Zacks Small-Cap Research

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CAS Medical Systems Inc. (CASM-NASDAQ)

CASM: FORE-SIGHT Gobbling Up Market Share. Initiating Coverage

Based on EV/S and P/S comps other publicly traded companies in the tissue oximeter, patient monitoring and cardiac surgery industries including BABY, MASI, BRSYF, HPHTY and MDT, CASM should trade near $4/share.

Current Price (05/23/16)	$1.85
Valuation	**$4.00**

OUTLOOK

CASM recently divested two non-core and lower-margin product lines to shift full-focus on their flagship FORE-SIGHT tissue oximetry business. Recently launched next-gen ELITE product has been the main impetus to recent sales growth, helping to push the topline to 24 consecutive quarters of double-digit growth. Plethora of clinical data supporting utility of cerebral oximetry is expanding total market. Clinical studies showing that ELITE outperforms market-share leading cerebral oximeters has been a major catalyst to CASM's growth and has resulted in about one-half of new business coming from customers switching from competing devices. The growing monitor installed base is providing a multiplier effect to sensor (i.e consumables) sales. This, combined with expanding gross margin and growing leverage in OpEx should result in rapid improvement in profitability and cash flow. Based on comp valuation, CASM shares should trade near $4.

SUMMARY DATA

52-Week High	**$2.09**
52-Week Low	**$1.01**
One-Year Return (%)	**40.15**
Beta	**-0.19**
Average Daily Volume (sh)	**56,207**
Shares Outstanding (mil)	**27**
Market Capitalization ($mil)	**$51**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**36**
Insider Ownership (%)	**33**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-0.1**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2016 Estimate	**N/A**
P/E using 2017 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**N/A**
Industry	**Med Products**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015					19.5 A
2016	5.5 A	5.5 E	5.7 E	6.1 E	22.8 E
2017					27.6 E
2018					31.2 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2015					-$0.40 A
2016	-$0.03 A	-$0.08 E	-$0.07 E	-$0.06 E	-$0.24 E
2017					-$0.14 E
2018					-$0.03 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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SNAPSHOT

CAS Medical Systems, Inc (CASM) is an established medical device company engaged in the manufacture and sale of non-invasive monitoring products. Over 30 years ago they brought to market the first blood pressure cuff designed specifically for neonates. Their product offerings evolved over the years into a collection of unrelated low margin monitoring products. However, in the past few years the company has largely transformed their menu from low-margin commodity products to higher-margin medical disposables through investment and growth in their tissue oximetry product line and the divestiture of their legacy products.

Lead products are the FORE-SIGHT line of tissue oximeters (and disposable sensors) which includes ELITE, a second-generation model that launched in September 2013 and which has been the major impetus to the 37% and 24% revenue growth of their tissue oximetry segment in 2014 and 2015, respectively. FORE-SIGHT ELITE neonatal and pediatric sensors were launched in September 2015 which are expected to further steepen the revenue curve as this segment comprises ~25% of the total market.

The company recently began to divest most of its lower-margin legacy portfolio ("Traditional Monitoring"), shedding their blood pressure cuffs in 2010, vital signs monitoring products in late-2015 and non-FORE-SIGHT neonatal disposable products in March 2016. OEM non-invasive blood pressure measurement products are the only remaining legacy devices. Divestitures in Traditional Monitoring has allowed CASM to shift more of their focus to exploiting the higher growth and bigger margin opportunities afforded by the FORE-SIGHT product line and the tissue oximetry segment in general.

Cerebral oximeters are used to monitor the level of oxygen in the blood. Low levels of cerebral oxygen can result in brain injury, leave a person with permanent cognitive impairment and even result in death. While cerebral oximetry is not currently considered standard of care during surgery, there has been a consistent trend towards greater adoption among anesthesiologists. This is being driven by more evidence supporting the cost and patient-outcome benefits of accurate brain oxygen monitoring as well as studies showing that cerebral desaturation events occur in up to 60% of certain common surgeries but are often undetected by current standard monitoring techniques.

Not all cerebral oximeters provide the same amount of information or level of accuracy. Over 200 manuscripts, clinical studies and publications have referenced FORE-SIGHT since 2005. This includes a study by the University of California San Francisco which showed that FORE-SIGHT outperformed competing devices and a study by Duke University which indicates that ELITE (the second-gen device) is even more accurate.

The FORE-SIGHT system consists of a monitor and higher margin disposable sensors. Management's goal is to transition from a medical capital equipment company to one which primarily provides disposables to an installed base. The growing monitor installed base is providing a multiplier effect to sensor sales, resulting in rapidly improving profitability and increasing the proportion of total tissue oximetry revenue contributed by consumables.

As of the end of 2015 cumulative monitor shipments stood at 1,708, up almost 29% from the end of 2014. In 2015 revenue from continuing operations (i.e. excluding the divested vital signs monitoring and neonatal disposable products) grew 15% year-over-year. This includes 25% growth in disposable sensor sales which helped push gross margin up by almost 525 basis points, improved operating loss of more than 10% and resulted in significantly lower cash burn. Gross profit is expected to also benefit from the lower manufacturing and service costs of ELITE as compared to the first generation FORE-SIGHT monitor.

CASM pegs the current worldwide market for cerebral oximetry at approximately $100 million but expects this to rapidly expand due to further penetration in surgical procedures where it is already seeing moderate and growing use as well as initial adoption in others. If it becomes standard of care in surgical applications, management believes the global cerebral oximeter market could be worth as much as $500 million or more. The ICU is a possible follow-on opportunity, a market which could be worth more than double that of the surgical space.

Much of CASM's unit placement and revenue growth appears to be coming at the expense of competitors' market share as hospitals are increasingly switching to FORE-SIGHT. Management estimates that

approximately one-half of new accounts are coming from competitor-switching and the other half from hospitals' initial adoption of tissue oximetry. Nine of the top twenty adult cardiac hospitals in the U.S. are now using CASM's oximeters and utilization is increasing - in 2015 sensor sales to existing domestic customers increased by 10%.

The company is looking to further leverage FORE-SIGHT's performance-leading message and recently increased headcount in their direct sales force from 14 to 22 in order to expand on their current ~20% share of the U.S. market. And in late 2015 they brought on an experienced medical device sales executive to lead their domestic sales efforts. Some of the growth in FORE-SIGHT utilization is also extending to international markets where the products are sold via third-party distributors. International total tissue oximetry and sensor sales increased 17% and 55%, respectively, in the fourth quarter 2015 driven by additional gains in larger territories including China, Japan, Germany and the U.K.

The U.S. market is where CASM is focusing most of their efforts. Management is guiding for FORE-SIGHT revenue growth of 20% in 2016, driven mostly from domestic sales and facilitated by sales force productivity gains, continued market share gains and growing contribution from the recent introductions into the neonatal and pediatric markets. Meanwhile, international sales growth expectations are less robust due to unfavorable currency exchange rates, pricing pressures and year-over-year comparisons which will compete against distributor stocking orders from early 2015.

BACKGROUND

Tissue Oxygenation Monitoring

Oxygenation refers to the saturation of the tissues, blood or organs with oxygen. Sufficient saturation is required to generate energy in order to maintain the body's functions. The brain, which is constantly consuming energy even when at rest, is the organ that consumes the most oxygen – approximately 20% of the oxygen that enters the bloodstream.

Cerebral hypoxia, which refers to inadequate supply of oxygen to the brain, can result from a variety of conditions including certain diseases (such as heart disease, atherosclerosis or anemia), trauma, heart attack or environmental factors (such as high altitudes) and others. Cerebral desaturation events can also occur during surgery – and at rates that are much higher than previously thought.

Brain cells are highly sensitive to lack of oxygen. Patients undergoing surgery are particularly susceptible to experiencing oxygen deprivation as illness and anesthesia can exacerbate this risk. The proper management of brain oxygenation is one of the principal endpoints of all anesthesia procedures, but the brain remains one of the least monitored organs during clinical anesthesiology[1]. Clinical studies have shown that cerebral desaturation events (CDE) occurring during surgery;

- can result in severe complications including cognitive dysfunction, stroke, coma and even death
- are associated with prolonged hospital stays and related significant additional cost
- happen as often as 60% or more and occur more frequently than previously believed

Traditional Monitoring Does Not Directly Monitor Cerebral Oxygen…

Traditional monitoring uses measurements non-specific to cerebral oxygen with the goal of balancing oxygen supply and demand within the body globally, but not necessarily specifically the brain. The traditional methods used to monitor oxygen status include pulse oximetry, heart rate and blood pressure, capnometry and cardiac output assessment.



