

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, DC 20549

**FORM 10-K**

Annual Report Pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934  
For the Fiscal Year ended December 31, 2010

Commission File Number 0-13839

**CAS MEDICAL SYSTEMS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**06-1123096**

(I.R.S. Employer Identification No.)

**44 East Industrial Road, Branford, Connecticut 06405**

(Address of principal executive offices, including zip code)

**(203) 488-6056**

(Registrant's telephone number, including area code)

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

**Title of Each Class**

Common Stock, \$.004 par value

**Name of Each Exchange on Which Registered**

The NASDAQ Global Market

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes \_\_\_ No X

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes \_\_\_ No X

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 whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes \_\_\_ No \_\_\_

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer \_\_\_

Accelerated filer \_\_\_

Non-accelerated filer \_\_\_

Smaller reporting company X

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).  
Yes  No

As of June 30, 2010, which is the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was \$16,710,000 based on the closing price as reported on the NASDAQ Global Market. This calculation does not reflect a determination that persons are affiliates for any other purpose.

As of March 15, 2011, there were 13,547,783 shares of common stock outstanding.

#### **DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Registrant's Proxy Statement for its Annual Meeting of Stockholders to be held on June 8, 2011 are incorporated by reference in Part III of this Report. Except as expressly incorporated by reference, the Registrant's Proxy Statement shall not be deemed to be part of this Form 10-K.

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## PART I

This report may contain information that includes or is based on forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks and uncertainties. These statements may be identified by the use of words such as "anticipates," "expects," "estimates," "projects," "intends" and "believes" and variations thereof and other terms of similar meaning. Factors that could cause the Company's actual results and financial condition to differ from the Company's expectations include, but are not limited to: potential liquidity constraints; price and product competition; rapid technological changes; dependence on new product development; failure to introduce new products effectively or on a timely basis; the mix of products sold; supply and prices of raw materials and products; customer demand for the Company's products; regulatory actions; changes in reimbursement levels from third-party payors; product liability or other litigation claims; changes in economic conditions that adversely affect the level of demand for the Company's products; changes in foreign exchange markets; changes in financial markets; changes in the competitive environment; and other risks described in Item 1A "Risk Factors" and Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this Annual Report on Form 10-K. While the Company believes that the assumptions underlying such forward-looking statements are reasonable, there can be no assurance that future events or developments will not cause such statements to be inaccurate. All forward-looking statements contained in this report are qualified in their entirety by this cautionary statement.

The Company cautions you not to place undue reliance on these forward-looking statements, which speak only as of their respective dates. The Company undertakes no obligation to publicly update or revise forward-looking statements to reflect events or circumstances after the date of this Annual Report on Form 10-K or to reflect the occurrence of unanticipated events.

Unless the context indicates otherwise, as used in this report, the terms "CAS," "CASMED," the "Company," "we," "us" and "our" refer to CAS Medical Systems, Inc.

### Item 1. Business

#### Overview

We are a medical technology company that develops, manufactures and markets non-invasive patient monitoring products that are vital to patient care. Our products include the FORE-SIGHT® Absolute Tissue Oximeter and sensors, and our Traditional Monitoring products which include MAXNIBP® blood pressure measurement technology, bedside monitoring products, and neonatal vital signs supplies. These products are designed to provide accurate, non-invasive, biologic measurements that guide healthcare providers to provide better patient care.

With our FORE-SIGHT Absolute Tissue Oximeter, we believe CASMED is in a unique position to capitalize on the growing demand from healthcare providers for the monitoring of the oxygenation of biologic tissue. Without sufficient oxygenation to maintain metabolism, biologic tissue, such as the gray matter of the human brain, will die. It is axiomatic that preventing cell death from the lack of oxygenation is a primary goal of clinicians. However, other non-invasive vital signs parameters only provide indirect proxies for actual oxygenation levels that often do not correlate with tissue oxygenation levels. Therefore, direct monitoring of tissue oxygenation provides a unique and powerful tool for clinicians to be alerted to, and treat, otherwise dangerously low tissue oxygenation levels.

Because of its clear advantages to improving patient care, we believe the tissue oxygenation market will continue to expand at attractive rates as clinician education regarding this vital parameter increases. CASMED's FORE-SIGHT Absolute Tissue Oximeter, launched just a little over three years ago, provides what we believe to be the most accurate, best-in-class technology that is well-positioned to compete in that expanding market. In 2010, worldwide revenues of FORE-SIGHT products grew 29% over the prior year to \$5.2 million.

## Strategy

This past year was transitional for CASMED. After a comprehensive review of our product lines, the market opportunities for growth and our internal capabilities, we developed a strategy that we believe will return the Company to growth and create value for our shareholders.

Specifically, our strategy is:

- To Rationalize our Business Lines - We undertook efforts to rationalize our product offerings to those that provide the best opportunities for growth. Consistent with that strategy, we divested our Statcorp business unit, transitioned out of our sleep apnea product line and terminated our relationship with Analogic to distribute their cardio-respiratory products. With the additional working capital generated from those actions, we also developed plans to invest more heavily in our FORE-SIGHT Tissue Oximetry business in an attempt to accelerate growth, and to add resources to our Traditional Vital Signs Monitoring business with the aim of returning that segment to growth.
- To Refresh our Product Portfolio - We commenced efforts to re-invest in, and refresh our remaining product portfolio with investments in research and development. We commenced the development of a second generation FORE-SIGHT monitor and sensors to meet the changing expectations of our customers, to improve functionality, and to enhance gross margins. We initiated efforts to enhance our OEM NIBP functionality to maintain our technical advantages in the market place. We began the redesign of our bedside vital signs monitor to provide an updated product with all the reliability and functionality that our customers have come to expect.
- To Revitalize our Distribution - We began to execute on our plan to improve the quality and quantity of the world-wide distribution of our products, and in particular those distribution channels focused on our FORE-SIGHT Tissue Oximeter products. Coincident with those improvements, we have begun the process of developing enhanced marketing programs and support for our distribution in ways that we hope will both expand the overall market for tissue oximetry through clinical evidence and selling efforts, and permit us to gain market share in the process.

In connection with a change in management in August 2010, we believe we made material progress in the execution of that strategy to further position the Company to achieve high levels of revenue growth of its FORE-SIGHT products, and to return our Traditional Monitoring products to overall growth in the near future.

Specific accomplishments included:

- On April 1, 2010, the Board of Directors appointed Kenneth R. Weisshaar as a Director of the Company. Mr. Weisshaar brings extensive experience in financial operations within the medical technology market, in strategic planning and in management consulting.
- Effective July 31, 2010, the Company exited the market for sales of cardio-respiratory products previously supplied to it by Analogic Corporation.
- On August 27, 2010, the Company appointed Thomas M. Patton as President and CEO and as a Director of the Company. Mr. Patton is a seasoned executive in the medical products field with a broad range of operational and strategic experience from start-ups to growth companies, both public and private.
- On October 27, 2010, the Company announced the settlement of an ongoing patent suit brought against it by a major competitor.
- On October 28, 2010, the Board of Directors appointed Gregory P. Rainey as a Director of the Company as the Board expanded from six members to seven members. Mr. Rainey brings broad expertise in the healthcare field with more than twenty-five years of experience in medical products sales.

- On November 5, 2010, the Company consummated the sale of its non-strategic Statcorp business unit which included its blood pressure cuff and rapid infusor cuff product lines for \$3.2 million in cash, plus the potential for an additional \$350,000 payment upon reaching specified revenue targets six months from the date of the transaction.
- The Company utilized a portion of the proceeds from the Statcorp transaction to fully retire its bank term debt in the amount of \$1.1 million. As of December 31, 2010, the Company had approximately \$4.5 million of cash on hand and no bank debt.
- On January 7, 2011, the Company hired Matthew J. Herwig as its Vice President of Global Sales and Marketing. Mr. Herwig has more than twenty years of experience in the medical products field including various senior leadership positions in both sales and marketing functions.

#### Description of Products and Services

The Company reports two categories of revenue within one reportable business unit.

- ***Tissue Oximetry Monitoring*** – includes sales of the Company’s FORE-SIGHT Absolute Tissue Oximeter monitors, sensors and accessories.
- ***Traditional Vital Signs Monitoring*** – includes sales of the Company’s traditional vital signs products and services including: a) sales to Original Equipment Manufacturers (“OEM”) of the Company’s proprietary non-invasive blood pressure technology (MAXNIBP) for inclusion in the OEM customers’ own multi-parameter monitors; b) bedside vital signs monitors and accessories incorporating various combinations of measurement parameters for both human and veterinary use such as MAXNIBP non-invasive blood pressure, pulse oximetry, electro-cardiography (ECG), temperature, and capnography (CO<sub>2</sub> measurements); c) neonatal intensive care vital signs supplies including electrodes and skin temperature probes; and d) service repair.

#### ***Tissue Oximetry Monitoring***

CASMED’s FORE-SIGHT technology provides a simple, absolute, best-in-class measurement of the oxygenation of cerebral tissue. A cerebral measurement is obtained by placing two sensors upon the forehead of the patient, one each on the left and right side. FORE-SIGHT can also be used to determine the oxygenation of muscle tissue in certain patients by placing the sensor directly upon the muscle to be interrogated. Using near infrared spectroscopy (NIRS), the FORE-SIGHT sensors deliver four different wave lengths of laser light that harmlessly penetrate into the tissue and are reflected back to photo-detectors in two locations on the sensor. An exclusive and proprietary algorithm then interprets the signals received by the photo-detectors and solves for the oxygenation of the hemoglobin in the blood being interrogated by the light. Through this combination of proprietary and patented processes, FORE-SIGHT provides clinicians with an accurate, absolute measure of the tissue oxygenation which is otherwise unavailable from any other type of non-invasive vital signs monitor.

#### The Need for Tissue Oxygenation Monitoring

Oxygen is necessary to keep cells alive and the lack of sufficient oxygenated blood flow to the brain can lead to cell death. The brain is the organ with the highest need for oxygen, consuming approximately 20% of the body’s oxygen at rest. It is also the organ least tolerant of oxygen deprivation. Therefore, without sufficient oxygen, brain damage may occur within minutes, and can result in cognitive impairment, stroke, paralysis, other disabilities or even death.

Dangerous deficits in brain oxygen levels, called “desaturation events” can be caused by many factors. In most adults, the brain reacts to insufficient levels of oxygenation by preferentially drawing blood from the rest of the body to protect the brain. This process is called “auto-regulation.” However, neonates and children have undeveloped or under-developed auto-regulation capabilities. In addition, the auto-regulation feature of the adult brain can be compromised due to surgical interventions, trauma, anesthesia, illness, age and a patient’s unique physiology.

Therefore, despite the human auto-regulation feature, inadequate oxygen supply to the brain can occur from:

- Hypoxemia: a decrease in the oxygen saturation levels of the arterial blood being delivered to the brain due to a failure in the respiratory system (*quality* of the supply);
- Ischemia: a decrease in blood flow to the brain due to inadequate volume pumped from the heart, problems with the vasculature system, or blockage (*quantity* of the supply);
- Anemia: an inadequate concentration of red blood cells in the blood (oxygen carrying *capacity* of the supply).

Each of these issues of supply must be considered in conjunction with the metabolic rate of the brain, or its rate of oxygen consumption, or demand.

Reliable measurement of the complicated interactions between oxygen supply and demand, as important as they are, has historically been difficult to obtain without surgically invasive techniques. Although cerebral oximetry monitors were first introduced many years ago, our FORE-SIGHT monitor became the first cerebral oximeter with sufficient accuracy to provide an absolute (rather than trended) measure of cerebral tissue oxygen saturation. Today, FORE-SIGHT still remains the only tissue oximeter cleared by the FDA for use as an absolute measure of cerebral oxygenation for all patients, regardless of age or weight.

### The Market for Tissue Oximetry

Research has shown that cerebral desaturation events occur with much greater frequency than previously believed. Desaturation events have been recorded in surgeries for abdominal surgery, various open heart procedures, various orthopedic surgeries and heart catheterization procedures, among many others. Desaturation events have also been recorded during monitoring in the ICU for neonates, pediatrics, and most recently, for adults. In the U.S. alone, cerebral monitoring could apply to approximately 5 million surgical procedures per year.

Approximately 550 hospitals in the U.S. contain Neonatal Intensive Care Units (“NICU”) with 13,000 high acuity Level Three beds. Approximately 4 million births occur in the U.S. each year of which approximately 4% are babies with birth defects and about 12% are pre-term births (defined as less than 37 weeks gestation.) All of these patients are also candidates for tissue oximetry monitoring.

We also believe cerebral and other tissue monitoring has great application in emergency care environments. Understanding cerebral oxygenation levels for cardiac arrest patients and trauma victims, or to predict shock and sepsis may guide future therapies. Research in this field is also being conducted.

While we believe the addressable market for tissue oximetry could be as large as \$1 billion, we estimate current total world-wide annual revenues from the sale of tissue oximetry to be approximately \$75 million to \$85 million. We believe the market is growing at a rate of approximately 20-25% per year. Given the broad potential applicability of this parameter, and the small current rate of market penetration, we also believe that market rates of growth will continue to be attractive into the foreseeable future.

The growing body of published literature in support of tissue oximetry will play an increasingly important role in the expansion of the tissue oximetry market as clinicians continue to be educated regarding the potential benefits of this parameter.

### Clinical Evidence in Support of Tissue Oximetry Monitoring

The market for tissue oximetry continues to expand in part due to an increasing body of favorable clinical evidence

being published by clinicians world-wide. For example, CASMED now has over 103 publications in support of our FORE-SIGHT technology, of which 52 were published in 2010.

Literature relating to the effective use of FORE-SIGHT oximeters, and to oximeters of our competitors, shows that desaturation events can correlate with adverse clinical outcome. Low levels of cerebral tissue oxygenation have been shown to correlate with major post-surgical complications, increased major organ failure, and even death. These comorbidities and poorer outcomes result in increased costs to hospitals.

Some of the more significant examples of findings in support of poor outcomes from cerebral desaturation events in general include:

- “Decreased [cerebral tissue oxygen saturation] values were associated with major complications, prolonged postoperative mechanical ventilation, and prolonged ICU and hospital [length of stay.] The total cost of this additional stay was calculated to be \$8,300 at our institution using hospital financial estimates of cardiac surgical inpatient costs.”

Fischer GW, et.al. Noninvasive cerebral oxygenation may predict outcome in patients undergoing aortic arch surgery. *J Thoracic Cardiovascular Surg.* March 2011; 141(3): 815-21.

- “Intraoperative cerebral oxygen desaturation is significantly associated with an increased risk of cognitive decline and prolonged hospital stay after CABG.” (Showing a three times increase in length of stay.)

Slater JP, et al. Cerebral oxygen desaturation predicts cognitive decline and longer hospital stay after cardiac surgery. *Ann Thorac Surg.* 2009; 87:36-45.

- “[We] demonstrated that treatment of declining [cerebral oxygen saturation] prevented prolonged desaturations and was associated with a shorter ICU LOS and significantly reduced incidence of [major organ morbidity and mortality.]”

Murkin JM, et al. Monitoring brain oxygen saturation during coronary bypass surgery: a randomized, prospective study. *Anesth Analg.* January 2007; 104(1): 51-58.

- “The incidence of cerebrovascular accident in the study group was 0.97%, compared with 2.03% in the controls. This translated to a potential avoidance of 12 cerebrovascular accidents and approximately \$254,214 in direct costs and more than \$425,000 in total costs. The results show that specific measures can improve outcomes and reduce costs in cardiac surgery. Therefore, the use of a clinical effectiveness quality initiative and cerebral oximetry in all cardiac surgery should be advocated.”

Goldman SM, et al. Outcome improvement and cost reduction in an increasingly morbid cardiac surgery population. *Semin Cardiothorac Vasc Anesth,* June 2006; 10(2):171-175.

Once a desaturation event is identified, clinicians can react to dangerously low oxygen levels and apply various therapies to reverse the condition. For example, clinicians can increase the levels of inspired oxygen, provide drugs that constrict the vasculature thereby increasing pressures, or adjust respiratory levels. In instances where the desaturation event is caused by a surgical error (such as clamping or occluding an artery in error) monitoring can aid in the quick identification of the issue so it can be remedied. Therefore, by monitoring and treating patients to avoid desaturation events, clinicians should be able to improve patient care and improve outcomes.

### The FORE-SIGHT Technology

Our FORE-SIGHT Tissue Oximeter non-invasively and continuously measures absolute cerebral tissue oxygen levels, enabling clinicians to identify and quickly react to dangerously low brain oxygen levels and provide better care. We believe the FORE-SIGHT technology to be best-in-class, providing the most accurate measure of non-invasive tissue saturation levels available.

