to Foothill Capital Corporation and Fleet Business Credit, LLC have a variable interest rate and, therefore, fluctuate based on market conditions. As of September 29, 2001, the fair values of the notes payable





approximate their carrying amounts based on comparable market terms and conditions.

(g) Inventories

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

| | September 30, 2000 | September 29, 2001 |
|---|---|---|
| Raw materials and work-in-process | $24,742 | $27,421 |
| Finished goods | 14,964 | 11,864 |
| | $39,706 | $39,285 |

Work-in-process and finished goods inventories consist of materials, labor and manufacturing overhead.

(h) Depreciation and Amortization

The Company provides for depreciation and amortization by charges to operations, using the straight-line method, which allocate the cost of property and equipment over the following estimated useful lives:

| Asset Classification | Estimated Useful Life |
|---|---|

| | |
|---|---|
| Building and improvements | 40 years |
| Equipment | 3-5 years |
| Furniture and fixtures | 5-7 years |
| Leasehold improvements | Life of lease |





(i) Long-Lived Assets

The Company assesses the realizability of its long-lived assets, including intangible assets, in accordance with SFAS No. 121, Accounting for Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of. To date, the Company has not identified any impairments requiring adjustment.

(j) Deferred Financing Costs

Included in other assets in the accompanying balance sheet are deferred financing costs of approximately $393 related to the Company's closing of the credit facility with Foothill Capital Corporation (see Note 4.) The Company is amortizing these amounts to interest expense over a three-year period, which approximates the level yield method.

(k) Foreign Currency Translation

The Company translates the financial statements of its foreign subsidiaries in accordance with SFAS No. 52, Foreign Currency Translation. In translating the accounts of the foreign subsidiaries into U.S. dollars, assets and liabilities are translated at the rate of exchange in effect at year-end, while stockholders' equity is translated at historical rates. Revenue and expense accounts are translated using the weighted average exchange rate in effect during the year. Gains and losses from foreign currency translation are credited or charged to cumulative translation adjustment, included in stockholders' equity, in the accompanying consolidated balance sheets.

Transaction gains and losses in fiscal 1999, 2000 and 2001 were not significant.

(l) Revenue Recognition

The Company recognizes product revenue upon shipment, provided that there is persuasive evidence of an arrangement, there are no uncertainties regarding acceptance, the sales price is fixed or determinable, collection of the resulting receivable is probable and only perfunctory Company obligations included in the arrangement remain to be completed. A provision is made at that time for estimated warranty costs to be incurred. Other product revenues, which includes primarily replacement parts and services, are recorded at the time of shipment or as the service is rendered.

In connection with a fee-per-scan program with a leasing company for certain products, the Company entered into a remarketing agreement whereby it agreed to perform certain remarketing activities on a best efforts

basis. The Company agreed to perform these activities to help recover any losses incurred by the leasing company up to 10% of the total fee-per-scan contracts funded. The leasing company purchased all such products covered under these contracts from the Company. The Company had reserved for potential losses under these contracts by deferring revenue in an amount equal to 10%





of the contracts funded. This program was terminated in fiscal 1999 (see Notes 10 and 13).

Maintenance contract revenues are recognized over the term of the contract.

(m) Research and Development and Software Development Costs

Research and development costs have been charged to operations as incurred. SFAS No. 86, Accounting for the Costs of Computer Software to Be Sold, Leased or Otherwise Marketed, requires the capitalization of certain computer software development costs incurred after technological feasibility is established. The Company believes that once technological feasibility of a software product has been established, the additional development costs incurred to bring the product to a commercially acceptable level are not significant.

(n) Net Loss Per Share

Basic and diluted net loss per share are presented in conformity with SFAS No. 128, Earnings per Share. Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per share in 1999, 2000 and 2001 is computed in the same way as basic, as all common equivalent shares are considered antidilutive due to the Company's net loss position.

Dilutive weighted average shares outstanding do not include 2,130, 2,712 and 3,367 common-equivalent shares for the end of fiscal years 1999, 2000 and 2001, respectively, as their effect would have been antidilutive.