SOURCE emsjunkie.com

- **Pulse oximetry**: is similar to cerebral oximetry in that it uses emitted light to estimate oxygen saturation. However, an important difference is that pulse oximeters only measure arterial oxygen saturation, which provides a measure of how well the hemoglobin is oxygenated by the lungs. It does not indicate how much of that oxygenated blood is made available to meet the metabolic demand of particular tissue beds like the brain. This differs from cerebral oximeters which measure the combination of both venous and arterial blood oxygenation. As ~75% of blood volume is venous, and as venous blood oxygenation reflects the end result of oxygen extraction by the tissue, cerebral oximeters allow for a comprehensive understanding of the balance between oxygen demand and oxygen supply of the tissue.


SOURCE wisegeek.com

- **Capnometry**: often used during surgery, a capnometry device is hooked up to a breathing circuit or ventilator to directly monitor the concentration of inhaled and exhaled carbon dioxide. This can provide a measure of the total metabolic function of the body and an indirect gauge of the amount of carbon dioxide expected to be in the blood. While considered more informative than pulse oximetry relative to global cardiorespiratory function and ventilation, similar to pulse oximetry it does not directly measure cerebral oxygen saturation.
- **Cardiac output**: measures the amount of blood pumped by the heart over a given time (e.g. liters per minute). Several methods can be employed to measure cardiac output including in-dwelling catheters and trans-esophageal Doppler Cardiac output, which is useful to measure heart function and overall hemodynamic status but reveals little about end-organ blood perfusion. Other surrogates for cerebral blood flow include Transcranial Doppler (TCD) sonography, in which sound waves are used to estimate blood flow velocity in arteries in the skull. But since it measures velocity, not actual blood flow, which can change during surgery due to factors not associated with flow (such as blood vessel constriction and dilation), its utility in cerebral oxygen monitoring is limited. A study in neonatal aortic arch surgery showed NIRS reliably detected antegrade cerebral flow rates in all (n=10) children at all measurement points while TCD failed to obtain a signal in at least one measurement point in 80% (8/10) of patients[2]. Other drawbacks of TCD include the need for an ultrasound technician and it does not always provide for real-time decision-making. Other types of cardiac output measures are more global and do not specifically measure cerebral blood flow.

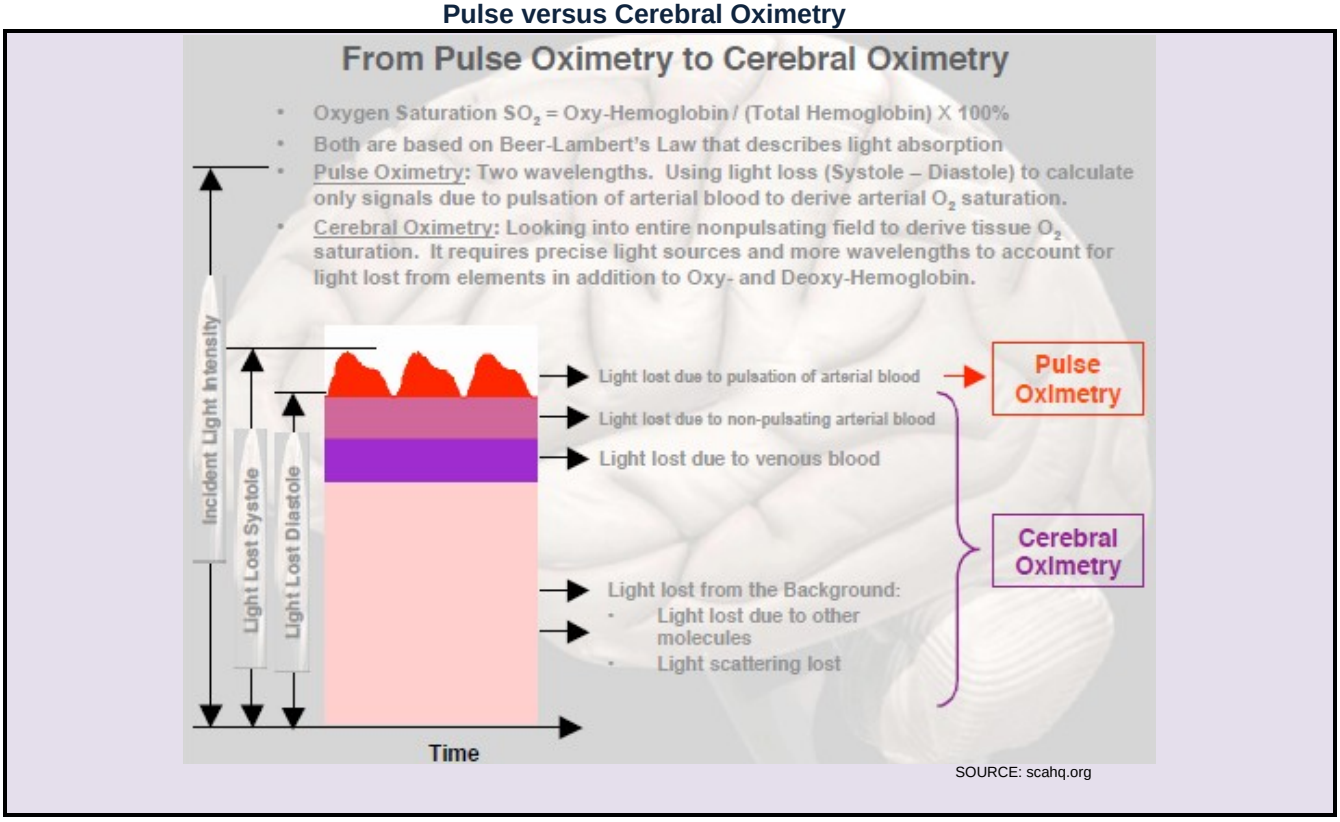
- **Blood pressure**: appropriate systemic blood pressure is a necessary requirement to force blood through the vascular system. Therefore, a drop in blood pressure may suggest less blood flow, and therefore, less oxygen reaching the brain. However, clinical studies have shown that blood pressure is not a reliable indicator of cerebral desaturation events[3,4] and that historically acceptable levels of blood pressure maintained by clinicians may be inadequate to perfuse the brain.

These methods, along with heart rate, provide indirect information about global oxygen delivery as well as how the respiratory system is functioning. Clinicians can then infer that if these surrogate markers are "acceptable" or if oxygen delivery is satisfactory at a periphery of the body and the respiratory system is functioning correctly, that oxygen delivery in the entire body, including the brain, is satisfactory. But, as clinical studies attest, these indirect methods are not sufficient or reliable to monitor the adequacy of oxygen[5] delivery to the brain. This is part of the reason that there is growing demand for cerebral oximetry.

FORE-SIGHT identifies CDE while traditional monitoring does not…

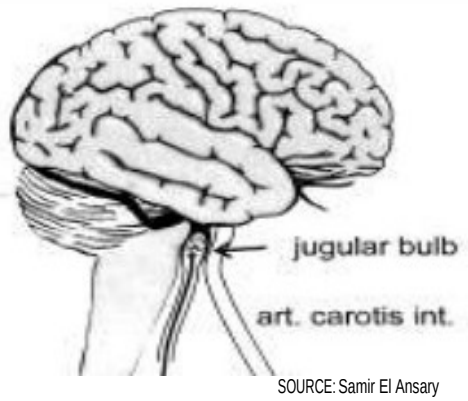
A case report highlights the limitations of traditional monitoring. The beach chair position, where the patient is sat up at an angle during surgery, is preferred by most surgeons for shoulder surgery but several studies have found that the procedure frequently results in CDEs. A case report of a patient undergoing shoulder surgery in the beach chair position showed that FORE-SIGHT detected cerebral desaturation while standard monitoring (including blood pressure, heart rate and pulse oximetry) indicated cerebral oxygen remained at normal (i.e. safe) levels. The author of the report noted that, "This case illustrates that cerebral desaturation can occur during surgical manipulation in the beach chair position without any evident change in other monitored parameters."[6] Broader studies of beach chair shoulder procedures have reported CDE's in up to 80% of patients.[7]

