CAS MEDICAL SYSTEMS INC
Form 10-K
March 15, 2017

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, 2016

Commission File Number 0-13839

CAS MEDICAL SYSTEMS, INC.
(Exact name of registrant as specified in its charter)

Delaware	06-1123096
(State or other jurisdiction of Incorporation or organization)	(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	Name of Each Exchange on Which Registered
Common Stock, $.004 par value	The Nasdaq Capital 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

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

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

Indicate by check mark 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.

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 (Do not check if a smaller reporting company)	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, 2016, 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 approximately $28,867,000 based on the closing price as reported on the Nasdaq Capital Market. This calculation does not reflect a determination that persons are affiliates for any other purpose.

As of March 14, 2017, there were 28,229,081 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 21, 2017, 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 contains 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", "goal", "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, except as required by law.

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 consistent with our vision: That no patient is harmed by undetected tissue hypoxia. Our principal products are the FORE-SIGHT® and FORE-SIGHT ELITE® brand tissue oximeters and sensors. With a simple non-invasive sensor applied to the skin, these products alert clinicians to the oxygenation levels of a patient's brain or other body tissue during medical procedures to avoid harm caused by insufficient oxygen, or hypoxia. The FORE-SIGHT product line comprised 81% of our 2016 sales from continuing operations. We also sell legacy products that we group into a category entitled Traditional Monitoring, which includes non-invasive blood pressure measurement technologies and service sales.

We believe that our FORE-SIGHT tissue oximetry products place CASMED in a unique position to expand the clinical application for monitoring tissue oxygenation. Standard non-invasive parameters, such as pulse oximetry and blood pressure, provide only surrogate markers of tissue oxygen delivery. The indirect nature of these parameters forces clinicians to infer the adequacy of oxygenation in vital organs, including the brain, during medical procedures. However, data convincingly shows that clinician inferences of cerebral oxygenation during medical procedures often does not correlate with actual tissue oxygenation levels and that potentially dangerously low levels of cerebral oxygenation often go unrecognized, correlating to high levels of patient harm. Therefore, direct monitoring of cerebral oxygenation with FORE-SIGHT oximeters provides a unique and powerful tool that allows clinicians to

recognize and treat potentially dangerous tissue hypoxia to avoid adverse clinical outcomes.

As clinician education and experience demonstrates that use of cerebral and tissue oximetry improves patient care, the market for these monitors should continue to expand at attractive rates as the industry penetrates what we believe is more than a $500-million addressable market. We believe the FORE-SIGHT tissue oximeter provides clinicians the most accurate and reliable readings and is well-positioned to compete in that expanding market.

Strategy Execution

In 2016, we made progress towards our multi-year strategic goal of focusing on FORE-SIGHT's opportunity to redefine the tissue oximetry market and of transforming CASMED from a low-margin commodity capital medical equipment business into a high-growth, high-margin medical disposables business.

Given the unique clinical value of FORE-SIGHT and its position as a best-in-class cerebral oximeter in an expanding market, we believe that substantial investment in the FORE-SIGHT opportunity is warranted to drive increases in the Company's enterprise value over the longer term. Our FORE-SIGHT ELITE technology, introduced in late 2013, has significantly lower costs than the first-generation technology. As a result, our gross profit margins have continued to expand. This enables us to invest those gross profits to expand, upgrade, and revitalize our FORE-SIGHT sales organization; increase our marketing and clinical support; and continue to further reduce FORE-SIGHT product costs through prudent R&D spending.

Specific recent achievements include:

- FORE-SIGHT sales increased 17% over the prior year, driven by a 22% increase in FORE-SIGHT disposable sensor sales. Sensor revenue growth was attributable to a combination of taking customers from competitors, gaining customers who had not used cerebral oximetry in the past, and increases in sensor sales to existing customers as their utilization expanded.

- FORE-SIGHT sales represented 81% of CASMED's total sales from continuing operations in the fourth quarter of 2016, and FORE-SIGHT sensor sales accounted for 71% of total sales.

- We shipped a net of 380 FORE-SIGHT monitors worldwide in 2016, raising the cumulative net shipments from launch to 2,088 units as of year-end. The U.S. installed base accounts for 54% of the total shipped, or 1,120 monitors, which represents an increase of 23% over the prior year-end installed base.

- The five-year FORE-SIGHT sales compound average growth rate reached 23% at the end of 2016 for overall sales and 28% for U.S. sales. The fourth quarter of 2016 was the 27th consecutive quarter of double-digit U.S. FORE-SIGHT sensor sales growth over the prior-year quarter.

- CASMED largely accomplished its goal in 2016 to improve the quality of its U.S. distribution team since the hiring of new sales leadership in late 2015. In the past 12 months, We hired ten new sales representatives (to replace former sales reps and to fill new territories) and, as of March 2017, have 15 territories staffed with two open territories we expect to fill by mid-2017.

- We continue to gain name-brand hospitals as customers around the world, particularly in the U.S. We count as customers nine of the top 20 U.S. adult cardiac hospitals, as ranked by U.S. News and World Report.

- Our gross profit margin increased to 54.6% in 2016, from 51.2% in 2015, as product mix continued to shift to FORE-SIGHT oximetry, and to disposable sensors, in particular, aided further by realized cost reductions.

- On March 28, 2016, we sold our neonatal intensive care disposable supplies product line for $3.35 million. This transaction allows for enhanced focus on our FORE-SIGHT oximetry business, provides additional working capital, and is reported in our financial statements as a discontinued operation.

Description of Products and Services

The Company reports two categories of sales within one reportable business unit:

- Tissue Oximetry Monitoring – includes sales of the Company's FORE-SIGHT tissue oximeter monitors, sensors, and accessories.

- Traditional Monitoring – includes sales of the Company's legacy products comprising the OEM sales of the Company's proprietary non-invasive blood pressure technology (MAXNIBP® and MAXIQ™) and legacy monitor service and repair.

Tissue Oximetry Monitoring

CASMED's FORE-SIGHT tissue oximeter technology provides clinicians with a simple, non-invasive, quantitative measurement of oxygenation of cerebral tissue typically during surgery or critical care situations. The percentage saturation of cerebral hemoglobin with oxygen is obtained by placing a sensor on the skin on both the right and the left side of the patient's forehead. The FORE-SIGHT ELITE sensors emit five different wavelengths of infrared light that harmlessly penetrate into the cerebral tissue and are reflected back to photo-detectors in the same sensor. An exclusive algorithm then determines the percentage of hemoglobin that is saturated with oxygen in the blood of the brain tissue underlying each sensor. Through these proprietary and patented processes, FORE-SIGHT provides clinicians with an accurate, absolute numerical measure of tissue oxygenation. FORE-SIGHT can also be used to monitor the oxygenation of other tissues such as muscle and abdominal tissues in newborns weighing less than four kilograms.

By non-invasively and continuously measuring absolute cerebral tissue oxygen levels, our FORE-SIGHT tissue oximeter enables clinicians to identify and quickly react to dangerously low brain oxygen levels and empowers them to provide better care.

We believe that FORE-SIGHT incorporates a combination of features that permit obtained oxygenation values to be more reliable and more accurate and, therefore, more actionable by clinicians in critical care environments.

- CASMED's FORE-SIGHT ELITE monitor emits five wavelengths of light, permitting an increased level of signal acquisition, thus providing sufficient data to solve for other optical variables in the tissue sample, such as melanin in the skin, which would otherwise be confused as 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 tissue sample for interrogation, particularly if the grey matter of the brain is farther from the scalp.

- CASMED's FORE-SIGHT patented and proprietary algorithm utilizes a combination of methods to sort out optical signals created by non-critical background tissue that otherwise confound measurement of oxygenated hemoglobin levels.

Monitors that predominantly provide trend-based values differ significantly from the FORE-SIGHT oximeter 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 an accurate reflection of the actual tissue oxygenation to enable 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 helps clinicians solve a serious deficit in the care of many critical care patients. Unrecognized and dangerous desaturation events occur with much greater frequency than previously known and can only be properly identified with the direct measurement that tissue oximeters provide. Given this evidence, we believe our best-in-class FORE-SIGHT technology continues to gain clinical adoption in new and existing accounts and is well-positioned in the market for future growth.

We launched our next-generation FORE-SIGHT ELITE Tissue Oximeter late in the third quarter of 2013, creating an inflection point for the Company. The FORE-SIGHT ELITE monitor is lighter and more portable than our prior model, includes more features, and provides for enhanced ease-of-use. New features include the ability to monitor four channels of patient data; a larger, higher contrast viewing screen; and intuitive touch-screen controls. Its revolutionary system, using five wavelengths of light to interrogate tissue under the sensor, allows the ELITE system to measure oxygenation at levels of accuracy previously not seen.

The FORE-SIGHT ELITE has also been designed for lower manufacturing and service costs, and the Company continues to execute on the strategy to enhance design and production to reduce those costs further.

During 2016, 380 net monitors were shipped worldwide. As of December 31, 2016, the installed base of U.S. monitors was 1,120 monitors, up 23% from the installed base at December 31, 2015, driving an increase of U.S. sensor sales of 23%. The quantity of "net units shipped" that we report each fiscal quarter adds to this cumulative total and reflects the number of monitors shipped to customers less returns. The cumulative total is not affected by exchanges or monitor upgrades.

The Need for Tissue Oxygenation Monitoring

Oxygen is necessary to keep cells viable. The brain has a very high metabolic rate, consuming approximately 20% of the body's oxygen at rest. The brain, of course, through cognitive function and memory, defines who we are. It is also the organ that is least resistant to oxygen deprivation. Lack of sufficient oxygenation in the brain causes neurologic injury such as cognitive impairment, stroke, paralysis, coma, and/or hypoxic encephalopathy. These injuries can result in severe morbidity or even death. Dangerous deficits in brain hemoglobin saturation (reflecting decreased brain oxygen levels) are termed "desaturation events" because the hemoglobin of the blood is no longer sufficiently "saturated" with oxygen molecules. Desaturations can be caused by many factors. The brain responds to insufficient levels of oxygen by increasing ventilation, cardiac output, and blood pressure in order to increase oxygen delivery. It also vasodilates to increase brain blood flow. This biologic process is called "auto-regulation." However, auto-regulation is compromised by illness, surgical intervention, trauma, and anesthesia; and neonates and children have immature auto-regulation capabilities.

Inadequate oxygen delivery to the brain can be caused by:

- Hypoxemia: a decrease of hemoglobin oxygen saturation in arterial blood (inadequate oxygenation of the supply);
- Ischemia: a decrease in blood flow to the brain caused by inadequate cardiac output, occlusion of cerebral vessels, or increased intracranial pressure (inadequate volume of supply); and
- Anemia: a decrease in the concentration of red blood cells in the blood (inadequate oxygen carrying capacity).

Oxygen delivery must also match oxygen consumption related to the metabolic rate of the brain.

Most conventional monitoring is ultimately employed to assure an adequate balance between oxygen supply and demand. Reliably measuring the impact of complicated interactions among factors affecting cerebral oxygenation requires unacceptably invasive techniques. Standard parameters, such as pulse oximetry, heart rate and blood pressure determinations, capnometry, and cardiac output assessment, each provide only indirect predictions of cerebral oxygenation. From that information, a clinician can only infer that a patient's brain inadequately oxygenated. Data from cerebral oximetry convincingly shows that the estimations clinicians make about cerebral oxygenation based solely on these indirect measures are frequently wrong and that threatening cerebral desaturation events occur without recognition. Thus, in many acute care settings, such as surgery, intensive care, and other critical care environments, patients are exposed to potentially damaging cerebral hypoxia that could likely be prevented if recognized.

Data in support of this clinical proposition is substantial. FORE-SIGHT and FORE-SIGHT ELITE have been well validated with FDA-compliant methods. FORE-SIGHT also has proven to have high levels of accuracy even when compared to competitive technologies. The incidence rate of cerebral desaturation events (CDE's) is very high and is prevalent in many common surgeries as indicated in the sampling of studies cited in the following table.

