CAS MEDICAL SYSTEMS INC
Form 10-K
March 25, 2019

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, 2018

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 every Interactive Data File required to be submitted 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 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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company", and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
	Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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, 2018, 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 $30,655,000 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 15, 2019, there were 29,340,787 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None

TABLE OF CONTENTS

PART III

PART IV

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, risks relating to the potential merger with Edwards, 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

The Merger Agreement

On February 11, 2019, the Company, Edwards Lifesciences Holding, Inc., a Delaware corporation and a wholly-owned subsidiary of Edwards Lifesciences Corporation ("Edwards" or the "Acquiror") and Crown Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of the Acquiror ("Merger Sub"), entered into an Agreement and Plan of Merger (the "Merger Agreement") pursuant to which, subject to the satisfaction or waiver of the conditions set forth therein, Merger Sub will merge with and into the Company (the "Merger"), with the Company continuing as the surviving company and a wholly-owned subsidiary of the Acquiror. The Board of Directors of the Company has unanimously approved the Merger Agreement, the Merger, and the other transactions contemplated thereby.

On the terms and subject to the conditions set forth in the Merger Agreement, at the effective time of the Merger (the "Effective Time") and as a result of the Merger, each share of Company common stock issued and outstanding immediately prior to the Effective Time (other than shares of Company common stock owned by the Company as treasury stock or owned directly by the Acquiror or any of its subsidiaries (including Merger Sub) or shares of Company common stock the holders of which have properly perfected their appraisal rights under Delaware law) will be converted into the right to receive $2.45 per share in cash (the "Merger Consideration") without interest or dividends thereon.

The Merger Agreement also provides that, as a condition to the Acquiror's obligation to effect the Merger, each holder of Company Series A Convertible Preferred Stock and Series A Exchangeable Preferred Stock outstanding, immediately prior to the Effective Time, shall consent to the conversion of such stock into Company common stock.

Subject to such conversion, at the Effective Time, the holders of such preferred stock will be entitled to receive the Merger Consideration as holders of the Company's common stock.

The parties' obligations to consummate the Merger, which is expected to close during the second quarter of 2019, are subject to stockholder approval and certain additional customary closing conditions, including, among other things, (i) the accuracy of the other party's representations and warranties contained in the Merger Agreement (subject to certain materiality or material adverse effect qualifiers, as described in the Merger Agreement) and the other party's compliance with its covenants and agreements contained in the Merger Agreement in all material respects; (ii) the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the receipt of other required antitrust approvals; and (iii) no law having been enacted after the date of the Merger Agreement that prohibits the Merger and no order having been issued after the date of the Merger Agreement preventing the consummation of the Merger. The obligations of the Acquiror and Merger Sub to consummate the Merger are further subject to the following conditions: (i) no pending proceeding brought by a governmental entity in a U.S. federal district court seeking to restrain, prohibit, challenge, or otherwise materially limit the parties' or their subsidiaries' ability to consummate the Merger or the other transactions contemplated by the Merger Agreement; and (ii) the absence of any effect, change, development, event, circumstance, occurrence, condition, fact, or state of facts that has had or would reasonably be expected to have a "company material adverse effect" (as defined in the Merger Agreement) with respect to the Company and its subsidiaries, taken as a whole. The closing of the Merger is not subject to a financing condition.

The Merger Agreement contains certain termination rights for the Company and the Acquiror, including the right of the Company to terminate the Merger Agreement to accept a "company superior proposal" (as defined the Merger Agreement) after complying with certain requirements. In addition, either party may terminate the Merger Agreement if the Merger is not consummated on or before November 8, 2019. The Merger Agreement further provides that the Company may be required to pay the Acquiror a termination fee of $3.5 million under certain specified circumstances, including if the Acquiror terminates the Merger Agreement due to a change in the recommendation by the Company's Board of Directors for the Merger or due to the Company's material breach of its non-solicitation obligations set forth in the Merger Agreement. The Merger Agreement also provides that in case it is terminated by either the Acquiror or the Company following a failure to obtain the required vote of the Company's stockholders to adopt the Merger Agreement, the Company shall reimburse the Acquiror up to $1.0 million of certain of its transaction expenses, which payment, if any, will reduce on a dollar-for-dollar basis any termination fee otherwise owed to the Acquiror.

The foregoing description of the Merger Agreement is not complete and is qualified in its entirety by reference to the Merger Agreement, which is attached as Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the SEC on February 12, 2019. Additional information about the Merger and the Merger Agreement is set forth in the Company's definitive proxy statement filed with the SEC on March 13, 2019.

Our Business

We are a medical technology company that develops, manufactures, and markets non-invasive cerebral and tissue oximeters used in patient monitoring 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 adhesive sensor applied to the skin, these products alert clinicians to the oxygenation levels of a patient's brain or other body tissue under the sensor during medical procedures to avoid harm caused by insufficient oxygen, otherwise known as hypoxia. The FORE-SIGHT product line represented nearly all of our 2018 sales from continuing operations. We also sell a small volume of service repairs for legacy products.

We believe our FORE-SIGHT tissue oximetry products are best-in-class and place CASMED in a unique position both to gain accounts from competitors and 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 or systemic nature of these parameters forces clinicians to infer the adequacy of

oxygenation in vital organs, including the brain, during medical procedures. However, data convincingly show that clinician inferences of cerebral oxygenation during medical procedures often do not correlate with actual tissue oxygenation levels. Therefore, potentially dangerously low levels of cerebral oxygenation often go unrecognized, correlating to high levels of patient harm. However, direct monitoring of cerebral and tissue oxygenation with FORE-SIGHT oximeters provides a unique and powerful tool that empowers clinicians to recognize and treat potentially dangerous tissue hypoxia to avoid adverse clinical outcomes.

We believe the FORE-SIGHT tissue oximeter provides clinicians the most accurate and reliable readings and is well-positioned to compete in an expanding market.

Our products are typically sold to hospitals. Clinician users include anesthesiologists, perfusionists, and surgeons in an operating room, and intensivists and nurses in intensive care units.

Strategy Execution

CASMED has completed significant product line divestitures in recent years and has successfully executed its multi-year strategic goal of solely focusing on the market opportunity for FORE-SIGHT oximetry. With the divestiture of its last two non-FORE-SIGHT legacy product lines completed in 2017, the Company's transformation from a low-margin, commodity, capital medical equipment business into a high-growth, high-margin business is complete, with disposable sensor sales representing 88% of 2018 sales from continuing operations.

Our 2018 achievements include the following:

- Worldwide FORE-SIGHT sales rebounded in 2018, increasing 18% over 2017.
- Worldwide sensor revenue growth accelerated to greater than 20% in the third and fourth quarters, with full-year growth of 18%.
- We shipped a net of 363 FORE-SIGHT ELITE monitors worldwide in 2018, including 203 net monitors in the U.S., raising the U.S. adjusted installed base to 1,458 FORE-SIGHT ELITE monitors, an increase of 17% over the adjusted installed base at December 31, 2017.
- The five-year FORE-SIGHT sales compound average growth rate was 19% at the end of 2018 for overall sales and 20% for U.S. sales.
- We completed a multi-year effort to redesign our FORE-SIGHT ELITE disposable sensors for manufactur-ability, realizing substantial cost reductions beginning in the second quarter of 2018.
- We received FDA 510(k) clearance for our FORE-SIGHT OEM Oximetry Module. The OEM module permits the use of FORE-SIGHT oximetry without a standalone FORE-SIGHT monitor. The design allows tissue oximetry values to be displayed on a third-party monitor with minimal user-interface modifications.

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.
- Service and Other – includes sales of service parts and repairs and other miscellaneous sales.

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 partially 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.

In addition to cerebral monitoring, FORE-SIGHT can also be used to monitor the oxygenation of other tissues such as muscle tissues of adults and the abdominal tissues in newborns even weighing less than four kilograms.

By non-invasively and continuously measuring absolute cerebral and 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 accurate and, therefore, more actionable by clinicians in critical care environments. Special design features include the following:

- CASMED's FORE-SIGHT ELITE sensors emit 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 confound a tissue oximetry reading.

- CASMED's FORE-SIGHT sensors for adults 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.

- CASMED'S FORE-SIGHT sensors also are maximized for children and come in different configurations with each being tailored precisely to the size of the patient to maximize accuracy and ease of use, all with the preservation of skin integrity in mind.

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

- CASMED's FORE-SIGHT algorithms are specifically designed for different body locations given that we believe clinicians' expected levels of accuracy cannot be met with the same algorithm for such materially different physiologies as, for example, that of an adult forehead and that of a newborn's flank.

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.

During 2018, a net total of 363 monitors were shipped worldwide. As of December 31, 2018, the adjusted installed base of U.S. monitors was 1,458 monitors, up 17% from the adjusted installed base at December 31, 2017. The adjusted installed base includes only FORE-SIGHT ELITE monitors and excludes first-generation devices which are no longer in use by U.S. customers. 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 reported installed base 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 can cause 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. These biologic processes of optimizing oxygen delivery vs. demand can be compromised by illness, surgical intervention, trauma, and anesthesia; and neonates and children have immature auto-regulation capabilities.

Most conventional monitoring is ultimately employed to assure an adequate balance between oxygen supply and demand. 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 might 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 is well documented. Low levels of cerebral oxygen saturation

correlate to poorer outcomes such as: post-operative nausea; cognitive impairment including memory loss; longer lengths of stay; stroke; and even death. Yet, very simple interventions are available to clinicians to successfully reverse these low levels of oxygen. Standard interventions include eliminating mechanical blockage, increasing inspired oxygen levels, increasing blood flow or blood pressures, or transfusing units of blood.

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 prove valuable for millions of patients each year.

While we believe the eventual addressable market for tissue oximetry exceeds $800 million, we estimate current total worldwide annual sales of tissue oximetry to be approximately $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.

Service and Other

The Company provides various repair services from its corporate facility in Branford, Connecticut, to its customers for legacy and FORE-SIGHT monitors installed in the field.

Sales and Marketing

The Company markets its products globally, primarily to hospitals, surgery centers, and outpatient facilities.

The Company's FORE-SIGHT tissue oximeters are sold via a direct sales force in the U.S. (with the exception of a single manufacturer's representative), and stocking distribution partners outside the U.S. As of December 31, 2018, the Company's U.S. selling organization was comprised of 25 management, sales, sales operations, and clinical support personnel in 16 territories. The international sales organization included one executive vice president and four sales consultants located in Europe, the Middle East, Latin America, 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.

Total sales from continuing operations for the years ended December 31, 2018 and 2017 are as follows:

	Financial Information Relating to Sales Year Ended December 31,		
	2018	2017	% Change
Domestic Sales	$18,439,354	$16,063,173	15%
International Sales	3,480,633	2,699,963	29%
Total	$21,919,987	$18,763,136	17%

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, access, 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 Medtronic, Masimo, Nonin Medical, and Hamamatsu.

Research and Development

As of December 31, 2018, our Research and Development ("R&D") organization consisted of a staff of 14 engineers and scientists focused on the following primary areas:

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

Our R&D efforts in 2018 were primarily focused on the development of our FORE-SIGHT OEM Oximetry Module and reducing FORE-SIGHT ELITE sensor manufacturing costs. During 2018 and 2017, the Company incurred R&D expenses of approximately $3,182,000 and $3,234,000, or 15% and 17% 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 WHAT'S VITAL®, INTELLIGENT MONITORING DEFINED®, and THE CONFIDENCE OF KNOWING®.

The Company holds 24 U.S. patents and 14 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 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, 2018, the Company had 73 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 13485:2016 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 believes it maintains full compliance with ISO 13485:2016 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 16% and 14% of sales from continuing operations in 2018 and 2017, respectively. Each of these customers accounted for less than 10% of sales from continuing operations.

Backlog

The Company's backlog generally includes 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.

Our merger with Edwards could be delayed or fail to close, which could adversely affect our financial condition and could negatively impact our stock price.

On February 11, 2019, we entered into a Merger Agreement pursuant to which we agreed to be merged into a wholly-owned subsidiary of Edwards. We will incur significant transaction costs relating to the Merger, including legal, financial advisory, and other expenses. In general, these expenses are payable by us whether or not the Merger is completed. If the Merger is not completed under specific circumstances provided in the Merger Agreement, we may be required to pay Edwards a termination fee of $3.5 million or reimburse Edwards for certain expenses up to $1 million. The payment of such transaction costs or termination fees and expense would have an adverse effect on our financial condition, results of operations, and cash flows. In addition, we could be subject to litigation in the event the Merger is not consummated, which could subject us to significant liability for damages and result in the incurrence of substantial legal fees. The current price of our stock may reflect an assumption that the pending Merger will occur, and failure to complete the Merger could result in a decline in our stock price.

In addition, the Merger presents the following additional risks and uncertainties for the Company:

- the occurrence of any event, change, or other circumstances that could give rise to the termination of the Merger Agreement;
- the outcome of any legal proceeding that has been or may be instituted against CASMED and others relating to the Merger Agreement;
- the inability to complete the Merger due to the failure to obtain stockholder approval, the failure to obtain regulatory approvals, or the failure to satisfy other conditions to consummation of the Merger;
- the failure of the Merger to close for any other reason;
- risks that the proposed transactions disrupt current business plans and operations and the potential difficulties in attracting and retaining senior management or employees as a result of the Merger;
- business uncertainty and contractual restrictions during the pendency of the Merger;
- the fact that, under the terms of the Merger Agreement, we are unable to solicit certain other acquisition proposals during the pendency of the Merger;
- the diversion of management's attention from ongoing business concerns;
- the effect of the announcement of the Merger on our customer and supplier relationships, operating results, and business generally; and

the timing of the completion of the Merger and the impact of the merger on our indebtedness, capital resources, cash requirements, profitability, management resources, and liquidity.

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

We have experienced operating losses during our last ten fiscal years. The loss from continuing operations was approximately $5,961,000 for the 2018 calendar year, and the accumulated deficit was approximately $49,388,000 as of December 31, 2018. 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.

As of December 31, 2018, the Company had cash-on-hand and amounts available under its Loan Agreement totaling $5,272,000. As such, our ordinary short-term capital needs are expected to be met from cash-on-hand and borrowings available from the revolving line-of-credit under our Loan Agreement, which was unused as of December 31, 2018. Management also believes its cash balances and available borrowings are sufficient to support operations through March 31, 2020. Management further believes that, given the Company's current and expected rate of cash consumption over the next 12 months together with the principal repayments required under its Loan Agreement, it should, nonetheless, if the merger transaction with Edwards is not completed, take action to improve its liquidity until such time that the Company can generate positive cash flow from operations. Management estimates it will not achieve positive cash flow until late 2020. Such actions to enhance liquidity may include seeking further changes in its debt instruments (including waivers, modifications, and/or replacement of current agreements), reducing otherwise planned expenditures and operating expenses, or raising additional funds through the issuance of equity securities.

Cash flows may be impacted by a number of factors, including changing market conditions; market acceptance of the FORE-SIGHT system; and U.S. government regulations, including the continued imposition of substantial tariffs, and other trade barriers imposed by foreign governments on our exports, and the loss of one or more key customers. There can be no assurance that we will be successful in modifying or refinancing our debt instruments or raising additional capital if the need arises. The failure to raise any necessary additional capital on acceptable terms, or at all, would 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 almost entirely dependent on our FORE-SIGHT tissue oximetry products.

Sales of our FORE-SIGHT tissue oximetry products represented nearly all of our net sales from continuing operations for both 2018 and 2017. 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, this strategy 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 the inability to obtain sufficient levels of product from our overseas or U.S. based suppliers due to manufacturing disruptions, transportation delays, new or substantial customs or tariffs on the manufacture of foreign goods, or other risks as 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 16% and 14% of sales from continuing operations in 2018 and 2017, respectively. The loss of significant customers, especially in the aggregate, could have a material adverse effect on our financial position and results of operations.

Our operations depend on a small number of key suppliers.