Pulse versus Cerebral Oximetry



Jugular venous bulb oximetry is another method of estimating cerebral oxygenation. It has an advantage over those just discussed in that it is a more direct measure of cerebral oxygenation. But also has a disadvantage in that, unlike the others, it is invasive. Jugular venous bulb oximetry involves insertion of a catheter into the jugular vein with the tip in the jugular venous bulb at the base of the brain from which samples are obtained to measure oxygen saturation of the blood exiting the brain. But while jugular bulb is considered the gold-standard for measuring cerebral oxygen saturation, clinical studies have also cited drawbacks such as that catheter misplacements can result in skewed readings[8]. And in some cases, high jugular bulb saturation values have been correlated to low regional oxygen saturation – suggesting it may not

always recognize brain oxygen desaturations[8]. And while jugular venous bulb oximetry provides a more direct measure of regional cerebral oxygen than the other indirect methods that we described above, it is not continuous and does not allow for measurements at specific areas of the brain (i.e. focal) like NIRS does based on where the sensors are placed. A study which used jugular venous bulb oximetry to monitor cerebral oxygenation in patients with traumatic brain injury suggested that a more sensitive measure should be used[9]. Given its drawbacks and the fact that it is a technically difficult procedure, jugular venous bulb oximetry has fallen out of favor with many clinicians.



SOURCE: Samir El Ansary

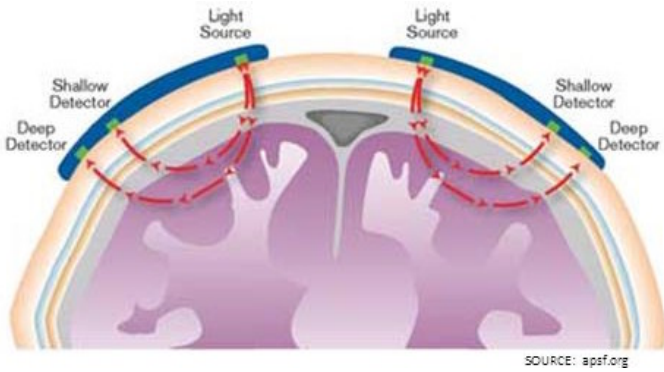
Cerebral Oximetry <u>Does</u> Directly Monitor Cerebral Oxygen…

Near-infrared spectroscopy uses light to identify the concentration of oxygenated and de-oxygenated hemoglobin in the blood. It is based on the Beer-Lambert law which states that the amount of light absorbed by a substance dissolved in a solvent is directly proportional to the concentration of the substance and the path length of the light through the solution.[10] Different substances absorb different amounts of light. Near-infrared light is emitted into a substance and by measuring the amount of light that returns, the specific structure or volume of the substance can be determined.

Near-infrared spectroscopy uses light in the 660 – 900nm spectrum as this easily penetrates skin, tissue and bone but is largely absorbed by hemoglobin. Certain wavelengths within that spectrum are absorbed at different levels by oxygenated hemoglobin and de-oxygenated hemoglobin and therefore, oxygen saturation can be determined. In addition, changes in oxygen levels will change the amount of light that is absorbed. However, many additional substances within that tissue absorb those same wavelengths, so the ability to provide a highly accurate oxygen saturation assessment requires multiple wavelengths of light within that spectrum. The greater number of wavelengths utilized can increase accuracy significantly as it allows the monitor to distinguish between the substances of interest (i.e. oxygenated and de-oxygenated hemoglobin) and substances that can confound that analysis such as melanin and bilirubin. Algorithms within the NIRS device use this absorption information to continuously determine how much oxygen is in the blood in the tissue under the sensor. Oxygen saturation is calculated as oxygenated hemoglobin (HbO_2) divided by [HbO_2+deoxygenated hemoglobin (Hb)].

Cerebral oximetry estimates regional oxygen saturation of the cerebral cortex (i.e. under the forehead), which is the area of the brain that is most sensitive to oxygen deprivation and responsible for many higher cognitive functions. While NIRS technology and cerebral oximetry have been studied and commercially available for several decades, only recently have they been used more extensively in patient monitoring, which is being driven by additional clinical data supporting its use in this application as well as the use of more accurate devices.

Cerebral oximeters consist of adhesive pads that are affixed to the skull and connected to a monitor via cables. The pads include near-infrared light sources (emitters) and light sensors (detectors). As penetration of the light into the tissue is proportional to the distance between the light source and sensors, the distance between the light emitter and the detectors dictates the maximum depth of signal penetration. Also, the use of two separate detectors spaced a distance from the emitter permits the monitor to differentiate between oxygenation of the scalp versus that of the brain tissue. The monitor, using an algorithm that calculates the amount of light that is received by the two detectors in comparison to the amount that the light source emitted, displays the level (or change in level) of cerebral oxygenation.



SOURCE: apsf.org

Studies related to CDE's and patient outcomes…
Results of numerous studies have shown high rates of CDEs during surgery and an association between oxygen desaturation and adverse outcomes. Studies also show that near-infrared spectroscopy (NIRS) is effective in identifying CDEs, providing actionable information for anesthesiologists to immediately restore oxygen saturation (through a variety of techniques which we detail later). Our sampling below, which is categorized by topic (some cited studies have crossover in our categories), is a small portion of the available evidence offering what we believe is ample support for the proposition that NIRS provides accurate, actionable and superior tissue oxygenation monitoring.

- Adverse patient outcomes;
    - **Yao FS, et al**.[11]: showed that cerebral oxygen desaturation occurring during cardiac surgery is associated with neuropsychological dysfunction as measured by the mini-mental state examination (MMSE) and antisaccade eye movement test (ASEM)
    - **Slater, et al**.[12]**:** showed that intraoperative cerebral oxygen desaturation is significantly associated with an increased risk of cognitive decline and prolonged hospital stay after coronary artery bypass grafting
    - **Fischer GD, et al**.[13]: 30 subjects undergoing aortic arch surgery with oxygen saturation measured by CASM's FORE-SIGHT. Showed statistically significant association between accumulated duration of decreased cerebral oxygen saturation and severe adverse outcomes which included death, stroke with persistent neurological deficits, new heart problems, respiratory failure, sever infection, delirium, new kidney failure, GI complications and severe fluid retention. Additionally, oxygen desaturation was correlated to longer stay in the ICU and hospital and additional related cost of $8,300
    - **Murkin JM, et al**.[14]: landmark study showing significantly higher rates of death and major organ morbidity among patients with cerebral desaturation. 200 coronary bypass patients randomized to either cerebral oxygen saturation monitoring and treatment intervention (n=100) or blinded monitoring (n=100). Significantly more patients in control group (i.e. sham monitoring) experienced prolonged oxygen desaturation and in addition to having higher rates of death and major organ morbidity, these patients also had longer stay in the ICU and post-surgery hospitalization. Study concluded that cerebral oxygen monitoring in coronary artery bypass patients avoids profound cerebral desaturation and is associated with significantly fewer incidences of major organ dysfunction
    - **de Tournay-Jetté E, et al**.[15]: 61 elderly (mean age 70+) patients monitored for cerebral oxygen saturation during coronary bypass grafting (CABG) surgery and evaluated for postoperative neurocognitive dysfunction (POCD). Follow up occurred 4 – 7 days and 1 month after surgery. 81% developed early POCD and 38% late POCD. Patients which had cerebral oxygen saturation fall below 50% experienced more POCD 4 – 7 days after surgery and a decrease of more than 30% from baseline was associated with POCE 1 month following surgery
    - **Kazan R, et al**.[16]: Assessed postoperative complications in 50 patients undergoing thoracic surgery with single-lung ventilation. 82% of patients had regional cerebral oxygen saturation decrease of > 15% and 10% of patients had decrease of 45% - 55%. Lower cerebral oxygen saturation values were associated with non-respiratory organ failure and higher rates of pos-operative complications according to the Clavien score
    - **Greenberg SB, et al**.[17]: 53 patients undergoing cardiac surgery monitored for cerebral oximetry. Was found that 53% (28/53) of patients experienced early post-operative CDEs and 64% of these lasted for more than one hour. 18% (5/28) that experienced early post-operative CDEs died while none of the patients without early post-operative CDEs died