Incidence Of CDEs	Procedure	Citation
73%	Aortic arch surgery	Fischer GW, et.al. Noninvasive cerebral oxygenation may predict outcome in patients undergoing aortic arch surgery. J Thorac Cardiovasc Surg. 2011;141(3):815-21.
63%	Cardiac Surgery	Deschamps A, et.al. Cerebral oximetry monitoring to maintain normal cerebral oxygen saturation during high-risk cardiac surgery. A randomized controlled feasibility trial. Anesthesiology. 2016 Apr;124(4):826-36.
25% with shunts 3.9% without	Carotid Endarterectomy	DeNaeyer S, et.al. Non-invasive absolute cerebral oximetry and intraluminal shunting during carotid endarterectomy. Presented at American Society of Anesthesiologists Annual Meeting 2010 # A398.
45.9± 134 (min-%)	EP Lab	Miller MA,et.al. Activation and entrainment mapping of hemodynamically unstable ventricular tachycardia using a percutaneous left ventricular assist device. J Am Coll Cardiol. 2011; 58(13):1363-71.
50%	ICU, Post-cardiac surgery	Greenberg SB,et.al. The Incidence of cerebral oxygen desaturation event in the intensive care unit (ICU) following cardiac surgery. Presented at American Society of Anesthesiologists Annual Meeting 2011 #A1454.
80%	Shoulder surgery-beach chair position	Murphy GS,et.al. Cerebral oxygen desaturation events assessed by near-infrared spectroscopy during shoulder arthroscopy in the beach chair and lateral decubitus positions. Anesth Analg 2010; 111(20: 496-5.
36%	Spine surgery in prone position	Hemmerling, Thomas M., et.al. Decrease of Cerebral Oxygen Saturation in Prone Position During Spine Surgery Measured by Absolute Cerebral Oximetry Presented at American Society of Anesthesiologists Annual Meeting 2010 #LB07.
43%	Thoracic Surgery	Roberts, et.al. Cerebral Oximetry and Recovery in Thoracic Surgery Presented at American Society of Anesthesiologists Annual Meeting 2013 #A2030.

The harm associated with these cerebral desaturations are well documented. Yet, very simple interventions are available to clinicians to successfully reverse these low levels of oxygen. Finally, when clinicians are alerted to CDEs and do successfully intervene to reverse low levels of brain oxygenation, patient outcomes improve.

This solid and growing body of clinical evidence substantiates the premise that measuring cerebral oximetry offers valuable insight to clinicians during the management of critical care patients which could permit them to increase safety, improve clinical outcomes, and reduce costs.

The Market for Tissue Oximetry

Cerebral desaturation events occur with much greater frequency than previously believed. The large and growing body of published literature in support of cerebral oximetry provides a solid academic and data-driven support for the expanded use of the product in a variety of critical care settings including: heart surgery; lung surgery; major vascular

surgery; neurosurgery; surgeries that provide a risk of large blood loss, such as orthopedic hip and spine; surgeries on elderly patients or those with compromised vascular systems or other co-morbidities; surgeries with non-supine patient positioning, such as orthopedic "beach chair" shoulder surgery and bariatric surgery; trauma care; cardiac arrest; and intensive care patient management in adult, pediatric, and neonatal wards, among others. Therefore, in the U.S. alone, cerebral monitoring could safeguard millions of patients each year.

While we believe the eventual addressable market for tissue oximetry exceeds $500 million, we estimate current total worldwide annual sales of tissue oximetry to be approximately $100 to $125 million. Given the broad potential applicability of this parameter and the small current rate of market penetration, we also believe that market rates of growth can accelerate, particularly as the use of oximetry moves toward becoming a standard of care.

The literature in support of tissue oximetry, in general, and FORE-SIGHT oximetry, in particular, 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. Consequently, a significant part of our longer-term strategy is to continue to encourage and support research related to the need for cerebral oximetry and its efficacy in improving care. FORE-SIGHT has already been referenced in hundreds of papers, abstracts, and posters, and the literature in support of the product grows every year.

Traditional Monitoring

CASMED provides blood pressure 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 and MAXIQ) for inclusion in the OEM customers' own multi-parameter monitors and monitor service and repair.

Blood Pressure Measurement Technology

The Company has developed a proprietary non-invasive blood pressure measurement technology which the Company believes is more accurate, reliable, and able to produce a measurement result faster than its competitors in high-motion environments. These advantages are important, especially in the most challenging clinical situations where measurements can be difficult to obtain, such as emergency care and when caring for pediatric patients. The Company has entered into OEM agreements to supply its MAXNIBP and MAXIQ technology to various companies throughout the world. This technology is used in other monitoring systems where non-invasive blood pressure is one of many measurement parameters. The Company's OEM relationships are typically multi-year.

Service

As part of the Company's traditional monitoring offerings, it provides various repair services to its customers for monitors installed in the field.

Sales and Marketing

The Company markets its products globally, through hospital, surgery center and outpatient facility, homecare, veterinary, and emergency medical distribution channels. A number of different sales channels are utilized to maximize sales opportunities for our products.

Tissue Oximetry Monitoring

The Company's FORE-SIGHT tissue oximeters are sold via a direct sales force, a single manufacturer's representative within the U.S., and stocking distribution partners outside the U.S. As of December 31, 2016, the Company's U.S. sales organization was comprised of 21 management, sales, and support personnel in 13 territories, with a goal to have 17 territories staffed by mid-2017. The international sales organization included one executive vice president and three sales consultants located in Europe, the Middle East, and the Pacific Rim, all managing FORE-SIGHT sales through our distribution partners.

The Company continues to invest significant resources in hiring, engaging, educating, and supporting its FORE-SIGHT field sales organization.

Traditional 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 this product line on a direct basis, utilizing

headquarters-based employees to solicit companies operating in both the domestic and international markets.

Total sales from continuing operations for the years ended December 31, 2016 and 2015 are as follows:

	Financial Information Relating to Sales Year Ended December 31,		
	2016	2015	% Change
Domestic Sales	$18,104,755	$15,571,093	16%
International Sales	4,133,070	3,915,477	6%
Total	$22,237,825	$19,486,570	14%

Competition

The Company competes in the broader medical equipment market for patient monitoring equipment and supplies. We believe that our reputation for producing innovative, accurate, and reliable products that are user-friendly and contain best-in-class technology are key factors in our ability to successfully compete with larger organizations in the medical products market.

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

- FDA clearance and other regulatory approvals;
- The accuracy, reliability, and precision of any biologic measurements provided;
- Publication of peer-reviewed clinical studies in support of the clinical use of product;
- Acceptance by thought-leaders in anesthesia, surgery, perfusion, and other key clinical roles for new technologies, such as cerebral oxygenation monitoring;
- Documented correlation to improved patient outcomes and lower costs;
- The cost effectiveness of monitoring solutions and overall pricing;
- Data interfaces with multi-parameter patient monitoring and data solutions;
- The overall ease-of-use and product quality;
- The scale and capability of sales and marketing organizations, including established sales distribution channels;
- Contractual arrangements with hospitals, hospital systems, buying groups, and professional service providers; and
- Proprietary technology.

Competitors for our Tissue Oximetry products include Covidien, Ornim, Masimo, Hutchinson Technology, Nonin Medical, and Hamamatsu. Competition for brain monitoring products is varied.

For our Traditional Monitoring products, there are a myriad of competitors, which include large corporations such as the SunTech Medical Division of Halma, 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, 2016, our Research and Development ("R&D") organization consisted of a staff of 18 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 2016 were primarily focused on expanding the applications for our FORE-SIGHT ELITE monitor, reducing FORE-SIGHT ELITE sensor manufacturing costs and advancing the design and the performance of our MAXNIBP non-invasive blood pressure technology. During 2016 and 2015, the Company incurred R&D expenses of approximately $3,437,000 and $3,514,000, or 15% and 18% of sales, respectively.

Trademarks, Patents, and Copyrights

Certificates of Registration have been issued to the Company by the United States Patent and Trademark Office for the following marks: CAS®, CASMED®, FORE-SIGHT®, FORE-SIGHT ELITE®, COOL-LIGHT®, For Every Life and Breath Situation®, For What's Vital®, LASER-SIGHT®, MAXIQ®, Intelligent Monitoring Defined®, and MAXNIBP®. In addition, the Company has pending trademark applications.

The Company holds 18 U.S. patents and 16 non-U.S. patents and has multiple pending patent applications for its FORE-SIGHT technologies, which it believes provide it with a competitive market advantage. The Company believes the design concepts covered in its patents, patent applications, and provisional patent applications are important to providing a tissue oximeter capable of absolute tissue oxygen saturation measurements with the FORE-SIGHT oximeter level of accuracy. Although the Company holds such patents and has patents pending related to certain products, it does not believe that its business as a whole is significantly dependent upon patent protection. 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 monitors.

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.

Employees

As of December 31, 2016, the Company had 96 employees, nearly all of which 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").

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 studies 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 Class II devices, and most require FDA clearance under Section 510(k) of the FD&C Act.

The last factory inspection of the Company by the FDA occurred during April 2016. The inspection resulted in an FDA-483 Inspection Observation Report which listed various non-conformities. The Company provided a written response to those observations. The FDA, satisfied with the Company's response and the related actions taken, closed the inspection on June 2, 2016.

International Regulatory Compliance

CASMED maintains certification to ISO 13485:2003 by the Notified Body, BSI Inc., for its manufacturing facility. These certifications and compliance with the Medical Device Directive 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 and other non-EU markets as well. 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, as evaluated by annual assessment.

Manufacturing and Quality Assurance

The Company assembles, tests, packages, or ships its products from its facility in Branford, Connecticut. The various finished goods or components for the products, which include plastic moldings, wire, printed circuit boards, sub-assemblies, and many other parts, are obtained from outside vendors, some of which are outside of the United States. 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 at its suppliers' facilities to standards set forth in the FDA's "Quality System Regulations." These procedures include the initial qualification of the supplier, inspection of components, and testing of finished goods.

Customers

Our five largest customers accounted for approximately 21% and 25% of sales from continuing operations in 2016 and 2015, respectively. Among these customers, Physio-Control, Inc. accounted for 11% and 12% of sales from continuing operations during each of 2016 and 2015, 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. The majority of the Company orders are shipped within several days of customer purchase order acceptance. 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. The information available on 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 occur, 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 last eight fiscal years. The operating loss from continuing operations was approximately $4,923,000 for the 2016 calendar year, and the accumulated deficit was approximately $41,090,000 as of December 31, 2016. We do 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 are expected to be met from cash-on-hand which was supplemented by net proceeds of approximately $8,517,000 from a public offering of our common stock consummated on February 17, 2015. In addition, on March 28, 2016, the Company sold its neonatal intensive care disposables product line for $3,350,000, including $3,035,000 paid in cash at closing. The Company also has a revolving credit agreement in the maximum amount of $2,500,000 which, to date, has not been utilized.

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. There can be no assurance that we will be successful in raising additional capital if the need arises. The failure to raise any necessary additional capital on acceptable terms, or at all, could have a material adverse effect on our business and results of operations.

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, as well as greater development capabilities, and substantially greater experience in testing products, obtaining regulatory approvals, and manufacturing, marketing, and distributing medical devices than we do.

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 and hospital systems. 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 materially and increasingly dependent on our FORE-SIGHT tissue oximetry products.

Sales of our FORE-SIGHT tissue oximetry products represented approximately 81% of our 2016 net sales from continuing operations, up from 79% during 2015. Our business strategy in recent years has been to transform CASMED from a low-margin commodity capital medical equipment business into a high-growth, high-margin medical disposables business. A key aspect of this strategy has been to focus on the growth of our FORE-SIGHT tissue oximetry products, while exiting or de-emphasizing our other various lines of business. However, the relative growth of FORE-SIGHT results in additional concentration risks. In the absence of significant other lines of business, we are subject to a greater degree on the success of our FORE-SIGHT tissue oximetry products. Any adverse business or other events relating to our FORE-SIGHT tissue oximetry products, including those described elsewhere in this Item 1A, will result in a proportionately greater potential negative impact on our business and financial condition.

Our business is impacted by customer concentration.

The Company's five largest customers accounted for approximately 21% and 25% of sales from continuing operations in 2016 and 2015, respectively. Among these customers, Physio-Control, Inc. accounted for 11% and 12% of such sales during 2016 and 2015, respectively. The loss of any 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, involving 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 non-invasive blood pressure technology product line, 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 equipment and products, 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. 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 or have filed applications for 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 sales and earnings.