Like all tissue oximeters, the FORE-SIGHT monitor and sensor shines harmless light into tissue under a sensor and measures the reflected signals to provide a tissue oxygenation value from interrogation of oxygenated hemoglobin and de-oxygenated hemoglobin under the sensor. However, we believe that FORE-SIGHT incorporates a combination of features that permit oxygenation values obtained to be more reliable and more accurate, and therefore more actionable by clinicians in critical care environments.

- CASMED's LASER-SIGHT® Optical Technology projects near infrared laser light into the tissue at precise and narrow wavelengths, thereby reducing the signal interference of lights with broader wave-length ranges.
- CASMED's FORE-SIGHT monitors emit four wavelengths of light, permitting an increased level of signal acquisition and thereby providing sufficient data to solve for other optical variables in the tissue sample that would otherwise interfere with hemoglobin signals.
- CASMED's FORE-SIGHT sensors are designed with a preferred geometry, maximizing the distance between the light source and the farthest photo-detector, thereby providing a light pathway that penetrates deeper into the tissue giving a greater sample for interrogation.
- CASMED's FORE-SIGHT monitors permit the clinician to enter age and weight parameters of the patients. These factors are considered by our algorithm when interpreting signal variables that are affected by those parameters (such as skull shape and composition.)
- CASMED's FORE-SIGHT patented algorithm utilizes a combination of patented and proprietary methods to sort out optical signals created by non-critical background tissue.

Our competitors that provide trend-based values differ significantly from FORE-SIGHT, which provides absolute values. Trend-based monitors rely upon a baseline measurement from which a declination of some percentage is then considered to be an actionable "desaturation" event. However, the baseline presumes the patient's oxygenation levels are not already compromised by the introduction of anesthesia, inspired oxygen, existing cardiovascular disease, compromised physiology or other confounding factors. Therefore, in those instances where a patient is already ill, is already being treated, or for which a single "spot check" value is sought, a valid baseline measurement may not be available.

With FORE-SIGHT's absolute tissue oxygenation measurement, clinicians can have confidence that the value displayed is a more accurate value of the actual tissue oxygenation and can signal clinical interventions once a predetermined absolute threshold is reached (for example if the oxygen saturation levels drop below an absolute value of 60%).

We believe our FORE-SIGHT oximeter is well-positioned in the growing market for tissue oximetry. We think it is a best-in-class technology that continues to benefit from a growing body of published clinical evidence. As a result, the FORE-SIGHT oximeter has been well-received by the market since its limited introduction in late 2007.

In 2010, our total FORE-SIGHT revenues were \$5.2 million, a 29% increase over 2009 revenues.

### ***Traditional Vital Signs Monitoring***

In addition to Tissue Oximetry products, CASMED provides a series of traditional vital signs monitoring products and services to clinicians around the world. Those include:

- sales to Original Equipment Manufacturers ("OEM") of the Company's proprietary non-invasive blood pressure technology (MAXNIBP) for inclusion in the OEM customers' own multi-parameter monitors;
- vital signs monitors and accessories incorporating various combinations of measurement parameters for both human and veterinary use such as MAXNIBP non-invasive blood pressure, pulse oximetry, electrocardiography (ECG), temperature, and capnography (CO<sub>2</sub> measurements); and

- supplies and service including neonatal intensive care vital signs supplies (such as electrodes and skin temperature probes).

#### Blood Pressure Measurement Technology

The Company has developed a proprietary non-invasive blood pressure measurement technology that it sells under the MAXNIBP brand. The Company believes this technology is more accurate, reliable, and able to produce a measurement result faster than its competitors. These advantages are important, especially in the most challenging clinical situations where measurements can be difficult to obtain. The Company has entered into OEM agreements to supply its MAXNIBP technology to various companies throughout the world. This technology is used in larger monitoring systems where non-invasive blood pressure is one of many measurement parameters. The Company's OEM agreements are typically multi-year arrangements. The Company has a multi-year supply agreement with its largest OEM customer – Medtronic Physio-Control, which was renewed during the first quarter of 2010 and will expire in 2013.

#### Bedside Monitoring

The Company offers a full line of non-invasive vital signs monitoring products for a variety of general care settings such as hospital wards, outpatient medical surgical units, recovery rooms, procedure labs, physician offices and emergency response settings. The monitors are small, lightweight, portable and easy to use with central station capabilities.

The Company manufactures two platforms of vital signs monitors based around its proprietary MAXNIBP non-invasive blood pressure technology and incorporating various combinations of other industry-leading measurement parameters including pulse oximetry, electro-cardiography, temperature, and capnography. CASMED monitors are ideal for a range of clinical settings (both human and veterinary) including emergency medical service, medical/surgical units, out-patient care, and procedural sedation. The Company has a blanket agreement with the U.S. Department of Veterans Affairs (the "VA") for purchase of its vital signs monitors through December 2011. Over the past five years, the Company has sold approximately 12,000 vital signs monitors to the VA hospitals and clinics throughout the U.S. Collective sales to VA hospitals accounted for over 14% of the Company's overall sales for 2010.

#### Supplies and Service

CASMED supplies a line of specialty neonatal supplies including Klear-Trace® ECG Electrodes, NeoGuard® skin temperature probes and adhesive reflectors. These high quality single-patient-use products are designed specifically to meet the unique needs of neonatal intensive care. The Company also provides various repair services to its customers for monitors already in the field.

#### Sales and Marketing

The Company markets its products globally, through hospitals, surgery centers and other outpatient facilities, homecare, veterinary and emergency medical distribution channels. A number of different sales channels are utilized to maximize opportunities for the various product lines we offer.

#### *Tissue Oximetry Monitoring*

The Company's critical care FORE-SIGHT Absolute Tissue Oximeters are sold via a direct sales force and key manufacturer's representatives groups within the U.S. and via stocking distribution partners outside the U.S.

As of December 31, 2010, the Company utilized a team of twenty-nine sales and clinical support specialists dedicated to the FORE-SIGHT product line in the U.S. including two direct sales representatives and seven manufacturer's representative organizations.

Outside the U.S., as of December 31, 2010, the Company had three exclusive FORE-SIGHT sales consultants located in Europe, and four non-exclusive sales consultants located in Europe, the Middle East and the Pacific Rim all managing FORE-SIGHT sales via our distribution partners.

#### *Traditional Vital Signs Monitoring*

The Company sells its non-invasive blood pressure technology in the form of sub-assemblies to be assembled into other OEM companies' multi-parameter monitors. The Company sells on a direct basis utilizing headquarters-based employees to solicit companies operating in both the domestic and international markets.

The Company's vital signs monitoring products are sold within the U.S. via manufacturer's representatives and distributors. Outside of the U.S., sales are conducted through exclusive distributors in Europe, Africa, the Middle East, Pacific Rim, Latin America and Canada and are managed by the same organization that manages the FORE-SIGHT sales efforts.

Sales of the Company's neonatal supplies are primarily sold via key stocking distribution partners in both the U.S. and international markets.

#### **Financial Information Relating to Sales**

##### **Year Ended December 31**

	<u>2010</u>	<u>2009</u>
Domestic Sales	\$17,131,689	\$16,679,897
International Sales	<u>6,954,322</u>	<u>8,361,401</u>
Totals	<u>\$24,086,011</u>	<u>\$25,041,298</u>

#### Competition

The Company competes in the broader medical equipment market for patient monitoring equipment and supplies. We believe our products maintain a high, professional standard of accuracy and quality in demanding environments. We believe that our reputation for producing innovative, accurate and reliable products that are user-friendly, manufactured in the U.S., and contain best-in-class technology are key factors in our ability to successfully compete with larger organizations in the medical equipment market.

We believe that the principal competitive factors that we and other companies competing in our markets face are:

- FDA clearance;
- The accuracy, reliability and repeatability of measurements;
- Publication of peer reviewed clinical studies;
- Acceptance by leading thought-leaders in anesthesia, surgery, perfusion and other key clinical roles for new technologies such as cerebral oxygenation monitoring;
- Documented improved patient outcomes;
- The cost effectiveness of monitoring solutions and overall pricing;
- Interfacing with multi-parameter patient monitoring and data solutions;
- The overall ease of use and product quality;
- Sales and marketing capability and established sales distribution channels; and
- IP protection, and timing and acceptance of product innovation.

Competitors for our Tissue Oximetry products include Covidien, Hutchinson Technology Inc., Nonin Medical Inc., and Hamamatsu Corp. A number of smaller competitors have also recently introduced or have made plans to introduce competitive tissue oxygenation monitors into the marketplace.

Competitors for our Traditional Vital Signs Monitoring products are myriad and include large corporations such as Philips, General Electric, Mindray Medical International Ltd., and Welch Allyn Inc. among others in the vital signs monitor market and companies such as SunTech Medical Inc., Omron Corp. and Mindray in the OEM NIBP market. Many of the major patient monitoring solutions companies also have their own proprietary NIBP technology.

### Research and Development

As of December 31, 2010, our R&D department consisted of a staff of 18 full-time engineers and scientists focused on the following primary areas:

- Advanced algorithm research;
- Sensor and optical development;
- Hardware development and support; and
- Clinical research.

Our R&D efforts in 2010 were directed primarily toward continuing to improve the function and features of the Company's FORE-SIGHT Absolute Tissue Oximeter and related technologies. We also commenced efforts to advance the design and enhance the performance of the Company's MAXNIBP non-invasive blood pressure technology. Finally, we began to explore an update of our vital signs monitors.

CASMED began initial research efforts in Near-Infrared Spectroscopy ("NIRS") based cerebral oximetry in 1999 and, after successful initial clinical research proof of concept studies, began the development task for our first commercial cerebral oximeter in 2003. The adult version FORE-SIGHT cerebral oximeter was first sold in May 2007 and was followed by a number of enhancements including the addition of the small (neonatal) sensor in 2008. In 2009 the Company completed its cerebral oximetry sensor offerings with the releases of the non-adhesive small sensor and the medium sensor. The target markets for the medium sensor are in the areas of pediatric intensive care, pediatric cardiovascular OR and cardiovascular intensive care. The non-adhesive small sensor is designed specifically for preserving the skin integrity of newborns and preterm infants.

During January 2011, CASMED received 510(k) clearance from the FDA for expanded labeling of the FORE-SIGHT technology to monitor skeletal muscles on infants, children and adolescents weighing between 5 and 50 kilograms (approximately 11 to 110 pounds).

Our FORE-SIGHT Absolute Tissue Oximeters and sensors remain the only oximeter products cleared by the FDA to provide absolute cerebral oxygenation levels for all patients, regardless of age or weight.

During 2010 and 2009, the Company incurred R&D related expenses of approximately \$2,475,000 and \$3,180,000, or 10% and 13% of revenues, respectively. After consideration of reimbursements received from the National Institutes of Health ("NIH") as discussed under Grant Awards below and various federal tax grants and state tax credits, net R&D expenses for 2010 and 2009 were approximately \$1,689,000 and \$2,443,000, or 7% and 10% of revenues. Reimbursements from the NIH were approximately \$483,000 for 2010 and \$737,000 for 2009. The Company also received approximately \$303,000 of federal and state tax incentives during 2010. Funding provided to the Company is recorded as a reduction in R&D expenses.

For 2011, we expect our net R&D expenses to be substantially greater than our 2010 expenditures. R&D activities for 2011 will be primarily focused on the continued advancement of the Company's proprietary LASER-SIGHT and MAXNIBP technologies with continued algorithm development programs, technology integration and cost reduction programs, other enhancements and continued clinical research efforts.

### Grant Awards

On September 17, 2007, the Company was awarded a three year grant, which was subsequently extended, totaling \$2.8 million by the National Institute of Neurological Disorders and Stroke ("NINDS") of the NIH under its Small Business Innovative Research Program. The grant was awarded primarily to support advanced clinical outcome studies that focus on the Company's proprietary LASER-SIGHT technology that is incorporated into the FORE-SIGHT cerebral oximeter. Further clinical studies funded by this grant will be used to expand the clinical applications for FORE-SIGHT

outside of the initial target market of high risk cardio-vascular surgery. As of December 31, 2010, a maximum of approximately \$0.7 million remained under the 2007 grant award.

The Company has, in prior years, been awarded various grants by the NINDS under its Small Business Innovative Research Program. In accordance with the terms of these grants, the Company is reimbursed for certain qualifying expenditures. Such grant awards provide substantial support for the Company's clinical efforts currently being undertaken at multiple adult and neonatal sites.

Reimbursements from the NIH were approximately \$483,000 for 2010 and \$737,000 for 2009. The funding provided to the Company is recorded as a reduction in R&D expenses.

#### Trademarks, Patents and Copyrights

Certificates of Registration have been issued to the Company by the United States Department of Commerce Patent and Trademark Office for the following marks: CAS<sup>®</sup>, CASMED<sup>®</sup>, COOL-LIGHT<sup>®</sup>, For Every Life and Breath Situation<sup>®</sup>, For What's Vital<sup>®</sup>, FORE-SIGHT<sup>®</sup>, HOLD-TIGHT<sup>®</sup>, Klear-Trace<sup>®</sup>, LASER-SIGHT<sup>®</sup>, Limboard<sup>®</sup>, MAXNIBP<sup>®</sup>, Mother/baby<sup>®</sup>, NeoGuard<sup>®</sup>, the heart shaped mark for use as a thermal reflector, and the Company's corporate logo.

The Company holds various patents for its blood pressure measurement and FORE-SIGHT technologies which it believes provide it with a competitive market advantage. Although the Company holds such patents and has patents pending related to certain of its products, it does not believe that its business as a whole is significantly dependent upon patent protection.

The FORE-SIGHT NIRS tissue oximetry technology has four U.S. patents issued (U.S. 6,456,862 B2, 7,047,054, 7,072,701, and 7,313,427) and four international patents issued. In addition, the Company currently has several patents pending with U.S. and foreign patent offices. The Company believes the design concepts covered in its current patent applications and provisional patent applications are important to providing a tissue oximeter capable of absolute brain tissue oxygen saturation measurements with FORE-SIGHT's level of accuracy.

The Company also relies on trade secret, copyright and other laws and on confidentiality agreements to protect its technology. The Company has copyright protection for the software used in its blood pressure and tissue oximeter monitor.

The Company will continue to seek patent, trademark and copyright protections as it deems advisable to protect the markets for its products and its R&D efforts. We believe that neither our patents nor our other legal rights will necessarily prevent third parties from developing or using a similar or a related technology to compete against our products.

#### Employees

As of December 31, 2010, the Company had 102 employees, of which 101 were full-time. The Company has no collective bargaining agreements and believes that relations with its employees are good.

#### Government Regulation

Medical products of the type currently being marketed and under development by the Company are subject to regulation under the Food, Drug and Cosmetic Act (the "FD&C Act") and numerous acts and amendments such as the Quality System Regulations ("QSR"), often referred to as Good Manufacturing Practices ("GMP's").

In addition, depending upon product type, the Company must also comply with those regulations governing the Conduct of Human Investigations, Pre-Market Notification Regulations and other requirements, as promulgated by the FDA. The FDA is authorized to inspect a device, its labeling and advertising, and the facilities in which it is manufactured in order to ensure that the device is not manufactured or labeled in a manner which could cause it to be in violation of the FD&C Act.

The FDA has adopted regulations which classify medical devices based upon the degree of regulation believed necessary to assure safety and efficacy. A device is classified as a Class I, II, or III device. Class I devices are subject only to general controls. Class II devices, in addition to general controls, are or will be subject to "performance standards." Most devices are also subject to the 510(k) pre-market notification provision. In addition, some Class III devices require FDA pre-market approval before they may be marketed commercially because their safety and effectiveness cannot be assured by the general controls and performance standards of Class I or II devices.

The Company's products are primarily Class I and II devices and several of them have required FDA notification under Section 510(k) of the FD&C Act.

In the last factory inspection of the Company by the FDA during August 2010 there were no material non-conformities issued.

#### International Regulatory Compliance

CASMED maintains certification to ISO 13485:2003 by the accredited body, BSI Inc., in its manufacturing facility. These certifications allow CASMED to use the "CE" mark on its products. The CE mark is required for medical devices to gain access to the European Union ("EU") common market. The FDA, recognizing the value of this universally accepted quality system, has patterned its Quality System Regulations after ISO 9001 and ISO 13485. CASMED maintains full compliance with ISO 13485:2003 and the EU's Medical Device Directive.

#### Manufacturing and Quality Assurance

The Company assembles its products at its facility in Branford, Connecticut. The various components for the products, which include plastic moldings, wire, printed circuit boards, semi-conductor circuits, electronic and pneumatic components, power supplies, proprietary software and many other parts and sub-assemblies are obtained from outside vendors. The Company has not experienced any sustained interruption in production or the supply of components and does not anticipate any difficulties in obtaining the components necessary to manufacture its products.