- High rates of CDEs;
    - **Edmonds HL Jr**.[18]**:** found that there were imbalances in cerebral perfusion and oxygenation in 59% of CABG surgeries
    - **Austin EH, et al**.[19]: showed that 70% (176/250) of pediatric patients undergoing cardiac surgery experienced deficiencies in cerebral perfusion or oxygenation as detected by NIRS and other methods. 74% (130/176) of these patients showed neurophysiologic changes and required intervention to correct deficiencies in cerebral perfusion or oxygenation
    - **Casati A, et al**.[20]: 122 elderly patients undergoing major abdominal surgery were randomized to either monitoring of cerebral oxygen saturation (rSO2) which were maintained at a rSO2 level of

≥ 75% (n=56) or blinded monitor and routine anesthesia management (n=66). Results showed 20% of treatment (i.e. monitored) and 23% of control patients experienced oxygen desaturation

- **Murphy GS, et al**.[21]: compared rates of cerebral oxygen desaturation of patients undergoing shoulder surgery (n=124) using the beach chair position (BCP, n=61) versus the lateral decubitus position (LDP, n=63). Incidence of CDE's were 80% in the BCP group and 0% in the LDP group and cerebral oxygen saturation values were lower in the BCP group throughout the surgery
- **Greenberg SB, et al**.[17]: 53 patients undergoing cardiac surgery monitored for cerebral oximetry. Was found that 53% of patients experienced early post-operative CDEs and 64% of these lasted for more than one hour. Patients with post-operative CDEs were more likely to have intraoperative CDEs

- Benefits of monitoring:
  - **Austin EH, et al**.[19]**:** showed that intervention to correct deficiencies in cerebral perfusion or oxygenation as detected by NIRS and other methods during pediatric cardiac surgery, decreases the incidence of post-operative neurologic complications and reduces the length (and cost) of hospital stays
  - **Goldman S, et al**.[22]: compared incidence of stroke among two sets of cardiac surgery patients; those which had cerebral oxygen monitored and optimized during surgery (n=1,034) and those that did not (n=1,245). Both groups followed for 18 months post-surgery. Results showed the oxygen monitored/optimized group had significantly less strokes, fewer patients in this group required prolonged ventilation and length of hospital stay was shorter as compared to the unmonitored group
  - **Casati A, et al**.[20]: 122 elderly patients undergoing major abdominal surgery were randomized to either monitoring of cerebral oxygen saturation (rSO2) which were maintained at a rSO2 level of ≥ 75% (n=56) or blinded monitor and routine anesthesia management (n=66). Results showed average rSO2 levels in treatment group were higher than those of control. And of the patients experiencing desaturation events (20% of treatment, 23% of control), there was a correlation between oxygen level and postoperative decrease in neuropsychological dysfunction. Patients in control group which experienced intraoperative desaturation also had longer hospital stay compare to those in the treatment group. Authors concluded that using rSO2 monitoring to manage anesthesia in elderly patients undergoing major abdominal surgery reduces the potential exposure of the brain to hypoxia; this might be associated with decreased effects on cognitive function and shorter PACU and hospital stay

Studies related to utility of NIRS

- **Putnam B, et al**.[23]: compared regional tissue oxygenation saturation (STO2) as measured by NIRS to traditional monitoring (including arterial pressure, cardiac output, oxygen delivery, arterial blood gases and lactate) in 40 patients undergoing cardiopulmonary bypass. Showed that with initiation of surgery STO2 value declined sooner than lactate levels increased (i.e. NIRS showed faster response) and minimum STO2 value preceded the maximum lactate level by an average of ~94 minutes. Authors concluded that STO2 (NIRS) is a reliable monitor which correlates well with oxygen delivery and identifies perfusion deficits earlier than lactate or base deficit
- **Taillefer MC, Denault AY**[24]: review of NIRS in adult heart surgery published in 2005 in Canadian Journal of Anesthesia. Included 48 papers and 5,931 cardiac surgery patients. Found NIRS monitoring appears to detect brain desaturation episodes encountered during surgery. Authors noted several study limitations, however, including methodological limitations and a low level of evidence.
- **Daubeney PE et al**.[8]: compared NIRS to jugular bulb oximetry in measuring cerebral oxygenation in 40 children undergoing cardiac surgery. Concluded that near-infrared spectroscopy may be a useful tool for assessing intravascular cerebral oxygenation during pediatric cardiac operations.
- **Orihashi K, et al**.[25]: Fifty-nine patients undergoing aortic surgery with selective cerebral perfusion monitored with NIRS. Concluded that a sustained drop in regional oxygen saturation during aortic surgery is closely related to the occurrence of neurological events following surgery.
- **Plachky J, et al**.[26]: Sixteen patients undergoing orthotopic liver transplantation monitored with NIRS. Found decrease in regional cerebral oxygen saturation was correlated significantly with post-operative increases in markers indicative of cerebral disturbances due to hypoxia/ischemia. Concluded that monitoring with NIRS may be useful during orthotopic liver transplantation.

- **Hofer, et al**.[2]: Ten neonates undergoing aortic arch surgery. NIRS was able to detect antegrade cerebral flow rates in all (n=10) children at all measurement points while Doppler failed to obtain a signal in at least one measurement point in 80% (8/10) of patient. Authors concluded that near infrared spectroscopy reliably detects flow alterations during ACP with profound hypothermia.
- **Olsson C, Thelin S**.[27]: Assessed cerebral tissue oxygen saturation using NIRS of 46 patients during selective antegrade cerebral perfusion. Concluded that NIRS allows detection of clinically important cerebral desaturation. It can help predict perioperative neurologic sequelae. Its performance as a diagnostic instrument is satisfying and supports its use as a noninvasive trend monitor of cerebral saturation

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Cerebral Oximeters, not all are created equal…

There are two general types of cerebral oximeters; those that are;

- **Trend-based:** focus on the change in oxygenation from a pre-established baseline. Trend-based oximeters rely on the percentage change in cerebral oxygen from a measurement taken prior to initiation of surgery to define intervention thresholds for clinicians. These monitors are susceptible to providing flawed feedback, however, as they rely on the assumption that the baseline oxygen measurement is not already compromised by factors such as illness (e.g. existing cardiovascular disease or heart failure), generally weak health, anesthesia, medications and therapy (such as supplemental oxygen) and other variables. So if baseline is already compromised, clinicians must assess whether to intervene (or not) even if a standard decrement in the reading has not occurred.
- **Absolute oximeters**: such as FORE-SIGHT, focus on the absolute level of oxygen and how that compares to clinically meaningful reference ranges. Measurement of the actual oxygen level, as opposed to the change from baseline, provides more actionable and accurate information to clinicians which can be used to intervene if oxygen saturation falls below a pre-determined trigger level. As such, direct oxygen measurement via absolute oximeter readings, as opposed to trend-based measurements, is the protocol which could provide clinicians more confidence in identifying CDEs and when intervention is necessary.

FORE-SIGHT Absolute Oximeter

FORE-SIGHT provides absolute oxygen saturation measurements. It consists of a monitor and two sensors, which are placed on the left and right side of the forehead. It can also be used to measure non-cerebral tissue oxygenation such as that of the calf during cannulated surgeries, or on the flank or gut for children. 14 U.S. patents, 15 non-U.S. patents and multiple patents pending cover the FORE-SIGHT technology.

The original FORE-SIGHT device received FDA 510(k) clearance in late 2005. The second-generation model, FORE-SIGHT ELITE received FDA clearance in April 2013 and launched in September of that same year. It is indicated for use to monitor the brain as well skeletal muscle with adults, children and neonates. ELITE provides greater accuracy than the first generation model as it emits five wavelengths of light instead of just four, providing for greater level of signal acquisition (i.e. minimizes what would otherwise be confounding variables) and allows for monitoring of four channels (instead of just two) of patient data. Additional channels allow for the monitoring of both cerebral and somatic (i.e. body) tissue oxygenation. In addition, ELITE has a larger viewing screen touch-screen controls and has been designed as to have lower manufacturing and servicing costs.