Cost-containment efforts of our customers, purchasing groups, third-party payors, and governmental organizations could adversely affect our sales and profitability.

Many existing and potential customers for our products within the United States have become members of group purchase organizations (GPOs) and integrated delivery networks (IDNs) in an effort to reduce costs. GPOs and IDNs negotiate pricing arrangements with healthcare product manufacturers and distributors and offer the negotiated prices to affiliated hospitals and other members. GPOs and IDNs typically award contracts on a category-by-category basis through a competitive bidding process. Bids are generally solicited from multiple manufacturers with the intention of driving down pricing. Due to the highly competitive nature of the GPO and IDN contracting processes, we may not be able to obtain or maintain contract positions with major GPOs and IDNs across our product portfolio. Furthermore, the increasing leverage of organized buying groups may reduce market prices for our products, thereby reducing our profitability.

While having a contract with a GPO or IDN for a given product category can facilitate sales to members of that GPO or IDN, such contract positions can offer no assurance that sales volumes of those products will be maintained. GPOs and IDNs increasingly are awarding contracts to multiple suppliers for the same product category. Even when we are the sole contracted supplier of a GPO or IDN for a certain product category, members of the GPO or IDN generally are free to purchase from other suppliers. Furthermore, GPO and IDN contracts typically are terminable without cause upon notice of 60 to 90 days. Accordingly, the members of such groups may choose to purchase from our competitors due to the price or quality offered by such competitors, which could result in a decline in our sales and profitability.

Distributors of our products and hospital purchasers negotiate terms of sale aggressively to increase their profitability. Reductions in our average selling prices or failure to negotiate arrangements having advantageous pricing and other terms of sale could adversely affect our business, results of operations, financial condition, and cash flows.

Outside the United States, we have experienced pricing pressure from centralized governmental healthcare authorities and increased efforts by such authorities to lower healthcare costs. We frequently are required to engage in competitive bidding for the sale of our products to governmental purchasing agents. Our failure to offer acceptable prices to these customers could adversely affect our sales and profitability in these markets.

Defects or failures associated with our products could lead to recalls or safety alerts and negative publicity.

Manufacturing flaws, component failures, design defects, off-label uses, or inadequate disclosure of product-related information could result in an unsafe condition or the injury or death of a patient. These problems could lead to a recall of, or issuance of a safety alert relating to, our products and result in significant costs and negative publicity. Due to the strong name recognition of our brands, an adverse event involving one of our products could result in reduced market acceptance and demand for all products within that brand and could harm our reputation and our ability to market our products in the future. In some circumstances, adverse events arising from or associated with the design, manufacture, or marketing of our products could result in the suspension or delay of regulatory reviews of our applications for new product approvals. We also may undertake a voluntary recall of products or temporarily shut down production lines based on performance relative to our own internal safety and quality monitoring and testing data. Any of the foregoing problems could disrupt our business and have a material effect on our business, results of operations, financial condition, and cash flows.

We depend on international distributors for a substantial portion of our sales. Failure to establish and maintain relationships with distributors could materially and adversely affect our business, financial condition, and results of operations.

We depend on international distributors for a substantial percentage of our sales. Certain of our distribution agreements may contain terms that are not favorable to us, and as our existing distribution agreements expire, we may be unable to renew with our desired distributors on favorable terms or at all. Furthermore, competition for distributors is intense. We compete for distributors internationally with other leading medical equipment and device companies that may have higher visibility, greater name recognition and financial resources, and a broader product selection than we do. Our competitors also often enter into long-term distribution agreements that effectively prevent their distributors from selling our products. At times, we may also become engaged in contract disputes or other negotiations with distributors. Consequently, establishing relationships with new distributors, maintaining relationships with existing distributors, and replacing distributors may be difficult and time-consuming. Any disruption of our distribution network, including our failure to renew distribution agreements at favorable terms or our failure to successfully negotiate contract disputes, could negatively affect our ability to effectively sell our products and could materially and adversely affect our business, financial condition, and results of operations.

If we are unable to effectively structure and manage our distribution network, actions taken by our distributors could harm our corporate image and cause us to fail to meet our sales goals.

We have limited ability to manage the activities of our independent international distributors. Our distributors could take one or more of the following actions, some of which we have previously experienced and any of which could have a material adverse effect on our business, prospects, and brand:

- sell products that compete with products that they have contracted to sell for us;
- sell our products outside of our pricing guidelines, distorting the market price of our products;
- sell our products outside their designated territory or to non-authorized end-users, possibly in violation of the exclusive distribution rights of other distributors;
- directly or indirectly distribute products lacking necessary certifications into markets in violation of applicable in-country laws;
- fail to adequately promote our products; and/or
- fail to provide proper training, repair, and service to our end-users.

Failure to adequately manage our distribution network, or non-compliance by distributors with our distribution agreements or applicable law, could harm our corporate image among end-users of our products and disrupt our sales, resulting in a failure to meet our sales goals.

Our direct sales operations are costly, and the related ongoing operational costs could have a material adverse effect on our business.

We maintain direct sales operations in the United States and rely on direct sales for a significant portion of our sales from the United States. Maintaining a direct sales force is costly. In the United States, we typically provide our direct operations personnel with payroll and other benefits that we do not provide independent distributors or manufacturer representatives. Many of these benefits are fixed costs that do not depend on sales generation. Maintaining these direct operations is costly, and ongoing operational costs could have a material adverse effect on our business.

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 the product enters 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 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, failure to obtain, or revocation of these clearances or approvals would adversely affect the manufacturing and marketing of our products and the ability to generate additional product sales. 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.

Efforts to reform the U.S. health care industry have resulted in legislation such as the Patient Protection and Affordable Care Act ("Affordable Care Act") 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.

The Affordable Care Act provisions are funded by a variety of taxes including a medical device excise tax ("MDET") of 2.3% imposed on manufacturers and importers of certain medical devices. The Company became subject to the MDET effective January 1, 2013. The MDET tax was suspended effective January 1, 2016, until December 31, 2017. As such, the Company did not incur MDET expenses for 2016. Expenses were $365,000 for 2015. The Company recorded a refund during 2016 of $205,000 for MDET expenses paid in prior periods which it received during the first quarter of 2017.

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.

Our products may become rapidly obsolete.

The markets in which we compete involve rapidly developing technology. Others may develop products that might cause products being developed, distributed, or licensed by us to become obsolete, uneconomical, or result in products superior to our products.

Our international business is subject to currency, regulatory, 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 have only limited 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 19% and 20% of our total net sales from continuing operations for the 2016 and 2015 fiscal years, respectively.

Substantial levels of products and components purchased by us are sourced from outside the U.S. Changes in importation laws, regulations, duties or taxes by the U.S. or by other countries could have a material adverse impact on the costs and/or availability of our products.

Our business practices in countries other than the United States are governed by U.S. laws, including the Foreign Corrupt Practices Act, as well as local laws and regulatory schemes. While we believe we maintain a robust compliance program requiring adherence by our employees and distribution partners to all U.S. and foreign laws and regulatory schemes, there can be no assurances that our foreign distribution partners comply; therefore, failure could cause us to suffer the loss of the ability to sell in those jurisdictions or other liability.

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.

We have outstanding shares of preferred stock with rights and preferences superior to those of our common stock.

The issued and outstanding shares of Series A Convertible Preferred Stock and Series A Exchangeable Preferred Stock grant the holders of such preferred stock voting, accretion, dividend, and liquidation rights that are superior to those held by the holders of our common stock.

Ownership of our shares is concentrated in the hands of a few investors which could limit the ability of our other stockholders to influence the direction of the company.

As calculated by SEC rules of beneficial ownership, Thomas, McNerney & Partners and their affiliates, and Acuta Capital Partners, LLC, and Deerfield Management Company, L.P., each beneficially owned 29.4%, 15.0%, and 11.5%, respectively, of our common stock as of the dates of their most recent public filings with the SEC and other available data. Accordingly, although they are not affiliated with one another, they collectively may have the ability to significantly influence or determine the election of all of our directors or the outcome of most corporate actions requiring stockholder approval. They may exercise this ability in a manner that advances their best interests and not necessarily those of our other stockholders.

Sales of a substantial number of shares of our common stock in the public market, originally issued through the conversion of preferred stock, 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 stockholders.

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, 2016, options and warrants for the purchase of 3,680,958 shares of our common stock were outstanding, and 9,256,844 shares of common stock were issuable upon conversion of our outstanding Series A Convertible Preferred Stock and Series A Exchangeable Preferred Stock.

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; Dr. Paul Benni, our Chief Scientific Officer; Dr. John Gamelin, our Vice President of Research and Development; 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 on our common stock in the foreseeable future. Furthermore, we are currently precluded from issuing dividends on our common stock unless we receive the consent of holders of a majority of our outstanding Series A Convertible Preferred Stock and Series A Exchangeable Preferred Stock.

Furthermore, our agreement with our secured lender prohibits the payment of cash dividends to both common and preferred stockholders. As of December 31, 2016, $7,114,600 in accretion had accumulated on the Series A Convertible Preferred Stock and the Series A Exchangeable Preferred Stock.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

The Company currently leases two 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. The lease had an initial term of ten years, expiring on September 6, 2017, and contained an option for two additional five-year periods. The lease provided for an annual base rent in years one through five of $244,800 and $268,800 in years six through ten. Under the lease, the Company was 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.

On January 23, 2017, the Company executed a five-year extension on the lease effective February 1, 2017, through January 31, 2022. Annual base rent is $274,176 for the first year of the lease and is subject to annual increases of 2% for the remaining term of the lease.

The Company is also leasing one property adjacent to its corporate facilities. 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, 2017. Minimum annual rental expense is approximately $103,000, 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

None.

Item 4. Mine Safety Disclosures

Not applicable.

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 Capital 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.

Quarter Ended	High	Low
March 31, 2015	$1.92	$1.16
June 30, 2015	$1.46	$1.09
September 30, 2015	$1.31	$1.02
December 31, 2015	$1.98	$1.13
March 31, 2016	$1.80	$1.42
June 30, 2016	$2.11	$1.43
September 30, 2016	$1.90	$1.62
December 31, 2016	$1.78	$1.54

The following table sets forth the approximate number of beneficial owners of common stock of the Company on December 31, 2016.

Title of Class	Number of Stockholders
Common stock, $.004 par value	1,731

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 on its common stock in the near future. Furthermore, we are currently precluded from issuing dividends on our common stock unless we receive the consent of holders of a majority of our outstanding Series A Convertible Preferred Stock and Series A Exchangeable Preferred Stock and are precluded from paying cash dividends on both common and preferred stock pursuant to our bank loan agreement.

As of December 31, 2016, a dividend accretion of $7,114,600 had accumulated on the Series A Convertible Preferred Stock and the Series A Exchangeable Preferred Stock.

The Company did not issue any shares of common stock during the fourth quarter of 2016 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 2016.

On February 17, 2015, the Company completed a public offering (the "Offering") underwritten by Craig-Hallum Capital Group, LLC ("Craig-Hallum") of 7,130,000 shares of its common stock at $1.30 per share, resulting in gross proceeds of $9,269,000. The Offering included an over-allotment option exercised by Craig-Hallum to purchase up to 930,000 shares. Pursuant to the underwriting agreement, Craig-Hallum purchased the shares of common stock from the Company at a price of $1.222 per share. Net proceeds to the Company under the transaction, after fees and expenses, were approximately $8,517,000. Proceeds from the transaction are being used for general corporate purposes.

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 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

In 2016, we made progress towards our multi-year strategic goal of focusing on FORE-SIGHT's opportunity to redefine the tissue oximetry market and of transforming CASMED from a low-margin commodity capital medical equipment business into a high-growth, high-margin medical disposables business.

Given the unique clinical value of FORE-SIGHT and its position as a best-in-class cerebral oximeter in an expanding market, we believe that substantial investment in the FORE-SIGHT opportunity is warranted to drive increases in the Company's enterprise value over the longer term. Our FORE-SIGHT ELITE technology, introduced in late 2013, has significantly lower costs than the first-generation technology. As a result, our gross profit margins have continued to expand. This will enable us to invest those gross profits to expand, upgrade, and revitalize our FORE-SIGHT sales organization; increase our marketing and clinical support; and continue to reduce FORE-SIGHT product costs further through prudent R&D spending.