A significant percentage of our product components are purchased from a few suppliers located outside of the United States. Our suppliers may encounter problems during manufacturing due to a variety of reasons, including failure to follow specific protocols and procedures, failure to comply with applicable regulations, equipment malfunctions, labor shortages, or environmental factors. In addition, we purchase both raw materials used in our products and finished goods from various suppliers and may have to rely on a single-source supplier for certain components of our products where there are no alternatives available. Although we anticipate that we have adequate sources of supply and/or inventory of these components to handle our production needs for the foreseeable future, if we are unable to secure on a timely basis sufficient quantities of the products we use for manufacture or for sale, if we encounter delays or contractual or other difficulties in our relationships with these suppliers, or if we cannot find suppliers at an acceptable cost, then the manufacture or sale of our products may be disrupted, which could have a material adverse effect on our business.

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. Due to our limited financial resources, there can be no assurance that we will be successful in these endeavors.

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. In addition, competitors often approach GPO's and IDN's with attractive discounts for the purchase of bundles of products offered by those competitors that may also include tissue oximetry. 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 and we may lose customers as they enter into contracts with our competitors. Furthermore, the increasing leverage of organized buying groups may reduce market prices for our products, thereby reducing our profitability.

The members of such groups may choose to purchase from our competitors due to the price or quality offered by such competitors, or due to additional or "bundled" products that can be offered by our competitors to these same IDN's and GPO's. Any of these actions could result in a decline in our sales and profitability.

Distributors of our products outside of the United States and hospital purchasers also 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 of the United States, we have also 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 nearly all 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 if we are unable to generate sales as planned, such 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.

Our business is impacted by tariffs.

Effective July 2018, the U.S. government imposed additional duties of 25% on certain imports from China under Section 301 of the Trade Act of 1974. All of our FORE-SIGHT ELITE sensor products provided by our contract manufacturer and certain of our monitor product components are subject to the tariffs. While management has considered strategies to mitigate any negative financial impact if the tariffs persist, we cannot be certain that we will be successful in our efforts to reduce or eliminate any additional costs imposed by the new tariffs or whether a financial impact will be of a short-term or long-term nature. Our gross margins were negatively affected by $355,000 of tariff costs, or 1.6% of sales during 2018. Tariff costs for the fourth quarter of 2018 were $253,000, or 4.4% of sales and at current levels of sales may exceed $1.0 million for 2019 if tariffs are levied for a full year. Other non-sensor components also have or may increase as vendors of component parts pass on tariff costs to end-users.

In response to the U.S. government tariffs on imports, the government of China imposed tariffs on certain U.S. products entering China, including products shipped to our China distributor. These tariff costs may also impact exports to China of FORE-SIGHT finished goods.

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

Efforts to reform the U.S. healthcare 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.

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 16% and 14% of our total net sales from continuing operations for the 2018 and 2017 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.

Subject to the limitations set forth in the Merger Agreement with Edwards, 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, each beneficially owned 31.3% and 18.0%, 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, 2018, options and warrants for the purchase of 3,711,032 shares of our common stock were outstanding, and 10,635,019 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 pursuant to the Merger Agreement with Edwards and 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, 2018, $10,407,061 in dividend 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 is leasing its headquarters and manufacturing facility in Branford, Connecticut (the "Property"), which is comprised of approximately 24,000 square feet of office and manufacturing space. The lease had an initial term of ten years, expired on September 6, 2017, and contained an option for two additional five-year periods. In January 2017, the Company executed a five-year extension on the lease effective February 1, 2017, through January 31, 2022. Annual base rent was $274,000 for the first year of the lease and is subject to annual increases of 2% for the remaining term of the lease. Under the lease, the Company is responsible for the costs of utilities, insurance, taxes, and maintenance expenses. Further, the Company is required to maintain at least $600,000 in cash and cash equivalents (increasing at 3% per annum) and net current assets of not less than $3,600,000.

The Company had leased approximately 5,000 square feet of office space adjacent to its corporate facility until such lease expired on May 31, 2018. The Company consolidated its resources into one corporate facility, following completion of approximately $118,000 of needed leasehold improvements to its main facility.

The Company believes that the corporate facility meets its current and expected operating needs and is adequately insured.

Item 3. Legal Proceedings

The manufacture and sale of our products exposes us to product liability claims and product recalls, including those which may arise from misuse or malfunction of, or design flaws in, our products or use of our products with components or systems not manufactured or sold by us. Product liability claims or product recalls, regardless of their ultimate outcome, could require us to spend significant time and money in litigation or to pay significant damages. We are currently a defendant in a product liability action related to our former sleep apnea product line. We believe that our insurance is sufficient to cover any damages and costs that are likely, with respect to these matters. There can be no assurance, however, that this will be the case with respect to these matters or any future matters.

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

Merger-Related Litigation

On or about March 7, 11, 14 and 21, 2019, four putative class action complaints challenging the Merger were filed in the United States District Court for the District of Delaware, captioned Adam Franchi v. CAS Medical Systems, Inc., et al., Shiva Stein v. CAS Medical Systems, Inc., et al., Thomas Torreano v. CAS Medical Systems, Inc. et al. and Joseph Rish Jr. v. CAS Medical Systems, Inc. et al., respectively, and on or about March 11, 2019 an additional putative class action complaint challenging the merger was filed in the Superior Court for the State of Connecticut, Judicial District of New Haven at New Haven, captioned Charles New v. CAS Medical Systems, Inc., et al. The complaints were filed on behalf of the public shareholders of CASMED and name as defendants CASMED and the members of its board of directors. The complaints generally allege violations of federal securities laws with respect to purported disclosure deficiencies in the preliminary proxy statement for the merger that CASMED filed with the SEC on March 1, 2019. The complaint in the Stein action also alleges that CASMED's directors agreed to sell CASMED for inadequate consideration, the complaint in the New action also alleges that CASMED's directors agreed to sell CASMED for an unfair price as a result of an unfair sale process and the complaint in Torreano also alleges that the Merger contains preclusive deal protection provisions. The Torreano complaint also alleges claims against Edwards Lifesciences Holding, Inc. Crown Merger Sub, Inc. and Edwards Lifesciences Corporation. The complaints seek a variety of relief, including an injunction preventing the consummation of the Merger, rescission of the Merger if it is consummated or rescissory damages, attorneys' fees and expenses. The defendants have not yet responded to the complaints, but believe that the claims asserted against them are without merit.

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 sets forth the approximate number of beneficial owners of common stock of the Company on December 31, 2018.

Title of Class	Number of Stockholders
Common stock, $.004 par value	2,402

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 Edwards pursuant to the Merger Agreement and 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 secured loan agreement.

As of December 31, 2018, a dividend accretion of $10,407,061 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 2018 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 2018.

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: risks relating to the potential merger with Edwards; 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.

The Merger Agreement

On February 11, 2019, the Company, Edwards Lifesciences Holding, Inc., a Delaware corporation and a wholly-owned subsidiary of Edwards Lifesciences Corporation ("Edwards" or the "Acquiror") and Crown Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of the Acquiror ("Merger Sub"), entered into an Agreement and Plan of Merger (the "Merger Agreement") pursuant to which, subject to the satisfaction or waiver of the conditions set forth therein, Merger Sub will merge with and into the Company (the "Merger"), with the Company continuing as the surviving company and a wholly-owned subsidiary of the Acquiror. The Board of Directors of the Company has unanimously approved the Merger Agreement, the Merger, and the other transactions contemplated thereby.

On the terms and subject to the conditions set forth in the Merger Agreement, at the effective time of the Merger (the "Effective Time") and as a result of the Merger, each share of Company common stock issued and outstanding immediately prior to the Effective Time (other than shares of Company common stock owned by the Company as treasury stock or owned directly by the Acquiror or any of its subsidiaries (including Merger Sub) or shares of Company common stock the holders of which have properly perfected their appraisal rights under Delaware law) will be converted into the right to receive $2.45 per share in cash (the "Merger Consideration") without interest or dividends thereon.

The Merger Agreement also provides that, as a condition to the Acquiror's obligation to effect the Merger, each holder of Company Series A Convertible Preferred Stock and Series A Exchangeable Preferred Stock outstanding, immediately prior to the Effective Time, shall provide a consent or other instrument to effectuate the conversion of such stock into Company common stock pursuant to the Company's certificate of incorporation. Subject to such conversion, at the Effective Time, the holders of such preferred stock will be entitled to receive the Merger Consideration as holders of Company's common stock.

The parties' obligations to consummate the Merger, which is expected to close during the second quarter of 2019, are subject to stockholder approval and certain additional customary closing conditions, including, among other things, (i) the accuracy of the other party's representations and warranties contained in the Merger Agreement (subject to certain materiality or material adverse effect qualifiers, as described in the Merger Agreement) and the other party's compliance with its covenants and agreements contained in the Merger Agreement in all material respects; (ii) the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the receipt of other required antitrust approvals; and (iii) no law having been enacted after the date of the Merger Agreement that prohibits the Merger and no order having been issued after the date of the Merger Agreement preventing the consummation of the Merger. The obligations of the Acquiror and Merger Sub to consummate the Merger are further subject to the following conditions: (i) no pending proceeding brought by a governmental entity in a U.S. federal district court seeking to restrain, prohibit, challenge, or otherwise materially limit the parties' or their subsidiaries' ability to consummate the Merger or the other transactions contemplated by the Merger Agreement; and (ii) the absence of any effect, change, development, event, circumstance, occurrence, condition, fact, or state of facts that has had or would reasonably be expected to have a "company material adverse effect" (as defined in the Merger Agreement) with respect to the Company and its subsidiaries, taken as a whole. The closing of the Merger is not subject to a financing condition.

The Merger Agreement contains certain termination rights for the Company and the Acquiror, including the right of the Company to terminate the Merger Agreement to accept a "company superior proposal" (as defined the Merger Agreement) after complying with certain requirements. In addition, either party may terminate the Merger Agreement if the Merger is not consummated on or before November 8, 2019. The Merger Agreement further provides that the Company may be required to pay the Acquiror a termination fee of $3.5 million under certain specified circumstances, including if the Acquiror terminates the Merger Agreement due to a change in the recommendation by the Company's Board of Directors for the Merger or due to the Company's material breach of its non-solicitation obligations set forth in the Merger Agreement. The Merger Agreement also provides that in case it is terminated by either the Acquiror or the Company following a failure to obtain the required vote of the Company's stockholders to adopt the Merger

Agreement, the Company shall reimburse the Acquiror up to $1.0 million of certain of its transaction expenses, which payment, if any, will reduce on a dollar-for-dollar basis any termination fee otherwise owed to the Acquiror.

The foregoing description of the Merger Agreement is not complete and is qualified in its entirety by reference to the Merger Agreement, which is attached as Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the SEC on February 12, 2019. Additional information about the Merger and the Merger Agreement is set forth in the Company's definitive proxy statement filed with the SEC on March 13, 2019.

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, 2018 Compared to Year Ended December 31, 2017

Management Summary

CASMED has completed significant product line divestitures in recent years and has successfully executed its multi-year strategic goal of solely focusing on the market opportunity for FORE-SIGHT oximetry. With the divestiture of its last two non-FORE-SIGHT legacy product lines completed in 2017, the Company's transformation from a low-margin, commodity, capital medical equipment business into a high-growth, high-margin business is complete, with disposable sensor sales representing 88% of 2018 sales from continuing operations.

Our 2018 achievements include the following:

- Worldwide FORE-SIGHT sales rebounded in 2018, increasing 18% over 2017.
- Worldwide sensor revenue growth accelerated to greater than 20% in the third and fourth quarters, with full-year growth of 18%.
- We shipped a net of 363 FORE-SIGHT ELITE monitors worldwide in 2018, including 203 net monitors in the U.S., raising the U.S. adjusted installed base to 1,458 FORE-SIGHT ELITE monitors, an increase of 17% over the adjusted installed base at December 31, 2017.
- The five-year FORE-SIGHT sales compound average growth rate was 19% at the end of 2018 for overall sales and 20% for U.S. sales.
- We completed a multi-year effort to redesign our FORE-SIGHT ELITE disposable sensors for manufactur-ability, realizing substantial cost reductions beginning in the second quarter of 2018.
- We received FDA 510(k) clearance for our FORE-SIGHT OEM Oximetry Module. The OEM module permits the use of FORE-SIGHT oximetry without a standalone FORE-SIGHT monitor. The design allows tissue oximetry values to be displayed on a third-party monitor with minimal user-interface modifications.

Results of Operations

The Company incurred a loss from continuing operations before income taxes for 2018 of $5,961,000, which represents an improvement of $1,510,000, or 20%, from the $7,471,000 of losses from continuing operations before income taxes reported for 2017. Increased revenues, higher gross profit margins, and controlled spending accounted for the improvement in operating results. There was no income from discontinued operations for 2018 compared to $3,388,000, net of income taxes, for 2017. Income tax expense of $1,745,000 for 2017 was offset by income tax benefits recorded against continuing operations. The Company does not expect to pay income taxes for 2018, and none were paid for 2017.

The Company incurred a net loss applicable to common stockholders of $7,664,000 for 2018, or ($0.28) per basic and diluted common share, compared to a net loss applicable to common stockholders of $3,926,000, or ($0.14) per basic and diluted common share, for 2017.

Total worldwide sales from continuing operations of $21,920,000 for 2018 increased $3,157,000, or 17%, over 2017 sales of $18,763,000. The following table provides comparative results of net sales by product and geographic category:

($000's)

	Year Ended December 31, 2018	Year Ended December 31, 2017	Increase / (Decrease)	% Change
Tissue Oximetry:				
Sensors	$ 19,365	$ 16,373	$ 2,992	18%
Monitors and Accessories	2,046	1,727	319	18%
	21,411	18,100	3,311	18%
Service and Other	509	663	(154)	(23%)
	$ 21,920	$ 18,763	$ 3,157	17%
Domestic Sales	$ 18,439	$ 16,063	$ 2,376	15%
International Sales	3,481	2,700	781	29%
	$ 21,920	$ 18,763	$ 3,157	17%

Worldwide tissue oximetry product sales of $21,411,000 for 2018 increased $3,311,000 or 18% over 2017 sales of $18,100,000.

Service and Other sales were $509,000 for 2018, compared to $663,000 for 2017.

Total U.S. sales increased $2,376,000, or 15%, to $18,439,000 from $16,063,000 for 2017 driven by U.S. tissue oximetry sales. Total U.S. sales accounted for 84% of total worldwide sales for 2018, compared to 86% for 2017.

International sales increased $781,000, or 29%, to $3,481,000, or 16% of total sales from continuing operations for 2018, from $2,700,000, or 14% of total sales from continuing operations for 2017. Tissue oximetry sales were responsible for the increase.

The following table provides tissue oximetry details by geographic category:

($000's)

	Year Ended December 31, 2018	Year Ended December 31, 2017	Increase / (Decrease)	% Change
Sensor Sales:				
Domestic	$ 16,673	$ 14,298	$ 2,375	17%
International	2,693	2,075	618	30%
	$ 19,366	$ 16,373	$ 2,993	18%
Monitor and Accessory Sales:				
Domestic	$ 1,337	$ 1,207	$ 130	11%

International	708	520	188	36%
	$ 2,045	$ 1,727	$ 318	18%
Total Domestic Sales	$ 18,010	$ 15,505	$ 2,505	16%
Total International Sales	3,401	2,595	806	31%
	$ 21,411	$ 18,100	$ 3,311	18%

Worldwide tissue oximetry sensor sales for 2018 were $19,366,000, an increase of $2,993,000, or 18%, over 2017 sensor sales of $16,373,000. Worldwide sales of oximetry monitors and accessories for 2018 increased $318,000, or 18%, to $2,045,000 from 2017 sales of $1,727,000. A total of 358 net FORE-SIGHT ELITE monitors were shipped worldwide of which 203 ELITE monitors were shipped to U.S. customers. The U.S. adjusted FORE-SIGHT ELITE installed base of 1,458 monitors as of December 31, 2018, increased 17% over December 31, 2017.