Quality assurance procedures are performed by the Company at its Branford, Connecticut facility and occasionally at its suppliers' facilities to standards set forth in the FDA's "Quality System Regulations." These procedures include the inspection of components and full testing of finished goods. The Company has a controlled environment where the final assembly of single-patient-use products is conducted.

#### Customers

Our five largest customers accounted for approximately 36% and 30% of revenues in 2010 and 2009, respectively. Among these customers, Medtronic Physio-Control Inc., customarily the Company's largest individual customer accounted for 14% and 12% of revenues during 2010 and 2009, respectively.

#### Backlog

The Company's backlog includes orders pursuant to long-term OEM agreements as well as orders for products shippable on a current basis. Total backlog, therefore, is not a meaningful indicator of the Company's future sales.

#### Corporate Information

CAS Medical Systems, Inc. is a Delaware corporation organized in 1984. Our corporate offices are located at 44 East Industrial Road, Branford, CT 06405, and our telephone number is (203) 488-6056. Our website address is [www.casmed.com](http://www.casmed.com). The information on or that can be accessed through our website is not a part of this Annual Report on Form 10-K.

#### Item 1A. Risk Factors

Our business faces many risks. If any of the events or circumstances described in the following risk factors actually occurs, our business, financial condition or results of operations could suffer, and the trading price of our common stock could decline. The risks described below may not be the only risks we face. Additional risks that we do not yet know of or that we currently believe are immaterial may also impair our business operations. You should consider the following risks, as well as the other information included or incorporated by reference in this Form 10-K before deciding to invest in our common stock.

***We have a recent history of net losses and are subject to risks regarding future liquidity***

We have experienced operating losses during our two most recent fiscal years. The Company does not anticipate a return to operating profits in the near term and there can be no assurance that we will be able to improve our results of operations in the near term or at all.

Our ordinary short-term capital needs for 2011 are expected to be met from our current cash on hand. However, our 2011 business plans call for additional discretionary expenditures primarily to increase our efforts to develop and market our FORE-SIGHT technology. Those plans are expected to be funded from our current cash on hand and additional capital which the Company will be required to raise. To the extent that the Company is unable secure such funding, it may be required to alter some of its 2011 operating objectives and reduce its planned level of spending.

Cash flows may be impacted by a number of factors, including changing market conditions, market acceptance of the FORE-SIGHT system, and the loss of one or more key customers. Borrowings under our current line-of-credit agreement or any future loan agreement may be impacted by our failure to meet financial covenants or the discretionary actions of our lender. There can be no assurance that we will be successful in raising additional capital or extending our line-of-credit agreement.

***We are a small company in a highly competitive industry***

Competition from other medical device companies, diversified healthcare companies and research and academic institutions is intense and expected to increase. Many companies engaged in the medical device sector have substantially greater financial and other resources and development capabilities than we do, and have substantially greater experience in testing products, obtaining regulatory approvals and manufacturing and marketing medical devices. Therefore, our competitors may succeed in obtaining approval for products more rapidly than we can. Other companies may succeed in developing and commercializing products earlier than we do. In addition to competing with universities and other research institutions in the development of products, technologies and processes, the Company may compete with other companies in acquiring rights to products or technologies from universities. Also, the medical device market is experiencing increasing customer concentration, due to the emergence of large purchasing groups. We cannot assure you that we will develop products that are more effective or achieve greater market acceptance than competitive products, or that our competitors will not succeed in developing products and technologies that are more effective than those being developed by us or that would render our products and technologies less competitive or obsolete. Moreover, there can be no assurance that we will be able to successfully sell to large purchasing groups, which are increasingly looking to suppliers that can provide a broader range of products than we currently offer.

***Our business is impacted by customer concentration***

Our five largest customers accounted for approximately 36% and 30% of revenues in 2010 and 2009, respectively. Among these customers, Medtronic Physio-Control, Inc., customarily the Company's largest single customer accounted for 14% and 12% of revenues during 2010 and 2009, respectively. In addition, the Company has a blanket agreement with the U.S. Department of Veterans Affairs ("VA") for purchase of its vital signs monitors through December 2011. Collective sales to VA hospitals accounted for over 14% of overall sales for each of 2010 and 2009. The failure to renew the blanket agreement with the VA or the loss of any other significant customer could have a material adverse effect on our financial position and results of operations.

***We are devoting substantial resources to the development and marketing of our tissue oximetry products***

We expect to devote a significant amount of resources to continue the development and marketing of our FORE-

SIGHT tissue oximetry products. We believe that substantial additional resources are required to further penetrate the markets for these products. Such investments include further research and development, including significant expenditures for clinical studies, equipment for placements at customer sites, further expansion of our selling organization, marketing expenditures and general working capital requirements. There can be no assurance that we will be successful in these endeavors. In addition, since we have limited financial resources, our emphasis on FORE-SIGHT tissue oximetry products may result in a lack of sufficient resources for our other product lines, which may negatively impact our overall financial results.

***The sale of our products may result in significant product liability exposure***

As a manufacturer of medical diagnostic equipment, we face product liability claims. We maintain product liability insurance in an aggregate amount of \$5 million. We cannot assure you that this insurance coverage will be adequate to cover any product liability claims that occur in the future or that product liability insurance will continue to be available at reasonable prices. We are currently a defendant in a product liability action related to our discontinued infant sleep apnea product line. We believe that our product liability insurance is sufficient to cover any damages and costs that are likely with respect to this matter. Any product liability judgments or settlements in excess of insurance coverage could have a material adverse effect on our business and results of operations.

***Our business could be adversely affected if we cannot protect our proprietary technology or if we infringe on the proprietary technology of others***

Our proprietary technology aids our ability to compete effectively with other companies in certain markets in which we compete. Although we have been awarded, have filed applications for, or have been licensed under numerous patents, these patents may not fully protect our technology or competitive position. Further, our competitors may apply for and obtain patents that will restrict our ability to make and sell our products.

Our competitors may intentionally infringe our patents. Third parties may also assert infringement claims against us. Litigation may be necessary to enforce patents issued to us, to protect our trade secrets or know-how, to defend ourselves against claimed infringement of the rights of others or to determine the scope and validity of the proprietary rights of others. The defense and prosecution of patent suits are both costly and time-consuming, even if the outcome is favorable to us. Such proceedings can be extremely expensive and their outcome very unpredictable. An adverse outcome in the defense of a patent suit could cause us to lose proprietary rights, subject us to significant liabilities to third parties or require us to license rights from third parties or to cease selling our products. Any of these events could have a material adverse effect on our business, operating results and financial condition. We also rely on unpatented proprietary technology that others may independently develop or otherwise obtain access to. Our inability to maintain the proprietary nature of our technologies could negatively affect our revenues and earnings.

***We are subject to significant government regulation***

Our business is subject to varying degrees of governmental regulation in the countries in which we operate. In the United States, our products are subject to regulation as medical devices by the FDA, and by other federal and state agencies. These regulations pertain to the manufacturing, labeling, development and testing of our devices as well as to the maintenance of required records. An FDA regulation also requires prompt reporting by all medical device manufacturers of an event or malfunction involving a medical device where the device caused or contributed to death or serious injury or is likely to do so.

Federal law provides for several routes by which the FDA reviews medical devices before their entry into the marketplace. Medical products of the type currently being marketed and under development by us are subject to regulation under the FD&C Act and numerous acts and amendments such as the Quality System Regulations which replaced the regulations formerly called Good Manufacturing Practices. In addition, depending upon product type, we must also comply with those regulations governing the Conduct of Human Investigations, Pre-Market Regulations and other requirements, as promulgated by the FDA. The FDA is authorized to inspect a device, its labeling and advertising, and the facilities in which it is manufactured in order to ensure that the device is not manufactured or labeled in a manner which could cause it to be injurious to health.

The FDA has adopted regulations which classify medical devices based upon the degree of regulation believed necessary to assure safety and efficacy. A device is classified as a Class I, II, or III device. Class I devices are subject only to general controls. Class II devices, in addition to general controls, are or will be subject to "performance standards." Most devices are also subject to the 510(k) pre-market notification provision. In addition, some Class III devices require FDA pre-market approval before they may be marketed commercially because their safety and effectiveness cannot be assured by the general controls and performance standards of Class I or II devices. Our products are primarily Class I and II devices and several of them have required FDA notification under Section 510(k) of the FD&C Act.

Satisfaction of clearance or approval requirements may take up to several years or more and may vary substantially based upon the type, complexity and novelty of the product. The effect of government regulation may be to delay marketing of new products for a considerable or indefinite period of time, to impose costly procedures upon our activities and to furnish a competitive advantage to larger companies that compete with us. We cannot assure you that FDA or other regulatory clearance or approval for any products we develop will be granted on a timely basis, if at all, or, once granted, that clearances or approvals will not be withdrawn or other regulatory action taken which might limit our ability to market our proposed products. Any delay in obtaining or failure to obtain these clearances or approvals would adversely affect the manufacturing and marketing of our products and the ability to generate additional product revenue. The FDA also has the authority to, among other things, deny marketing approval until all regulatory protocols are deemed acceptable, halt the shipment of defective products, and seize defective products sold to customers. Adverse action or publicity from the FDA, if any, could have a negative impact upon our results from operations.

***Federal regulatory reforms may adversely affect our ability to successfully market our products and impact our financial condition***

Recent federal efforts to reform the U.S. health care industry have resulted in legislation and other measures which will effect changes in healthcare delivery and coverage, and public and private reimbursements for services performed. Federal initiatives may also affect state programs. Legislative changes may affect hospital market expenditures for medical devices, the type and volume of procedures performed, and the demand for new and innovative products. These changes could be significant and may adversely affect the demand for our products, our results of operations, cash flows and our overall financial condition.

Outside of the U.S., healthcare delivery and reimbursement systems vary by country. Efforts to control rising healthcare costs, changes in government sponsored programs and participation and various other economic factors may impact our ability to successfully market our products outside of the U.S.

***We rely to a significant degree on our proprietary rights***

We rely on a combination of patents, trade secrets, trademarks and non-disclosure agreements to protect our proprietary rights. We cannot assure you that our patent applications will result in the issuance of patents or that any patents owned by us now or in the future will afford protection against competitors that develop similar technology. We also cannot assure you that our non-disclosure agreements will provide meaningful protection for our trade secrets or other proprietary information. Moreover, in the absence of patent protection, our business may be adversely affected by competitors who independently develop substantially equivalent or superior technology.

***Our products may become rapidly obsolete***

The areas in which we are developing, distributing, and/or licensing products involve rapidly developing technology. Others may develop products that might cause products being developed, distributed or licensed by us to become obsolete or uneconomical or result in products superior to our products.

***We are subject to currency and related risks***

Our international sales subject us to currency and related risks. We expect that international sales will continue to constitute a significant portion of our business. Although we sell our products in United States dollars and are not subject to significant currency risks, an increase in the value of the United States dollar relative to foreign currencies in our international markets could make our products less price competitive in these markets. Our international sales

accounted for 29% and 33% of our total net sales for the 2010 and 2009 fiscal years, respectively.

***An acquisition of the company may be hindered***

Our Board of Directors is authorized to issue from time to time, without stockholder authorization, shares of preferred stock, in one or more designated series or classes. We are also subject to a Delaware statute regulating business combinations. These provisions could discourage, hinder or preclude an unsolicited acquisition of the Company and could make it less likely that stockholders receive a premium for their shares as a result of any takeover attempt.

***Sales of a substantial number of shares of our common stock in the public market originally issued through the exercise of options or warrants or additional financing transactions could adversely affect the market price of our common stock and would have a dilutive effect upon our shareholders***

Historically, our common stock has been thinly traded. This low trading volume may have had a significant effect on the market price of our common stock, which may not be indicative of the market price in a more liquid market. As of December 31, 2010, options and warrants for the purchase of 1,825,276 shares of our common stock were outstanding. Further, we may seek additional capital to support operating objectives or improve our liquidity.

***We depend highly on certain key management personnel***

We believe that our future success will depend to a significant extent on the efforts and abilities of our senior management, in particular, Thomas Patton, our President and Chief Executive Officer, Matthew Herwig, our Vice President of Sales and Marketing, Dr. Paul Benni, our Chief Scientific Officer and Jeffery Baird, our Chief Financial Officer. The loss of the services of these executives could have a material adverse effect on our business and results of operations.

***We do not expect to pay cash dividends***

We have not paid cash dividends on our common stock since inception, and at this time we do not anticipate that we will pay cash dividends in the foreseeable future.

**Item 1B. Unresolved Staff Comments**

None.

**Item 2. Properties**

The Company currently leases three separate operating facilities as described in further detail below.

On September 6, 2007, the Company closed the sale and leaseback of its headquarters and manufacturing facility in Branford, Connecticut (the "Property") which comprises approximately 24,000 square feet of office and manufacturing space. Net proceeds from the sale were \$2,791,529 of which \$928,872 was used to retire the related outstanding mortgage debt. The gain of \$1,346,373 realized on the sale was deferred and is being recognized in operations against rent expense over the initial term of the lease. The lease has an initial term of ten years expiring on September 6, 2017 and contains an option for two additional five-year periods. The lease provides for an annual base rent in years one through five of \$244,800 and \$268,800 in years six through ten. The Company is recognizing rent expense on a straight-line basis over the ten years. Under the lease, the Company is responsible for the costs of utilities, insurance, taxes and maintenance expenses. Further, the Company is required to maintain at least \$600,000 in cash and cash equivalents (increasing at 3% per annum) and net current assets of not less than \$3,600,000.

In addition, the Company has a right of first offer to lease any additional space or building built by the lessor on the Property, subject to certain restrictions. The Company also has the right to require the lessor to build an addition or additional building ("Expansion Premises"), subject to certain restrictions. Upon the delivery of any Expansion Premises, the term of the Lease would extend for a ten year term. The base rent for the Expansion Premises would be the greater of the then prevailing market rent or an amount equal to a return on actual costs of construction of the greater of 250 basis points over the rate on ten year U.S. Treasury Notes, or 8%. Upon delivery of the Expansion

Premises, the lessor would assume obligations under the Company's leases of its two adjacent properties, in exchange for a payment equal to three months rent and certain unamortized costs incurred in these facilities.

The Company is leasing two properties adjacent to its corporate facilities. Approximately 8,300 square feet of office and limited warehouse space is being leased under an agreement effective June 1, 2006, as amended, and expiring on May 31, 2014. Minimum annual rental expense is approximately \$84,000 excluding apportioned real estate taxes and certain utility costs. Approximately 9,600 square feet of office and warehouse space is being leased under an agreement effective July 1, 2007, as amended and expiring June 30, 2015. Minimum annual rental expense is approximately \$89,000 excluding apportioned real estate taxes and certain common area maintenance charges.

The Company believes that its premises meet its current and expected operating needs and are adequately insured.

### Item 3. Legal Proceedings

The manufacture and sale of our products exposes us to product liability claims and product recalls, including those which may arise from misuse or malfunction of, or design flaws in, our products or use of our products with components or systems not manufactured or sold by us. Product liability claims or product recalls, regardless of their ultimate outcome, could require us to spend significant time and money in litigation or to pay significant damages. We are currently a defendant in a product liability action related to our former sleep apnea product line. We believe that our product liability insurance is sufficient to cover any damages and costs that are likely with respect to this matter. There can be no assurance however, that this will be the case with respect to this matter or any future matters. Furthermore, we may not be able to obtain insurance in the future at satisfactory rates or in adequate amounts. In addition, publicity pertaining to the misuse or malfunction of, or design flaws in, our products could impair our ability to successfully market and sell our products and could lead to product recalls.

In addition, we may become in the normal course of our business operations, a party to other legal proceedings in addition to those described in the paragraph above. None of these other proceedings would be expected to have a material adverse impact on our results of operations, financial condition, or cash flows.

On August 7, 2009, Somanetics Corporation filed an action against the Company in the United States District Court for the Eastern District of Michigan alleging patent infringement, false advertising, and common law unfair competition and libel. The complaint requested injunctive relief and unspecified monetary damages, including treble damages and reasonable attorneys' fees. On October 19, 2009, the Company answered the complaint, denying all allegations against it. In addition, the Company asserted counterclaims against Somanetics for violation of the antitrust laws and for a declaration that the patents sued upon were invalid, unenforceable, and/or have not been infringed by the Company.

On October 27, 2010, a settlement was reached with Nellcor Puritan Bennett, LLC, a successor in interest to Somanetics Corporation, on Somanetics' action for patent infringement and other claims against the Company. The terms of the confidential settlement resolved all matters between the two parties as of the initiation of the lawsuit and caused the dismissal of the action with prejudice in a manner by which no payments were made to either party. The Company incurred \$737,000 of legal expenses during 2010 related to this matter.