Specific recent achievements include:

- FORE-SIGHT sales increased 17% over the prior year, driven by a 22% increase in FORE-SIGHT disposable sensor sales. Sensor revenue growth was attributable to a combination of taking customers from competitors, gaining customers who had not used cerebral oximetry in the past, and increases in sensor sales to existing customers as their utilization expanded.

- FORE-SIGHT sales represented 81% of CASMED's total sales from continuing operations in the fourth quarter of 2016, and FORE-SIGHT sensor sales accounted for 71% of total sales.

- We shipped a net of 380 FORE-SIGHT monitors worldwide in 2016, raising the cumulative net shipments from launch to 2,088 units as of year-end. The U.S. installed base accounts for 54% of the total shipped, or 1,120 monitors, which represents an increase of 23% over the prior year-end installed base.

- The five-year FORE-SIGHT sales compound average growth rate reached 23% at the end of 2016 for overall sales and 28% for U.S. sales. The fourth quarter of 2016 was the 27th consecutive quarter of double-digit U.S. FORE-SIGHT sensor sales growth over the prior-year quarter.

- CASMED largely accomplished its goal in 2016 to improve the quality of its U.S. distribution team since the hiring of new sales leadership in late 2015. In the past 12 months, we hired ten new sales representatives (to replace former sales reps and to fill new territories) and, as of March 2017, have 15 territories staffed with two open territories we expect to fill by mid-2017.

- We continue to gain name-brand hospitals as customers around the world, particularly in the U.S. We count as customers nine of the top 20 U.S. adult cardiac hospitals, as ranked by U.S. News and World Report.

- Our gross profit margin increased to 54.6% in 2016, from 51.2% in 2015, as product mix continued to shift to FORE-SIGHT oximetry, and to disposable sensors, in particular, aided further by realized cost reductions.

- On March 28, 2016, we sold our neonatal intensive care disposable supplies product line for $3.35 million. This transaction allows for enhanced focus on our FORE-SIGHT oximetry business, provides additional working capital, and is reported in our financial statements as a discontinued operation.

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, 2016 Compared to Year Ended December 31, 2015

Management Summary

During late 2015 and early 2016, the Company divested two legacy product lines deemed non-strategic by the Company's management in order to continue to focus on its FORE-SIGHT tissue oximetry product line. On October 26, 2015, the Company entered into an agreement pursuant to which it sold certain assets related to its 740 SELECT vital signs monitoring product line in exchange for $220,000 at closing and a one-year promissory note in the principal amount of $329,967. The agreement provides for royalty payments to the Company for sales of 740 SELECT products during the three-year period following the closing. In accordance with the Company's agreement with its lender, the closing proceeds and the promissory note payments will be applied to the outstanding loan balance on the Company's term loan.

On March 28, 2016, the Company entered into an agreement pursuant to which it sold its neonatal intensive care disposables product line assets in exchange for $3,350,000, including $3,035,000 paid in cash at closing. The closing proceeds were net of $100,000 to be held in escrow for 12 months following the closing and $215,000 for inventory to be held by the Company and purchased at the conclusion of a transition period, under which the Company would provide certain services, including materials procurement, inventory control, manufacturing, and order processing and fulfilment throughout the remainder of 2016. The Company effectively concluded its transition services as of December 31, 2016. The inventory to be purchased from the Company was $167,000 as of that date.

The Company has reclassified its vital signs monitoring and neonatal intensive care results to discontinued operations for all periods reported. There have been no material charges related to the Company's exit from these markets, and management does not expect such charges to be incurred in the future.

Results of Operations

The Company incurred a loss from continuing operations for 2016 of $4,923,000, or ($0.24) per basic and diluted common share, compared to $7,287,000, or ($0.34) per basic and diluted common share, for 2015. The improvement in results was led by increased net sales from continuing operations, higher gross profit margins, and from income tax benefits associated with the sale of the Company's neonatal intensive care disposable product line assets in March 2016 for $3,350,000. The sale resulted in a pre-tax gain from discontinued operations of approximately $2,911,000 and income tax expense of $1,019,000. The income tax expense was offset by an income tax benefit of $1,019,000 recorded against losses generated from continuing operations. The Company does not expect to pay income taxes in 2016. Losses from continuing operations before income taxes for 2016 were $5,871,000, compared to $7,496,000, an improvement in operating results of $1,625,000 or 22%.

The Company incurred a net loss applicable to common stockholders of $4,644,000 for 2016, or ($0.17) per basic and diluted common share, compared to a net loss applicable to common stockholders of $8,282,000, or ($0.32) per basic and diluted common share, for 2015.

Overall, net worldwide sales from continuing operations for 2016 increased $2,751,000 or 14% to $22,238,000 from $19,487,000 in 2015. The following table provides comparative results of net sales by product and geographic category:

($000's)

	Year Ended December 31, 2016	Year Ended December 31, 2015	Increase / (Decrease)	% Change
Tissue Oximetry Monitoring	$ 18,010	$ 15,399	$ 2,611	17%
Traditional Monitoring	4,228	4,088	140	3%
	$ 22,238	$ 19,487	$ 2,751	14%
Domestic Sales	$ 18,105	$ 15,571	$ 2,534	16%
International Sales	4,133	3,916	217	6%
	$ 22,238	$ 19,487	$ 2,751	14%

Worldwide tissue oximetry product sales of $18,010,000 for 2016 increased $2,611,000, or 17%, over the $15,399,000 reported for 2015, led by increased disposable sensor sales.

Traditional monitoring sales increased $140,000, or 3%, to $4,228,000 for 2016, from $4,088,000 for 2015. The increase was primarily associated with OEM technology product sales.

Total domestic sales increased $2,534,000, or 16%, to $18,105,000, or 81% of total sales from continuing operations for 2016, from $15,571,000, or 80% of total sales from continuing operations, for 2015. Domestic tissue oximetry sales increases of 20% were responsible for the increase.

International sales increased $217,000, or 6%, to $4,133,000, or 19% of total sales from continuing operations for 2016, from $3,916,000, or 20% of total sales from continuing operations, for 2015. The increase was generated by sales of both tissue oximetry and traditional monitoring products.

The following table provides additional information with respect to tissue oximetry monitoring sales:

($000's)

	Year Ended December 31, 2016	Year Ended December 31, 2015	Increase / (Decrease)	% Change
Sensor Sales	$ 15,883	$ 13,024	$ 2,859	22%
Monitors & Accessories	2,127	2,375	(248)	(10%)
	$ 18,010	$ 15,399	$ 2,611	17%
Domestic Sales	$ 14,730	$ 12,274	$ 2,456	20%
International Sales	3,280	3,125	155	5%
	$ 18,010	$ 15,399	$ 2,611	17%

Worldwide tissue oximetry sensor sales for 2016 were $15,883,000, an increase of $2,859,000, or 22%, over 2015 sensor sales of $13,024,000. Worldwide sales of oximetry monitors and accessories for 2016 decreased $248,000, or 10%, to $2,127,000 from 2015 sales of $2,375,000. As of December 31, 2016, the Company's worldwide cumulative shipments of oximetry monitors were 2,088 units, an increase of 22%, compared to December 31, 2015. The U.S. installed base increased 23% over 2016 to 1,120 monitors as of December 31, 2016.

Gross profit as a percentage of net sales from continuing operations was 54.6% for 2016 and 51.2% for 2015. The improvement for 2016 was largely driven by the increase in FORE-SIGHT sales as a percent of total sales, an increase in disposable sensor sales as percent of total sales, and reductions in our cost of goods sold. Overall FORE-SIGHT sales accounted for 81% and 79% of total net sales from continuing operations for 2016 and 2015, respectively.

During 2016 and 2015, the Company incurred research and development ("R&D") expenses of approximately $3,437,000 and $3,514,000. The slight decrease of 2% in 2016 was due to lower R&D project expenses. R&D expenses were approximately 15% of sales from continuing operations in 2016, down from 18% in 2015.

Selling, general, and administrative ("S,G&A") expenses increased $478,000, or 4%, to $13,575,000 for 2016 from $13,097,000 for 2015. The increases in spending resulted primarily from the Company's expansion of its FORE-SIGHT sales organization during the second half of 2016 and were partially offset by reductions in marketing expenses.

Interest expense for 2016 was $1,048,000, an increase of $189,000 over 2015, reflecting both increased debt levels and amortization of deferred finance charges.

There was no income tax benefit in the aggregate recorded for either 2016 or 2015. The Company does not expect to record taxable income during its 2016 fiscal year. Income tax benefits that may be generated during 2016 would be offset by a deferred income tax asset valuation allowance. Management established the valuation allowance as of December 31, 2009, as a result of then recent cumulative pre-tax losses and its estimates of future taxable income. Management has continued to perform the required analysis regarding the realization of our deferred income tax assets, concluding that a full valuation allowance is warranted. As of December 31, 2016, the deferred income tax asset valuation allowance balance was $16,559,000.

Financial Condition, Liquidity, and Capital Resources

The Company's continuing operations used $4,564,000 of cash for 2016, compared to $4,806,000 used by continuing operations during 2015, due to reduced losses from continuing operations which were partially offset by unfavorable changes in working capital, particularly inventory and accounts payable.

Net cash provided by investing activities of continuing operations was $1,945,000 for 2016, compared to cash used of $1,225,000 for 2015. Cash provided by investing activities for 2016 included $3,304,000 pertaining to the sale of the Company's neonatal intensive care disposables product line in March 2016. The Company incurred $1,265,000 of capital expenditures during 2016, compared to $1,129,000 for 2015. For both periods, the expenditures were primarily related to placements of FORE-SIGHT oximeter monitors at customer locations. The Company also expended $94,000 and $96,000 during 2016 and 2015, respectively, to purchase intangible assets which were primarily related to patent costs.

Net cash provided by financing activities of continuing operations was $144,000 for 2016, compared to cash provided of $7,221,000 for 2015. During 2016, the Company entered into a bank agreement with new lenders, as described below, and repaid the outstanding balance under its previous loan. During 2015, the Company consummated a public offering which realized $8,517,000 in net proceeds after transaction costs. In addition, the Company repaid $1,000,000 of advances during January 2015 from its line-of-credit borrowings initiated in December 2014.

On June 30, 2016, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with Solar Capital Ltd. and Western Alliance Bank (collectively, the "Lenders"). Pursuant to the Loan Agreement, the Lenders have provided the Company with a 48-month secured term loan in the amount of $8,000,000 (the "Term Loan") and a Revolving Loan in the maximum amount of $2,500,000 (the "Revolver"). The Revolver expires on July 1, 2018, and the Term Loan matures on July 1, 2020. The obligations under the Loan Agreement are secured by a lien on substantially all assets of the Company.

The Term Loan bears interest at a floating rate equal to 8.75% plus the 30-day LIBOR rate (9.36% as of December 31, 2016). Under the Term Loan, 36 equal payments of $222,222 commence on August 1, 2017, with one final payment in an amount equal to the remaining principal balance on the final maturity date. Principal payments under the Term Loan may be deferred an additional six months if the Company reaches a specified product line sales target for the 12 months ending June 30, 2017.

Revolver advances will bear interest at a floating rate equal to 2.5% plus the higher of 3.5% per annum or a specified prime rate. Maximum borrowings under the Revolver are based upon the Company's eligible accounts receivable as defined in the Loan Agreement. There were no borrowings under the Revolver as of December 31, 2016, and the amount available for borrowing at that date was $2,113,000, according to the borrowing formula contained with the Loan Agreement and subject to other terms and conditions.

The Company has the right to prepay the loans under the Loan Agreement in full at any time. If the Term Loan is prepaid prior to maturity, an additional fee of 2% of the Term Loan amount is due if such prepayment takes place within one year from the closing date, and thereafter, the additional fee declines to 1% for any prepayment taking place after such first anniversary and prior to the scheduled maturity date. Amounts prepaid under the Term Loan may not be re-borrowed. Upon repayment of the Term Loan at any time, the Lenders are entitled to an additional fee equal to 4% of the Term Loan amount. A separate early termination fee equal to 1% of the Revolver commitment amount is payable only if the Revolver is terminated on or before the one-year anniversary of the closing date.