Gross profit as a percentage of net sales from continuing operations was 58.0% for 2018 and 54.7% for 2017. The improvement was primarily related to the production and sales of lower cost disposable sensors which were partially offset by increased U.S. tariff charges effective July 2018. The tariff costs negatively impacted our gross profit by $355,000, or 1.6% of sales, for 2018. Slightly lower average selling prices also affected our 2018 gross profit margins.

Research and development ("R&D") expenses were $3,182,000 and $3,234,000, respectively for 2018 and 2017. The decrease of $52,000, or 2%, in 2018 was due to lower R&D project expenses. R&D expenses were approximately 15% of sales from continuing operations in 2018, down from 17% in 2017.

Selling, general, and administrative ("S,G&A") expenses increased $598,000, or 4%, to $14,016,000 for 2018 from $13,418,000 for 2017. The increases in spending resulted primarily from additional investments in our international sales effort and from certain G&A expenses including legal, consulting, and incentives.

Interest expense for 2018 was $1,470,000, an increase of $393,000 over 2017, reflecting increased debt levels, higher interest rates, and amortization of deferred finance charges.

There was no income tax benefit in the aggregate recorded for either 2018 or 2017. The Company does not expect to record taxable income during its 2018 fiscal year. Income tax benefits that have been recorded during 2018 have been 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, 2018, the deferred income tax asset valuation allowance balance was $13,016,000.

Financial Condition, Liquidity, and Capital Resources

The Company's continuing operations used $2,598,000 of cash for 2018, compared to $4,675,000 used in continuing operations during 2017, largely due to favorable changes in working capital items, such as accounts payable and accrued expense.

Net cash used in investing activities of continuing operations was $863,000 for 2018, compared to net cash provided of $3,863,000 for 2017. Cash provided by investing activities for 2017 included $4,527,000 pertaining to the sale of the Company's non-invasive blood pressure product line. The Company incurred $783,000 of capital expenditures during 2018, compared to $596,000 for 2017. For both periods, the expenditures were primarily related to placements of FORE-SIGHT oximeter monitors at customer locations. The 2018 expenditures included approximately $118,000 of leasehold improvements incurred to provide additional office space. The Company also expended $80,000 and $67,000 during 2018 and 2017, respectively, primarily related to patent registrations.

Net cash provided by financing activities of continuing operations was $1,115,000 for 2018, compared to cash used of $215,000 for 2017. During 2018, the Company entered into a bank agreement with a new lender, as described below, and repaid the outstanding balance under its previous loans together with associated payoff fees.

On May 8, 2018, the Company consummated a Loan and Security Agreement (the "Loan Agreement") with East West Bank (the "Bank"). Pursuant to the Loan Agreement, the Bank has provided a 48-month term loan (the "Term Loan") in the amount of $10,000,000 and a revolving loan (the "Revolver") in the maximum of $2,000,000, each of which expires May 8, 2022. The obligations under the Loan Agreement are secured by a lien on substantially all of the non-intellectual property assets of the Company. As of December 31, 2018, there was no outstanding balance under the Revolver. Available borrowings under the Revolver were $2,000,000 as of that date.

The Term Loan bears interest at a floating rate equal to the Bank's prime rate (not less than 4.75%) plus 3.65% (9.15% as of December 31, 2018). Under the Term Loan, 30 equal payments of $333,333 are scheduled to commence on December 1, 2019, following an 18-month period during which the Company shall make interest-only payments. The interest-only period may be extended to 21 months or 24 months under certain circumstances.

Revolver advances will bear interest at a floating rate equal to the Bank's prime rate (not less than 4.75%) plus 2.40% (7.90% as of December 31, 2018). Maximum borrowings under the Revolver are based upon the Company's eligible accounts receivable, as defined in the Loan Agreement, and subject to other terms and conditions.

The Company has the right to prepay the loan under the Loan Agreement in full at any time; however, if the Term Loan is prepaid prior to the first or second anniversaries of the Loan Agreement or prior to maturity, a fee of 3%, 2%, or 1%, respectively, of the Term Loan amount is due. Amounts prepaid under the Term Loan may not be re-borrowed. Upon repayment of the Term Loan at any time, the Bank is entitled to an additional fee equal to 4% of the Term Loan amount.

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 or the Company's intellectual property, incur additional indebtedness, make certain investments and acquisitions, and dispose of assets outside the ordinary course of business. The Loan Agreement also contains financial covenants requiring the Company to achieve certain sales results and to maintain a continuing level of cash plus available borrowing capacity based on a formula. Management believes the Company was in compliance with all covenants under the Loan Agreement as of December 31, 2018.

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.

In connection with the Loan Agreement, on May 8, 2018, the Company issued a warrant (the "Warrant") to the Bank, which provides for the right to purchase an aggregate of 218,914 shares of the Company's common stock for a five-year period, expiring on May 8, 2023, at an exercise price of $1.142 per share.

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

The shares associated with the Warrant were fully vested at the time of issuance. The value of the Warrant was estimated on the date of grant to be $0.57 per share using the Black-Scholes option pricing model, assuming a weighted-average expected stock price volatility of 54.8%, an expected warrant life of five years, an average risk-free interest rate of 2.76%, and a 0.0% average dividend yield. The value of the Warrant of $124,248, 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 incurred debt issuance costs and discounts of $895,000 associated with the Loan Agreement, including $120,000 of commitment fees together with legal and brokerage costs paid at the closing, $400,000 of final payment fees to be accrued, and $124,248 of non-cash expenses pertaining to the Warrant. The debt issuance costs and discounts will be amortized through May 8, 2022, the maturity date of the Loan Agreement. As a result of the debt issuance costs, the effective rate of the Term Loan was 11.23% at May 8, 2018 (11.96% at December 31, 2018). In addition, unamortized debt issuance costs of $264,539 together with a prepayment fee of $69,333, each pertaining to the Company's prior loan agreement, were recorded as interest expense during the second quarter of 2018 corresponding with the termination of that agreement. Finally, the accrued final payment fee of $320,000 owed to the former lenders, was repaid concurrently with the execution of the new Agreement.

The Company financed its directors' and officers' insurance premiums during 2018 under a note payable in the amount of $100,841. The note payable requires ten payments of $10,335, including interest, and is scheduled to be repaid in full by September 2019.

As of December 31, 2018, the Company had cash-on-hand and amounts available under its Loan Agreement totaling $5,272,000. As such, our ordinary short-term capital needs are expected to be met from cash-on-hand and borrowings available from the revolving line-of-credit under our Loan Agreement which was unused as of December 31, 2018. In addition, the Company is anticipating an earn-out payment from the sale of its non-invasive blood pressure technology in July 2017. In accordance with that agreement, the Company is entitled to a payment in August 2019 not to exceed $2,000,000, following a 24-month period ending June 30, 2019. The Company has not recorded any amounts potentially due from the earn-out payment but believes that the Company will earn all, or nearly all, of the entire amount. Management believes its cash balances and available borrowings are sufficient to support operations through March 31, 2020. Management further believes that given the Company's current and expected rate of cash consumption over the next 12 months, together with the principal repayments required under its Loan Agreement, it should, nonetheless, if the merger transaction with Edwards is not completed, take action to improve its liquidity until such time that the Company can generate positive cash flow from operations. Management estimates it can achieve positive cash flow in late 2020. Such actions to enhance liquidity may include seeking further changes in its debt instruments (including waivers, modifications, and/or replacement of current agreements), reducing otherwise planned expenditures and operating expenses, or raising additional funds through the issuance of equity securities.

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 modifying or refinancing our debt instruments or 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 2019 business plans call for operating expenditures to be slightly above 2018 levels. Capital expenditures for 2019 are expected to approximate 2018 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 significantly affected by inflation during 2018.

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.

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 – Effective January 1, 2018, the Company adopted Accounting Standards Update ("ASU") 2016-10, Topic 606, Revenue from Contracts with Customers. The Company used the Modified Retrospective method, under which prior-year results are not restated. The standard, including the cumulative effect of its adoption, did not have a material impact on the Company's financial statements.

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 is 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. In adopting ASU 2016-10, the Company reviewed the five steps considered fundamental to determining when to recognize revenue. Those five steps are as follows: (1) Identify the contract(s) with a customer; (2) Identify the performance obligations in the contract; (3) Determine the transaction price; (4) Allocate the transaction price to the performance obligations in the contract; and (5) Recognize revenue when (or as) the entity satisfied a performance obligation.

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.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of CAS Medical Systems, Inc. and Subsidiary (the "Company") as of December 31, 2018 and 2017, and the related consolidated statements of operations, changes in stockholders' equity (deficiency), and cash flows for the years then ended, and the related notes (collectively referred to as the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. Federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, 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.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ CohnReznick LLP

We have served as CAS Medical Systems, Inc.'s auditor since 2010.

Roseland, New Jersey
March 25, 2019

F-1

CAS Medical Systems, Inc.
Consolidated Balance Sheets
As of December 31, 2018 and 2017

ASSETS	2018	2017
CURRENT ASSETS:		
Cash and cash equivalents	$3,271,999	$5,652,996
Accounts receivable, net	3,182,821	2,918,950
Inventories	1,011,594	1,076,261
Other current assets	620,419	353,079
Total current assets	8,086,833	10,001,286
PROPERTY AND EQUIPMENT:		
Leasehold improvements	147,373	151,377
Equipment at customers	3,938,022	3,506,386
Machinery and equipment	4,422,720	4,593,473
	8,508,115	8,251,236
Accumulated depreciation and amortization	(6,566,877)	(6,080,350)
Property and equipment, net	1,941,238	2,170,886
Intangible and other assets, net	821,541	802,391
Total assets	$10,849,612	$12,974,563

CAS Medical Systems, Inc.
Consolidated Balance Sheets
As of December 31, 2018 and 2017

LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIENCY)	2018	2017
CURRENT LIABILITIES:		
Accounts payable	$1,133,874	$691,596
Accrued expenses	2,199,052	1,651,873
Note payable	90,959	86,079
Current portion of long-term debt, less unamortized debt issuance costs	49,463	2,733,831
Liabilities associated with discontinued operations	—	35,000
Total current liabilities	3,473,348	5,198,379
Long-term debt, less current portion and unamortized debt issuance costs	9,239,610	4,943,195
Other long-term liability	400,000	320,000
Total liabilities	13,112,958	10,461,574
Commitments and contingencies (Note 11)		
STOCKHOLDERS' EQUITY (DEFICIENCY):		
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 $16,175,829 and $15,091,377 at December 31, 2018 and December 31, 2017, respectively	8,802,000	8,802,000
Series A exchangeable preferred stock, 54,500 shares issued and outstanding, liquidation value of $9,231,232 and $8,612,356 at December 31, 2018 and December 31, 2017, respectively	5,135,640	5,135,640
Common stock, $.004 par value per share, 60,000,000 shares authorized, 29,341,211 and 28,621,697 shares issued at December 31, 2018 and December 31, 2017, respectively, including shares held in treasury	117,365	114,487
Common stock held in treasury, at cost - 86,000 shares	(101,480)	(101,480)
Additional paid-in capital	33,171,165	31,989,207
Accumulated deficit	(49,388,036)	(43,426,865)
Total stockholders' equity (deficiency)	(2,263,346)	2,512,989
Total liabilities and stockholders' equity (deficiency)	$10,849,612	$12,974,563

See accompanying notes.

F-3

CAS Medical Systems, Inc.
Consolidated Statements of Operations
For the Years Ended December 31, 2018 and 2017

	2018	2017
Net sales from continuing operations	$21,919,987	$18,763,136
Cost of sales	9,213,763	8,505,010
Gross profit	12,706,224	10,258,126
Operating expenses:		
Research and development	3,181,915	3,234,101
Selling, general and administrative	14,015,583	13,418,332
Total operating expenses	17,197,498	16,652,433
Operating loss	(4,491,274)	(6,394,307)
Interest expense, net	1,469,897	1,076,400
Loss from continuing operations before income taxes	(5,961,171)	(7,470,707)
Income tax benefit	—	(1,745,441)
Loss from continuing operations	(5,961,171)	(5,725,266)
Discontinued operations:		
Income from discontinued operations	—	745,396
Gain on sale of discontinued operations	—	4,388,254
Income tax expense	—	1,745,441
Income from discontinued operations	—	3,388,209
Net loss	(5,961,171)	(2,337,057)
Preferred stock dividend accretion	1,703,327	1,589,134
Net loss applicable to common stockholders	$(7,664,498)	$(3,926,191)
Loss per common share from continuing operations - basic and diluted	$(0.28)	$(0.27)
Income per common share from discontinued operations - basic and diluted	—	0.13
Per share basic and diluted net loss applicable to common stockholders	$(0.28)	$(0.14)
Weighted-average number of common shares outstanding:		
Basic and diluted	27,769,706	27,260,688

See accompanying notes.

CAS Medical Systems, Inc.
Consolidated Statements of Changes in Stockholders' Equity (Deficiency)
For the Years Ended December 31, 2018 and 2017

	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, 2016	150,000	$13,937,640	27,428,752	$109,715	86,000	$(101,480)	$30,557,093	$(41,089,808)	$3,413,
Net loss								(2,337,057)	(2,337
Common stock issued under stock purchase plan			14,455	58			18,836		18,894
Issuance of common stock to settle accrued liability			390,240	1,561			572,092		573,65
Restricted stock granted			788,250	3,153			(3,153)		—
Stock compensation							844,339		844,33
BALANCE, December 31, 2017	150,000	13,937,640	28,621,697	114,487	86,000	(101,480)	31,989,207	(43,426,865)	2,512,
Net loss								(5,961,171)	(5,961
Common stock issued under stock purchase plan			16,157	65			16,235		16,300
Common stock issued - options exercised			53,824	215			10,510		10,725
Warrants exercised			34,000	136			31,484		31,620

Issuance of common stock to settle accrued liability			193,033	772			241,667		242,43
Restricted stock granted			422,500	1,690			(1,690)		—
Warrant issued to lender							124,248		124,24
Stock compensation							759,504		759,50
BALANCE, December 31, 2018	150,000	$13,937,640	29,341,211	$117,365	86,000	$(101,480)	$33,171,165	$(49,388,036)	$(2,263

See accompanying notes.

CAS Medical Systems, Inc.
Consolidated Statements of Cash Flows
For the Years Ended December 31, 2018 and 2017

	2018	2017
OPERATING ACTIVITIES:		
Net loss	$(5,961,171)	$(2,337,057)
Income from discontinued operations	—	3,388,209
Loss from continuing operations	(5,961,171)	(5,725,266)
Adjustments to reconcile loss from continuing operations to net cash used in operating activities of continuing operations:		
Depreciation and amortization	1,052,476	1,025,786
Amortization of debt issuance costs and discounts	507,127	255,705
Deferred income taxes	—	(1,745,441)
Provision for doubtful accounts	—	191,567
Stock compensation	759,504	844,339
Impairment of capitalized costs	21,340	17,276
Amortization of gain on sale and leaseback of property	—	(91,603)
Changes in operating assets and liabilities:		
Accounts receivable	(263,871)	(151,966)
Inventories	64,668	297,603
Other current assets	(10,082)	720,459
Accounts payable and accrued expenses	1,231,894	(313,839)
Net cash used in operating activities of continuing operations	(2,598,115)	(4,675,380)
INVESTING ACTIVITIES:		
Expenditures for property and equipment	(783,483)	(596,381)
Proceeds from sale of discontinued operations	—	4,527,206
Additions to intangible assets	(79,834)	(67,480)
Net cash (used in) provided by investing activities of continuing operations	(863,317)	3,863,345
FINANCING ACTIVITIES:		
Proceeds from long-term debt	2,000,000	—
Payment of end-of-term loan fee	(320,000)	—
Deferred debt issuance costs	(370,832)	—
Proceeds from line-of-credit	—	1,000,000
Repayment of line-of-credit	—	(1,000,000)
Repayments of notes payable	(252,378)	(234,087)
Proceeds from issuance of common stock	58,645	18,894
Net cash provided by (used in) financing activities of continuing operations	1,115,435	(215,193)
Net decrease in cash and cash equivalents from continuing operations	(2,345,997)	(1,027,228)
CASH FLOWS FROM DISCONTINUED OPERATIONS:		
Cash (used in) provided by operating activities of discontinued operations	(35,000)	1,191,518
Net cash (used in) provided by discontinued operations	(35,000)	1,191,518
Net change in cash and cash equivalents	(2,380,997)	164,290

Cash and cash equivalents, beginning of year	5,652,996	5,488,706
CASH AND CASH EQUIVALENTS, END OF YEAR	$3,271,999	$5,652,996
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid during the period for interest	$946,649	$808,544
Accrued liability settled with common stock	$242,439	$573,653
Insurance premiums funded with note payable	$257,258	$250,151
End-of-term fee payable to lender	$400,000	$—
Warrant issued to lender	$124,248	$—

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 and are consistent with our vision that no patient is harmed by undetected tissue hypoxia. The Company's products include the FORE-SIGHT® series of absolute tissue oximeters and sensors, including the FORE-SIGHT ELITE® oximeter. We also perform service repairs that are separately reported as Service/Other. CASMED markets its products worldwide through its sales force, distributors, and manufacturers' representatives. The Company's main 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 $1,013,000 in 2018 and $987,000 in 2017.