## **PART II**

### Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

The common stock of the Company trades on the NASDAQ Global Market, under the symbol "CASM."

The following table shows the high and low sales prices for the Company's common stock during each quarterly period for the last two years.

<u>Quarter Ended</u>	<u>High</u>	<u>Low</u>
March 31, 2009	\$2.18	\$0.90
June 30, 2009	\$2.23	\$1.15
September 30, 2009	\$3.90	\$1.16
December 31, 2009	\$2.12	\$1.50
March 31, 2010	\$2.30	\$1.53
June 30, 2010	\$2.04	\$1.26
September 30, 2010	\$2.51	\$1.63
December 31, 2010	\$3.54	\$2.09

The following table sets forth the approximate number of beneficial owners of common stock of the Company on December 31, 2010.

<u>Title of Class</u>	<u>Number of Shareholders</u>
Common stock, \$.004 par value	1,915

To date, no cash dividends have been declared on the Company's common stock. The Company does not currently intend to pay a cash dividend in the near future.

The Company did not issue any shares of common stock during the fourth quarter of 2010 that were not registered under the Securities Act of 1933, as amended. In addition, the Company did not repurchase any of its common stock during the fourth quarter of 2010.

#### Item 6. Selected Financial Data

Information is not required for smaller reporting company filers.

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

Certain statements included in this report, including without limitation statements in the Management's Discussion and Analysis of Financial Condition and Results of Operations, which are not historical facts, are "forward looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements represent the Company's current expectations regarding future events. The Company cautions that such statements are qualified by important factors that could cause actual results to differ materially from expected results which may be contained in the forward-looking statements. All forward-looking statements involve risks and uncertainties, including, but not limited to, the following: potential liquidity constraints; price and product competition; rapid technological changes; dependence on new product development; failure to introduce new products effectively or on a timely basis; the mix of products sold; supply and prices of raw materials and products; customer demand for the Company's products; regulatory actions; changes in reimbursement levels from third-party payors; product liability or other litigation claims; changes in economic conditions that adversely affect the level of demand for the Company's products; changes in foreign exchange markets; changes in financial markets; changes in the competitive environment; and other risks described in Item 1A of this filing.

#### Overview

During 2010, the Company took several major steps toward revitalizing its business operations with the goal of positioning itself to achieve high levels of revenue growth of its FORE-SIGHT products, and to return its Traditional Monitoring products to overall growth in the near future.

## **Management and Board of Director Appointments**

- On August 27, 2010, the Company appointed Thomas M. Patton as President and CEO and as a Director of the Company. Mr. Patton is a seasoned executive in the medical products field with a broad range of operational and strategic experience from start-ups to growth companies, both public and private.
- On January 10, 2011, the Company announced that it had hired Matthew J. Herwig as its Vice President of Global Sales and Marketing. Mr. Herwig has more than twenty years of experience in the medical products field including various senior leadership positions in both sales and marketing functions.
- On April 1, 2010, the Board of Directors appointed Kenneth R. Weisshaar as a Director of the Company. Mr. Weisshaar brings extensive experience in financial operations within the medical technology environment, in strategic planning and management consulting.
- On October 28, 2010, the Board of Directors appointed Gregory P. Rainey as a Director of the Company as the Board expanded from six members to seven members. Mr. Rainey brings broad expertise in the healthcare field with more than twenty-five years of experience in medical products sales.

## **Settlement of patent infringement suit**

- On October 27, 2010, the Company announced the settlement of an ongoing patent suit brought against it by a major competitor.

## **Sale and exit of non-strategic product lines**

- Effective July 31, 2010, the Company exited the market for sales of cardio-respiratory products previously supplied to it by the Analogic Corporation.
- On November 5, 2010, the Company consummated the sale of its non-strategic Statcorp business unit, which included its blood pressure cuff and rapid infusor cuff product lines, for \$3.2 million in cash, plus the potential for an additional \$350,000 payment upon reaching specified revenue targets six months from the date of the transaction.
- During 2010, the Company completed its exit of the infant sleep apnea product line.

## **Capital raise and debt reduction**

- During June 2010, the Company consummated a non-brokered private sale of 1,375,000 shares of its common stock for net proceeds of \$1,887,000.
- The Company utilized a portion of the proceeds from the Statcorp transaction during November 2010 to fully retire its bank term debt in the amount of \$1.1 million and pay down the remaining \$500,000 balance against its line-of-credit agreement. As of December 31, 2010, the Company had approximately \$4.5 million of cash on hand and no bank debt.

The following discussion and analysis should be read together with our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K.

### Year Ended December 31, 2010 Compared to Year Ended December 31, 2009

As a result of the sale of the Company's Statcorp business unit on November 5, 2010, those operations are classified as discontinued operations for all reported periods.

The Company recorded a net loss of \$1,305,000 for 2010 or (\$0.11) per basic and diluted common share compared

to a net loss of \$5,790,000, or (\$0.51) per basic and diluted common share, for 2009. The net loss from continuing operations for 2010 was \$1,600,000, or (\$0.13) per basic and diluted common share, compared to a loss from continuing operations for 2009 of \$3,710,000, or (\$0.33) per basic and diluted common share. The reduction in losses from continuing operations of \$2,110,000 for 2010 from 2009 were due to decreases in operating expenses initiated during 2009 in response to difficult economic conditions.

The gain from discontinued operations was \$295,000, or \$0.02 per basic and diluted common share, for 2010 compared to a loss of \$2,079,000, or (\$0.18), for 2009. The results from discontinued operations for 2009 include a goodwill impairment charge of \$2,156,000. The results were also net of income tax expenses of \$159,000 and \$53,000 for 2010 and 2009, respectively.

The following table provides comparative results of net sales by product and geographic category:

(\$000's)	<u>Year Ended December 31, 2010</u>	<u>Year Ended December 31, 2009</u>	<u>Increase/ (Decrease)</u>
Traditional Vital Signs Monitoring	\$18,265	\$18,556	\$ (291)
Tissue Oximetry Monitoring	<u>5,264</u>	<u>4,093</u>	<u>1,171</u>
	23,529	22,649	880
Discontinued products – Apnea/Analogic	<u>557</u>	<u>2,392</u>	<u>(1,835)</u>
	<u>\$24,086</u>	<u>\$25,041</u>	<u>\$ (955)</u>
Domestic Sales	\$17,132	\$16,680	\$ 452
International Sales	<u>6,954</u>	<u>8,361</u>	<u>(1,407)</u>
	<u>\$24,086</u>	<u>\$25,041</u>	<u>\$ (955)</u>

Overall, net worldwide sales for 2010 decreased \$955,000 or 4% to \$24,086,000 from \$25,041,000 in 2009. Excluding sales of the discontinued apnea product line, revenues increased approximately 4% driven by strong increases in Tissue Oximetry products partially offset by weakness in sales of bedside monitors within our Traditional Monitoring products.

Tissue Oximetry sales, comprised of FORE-SIGHT tissue oximetry monitors, sensors and accessories, increased \$1,171,000 or 29% to \$5,264,000 from \$4,093,000 for 2009.

Despite a 7% increase in OEM sales of the Company's proprietary non-invasive blood pressure ("NIBP") technology, Traditional Vital Signs Monitoring sales decreased \$291,000 or 2% primarily due to lower international sales of bedside vital signs monitoring products. Supplies and service sales were relatively unchanged for 2010 from 2009. Supplies sales are primarily comprised of the Company's line of specialty neonatal products. Service sales include parts and labor for monitors previously sold.

During 2010, the Company concluded its exit from the infant sleep apnea market and terminated its agreement to distribute co-branded products manufactured by the Analogic Corporation. Those sales have been reported separately above and declined \$1,835,000 from 2009 sales levels.

Domestic sales increased \$452,000, or 3%, to \$17,132,000, or 71% of total revenues from \$16,680,000 for 2009 primarily due to a 29% increase in Tissue Oximetry product sales. Decreases in domestic Traditional Monitoring sales partially offset the Tissue Oximetry sales increases due to reductions in apnea product sales, Analogic product sales and bedside vital signs monitoring sales.

International sales declined \$1,407,000, or 17%, to \$6,954,000, or 29% of total revenues, from \$8,361,000 for 2009. Lower Traditional Monitoring product sales including bedside vital signs monitors, apnea products and Analogic products accounted for the decrease in sales. Strong Tissue Oximetry sales partially offset these declines, increasing 31% over 2009 levels.

Cost of sales as a percentage of net sales was 59% for both 2010 and 2009. Management expects to realize improvements in cost of sales as a percentage of sales for 2011 from productivity enhancements, improvements in inventory control, and certain product cost reductions from engineering design improvements.

R&D expenses decreased \$754,000, or 31%, to \$1,689,000 for 2010 from \$2,443,000 for 2009. Lower personnel headcount due to various reductions initiated during 2009 and reduced engineering project expenditures accounted for the decreases. The Company began hiring additional R&D personnel in the fourth quarter of 2010.

R&D expenses are reported net of reimbursements received from the National Institutes of Health (“NIH”) pertaining to the Company’s development of its Near-Infrared Spectroscopy (“NIRS”) technology. Amounts reimbursed from the NIH, including accruals, for 2010 and 2009 were \$483,000 and \$737,000, respectively. During September 2007 the Company was awarded a three year grant, which has subsequently been extended, totaling approximately \$2,800,000 to support its NIRS research. As of December 31, 2010, a maximum of approximately \$684,000 remains available under the grant. During 2010, the Company also received various federal and states tax incentives approximating \$303,000. R&D expenses before NIH reimbursements and tax incentives approximated 10% and 13%, respectively, of 2010 and 2009 revenues. R&D expenses are expected to increase significantly for 2011 due to various planned engineering project expenses, expanded clinical research expenditures and additional personnel which were added at the end of the 2010 calendar year.

Selling, general and administrative expenses decreased \$1,317,000, or 12%, to \$9,957,000 for 2010 from \$11,274,000 for 2009. Decreases in expenses were primarily associated with sales and marketing personnel reductions implemented during both May and November 2009. General and administrative expenses increased \$815,000 primarily due to increases in legal expenses associated with the Somanetics Corporation litigation which was settled during October 2010. Sales and marketing expenses are expected to increase during 2011 primarily from increases in field-based sales spending and additional marketing personnel and promotional expenditures.

Net interest expense decreased \$43,000 to \$60,000 for 2010 from \$103,000 for 2009 as a result of reduced average balances on the Company’s line-of-credit.

The income tax benefit for 2010 was \$148,000 compared to income tax expense of \$179,000 for 2009. The income tax expenses for 2009 related to the recording of a deferred income tax asset valuation allowance of \$1,449,000, which was partially offset by pre-tax operating losses.

#### Financial Condition, Liquidity and Capital Resources

The Company’s cash and cash equivalents were \$4,493,000 at December 31, 2010 compared to \$1,187,000 at December 31, 2009. Working capital increased \$721,000 to \$9,043,000 at December 31, 2010 from \$8,322,000 at December 31, 2009. The Company’s current ratio increased to 3.83 to 1 from 2.10 to 1.

The Company’s continuing operations used \$980,000 in cash for 2010 compared to \$3,160,000 for 2009. Cash provided from discontinued operations for 2010 was approximately \$4,286,000 which was primarily driven by the sale of the Statcorp business unit for \$3,200,000 during November 2010.

Net cash provided by operating activities of continuing operations for 2010 was \$2,532,000 compared to net cash used of \$2,814,000 for the prior year. Reductions in accounts receivable, inventories and recoverable income taxes together with increases in accounts payable and accrued expenses, were key drivers to the improvement in cash provided from the operating activities of continuing operations for 2010.

Net cash used by investing activities of continuing operations was \$960,000 for 2010 compared to cash used of \$372,000 for 2009. The Company incurred \$875,000 of capital expenditures during 2010 compared to \$259,000 for 2009. Equipment purchases during 2010 were driven by FORE-SIGHT oximeter monitor placements with customers, demonstration equipment and clinical research units. During 2011, the Company expects to further increase its expenditures in these areas. The Company also incurred \$85,000 of expenditures during 2010 to purchase intangible assets, which was primarily related to patent development costs.

Net cash used by financing activities of continuing operations was \$2,552,000 for 2010 compared to cash provided of \$26,000 for 2009. The Company repaid \$1,709,000 of long-term debt and \$2,670,000 against its line-of-credit agreement during 2010. A non-brokered private placement of 1,375,000 shares of the Company's common stock was consummated during June 2010 which provided approximately \$1,887,000 of net proceeds.

The Company currently leases three facilities and certain equipment under non-cancellable operating leases. The following table sets forth a summary of the Company's cash commitments under contractual obligations as of December 31, 2010.

<b><u>Contractual Obligations</u></b>	<b><u>Total</u></b>	<b><u>Less than One Year</u></b>	<b><u>2 - 3 Years</u></b>	<b><u>4 - 5 Years</u></b>	<b><u>More Than Five Years</u></b>
Operating leases	\$2,536,000	\$432,000	\$910,000	\$746,000	\$448,000

The Company maintains a line-of-credit facility with its primary lender. On March 11, 2010, the line-of-credit was amended by the Third Modification Agreement (the "Third Modification"). The Third Modification amended the Loan Agreement and the related promissory note each as previously amended. Under the Third Modification, the maturity date was extended to April 1, 2011 and the interest rate for the revolving loans under the Loan Agreement was increased from the Bank's Base Rate (as defined therein) plus 1.0% with a minimum of 4.0% per annum to the Bank's Base Rate (as defined therein) plus 2.0% with a minimum interest rate of 5.0% per annum. The interest rate effective upon execution of the Third Modification was 5.25% per annum. Additionally, the Third Modification amended the existing debt service coverage ratio covenant from 1.5 to 1.0 to 1.25 to 1.0, tested beginning March 31, 2010 and quarterly thereafter, measured on a year-to-date basis. The Bank waived the testing of the debt service coverage ratio covenants as of December 31, 2009 and 2010.

The Company is working with its lender to extend the line-of-credit facility to April 1, 2012. The Company has executed a non-binding financing proposal and issued a deposit with the intent to consummate an agreement during April 2011. While management is confident it will be successful in securing an agreement with its lender, there can be no assurance that we will be successful or that the terms under the agreement will be substantially equivalent to the current agreement.

During June 2010, the Company consummated a private placement of its common stock which raised approximately \$1,887,000.

During November 2010, the Company sold the Statcorp business unit for \$3,200,000 which was comprised of its blood pressure cuff and rapid infusor cuff product line which were considered to be non-strategic and used a portion of the proceeds to retire its long-term debt which had a balance of \$1,168,000 at closing and eliminate the outstanding balance of \$500,000 of its line-of-credit.

During 2010, the Company also received a refund of \$816,000 related to federal net operating loss carry backs from its 2009 income taxes. The Company also received \$245,000 from a federal R&D grant under the Patient Protection and Affordable Care Act of 2010.

Our ordinary short-term capital needs for 2011 are expected to be met from our current cash on hand. However, our 2011 business plans call for additional discretionary expenditures primarily to increase our efforts to develop and market our FORE-SIGHT technology. Those plans are expected to be funded from our current cash on hand and additional capital which the Company will be required to raise. To the extent that the Company is unable to secure such funding, it may be required to alter some of its 2011 operating objectives and reduce its planned level of spending.

Cash flows may be impacted by a number of factors, including changing market conditions, market acceptance of the FORE-SIGHT system, and the loss of one or more key customers. Borrowings under our current line-of-credit agreement or any future loan agreement may be impacted by our failure to meet financial covenants or the discretionary actions of our lender. There can be no assurance that we will be successful in raising additional capital or extending our line-of-credit agreement.

The Company's results of operations were not affected by inflation during 2010.

#### Off-Balance Sheet Arrangements

The Company has no off-balance sheet arrangements other than operating leases for office and warehouse space.

#### Critical Accounting Policies

The Company's financial statements have been prepared in accordance with generally accepted accounting principles in the United States. In preparing the financial statements, the Company is required to make estimated judgments. Such judgments are based upon historical experience and certain assumptions that are believed to be reasonable in the particular circumstances. Those judgments affect both balance sheet and income statement accounts and disclosures. The Company evaluates its assumptions on an ongoing basis by comparing actual results with its estimates. Actual results may differ from the original estimates. The following accounting policies are those that the Company believes to be most critical to the preparation of its financial statements.

Inventory Valuation—The Company's inventories are stated at the lower of cost or market. The Company provides allowances on inventories for any material that has become obsolete or may become unsalable based on estimates of future demand and the sale price in the market. Judgments with respect to salability and usage of inventories, estimated market value, and recoverability upon sale are complex and subjective. Such assumptions are reviewed periodically and adjustments are made, as necessary, to reflect changed conditions. There were no significant write-offs for any period presented with the exception of the discontinued infant sleep apnea product line.