The Loan Agreement contains customary affirmative covenants, including covenants regarding the payment of taxes and other obligations, maintenance of insurance, reporting requirements, and compliance with applicable laws and regulations. Further, the Loan Agreement contains customary negative covenants limiting the ability of the Company and its subsidiaries, among other things, to grant liens on the pledged collateral, incur additional indebtedness, make certain investments and acquisitions, and dispose of assets outside the ordinary course of business. The Loan Agreement also contains a financial covenant requiring the Company to maintain a continuing level of cash plus available borrowing capacity based on a formula. Management believes it was in compliance with all covenants as of December 31, 2016.

Upon an event of default, the Bank may declare all outstanding principal and accrued but unpaid interest under the Loan Agreement immediately due and payable and may exercise the other rights and remedies provided under the Loan Agreement. The events of default under the Loan Agreement include payment defaults, breaches of covenants or representations and warranties, a material adverse change, certain adverse regulatory events, specified change of control events, and bankruptcy events.

The Company's prior secured term loan with Solar was repaid in full at the closing, and the revolving line-of-credit with Solar, which had no outstanding balance, was terminated. The Company paid a fee of $218,000 in connection with the termination of the prior credit facility, in lieu of the original contractual fee.

In connection with the Loan Agreement, on June 30, 2016, the Company issued warrants (the "Warrants") to the Lenders, which provide for the right to purchase an aggregate of 64,655 shares of the Company's common stock for a ten-year period, expiring on June 30, 2026, at an exercise price of $1.856 per share (of which 48,491 shares may be purchased by Solar and 16,164 shares may be purchased by Western Alliance Bank).

The amount of shares issuable pursuant to the Warrants, and the exercise price thereof, are subject to adjustment only in the event of stock splits, subdivisions, reclassifications, exchanges, combinations, and similar transactions. The Warrants also contain a cashless exercise provision.

The shares associated with the Warrants were fully vested at the time of issuance. The value of the Warrants were estimated on the date of grant to be $1.44 per share using the Black-Scholes option pricing model, assuming a weighted-average expected stock price volatility of 73.4%, an expected warrant term of ten years, an average risk-free interest rate of 1.48%, and a 0.0% average dividend yield. The value of the Warrants of $92,906, as calculated above, has been recorded as a debt discount and is being recognized as interest expense over the 48-month term of the Loan Agreement.

The Company financed its directors' and officers' insurance premiums during 2016 under a note payable in the amount of $87,565. The note payable requires ten payments of $8,948, including interest, and is scheduled to be repaid in full by September 2017.

The Company currently leases two 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, 2016.

Contractual Obligations	Total	Less than One Year	2 - 3 Years	4 - 5 Years	More Than Five Years
Operating leases	$1,561,617	$364,558	$608,783	$588,276	$ —

The Company's ordinary short-term capital needs are expected to be met from its cash-on-hand, which was supplemented by net proceeds of approximately $8,517,000 from a public offering of its common stock consummated on February 17, 2015; funds received from the increase of its bank term debt refinanced during 2016; amounts available under the revolving credit agreement with Western Alliance; and the proceeds from sales of non-strategic assets. On March 28, 2016, the Company sold its neonatal intensive care disposables product line for $3,350,000, including $3,035,000 paid in cash at closing. The proceeds from the transaction are being used for general working capital purposes.

Cash flows may be impacted by a number of factors, including changing market conditions, market acceptance of the FORE-SIGHT system, the loss of one or more key customers, and other factors, including those detailed in Item 1A of this report, entitled Risk Factors. There can be no assurance that the Company will be successful in raising additional capital if the need arises. The failure to raise any necessary additional capital on acceptable terms, or at all, could have a material adverse effect on the Company's business and results of operations.

The Company's 2017 business plans call for operating expenditures to be above 2016 levels. Sales-related expenditures are estimated to expand modestly in 2017, as a result of higher anticipated sales and the effects of the Company's build-out of its U.S. FORE-SIGHT sales network during the second half of 2016 and the first half of

2017. R&D and G&A expenses are expected to increase slightly over 2016 levels. Capital expenditures for 2017 are expected to increase over 2016 levels. Capital expenditures include the Company's placement of FORE-SIGHT monitors in customer accounts, whereby the Company retains title to the monitor in exchange for customer purchases of disposable sensors.

The Company's results of operations were not affected by inflation during 2016.

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 inventory write-offs for any period presented.

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 carryforwards 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 warranties 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 historically material to operating results. 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 statements 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 based 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.

Sales and Accounts Receivable Recognition - 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 receipt. 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 a right-of-return at the time of sale. Historically, such returns have not been significant. Payment terms range from prepayment to net 90 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.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

The Company holds no derivative securities for trading purposes and is not subject in any material respect to currency or other commodity risk.

Report of Independent Registered Public Accounting Firm

The Stockholders and Board of Directors
CAS Medical Systems, Inc.

We have audited the accompanying consolidated balance sheets of CAS Medical Systems, Inc. and Subsidiary (the "Company") as of December 31, 2016 and 2015, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for the years 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 audits.

We conducted our audits 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. Our audit included 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 audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of CAS Medical Systems, Inc. and Subsidiary as of December 31, 2016 and 2015, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ CohnReznick LLP

Roseland, New Jersey
March 15, 2017

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CAS Medical Systems, Inc.
Consolidated Balance Sheets
As of December 31, 2016 and 2015

ASSETS	2016	2015
CURRENT ASSETS:		
Cash and cash equivalents	$5,488,706	$7,528,292
Accounts receivable, net	3,322,400	2,921,720
Notes and other receivables	557,217	384,673
Inventories	1,595,668	1,428,425
Other current assets	322,148	364,444
Assets associated with discontinued operations	85,349	906,339
Total current assets	11,371,488	13,533,893
PROPERTY AND EQUIPMENT:		
Leasehold improvements	151,377	139,970
Equipment at customers	3,762,632	3,513,617
Machinery and equipment	4,913,595	4,753,062
	8,827,604	8,406,649
Accumulated depreciation and amortization	(6,266,097)	(6,173,823)
Property and equipment, net	2,561,507	2,232,826
Intangible and other assets, net	790,971	813,017
Total assets	$14,723,966	$16,579,736

CAS Medical Systems, Inc.
Consolidated Balance Sheets
As of December 31, 2016 and 2015

LIABILITIES AND STOCKHOLDERS' EQUITY	2016	2015
CURRENT LIABILITIES:		
Accounts payable	$1,074,939	$1,459,798
Accrued expenses	2,239,985	1,833,502
Note payable	70,015	82,377
Current portion of long-term debt, less unamortized debt issuance costs	840,471	2,616,992
Liabilities associated with discontinued operations	92,942	199,940
Total current liabilities	4,318,352	6,192,609
Deferred gain on sale and leaseback of property	91,603	226,240
Long-term debt, less current portion and unamortized debt issuance costs	6,580,851	4,207,629
Other long-term liability	320,000	300,000
Total liabilities	11,310,806	10,926,478
Commitments and contingencies (Note 11)		
STOCKHOLDERS' EQUITY:		
Preferred stock, $.001 par value per share, 1,000,000 shares authorized		
Series A convertible preferred stock, 95,500 shares issued and outstanding, liquidation value of $14,079,629 and $13,135,709 at December 31, 2016 and December 31, 2015, respectively	8,802,000	8,802,000
Series A exchangeable preferred stock, 54,500 shares issued and outstanding, liquidation value of $8,034,971 and $7,496,295 at December 31, 2016 and December 31, 2015, respectively	5,135,640	5,135,640
Common stock, $.004 par value per share, 60,000,000 shares authorized, 27,428,752 and 27,391,722 shares issued at December 31, 2016 and December 31, 2015, respectively, including shares held in treasury	109,715	109,567
Common stock held in treasury, at cost - 86,000 shares	(101,480)	(101,480)
Additional paid-in capital	30,557,093	29,636,087
Accumulated deficit	(41,089,808)	(37,928,556)
Total stockholders' equity	3,413,160	5,653,258
Total liabilities and stockholders' equity	$14,723,966	$16,579,736

See accompanying notes.
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CAS Medical Systems, Inc.
Consolidated Statements of Operations
For the Years Ended December 31, 2016 and 2015

	2016	2015
Net sales from continuing operations	$22,237,825	$19,486,570
Cost of sales	10,091,331	9,516,525
Gross profit	12,146,494	9,970,045
Operating expenses:		
Research and development	3,436,618	3,514,362
Selling, general and administrative	13,575,219	13,097,167
Total operating expenses	17,011,837	16,611,529
Operating loss	(4,865,343)	(6,641,484)
Interest expense	1,048,207	859,372
Other income	(42,521)	(4,658)
Loss from continuing operations before income taxes	(5,871,029)	(7,496,198)
Income tax benefit	(948,422)	(209,197)
Loss from continuing operations	(4,922,607)	(7,287,001)
Discontinued operations:		
(Loss) income from discontinued operations	(201,239)	621,826
Gain (loss) on sale of discontinued operations	2,911,016	(24,120)
Income tax expense	948,422	209,197
Income from discontinued operations	1,761,355	388,509
Net loss	(3,161,252)	(6,898,492)
Preferred stock dividend accretion	1,482,595	1,383,200
Net loss applicable to common stockholders	$(4,643,847)	$(8,281,692)
Loss per common share from continuing operations - basic and diluted	$(0.24)	$(0.34)
Income per common share from discontinued operations - basic and diluted	0.07	0.02
Per share basic and diluted net loss applicable to common stockholders	$(0.17)	$(0.32)
Weighted-average number of common shares outstanding:		
Basic and diluted	26,826,792	25,700,942

See accompanying notes.

CAS Medical Systems, Inc.
Consolidated Statements of Changes in Stockholders' Equity
For the Years Ended December 31, 2016 and 2015

	Preferred Stock		Common Stock Issued		Common Stock Held in Treasury		Additional Paid-in	Accumulated	
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Total
BALANCE, December 31, 2014	150,000	$13,937,640	19,563,333	$78,253	86,000	$(101,480)	$20,285,008	$(31,030,064)	$3,169,
Net loss								(6,898,492)	(6,898
Common stock issued in public offering			7,130,000	28,520			8,488,975		8,517,
Common stock issued under stock purchase plan			9,988	40			14,615		14,65
Warrants exercised			330,401	1,322			144,078		145,4
Restricted stock issued, net of cancellations			358,000	1,432			(1,432)		—
Stock compensation							704,843		704,8
BALANCE, December 31, 2015	150,000	13,937,640	27,391,722	109,567	86,000	(101,480)	29,636,087	(37,928,556)	5,653,
Net loss								(3,161,252)	(3,161
Common stock issued under stock purchase plan			6,079	24			9,438		9,462
Common stock issued - options			30,951	124			32,835		32,95

exercised									
Warrants issued to lenders							92,906		92,906
Stock compensation							785,827		785,82
BALANCE, December 31, 2016	150,000	$13,937,640	27,428,752	$109,715	86,000	$(101,480)	$30,557,093	$(41,089,808)	$3,413,

See accompanying notes.