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 2018 and 2017, the Company charged-off $21,340 and $17,276, 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, 2018 and 2017 consist of:

	2018	2017
Patents and other assets	$782,566	$738,805
Patents pending	301,564	297,746
	1,084,130	1,036,551
Accumulated amortization	(262,589)	(234,160)
Total	$821,541	$802,391

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, 2018, over the next five calendar years follows:

2019	$38,000
2020	$38,000
2021	$37,000
2022	$37,000
2023	$36,000

Sales and accounts receivable recognition

In April 2016, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("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 Company adopted the new revenue standard effective January 1, 2018, using the Modified Retrospective method, under which prior-year results are not restated; however, supplemental information regarding the impact of the new standard must be provided, if material. The standard, including the cumulative effect of its adoption, did not have a material impact on the Company's financial statements.

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 is 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. In adopting ASU 2016-10, the Company reviewed the five steps considered fundamental to determining when to recognize revenue. Those five steps are as follows: (1) Identify the contract(s) with a customer; (2) Identify the performance obligations in the contract; (3) Determine the transaction price; (4) Allocate the transaction price to the performance obligations in the contract; and (5) Recognize revenue when (or as) the entity satisfied a performance obligation.

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 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 16% and 14% of sales from continuing operations in 2018 and 2017, respectively. Sales to each of these customers accounted for less than 10% of sales from continuing operations.

Income taxes

On December 22, 2017, the U.S. government enacted comprehensive tax reform legislation in the form of the Tax Cuts and Jobs Act of 2017 (the "Tax Act"). The Tax Act established new tax laws that affected 2017 and beyond. One of the principal new tax laws effective January 1, 2018, was the reduction on the U.S. Federal corporate income tax rate from 35% to 21%.

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 2015 are closed for audit. There have been no interest and penalties related to uncertain tax positions for any periods reported herein.

Warranty costs

The Company generally warrants products against defects and failures for up to two 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, 2018 and 2017 follows:

	2018	2017
Beginning balance	$65,000	$100,000
Provision	14,752	27,616
Warranty costs incurred	(29,752)	(62,616)
Ending balance	$50,000	$65,000

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 $710,000 and $696,000 in 2018 and 2017, respectively.

Loss per common share applicable to common stockholders

Basic loss per share is calculated by dividing net loss applicable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted 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, 2018, stock options and warrants to purchase 3,238,250 and 472,782 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, 10,635,019 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 July 25, 2017, the Company entered into an agreement pursuant to which it sold assets related to its NIBP technology product line in exchange for $4,500,000 in cash at closing and an additional payment for the purchase of inventory following a short transition services period, which concluded during September 2017. The final inventory purchased by the buyer was $86,000. In accordance with that agreement, the Company is also entitled to an additional payment in August 2019 not to exceed $2,000,000, following a 24-month period ending June 30, 2019.

On March 28, 2016, the Company consummated an agreement under which it sold certain assets related to its neonatal intensive care disposable product line for $3,350,000, including $3,035,000 in cash at closing after deductions of $100,000 for funds held in escrow for 12 months following the closing and $215,000 for inventory to be purchased following a transition services agreement which was effectively concluded at December 31, 2016. The inventory to be purchased from the Company was $167,000 as of that date. During March 2017, the funds in escrow were paid to the Company while payments on the inventory were scheduled to be made through year-end 2017, according to a promissory note executed between the Company and the seller. The Company reserved the amounts due under the note during the first quarter of 2017. As of December 31, 2018, the Company had not received any further payments under the note.

There were no assets or liabilities associated with the discontinued operations in the consolidated balance sheet as of December 31, 2018. As of December 31, 2017, there were $35,000 of accrued expenses.

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

	2018	2017
Net sales	$ —	$2,147,741
Cost of sales	—	1,340,089
Gross profit	—	807,652
Operating expenses	—	62,256
Income from discontinued operations before income taxes	—	745,396
Gain on sale of discontinued operations	—	4,388,254
Income tax expense	—	(1,745,441)
Income from discontinued operations	$ —	$3,388,209

(4) ALLOWANCE FOR DOUBTFUL ACCOUNTS

The allowance for doubtful accounts was $125,000 at December 31, 2018 and 2017.

(5) INVENTORIES

Inventories at December 31, 2018 and 2017 consist of:

	2018	2017
Raw materials	$657,019	$559,737
Work in process	2,086	1,633
Finished goods	352,489	514,891
Total	$1,011,594	$1,076,261

(6) FINANCING ARRANGEMENTS

Private Placement of Preferred Stock

As of December 31, 2018, 95,500 shares of Series A Convertible Preferred Stock and 54,500 shares of Series A Exchangeable Preferred Stock, issued on June 8, 2011, in connection with a 2011 private placement (collectively, the "Preferred Stock"), are outstanding. 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 Preferred Stock has a par value of $0.001 per share and is convertible into common stock of the Company at a price of $2.389 per share. The Company can force conversion of all of the outstanding Preferred Stock if the closing price of its common stock meets certain share price, trading volume requirements, and other conditions. The stated value ($100 per share) of the Preferred Stock accretes at an annual rate of 7% compounded quarterly. While such accretion may be paid in cash at the Company's option, the Company's current loan agreement prohibits the payment of cash dividends. As of December 31, 2018, dividend accretion of $10,407,061 had accumulated on the Preferred Stock. The Preferred Stock is entitled to a liquidation preference equal to the greater of 100% of the total accreted value for each share of 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 Preferred Stock into common stock immediately prior to the liquidation. Accordingly, based upon the liquidation value of the Preferred Stock at December 31, 2018, there were 10,635,019 shares of common stock issuable upon conversion of the Preferred Stock. The Preferred Stock votes together with the common stock as if converted on the original date of issuance. Holders of Preferred Stock are entitled to purchase their pro rata share of additional stock issuances in certain future financings.

The Company can force conversion of all, and not less than all, of the outstanding 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 Preferred Stock described above.

Bank Financing

On May 8, 2018, the Company consummated a Loan and Security Agreement (the "Loan Agreement") with East West Bank (the "Bank"). Pursuant to the Loan Agreement, the Bank has provided a 48-month term loan (the "Term Loan") in the amount of $10,000,000 and a revolving loan (the "Revolver") in the maximum of $2,000,000, each of which expires May 8, 2022. The obligations under the Loan Agreement are secured by a lien on substantially all of the

non-intellectual property assets of the Company. As of December 31, 2018, there was no outstanding balance under the Revolver. Available borrowings under the Revolver were $2,000,000 as of that date.

The Term Loan bears interest at a floating rate equal to the Bank's prime rate (not less than 4.75%) plus 3.65% (9.15% as of December 31, 2018). Under the Term Loan, 30 equal payments of $333,333 are scheduled to commence on December 1, 2019, following an 18-month period during which the Company shall make interest-only payments. The interest-only period may be extended to 21 months or 24 months under certain circumstances.

Revolver advances will bear interest at a floating rate equal to the Bank's prime rate (not less than 4.75%) plus 2.40% (7.90% as of December 31, 2018). Maximum borrowings under the Revolver are based upon the Company's eligible accounts receivable, as defined in the Loan Agreement, and subject to other terms and conditions.

The Company has the right to prepay the loan under the Loan Agreement in full at any time; however, if the Term Loan is prepaid prior to the first or second anniversaries of the Loan Agreement or prior to maturity, a fee of 3%, 2%, or 1%, respectively, of the Term Loan amount is due. Amounts prepaid under the Term Loan may not be re-borrowed. Upon repayment of the Term Loan at any time, the Bank is entitled to an additional fee equal to 4% of the Term Loan amount, or $400,000. Such amount has been accrued as of December 31, 2018.

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 or the Company's intellectual property, incur additional indebtedness, make certain investments and acquisitions, and dispose of assets outside the ordinary course of business. The Loan Agreement also contains financial covenants requiring the Company to achieve certain sales results and to maintain a continuing level of cash plus available borrowing capacity based on a formula. Management believes the Company was in compliance with all covenants under the Loan Agreement as of December 31, 2018.

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.

In connection with the Loan Agreement, on May 8, 2018, the Company issued a warrant (the "Warrant") to the Bank, which provides for the right to purchase an aggregate of 218,914 shares of the Company's common stock for a five-year period, expiring on May 8, 2023, at an exercise price of $1.142 per share.

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

The shares associated with the Warrant were fully vested at the time of issuance. The value of the Warrant was estimated on the date of grant to be $0.57 per share using the Black-Scholes option pricing model, assuming a weighted-average expected stock price volatility of 54.8%, an expected warrant life of five years, an average risk-free interest rate of 2.76%, and a 0.0% average dividend yield. The value of the Warrant of $124,248, 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 incurred debt issuance costs and discounts of $895,000 associated with the Loan Agreement, including $120,000 of commitment fees together with legal and brokerage costs paid at the closing, $400,000 of final payment fees to be accrued, and $124,248 of non-cash expenses pertaining to the Warrant. The debt issuance costs and discounts will be amortized through May 8, 2022, the maturity date of the Loan Agreement. As a result of the debt issuance costs, the effective rate of the Term Loan was 11.23% at May 8, 2018 (11.96% at December 31, 2018). In

addition, unamortized debt issuance costs of $264,539 together with a prepayment fee of $69,333, each pertaining to the Company's prior loan agreement, were recorded as interest expense during the second quarter of 2018 corresponding with the termination of that agreement. Finally, the accrued final payment fee of $320,000 owed to the former lenders, was repaid concurrently with the execution of the new Loan Agreement.

The outstanding balance of the bank term loan at December 31, 2018 and prior term loan at 2017 was as follows:

	December 31, 2018			December 31, 2017		
	Principal	Unamortized Debt Issuance Cost and Discounts	Debt, Net	Principal	Unamortized Debt Issuance Cost and Discounts	Debt, Net
Balance of term loan	$10,000,000	$ 710,927	$9,289,073	$8,000,000	$ 322,974	$7,677,026
Less current portion	333,333	283,870	49,463	2,933,333	199,502	2,733,831
Long-term portion	$9,666,667	$ 427,057	$9,239,610	$5,066,667	$ 123,472	$4,943,195

The Company financed its directors' and officers' insurance premiums during 2018 under a note payable in the amount of $100,841. The note payable requires ten payments of $10,335, including interest, and is scheduled to be repaid in full by September 2019.

(7) ACCRUED EXPENSES

Accrued expenses at December 31, 2018 and 2017 consist of:

	2018	2017
Payroll	$435,372	$394,527
Employee compensation	735,763	275,236
Professional fees	398,821	316,057
Warranty	50,000	65,000
Sales and use tax	208,765	215,086
Other	370,331	385,967
	$2,199,052	$1,651,873

(8) SHARE-BASED PAYMENT PLANS

On June 20, 2018, the Company's stockholders approved the CAS Medical Systems, Inc. 2018 Equity Incentive Plan (the "Plan"). The maximum number of shares of common stock that may be granted under the Plan is 2,500,000. Awards that may be granted under the Plan include options, restricted stock and restricted stock units, and other stock-based awards. 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, 2018, there remained a total of 2,120,988 shares available for issuance pursuant to our equity incentive plans, including 44,812 shares remaining under the 2011 Equity Incentive Plan.

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.

F-13

Stock Options

As of December 31, 2018, options to purchase 3,238,250 shares remain outstanding, of which 72,500 pertain to options granted under the 2018 Plan and 2,475,250 pertain to options granted under the 2011 Plan; 340,500 pertain to stock options granted under the now-expired 2003 Equity Incentive Plan; and 350,000 were issued as a non-plan inducement grant to the CEO commensurate with the start of his employment with the Company.

The unamortized stock compensation expense associated with the stock options at December 31, 2018, was $269,000 and will be recognized through 2022.

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

	2018			2017		
	Option Shares	Weighted-Average Exercise Price	Aggregate Intrinsic Value	Option Shares	Weighted-Average Exercise Price	Aggregate Intrinsic Value
Outstanding at beginning of year	3,573,250	$ 1.83		3,229,500	$ 1.97	
Granted	87,500	1.42		465,000	0.84	
Exercised	(53,824)	—		—	—	
Cancelled	(368,676)	2.31		(121,250)	1.79	
Outstanding at end of year	3,238,250	$ 1.77	$411,325	3,573,250	$ 1.83	$31,968
Exercisable at end of year	2,671,375	$ 1.92	$111,775	2,698,875	$ 2.03	$—
Vested and expected to vest at end of year	3,221,243	$ 1.78	$402,339	3,547,018	$ 1.83	$31,009
Weighted-average grant-date fair value of options granted during the year		$ 0.79			$ 0.72	

During 2018, the Company granted non-qualified stock options to employees to purchase 87,500 shares of common stock at a weighted-average exercise price of $1.42. The stock options were granted at exercise prices based upon the Nasdaq official closing price on the date of each grant. The fair values of the options were estimated on the grant dates 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 options granted was $0.79 and assumed a weighted-average expected stock volatility of 56.3%, a weighted-average expected option term of 6.25 years, an average risk-free interest rate of 2.6%, and a 0.0% dividend yield. The risk-free interest rate approximated U.S. Treasury yields in effect at the time of the grant. The expected life of the stock options was determined using historical data adjusted for the estimated exercise dates of unexercised options. Volatility was determined using both current and historical implied volatilities of the underlying stock which are obtained from public data sources.

During 2018, stock options to purchase 53,824 shares of common stock were exercised, and options to purchase 368,676 shares were cancelled.

Additional information about stock options outstanding and exercisable at December 31, 2018, follows:

		Weighted Remaining	Average		Average

Range of Exercise Prices	Number Outstanding	Contractual Life in Years	Exercise Price	Number Exercisable	Exercise Price
$0.67 - $1.26	532,500	5.4	$0.84	166,250	$0.93
1.43 - 1.98	1,680,250	8.6	1.74	1,479,625	1.76
2.09 - 2.54	847,500	5.3	2.15	847,500	2.15
2.95 - 3.16	178,000	2.0	3.04	178,000	3.04
	3,238,250	6.8	$1.77	2,671,375	$1.92

Restricted Stock

During 2018, members of the management team were granted 332,500 shares of restricted common stock, which primarily vest 25% per year on each anniversary of the grant date, and 90,000 restricted common shares were granted to outside members of the Board of Directors, which vest 50% per year on each anniversary of the grant date.

As of December 31, 2018, there were 1,202,562 restricted shares issued to employees, a consultant, and outside members of the Board of Directors, which remained issued and non-vested.

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

	2018	2017
Outstanding at beginning of year	1,107,250	418,500
Granted	422,500	798,250
Cancelled	—	(10,000)
Vested	(327,188)	(99,500)
Outstanding at end of year	1,202,562	1,107,250

The fair value of the restricted common share grants has 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 $450,000 and $374,000 related to restricted shares was recorded for 2018 and 2017, respectively. The unamortized stock compensation expense associated with the restricted shares at December 31, 2018, was $1,233,000 and will be recognized through 2022.