(o) Derivative Financial Instruments

At September 30, 2000 and September 29, 2001, the Company had no instruments.

(p) Reclassifications

Certain prior-period amounts have been reclassified to conform with the current-period presentation.

(q) Recently Issued Accounting Standards

Staff Accounting Bulletin (SAB) No. 101, Revenue Recognition, was issued in December 1999. On March 24, 2000, the Securities and Exchange Commission (SEC) deferred implementation of SAB No. 101 until the second calendar quarter of 2000, and on June 26, 2000, implementation was further deferred until the fourth quarter of calendar 2000. The Company was required to

adopt this new accounting principle in the fourth quarter of fiscal 2001. The adoption of this principle did not have a material effect on the Company's results of operations, financial position or cash flows.





In July 2001, the Financial Accounting Standards Board (FASB) issued SFAS No. 141, Business Combinations. SFAS No. 141 requires all business combinations initiated after June 30, 2001 to be accounted for using the purchase method. This statement is effective for all business combinations initiated after June 30, 2001.

In July 2001, the FASB issued SFAS No. 142, Goodwill and Other Intangible Assets. This statement applies to goodwill and intangible assets acquired after June 30, 2001, as well as goodwill and intangible assets previously acquired. Under this statement, goodwill will no longer be amortized, instead goodwill will be reviewed for impairment annually, at a minimum, by applying a fair-value-based test. The Company will early adopt this statement effective the first quarter in the fiscal year ended September 2002. Accordingly, the Company will reclassify the net book value of assembled workforce to goodwill and cease amortization. The Company expects this will reduce annual amortization expense by approximately $700. Management is currently evaluating the impact that this statement will have on the Company's financial statements in reviewing goodwill for impairment when applying a fair-value-based test.

In August 2001, the FASB issued SFAS No. 144, Accounting for the Impairment or Disposal of Long-Lived Assets. This statement supercedes SFAS No. 121, Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of, and certain accounting and reporting provisions of Accounting Principles Board (APB) Opinion No. 30, Reporting the Results of Operations - Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions. Under this statement it is required that one accounting model be used for long-lived assets to be disposed of by sale, whether previously held and used or newly acquired, and it broadens the presentation of discontinued operations to include more disposal transactions. The provisions of this statement are effective for financial statements issued for fiscal years beginning after December 15, 2001, and interim periods within those fiscal years, with early adoption permitted. The Company is currently evaluating the ultimate impact of this statement on its results of operations or financial position until such time as its provisions are applied.

(3) ACQUISITIONS

(a) Direct Radiography Corporation

On June 3, 1999, pursuant to a securities purchase agreement dated

(In Thousands, except per share data)

April 28, 1999, as amended (the Securities Purchase Agreement), between Hologic, Sterling Diagnostic Imaging, Inc., a Delaware corporation (SDI) and SDI Investments, LLC, a Delaware limited liability company (SDI Investments), Hologic purchased 100% of the issued and outstanding shares of capital stock of Direct Radiography Corporation Holding Corp., the parent company of Direct Radiography Corp. (DRC), a manufacturer of digital X-ray systems for medical imaging and non-destructive testing applications. On June 3, 1999, pursuant to a contract of sale (the Contract of Sale) with Glasgow Land Company, a Delaware limited liability company and a wholly-owned subsidiary of SDI Investments, Hologic also purchased the land and building





In Glasgow, Delaware, at which DRC conducted its business, Hologic paid approximately $21,145 for DRC and the real estate, of which approximately $7,216 was paid in cash and of which approximately $13,929 was paid by delivery of 1,857 shares of Hologic's common stock, par value $0.01 per share (the Purchase Price). In connection with the acquisition, Hologic incurred $756 of acquisition costs. The Acquisition was accounted for as a purchase in accordance with APB Opinion No. 16. Accordingly, the results of the operations of DRC have been included in the accompanying consolidated financial statements from the date of acquisition. In accordance with APB Opinion No. 16, the Company allocated the purchase price of the acquisition based on the fair value of the assets acquired and liabilities assumed.