CAS Medical Systems, Inc.
Consolidated Statements of Cash Flows
For the Years Ended December 31, 2016 and 2015

	2016	2015
OPERATING ACTIVITIES:		
Net loss	$(3,161,252)	$(6,898,492)
Income from discontinued operations	1,761,355	388,509
Loss from continuing operations	(4,922,607)	(7,287,001)
Adjustments to reconcile loss from continuing operations to net cash used in operating activities of continuing operations:		
Depreciation and amortization	1,012,957	1,363,266
Amortization of debt issuance costs and discounts	351,636	72,492
Deferred income taxes	(948,422)	(209,197)
Provision for doubtful accounts	—	2,335
Stock compensation	785,827	706,161
Impairment of capitalized costs	56,857	16,466
Amortization of gain on sale and leaseback of property	(134,637)	(134,637)
Changes in operating assets and liabilities:		
Accounts receivable	(400,680)	(667,829)
Notes and other receivables	(505,550)	108,622
Inventories	(167,243)	568,770
Other current assets	286,478	264,306
Accounts payable and accrued expenses	21,626	390,622
Net cash used in operating activities of continuing operations	(4,563,758)	(4,805,624)
INVESTING ACTIVITIES:		
Expenditures for property and equipment	(1,265,095)	(1,129,269)
Proceeds from sale of discontinued operations	3,303,739	—
Additions to intangible assets	(93,572)	(95,914)
Net cash provided by (used in) investing activities of continuing operations	1,945,072	(1,225,183)
FINANCING ACTIVITIES:		
Proceeds from long-term debt	8,000,000	—
Repayment of long-term debt	(7,280,000)	(220,000)
Payment of end-of-term loan fee	(218,000)	—
Deferred financing costs	(144,030)	—
Repayment of line-of-credit	—	(1,000,000)
Repayments of notes payable	(256,543)	(236,844)
Proceeds from issuance of common stock	42,421	8,677,550
Net cash provided by financing activities of continuing operations	143,848	7,220,706
Net (decrease) increase in cash and cash equivalents from continuing operations	(2,474,838)	1,189,899
CASH FLOWS FROM DISCONTINUED OPERATIONS:		
Cash provided by operating activities of discontinued operations	435,252	1,847,090
Cash used in investing activities of discontinued operations	—	(3,360)
Net cash provided by discontinued operations	435,252	1,843,730

Net change in cash and cash equivalents	(2,039,586)	3,033,629
Cash and cash equivalents, beginning of year	7,528,292	4,494,663
CASH AND CASH EQUIVALENTS, END OF YEAR	$5,488,706	$7,528,292
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid during the period for interest	$848,335	$779,748
Insurance premiums funded with note payable	$244,182	$232,279
End-of-term fee payable to lenders	$320,000	$—
Warrants issued to lenders	$92,906	$—

See accompanying notes.

CAS Medical Systems, Inc.

Notes to Consolidated Financial Statements

(1) THE COMPANY

CAS Medical Systems, Inc. ("CASMED" or the "Company") is a medical technology company that develops, manufactures, and distributes non-invasive patient monitoring products that are vital to patient care. The Company's products include the FORE-SIGHT® series of absolute tissue oximeters and sensors, including the FORE-SIGHT ELITE® oximeter, and traditional monitoring products which include blood pressure measurement technologies, and monitor service and repair. These products are designed to provide accurate, non-invasive, biologic measurements that guide healthcare providers to deliver improved patient care. CASMED markets its products worldwide through its sales force, distributors, manufacturers' representatives, and original equipment manufacturers. The Company's facility and manufacturing operations are located in the United States.

(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

The consolidated financial statements include the accounts of CASMED and one inactive subsidiary.

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.

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 certain FORE-SIGHT tissue oximetry monitors primarily located at customer sites within the United States. Such equipment is typically 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 to cost-of-sales on a straight-line basis over five years.

Depreciation expense on property and equipment was $943,000 in 2016 and $1,167,000 in 2015.

Intangible and other assets

The Company reviews its intangible and other long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. During 2016 and 2015, the Company charged-off $56,857 and $16,466, respectively, of capitalized costs related to certain abandoned patents and trademarks. The Company believes that the carrying amounts of its long-lived assets are fully recoverable.

Intangible and other assets at December 31, 2016 and 2015 consist of:

	2016	2015
Patents and other assets	$654,566	$905,454
Patents pending	335,702	315,826
	990,268	1,221,280
Accumulated amortization	(199,297)	(408,263)
Total	$790,971	$813,017

Intangible and other assets are stated at cost. Patents are amortized on a straight-line basis over 20 years.

Expected amortization expense of intangible assets as of December 31, 2016, over the next five calendar years follows:

2017	$36,300
2018	$32,700
2019	$28,700
2020	$28,200
2021	$27,800

Sales and accounts receivable recognition

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 receipt. 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 a right-of-return at the time of sale. Historically, such returns have not been significant. Payment terms range from prepayment to net 90 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 includs 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 facility 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.

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.

The Company's five largest customers accounted for approximately 21% and 25% of sales from continuing operations in 2016 and 2015, respectively. Among these customers, Physio-Control, Inc. accounted for 11% and 12% of such sales during each of 2016 and 2015, 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 carryforwards. A valuation allowance is provided for that portion of deferred income tax assets which may not be realized.

The Company accrues for uncertain tax positions in accordance with accounting standards which prescribe 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. The Company's U.S. Federal and State income tax returns prior to 2013 are closed. 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 at December 31, 2016 and 2015 follows:

	2016	2015
Beginning balance	$178,424	$100,000
Provision	40,705	154,292
Warranty costs incurred	(81,109)	(75,868)
Ending balance	$138,020	$178,424

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, clinical studies, materials, and facility-related expenses.

Advertising costs

Non-direct response advertising costs are expensed as incurred and include product promotion, samples, meetings and conventions, and print media. Advertising expense related to continuing operations was $725,000 and $680,000 in 2016 and 2015, respectively.

Loss per common share applicable to common stockholders

Basic earnings (loss) per share is calculated by dividing net income (loss) applicable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted earnings (loss) per share reflects the potential dilution that could occur if common stock equivalents, such as unvested restricted common shares, outstanding warrants and options, or convertible preferred stock were exercised or converted into common stock. For all periods reported, the Company incurred net losses from continuing operations. Therefore, for each period reported, diluted loss per share is equal to basic loss per share because the effect of including such common stock equivalents or other securities would have been anti-dilutive.

At December 31, 2016, stock options and warrants to purchase 3,229,500 and 451,458 shares of common stock, respectively, were excluded from the diluted earnings per share calculation as they would have been anti-dilutive. On an as-converted basis, 9,256,844 shares of common stock pertaining to the private placement of 150,000 shares of Series A convertible and exchangeable preferred stock issued on June 8, 2011, were also excluded as they would have been anti-dilutive.

(3) DISCONTINUED OPERATIONS

On October 26, 2015, the Company entered into an agreement pursuant to which it sold certain assets related to its 740 SELECT vital signs monitoring product line in exchange for $220,000 at closing and a one-year promissory note in the principal amount of $329,967. The promissory note has been satisfied in full as of December 31, 2016. The agreement provides for royalty payments to the Company for sales of 740 SELECT product during the three-year period following the closing. Royalties earned by the Company through December 31, 2016, were not material.

The Company reclassified its vital signs monitoring results to discontinued operations for all periods reported. There have been no material charges related to the Company's exit from this market.

On March 28, 2016, the Company entered into an agreement pursuant to which it sold its neonatal intensive care disposables product line assets in exchange for $3,350,000, including $3,035,000 paid in cash at closing. The closing proceeds were net of $100,000 to be held in escrow for 12 months following the closing and $215,000 for inventory to be held by the Company and purchased at the conclusion of a transition period, under which the Company would provide certain services, including materials procurement, inventory control, manufacturing, and order processing and fulfilment throughout the remainder of 2016. The Company effectively concluded its transition services as of December 31, 2016. The inventory to be purchased from the Company was $167,000 as of that date.

The following table presents the assets and liabilities related to the vital signs monitoring and neonatal intensive care disposables product lines, classified as assets and liabilities associated with discontinued operations in the consolidated balance sheets as of the periods below:

	December 31, 2016	December 31, 2015
Accounts receivable	$ 85,349	$ 697,726
Inventories	—	190,830
Property and equipment, net	—	6,681
Intangible assets	—	11,102
Total assets associated with discontinued operations	$ 85,349	$ 906,339
Accounts payable	$ 22,692	$ 144,106
Accrued expenses	70,250	55,834
Total liabilities associated with discontinued operations	$ 92,942	$ 199,940

The following table represents the results of the discontinued operations for years ended December 31:

	2016	2015
Net sales	$799,690	$4,845,701
Cost of sales	583,913	3,488,243
Gross profit	215,777	1,357,458
Operating expenses	417,016	735,632
(Loss) income from discontinued operations before income taxes	(201,239)	621,826
Gain (loss) on sale of discontinued operations	2,911,016	(24,120)
Income tax expense	(948,422)	(209,197)
Income from discontinued operations	$1,761,355	$388,509

(4) ALLOWANCE FOR DOUBTFUL ACCOUNTS

Changes in the allowance for doubtful accounts during the years ended December 31, 2016 and 2015 follow:

	2016	2015
Balance at beginning of year	$110,000	$110,000
Provision	—	2,335
Accounts written off	—	(2,335)
Balance at end of year	$110,000	$110,000

(5) INVENTORIES

Inventories at December 31, 2016 and 2015 consist of:

	2016	2015
Raw materials	$1,027,145	$919,870
Work in process	23,252	20,917
Finished goods	545,271	487,638
Total	$1,595,668	$1,428,425

(6) FINANCING ARRANGEMENTS

Common Stock Public Offering

On February 17, 2015, the Company completed a public offering underwritten by Craig-Hallum Capital Group, LLC ("Craig-Hallum") of 7,130,000 shares of its common stock at $1.30 per share, resulting in gross proceeds of $9,269,000. The offering included an over-allotment option exercised by Craig-Hallum to purchase up to 930,000 shares. Pursuant to the underwriting agreement, Craig-Hallum purchased the shares of common stock from the Company at a price of $1.222 per share. Net proceeds to the Company from the transaction, after fees and expenses, were approximately $8,517,000. Proceeds from the transaction are being used for general corporate purposes.

Private Placement of Preferred Stock

On June 8, 2011, the Company issued 95,500 shares of "Series A Convertible Preferred Stock" and 54,500 shares of "Series A Exchangeable Preferred Stock," (collectively, the "Series A Preferred Stock"), each with a par value $0.001 per share, which are convertible into authorized but unissued shares of common stock, par value $0.004 per share, of the Company. The Series A Exchangeable Preferred Stock now has substantially identical terms to the Series A Convertible Preferred Stock.

The Company received an aggregate cash purchase price of $15,000,000, representing a per-share purchase price of $100 for the Series A Convertible Preferred Stock and $100 for the Series A Exchangeable Preferred Stock. The Company received net proceeds, after transaction costs and expenses, of $13,825,000.

The shares of Series A Preferred Stock were initially convertible at the option of the holder into common stock at a conversion price of $2.82 (the "Conversion Price"). The Conversion Price for a period of time was subject to standard weighted-average anti-dilution adjustments. On July 22, 2013, upon completion of the Company's public offering of common stock, the Conversion Price was adjusted to $2.389 per share. Those anti-dilution rights expired during June 2014.

The stated value ($100.00 per share) of the Series A Preferred Stock accretes at an annual rate of 7% compounded quarterly. On an annual basis, prior to the third anniversary of the original date of issuance, the holders could have elected, pursuant to certain requirements, to receive the following 12 months of accretion in the form of a dividend of 7% per annum, payable quarterly in cash at the holder's option. After the third anniversary of the closing, such accretion may be made in cash at the Company's option. The Series A Preferred Stock is subject to certain default provisions whereby the dividend rate would be increased by an additional 5% per annum.

After the third anniversary of the original date of issuance, the Company can force conversion of all, and not less than all, of the outstanding Series A Preferred Stock into Company common stock as long as the closing price of its common stock is at least 250% of the Conversion Price, or $5.9725 per common share, for at least 20 of the 30 consecutive trading days immediately prior to the conversion and the average daily trading volume is greater than 50,000 shares per day over the 30 consecutive trading days immediately prior to such conversion. The Company's ability to cause a conversion is subject to certain other conditions as provided pursuant to the terms of the Series A Preferred Stock described above.

The Series A Preferred Stock is entitled to a liquidation preference equal to the greater of 100% of the accreted value for each share of Series A Preferred Stock outstanding on the date of a liquidation plus all accrued and unpaid dividends or the amount a holder would have been entitled to had the holder converted the shares of Series A Preferred Stock into common stock immediately prior to the liquidation. The Series A Preferred Stock votes together with the common stock as if converted on the original date of issuance. Holders of Series A Preferred Stock are entitled to purchase their pro rata share of additional stock issuances in certain future financings.

The Company's bank agreement with Solar Capital prohibits the payment of cash dividends. As of December 31, 2016, dividend accretion of $7,114,600 has accumulated on the Series A Preferred Stock.