Total stock compensation expense was $759,504 and $844,339 for 2018 and 2017, respectively.

Warrants

Warrants to purchase 472,782 shares of common stock at a weighted-average exercise price of $1.39 per share were outstanding at December 31, 2018. The warrants have an exercise price range of $0.38 to $1.98 per share. A total of 75,000 shares issued to former members of the board of directors have no expiration date. The balance of the outstanding warrants have been granted to the Company's current and former bank lenders and have expiration dates ranging from five to ten years from date of grant.

In connection with the Loan Agreement executed on May 8, 2018, the Company issued a warrant to the Lender, which provides for the right to purchase an aggregate of 218,194 shares of the Company's common stock for a five-year period, expiring on May 8, 2023, at an exercise price of $1.142 per share.

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, 2018, there were 105,148 shares issued under the Stock Purchase Plan, and certain amounts had been withheld from employees' compensation to purchase an additional 8,778 shares which were issued during January 2019. 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 2018 and 2017 were $110,738 and $109,151, respectively.

(10) INCOME TAXES

There are no current and deferred Federal and state income tax benefits for the years ended December 31, 2018 and 2017.

On December 22, 2017, the U.S. government enacted comprehensive tax reform legislation in the form of the Tax Cuts and Jobs Act of 2017 (the "Tax Act"). The Tax Act establishes new tax laws that affect 2017 and beyond. One of the principal new tax laws effective January 1, 2018, is the reduction of the U.S. Federal corporate income tax rate from 35% to 21%. As a result of the reduction in the Federal income tax rate, the Company revalued its net deferred tax assets as of December 31, 2017.

A reconciliation of U.S. Federal income taxes computed at the statutory rate to income taxes shown in the statement of operations for the years ended December 31, 2018 and 2017 follows:

	2018	2017
Income tax benefit at the statutory rate	$(1,250,231)	$(2,540,040)
State income taxes, net of Federal effect	(128,169)	(33,130)
R&D and other tax credits	(95,666)	(106,772)
Federal rate change	—	5,897,964
Change in valuation allowance	1,454,683	(4,997,595)
Other	19,383	34,132
Income tax benefit from continuing operations	$—	$(1,745,441)

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

	2018	2017
Inventories	$130,140	$106,537
Warranty accrual	11,093	22,185
Allowance for doubtful accounts	27,731	66,903
Tax credits	1,268,490	1,172,824
Restricted stock	957,375	938,157
Net operating loss carryforwards	10,732,452	9,531,339
Other	362,101	258,822
	13,489,382	12,096,767
Prepaid expenses	(28,457)	(31,170)
Fixed assets	(444,752)	(504,106)
Deferred income tax assets and liabilities	13,016,173	11,561,491
Valuation allowance	(13,016,173)	(11,561,491)
Net deferred income tax assets and liabilities	$—	$—

The Company has performed the required analysis of both positive and negative evidence regarding the realization of its 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 its products in the marketplace, competitive influences, and the investments required to increase market share in certain markets for its products. As of December 31, 2018, 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 $13,016,173.

The Company's Federal net operating loss carryforward of $42,089,000 is scheduled to expire beginning in 2031. State net operating loss carryforwards of $11,729,000 are scheduled to expire between 2028 and 2038. 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 as well as limitations imposed by the Tax Act. 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, 2018 or 2017, and expects no significant changes in 2019.

(11) COMMITMENTS AND CONTINGENCIES

Product 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. We are currently a defendant in a product liability action related to our former sleep apnea product line. Product liability claims, regardless of their ultimate outcome, could require us to spend significant time and money in litigation or to pay significant damages.

We believe that our product liability insurance is sufficient to cover any damages and costs that may be incurred, with respect to this matter.

Merger-Related Litigation

On or about March 7, 11, 14 and 21, 2019, four putative class action complaints challenging the Merger were filed in the United States District Court for the District of Delaware, captioned Adam Franchi v. CAS Medical Systems, Inc., et al., Shiva Stein v. CAS Medical Systems, Inc., et al., Thomas Torreano v. CAS Medical Systems, Inc. et al. and Joseph Rish Jr. v. CAS Medical Systems, Inc. et al., respectively, and on or about March 11, 2019 an additional putative class action complaint challenging the merger was filed in the Superior Court for the State of Connecticut, Judicial District of New Haven at New Haven, captioned Charles New v. CAS Medical Systems, Inc., et al. The complaints were filed on behalf of the public shareholders of CASMED and name as defendants CASMED and the members of its board of directors. The complaints generally allege violations of federal securities laws with respect to purported disclosure deficiencies in the preliminary proxy statement for the merger that CASMED filed with the SEC on March 1, 2019. The complaint in the Stein action also alleges that CASMED's directors agreed to sell CASMED for inadequate consideration, the complaint in the New action also alleges that CASMED's directors agreed to sell CASMED for an unfair price as a result of an unfair sale process and the complaint in Torreano also alleges that the Merger contains preclusive deal protection provisions. The Torreano complaint also alleges claims against Edwards Lifesciences Holding, Inc. Crown Merger Sub, Inc. and Edwards Lifesciences Corporation. The complaints seek a variety of relief, including an injunction preventing the consummation of the Merger, rescission of the Merger if it is consummated or rescissory damages, attorneys' fees and expenses. The defendants have not yet responded to the complaints, but believe that the claims asserted against them are without merit.

Operating Leases

The Company currently leases one corporate facility and certain equipment under non-cancellable operating leases. Rent expense under these leases was $353,000 in 2018 and $393,000 in 2017. Future annual minimum rental payments as of December 31, 2018, to the expiration of the leases follow:

2019	$294,000
2020	291,000
2021	297,000
2022	25,000

2023	—
Total	$907,000

(12) RECENT ACCOUNTING PRONOUNCEMENTS

In February 2016, the FASB issued ASU 2016-02, Leases - Topic 842. The amendment improves transparency and comparability among companies by recognizing lease assets and lease liabilities on the balance sheet and by disclosing key information about leasing arrangements. 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 will apply the new guidance at the effective date of January 1, 2019. Management will also make an accounting policy election to not recognize on its balance sheet right-of-use assets and liabilities arising from short-term leases which are generally characterized as those leases less than one-year in length from commencement date. Management estimates that the adoption of the guidance will result in the recognition of additional right-of-use assets and lease liabilities for operating leases of approximately $863,000 as of January 1, 2019. The Company does not believe the guidance will have a material impact on its statements of operations.

In April 2016, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("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 is 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. In adopting ASU 2016-10, the Company reviewed the five steps considered fundamental to determining when to recognize revenue. Those five steps are as follows: (1) Identify the contract(s) with a customer; (2) Identify the performance obligations in the contract; (3) Determine the transaction price; (4) Allocate the transaction price to the performance obligations in the contract; and (5) Recognize revenue when (or as) the entity satisfied a performance obligation.

The Company adopted the new revenue standard effective January 1, 2018, using the Modified Retrospective method, under which prior-year results are not restated; however, supplemental information regarding the impact of the new standard must be provided, if material. The standard, including the cumulative effect of its adoption, did not have a material impact on the Company's financial statements.

(13) SUBSEQUENT EVENT

The Merger Agreement

On February 11, 2019, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") pursuant to which the Company would become a wholly-owned subsidiary of Edwards Lifesciences Corporation (the "Merger"). The Board of Directors of the Company has unanimously approved the Merger Agreement, the Merger, and the other transactions contemplated thereby.

As a result of the Merger, and at the effective time (the "Effective Time") each share of Company common stock issued and outstanding immediately prior to the Effective Time will be converted into the right to receive $2.45 per share in cash (the "Merger Consideration").

The Merger Agreement also provides that each holder of Company Series A Convertible Preferred Stock and Series A Exchangeable Preferred Stock shall provide a consent to convert such preferred stock, outstanding immediately prior to the Effective Time, into the right to receive the Merger Consideration as holders of the Company's common stock.

The Merger is subject to stockholder approval and certain additional customary closing conditions, including, among other things, the expiration of a required waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

The Merger Agreement contains certain termination rights for each party, including the right of the Company to terminate the Merger Agreement to accept a company superior proposal after complying with certain requirements. In addition, either party may terminate the Merger Agreement if the Merger is not consummated on or before November 8, 2019. The Merger Agreement further provides that the Company may be required to pay Edwards Lifesciences Holding, Inc. ("Edwards") a termination fee of $3.5 million under certain circumstances, including if Edwards terminates the Merger Agreement due to a change in the recommendation by the Company's Board of Directors for the Merger or due to the Company's material breach of its non-solicitation obligations set forth in the Merger Agreement. The Merger Agreement also provides that in case it is terminated by either Edwards or the Company following a failure to obtain the required vote of the Company's stockholders to adopt the Merger Agreement, the Company shall reimburse Edwards up to $1.0 million of certain of its transaction expenses, which would reduce on a dollar-for-dollar basis any termination fee otherwise owed to Edwards.

The Merger is expected to close during the second quarter of 2019 and is not subject to a financing condition.

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, 2018. 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, 2018, 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, 2018.

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

The Company currently has seven Directors (the "Board"). Their term expires at the next Annual Meeting of Stockholders. The following table contains information regarding all Directors and executive officers of the Company as of March 15, 2019:

Name	Age	Principal Occupation	Director Since
Alan Milinazzo	59	Director	2015
Paul Molloy	57	Director	2015
Thomas M. Patton	55	President and Chief Executive Officer and Director	2010
Gregory Rainey	66	Director	2010
James Thomas	58	Director	2011
Kathleen Tune	54	Director	2011
Kenneth Weisshaar	68	Director	2010
Jeffery A. Baird	65	Chief Financial Officer	
Paul B. Benni	51	Chief Scientific Officer	
John K. Gamelin	53	Vice President – Research and Development	

Principal Occupations and Business Experience of Directors and Executive Officers

The following is a brief summary of the business experience of the Company's Directors and executive officers:

Directors

Alan W. Milinazzo is currently a Partner of the consulting firm of Heidrick & Struggles. From 2013 to 2016, he served as President and Chief Executive Officer of InspireMD, Inc., a publicly-traded interventional device company focused on developing novel embolic protection products. From 2005 to 2012, he served as Chief Executive Officer and Director of Orthofix International, N.V., a publicly-traded global orthopedic company. From 2002 to 2005, he served as Vice President of the vascular business as well as Vice President and G.M. of the coronary and peripheral businesses at Medtronic Inc. Mr. Milinazzo also served in executive positions at Boston Scientific Corporation. In addition to serving as a board member for the Musculoskeletal Transplant Foundation, he is also on the board of Flexion Therapeutics Inc. He formerly served on the boards of InspireMD, Inc.; Orthofix International, N.V.; Medpace; and HET Systems. Mr. Milinazzo graduated cum laude from Boston College. He is an experienced senior executive and board director, developing high-growth, profitable, global healthcare businesses, including biologics and therapeutic devices. With his expertise in management and marketing within the healthcare industry, Mr. Milinazzo provides the Board the expanded ability to evaluate key decisions on business development and operations.

Paul A. Molloy is currently the Chief Executive Officer of ClearFlow Inc., a commercial-stage medical device company focused on post-surgical wound management. From 2010 to 2013, Mr. Molloy served as the President of the Vascular Division of Teleflex Inc. (NYSE: TFX) and as the Chief Executive Officer of VasoNova, Inc., a vascular ultrasound navigation technology company, which was acquired by Teleflex. From 2008 to 2010, Mr. Molloy served as the President and Chief Executive Officer of MiCardia Corporation, a medical device company focused on cardiology. Mr. Molloy has over 25 years of management experience in the medical device industry and currently

serves on the board of privately-held ClearFlow Inc. and previously served on the board of Revolutionary Medical Devices, Inc., and serves as an advisor at Piccolo Medical Inc. He is a graduate of the Instituut der Bedrijfswetenschappen, Utrecht, Netherlands, and has an M.B.A. from the University of Chicago Booth School of Business. Mr. Molloy has extensive experience in finance as well as sales and marketing, adding to the Board's ability to evaluate key business initiatives and program development.

Thomas M. Patton has served as the Company's President and Chief Executive Officer and as a member of the CASMED Board of Directors since August 2010. He previously served as the CEO of Wright Medical Group, an orthopedic device company, located in Memphis, Tennessee, and as President of Novametrix Medical Systems, a patient-monitoring company, located in Wallingford, Connecticut. From 2003 to 2010, Mr. Patton acted as an advisor to the healthcare-focused private equity group of Ferrer Freeman & Company and, in that capacity, served as the interim CEO of Informed Medical Communications on a part-time basis in 2006 and 2007. Mr. Patton was a co-founder and the CEO of QDx, Inc., a company that developed a platform for hematology diagnostics beginning in 2003 and sold its technology assets to Abbott Labs in 2008, ceasing operations in 2017. Mr. Patton has served on the boards of directors of various public and private companies, including K2M, Genova Diagnostics, and Osteotech. He currently serves on the boards of Misonix, Inc. and The Marlin Company. Mr. Patton attended The College of the Holy Cross, where he majored in Economics and Accounting. After graduating magna cum laude from Georgetown University Law Center, Mr. Patton worked at the law firm of Williams & Connolly in Washington, D.C. Thereafter, he joined Wright Medical Group as its General Counsel, where he served in various executive roles until being appointed CEO. Mr. Patton has extensive experience in the medical device industry and, as President and Chief Executive Officer, provides the Board with primary knowledge of CASMED's business operations.

Gregory P. Rainey is currently President of CCI Performance Group, LLC, which provides strategic and sales management consulting services for healthcare companies. From 1994 to 2004, Mr. Rainey was employed by Stryker Corporation where he held various sales management positions including the position of Vice President of Sales. He has also held various sales positions with Joint Medical Corporation and U.S. Surgical Corporation. Mr. Rainey currently serves on the board of directors for Catalyst OrthoScience, a provider of medical solutions for orthopedic surgery, and has served on the boards of RTI Biologics, Inc., a leading provider of sterile biological implants, until December 2013 and NuOrtho Surgical, Inc. until October 2011. Mr. Rainey also serves as a board member and Chairman of the Marketing Committee of The Community Foundation of Middlesex County, a non-profit entity dedicated to philanthropy in Middlesex County, Connecticut. Mr. Rainey is a graduate of Loyola University with a B.S. in Biology. Mr. Rainey's extensive experience is valuable to the Board's ability to assess our sales management and product distribution strategies.

James E. Thomas is a co-founder of Thomas, McNerney & Partners and has been investing in health care companies since 1992. He previously headed Warburg Pincus LLC's medical technology private equity practice, where he had responsibility for investments in biotechnology, pharmaceutical, medical device, and diagnostic companies. Mr. Thomas is currently a board member of Clarus Therapeutics, Inc. and Stamford Health Inc., the parent of the Stamford Hospital System. Prior to joining Warburg, he was a Vice President at Goldman Sachs International in London. He graduated magna cum laude with a B.S. in Economics from the Wharton School at the University of Pennsylvania and received a M.Sc. in Economics from the London School of Economics. Mr. Thomas's extensive experience in the health care and investment industries is valuable to the Board's ability to assess our business initiatives and financing alternatives.

Kathleen A. Tune is currently a managing director of Fourth Element Capital, a healthcare venture capital firm. She is also an advisor to Thomas, McNerney & Partners and Managing Partner at Eyrie Partners, a healthcare advisory firm. She was employed by Thomas, McNerney & Partners from 2003 to 2016, and during that time was Partner in the firm. From 2000 to 2003, Ms. Tune was employed by Piper Jaffray Companies, where she was a health care analyst focused on medical technology companies. While at Piper, she covered companies in the medical device, medical supply, and diagnostic areas. Ms. Tune was also employed by Solvay, S.A. (in a division that is now part of Zoetis), where she was responsible for new product development. She was also a Senior Scientist at the University of Minnesota. Ms. Tune currently serves on the boards of directors of VertiFlex, Inc., Odonata Health, Inc., and Gillette Children's Specialty Healthcare and Foundation. Her educational background includes an M.S. degree in Microbiology from the University of Minnesota and an M.B.A. from the University of Minnesota's Carlson School of Management. Ms. Tune's extensive experience in the medical device industry and finance is valuable to the Board's ability to evaluate key business decisions.