Deferred Income Tax Assets — The Company has recorded deferred income tax assets for the estimated benefit of future tax deductions on inventories, property and equipment and other accruals, as well as net operating loss carry forwards and tax credits. Based on recent cumulative pre-tax losses and the Company's estimates of future taxable income, management has established a deferred tax asset valuation allowance.

Accrued Warranty Costs — The Company warrants its products for up to three years and records the estimated cost of such product warranties at the time the sale is recorded. Estimated warranty costs are based upon actual past experience of product returns and the related estimated cost of labor and material to make the necessary repairs. Warranty costs have not been material to operating results over the past several years. However, if actual future product return rates or the actual costs of material and labor differ from the estimates, adjustments to the accrued warranty liability would be made.

Stock-based Compensation - The Company records the fair value of stock-based compensation awards as expenses in its consolidated statement of operations. In order to determine the fair value of stock options on the date of grant, we apply the Black-Scholes option-pricing model. Inherent in this model are assumptions related to expected dividend yield, risk-free interest rate, expected stock-price volatility, expected term, and forfeiture rate. Restricted stock awards are generally valued upon the closing price of the common stock on the date of the grant. Amortization of stock-based awards takes place over the vesting period associated with the award.

Revenue and Accounts Receivable Recognition - Revenue from sales and accounts receivable are recognized when evidence of an arrangement exists, delivery has occurred based upon shipping terms, the selling price is fixed and determinable, and collectability is reasonably assured. Terms of sale for most domestic sales are FOB origin and for most international sales are EX-Works reflecting that ownership and risk of loss are assumed by the buyer at the shipping point. In addition, the Company has certain agreements with its customers to ship FOB destination reflecting that ownership and risk of loss are assumed by the buyer upon delivery. While the Company accepts returns of products from its customers from time to time for various reasons including defective goods, order entry, shipping or other errors, the Company's business practices do not include providing right of return at the time of sale. Historically, such returns have not been significant. The Company has entered into agreements with several customers to provide them with price rebates based upon their level of purchases. Rebates are accrued by the Company as a reduction in net sales as they are earned by customers. Payment terms range from prepayment to net sixty days depending upon certain factors including customer credit worthiness, geographic location and customer type (i.e., end-user, distributor, government or private entity) and also includes irrevocable letters of credit for certain international shipments. Price discounts that may be taken by customers under contractual arrangements for

payment of invoices within specified periods are recorded as reductions to net sales. Further, the Company accrues expected payment discounts based upon specific customer accounts receivable balances. The Company does not incur post shipment obligations with the exception of product warranties which are generally fulfilled from the Company's corporate facilities and which costs are not material relative to the sale of the product. Accounts receivable are charged to the allowance for doubtful accounts when deemed uncollectible.

#### Recent Accounting Pronouncements

In October 2009, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update 2009-13 ("ASU 2009-13") with respect to Subtopic 605-25, Revenue Recognition – Multiple Element Arrangements of the FASB Accounting Standards Codification. This guidance updates and addresses the measurement and separation of revenues in multiple deliverable activities and significantly expands the related disclosures. The amendments in FASB ASU 2009-13 are effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. The Company plans to adopt FASB ASU 2009-13 effective January 1, 2011. The Company does not expect the adoption to impact the Company's financial position or results of operations.

In January 2010, the FASB issued Accounting Standards Update 2010-06 ("ASU 2010-06") related to Fair Value Measurements and Disclosures – Overall Subtopic 820-10 of the FASB Accounting Standards Codification. This guidance updates and improves the disclosures about valuation techniques and inputs to fair value measurements. The amendments in FASB ASU 2010-06 are effective for fiscal years beginning after December 15, 2010 and for interim periods within those fiscal years. The Company plans to adopt FASB ASU 2010-06 effective January 1, 2011. The Company does not expect the adoption to impact the Company's financial position or results of operations.

#### Item 7A. Quantitative and Qualitative Disclosures about Market Risk

The Company has certain exposures to market risk related to changes in interest rates. The Company has an outstanding line-of-credit agreement however there was no outstanding balance as of December 31, 2010. The line-of-credit agreement, amended effective March 11, 2010, bears interest at variable rates based on prime rate indices. The Company holds no derivative securities for trading purposes and is not subject in any material respect to currency or other commodity risk.

<u>Item 8. Financial Statements and Supplementary Data</u>	Page
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**Report of J.H. Cohn LLP, Independent Registered Public Accounting Firm**

Shareholders and Board of Directors  
CAS Medical Systems, Inc:

We have audited the accompanying consolidated balance sheet of CAS Medical Systems, Inc. (the "Company") as of December 31, 2010, and the related consolidated statements of operations, changes in shareholders' equity and cash flows for the year then ended. The Company's management is responsible for these financial statements. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (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 audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2010, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ J.H. Cohn LLP

Glastonbury, Connecticut  
March 24, 2011

**Report of Independent Registered Public Accounting Firm**

To the Board of Directors of  
CAS Medical Systems, Inc.

We have audited the accompanying consolidated balance sheet of CAS Medical Systems, Inc. and subsidiaries (the “Company”) as of December 31, 2009, and the related consolidated statements of operations, changes in stockholders’ equity, and cash flows for the year then ended. These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (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. The Company is not required to have, nor were we engaged to perform, an audit of the Company’s internal control over financial reporting. An audit includes consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides 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 the Company as of December 31, 2009, and the consolidated results of their operations and their cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ UHY LLP

New Haven, Connecticut  
March 29, 2010, except for Note 3 as to which  
the date is March 24, 2011

**CAS MEDICAL SYSTEMS, INC.**  
Consolidated Balance Sheets  
As of December 31, 2010 and 2009

<b>ASSETS</b>	<b><u>2010</u></b>	<b><u>2009</u></b>
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 4,492,690	\$1,186,779
Accounts receivable, less allowance of \$175,000 in 2010 and 2009	2,606,616	3,350,792
Recoverable income taxes	13,655	871,206
Inventories	4,812,965	5,782,638
Other current assets	310,187	374,547
Assets associated with discontinued operations (Note 3)	-	4,346,609
Total current assets	<u>12,236,113</u>	<u>15,912,571</u>
<b>PROPERTY AND EQUIPMENT:</b>		
Leasehold improvements	252,517	252,517
Equipment at customers	1,686,919	1,219,418
Machinery and equipment	<u>5,114,460</u>	<u>4,761,069</u>
	7,053,896	6,233,004
Accumulated depreciation and amortization	<u>(5,244,819)</u>	<u>(4,511,753)</u>
Property and equipment, net	1,809,077	1,721,251
<b>INTANGIBLE AND OTHER ASSETS, net</b>	<u>651,626</u>	<u>616,631</u>
Total assets	<u>\$14,696,816</u>	<u>\$18,250,453</u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Current portion of long-term debt	\$ --	\$ 652,482
Line-of-credit	-	2,669,657
Note payable	-	50,678
Accounts payable	2,283,906	1,407,672
Accrued expenses	909,331	1,229,162
Liabilities associated with discontinued operations (Note 3)	-	524,515
Total current liabilities	<u>3,193,237</u>	<u>6,534,166</u>
<b>LONG-TERM DEBT</b>	-	1,056,273
<b>DEFERRED GAIN ON SALE AND LEASEBACK OF PROPERTY</b>	899,426	1,034,064
<b>INCOME TAXES PAYABLE</b>	211,159	277,280
<b>COMMITMENTS AND CONTINGENCIES (Note 13)</b>	-	-
Total liabilities	<u>4,303,822</u>	<u>8,901,783</u>
<b>SHAREHOLDERS' EQUITY:</b>		
Series A cumulative convertible preferred stock, \$.001 par value per share, 1,000,000 shares authorized, no shares issued or outstanding	-	-
Common stock, \$.004 par value per share, 40,000,000 shares authorized, 13,575,401 and 11,610,075 shares issued as of December 31, 2010 and 2009, respectively, including shares held in treasury	54,302	46,440
Common stock held in treasury, at cost – 86,000 shares	(101,480)	(101,480)
Additional paid-in capital	10,002,600	7,661,061
Retained earnings	<u>437,572</u>	<u>1,742,649</u>
Total shareholders' equity	<u>10,392,994</u>	<u>9,348,670</u>
Total liabilities and shareholders' equity	<u>\$14,696,816</u>	<u>\$18,250,453</u>

See accompanying notes.

**CAS MEDICAL SYSTEMS, INC.**

Consolidated Statements of Operations  
For the Years Ended December 31, 2010 and 2009

	<u>2010</u>	<u>2009</u>
NET SALES	\$24,086,011	\$25,041,298
COST OF SALES	<u>14,128,200</u>	<u>14,753,076</u>
Gross profit	9,957,811	10,288,222
OPERATING EXPENSES:		
Research and development	1,689,167	2,442,920
Selling, general and administrative	<u>9,956,638</u>	<u>11,274,314</u>
	<u>11,645,805</u>	<u>13,717,234</u>
OPERATING LOSS FROM CONTINUING OPERATIONS	(1,687,994)	(3,429,012)
Interest expense, net	<u>59,927</u>	<u>102,796</u>
LOSS FROM CONTINUING OPERATIONS BEFORE INCOME TAXES	(1,747,921)	(3,531,808)
Income tax (benefit) expense	<u>(147,923)</u>	<u>178,515</u>
LOSS FROM CONTINUING OPERATIONS	(1,599,998)	(3,710,323)
INCOME (LOSS) FROM DISCONTINUED OPERATIONS, NET OF INCOME TAXES	<u>294,921</u>	<u>(2,079,341)</u>
NET LOSS	<u>\$(1,305,077)</u>	<u>\$(5,789,664)</u>
LOSS PER COMMON SHARE FROM CONTINUING OPERATIONS - basic and diluted	\$(0.13)	\$(0.33)
INCOME (LOSS) PER COMMON SHARE FROM DISCONTINUED OPERATIONS – basic and diluted	<u>0.02</u>	<u>(0.18)</u>
NET LOSS PER COMMON SHARE – basic and diluted	<u>\$(0.11)</u>	<u>\$(0.51)</u>
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING - basic and diluted	<u>12,175,812</u>	<u>11,260,553</u>

See accompanying notes.

**CAS MEDICAL SYSTEMS, INC.**

Consolidated Statements of Changes in Shareholders' Equity  
For the Years Ended December 31, 2010 and 2009

	<u>Common Stock</u>		<u>Held in Treasury</u>		<u>Additional Paid-in Capital</u>	<u>Retained Earnings</u>	<u>Total</u>
	<u>Issued Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>			
<b>BALANCE, December 31, 2008</b>	<b>11,419,535</b>	<b>\$ 45,675</b>	<b>86,000</b>	<b>\$(101,480)</b>	<b>\$7,423,340</b>	<b>\$7,532,313</b>	<b>\$14,899,848</b>
Net loss						(5,789,664)	(5,789,664)
Common stock issued upon exercise of stock options	24,700	99			23,542		23,641
Common stock issued under stock purchase plan	37,813	151			60,581		60,732
Restricted stock issued under equity incentive plans, net of cancellations	128,027	515			(515)		-
Deferred income taxes regarding restricted stock					(170,757)		(170,757)
Stock compensation					<u>324,870</u>		<u>324,870</u>
<b>BALANCE, December 31, 2009</b>	<b>11,610,075</b>	<b>46,440</b>	<b>86,000</b>	<b>(101,480)</b>	<b>7,661,061</b>	<b>1,742,649</b>	<b>9,348,670</b>
Net loss						(1,305,077)	(1,305,077)
Common stock issued upon exercise of stock options and warrants	145,300	581			91,319		91,900
Common stock issued under stock purchase plan	12,305	49			22,180		22,229
Restricted stock issued, net of cancellations	432,721	1,732			(1,732)		-
Private placement	1,375,000	5,500			1,881,112		1,886,612
Stock compensation					<u>348,660</u>		<u>348,660</u>
<b>BALANCE, December 31, 2010</b>	<b><u>13,575,401</u></b>	<b><u>\$54,302</u></b>	<b><u>86,000</u></b>	<b><u>\$(101,480)</u></b>	<b><u>\$10,002,600</u></b>	<b><u>\$437,572</u></b>	<b><u>\$10,392,994</u></b>

See accompanying notes.

Consolidated Statements of Cash Flows  
For the Years Ended December 31, 2010 and 2009

	<u>2010</u>	<u>2009</u>
<b>OPERATING ACTIVITIES:</b>		
<b>Cash flows from operating activities</b>		
Net loss	\$(1,305,077)	\$(5,789,664)
Income (loss) from discontinued operations	<u>294,921</u>	<u>(2,079,341)</u>
Loss from continuing operations	(1,599,998)	(3,710,323)
Adjustments to reconcile net loss from continuing operations to net cash provided by (used in) operating activities:		
Depreciation and amortization	960,450	1,070,340
Deferred income taxes	(158,803)	1,041,863
Provision for doubtful accounts	35,760	63,689
Stock compensation	338,685	324,870
Impairment of assets	-	107,768
Amortization of gain on sale and leaseback	(134,638)	(134,637)
Changes in operating assets and liabilities:		
Accounts receivable	708,416	(1,378,673)
Recoverable income taxes	857,551	(770,021)
Inventories	969,673	324,434
Other current assets	64,360	22,658
Accounts payable and accrued expenses	556,403	102,265
Income taxes payable	<u>(66,121)</u>	<u>121,405</u>
Net cash provided (used) by operating activities of continuing operations	<u>2,531,738</u>	<u>(2,814,362)</u>
<b>INVESTING ACTIVITIES:</b>		
Purchases of property and equipment	(875,110)	(258,957)
Purchases of intangible assets	<u>(84,942)</u>	<u>(112,967)</u>
Net cash used by investing activities of continuing operations	<u>(960,052)</u>	<u>(371,924)</u>
<b>FINANCING ACTIVITIES:</b>		
Borrowings under notes payable	183,656	223,175
Repayments of notes payable	(234,334)	(172,497)
Repayments (borrowings) under line-of-credit, net	(2,669,657)	675,649
Repayments of long-term debt	(1,708,755)	(613,805)
Deferred financing costs	(123,219)	-
Income tax reversal related to equity instruments	-	(170,757)
Proceeds from issuance of common stock	<u>2,000,741</u>	<u>84,373</u>
Net cash (used) provided by financing activities of continuing operations	<u>(2,551,568)</u>	<u>26,138</u>
Net cash used by continuing operations	<u>(979,882)</u>	<u>(3,160,148)</u>
<b>Cash flows from discontinued operations</b>		
Cash provided by operating activities of discontinued operations	940,409	3,264,308
Cash provided by investing activities of discontinued operations	<u>3,345,384</u>	<u>-</u>
Net cash provided by discontinued operations	<u>4,285,793</u>	<u>3,264,308</u>
Net change in cash and cash equivalents	3,305,911	104,160
Cash and cash equivalents, beginning of year	<u>1,186,779</u>	<u>1,082,619</u>
CASH AND CASH EQUIVALENTS, END OF YEAR	<u>\$4,492,690</u>	<u>\$1,186,779</u>
<b>SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:</b>		
Cash paid during the year for interest	\$152,670	\$224,059
Cash paid (collected) during the year for income taxes, net	\$(827,895)	\$9,318

See accompanying notes

**CAS MEDICAL SYSTEMS, INC.**

## Notes to Consolidated Financial Statements

**(1) THE COMPANY**

CAS Medical Systems, Inc. (“CASMED”) develops, manufactures and distributes non-invasive vital signs monitoring equipment and products for use in the healthcare industry. These products are sold by the Company through its own sales force, via distributors and manufacturers representatives under contract, and pursuant to original equipment manufacturer (“OEM”) agreements both internationally and in the United States. The Company’s operations and manufacturing facilities are located in the United States. During 2010 and 2009, one customer accounted for approximately 14% and 12%, respectively, of net sales. The Company generated international sales of approximately \$7.0 million in 2010 and \$8.4 million in 2009. In the normal course of business, the Company grants credit to its customers and does not require collateral. Credit losses are provided for in the period the related sales are recognized based upon experience and an evaluation of the likelihood of collection. Credit losses have been within management’s expectations.

**(2) SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES****Use of estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of sales and expenses during the reporting period. Estimates that are particularly sensitive to change in the near-term are inventory valuation allowances, deferred income tax asset valuation allowances, allowance for doubtful accounts and warranty accrual. Actual results could differ from those estimates.

**Principles of consolidation**

Through November 4, 2010, the consolidated financial statements included the accounts of CASMED and its wholly-owned subsidiary, Statcorp, Inc. (“Statcorp”). On November 5, 2010, the assets related to Statcorp were sold under an asset purchase agreement. Accordingly, the consolidated financial statements for all periods reported reflect the results of that operation as discontinued and all assets related to the operation and held as of December 31, 2009 are stated as assets associated with discontinued operations (see Note 3). Further, all 2009 notes to the financial statements have been restated to conform to this change. All intercompany accounts and transactions are eliminated in consolidation.