Bank Financing

On June 30, 2016, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with Solar Capital Ltd. ("Solar") and Western Alliance Bank (collectively, the "Lenders"). Pursuant to the Loan Agreement, the Lenders have provided the Company with a 48-month secured term loan in the amount of $8,000,000 (the "Term Loan") and a Revolving Loan in the maximum amount of $2,500,000 (the "Revolver"). The Revolver expires on July 1, 2018, and the Term Loan matures on July 1, 2020. The obligations under the Loan Agreement are secured by a lien on substantially all assets of the Company.

The Term Loan bears interest at a floating rate equal to 8.75% plus the 30-day LIBOR rate (9.36% as of December 31, 2016). Under the Term Loan, 36 equal payments of $222,222 commence on August 1, 2017, with one final payment in an amount equal to the remaining principal balance on the final maturity date. Principal payments under the Term Loan may be deferred an additional six months if the Company reaches a specified product line sales target for the 12 months ending June 30, 2017.

Revolver advances will bear interest at a floating rate equal to 2.5% plus the higher of 3.5% per annum or a specified prime rate. Maximum borrowings under the Revolver are based upon the Company's eligible accounts receivable as defined in the Loan Agreement. There were no borrowings under the Revolver as of December 31, 2016, and the amount available for borrowing at that date was $2,113,000, according to the borrowing formula contained in the Loan Agreement and subject to other terms and conditions.

The Company has the right to prepay the loans under the Loan Agreement in full at any time. If the Term Loan is prepaid prior to maturity, an additional fee of 2% of the Term Loan amount is due if such prepayment takes place within one year from the closing date, and thereafter, the additional fee declines to 1% for any prepayment taking place after such first anniversary and prior to the scheduled maturity date. Amounts prepaid under the Term Loan may not be re-borrowed. Upon repayment of the Term Loan at any time, the Lenders are entitled to an additional fee equal to 4% of the Term Loan amount. A separate early termination fee equal to 1% of the Revolver commitment amount is payable only if the Revolver is terminated on or before the one-year anniversary of the closing date.

The Loan Agreement contains customary affirmative covenants, including covenants regarding the payment of taxes and other obligations, maintenance of insurance, reporting requirements, and compliance with applicable laws and regulations. Further, the Loan Agreement contains customary negative covenants limiting the ability of the Company and its subsidiaries, among other things, to grant liens on the pledged collateral, incur additional indebtedness, make certain investments and acquisitions, and dispose of assets outside the ordinary course of business. The Loan Agreement also contains a financial covenant requiring the Company to maintain a continuing level of cash plus available borrowing capacity based on a formula. The Company was in compliance with all covenants as of December 31, 2016.

Upon an event of default, the Lenders may declare all outstanding principal and accrued but unpaid interest under the Loan Agreement immediately due and payable and may exercise the other rights and remedies provided under the Loan Agreement. The events of default under the Loan Agreement include payment defaults, breaches of covenants or representations and warranties, a material adverse change, certain adverse regulatory events, specified change of control events, and bankruptcy events.

The Company's prior secured term loan with Solar was repaid in full at the closing, and the revolving line-of-credit with Solar, which had no outstanding balance, was terminated. The Company paid a fee of $218,000 in connection with the termination of the prior credit facility, in lieu of the original contractual fee.

In connection with the Loan Agreement, on June 30, 2016, the Company issued warrants (the "Warrants") to the Lenders, which provide for the right to purchase an aggregate of 64,655 shares of the Company's common stock for a ten-year period, expiring on June 30, 2026, at an exercise price of $1.856 per share (of which 48,491 shares may be purchased by Solar and 16,164 shares may be purchased by Western Alliance Bank).

The amount of shares issuable pursuant to the Warrants, and the exercise price thereof, are subject to adjustment only in the event of stock splits, subdivisions, reclassifications, exchanges, combinations, and similar transactions. The Warrants also contain a cashless exercise provision.

The shares associated with the Warrants were fully vested at the time of issuance. The value of the Warrants were estimated on the date of grant to be $1.44 per share using the Black-Scholes option pricing model, assuming a weighted-average expected stock price volatility of 73.4%, an expected warrant life of ten years, an average risk-free interest rate of 1.48%, and a 0.0% average dividend yield. The value of the Warrants of $92,906, as calculated above, has been recorded as a debt discount and is being recognized as interest expense over the 48-month term of the Loan Agreement.

The outstanding balance of the bank term loan at December 31, 2016 and 2015 was as follows:

	December 31, 2016			December 31, 2015		
	Principal	Unamortized Debt Issuance Cost and Discounts	Debt, Net	Principal	Unamortized Debt Issuance Cost and Discounts	Debt, Net
Balance of term loan	$8,000,000	$ 578,678	$7,421,322	$7,280,000	$ 455,379	$6,824,621
Less current portion	1,111,111	270,640	840,471	2,817,940	200,948	2,616,992
Long-term portion	$6,888,889	$ 308,038	$6,580,851	$4,462,060	$ 254,431	$4,207,629

The Company financed its directors' and officers' insurance premiums during 2016 under a note payable in the amount of $87,565. The note payable requires ten payments of $8,948, including interest, and is scheduled to be repaid in full by September 2017.

(7) ACCRUED EXPENSES

Accrued expenses at December 31, 2016 and 2015 consist of:

	2016	2015
Payroll	$367,193	$261,374
Employee compensation	791,228	525,000
Professional fees	287,252	310,442
Warranty	138,020	178,424
Sales and use tax	297,844	295,014
Other	358,448	263,248
	$2,239,985	$1,833,502

(8) SHARE-BASED PAYMENT PLANS

On June 22, 2016, the Company's stockholders approved an amendment to the CAS Medical Systems, Inc. 2011 Equity Incentive Plan (the "Plan") which increased the maximum number of shares that can be issued under the Plan by 1,500,000 to 4,500,000. Awards that may be granted under the Plan include options, restricted stock and restricted stock units, and other stock-based awards. In addition, the sublimit of awards of restricted stock and restricted stock units was increased from 500,000 to 1,250,000. The purposes of the Plan are to make available to our key employees and directors certain compensatory arrangements related to growth in value of our 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 to align, in general, the interests of employees and directors with the interests of our stockholders. As of December 31, 2016, there remained 1,637,585 total shares available for issuance, including a sublimit of 788,536 shares available for restricted stock and restricted stock units.

The 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.

Stock Options

During 2016, stock options to purchase 30,000 shares of common stock were granted to an employee as an employment incentive. The stock option vests over a four-year period. As of December 31, 2016, options to purchase 3,229,500 shares remain outstanding, of which 2,399,000 pertain to options granted under the Plan; 330,500 pertain to stock options granted under the now-expired 2003 Plan; and 500,000 were issued as non-plan inducement grants to officers commensurate with the start of their employment with the Company.

The unamortized stock compensation expense associated with the stock options at December 31, 2016, was $831,000 and will be recognized through the third quarter of 2020.

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

	2016			2015		
	Option Shares	Weighted-Average Exercise Price	Aggregate Intrinsic Value	Option Shares	Weighted-Average Exercise Price	Aggregate Intrinsic Value
Outstanding at beginning of year	3,374,875	$ 1.95		3,106,000	$ 2.05	
Granted	30,000	1.78		693,500	1.51	
Exercised	(30,951)	1.61		—	—	
Cancelled	(144,424)	1.57		(424,625)	1.92	
Outstanding at end of year	3,229,500	$ 1.97	$ 82,250	3,374,875	$ 1.95	$ 235,443
Exercisable at end of year	2,360,375	$ 2.08	$ 20,563	1,935,000	$ 2.13	$ 52,888
Vested and expected to vest at end of year	3,203,432	$ 1.97	$ 80,399	3,331,699	$ 1.95	$ 229,966
Weighted-average grant-date fair value of options granted during the year		$ 0.98			$ 0.93	

During 2016, stock options to purchase 30,951 shares of common stock were exercised, and options to purchase 144,424 shares were cancelled.

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 fair value of the stock option granted during 2016 was $0.98 and assumed a weighted-average expected stock volatility of 58.2%, a weighted-average expected option term of 6.3 years, an average risk-free interest rate of 1.31%, and a 0.0% dividend yield. 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 are obtained from public data sources.

Additional information about stock options outstanding and exercisable at December 31, 2016, follows:

Range of Exercise Prices	Number Outstanding	Weighted Remaining Contractual Life in Years	Average Exercise Price	Number Exercisable	Average Exercise Price
$1.20 - $1.26	205,000	8.6	$1.21	51,250	$1.21
1.64 - 1.98	1,786,500	7.9	1.76	1,121,125	1.77
2.09 - 2.54	910,000	5.7	2.15	860,000	2.16
2.95 - 3.16	328,000	3.9	3.09	328,000	3.09
	3,229,500	7.3	$1.97	2,360,375	$2.08

Restricted Stock

There were no shares of restricted stock granted during 2016. As of December 31, 2016, there were 418,500 restricted shares issued to employees which remained issued and non-vested.

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

	2016	2015
Outstanding at beginning of year	508,000	178,694
Granted	—	358,000
Cancelled	—	—
Vested	(89,500)	(28,694)
Outstanding at end of year	418,500	508,000

The fair value of the restricted common share grants have been calculated based upon the market value of the common stock on the date of issuance. Restricted stock granted to employees typically vests over a period of not less than three years, while restricted stock granted to members of the Board of Directors typically vests over a period of not more than two years from date of grant.

Stock compensation expense of $147,000 and $31,000 related to restricted shares was recorded for 2016 and 2015, respectively. The unamortized stock compensation expense associated with the restricted shares at December 31, 2016, was $421,000 and will be recognized through 2019.

On January 9, 2017, the management team was granted 413,250 shares of restricted common stock which vest 25% per year from the first anniversary of the grant date, and 75,000 restricted common shares were granted to the Board of Directors which vest 50% per year from the first anniversary of the grant date.

Total stock compensation expense was $785,827 and $704,843 for 2016 and 2015, respectively.

Warrants

Warrants to purchase 451,458 shares of common stock at a weighted-average exercise price of $1.64 per share were outstanding at December 31, 2016. The warrants have an exercise price range of $0.38 to $1.98 per share and, with the exception of the 342,458 shares subject to warrants issued to the Company's current and former bank lenders, have no expiration date.

In connection with the Loan Agreement executed on June 30, 2016, the Company issued warrants to the Lenders, which provide for the right to purchase an aggregate of 64,655 shares of the Company's common stock for a ten-year period, expiring on June 30, 2026, at an exercise price of $1.856 per share (of which 48,491 shares may be purchased by Solar and 16,164 shares may be purchased by Western Alliance Bank).

Stock Purchase Plan

The Company maintains an employee stock purchase plan. The CAS Medical Systems, Inc. Employee Stock Purchase Plan (the "Stock Purchase Plan") was approved by stockholders 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, 2016, there were 75,464 shares issued under the Stock Purchase Plan, and certain amounts had been withheld from employees' compensation to purchase an additional 7,839 shares which were issued during January 2017. 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.

(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. The matching contributions for 2016 and 2015 were $64,484 and $68,479, respectively.

(10) INCOME TAXES

There are no current and deferred Federal and state income tax benefits for the years ended December 31, 2016 and 2015.

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, 2016 and 2015 follows:

	2016	2015
Income tax benefit at the statutory rate	$(1,996,150)	$(2,339,418)
State income taxes, net of Federal effect	(39,714)	(88,242)
R&D and other tax credits	(110,155)	(37,054)
Change in valuation allowance	2,112,165	2,434,198
Other	33,854	30,516
Income tax benefit from continuing operations	$—	$—

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

	2016	2015
Inventories	$131,672	$207,236
Warranty accrual	48,293	62,431
Allowance for doubtful accounts	87,475	87,475
Tax credits	1,066,052	955,897
Deferred gain on sale and leaseback	32,052	79,162
Restricted stock	1,405,001	1,178,525
Net operating loss carryforwards	13,684,331	12,667,926
Other	715,845	631,497
	17,170,721	15,870,149
Prepaid expenses	(112,719)	(116,842)
Fixed assets	(498,916)	(385,062)
Deferred income tax assets and liabilities	16,559,086	15,368,245
Valuation allowance	(16,559,086)	(15,368,245)
Net deferred income tax assets and liabilities	$—	$—

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 sales and pre-tax income, making allowance for uncertainties surrounding the rate of adoption of our products in the marketplace, competitive influences, and the investments required to increase our market share in certain markets for our products. As of December 31, 2016, 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 $16,559,086.