FORE-SIGHT ELITE



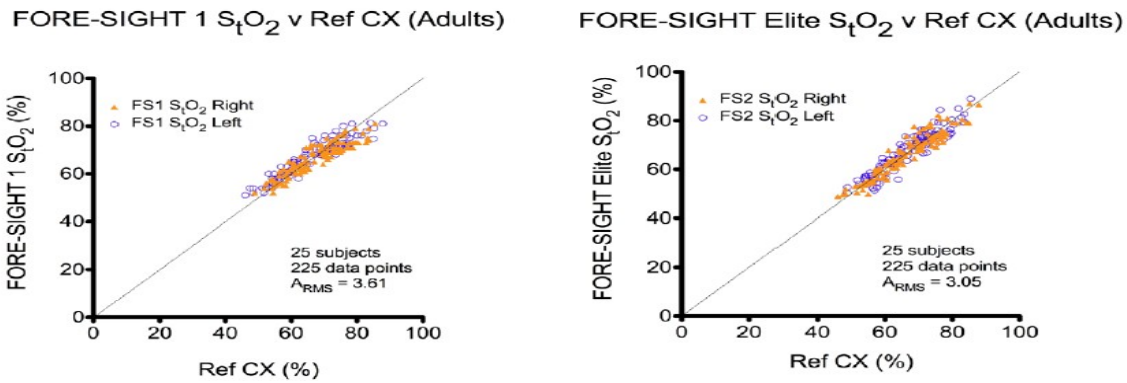
SOURCE: CAS Medical

ELITE outperforms first-generation model…

In a head-to-head study conducted by Duke University ELITE demonstrated greater accuracy than the legacy model, data from which was presented at the Annual Meeting of the Society for Cardiac Anesthesiologists in 2013. The study compared cerebral oxygen saturation as measured by ELITE (F2) and legacy (F1). A F2 sensor was placed on one side of the forehead and a F1 sensor on the other side of 25 healthy subjects which were intentionally desaturated in a controlled manner. Arterial oxygen concentrations as measured by pulse oximetry were varied between 70% and 100% in 5% increments and blood samples were taken at each step (via jugular bulb and arterial catheters) and analyzed with a blood gas analyzer. These blood results reflecting the biological condition were compared to readings of the two oximeters – precision and bias were measured.

Results showed that F2 (i.e. ELITE) had less bias and greater precision than F1 (i.e. the legacy model). Investigators concluded that ELITE demonstrated a high level of accuracy for measuring cerebral tissue oxygen saturation with greater accuracy than the FORE-SIGHT first generation model.

ELITE (F2) More Accurate Than Legacy (F1)



ELITE has been the major impetus to the 37% and 24% revenue growth of CASM's tissue oximetry segment in 2014 and 2015, respectively. FORE-SIGHT ELITE neonatal and pediatric sensors were launched in September 2015 which are expected to further steepen the revenue curve. CASM divested their vital signs monitoring products in late-2015 and their non-FORE-SIGHT neonatal products in March 2016 as they continue to shift more of their focus to the FORE-SIGHT product line and the tissue oximetry segment in general.

Competition

Other cerebral oximeters on the market include INVOS (Medtronic plc), Equanox/SenSmart (Nonin Medical), CerOx (Ornim Medical) and NIRO (Hamamatsu Photonics). FORE-SIGHT ELITE is the only oximeter with five wavelengths, has a greater depth of signal penetration and has a unique proprietary and patented algorithm, all of which CASM believes provides for greater accuracy. There have been no formal large randomized, controlled head-to-head studies between the different devices. In addition, there is no set industry or clinical standard for what is considered 'normal' cerebral oxygen saturation, which instead is inferred from the plethora of clinical data supporting the use of cerebral oximeters. This leaves the market and adoption-curve for these devices wide open. We provide a brief background on the different manufacturers and their devices as well as a general comparison to FORE-SIGHT.

Somanetics introduced the first adult cerebral oximeter, in 1996, and the first pediatric cerebral oximeter, in 2000. Somanetics was purchased by Covidien plc in 2010 (for $291M, net of $37M in acquired cash) which was subsequently acquired by Medtronic plc, in early 2015. According to Millennium Research Group, their **INVOS** device is the most widely used cerebral oximeter in the world.[28] INVOS 5100 C, the current model, uses just two wavelengths of light. Medtronic notes that INVOS is "backed by an unmatched level of quality clinical data". INVOS is FDA-cleared for adult, pediatric and neonatal use. While we have not been able to find current usage or installed base figures, a 2011 product brochure[29] notes that they had 6k INVOS units placed worldwide and it was being used in 250k procedures annually. This compares to FORE-SIGHT's installed base of 1,708 units as of December 31, 2015.

Minnesota-based Nonin (a play on 'noninvasive') Medical claims to have invented the first finger pulse oximeter. The company offers a catalog of monitoring devices including pulse and cerebral oximeters, capnographs and others. Their cerebral oximeters, which use up to four wavelengths, includes their **Equanox 7600 model**, a stand-alone cerebral oximeter, as well as **SenSmart X-100**, a combination pulse and cerebral oximeter. Nonin's monitors are FDA-cleared for neonatal, pediatric and adult use. Nonin is privately held with no publicly available sales or unit placement/installed base information.

Ornim Medical is an Israeli company which sells tissue and cerebral blood flow monitors in the U.S. Their lead product is a bedside cerebral monitor called c-FLOW, which is intended to be used to continuously monitor microcirculatory blood flow in the body. They also have **CerOx**, with three wavelengths, which measures both blood flow and oxygen saturation. CerOx is FDA-cleared for use in monitoring newborns through adults, although the product is no longer promoted by the company. Ornim is privately held with no publicly available sales or unit placement information.

Japanese company Hamamatsu Photonics is the world's leader of optoelectronics components with a major emphasis on medical devices. Their systems division develops and manufactures systems that utilize optic sensors. Their **NIRO-200NX** tissue oximeter, which measures three wavelengths, received FDA clearance in July 2015 for monitoring of blood oxygen of the brain and other tissue under the probes. It had been available in Europe and Japan for more than four years prior to FDA clearance.

FORE-SIGHT Versus the Competition

There are no large head-to-head, randomized clinical trials comparing the different cerebral oximeters that we are aware of. However, smaller studies comparing FORE-SIGHT to the market leader, INVOS, as well as devices from Nonin and Hamamatsu, have suggested superior accuracy of CASM's oximeters. And, noteworthy is the fact the first generation model of FORE-SIGHT was used in these studies. Had ELITE been used instead, which showed even better accuracy than the original model, results of these competitor studies would likely have been even more favorable to FORE-SIGHT.

FORE-SIGHT vs. Three Competing Devices…

CASM sponsored a clinical study comparing FORE-SIGHT (first-generation model) to the current models of INVOS, Nonin and Hamamatsu. An abstract of the results titled, *Direct Performance Comparison of Cerebral Oximeter Devices*, was first presented at the 2011 Annual Meeting of the American Society of Anesthesiologists and later published in the peer-reviewed journal, Anesthesia & Analgesia. The study compared oxygen saturation values as measured by four cerebral oximeters (FORE-SIGHT first-generation, INVOS 5100C, Equanox 7600 with both Advance and Classic sensors, and NIRO-200NX) during controlled oxygen desaturation to that of simultaneous blood gas readings from blood taken via jugular bulb and arterial catheters. Sensors from the different manufacturers were randomly placed on alternating sides of each of the 23 healthy subject's foreheads. Subjects were administered oxygen/carbon dioxide mixture to adjust arterial oxygen concentrations from 98% down to ~68% in equal increments. Oxygen values from blood samples were compared to cerebral oximetry values of each device.

Results showed that FORE-SIGHT measured cerebral oxygen with the greatest precision (3.90%) and accuracy (A_{rms} 4.26%), compared with (lower is better on both measures) precision and accuracy of INVOS of 9.72% / 9.69%, NIRO-200NX of 9.64% / 9.68%, Equanox (Classic sensor) of 8.12% / 8.47% and Equanox (Advance sensor) of 6.27% / 6.86%. The values among all four of the monitors was also generally consistent with several earlier studies.