**Cash and cash equivalents**

The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. The Company has deposits in a limited number of financial institutions with federally insured limits. Cash (including cash equivalents) at these institutions is normally in excess of the insured limits. However, the Company believes that the institutions are financially sound and there is only nominal risk of loss.

**Inventories**

Inventories are stated at the lower of cost, determined by the first-in, first-out method, or market.

### Property and equipment

Property and equipment, including leasehold improvements, are stated at cost. Depreciation is computed using the straight-line method based on the estimated useful lives of the assets, which range from two to five years for machinery and equipment. Leasehold improvements are amortized over the life of the improvement or the lease term, whichever is shorter. Maintenance and repairs are charged to expense when incurred.

The Company owns some FORE-SIGHT tissue oximetry monitors located at customer sites. Such equipment is held under a no cost program whereby customers purchase disposable sensors for use with the Company's equipment. The Company retains title to the monitors shipped to its customers under this program. The monitors are depreciated on a straight-line basis over five years to cost of sales.

Depreciation and amortization expense on property and equipment was \$787,284 in 2010 and \$935,060 in 2009.

### Goodwill

The Company's goodwill of \$1,223,326 as of December 31, 2009 was attributable to its Statcorp business unit. On November 5, 2010, the Company sold the assets and liabilities related to this business unit. Accordingly, the Company included the carrying amount of its goodwill in the determination of the loss on disposal of the business unit (See Note 3).

### Intangible and other assets

The Company reviews its intangible and other assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The Company believes that the carrying amounts of its long-lived assets are fully recoverable.

Intangible and other assets at December 31, 2010 and 2009 consist of:

	<u>2010</u>	<u>2009</u>
Patents and other assets	\$593,166	\$597,141
Patents pending	254,975	240,981
Purchased technology	46,026	213,839
Deferred finance charges	<u>170,205</u>	<u>46,986</u>
	1,064,372	1,098,947
Accumulated amortization	<u>(412,746)</u>	<u>(482,316)</u>
	<u>\$651,626</u>	<u>\$616,631</u>

Intangible and other assets are stated at cost. Patents are amortized over their estimated useful lives which range from 1 to 20 years. Purchased technology is amortized over five years. Deferred financing costs are amortized over the term of the related debt. Amortization expense was \$173,166 in 2010 and \$135,280 in 2009.

Expected amortization expense of intangible assets as of December 31, 2010 over the next five years follows:

2011	\$ 75,000
2012	34,000
2013	21,000
2014	15,000
2015	<u>13,000</u>
	<u>\$158,000</u>

### **Revenue and accounts receivable recognition**

Revenue from sales and accounts receivable are recognized when evidence of an arrangement exists, delivery has occurred based upon shipping terms, the selling price is fixed and determinable, and collectability is reasonably assured. Terms of sale for most domestic sales are FOB origin and for most international sales are EX-Works reflecting that ownership and risk of loss are assumed by the buyer at the shipping point. In addition, the Company has certain agreements with its customers to ship FOB destination reflecting that ownership and risk of loss are assumed by the buyer upon delivery. While the Company accepts returns of products from its customers from time to time for various reasons including defective goods, order entry, shipping or other errors, the Company's business practices do not include providing right of return at the time of sale. Historically, such returns have not been significant. The Company has entered into agreements with several customers to provide them with price rebates based upon their level of purchases. Rebates are accrued by the Company as a reduction in net sales as they are earned by customers. Payment terms range from prepayment to net sixty days depending upon certain factors including customer credit worthiness, geographic location and customer type (i.e., end-user, distributor, government or private entity) and also includes irrevocable letters of credit for certain international shipments. Price discounts that may be taken by customers under contractual arrangements for payment of invoices within specified periods are recorded as reductions to net sales. Further, the Company accrues expected payment discounts based upon specific customer accounts receivable balances. The Company does not incur post shipment obligations with the exception of product warranties which are generally fulfilled from the Company's corporate facilities and which costs are not material relative to the sale of the product. Accounts receivable are charged to the allowance for doubtful accounts when deemed uncollectible.

The Company's five largest customers accounted for approximately 36% and 30% of revenues in 2010 and 2009, respectively. Among these customers, Medtronic Physio-Control, Inc., customarily the Company's largest single customer accounted for 14% and 12% of revenues during 2010 and 2009, respectively.

### **Income taxes**

The Company recognizes deferred income tax assets and liabilities for future tax consequences resulting from differences between the book and tax bases of existing assets and liabilities as well as for loss carry forwards. A valuation allowance is provided for that portion of deferred income tax assets which may not be realized.

The Company has accrued for uncertain tax positions in accordance with accounting standards which prescribes a more likely-than-not threshold for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return.

The Company files U.S. Federal and multiple state income tax returns. With few exceptions, the Company's tax returns have been examined for years prior to 2005. Interest and penalties related to uncertain tax positions are classified with income taxes.

### **Warranty costs**

The Company warrants some of its products against defects and failures for up to three years and records the

estimated cost of such warranties at the time the sale is recorded. Estimated warranty costs are based upon actual past experiences of product returns and the related estimated cost of labor and material to make the necessary repairs.

A summary of the changes in the Company's warranty accrual follows:

	<u>2010</u>	<u>2009</u>
Beginning balance	\$50,000	\$50,000
Provision	96,932	141,265
Warranty costs incurred	<u>(96,932)</u>	<u>(141,265)</u>
Ending balance	<u>\$50,000</u>	<u>\$50,000</u>

### **Research and development costs**

The Company expenses all research and development costs as incurred. Research and development ("R&D") includes, among other expenses, direct costs for salaries, employee benefits, professional services, materials and facility related expenses.

The Company has received various grants which support its R&D efforts. In accordance with the terms of these grants, the Company is being reimbursed for certain qualifying expenditures. Funding provided to the Company is being recorded as a reduction of R&D expenses. The Company recognizes the reimbursement on an accrual basis as the qualifying costs are incurred.

### **Advertising costs**

Non-direct response advertising costs are expensed as incurred and include product promotion, samples, meetings and conventions, and print media. Advertising expense was \$666,000 in 2010 and \$696,000 in 2009.

### **Earnings per common share**

Basic earnings per share is calculated by dividing net income (loss) by the weighted average number of shares of common stock outstanding during the year. Diluted earnings per share assumes the exercise or conversion of dilutive securities using the treasury stock method.

Weighted average shares outstanding, net of restricted shares, used to compute basic and diluted loss per share for 2010 and 2009 were 12,175,812 and 11,260,553, respectively. All outstanding stock related grants were excluded from the 2010 and 2009 diluted loss per share calculations as they would have been anti-dilutive.

### **Fair value of financial instruments**

The fair value of the Company's long-term debt as of December 31, 2009 approximates its carrying value of \$1,708,755. Fair value was determined using unobservable inputs (i.e. Level III).

### **New accounting pronouncements**

In October 2009, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update 2009-13 ("ASU 2009-13") with respect to Subtopic 605-25, Revenue Recognition – Multiple Element Arrangements of the FASB Accounting Standards Codification. This guidance updates and addresses the

measurement and separation of revenues in multiple deliverable activities and significantly expands the related disclosures. The amendments in FASB ASU 2009-13 are effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. The Company plans to adopt FASB ASU 2009-13 effective January 1, 2011. The Company does not expect the adoption to impact the Company's financial position or results of operations.

In January 2010, the FASB issued Accounting Standards Update 2010-06 ("ASU 2010-06") related to Fair Value Measurements and Disclosures – Overall Subtopic 820-10 of the FASB Accounting Standards Codification. This guidance updates and improves the disclosures about valuation techniques and inputs to fair value measurements. The amendments in FASB ASU 2010-06 are effective for fiscal years beginning after December 15, 2010 and for interim periods within those fiscal years. The Company plans to adopt FASB ASU 2010-06 effective January 1, 2011. The Company does not expect the adoption to impact the Company's financial position or results of operations.

### (3) DISCONTINUED OPERATIONS

On November 5, 2010, the Company consummated an agreement to sell certain assets and liabilities related to its Statcorp business unit, which includes its blood pressure and infusor cuff product lines, in exchange for \$3,200,000 in cash at closing. As provided in the purchase agreement, the aggregate consideration paid to the Company at closing was subject to an adjustment based upon changes in the net working capital of the business as of the closing date relative to a net working capital target. The adjustment resulted in \$78,964 of additional consideration paid to the Company. Further, the agreement provides for the buyer to pay up to an additional \$350,000 in earn-out payments if certain net revenue thresholds are achieved in the six month period following the closing. As of December 31, 2010, the Company has not recorded an accrual for potential earn-out revenues due to the uncertainty associated with reaching the net revenue targets.

The Company utilized a portion of the proceeds from the sale to repay in full the outstanding balance under its bank term note of \$1,167,814.

The following table presents the assets and liabilities of the Statcorp business unit classified as assets and liabilities associated with discontinued operations in the consolidated balance sheet as of December 31, 2009:

Accounts receivable	\$ 841,938
Inventories	2,024,274
Prepaid expenses and other	17,735
Fixed assets, net	239,426
Goodwill	<u>1,223,236</u>
Total assets associated with discontinued operations	<u>\$4,346,609</u>
Accounts payable and accrued expenses	<u>\$ 524,515</u>
Total liabilities associated with discontinued operations	<u>\$ 524,515</u>

The following table represents the financial results of the discontinued operations for the period from January 1, 2010 to November 5, 2010 and for the twelve months ended December 31, 2009:

	<u>2010</u>	<u>2009</u>
Revenues	\$7,065,102	\$9,193,920
Cost of products sold	<u>5,714,066</u>	<u>8,597,560</u>
Gross profit	1,351,036	596,360
Operating expenses	388,288	345,202
Goodwill impairment	--	2,155,785
Interest expense	73,134	121,419
Loss on sale of discontinued operations	<u>435,890</u>	<u>--</u>
Income (loss) from discontinued operations before income taxes	453,724	(2,026,046)
Income tax expense	<u>158,803</u>	<u>53,295</u>
Income (loss) from discontinued operations	<u>\$294,921</u>	<u>\$(2,079,341)</u>

Interest expense allocated to discontinued operations relates to the Company's bank term note which was repaid in full commensurate with the transaction. The proceeds from the term note had been used to finance the acquisition of the Statcorp business unit in May 2005.

#### (4) ALLOWANCE FOR DOUBTFUL ACCOUNTS

Changes in the allowance for doubtful accounts during the years ended December 31, 2010 and 2009 follow:

	<u>2010</u>	<u>2009</u>
Balance at beginning of year	\$175,000	\$150,000
Provision	35,760	63,689
Accounts written off	<u>(35,760)</u>	<u>(38,689)</u>
Balance at end of year	<u>\$175,000</u>	<u>\$175,000</u>

#### (5) INVENTORIES

Inventories at December 31, 2010 and 2009 consist of:

	<u>2010</u>	<u>2009</u>
Raw materials	\$3,733,550	\$4,441,120
Work in process	2,950	8,471
Finished goods	<u>1,076,465</u>	<u>1,333,047</u>
	<u>\$4,812,965</u>	<u>\$5,782,638</u>

**(6) FINANCING ARRANGEMENTS****Line-of-credit**

The Company maintains a line-of-credit with its bank lender. On March 11, 2010, the line-of-credit was amended by the Third Modification Agreement (the "Third Modification"). The Third Modification amended the loan agreement and the related promissory note each as previously amended. Under the Third Modification, the maturity date was extended to April 1, 2011 and the interest rate for the revolving loans under the Loan Agreement was increased from the Bank's Base Rate (as defined) plus 1.0% with a minimum of 4.0% per annum to the Bank's Base Rate (as defined) plus 2.0% with a minimum interest rate of 5.0% per annum. The interest rate effective upon execution of the Third Modification was 5.25% per annum. Additionally, the Third Modification amended the existing debt service coverage ratio covenant from 1.5 to 1.0 to 1.25 to 1.0, tested beginning March 31, 2010 and quarterly thereafter, measured on a year-to-date basis. In connection with the Third Modification, the Bank waived the testing of the debt service coverage ratio covenants as of December 31, 2010 and 2009.

The Company is working with its lender to extend the line-of-credit facility to April 1, 2012. The Company has executed a non-binding financing proposal and issued a deposit with the intent to consummate an agreement during April 2011. While management is confident it will be successful in securing an agreement with its lender, there can be no assurance that we will be successful or that the terms under the agreement will be substantially equivalent to the current agreement.

As of December 31, 2010, there was no outstanding balance under the line of credit. Approximately \$2,522,000 remained available according to the borrowing formula.

**Notes payable**

The Company financed the premiums for its property casualty and directors' and officers' insurance policies with short-term borrowings of \$183,656 and \$223,175 in 2010 and 2009, respectively. The notes were paid in full as of December 31, 2010.

**Long-term debt**

On November 5, 2010, commensurate with the sale of the Company's Statcorp business unit (see Note 3), the Company repaid its term note payable in the amount of \$1,167,814.

**Private Placement**

During June 2010, the Company consummated a non-brokered private placement of 1,375,000 shares of its common stock for net proceeds of approximately \$1,887,000.

**Collateral and covenants**

Substantially all of the Company's assets are pledged as collateral for borrowings under the line-of-credit. In addition, the Company is required to meet, among others, debt service and debt to equity covenants. As of December 31, 2010, the Company was not in compliance with its debt service covenant. The Company has received a waiver from its lender to this effect with respect to the December 31, 2010 measurements.

**(7) ACCRUED EXPENSES**

Accrued expenses at December 31, 2010 and 2009 consist of:

	<u>2010</u>	<u>2009</u>
Payroll	\$213,166	\$192,941
Severance	21,862	250,827
Professional fees	339,195	447,851
Warranty	50,000	50,000
Travel and entertainment	53,367	64,400
Other	<u>231,741</u>	<u>223,143</u>
	<u>\$909,331</u>	<u>\$1,229,162</u>

## (8) SHARE-BASED PAYMENT PLANS

Under the CAS Medical Systems, Inc. 2003 Equity Incentive Plan, as amended, (the "Incentive Plan"), 1,250,000 shares of common stock were originally reserved for issuance. As of December 31, 2010, 201,552 shares remain available for issuance under the Incentive Plan.

Awards that may be granted under the Incentive Plan include options, restricted stock, restricted stock units, and other stock-based awards. The purposes of the Incentive Plan are to make available to key employees and directors, certain compensatory arrangements related to growth in the value of the Company's stock so as to generate an increased incentive to contribute to the Company's financial success and prosperity; to enhance the Company's ability to attract and retain exceptionally qualified individuals whose efforts can affect the Company's financial growth and profitability; and align in general the interests of employees and directors with the interests of stockholders. The Incentive Plan is administered by the Compensation Committee of the Board of Directors, which in turn determines the employees, officers and directors to receive awards and the terms and conditions of these awards.

During 2010, the Company issued 15,000 shares of restricted stock to employees and 36,222 shares of restricted stock to outside members of the Board of Directors under the Incentive Plan. The restricted stock issued to employees during 2010 vests over thirty-six months from date of grant while the restricted stock issued to members of the Board of Directors vests ratably over twelve months from date of grant. The weighted average fair value of the restricted stock was \$1.71 per share and the aggregate fair value of the stock issued based on the closing market price on the date granted was \$87,382. The fair value of the restricted common shares was calculated based upon the market value of the common stock on the date of issuance. In addition, an aggregate of 400,000 shares of restricted stock under two inducement grants were issued outside of the Incentive Plan to the Company's President and Chief Executive Officer upon appointment by the Board of Directors. The first grant of 250,000 shares vests monthly over a period of three years and was valued for purposes of measuring stock compensation expense based upon the market value of the Company's common stock on the grant date of \$2.10 per share. The second grant of 150,000 shares vests upon reaching an average market price for the Company's common stock of \$4.15 for sixty consecutive trading days. The fair value of the second grant of \$1.18 per share was determined by using a lattice pricing model assuming a weighted average expected stock price volatility of 96.8%, a weighted average expected option life of 4.4 years, an average risk free interest rate of 2.66%, an average dividend yield of 0.0% and is being amortized over a period of two years from date of grant.

During 2010, 18,501 shares of restricted stock were cancelled. As of December 31, 2010, 484,070 shares of non-vested restricted common stock remain outstanding. Stock compensation expense of \$1,258,000 has been recognized to December 31, 2010 related to restricted shares granted in 2010 and in prior years. The unamortized stock compensation expense associated with the restricted shares at December 31, 2010 was \$769,000 and will be recognized through the third quarter of 2014.