Kenneth R. Weisshaar previously served as a member of the boards of directors of Orthofix International, N.V., a Nasdaq-listed orthopedic device company; Digene Corporation, a publicly-traded biotechnology company focused on women's health and molecular diagnostic testing; and CenterLight Health System, a large non-profit nursing home and managed care organization located in the New York City area. Mr. Weisshaar spent 12 years as a corporate officer at Becton Dickinson and Company, a medical technology company where, at different times, he was responsible for global businesses in medical devices and diagnostic products and served as Chief Financial Officer and Vice President, Strategic Planning. Mr. Weisshaar was also employed by McKinsey and Company, primarily as a healthcare and manufacturing consultant. Mr. Weisshaar received a B.S. in Chemical Engineering from the Massachusetts Institute of Technology and an MBA from the Harvard Business School. Mr. Weisshaar, our audit committee chairman, has extensive operating and financial management experience in the medical device market, which is valuable to the Board's ability to oversee finances and operations as well as to evaluate business alternatives.

Executive Officers Who Are Not Directors

Jeffery A. Baird joined the Company during January 2004 as Chief Financial Officer and Secretary. From April 2003 to December 2003, Mr. Baird was CFO of QDx, Inc., a start-up venture engaged in the development of novel medical diagnostic products. Mr. Baird was employed by Novametrix Medical Systems, Inc. from 1988 to 2002 and held various positions, including Controller, Treasurer, and CFO. Prior to joining Novametrix, Mr. Baird was employed by Philips Medical Systems, Inc., a medical diagnostic imaging company.

Paul B. Benni, Ph.D., joined the Company in 1998 and in 2006 became Chief Scientific Officer. Dr. Benni is the primary inventor of our FORE-SIGHT® Tissue Oximeter, a near-infrared spectroscopy- (NIRS-) based device to monitor the oxygen saturation of the brain and other tissues of the human body non-invasively by using various wavelengths of light. With the support of several grants from the National Institutes for Health for his unique approach, Dr. Benni made possible the development and first commercialization of FORE-SIGHT for CASMED in 2007. Dr. Benni graduated from Rutgers, The State University of New Jersey, in 1990 with a B.S. in Electrical Engineering and in 1999 with a Ph.D. in Biomedical Engineering focused on NIRS research. Prior to attending graduate school, he worked as an engineer with GE Astrospace on satellites and the Mars Observer spacecraft. Dr. Benni holds several patents on NIRS technology and authored several peer-reviewed journal articles on the topic.

John K. Gamelin, Ph.D., joined the Company in 2009, became the Director of Research and Development in 2010, and was appointed as Vice President of Research and Development in 2012. He has more than 25 years of experience inventing and developing optical, acoustic, and electronic instrumentation, from research concept to commercial production. Previously, he was a co-founder and Vice President of Engineering for Tellium, an optical switching company. He began his career as a Senior Scientist at Bellcore, the research and engineering organization for the Regional Bell Operating Companies. Dr. Gamelin holds four U.S. patents in optical cross-connects and switching technology and five patents in biomedical imaging and medical devices. He is the author or co-author of more than 50 publications on topics that include biomedical imaging and laser transmitters. He received his Ph.D. in Electrical Engineering from the University of California.

Executive officers are elected annually by, and serve at the discretion of, the Board.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires the Company's executive officers, directors and person who own more than 10% of a registered class of the Company's equity securities ("Reporting Persons") to file reports of ownership on Forms 3, 4 and 5 with the SEC. These Reporting Persons are required by SEC regulation to furnish the Company with copies of all Forms 3, 4 and 5 they file with the SEC. Based solely on the Company's review of the copies of the forms it has received, the Company believed that all Reporting Persons, complied on a timely basis with all filing requirements applicable to them with respect to transactions during fiscal year 2018.

Code of Ethics

Our Board of Directors has approved a Code of Ethics, in accordance with the rules of the Securities and Exchange Commission and Nasdaq, which governs the conduct of each of our directors and senior executive officers, including our principal executive officer, principal financial officer, principal accounting officer, and controller. Our Code of Ethics is maintained on our website at www.casmed.com. Any amendments to or waivers of the Code of Ethics that apply to our principal executive officer, principal financial officer, or principal accounting officer and that relates to any element of the definition of the term "code of ethics", as the term is defined by the Securities and Exchange Commission, will be posted on our website at www.casmed.com. There are currently no such amendments or waivers.

We recognize the importance of preventing both actual conflicts of interest and the appearance of such conflicts in dealings between the Company and "related persons" (CASMED directors, director nominees, executive officers, stockholders beneficially owning 5% or greater of our common stock, or the immediate family members of any of the foregoing). In accordance with its charter, the Audit Committee regularly reviews our corporate policies with respect to conflicts of interest, including related party transactions, and investigates instances of such conflicts.

Nomination of Directors

The Nominating and Governance Committee assists the Board of Directors in identifying, screening, and reviewing individuals qualified to serve as directors in accordance with criteria approved by the Board and shall recommend to the Board candidates for nomination for election at the annual meeting of stockholders or to fill Board vacancies. The Nominating and Governance Committee develops and recommends to the Board and oversees implementation of our policies and procedures for the receipt of stockholder suggestions, regarding Board composition and recommendations of candidates for nomination by the Board. The full Board has adopted specifications applicable to members of the Board, and nominees for the Board must meet these specifications. The specifications provide that a candidate for director should:

Have a reputation for industry, integrity, honesty, candor, fairness, and discretion;

Be knowledgeable in his or her chosen field of endeavor, which field should have such relevance to our businesses as would contribute to the company's success;

Be knowledgeable, or willing and able to become so quickly, in the critical aspects of our businesses and operations; and

Be experienced and skillful in serving as a competent overseer of, and trusted advisor to, senior management of a publicly-held corporation.

In addition, nominees for the Board of Directors should contribute to the mix of skills, core competencies, and qualifications of the Board through expertise in one or more of the following areas: accounting and finance, the healthcare industry, international business, mergers and acquisitions, leadership, business and management, strategic planning, government relations, investor relations, executive leadership development, and executive compensation.

The Board of Directors also seeks nominees who will contribute to the Board's diversity. While the Board of Directors does not maintain a formulaic policy or approach with respect to diversity, it continually seeks a wide range of perspectives and experiences among its members.

The Board also considers nominees recommended by stockholders. Any recommendation must be in writing addressed to our Secretary and must include a detailed description of the business experience and other qualifications of the recommended nominee, as well as the signed consent of the nominee to serve if nominated and elected, so that the candidate may be properly considered. All stockholder recommendations are reviewed in the same manner as other potential candidates for board membership.

Board Information and Committees

The Board met eight times in 2018. Each director serving on the Board during 2018 attended at least 75% of the total number of Board meetings and meetings held by the Board committees on which he or she served during 2018. The Board has determined that each of our non-employee directors currently serving on the Board or who served on the Board during 2018 is independent based upon the criteria provided by Nasdaq rules. Members of the Board serve on one or more of the committees described below, except for directors who are also employees of CASMED.

Pursuant to the terms of the June 2011 Investment Agreement among the Company, Thomas, McNerney & Partners, L.P., and certain affiliates of Thomas, McNerney & Partners, L.P., two of the members of our seven-member Board of Directors tendered their resignations, and the purchasers nominated James E. Thomas and Kathleen A. Tune (the "Purchaser Designees") to serve as members of our Board of Directors as of the closing. Pursuant to the Investment Agreement, the purchasers' right to nominate the Purchaser Designees shall at no time be in excess of the level considered proportionate for purposes of the Nasdaq listing rules or other applicable listing rules. Mr. Thomas and Ms. Tune are currently serving as the Purchaser Designees.

Since June 2011, the Board of Directors has operated without a formal chairman. In April 2012, Mr. Thomas was appointed as our lead director, although all directors have input into the preparation of the meeting agenda and topics of board discussion and oversight. The Board of Directors believes that this is an appropriate structure for the overall governance of the Board.

The Board of Directors has general risk oversight responsibilities. The Board believes that its structure enables it to effectively oversee risk management.

The Board has standing Audit, Compensation, and Nominating and Governance Committees. Further information regarding these committees is provided below.

The Audit Committee, which met five times in 2018, monitors our financial reporting standards and practices and our internal financial controls to ensure compliance with the policies and objectives established by the Board of Directors. The committee directly retains and recommends for stockholder approval an independent accounting firm to conduct the annual audit and discusses with our independent accountants the scope of their examinations, with particular attention to areas where either the committee or the independent accountants believe special emphasis should be directed. The committee reviews the quarterly and annual financial statements and the annual independent accountants' report, invites the accountants' recommendations on internal controls and on other matters, and reviews the evaluation given and corrective action taken by management. It reviews the independence of the accountants and pre-approves audit and permissible non-audit services. It has primary oversight responsibility for our Compliance Program. Members of the committee are Paul Molloy, Kathleen Tune, and Kenneth Weisshaar. Mr. Weisshaar chairs the committee. Each member of the committee is independent as defined in Rule 10A-3 of the Securities and Exchange Commission and the listing standards of Nasdaq. The Board of Directors has determined that each of Paul Molloy, Kathleen Tune, and Kenneth Weisshaar qualifies as an "audit committee financial expert", as that term is defined in Regulation S-K of the Securities and Exchange Commission.

The Compensation Committee, which met four times in 2018, oversees our executive and director compensation programs and policies and annually reviews all components of compensation to ensure that our objectives are appropriately achieved. These functions are not delegated to our officers or to third-party professionals, although the committee may from time to time retain third-party consultants to provide advice regarding compensation issues. No such consultants were retained during 2018. The committee also considers input from our executive officers, although final decisions regarding executive compensation are made by the committee. The committee is also responsible for certain administrative aspects of our compensation plans and stock plans and approves or recommends changes in these plans. It also approves performance targets and grants under our incentive plans and our stock plan for our executive officers. The committee also reviews officers' potential for growth and, with the chief executive officer, will be responsible for succession planning. The members are Gregory Rainey, James Thomas, and Alan Milinazzo. Mr. Thomas is chairman of the committee. All members serving on the Compensation Committee during 2018 were independent, based upon the criteria provided by Nasdaq rules.

The Nominating and Governance Committee, which met once in 2018, reviews, on a periodic basis, the overall effectiveness and/or appropriateness of our corporate governance and recommends improvements when necessary; assists the Board in identifying, screening, and reviewing individuals qualified to serve as directors in accordance with criteria approved by the Board and shall recommend to the board candidates for nomination for election at the annual meeting of stockholders or to fill board vacancies; develops and recommends to the Board and oversees implementation of our policies and procedures for the receipt of stockholder suggestions regarding board composition and recommendations of candidates for nomination by the Board; and assists the Board in disclosing information relating to functions of the committee as may be required in accordance with the Federal securities laws. Members of the committee are Gregory Rainey, James Thomas, and Kenneth Weisshaar. Mr. Rainey is the chairman of the committee. All members serving on the committee during 2018 were independent, based upon the criteria provided by Nasdaq rules.

Each committee is governed by a written charter. Copies of each committee charter are available on our website at www.casmed.com.

Item 11. Executive Compensation

Compensation Discussion and Analysis

Our Compensation Committee, which is comprised of three independent non-employee directors, has formulated a compensation philosophy that is designed to enable us to attract, retain, and reward capable employees who can contribute to the success of the Company, principally through a combination of (1) base salaries, (2) annual incentive opportunities, and (3) longer-term incentive opportunities for senior management. We believe that implementation of a system of compensation that emphasizes performance-based compensation provides a strong alignment to stockholders' interests. Five key principles serve as the guiding framework for compensation decisions for all executive officers of CASMED:

· To attract and retain the most highly qualified management and employee team;
· To pay competitively, compared to similar companies in our industry;
· To encourage superior employee performance by aligning rewards with stockholder interests;
· To motivate senior executives to achieve CASMED's annual and long-term business goals by providing equity-based incentive opportunities; and
· To strive for fairness in administration by emphasizing performance-related contributions as the basis for pay decisions.

To implement these policies, we have designed the framework for a four-part executive compensation program consisting of base salary, annual incentives, long-term incentive opportunities for senior management, and other employment benefits.

Base Salary. We will seek to maintain levels of compensation that are competitive with similar companies in our industry. Base salary represents the fixed component of the executive compensation program. CASMED's philosophy regarding base salaries is to maintain salaries for the aggregate officer group at or near the competitive industry average. Periodic increases in base salary will relate to individual contributions evaluated against established objectives, length of service, and the industry's annual competitive pay practice movement. We believe that base salary for 2018 for our Chief Executive Officer and for the other executive officers was generally at the competitive industry average.

Annual Incentive Program. During February 2018, the Compensation Committee approved the 2018 management annual incentive program which includes various targets, including sales, adjusted cash flow from operations, and personal goals. Total bonus payments of approximately $730,000 (exclusive of tax obligations) would be payable to the management team, including the named executive officers, upon achieving 100% of the targets, payable in either cash or vested common stock. The program provides for reduced payouts at certain achievement levels below 100% as well as increased payouts for performance above target up to a capitated level. The actual payment to management for 2018 approximates $735,000, which is to be paid during 2019.

Certain of our executive officers, including Messrs. Patton, Baird, Gamelin, and Benni, are also eligible to receive supplemental lump-sum cash transaction bonus payments upon closing of a change of control transaction. In order to be eligible for the transaction bonus, each executive generally must remain employed through the proposed merger. The amounts to which each executive officer will be eligible are as follows: Mr. Patton ($325,000); Mr. Baird ($240,000); Mr. Gamelin ($220,000); and Mr. Benni ($75,000).

During February 2019, the Compensation Committee approved the 2019 management annual incentive program, which is based upon achieving certain revenue targets. Total cash bonus payments of approximately $690,000 (exclusive of tax obligations) would be payable to the management team including the named executive officers upon achieving 100% of the target. The program provides for reduced payouts at certain achievement levels below 100% as well as increased payouts for performance above target up to a capitated level.

The Compensation Committee also assesses whether to pay discretionary bonuses to our employees, including senior executives, either in cash or stock, based upon performance. Payment of the performance bonuses is at the sole discretion of the Compensation Committee and is not based on specific metrics, although the Compensation Committee bases its decisions on numerous factors, including overall corporate and personal performance. No additional discretionary cash bonus payments were made to the named executive officers for 2017 or 2018.

Long-Term Incentives. We believe that long-term incentives should provide senior executives with an opportunity to increase their ownership and potentially gain financially from CASMED stock price increases. By this approach, the best interests of stockholders and senior executives will be closely aligned. Therefore, senior executives are eligible to receive restricted stock and stock options (which give them the right to purchase shares of common stock at a specified price in the future). These grants will vest based upon the passage of time, the achievement of performance metrics, or both. We believe that the use of restricted stock and stock options as the basis for long-term incentive compensation meets our defined compensation strategy and business needs by achieving increased value for stockholders and retaining key employees.

Other Benefits. Our philosophy is to provide competitive health and welfare benefits to executives and employees but to maintain a conservative posture relative to executive benefits. We do provide life insurance and supplemental disability insurance to certain of our senior executive officers.

Compensation Disclosure Tables

Summary Compensation Table. The following table (Table I) shows all compensation paid or granted, during or with respect to the 2017 and 2018 fiscal years to (i) our Chief Executive Officer, and (ii) the two other most highly-compensated executive officers, other than the CEO, whose total compensation during 2018 exceeded $100,000 and who were serving as executive officers as of December 31, 2018. (Persons in this group are referred to individually as a "named executive officer" and collectively as the "named executive officers", and unless otherwise noted, the titles listed are the titles held as of the end of the 2018 fiscal year.)