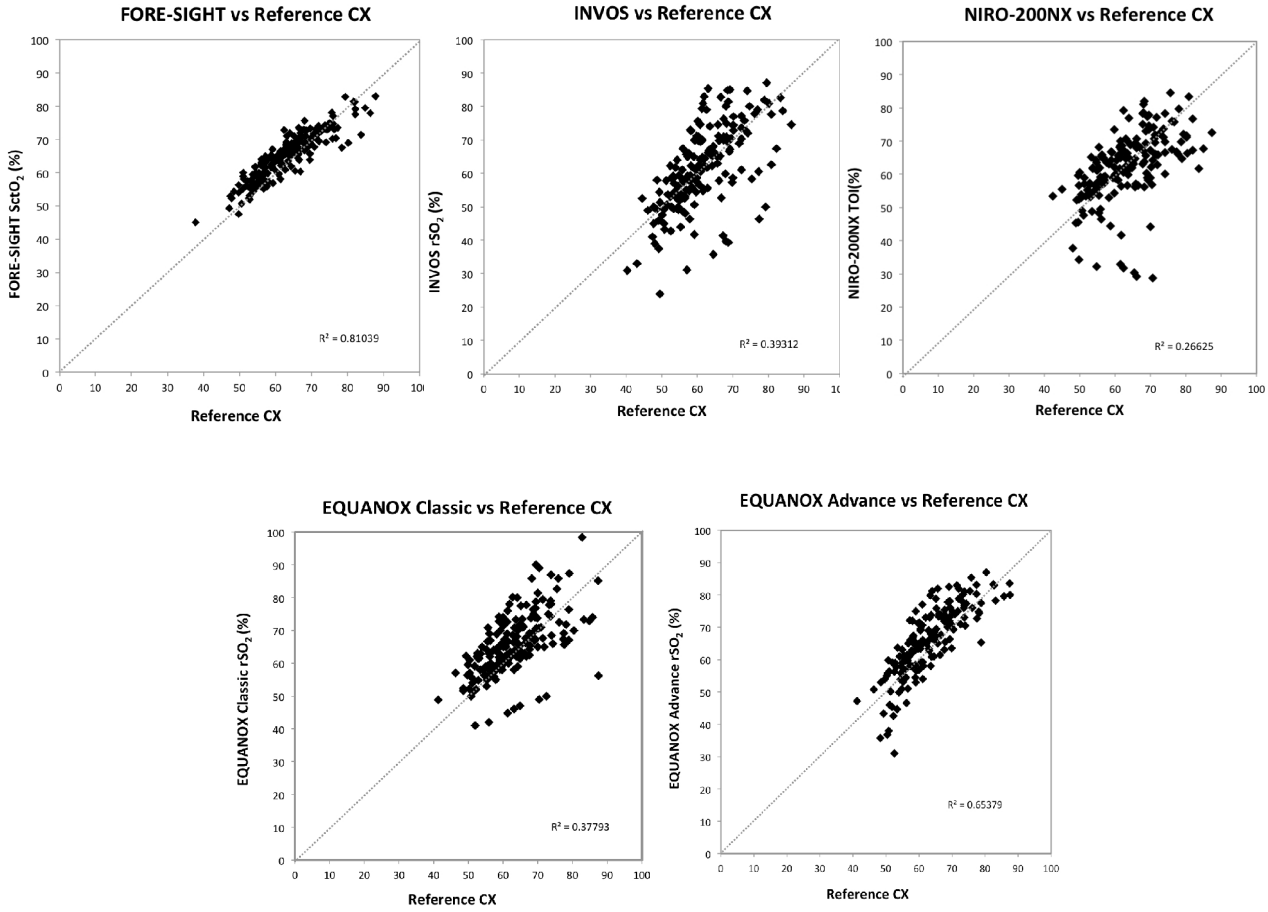
Greater Precision and Accuracy of FORE-SIGHT[30]

	FORE-SIGHT	INVOS	NIRO-200NX	EQUANOX Classic	EQUANOX Advance
Prec (±1SD)	3.90	9.72	9.64	8.12	6.27
Bias	-1.73	-0.05	1.23	-2.48	-2.84
A_{rms}	4.26	9.69	9.68	8.47	6.86

Table 1: Precision, Bias, and A_{rms} of different manufacturer's device. Bias is presented as [Reference CX - Measured Value].

SOURCE: CAS Medical

Tighter Scatterplot of FORE-SIGHT Highlights Greater Accuracy

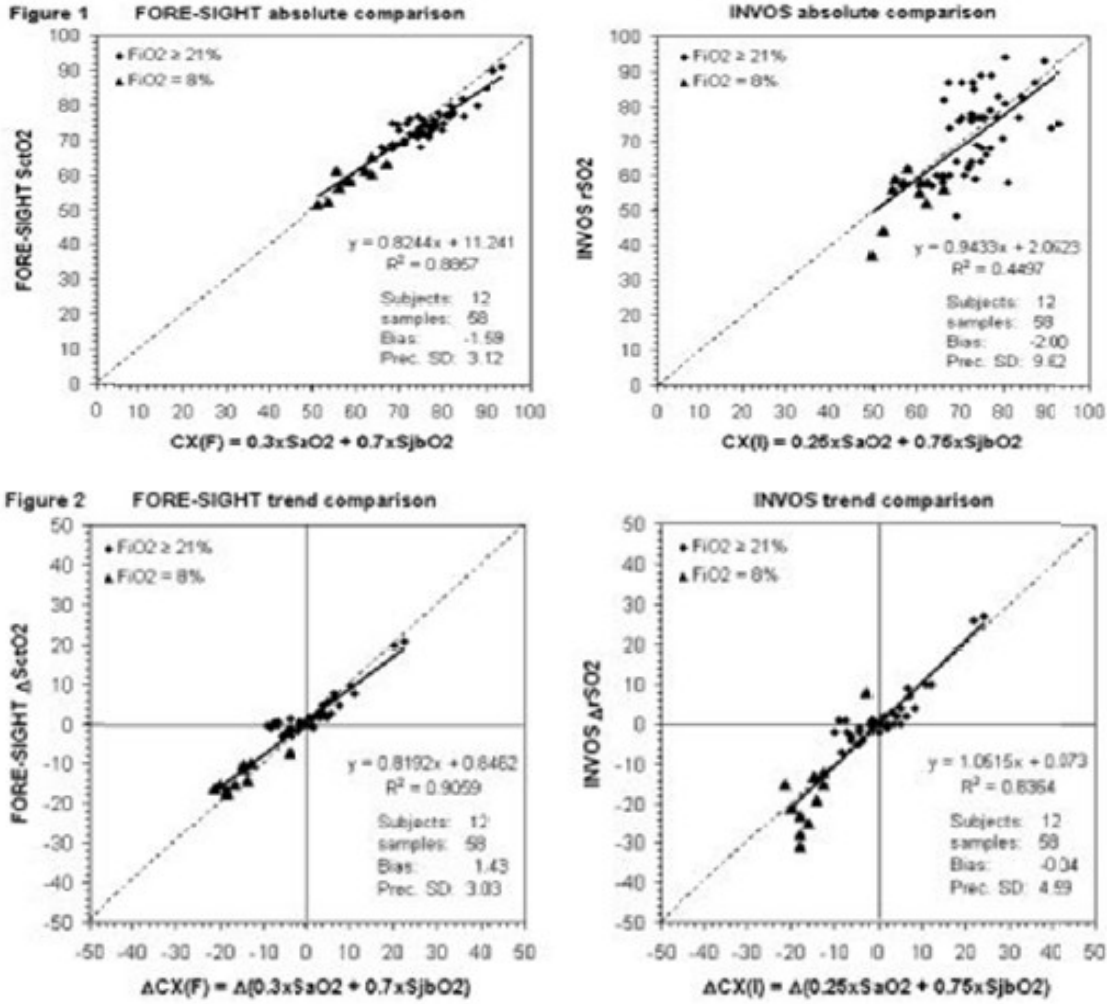


FORE-SIGHT vs. INVOS…

Below we detail small head-to-head studies comparing FORE-SIGHT to INVOS 5100C which also suggests superior accuracy of CASM's device.