During 2009, the Company issued an aggregate of 150,000 shares of restricted stock to employees and 23,528 shares of restricted stock to outside members of the Board of Directors under the Incentive Plan. The restricted stock issued to employees during 2009 vests from twenty-four months to thirty-six months from date of grant while the restricted stock issued to members of the Board of Directors vests ratably over twelve months from date of grant. The weighted average fair value of the restricted stock was \$1.80 per share and the

aggregate fair value of the stock issued was approximately \$312,000. The fair value of the restricted common shares was calculated based upon the market value of the common stock on the date of issuance. During 2009, 45,501 shares of restricted stock were cancelled.

A summary of the restricted shares outstanding and changes for the years follow:

	<u>2010</u>	<u>2009</u>
Outstanding at beginning of year	190,265	147,622
Granted	451,222	173,528
Cancelled	(18,501)	(45,501)
Vested	<u>(138,916)</u>	<u>(85,384)</u>
Outstanding at end of year	<u>484,070</u>	<u>190,265</u>

During 2010, under the Incentive Plan, stock options for 218,000 shares of common stock were granted to the Company's employees and outside board of directors at a weighted average exercise price of \$2.60 per share. During 2010, options for the exercise of 50,000 shares were forfeited. The aggregate fair value of the options granted based on the closing market price on the grant date approximated \$567,000. In addition, stock options for 350,000 shares of common stock were granted to the Company's President and Chief Executive Officer upon appointment at an exercise price of \$2.10. The fair value of each option granted during 2010 was estimated on the date of grant using the Black-Scholes option-pricing model assuming a weighted average expected stock price volatility of 93.2% to 96.8%, a weighted average expected option life of 4.4 years, an average risk free interest rate of 2.66% to 3.63% and a 0.0% average dividend yield. The weighted average fair value of the stock options granted during 2010 was \$2.60 per share. The stock options grants contain vesting schedules of three to four years from the grant date.

During 2009, stock options for 25,000 shares of common stock were granted to the Company's employees at a weighted average exercise price of \$1.82 per share. The aggregate fair value of those options was \$29,900 based upon the closing market price on the grant date.

As of December 31, 2010, 935,875 shares granted under stock options remain outstanding of which 545,875 pertain to options granted under the 2003 Equity Incentive Plan, 40,000 pertain to stock options granted under the 1994 Employees Stock Option Plan (the "1994 Plan") and 350,000 were issued as inducement grants outside of a shareholder approved plan. The 1994 Plan expired during 2003 and, as such, there are no further options available for issuance under the 1994 Plan.

The unamortized stock compensation expense associated with the stock options at December 31, 2010 was \$828,000 and will be recognized through the fourth quarter of 2014.

A summary of the Company's stock options and changes during the years follow:

	2010			2009		
	<u>Option Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Aggregate Intrinsic Value</u>	<u>Option Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Aggregate Intrinsic Value</u>
Outstanding at beginning of year	488,175	\$2.19		590,125	\$2.43	
Granted	568,000	2.60		25,000	1.82	
Exercised	(70,300)	0.61		(24,700)	0.96	
Canceled	<u>50,000</u>	3.72		<u>(102,250)</u>	3.77	
Outstanding at end of year	<u>935,875</u>	<u>\$2.29</u>	<u>\$877,788</u>	<u>488,175</u>	<u>\$2.19</u>	<u>\$233,619</u>
Exercisable at end of year	<u>361,208</u>	<u>\$2.28</u>	<u>\$360,287</u>	<u>441,507</u>	<u>\$2.10</u>	<u>\$233,619</u>
Weighted average grant-date fair value of options granted during the year		<u>\$1.23</u>			<u>\$1.20</u>	

The total intrinsic value of stock options exercised was \$168,734 in 2010 and \$21,205 in 2009. The intrinsic value of a stock option is the amount by which the current market value of the underlying stock exceeds the option exercise price.

The fair value of each option is estimated on the date of grant using the Black-Scholes option pricing model. Similar to other option pricing models, the Black-Scholes model requires the input of highly subjective assumptions which may materially affect the estimated fair value of the Company's stock options.

The following weighted-average assumptions were used for grants in 2010 and 2009: risk-free interest rates of 2.8% and 3.4%; expected lives of 4.4 and 4.2 years; dividend yield of 0%; and expected volatility of 93%, and 88%. Risk-free interest rates approximate U.S. Treasury yields in effect at the time of the grant. The expected lives of the stock options are determined using historical data adjusted for the estimated exercise dates of unexercised options. Volatility is determined using both current and historical implied volatilities of the underlying stock which is obtained from public data sources.

Additional information about stock options outstanding and exercisable at December 31, 2010 follows:

<u>Range of Exercise Prices</u>	<u>Number Outstanding</u>	<u>Weighted Remaining Contractual Life in Years</u>	<u>Average Exercise Price</u>	<u>Number Exercisable</u>	<u>Average Exercise Price</u>
\$0.82 - \$1.50	155,375	2.5	\$1.30	155,375	\$1.30
1.90 - 2.30	487,500	9.1	2.11	47,500	2.30
2.50 - 3.10	258,000	7.4	3.00	123,333	3.02
3.59 - 4.50	<u>35,000</u>	4.6	3.98	<u>35,000</u>	3.98
\$0.82 - \$4.50	<u>935,875</u>	7.3	\$2.29	<u>361,208</u>	\$2.28

Warrants to purchase 889,401 shares of common stock at a weighted average exercise price of \$0.43 per share were outstanding at December 31, 2010. The warrants have no specific expiration date and have an exercise price range of \$0.30 to \$1.44 per share. During 2010, warrants to purchase 75,000 shares of common stock were exercised by a beneficiary of a former director of the Company. There were no warrants issued during 2010 and none granted or exercised during 2009.

The Company maintains an employee stock purchase plan. The CAS Medical Systems, Inc. Employee Stock Purchase Plan (the "Stock Purchase Plan") was approved by shareholders on June 10, 2009 and accordingly, 150,000 shares of common stock were reserved for issuance under the Stock Purchase Plan. The initial offering period began on July 1, 2009. As of December 31, 2010, 12,305 shares were issued under the Stock Purchase Plan and certain amounts had been withheld from employees' compensation to purchase an additional 1,516 shares which were issued during January 2011. The Stock Purchase Plan offers the Company's employees an opportunity to participate in a payroll-deduction based program designed to incentivize them to contribute to the Company's success. The Stock Purchase Plan replaced an employee stock purchase plan that had been in effect since June 2004.

**(9) BENEFIT PLANS**

The Company maintains a 401(k) benefit plan for its employees, which generally allows participants to make contributions via salary deductions up to allowable Internal Revenue Service limits on a tax-deferred basis. Such deductions may be matched in part by discretionary contributions by the Company. Matching contributions by the Company were \$0 in 2010 and \$18,091 in 2009. The Company suspended its discretionary matches during March 2009.

**(10) INCOME TAXES**

The components of current and deferred federal and state income tax expense (benefit) for the years ended December 31, 2010 and 2009 consist of:

	<u>2010</u>	<u>2009</u>
Current (benefit):		
Federal	\$ (3,116)	\$(880,457)
State	<u>13,996</u>	<u>17,109</u>
	<u>10,880</u>	<u>(863,348)</u>
Deferred (benefit):		
Federal	(158,803)	1,004,222
State	<u>-</u>	<u>37,641</u>
	<u>(158,803)</u>	<u>1,041,863</u>
Income taxes (benefit) from continuing operations	<u>\$ (147,923)</u>	<u>\$ 178,515</u>

A reconciliation of U.S. Federal income taxes computed at the statutory rate to income taxes shown in operations for the years ended December 31, 2010 and 2009 follows:

	<u>2010</u>	<u>2009</u>
Income taxes (benefit) from continuing operations at the statutory rate	\$(594,293)	\$(1,200,814)
State income taxes, net of federal effect	27,843	(18,018)
R&D and other tax credits	(23,082)	(54,951)
Stock options	57,181	-
Change in valuation allowance	410,360	1,439,446
Other	<u>(25,932)</u>	<u>12,852</u>
Income taxes (benefit) from continuing operations	<u><u>\$(147,923)</u></u>	<u><u>\$178,515</u></u>

Deferred income tax assets and (liabilities) at December 31 relate to:

	<u>2010</u>	<u>2009</u>
Inventories	\$259,804	\$636,159
Warranty accrual	17,495	17,495
Allowance for doubtful accounts	61,233	61,233
Tax credits	321,126	282,528
Deferred gain on sale and leaseback	314,709	361,819
Restricted stock	20,405	225,997
Net operating loss carry forward	442,699	-
Other	<u>168,218</u>	<u>216,201</u>
	1,605,689	1,801,432
Prepaid expenses	(108,534)	(134,065)
Fixed assets	<u>(216,075)</u>	<u>(218,737)</u>
Deferred income tax assets and liabilities	1,281,080	1,448,630
Valuation allowance	<u>(1,281,080)</u>	<u>(1,448,630)</u>
Net deferred income tax assets and liabilities	<u><u>\$ -</u></u>	<u><u>\$ -</u></u>

The Company has performed the required analysis of both positive and negative evidence regarding the realization of our deferred income tax assets, including our past results of operations, recent cumulative losses and our forecast for future taxable income. The assessment required the use of assumptions about future revenues and pre-tax income making allowance for uncertainties surrounding the rate of adoption of our products in the market place, competitive influences and the investments required to increase our market share in certain markets for our products. As of December 31, 2010, we have concluded that it is more likely than not that such deferred income tax assets will not be realized and, accordingly, have established a deferred income tax asset valuation allowance in the amount of \$1,281,080.

The Company's net operating loss carry forward of \$442,699 is scheduled to expire in 2030.

A reconciliation of unrecognized income tax benefits for 2010 and 2009 follows:

	<u>2010</u>	<u>2009</u>
Balance at beginning of year	\$277,280	\$155,875
Tax positions taken during a prior year	(87,121)	13,500
Increase for tax positions taken in current year	<u>21,000</u>	<u>107,905</u>
Balance at end of year	<u><u>\$211,159</u></u>	<u><u>\$277,280</u></u>

During 2010, \$21,000 of taxes, interest and penalties were recorded on uncertain tax positions while \$87,121 of tax positions taken during a prior year was decreased. During 2009, \$13,500 of interest on uncertain tax positions was recognized as income tax expense and \$107,905 was recognized for increases in certain tax positions taken during that year. As of December 31, 2010, \$61,875 of interest and penalties were accrued. The total amount of unrecognized income tax benefits, if recognized, would affect the Company's effective income tax rate by approximately \$76,000. Currently, the Company does not believe that the unrecognized

income tax benefits will significantly change in 2011.

#### **(11) GRANT AWARDS**

The Company has been awarded various grants by the National Institutes of Neurological Disorders and Stroke of the NIH under its Small Business Innovative Research Program. Grants under this program have been used to support the development of the Company's Near-Infrared Spectroscopy ("NIRS") technology which non-invasively measures the brain oxygenation level of a patient. In accordance with the terms of these grants, the Company has been reimbursed for certain qualifying expenditures. On September 17, 2007, the Company was awarded a three year grant, which was subsequently extended, totaling \$2,800,000 to support its NIRS research.

Qualifying R&D costs of \$483,000 in 2010 and \$737,000 in 2009 were reimbursed under grants. Such reimbursements are recorded as a reduction in R&D expenses. The Company recognizes these reimbursements on an accrual basis as the qualifying costs are incurred. As of December 31, 2010, a maximum of approximately \$684,000 remains available under the 2007 grant.

During the fourth quarter of 2010, the Company received a grant in the amount of \$244,479 for qualified investments in a qualifying therapeutic discovery project under Section 48D of the Internal Revenue Code. This program was created under the Patient Protection and Affordable Care Act of 2010 to provide tax credits or grants representing 50% of eligible qualified investments in therapeutic discovery projects during tax years 2009 and 2010. The Company recorded this grant as a reduction in research and development expense during the fourth quarter of 2010.

#### **(12) SALE AND LEASEBACK OF PROPERTY**

On September 6, 2007, the Company closed the sale and leaseback of its headquarters and manufacturing facility (the "Property"). Net proceeds from the sale were \$2,791,529 of which \$928,872 was used to retire the related outstanding mortgage debt. The gain of \$1,346,373 realized on the sale has been deferred and is being recognized in operations as a reduction in rent expense over the term of the lease. The lease has an initial term of ten years expiring on September 6, 2017 and an option for two additional five-year periods. The lease provides for an annual base rent in years one through five of \$244,800 and \$268,800 in years six through ten. The Company recognizes rent expense on a straight-line basis over the ten years. Under the lease, the Company is responsible for the costs of utilities, insurance, taxes and maintenance expenses. Further, the Company is required to maintain at least \$600,000 in cash and cash equivalents (increasing at 3% per annum) and net current assets of not less than \$3,600,000.

In addition, the Company has a right of first offer to lease any additional space or building built by the lessor on the Property, subject to certain restrictions. The Company also has the right to require the lessor to build an addition or additional building ("Expansion Premises"), subject to certain restrictions. Upon the delivery of any Expansion Premises, the term of the Lease would extend for a ten year term. The base rent for the Expansion Premises would be the greater of the then prevailing market rent or an amount equal to a return on actual costs of construction of the greater of 250 basis points over the rate on ten year U.S. Treasury Notes, or 8%. Upon delivery of the Expansion Premises, the lessor would assume obligations under the Company's existing leases of its two adjacent properties, in exchange for a payment equal to three months rent and certain unamortized costs incurred with respect to these two facilities.

**(13) COMMITMENTS AND CONTINGENCIES****Litigation**

The manufacture and sale of our products exposes us to product liability claims and product recalls, including those which may arise from misuse or malfunction of, or design flaws in, our products or use of our products with components or systems not manufactured or sold by us. Product liability claims or product recalls, regardless of their ultimate outcome, could require us to spend significant time and money in litigation or to pay significant damages. We are currently a defendant in a product liability action related to our discontinued infant sleep apnea product line. We believe that our product liability insurance is sufficient to cover any damages and costs that are likely with respect to this matter.

On August 7, 2009, Somanetics Corporation filed an action against the Company in the United States District Court for the Eastern District of Michigan alleging patent infringement, false advertising, and common law unfair competition and libel. The complaint requested injunctive relief and unspecified monetary damages, including treble damages and reasonable attorneys' fees. On October 19, 2009, the Company answered the complaint, denying all allegations against it. In addition, the Company asserted counterclaims against Somanetics for violation of the antitrust laws and for a declaration that the patents sued upon were invalid, unenforceable, and/or have not been infringed by the Company.

On October 27, 2010, a settlement was reached with Nellcor Puritan Bennett, LLC, a successor in interest to Somanetics Corporation, on Somanetics' action for patent infringement and other claims against the Company. The terms of the confidential settlement resolved all matters between the two parties as of the initiation of the lawsuit and caused the dismissal of the action with prejudice in a manner by which no payments were made to either party. The Company incurred \$737,000 of legal expenses during 2010 related to this matter.

**Operating Leases**

The Company currently leases three separate operating facilities and certain equipment under non-cancellable operating leases. Rent expense under these leases was \$462,000 in 2010 and \$485,000 in 2009. Future annual minimum rental payments as of December 31, 2010 to the expiration of the leases follow:

2011	\$432,000
2012	444,000
2013	466,000
2014	418,000
2015	328,000
Thereafter	<u>448,000</u>
Total	<u>\$2,536,000</u>

**(14) UNAUDITED QUARTERLY INFORMATION**

Unaudited quarterly financial information follows. The quarterly financial information disclosed below reflects the Statcorp business unit results as discontinued operations.