TABLE I

2017-2018 SUMMARY COMPENSATION TABLE

Name and Principal Position	Year	Salary	Stock Awards (a)	Option Awards (a)	Non-Equity Incentive Plan Compensation (b)	All Other Compensation (c)	Total
Thomas M. Patton President and Chief Executive Officer	2018	$ 347,820	$ 221,500	$ —	$ 187,658	$ 1,726	$ 758,704
	2017	$ 341,000	$ 188,800	$ 22,080	$ 36,176	$ 1,726	$ 589,782
Jeffery A. Baird Chief Financial Officer	2018	$ 241,740	$ 62,400	$ —	$ 78,255	$ 3,266	$ 385,661
	2017	$ 237,000	$ 96,350	$ 7,360	$ 32,304	$ 3,509	$ 376,523
John K. Gamelin Vice President - R&D	2018	$ 219,300	$ 62,400	$ —	$ 70,991	$ —	$ 352,691
	2017	$ 215,000	$ 96,350	$ 7,360	$ 29,306	$ —	$ 348,016

(a) Dollar amounts set forth with regard to unrestricted and restricted stock grants and stock option grants are computed in accordance with FASB ASC Topic 718. Share value utilized for purposes of this determination is the applicable fair market value on the date of grant. Fair market values utilized for unrestricted and restricted stock grants represent the closing market price on the date of grant. For a further discussion of the assumptions underlying these amounts, reference is made to the footnotes to CASMED's financial statements set forth in this Form 10-K for the fiscal year ended December 31, 2018.

(b) Amounts in this column represent sums paid to the executives in 2019 and 2018 pursuant to the achievement of incentives for calendar years 2018 and 2017, respectively. See "Compensation Discussion and Analysis – Annual Incentive Program" above.

(c) Amounts shown include the cost of disability insurance for Mr. Patton and term life insurance and disability insurance for Mr. Baird.

Grants of Plan-Based Awards Table. The following table (Table II) shows all plan-based equity and non-equity grants made by CASMED during the 2018 fiscal year to the named executive officers.

TABLE II

2018 GRANTS OF PLAN-BASED AWARDS

		Estimated Future Payouts Under Non-Equity Incentive Plan Awards			All Other Stock Awards: Number of Shares of Stock or Units	All Other Awards: Number of Securities Under-lying Options	Exercise or Base Price of Option Awards	Grant Date Fair Value of Stock and Option Awards
Name	Grant Date	Threshold ($)	Target ($)	Maximum ($)	(2) (#)	(#)	($/sh)	
Thomas M. Patton		$0	$173,910 $325,000(1)	$243,474				
	8/1/18				50,000			$104,500
	12/20/18				75,000			$117,000
Jeffery A. Baird		$0	$72,522 $240,000(1)	$101,531				
	12/20/18				40,000			$62,400
John K. Gamelin		$0	$65,790 $220,000(1)	$92,106				
	12/20/18				40,000			$62,400

(1) Messrs. Patton, Baird, and Gamelin, are eligible to receive supplemental lump-sum cash transaction bonus payments, upon closing of the proposed Merger.

(2) Mr. Patton was granted 50,000 shares of common stock on August 1, 2018, 25,000 shares of which were unrestricted and 25,000 shares which vest one-third per year from date of grant. Each of the restricted stock grants dated December 20, 2018, vest 25% per year on each anniversary of the grant date.

Outstanding Equity Awards at Fiscal Year-End Table. Shown in Table III below is information with respect to outstanding equity-based awards (consisting of unexercised options to purchase CASMED common stock and unvested restricted CASMED common stock) held by the named executive officers at December 31, 2018.

TABLE III

OUTSTANDING EQUITY AWARDS AT 2018 FISCAL YEAR END

	Option Awards				Stock Awards	
Name (a)	Number of Securities Underlying Unexercised Options(#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price ($)	Option Expiration Date	Number of Shares or Units of Stock That Have Not Vested (#)	Market Value of Shares or Units of Stock That Have Not Vested ($) (b)
Thomas M. Patton	350,000	0	$2.10	8/27/2020		
	100,000	0	$1.69	12/8/2021		
	100,000	0	$2.18	12/17/2022		
	100,000	0	$1.87	12/16/2023		
	100,000	0	$1.79	12/18/2024		
	15,000	45,000	$0.67	12/21/2027	392,500	$628,000
Jeffery A. Baird	50,000	0	$3.16	1/7/2021		
	25,000	0	$1.69	12/8/2021		
	40,000	0	$2.18	12/17/2022		
	50,000	0	$1.87	12/16/2023		
	40,000	0	$1.79	12/18/2024		
	5,000	15,000	$0.67	12/21/2027	115,000	$184,000
John K. Gamelin	44,000	0	$3.00	11/19/2020		
	56,000	0	$1.69	12/8/2021		
	60,000	0	$2.18	12/17/2022		
	40,000	0	$1.87	12/16/2023		
	40,000	0	$1.79	12/18/2024		
	5,000	15,000	$0.67	12/21/2027	115,000	$184,000

(a) Except as specified, all unvested options in the table above vest in four equal installments from the grant date (which grant date was ten years prior to the expiration date set forth in the table). For a discussion of the vesting of 150,000 shares of Mr. Patton's restricted stock, see "Executive Officer Compensation – Executive Contracts and Severance and Change of Control Arrangements – Thomas M. Patton" below.

(b) These values are based on $1.60 per share, the market price of a share of CASMED common stock as of December 31, 2018 (the final trading day of 2018).

Executive Contracts and Severance and Change of Control Arrangements

Thomas M. Patton. On August 27, 2010, we entered into an employment agreement with Thomas M. Patton, our President and Chief Executive Officer. Under the terms of the agreement, Mr. Patton is employed on an "at will" basis, will receive an annual base salary of $358,225, and will be eligible for an annual bonus in the form of cash or CASMED common stock, as determined at the sole discretion of the Compensation Committee of the Board. Accordingly, Mr. Patton will be eligible for a performance-based bonus for 2019 equal to 50% of his annual salary if certain targets are achieved. The designation of the performance targets and the attainment of such targets will be determined by the Compensation Committee of the Board of Directors in consultation with Mr. Patton. Mr. Patton will also be entitled to participate in all of our employee benefit programs, as such programs may be in effect from time to time.

As an inducement to cause Mr. Patton to accept employment with the Company, Mr. Patton was granted a ten-year, non-qualified stock option to purchase 350,000 shares of our common stock at an exercise price of $2.10 per share, the closing price of our common stock on Nasdaq upon the effective date of the agreement. Such stock options vested in equal monthly installments over a period of four years from date of grant. As a further inducement to consummate Mr. Patton's employment, Mr. Patton was granted 250,000 shares of restricted common stock of CASMED on the same date. Such restricted shares vested over a period of four years from date of grant. Additionally, upon being hired, Mr. Patton was also granted 150,000 shares of restricted common stock, the vesting of which will occur on the earlier of the following – (i) upon CASMED's stock price meeting or exceeding an average of $4.15 per share for 60 consecutive trading days based upon the daily closing price of the primary market in which our common stock is traded or (ii) a change in control subject to certain conditions.

If we terminate Mr. Patton's employment without Serious Cause (as defined in the Employment Agreement) or Mr. Patton terminates his employment for Good Reason (as defined in the Employment Agreement), we will continue to pay Mr. Patton his then-current base salary for a period of one year from the date of such termination. Mr. Patton will be entitled to participate in our health benefit plans (with standard employee payment not to exceed the payment level prior to termination) for the one-year period. In addition, if Mr. Patton terminates his employment for Good Reason or if we terminate Mr. Patton's employment without Serious Cause, all of Mr. Patton's equity-linked grants (such as stock options and restricted stock) shall immediately accelerate and vest in full.

If we (or a successor company) terminate Mr. Patton's employment without Serious Cause or Mr. Patton terminates his employment for Good Reason, within the period commencing on the date that a Change of Control (as defined in the Employment Agreement) is formally proposed to our Board of Directors and ending on the second anniversary of the date on which such Change of Control occurs, then Mr. Patton will be entitled to receive his then-current base salary for a period of one year from the date of such termination and in addition will be entitled to participate in our health benefit plans (with standard employee payment not to exceed the payment level prior to the change in control) for the period of one year. In addition, all of Mr. Patton's equity-linked grants (such as stock options and restricted stock) shall immediately accelerate and vest in full.

Jeffery A. Baird. On August 10, 2009, we entered into an employment agreement with Jeffery A. Baird pursuant to which Mr. Baird is serving as our Chief Financial Officer. Under the terms of the employment agreement, Mr. Baird is employed on an "at will" basis, will receive an annual base salary of $248,992, and will be eligible for an annual bonus in the form of cash or CASMED common stock, as determined at the sole discretion of the Compensation Committee of the Board. Mr. Baird will also be eligible for a performance-based bonus for 2019 equal to 30% of his annual salary if certain targets are achieved. Mr. Baird will also be entitled to participate in all of our employee benefit programs, as such programs may be in effect from time to time.

If we terminate Mr. Baird's employment without Serious Cause (as defined in the Employment Agreement) or Mr. Baird terminates his employment for Good Reason (as defined in the Employment Agreement), we will continue to pay Mr. Baird his then-current base salary for a period of six months from the date of such termination, and he will be entitled to participate in our health benefit plans (with standard employee payment not to exceed the payment level prior to termination) for the six-month period. In addition, if Mr. Baird terminates his employment for Good Reason or if we terminate Mr. Baird's employment without Serious Cause, all of Mr. Baird's equity-linked grants (such as stock options and restricted stock) shall immediately accelerate and vest in full.

If we (or a successor company) terminate Mr. Baird's employment without Serious Cause or Mr. Baird terminates his employment for Good Reason, within the period commencing on the date that a Change of Control (as defined in the Employment Agreement) is formally proposed to our Board of Directors and ending on the second anniversary of the date on which such Change of Control occurs, then Mr. Baird will be entitled to receive his then-current base salary for a period of one year from the date of such termination and in addition will be entitled to participate in our health benefit plans (with standard employee payment not to exceed the payment level prior to the change in control) for the period of one year. In addition, all of Mr. Baird's equity-linked grants (such as stock options and restricted stock) shall immediately accelerate and vest in full.

John K. Gamelin. On August 5, 2013, we entered into an employment agreement with John K. Gamelin pursuant to which Mr. Gamelin is serving as our Vice President – Research and Development. Under the terms of the employment agreement, Mr. Gamelin is employed on an "at will" basis, will receive an annual base salary of $225,879, and will be eligible for an annual bonus in the form of cash or CASMED common stock, as determined at the sole discretion of the Compensation Committee of the Board. Mr. Gamelin will also be eligible for a performance-based bonus for 2019 equal to 30% of his actual salary payable in the form of cash or CASMED common stock, as determined at the sole discretion of the Compensation Committee of the Board. Mr. Gamelin will also be entitled to participate in all of our employee benefit programs, as such programs may be in effect from time to time.

If we terminate Mr. Gamelin's employment without Serious Cause (as defined in the Employment Agreement) or Mr. Gamelin terminates his employment for Good Reason (as defined in the Employment Agreement), we will continue to pay Mr. Gamelin his then-current base salary for a period of six months from the date of such termination, he will be entitled to participate in our health benefit plans pursuant to COBRA with standard employee payment and employer subsidy level prior to termination, and if the separation of service occurs at a time when more than one-half of the performance measuring for an annual performance bonus has elapsed, Mr. Gamelin will be eligible for a pro-rated amount of the performance bonus he would have otherwise earned had he remained employed for the entire performance period. In addition, if Mr. Gamelin terminates his employment for Good Reason or if we terminate Mr. Gamelin's employment without Serious Cause, all of Mr. Gamelin's equity-linked grants (such as stock options and restricted stock) shall immediately accelerate and vest in full.

If we (or a successor company) terminate Mr. Gamelin's employment without Serious Cause or Mr. Gamelin terminates his employment for Good Reason, within the period commencing on the date that a Change of Control (as defined in the Employment Agreement) is formally proposed to our Board of Directors and ending six months after the date on which such Change of Control occurs, then Mr. Gamelin will be entitled to receive his then-current base salary for a period of six months from the date of such termination paid over a one-year period, he will be entitled to participate in our health benefit plans pursuant to COBRA with standard employee payment and employer subsidy level prior to termination, and if the separation of service occurs at a time when more than one-half of the performance measuring for an annual performance bonus has elapsed, Mr. Gamelin will be eligible for a pro-rated amount of the performance bonus he would have otherwise earned had he remained employed for the entire performance period. In addition, all of Mr. Gamelin's equity-linked grants (such as stock options and restricted stock) shall immediately accelerate and vest in full upon a Change of Control.

Director Compensation

Director Fees. During 2018, we paid our non-employee directors an annual retainer of $30,000, payable in quarterly installments. We also paid an additional annual retainer of $5,000 to the Audit Committee chairman, payable in quarterly installments. During 2018, we incurred total fees of $155,000 to the non-employee directors as a group for their participation as Board and committee members. Fees of $30,000 payable to Mr. Thomas as a member of the Board of Directors were accrued, at his direction, to Thomas, McNerney & Partners II, LLC.

Our non-employee directors are eligible to receive options, restricted stock, and other equity-linked grants under our 2011 and 2018 equity incentive plans. Effective with the 2016 calendar year, each new non-employee Board member shall be granted a ten-year stock option to purchase 30,000 shares of common stock upon initial appointment to the Board, which shall vest in four equal annual installments from the date of the grant. Further, each non-employee member of the Board shall receive annually a stock-based grant which shall vest in two equal annual installments from the date of the grant. On December 13, 2018, each non-employee member of the Board received a grant of 15,000 shares of restricted common stock which vest in two equal annual installments from the date of the grant.

Director Compensation Table. The following table shows all compensation paid or granted, during or with respect to the 2018 fiscal year, to each of the non-employee directors for services rendered to CASMED during 2018.

2018 DIRECTOR COMPENSATION

Name (a)	Fees Earned or Paid in Cash ($)	Stock Awards (b)	Stock Option Awards (b)	All Other Compensation ($)	Total ($)
Alan Milinazzo	$30,000	$25,650	$ —	$ —	$55,650
Paul Molloy	$30,000	$25,650	—	—	$55,650
Gregory Rainey	$30,000	$25,650	—	—	$55,650
James Thomas	$30,000	$25,650	—	—	$55,650
Kathleen Tune	$30,000	$25,650	—	—	$55,650
Kenneth Weisshaar	$35,000	$25,650	—	—	$60,650

(a) As of December 31, 2018, Ms. Tune and Messrs. Rainey, Thomas, and Weisshaar each held non-qualified options to purchase an aggregate of 65,000 shares of our common stock, and Messrs. Milinazzo and Molloy each held non-qualified options to purchase an aggregate of 45,000 shares of our common stock.

(b) On December 13, 2018, non-employee members of the Board of Directors each received a grant of 15,000 shares of our common stock. Each grant was valued at $25,650, based upon the Nasdaq official closing price of $1.71 per share on the date of the grant. All shares granted vest 50% per year on the first and second anniversaries of the grant.

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

The following table sets forth certain information known to CASMED regarding the beneficial ownership of CASMED common stock as of February 15, 2019, except as specified below, by: (i) CASMED's Chief Executive Officer and each of the next two most highly compensated executive officers for the year ended December 31, 2018, (referred to in this proxy statement as the named executive officers); (ii) each director of CASMED; (iii) each person known by CASMED to own beneficially more than five percent (5%) of the outstanding CASMED common stock; and (iv) all current directors and executive officers of the Company as a group. Except as otherwise indicated, (i) all shares are owned directly; and (ii) subject to community property laws where applicable, the persons named in the table have sole voting and investment power with respect to all shares of CASMED common stock shown as beneficially owned by them, other than restricted shares (over which they have sole voting power but no investment power). Unless otherwise noted below, the address for all stockholders is c/o CAS Medical Systems, Inc., 44 East Industrial Road, Branford, Connecticut 06405.