- **MacLeod David B, et al.**[31]: Conducted by Duke University and presented at 2009 Annual Meeting of the American Society of Anesthesiologists. Comparison of FORE-SIGHT (1st gen) and INVOS 5100C to co-oximetry jugular bulb and arterial oxygen saturation (i.e. reference) in 12 healthy subjects. FORE-SIGHT and INVOS sensors were placed on the right and left forehead of each subject. Sequential gas delivery delivered step changes of inspired oxygen at five minute intervals from room air to 21% to 8% to 21% and then 50%. A total of 58 samples were taken. Oxygen saturation was kept at >70% as measured at the finger. Results showed baseline room air reference values for FORE-SIGHT and INVOS were in the ranges of 69.7% - 80% and 67.6% - 78.7%, respectively. This compared to measured ranges of 68% - 76% for FORE-SIGHT and 48% - 89% for INVOS. The tighter range of FORE-SIGHT as compared to reference demonstrated much greater accuracy as compared to INVOS in measuring both absolute and trend changes in cerebral oxygen saturation. Standard deviation of FORE-SIGHT was much lower than that of INVOS (3.12% vs. 9.16%), implying FORE-SIGHT is 3x more accurate than INVOS. In addition, for two of the twelve subjects INVOS measured a change from baseline that exceeded the change in reference value by two standard deviations during a sudden change in oxygen mixture, inaccurately indicating cerebral oxygen saturation was falling faster than it was.

Tighter (more accurate) Regression Plots of FORE-SGHT in Measuring Absolute and Trend Changes

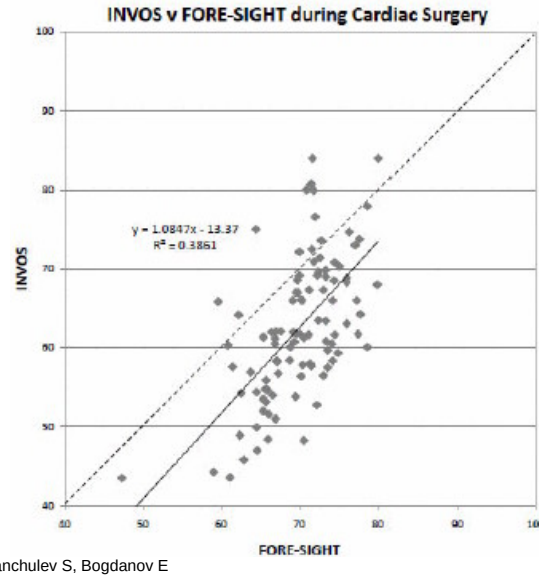


- **Ianchulev S, Bogdanov E[32].:** Conducted by anesthesiologists from Tufts Medical Center and Weill Cornell Medical Center and presented at the Society of Cardiovascular Anesthesiologists Annual Update on Cardiopulmonary Bypass in 2012. Comparison of FORE-SIGHT (1st gen) and INVOS 5100 during cardiac surgery in 11 patients (7 CABG, 4 open chamber surgery). One sensor from each device was placed on the left and right side of the forehead. Oxygen saturation values were recorded with each device and intervention was initiated when values fell below 55% or decreased by more than 20% from baseline. These pre-set intervention trigger points are the established standard treatment protocol for the investigators' institution. Results showed correlation, albeit weak (R^2 = 0.386), between the measurements of the two devices but significant (p<0.00001) differences in absolute values with INVOS showing lower values. INVOS showed values below the 55% trigger point more often than FORE-SIGHT including an average of 47 more minutes on the left side of the forehead and 110 more minutes on the right side which, per the study investigators, "consistently prompt[ed] treatment often without expected results." They further noted that, "Given the treatment protocol used we can assume that treating of false positive values can lead to possible injury, neurological deficit and an increase in morbidity and mortality."

Higher False Positive Rates for INVOS?

Patient	Time under threshold 55%, min			
	$SctO_2$ L	$SctO_2$ R	rSO_2 L	rSO_2 R
1	0.0	0.0	0.0	2.2
2	0.0	15.9	32.7	172.0
3	0.0	0.0	0.0	0.9
4	0.0	0.0	48.2	284.4
5	9.6	23.0	14.7	75.9
6	0.0	0.0	24.1	6.2
7	0.0	0.0	1.0	46.4
8	0.0	0.0	306.4	115.0
9	0.0	0.0	0.3	213.9
10	0.0	0.0	66.2	105.9
11	0.0	0.0	27.1	220.5
average	0.9	3.5	47.3	113.0
maximum	9.6	23.0	306.4	284.4

FORE-SIGHT / INVOS Weak Correlation



SOURCE: Ianchulev S, Bogdanov E

Investment Considerations

Traditional Monitoring

The company has now divested most of their legacy portfolio ("Traditional Monitoring"), which now only includes OEM non-invasive blood pressure measurement products. CASM divested their 740 brand vital signs monitoring products in late-2015 and their non-FORE-SIGHT neonatal disposable products in March 2016 as they continue to shift more of their focus to the FORE-SIGHT product line and the tissue oximetry segment in general. While we expect the traditional monitoring segment to continue to generate some revenue, the proportional contribution will likely continue to slide as CASM leverages the more significant growth opportunities surrounding FORE-SIGHT.

Excluding the 740 product line and the non-FORE-SIGHT neonatal disposable products which have been reclassified as discontinued operations, sales of traditional monitoring products were approximately $4.6M in 2014, accounting for about 27% of total sales. Revenue in this segment fell 11% in 2015 to $4.1M, contributing only about 21% of total revenue. On the Q1 2016 earnings call (May 2016) management guided that they expect sales in this segment to remain roughly flat in 2016 but for FORE-SIGHT sales to grow by more than 20%. If that happens, traditional monitoring's contribution will fall to less than 18% or less.

FORE-SIGHT

FORE-SIGHT, and particularly FORE-SIGHT ELITE in the U.S. market, is what represents the most significant growth opportunity for the company. Total FORE-SIGHT sales increased 24% to $15.4M in 2015, with disposable sensor revenue increasing 25% (+$2.6M) including 22% growth in the U.S. The first quarter of 2016 marked the 24th consecutive quarter of double-digit growth in U.S. sensors sales. We think there are several reasons why this streak will continue – some of which are related to the overall cerebral oximetry market and others which are specific to CASM.

- **Increasing adoption of cerebral oximetry**
  CASM estimates that worldwide annual sales of tissue oximetry products (monitors and consumables) currently sits at about $100M but expects this to grow to around $500M or more. This is expected to be driven by increasing adoption of cerebral oximetry in both the customer channel (i.e. – more hospitals using it) and the procedural channel (i.e. – use in additional types of surgeries and conditions), growth of both of which is being driven by the large and growing list of clinical evidence supporting its benefits. As we detailed earlier, there is a plethora of clinical data showing; a.) cerebral oxygen desaturation events are commonplace during certain surgeries and are associated with adverse patient outcomes as well as increased healthcare costs and b.) NIRS can rapidly and effectively identify CDEs can empower clinicians

to improve patient outcomes and reduce what might otherwise be extended hospital stays and related cost.

Important to understand is that while cerebral oximetry has been around for decades, adoption had been low, perhaps due to a lack of accuracy in historic monitors and lack of data supporting its utility[33]. This has recently started to change. Most or all of the tissue oximeter manufacturers continue to sponsor or otherwise support additional clinical studies, case reports and white papers aimed at further broadening the supporting evidence of the clinical utility and effectiveness of cerebral oximetry. We think this will drive further adoption of cerebral oximetry in general, promote increased use in surgery where it has already experienced a meaningful level of use such as in CABG and draw greater interest in others such as complex thoracic surgical procedures or shoulder surgery using the 'beach chair' position where adoption remains more nascent.

- **FORE-SIGHT's competitive performance**
  While industry data supporting the benefits of cerebral oximetry such as the ability to better identify CDEs and resultant improved patient outcomes and lower healthcare costs should have the effect of benefitting all manufacturers, head-to-head clinical evidence indicating superior accuracy of FORE-SIGHT over INVOS, the unquestionable market leader (by installed base), appears to be resulting in customers switching to CASM's device at the expense of competitors'. Management estimates ~one-half of new accounts are coming from competitor-switching and the other half from hospitals' initial adoption of tissue oximetry.

- **ELITE's benefits**
  Compared to the first-generation model, FORE-SIGHT ELITE provides greater accuracy as it emits five wavelengths of light instead of just four, providing for greater ability to sort out confounding variables (i.e. minimizes "noise" even further) and allows for monitoring of four channels (instead of just two) of patient data. Additional channels allow for the monitoring of both cerebral and somatic (i.e. body) tissue oxygenation. In addition, ELITE has a larger viewing screen touch-screen controls and has been designed as to have lower manufacturing and servicing costs. Customers are clearly finding value in the enhancements of ELITE as first-generation users have rapidly upgraded to the new model. These benefits are also showing up in the market share wins against competitors. CASM expects to add other functionality which could potentially include continuous hemoglobin measurement. And in addition to facilitating revenue growth, the lower manufacturing and servicing costs should show up in wider gross margins.