	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>	<u>Total Year</u>
<b>Year ended December 31, 2010</b>					
Net sales	\$6,108,444	\$6,318,343	\$5,801,603	\$5,857,621	\$24,086,011
Cost of sales	<u>3,454,178</u>	<u>3,585,318</u>	<u>3,407,482</u>	<u>3,681,222</u>	<u>14,128,200</u>
Gross profit	2,654,266	2,733,025	2,394,121	2,176,399	9,957,811
Income (loss) from continuing operations	38,880	(192,096)	(715,613)	(731,169)	(1,599,998)
Income (loss) from discontinued operations	<u>168,642</u>	<u>199,768</u>	<u>207,366</u>	<u>(280,855)</u>	<u>294,921</u>
Net income (loss)	<u>\$207,522</u>	<u>\$ 7,672</u>	<u>\$(508,247)</u>	<u>\$(1,012,024)</u>	<u>\$(1,305,077)</u>
Income (loss) per common share from continued operations - basic and diluted (1)	\$0.01	\$(0.02)	\$(0.06)	\$(0.06)	\$(0.13)
Income (loss) per share from discontinued operations - basic and diluted (1)	<u>\$0.01</u>	<u>\$0.02</u>	<u>\$0.02</u>	<u>\$(0.02)</u>	<u>\$0.02</u>
Net income (loss) per share - basic and diluted (1)	<u>\$0.02</u>	<u>\$0.00</u>	<u>\$(0.04)</u>	<u>\$(0.08)</u>	<u>\$(0.11)</u>
<b>Year ended December 31, 2009</b>					
Net sales	\$5,977,150	\$6,567,492	\$6,679,703	\$5,816,953	\$25,041,298
Cost of sales	<u>3,552,098</u>	<u>3,993,751</u>	<u>3,816,012</u>	<u>3,391,215</u>	<u>14,753,076</u>
Gross profit	2,425,052	2,573,741	2,863,691	2,425,738	10,288,222
(Loss) income from continuing operations	(863,621)	(729,118)	63,602	(2,181,186)	(3,710,323)
(Loss) income from discontinued operations	<u>(39,247)</u>	<u>(104,540)</u>	<u>133,536</u>	<u>(2,069,090)</u>	<u>(2,079,341)</u>
Net (loss) income	<u>\$(902,868)</u>	<u>\$(833,658)</u>	<u>\$197,138</u>	<u>\$(4,250,276)</u>	<u>\$(5,789,664)</u>
(Loss) income per common share from continued operations - basic and diluted (1)	\$(0.08)	\$(0.06)	\$0.01	\$(0.19)	\$(0.33)
(Loss) income per share from discontinued operations - basic and diluted (1)	<u>\$(0.00)</u>	<u>\$(0.01)</u>	<u>\$0.01</u>	<u>\$(0.19)</u>	<u>\$(0.18)</u>
Net (loss) income per share - basic and diluted (1)	<u>\$(0.08)</u>	<u>\$(0.07)</u>	<u>\$0.02</u>	<u>\$(0.38)</u>	<u>\$(0.51)</u>

(1) The sum of quarterly per share amounts may not equal per share amounts reported for year-to-date or full-year periods due to changes in the number of weighted average shares outstanding and the effects of rounding.

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

None.

Item 9A Controls and Procedures

The Company maintains disclosure controls and procedures that are designed to ensure that information required to be disclosed in the Company's Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to the Company's management, including its Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure based on the definition of "disclosure controls and procedures" in Rule 13a-15(e) of the Exchange Act. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

The Company carried out an evaluation, under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and the Company's Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of December 31, 2010. Based upon the foregoing evaluation, the Chief Executive Officer and the Chief Financial Officer have concluded that the Company's disclosure controls and procedures were effective as of that date.

There have been no changes in the Company's internal control over financial reporting during the quarter ended December 31, 2010 that have materially affected, or are reasonably likely to materially affect the Company's internal control over financial reporting.

Management's Annual Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Under the supervision and with the participation of the Company's management, including its Chief Executive Officer and Chief Financial Officer, an evaluation was conducted to determine the effectiveness of internal control over financial reporting based on the framework in *Internal Control - Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the Company's evaluation under the framework in *Internal Control - Integrated Framework*, the Company's management concluded that its internal control over financial reporting was effective as of December 31, 2010.

Reference is made to the Certifications of the Chief Executive Officer and the Chief Financial Officer about these and other matters attached as Exhibits 31.1, 31.2 and 32.1 to this report.

Item 9B. Other Information

None.

**PART III**Item 10. Directors, Executive Officers and Corporate Governance

Reference is made to the disclosure required by Items 401, 405, 406 and 407(c)(3), (d)(4) and (d)(5) of Regulation S-K to be contained in the Registrant's definitive proxy statement to be mailed to shareholders on or about April 23, 2011, and to be filed with the Securities and Exchange Commission.

Item 11. Executive Compensation

Reference is made to the disclosure required by Items 402 and 407 (e) (4) and (e) (5) of Regulation S-K to be contained in the Registrant's definitive proxy statement to be mailed to shareholders on or about April 23, 2011, and to be filed with the Securities and Exchange Commission.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Reference is made to the disclosure required by Item 403 of Regulation S-K to be contained in the Registrant's definitive proxy statement to be mailed to shareholders on or about April 23, 2011, and to be filed with the Securities Exchange Commission.

The following table provides information regarding the Company's equity compensation plans as of December 31, 2010:

<u>Plan Category</u>	Number of securities to be issued upon exercise of outstanding options and warrants	Weighted-average exercise price of outstanding options and warrants	Number of securities remaining available for future issuance under equity compensations plans
Equity compensation plans approved by security holders	585,875	\$ 2.41	201,552
Equity compensation plans not approved by security holders	<u>1,239,401</u>	0.90	-
Total	<u>1,825,276</u>	\$ 1.38	<u>201,552</u>

Securities remaining available for issuance under equity compensation plans approved by security holders are from the CAS Medical Systems, Inc. 2003 Equity Incentive Plan. The equity compensation plans not approved by security holders consist of warrants granted to both current and former directors of the Company as compensation for services rendered and inducement stock options granted to several executive officers commensurate with their employment with the Company. The warrants have no expiration date. See Note 8 "Share-Based Payment Plans" to the Company's Financial Statements.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Reference is made to the disclosure required by Items 404 and 407(a) of Regulation S-K to be contained in the Registrant's definitive proxy statement to be mailed to shareholders on or about April 23, 2011, and to be filed with the Securities and Exchange Commission.

Item 14. Principal Accountant Fees and Services

Reference is made to the proposal regarding the approval of the Registrant's independent registered public accounting firm to be contained in the Registrant's definitive proxy statement to be mailed to shareholders on or about April 23, 2011, and to be filed with the Securities and Exchange Commission.

**PART IV**Item 15. Exhibits and Financial Statement Schedules

## (a) (1) Financial Statements

The Company's financial statements are included in response to Item 8 of this report.

Report of J.H. Cohn LLP, Independent Registered Public Accounting Firm

Report of UHY LLP, Independent Registered Public Accounting Firm

Financial Statements

Consolidated Balance Sheets as of December 31, 2010 and 2009

Consolidated Statements of Operations for the Years Ended December 31, 2010 and 2009

Consolidated Statements of Changes in Shareholders' Equity for the Years Ended December 31, 2010 and 2009

Consolidated Statements of Cash Flows for the Years Ended December 31, 2010 and 2009

Notes to Consolidated Financial Statements

(2) Financial Statement Schedules

None.

(3) Exhibits

The Exhibits to this report are as set forth in the "Exhibit Index" beginning on page 30 of this report. Management contracts or compensatory plans or arrangements filed as an exhibit to this report are identified in the "Index to Exhibits" with an asterisk after the exhibit number.

**EXHIBIT INDEX**

- 2.1 Stock Purchase Agreement dated May 15, 2005 among CAS Medical Systems, Inc., Statcorp, Inc., and the Stockholders of Statcorp, Inc. (1)
- 3.1 Certificate of Incorporation of Registrant (2)
- 3.2 Amended and Restated Bylaws of Registrant (12)
- 10.1\* 1994 Employees' Incentive Stock Option Plan (5)
- 10.2\* CAS Medical Systems, Inc. Employee Stock Purchase Plan (6)
- 10.3\* CAS Medical Systems, Inc. 2003 Equity Incentive Plan (7)
- 10.4\* Form of Option Agreement (3)
- 10.5 Commercial Line of Credit Note and Loan Agreement with NewAlliance Bank (8)
- 10.6 Security Agreement between CAS Medical Systems, Inc. and NewAlliance Bank dated August 10, 2004 (8)
- 10.7 Commercial Loan and Security Agreement between CAS Medical Systems, Inc., NewAlliance Bank and Statcorp Inc. dated August 10, 2004 (1)
- 10.8 Modification Agreement between CAS Medical Systems, Inc. and NewAlliance Bank. (4)
- 10.9 Commercial Line of Credit Note and Loan Agreement between CAS Medical Systems, Inc. and NewAlliance Bank dated August 29, 2005 (9)
- 10.10 Security Agreement between CAS Medical Systems, Inc. and NewAlliance Bank dated August 29, 2005 (9)
- 10.11 Purchase and Sale Agreement between CAS Medical Systems, Inc. and Davis Marcus Partners, Inc. dated June 18, 2007 (10)
- 10.12 Lease Agreement between CAS Medical Systems, Inc. and DMP New Branford, LLC dated September 6, 2007 (10)
- 10.13 Commercial Loan Agreement dated February 11, 2008 between CAS Medical Systems, Inc. and NewAlliance Bank (12)
- 10.14 Commercial Revolving Promissory Note dated February 11, 2008 (12)
- 10.15 Security Agreement between CAS Medical Systems, Inc. and NewAlliance Bank dated February 11, 2008 (12)
- 10.16 Subscription Agreement dated May 9, 2008 with jVen Capital, LLC (13)
- 10.17 Amendment to the CAS Medical Systems, Inc. 2003 Equity Incentive Plan (14)
- 10.18 Debt Modification Agreement between CAS Medical Systems, Inc. and NewAlliance Bank dated December 31, 2008 (15)
- 10.19 Second Modification Agreement between CAS Medical Systems, Inc. and NewAlliance Bank dated April 3, 2009 (16)
- 10.20\* Employment Agreement with Jeffery A. Baird dated August 10, 2009 (17)
- 10.21\* Employment Agreement with Andrew E. Kersey dated August 10, 2009 (17)
- 10.22 Third Modification Agreement between CAS Medical Systems, Inc. and NewAlliance Bank dated March 11, 2010 (18)
- 10.23 Trademarks and Letters Patent Security Agreement between CAS Medical Systems, Inc. and NewAlliance Bank dated as of March 11, 2010 (18)
- 10.24 Guaranty dated as of March 11, 2010 from Statcorp, Inc. to NewAlliance Bank (18)
- 10.25 Security Agreement between Statcorp and NewAlliance Bank dated March 11, 2010 (18)
- 10.26 Modification and Reaffirmation of Commercial Loan and Security Agreement dated March 11, 2010 (18)
- 10.27 Subscription Agreement dated June 16, 2010 with several Subscribers (19)
- 10.28\* Employment Agreement between Thomas M. Patton dated August 27, 2010 (20)
- 10.29\* Inducement Non-Qualified Stock Option Agreement with Thomas M. Patton dated August 27, 2010 (20)
- 10.30\* Inducement Restricted Stock Agreement between Thomas M. Patton dated August 27, 2010 (20)
- 10.31\* Inducement Restricted Stock Agreement between Thomas M. Patton dated August 27, 2010 (20)
- 10.32 Asset Purchase Agreement dated November 5, 2010 by and among CAS Medical Systems, Inc., Statcorp, Inc. and OSI Optoelectronics, Inc. (21)
- 10.33\* Employment Agreement with Matthew J. Herwig dated January 7, 2011 (22)
- 10.34\* Inducement Non-Qualified Stock Option Agreement with Matthew J. Herwig dated January 7, 2011 (22)
- 10.35\* Inducement Restricted Stock Agreement with Matthew J. Herwig dated January 7, 2011 (22)

- 21.1 Subsidiaries of the Registrant
  - 23.1 Consent of J.H. Cohn LLP, Independent Registered Public Accounting Firm
  - 23.2 Consent of UHY LLP, Independent Registered Public Accounting Firm
  - 31.1 Certification of CEO Pursuant to Rule 13a-14
  - 31.2 Certification of CFO Pursuant to Rule 13a-14
  - 32.1 Certification of CEO and CFO Pursuant to 18 U.S.C. 1350
- 
- (1) Incorporated by reference to the Company's Form 8-K/A filed July 29, 2005
  - (2) Incorporated by reference to the Company's Registration Statement, dated April 15, 1985, filed with the Securities and Exchange Commission
  - (3) Incorporated by reference to the Company's Form 10-KSB filed March 31, 2005
  - (4) Incorporated by reference to the Company's Form 10-QSB filed November 14, 2005
  - (5) Incorporated by reference to the Company's Form S-8 filed October 4, 2000
  - (6) Incorporated by reference to the Company's Form S-8 filed June 10, 2004, (333-116348)
  - (7) Incorporated by reference to the Company's Form S-8 filed June 10, 2004, (333-116349)
  - (8) Incorporated by reference to the Company's Form 10-QSB filed November 12, 2004
  - (9) Incorporated by reference to the Company's Form 8-K filed October 30, 2006
  - (10) Incorporated by reference to the Company's Form 8-K filed September 10, 2007
  - (11) Incorporated by reference to the Company's Form 8-K filed November 30, 2007
  - (12) Incorporated by reference to the Company's Form 8-K filed February 14, 2008
  - (13) Incorporated by reference to the Company's Form 8-K filed May 14, 2008
  - (14) Incorporated by reference to the Company's Form 8-K filed December 31, 2008
  - (15) Incorporated by reference to the Company's Form 8-K filed January 6, 2009
  - (16) Incorporated by reference to the Company's Form 10-K filed April 3, 2009
  - (17) Incorporated by reference to the Company's Form 10-Q filed August 12, 2009
  - (18) Incorporated by reference to the Company's Form 8-K filed March 17, 2010
  - (19) Incorporated by reference to the Company's Form 8-K filed June 16, 2010
  - (20) Incorporated by reference to the Company's Form 8-K filed August 27, 2010
  - (21) Incorporated by reference to the Company's Form 10-Q filed November 10, 2010
  - (22) Incorporated by reference to the Company's Form 8-K filed January 10, 2011

**SIGNATURES**

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

**CAS MEDICAL SYSTEMS, INC.**

(Registrant)

/s/ Thomas M. Patton Date: March 24, 2011

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By: Thomas M. Patton  
President and Chief Executive Officer

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

/s/ Louis P. Scheps Date: March 24, 2011

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Louis P. Scheps, Chairman of the Board

/s/ Lawrence Burstein Date: March 24, 2011

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Lawrence Burstein, Director

/s/ Jerome Baron Date: March 24, 2011

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Jerome Baron, Director

/s/ Evan Jones Date: March 24, 2011

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Evan Jones, Director

/s/ Gregory P. Rainey Date: March 24, 2011

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Gregory P. Rainey, Director

/s/ Kenneth R. Weisshaar Date: March 24, 2011

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Kenneth R. Weisshaar, Director

/s/ Thomas M. Patton Date: March 24, 2011

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Thomas M. Patton, President, Chief Executive  
Officer and Director

/s/ Jeffery A. Baird Date: March 24, 2011

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Jeffery A. Baird, Chief Financial Officer  
(Chief Financial and Accounting Officer)

**SUBSIDIARIES OF THE REGISTRANT**

Statcorp, Inc., a Delaware corporation

**Consent of J.H. Cohn LLP, Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-135158 and 333-168585) and Forms S-8 (Nos. 33-90512, 333-47258, 333-116348, 333-116349, 333-160346, and 333-160347) of CAS Medical Systems, Inc. of our report dated March 24, 2011 relating to the financial statements of CAS Medical Systems, Inc. as of and for the year ended December 31, 2010 which report appears in the December 31, 2010 Annual Report on Form 10-K of CAS Medical Systems, Inc.

/s/J.H. Cohn LLP

Glastonbury, Connecticut  
March 24, 2011

**Consent of Independent Registered Public Accounting Firm**

We consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-135158 and 333-16585) and on Form S-8 (Nos. 33-90512, 333-47258, 333-116348, 333-116349, 333-160346, and 333-160347) of CAS Medical Systems, Inc. of our report dated March 29, 2010 except for Note 3 as to which the date is March 24, 2011, with respect to the consolidated financial statements of CAS Medical Systems, Inc. and subsidiaries as of December 31, 2009, and for the year then ended, which is included in this Annual Report on Form 10-K for the year ended December 31, 2010.

/s/ UHY LLP

Houston, Texas  
March 24, 2011

**CERTIFICATION**

I, Thomas M. Patton, certify that:

1. I have reviewed this annual report on Form 10-K of CAS Medical Systems, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrants' ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Thomas M. Patton

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Thomas M. Patton  
President and Chief Executive Officer

Date: March 24, 2011

**CERTIFICATION**

I, Jeffery A. Baird, certify that:

1. I have reviewed this annual report on Form 10-K of CAS Medical Systems, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Jeffery A. Baird

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Jeffery A. Baird  
Chief Financial Officer

Date: March 24, 2011

**Section 906 Certifications**

Pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned, Thomas M. Patton, the President and Chief Executive Officer and Jeffery A. Baird, the Chief Financial Officer of CAS Medical Systems, Inc. (the "Issuer"), do hereby certify that the report on Form 10-K accompanying this certification (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended ((15 U.S.C. 78m or 78o(d)) and that information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Issuer.

/s/ Thomas M. Patton

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Thomas M. Patton  
President and Chief Executive Officer  
CAS Medical Systems, Inc.  
March 24, 2011

/s/ Jeffery A. Baird

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Jeffery A. Baird  
Chief Financial Officer  
CAS Medical Systems, Inc.  
March 24, 2011