The Company's Federal net operating loss carryforward of $38,801,116 is scheduled to expire beginning in 2031. State net operating loss carryforwards of $9,039,556 are scheduled to expire between 2027 and 2036. The amount of the net operating loss carryforwards that may be utilized annually to offset future taxable income and tax liabilities may be limited as a result of certain ownership changes pursuant to Section 382 of the Internal Revenue Code. The Company has not completed a study to determine if there have been one or more ownership changes due to the costs associated with such study.

The Company does not believe that there are unrecognized income tax benefits for December 31, 2016 or 2015, and expects no significant changes in 2017.

(11) COMMITMENTS AND CONTINGENCIES

Litigation

The manufacture and sale of our products expose 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. Currently, there are no product liability claims pending against the Company.

Operating Leases

The Company currently leases two separate operating facilities and certain equipment under non-cancellable operating leases. Rent expense under these leases was $413,000 in 2016 and $412,000 in 2015. Future annual minimum rental payments as of December 31, 2016, to the expiration of the leases follow:

2017	$365,000
2018	319,000
2019	290,000
2020	291,000
2021	297,000
Total	$1,562,000

The table referenced above includes $1,402,000 of rental expense associated with the extension of the Company's headquarters and manufacturing facility effective February 1, 2017, through January 31, 2022. The annual base rent is $274,176 for the first fiscal year of the lease and is subject to annual increases of 2% for the remaining term of the lease.

(12) RECENT ACCOUNTING PRONOUNCEMENTS

On August 27, 2014, the FASB issued ASU 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern. Prior to the new guidance, there was no specific guidance in US GAAP about management's responsibility to evaluate and report on going concern. ASU 2014-15 requires management to evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued and to provide related disclosures. The new standard is effective for the Company for the year ending December 31, 2016. Management has reviewed the guidance provided by ASU 2014-15 and does not believe that conditions and events exist in the aggregate which impact the Company's ability to continue as a going concern.

In April 2015, the FASB issued ASU 2015-03, Interest – Imputation of Interest, to simplify the presentation of debt issuance costs. ASU 2015-03 requires that debt issuance costs related to a recognized debt obligation be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with the treatment of debt discounts, rather than being presented as an asset. The recognition and measurement guidance for debt issuance costs are not affected by the amendment in ASU 2015-03 which became effective for financial statements issued for fiscal years beginning after December 15, 2015. Early adoption was permitted for financial statements that had not been previously issued. The Company adopted ASU 2015-03 during the three months ended March 31, 2016. The new standard did not have a material impact on the Company's consolidated financial statements. The Company reclassified $402,783 and $455,379 of assets for the periods March 31, 2016, and December 31, 2015, respectively, and reported those amounts as reductions in the principal amounts of term debt liabilities outstanding.

In February 2016, the FASB issued ASU 2016-02, Leases - Topic 842. ASU 2016-02 requires the recognition by lessees on the balance sheet of lease assets and lease liabilities for those leases classified as operating leases. The new standard is effective for consolidated financial statements issued for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted for financial statements that have not been previously issued. The Company is evaluating the impact that this standard will have on its consolidated financial statements and results of operations.

In April 2016, the FASB issued ASU 2016-10, Topic 606, Revenue from Contracts with Customers. ASU 2016-10 amends the revenue recognition standard it had issued in May 2014 (ASU 2014-09). The core principle of the guidance in Topic 606 is that an entity should recognize revenue to depict the transfer of promised goods and services to customers in an amount that reflects the consideration to which an entity expected to be entitled in exchange for those goods and services. The amendments in ASU 2016-10 clarify the identification of performance obligations and the licensing implementation guidance. The new standard is effective for financial statements issued for fiscal years

beginning after December 15, 2017, including interim reporting periods therein. The Company is evaluating the impact that this standard will have on its consolidated financial statements and results of operations.

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

None.

Item 9A. Controls and Procedures

Disclosure 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, 2016. 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.

Internal Control over Financial Reporting

There have been no changes in the Company's internal control over financial reporting during the quarter ended December 31, 2016, 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) and 15(d)-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 2013 Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on the Company's evaluation, management concluded that its internal control over financial reporting was effective as of December 31, 2016.

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 stockholders on or about April 27, 2017, 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 stockholders on or about April 27, 2017, 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 stockholders on or about April 27, 2017, 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, 2016:

Plan Category	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 compensation plans
Equity compensation plans approved by security holders	2,729,500	$ 1.98	1,637,585
Equity compensation plans not approved by security holders	951,458	1.92	—
Total	3,680,958	$ 1.96	1,637,585

Securities remaining available for issuance under equity compensation plans approved by security holders are from the CAS Medical Systems, Inc. 2011 Equity Incentive Plan, as amended. The equity compensation plans not approved by security holders consist of warrants to purchase 109,000 shares granted to former directors of the Company as compensation for services rendered which have no expiration date, warrants to purchase 342,458 shares granted to the Company's current and former bank lenders, and 500,000 shares under inducement stock options granted to certain officers of the Company commensurate with their employment with the Company. 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 stockholders on or about April 27, 2017, 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 stockholders on or about April 27, 2017, 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 Independent Registered Public Accounting Firm

Financial Statements
Consolidated Balance Sheets as of December 31, 2016 and 2015
Consolidated Statements of Operations for the Years Ended December 31, 2016 and 2015
Consolidated Statements of Changes in Stockholders' Equity for the Years Ended December 31, 2016 and 2015
Consolidated Statements of Cash Flows for the Years Ended December 31, 2016 and 2015
Notes to Consolidated Financial Statements

(2) Financial Statement Schedules

Not applicable.

(3) Exhibits

The Exhibits to this report are as set forth in the "Exhibit Index" beginning on Page 31 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.

Item 16. Form 10-K Summary

Not provided.

EXHIBIT INDEX

1.1	Form of Purchase Agreement, dated February 11, 2015, by and between CAS Medical Systems, Inc. and Craig-Hallum Capital Group LLC (19)
3.1	Certificate of Incorporation of Registrant (1)
3.2	Certificate of Amendment to Certificate of Incorporation of the Registrant filed June 23, 2015 (20)
3.3	Amended and Restated Bylaws of Registrant (8)
10.1*	1994 Employees' Incentive Stock Option Plan (3)
10.2*	CAS Medical Systems, Inc. Employee Stock Purchase Plan (4)
10.3*	CAS Medical Systems, Inc. 2003 Equity Incentive Plan (5)
10.4*	Form of Option Agreement (2)
10.5	Purchase and Sale Agreement between CAS Medical Systems, Inc. and Davis Marcus Partners, Inc. dated June 18, 2007 (6)
10.6	Lease Agreement between CAS Medical Systems, Inc. and DMP New Branford, LLC dated September 6, 2007 (6)
10.7	Second Amendment to Lease Agreement between CAS Medical Systems, Inc. and Albany Road Branford II LLC, dated January 23, 2017
10.8*	Amendment to the CAS Medical Systems, Inc. 2003 Equity Incentive Plan (9)
10.9*	Employment Agreement with Jeffery A. Baird dated August 10, 2009 (10)
10.10*	Employment Agreement between CAS Medical Systems, Inc. and Thomas M. Patton dated August 27, 2010 (11)
10.11*	Inducement Non-Qualified Stock Option Agreement with Thomas M. Patton dated August 27, 2010 (11)
10.12*	Inducement Restricted Stock Agreement between CAS Medical Systems, Inc. and Thomas M. Patton dated August 27, 2010 (11)
10.13*	Inducement Restricted Stock Agreement between CAS Medical Systems, Inc. and Thomas M. Patton dated August 27, 2010 (11)
10.14*	Employment Agreement with Matthew J. Herwig dated January 7, 2011 (12)
10.15*	Inducement Non-Qualified Stock Option Agreement with Matthew J. Herwig dated January 7, 2011 (12)
10.16*	Inducement Restricted Stock Agreement with Matthew J. Herwig dated January 7, 2011 (12)
10.17	Investment Agreement, dated June 8, 2011, among CAS Medical Systems, Inc. and several Purchasers named therein (13)
10.18	Registration Rights Agreement, dated June 9, 2011, among CAS Medical Systems, Inc. and the several Purchasers named therein (13)
10.19	Form of Indemnification Agreement, dated June 9, 2011, between CAS Medical Systems, Inc. and the individual members of the Board of Directors of CAS Medical Systems, Inc. (13)
10.20*	CAS Medical Systems, Inc. 2011 Equity Incentive Plan, as amended (14)
10.21	Warrant to Purchase Stock, dated July 31, 2012, issued by the Company to East West Bank (15)
10.22	Warrant to Purchase Stock dated May 10, 2013 issued to East West Bank (16)
10.23*	Employment Agreement with John K. Gamelin dated August 5, 2013 (17)
10.24*	Employment Agreement with Paul Benni dated May 1, 2008 (17)
10.25	Warrant to Purchase Stock, dated June 27, 2014, issued by the Company to GE Capital Equity Investments, Inc. (18)
10.26	Asset Purchase Agreement dated March 28, 2016, by and between the Company and Trinity Medical Devices Inc. (21)
10.27	Loan and Security Agreement dated June 30, 2016 by and between the Company, Solar Capital Ltd., and Western Alliance Bank (22)
10.28	Warrant to Purchase Stock, dated June 30, 2016, issued by the Company to Solar Capital Ltd. (22)
10.29	Warrant to Purchase Stock, dated June 30, 2016, issued by the Company to Western Alliance Bank (22)

21.1	Subsidiaries of the Registrant
23.1	Consent of 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
101	Interactive data files pursuant to Rule 405 of Regulation S-T

(1) Incorporated by reference to the Company's Form 10-Q filed August 12, 2011
(2) Incorporated by reference to the Company's Form 10-KSB filed March 31, 2005
(3) Incorporated by reference to the Company's Form S-8 filed October 4, 2000
(4) Incorporated by reference to the Company's Form S-8 filed June 10, 2004, (333-116348)
(5) Incorporated by reference to the Company's Form S-8 filed June 10, 2004, (333-116349)
(6) Incorporated by reference to the Company's Form 8-K filed September 10, 2007
(7) Incorporated by reference to the Company's Form 8-K filed November 30, 2007
(8) Incorporated by reference to the Company's Form 8-K filed February 14, 2008
(9) Incorporated by reference to the Company's Form 8-K filed December 31, 2008
(10) Incorporated by reference to the Company's Form 10-Q filed August 12, 2009
(11) Incorporated by reference to the Company's Form 8-K filed August 27, 2010
(12) Incorporated by reference to the Company's Form 8-K filed January 10, 2011
(13) Incorporated by reference to the Company's Form 8-K filed June 13, 2011
(14) Incorporated by reference to the Company's Proxy Statement filed April 26, 2016
(15) Incorporated by reference to the Company's Form 8-K filed August 2, 2012
(16) Incorporated by reference to the Company's Form 8-K filed May 13, 2013
(17) Incorporated by reference to the Company's Form 10-Q filed August 7, 2013
(18) Incorporated by reference to the Company's Form 8-K filed June 30, 2014
(19) Incorporated by reference to the Company's Form 8-K filed February 11, 2015
(20) Incorporated by reference to the Company's Form 8-K filed June 25, 2015
(21) Incorporated by reference to the Company's Form 10-Q filed May 11, 2016
(22) Incorporated by reference to the Company's Form 8-K filed July 5, 2016.

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 15, 2017
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 / Alan W. Milinazzo Date: March 15, 2017
Alan W. Milinazzo, Director

/s/ Paul A. Molloy Date: March 15, 2017
Paul A. Molloy, Director

/s/ Gregory P. Rainey Date: March 15, 2017
Gregory P. Rainey, Director

/s/ James E. Thomas Date: March 15, 2017
James E. Thomas, Director

/s/ Kathleen A. Tune Date: March 15, 2017
Kathleen A. Tune, Director

/s/ Kenneth R. Weisshaar Date: March 15, 2017
Kenneth R. Weisshaar, Director

/s/ Thomas M. Patton Date: March 15, 2017
Thomas M. Patton, President, Chief Executive Officer and Director

/s/ Jeffery A. Baird Date: March 15, 2017
Jeffery A. Baird, Chief Financial Officer
(Principal Financial and Accounting Officer)