Name and Address of Beneficial Owners	Class of Stock	Amount and Nature of Beneficial Ownership	Percent of Class
Thomas, McNerney & Partners II, L.P. TMP Nominee II, LLC TMP Associates II, L.P. 263 Tresser Boulevard 9th Floor Stamford, CT 06901	Common	12,541,279 (a)	31.3%
	Series A Convertible Preferred	95,500 (a)	100%
	Series A	54,500 (a)	100%

	Exchangeable Preferred		
Acuta Capital Partners LLC 1301 Shoreway Road, Suite 350 Belmont, CA 94002	Common	5,263,508 (b)	18.0%
Norman H. Pessin and affiliates 366 Madison Avenue, 14th Floor New York, NY 10017	Common	2,524,810 (c)	8.6%
Thomas M. Patton	Common	1,845,889 (d)	6.1%
Alan W. Milinazzo	Common	87,500 (e)	*
Paul A. Molloy	Common	87,500 (f)	*
Gregory P. Rainey	Common	135,431 (g)	*
James E. Thomas	Common	12,541,279 (h)	31.3%
Kathleen A. Tune	Common	128,454 (i)	*
Kenneth R. Weisshaar	Common	135,303 (j)	*
Jeffery A. Baird	Common	514,418 (k)	1.7%
John K. Gamelin	Common	431,078 (l)	1.5%
All current executive officers and directors as a group (10)	Common	16,074,469 (m)	38.5%

_____

* Less than one percent of the class

(a) Based upon information set forth in a Form 4 filed with the SEC on February 13, 2015, by Thomas McNerney & Partners II, L.P. ("TMP II LP"); TMP Nominee II, LLC ("TMPN"); TMP Associates II, L.P. ("TMPA"); and Thomas, McNerney & Partners II, LLC ("TMP II LLC"). Also based upon information set forth in a Schedule 13D/A Amendment No. 3 filed with the SEC on February 13, 2019, by TMP II LP, TMPN, TMPA, TMP II LLC, and Mr. James Thomas, and other data available to CASMED. TMP II LP, TMPN, and TMPA hold, respectively, 94,182; 984; and 334 shares of Series A Convertible Preferred Stock (which represent in the aggregate 100% of the outstanding Series A Convertible Preferred Stock) and 53,748; 561; and 191 shares of Series A Exchangeable Preferred Stock (which represent in the aggregate 100% of the outstanding Series A Exchangeable Preferred Stock). The shares in the table above, with respect to common stock, include "common stock equivalent" rights on shares of Series A Convertible Preferred Stock and Series A Exchangeable Preferred Stock. Each share of Series A Convertible Preferred Stock and Series A Exchangeable Preferred Stock has "common stock equivalent" rights as of February 11, 2019, equal to approximately 71.5 shares of common stock, which is determined by dividing the stated value of $100 per share of Series A Convertible Preferred Stock and Series A Exchangeable Preferred Stock plus accretion by an effective conversion price of $2.389 per share. Of the 10,721,871 common stock equivalent rights in the table above (i) 10,573,909 are deemed owned directly by TMP II LP, (ii) 110,436 are owned directly by TMPN, and (iii) 37,526 are directly owned by TMPA. Data reflects accretion of dividends as of February 11, 2019. TMP II LLC, the general partner of TMP II LP and TMPA, has shared voting and dispositive power over the shares held by TMP II LP and TMPA. In addition, TMPN has entered into an agreement with TMP II LLC that directs TMPN to vote and dispose of securities in the same manner as directed by TMP II LLC with respect to the shares held by TMP II LP and TMPA. Mr. Thomas is the manager of TMPN and has voting and dispositive power over such securities, provided that they are obligated to exercise such power in the same manner as TMP II LLC votes and disposes of the securities of CASMED over which TMP II LLC exercises voting and dispositive power. Mr. Thomas is the manager of TMP II LLC. The persons and entities named in this footnote are referred to individually herein as a "Reporting Person" and collectively as the "Reporting Persons." Amounts in the table above also include 63,454 shares of common stock and options to purchase 65,000 shares of common stock held by Mr. Thomas and 20,954 shares of common stock and options to purchase 65,000 shares of common stock held by Ms. Kathleen A. Tune, directors of CASMED, which shares and options are held in their respective names but are being held for the benefit of TMP II LP. Each Reporting Person disclaims beneficial ownership of the above-referenced shares other than to the extent of their pecuniary interest therein.

(b) Based upon information set forth in a Schedule 13G filed with the SEC on February 14, 2019, by Acuta Capital Partners LLC. Acuta Capital Partners LLC holds sole voting and dispositive power over the indicated shares.

(c) Based upon information set forth in a Schedule 13D Amendment No. 3 filed with the SEC on January 4, 2017, by Norman H. Pessin, Sandra F. Pessin, and Brian Pessin. Norman H. Pessin holds sole voting and dispositive power over 1,395,777 of the indicated shares; Sandra F. Pessin holds sole voting and dispositive power over 708,487 of the indicated shares; and Brian Pessin holds sole voting and dispositive power over 420,546 of the indicated shares.

(d) Includes 367,500 shares of restricted common stock and 765,000 shares underlying options exercisable within 60 days held by Mr. Patton.

(e) Includes 22,500 shares of restricted common stock and 45,000 shares underlying options exercisable within 60 days held by Mr. Milinazzo.

(f) Includes 22,500 shares of restricted common stock and 45,000 shares underlying options exercisable within 60 days held by Mr. Molloy.

(g) Includes 22,500 shares of restricted common stock and 65,000 shares underlying options exercisable within 60 days held by Mr. Rainey.

(h) Includes 22,500 shares of restricted common stock and 65,000 shares underlying options exercisable within 60 days held by Mr. Thomas. Also includes, without duplication, shares referenced in footnote (a) above.

(i) Includes 22,500 shares of restricted common stock and 65,000 shares underlying options exercisable within 60 days by Ms. Tune.

(j) Includes 22,500 shares of restricted common stock and 65,000 shares underlying options exercisable within 60 days by Mr. Weisshaar.

(k) Includes 103,750 shares of restricted common stock and 210,000 shares underlying options exercisable within 60 days by Mr. Baird.

(l) Includes 103,750 shares of restricted common stock and 245,000 shares underlying options exercisable within 60 days by Mr. Gamelin.

(m) Includes 748,125 shares of restricted common stock and 1,750,000 shares underlying options exercisable within 60 days.

Securities Authorized for Issuance under Equity Compensation Plans

The following table provides information regarding the Company's equity compensation plans as of December 31, 2018:

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	2,888,250	$ 1.73	2,120,988
Equity compensation plans not approved by security holders	822,782	1.69	—
Total	3,711,032	$ 1.72	2,120,988

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 and 2018 Equity Incentive Plan. The equity compensation plans not approved by security holders consist of warrants to purchase 75,000 shares granted to former directors of the Company as compensation for services rendered which have no expiration date, warrants to purchase 397,782 shares granted to the Company's current and former bank lenders, and 350,000 shares under inducement stock options granted to the Chief Executive Officer commensurate with his 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

Director Compensation

Please see Item 11 – "Executive Compensation – Director Compensation" for a discussion of equity grants and other compensation to our non-employee directors.

Executive Compensation

Please see Item 11 – "Executive Compensation" for additional information on compensation of our named executive officers.

Directors Independence

The Company is required to have a Board of Directors a majority of whom are "independent" as defined by the Nasdaq listing standards and to disclose those Directors that the Board of Directors has determined to be independent.

Based on such definition, the Board of Directors determined that all Directors other than Thomas M. Patton, who is an officer of the Company, are independent. See "Item 10 Directors, Executive Officers and Corporate Governance".

Item 14. Principal Accountant Fees and Services

Audit Fees
CohnReznick LLP performed the audit of our annual consolidated financial statements included in the annual report on Form 10-K, the review of interim consolidated financial statements included in quarterly reports on Form 10-Q and certain other SEC filings. Aggregate fees billed for such services by CohnReznick LLP were $225,000 and $200,000 for the years ended December 31, 2018 and 2017, respectively.

Audit-Related Fees
CohnReznick LLP also provided 401(k) Plan audit services to the Company during 2018 and 2017 for the plan years ended December 31, 2017 and 2016, respectively. Fees billed for each year of those services were $14,300 and $13,900, respectively.
Tax Fees
CohnReznick LLP did not provide tax services to CASMED during the years ended December 31, 2018 and 2017. We utilize an independent third-party accounting firm to perform those services.
All Other Fees
CohnReznick LLP did not provide services in addition to those described above during the years ended December 31, 2018 and 2017.
Audit Committee Pre-Approval Policy
The Audit Committee operates under a written charter. Under this charter, the Audit Committee is responsible for selecting, approving, compensating, and overseeing the independence, qualifications, and performance of the independent accountants. Further, the Audit Committee has adopted a pre-approval policy pursuant to which certain permissible non-audit services may be provided by the independent accountants. Pre-approval is generally provided for up to one year and may be detailed as to the particular service or category of services and may be subject to a specific budget. The Audit Committee may also pre-approve particular services on a case-by-case basis. In assessing requests for services from the independent accountants by management, the Audit Committee considers whether such services are consistent with the auditor's independence, whether the independent accountants are likely to provide the most effective and efficient service based upon their familiarity with the company, and whether the service could enhance our ability to manage or control risk or improve audit quality.
Notwithstanding the pre-approval policy, all of the audit-related, tax, and other services provided by CohnReznick LLP in calendar year 2018 were approved in advance by the Audit Committee.

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, 2018 and 2017
Consolidated Statements of Operations for the Years Ended December 31, 2018 and 2017
Consolidated Statements of Changes in Stockholders' Equity (Deficiency) for the Years Ended December 31, 2018 and 2017
Consolidated Statements of Cash Flows for the Years Ended December 31, 2018 and 2017
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 "Exhibit Index" with an asterisk after the exhibit number.

Item 16. Form 10-K Summary

Not provided.

EXHIBIT INDEX

2.1	Asset Purchase Agreement dated July 25, 2017, by and between the Company and Suntech Medical Inc. (20)
2.2	Asset Purchase Agreement dated March 28, 2016, by and between the Company and Trinity Medical Devices Inc. (18)
2.3	Agreement and Plan of Merger dated as of February 11, 2019 by and among CAS Medical Systems, Inc., Edwards Lifesciences Holding, Inc., and Crown Merger Sub. Inc. (7)
3.1	Certificate of Incorporation of Registrant (1)
3.2	Certificate of Amendment to Certificate of Incorporation of the Registrant filed June 23, 2015 (17)
3.3	Amended and Restated Bylaws of Registrant (6)
3.4	Amendment to Amended and Restated Bylaws (7)
10.1*	CAS Medical Systems, Inc. Employee Stock Purchase Plan (3)
10.2*	CAS Medical Systems, Inc. 2003 Equity Incentive Plan (4)
10.3*	Form of Option Agreement (2)
10.4	Purchase and Sale Agreement between CAS Medical Systems, Inc. and Davis Marcus Partners, Inc. dated June 18, 2007 (5)
10.5	Lease Agreement between CAS Medical Systems, Inc. and DMP New Branford, LLC dated September 6, 2007 (5)
10.6	Second Amendment to Lease Agreement between CAS Medical Systems, Inc. and Albany Road Branford II LLC, dated January 23, 2017 (22)
10.7*	Amendment to the CAS Medical Systems, Inc. 2003 Equity Incentive Plan (8)
10.8*	Employment Agreement with Jeffery A. Baird dated August 10, 2009 (9)
10.9*	Employment Agreement between CAS Medical Systems, Inc. and Thomas M. Patton dated August 27, 2010 (10)
10.10*	Inducement Non-Qualified Stock Option Agreement with Thomas M. Patton dated August 27, 2010 (10)
10.11*	Inducement Restricted Stock Agreement between CAS Medical Systems, Inc. and Thomas M. Patton dated August 27, 2010 (10)
10.12*	Inducement Restricted Stock Agreement between CAS Medical Systems, Inc. and Thomas M. Patton dated August 27, 2010 (10)
10.13	Investment Agreement, dated June 8, 2011, among CAS Medical Systems, Inc. and several Purchasers named therein (12)
10.14	Registration Rights Agreement, dated June 9, 2011, among CAS Medical Systems, Inc. and the several Purchasers named therein (12)
10.15	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. (12)
10.16*	CAS Medical Systems, Inc. 2011 Equity Incentive Plan, as amended (13)
10.17*	Employment Agreement with John K. Gamelin dated August 5, 2013 (15)
10.18*	Employment Agreement with Paul Benni dated May 1, 2008 (15)
10.19	Warrant to Purchase Stock, dated June 27, 2014, issued by the Company to GE Capital Equity Investments, Inc. (16)
10.20	Loan and Security Agreement dated June 30, 2016 by and between the Company, Solar Capital Ltd., and Western Alliance Bank (19)
10.21	Warrant to Purchase Stock, dated June 30, 2016, issued by the Company to Solar Capital Ltd. (19)
10.22	Warrant to Purchase Stock, dated June 30, 2016, issued by the Company to Western Alliance Bank (19)
10.23	First Amendment to Loan and Security Agreement, dated November 3, 2017, by and between the Company, Solar Capital Ltd., and Western Alliance Bank (21)
10.24*	CAS Medical Systems, Inc. 2018 Equity Incentive Plan (23)
10.25	Loan and Security Agreement dated May 8, 2018, by and between the Company and East West Bank (11)
10.26	Form of Option Termination Agreement (14)

10.27	Restricted Stock Termination Agreement between CAS Medical Systems, Inc. and Thomas M. Patton (14)
10.28	Warrant to Purchase Stock, dated May 8, 2018, issued to East West Bank (11)
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 June 10, 2004, (333-116348)
(4) Incorporated by reference to the Company's Form S-8 filed June 10, 2004, (333-116349)
(5) Incorporated by reference to the Company's Form 8-K filed September 10, 2007
(6) Incorporated by reference to the Company's Form 8-K filed November 30, 2007
(7) Incorporated by reference to the Company's Form 8-K filed February 12, 2019
(8) Incorporated by reference to the Company's Form 8-K filed December 31, 2008
(9) Incorporated by reference to the Company's Form 10-Q filed August 12, 2009
(10) Incorporated by reference to the Company's Form 8-K filed August 27, 2010
(11) Incorporated by reference to the Company's Form 8-K filed May 8, 2018
(12) Incorporated by reference to the Company's Form 8-K filed June 13, 2011
(13) Incorporated by reference to the Company's Proxy Statement filed April 26, 2016
(14) Incorporated by reference to the Company's Form 8-K filed March 12, 2019
(15) Incorporated by reference to the Company's Form 10-Q filed August 7, 2013
(16) Incorporated by reference to the Company's Form 8-K filed June 30, 2014
(17) Incorporated by reference to the Company's Form 8-K filed June 25, 2015
(18) Incorporated by reference to the Company's Form 10-Q filed May 11, 2016
(19) Incorporated by reference to the Company's Form 8-K filed July 5, 2016.
(20) Incorporated by reference to the Company's Form 8-K filed July 26, 2017
(21) Incorporated by reference to the Company's Form 10-Q filed November 9, 2017
(22) Incorporated by reference to the Company's Form 10-K filed March 15, 2017
(23) Incorporated by reference to the Company's Registration Statement on Form S-8 filed August 7, 2018

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 25, 2019
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 25, 2019
Alan W. Milinazzo, Director

/s/ Paul A. Molloy Date: March 25, 2019
Paul A. Molloy, Director

/s/ Gregory P. Rainey Date: March 25, 2019
Gregory P. Rainey, Director

/s/ James E. Thomas Date: March 25, 2019
James E. Thomas, Director

/s/ Kathleen A. Tune Date: March 25, 2019
Kathleen A. Tune, Director

/s/ Kenneth R. Weisshaar Date: March 25, 2019
Kenneth R. Weisshaar, Director

/s/ Thomas M. Patton Date: March 25, 2019
Thomas M. Patton, President, Chief Executive Officer and Director

/s/ Jeffery A. Baird Date: March 25, 2019
Jeffery A. Baird, Chief Financial Officer
(Principal Financial and Accounting Officer)