The aggregate purchase price of $21,901 including acquisition costs was allocated as follows:

| | |
|---|---|
| Current assets | $ 4,788 |
| Property, plant and equipment | 18,635 |
| Liabilities assumed | (1,522) |
| | $ 21,901 |

Unaudited pro forma operating results for the Company, assuming the acquisition of DRC occurred on September 27, 1998 are as follows:

| | 1999 |
|---|---|
| Net sales | $ 86,466 |
| Net loss | (9,114) |
| Net loss per share- | |
| Basic | (0.60) |
| Diluted | (0.60) |

(b) Trex Medical Systems Corporation

On September 15, 2000, pursuant to an Asset Purchase and Sale Agreement between Hologic, Inc. (Hologic) and Trex Medical

Systems Corporation (Trex Medical) (the Purchase Agreement), dated August 13, 2000, Hologic acquired the U.S. business assets of Trex Medical in exchange for $30,000 in cash and a note in the amount of $25,000. The note has a term of three years, bears interest at a rate of 11.5% per annum and requires the full amount of principal be repaid on September 13, 2003. The note is secured by a mortgage on Hologic's principal office in Bedford, Massachusetts, as well as the facility in Danbury, Connecticut, which was acquired from Trex Medical. The Company recorded interest expense related to this note payable of $109 and $2,875 for the years ended September 30, 2000 and September 29, 2001, respectively, in the accompanying consolidated statement of operations.

The initial aggregate purchase price for Trex Medical was approximately $56,000, which included approximately $1,000 related to acquisition fees and expenses. The purchase price was subject to an adjustment based upon the working capital position of the business as of September 15, 2000. The Trex Medical acquisition has been accounted for as a purchase in accordance with APB Opinion No. 16 and,





accordingly, the results of the operations of Trex Medical have been included in the accompanying consolidated financial statements from the date of acquisition. In accordance with APB Opinion No. 16, the purchase price has been allocated to the acquired assets and assumed liabilities of Trex Medical based on their fair value.

In connection with the allocation of the purchase price to the acquired assets and assumed liabilities of Trex Medical based on their estimated fair value, management determined that the balance of certain reserves and accruals at the closing date were not sufficient to cover the estimated economic exposure. Therefore, the Company increased the balance of the applicable reserves and accruals to reflect management's estimated economic exposure through charges to earnings in the period after acquisition in accordance with the guidance provided under SAB No. 100, Restructuring and Impairment. As a result, in the period the acquisition occurred, the Company recorded pre-tax charges totaling $6,800 to increase the reserve for bad debts, warranty accruals and other liabilities.

In June, 2001, an independent arbitrator determined that adjustments of $2,839 in addition to $119 of adjustments agreed to by Thermo Electron Corporation before submission to arbitration, were required to the closing balance sheet submitted by Trex Medical. This resulted in a payment of approximately $932 to the Company as an adjustment to the purchase price. In addition, as a result of this arbitration settlement, the Company evaluated the components of the approximate $2,900 of adjustments and determined that approximately $2,100 of reserves and accruals provided for through charges to earnings in the fourth quarter of

fiscal 2000 should have been recorded in the allocation of the purchase price for this acquisition. The remaining $700 related to items that were recorded in the original purchase price allocation.

As a result of the above adjustments and other purchase accounting adjustments made during the year, the Company's results for the year ended September 29, 2001 include expense reductions totaling $2,526 relating to the purchase price reallocation as follows:

- $1,722 cost of product sales reduction for warranty accrual and for performance upgrades on prior sales; and

- $376 selling expense reduction for accrued sales commissions and $428 general and administrative expense reduction for various expense accruals and bad debt expense.

As part of the purchase price allocation, all intangible assets that are a part of the acquisition were identified and valued. It was determined that technology assets and assembled workforce had separately identifiable values. As a result of this identification and valuation process, the Company allocated approximately $5,000 of the purchase price to in-process research an