- **Bigger installed base + increasing utilization = sensor sales multiplier effect**
  FORE-SIGHT net cumulative worldwide shipments as of 2015 year-end were 1,708 units, up 29% (+26% in the U.S.) from 1,329 units at the end of 2014 (note that conversions from 1st-gen to ELITE are not considered new monitor placements) which was 42% greater than the 935 units on the market as of the close of 2013. Management has guided for another ~400 units (net) to be sold in 2016, which would push the total installed base up to about 2,100. Nine of the top twenty cardiac hospitals are now using FORE-SIGHT. Expect the customer base within the cardiac segment, but also in other areas of specialization on proxy label expansion by anesthesiologists, to continue to grow.

  Utilization per account is also increasing. In 2015 'same-store' accounts (i.e. – those in existence for at least one year) increased their sensor purchases by an average of 10% as compared to 2014. At least part of this increased usage relates to hospitals incorporating FORE-SIGHT into more and different types of applications and procedures – which is essentially analogous to expansion of the indications that it is appropriate for (i.e. label expansion). This is particularly telling, as it indicates that anesthesiologists may be using FORE-SIGHT in procedures where it is less commonplace – which relates to the expectation (as we discussed above) that adoption of cerebral oximetry will broaden within the procedural channel.

  More customers plus increased utilization per customer is a leverage effect which will result in steeping of the sensors sales curve. We are modeling sensors and monitoring sales growth of 8% and 24% in 2016 and even more leverage in 2017 when we look for sensors sales to increase 31%. This leverage effect also benefits profitability given the wider gross margins on the sensors (i.e. –'razor blade') as compared to that of the monitors (i.e. – 'razor').

- **Pediatric / neonatal applications**
  FORE-SIGHT ELITE neonatal and pediatric sensors were launched in September 2015 and are expected to further steepen the revenue curve. This is a big segment, comprising ~25% of total U.S. tissue oximetry. While adult cerebral oximetry uses two sensors (on each side of the forehead) and is mostly

limited to surgical procedures, pediatric/neonatal tissue oximetry may use sensors on the body as well as the head (i.e. more sensors used per application) and is commonly used in the ICU, as well as during surgery. As such, this represents a sizeable opportunity. Management noted on the Q4 2015 earnings call that their pediatric/neonatal offering is already being well-received and, similar to the adult version, they are seeing first-generation FORE-SIGHT users converting to ELITE neonatal/pediatric and also scoring new customer wins.

- **Sales force expansion**
  The company is looking to further leverage FORE-SIGHT's performance-leading message and recently increased headcount in their (U.S.) direct sales force from 14 to 22 and expects to incrementally add to this. As the new reps climb the productivity learning curve revenue-per-rep should increase. CASM is already seeing improvement in productivity from the newly-hired sales people.

Disposables business model
Management's goal is to transition into mostly a disposables company – that is, one which generates the vast majority of revenue from FORE-SIGHT sensors. This affords several benefits;

- the heavy-lifting in terms of sales and marketing with a razor/razor-blade business model is establishing a meaningful installed base (selling the 'razor' – i.e. FORE-SIGHT monitor)
- as consumables ('razor blade' - i.e. FORE-SIGHT sensors) feed an already established monitor installed base, re-orders require relatively minimal resources to sell and follow-on orders become predictable
- not only do the consumables require less resources and effort to sell, they also carry most of the margin

So as CASM leverages its business model discussed above, not only should sensors sales grow significantly faster than monitors, blended gross margin should also continue to expand up towards the sensors' margin. Likewise, there should be meaningful improvement in operating expenses as a percentage of sales – due to a combination of more revenue to dilute the fixed-cost portion of SG&A and less-resource and cost intensive sales proposition of sensors as compared to that of the monitors.

This transition to a disposables company is well underway as disposables are growing to account for a larger portion of both total oximetry sales as well as total overall product sales. On a continuing operations basis, FORE-SIGHT sensors accounted for 84% and 61% of tissue oximetry and total overall products sales (pro forma for exclusion of vital signs and non-FORE-SIGHT sensors businesses), respectively, in 2014. In 2015, these grew to 85% and 67% and we are modeling 86% and 71% for 2016.

This transition has and should continue to benefit margins. Gross margin in 2014 was 44.5% which grew to 49.2% in 2015. We are modeling gross margin of 53.1% in 2016, which could actually end up being conservative given that GM was 52.8% in Q1 2016. Gross margin should benefit from manufacturing efficiencies as well.

Balance sheet
Cash balance at Q1 2016 quarter-end stood at $8.4M. CASM also has access to a revolver through GE Capital Corp (subsequently assigned to Solar Capital) with a borrowing limit based on CASM's A/R and not to exceed $2.5M. Current availability is ~$2.2M. The revolver remains untapped. Maturity is June 27, 2018.

Cash used in operating activities was $3.9M ($4.7M ex-changes in working capital) in 2015, improved from $6.2M ($4.8M ex-changes in working capital) in 2014. We expect incremental improvement in operating loss in 2016 as compared to 2015 on revenue growth and expansion of gross margin. However, management expects an increased use of cash in 1H 2016 compared to 1H 2015 due to additional R&D initiatives and the expansion of the U.S. sales team. The HFS term loan (discussed below), which had been interest only, commenced principal repayment in January 2016 which will be another use of cash (assuming this is not refinanced or rolled-over into another interest-only loan). However, management noted on the Q1 2016 call that they hope to refinance this loan into another interest-only facility and are currently in negotiations with several lenders towards that end.

Based on our financial model, we believe cash on-hand plus availability under the revolver (~$10.6M total) may be sufficient to fund operations and repayment of term loan principal through the end of 2017. This is based on our assumed operating cash burn of approximately $4.5M in 2016, which drops to around $2.0M in 2017. We further model the company to be at or near break-even cash flow in 2H 2018. CASM will need to either refinance or repay the revolver at or prior to its June 2018 maturity.

In addition to the revolver, in June 2014 CASM borrowed $7.5M from GECC under a term loan. Balance was subsequently paid down to $6.6M (as of March 31, 2016) with some of the proceeds from the sale of the vital signs monitoring and neonatal product lines.

The loan bears annual interest of 9.29%. Principal payments were deferred until January 1, 2016 and are now being repaid in 30 monthly installments of ~$225k and the remaining balance paid on the June 27, 2018 maturity date. So, barring a refinancing or rolling this into another interest-only loan, CASM will need to pay cash principal of this term loan of approximately $2M through the remaining nine months of 2016, $2.7M in 2017 and the remainder (~$1.9M) in June 2018. Any borrowings under the revolver will also be due in June 2018.

150k shares (@ $100/share) of Series A convertible/exchangeable preferred stock is also outstanding. Dividends accrete at 7% annually, compounded quarterly. Terms of the Solar Capital loans do not allow for cash dividends and the option for the holders of the Series A preferred to receive cash dividends has expired. Preferred is convertible into common at $2.39/share. CASM can force conversion of all preferred (has to be all) if common stock price is 250% of $2.39 conversion price (or common = $5.97) for at least 20 of 30 days prior to conversion and average trading volume is over 50k. As of 3/31/2016, 8.8M common shares would be issuable to convert the preferred stock ($15M face) and accrued dividends ($6M). As a placeholder for now, our modeled outstanding share count assumes conversion of preferred principal and accrued interest in late 2017.

OUTLOOK / VALUATION

We think the performance advantages of FORE-SIGHT compared to competing systems, most notably market-leading INVOS, coupled with increasing adoption of cerebral oximetry in surgical and other applications sets the stage for deeper and wider market penetration of FORE-SIGHT. Shedding of the 740 vital signs and neonatal disposables product lines has allowed CASM to dedicate more resources and focus on that goal. Sales force expansion, improved productivity and the pediatric/neonatal indications should further facilitate growth of the installed base and, most importantly, increase utilization and related sensor sales. The transition to a disposables company is already well underway, the benefits of which we think will accelerate and result in continued double-digit growth of the tissue oximetry business, widening of gross margin and more rapid improvement towards reaching profitability.

2016 Outlook

Commensurate with management's guidance, we are modeling ~400 FORE-SIGHT monitor placements in 2016 and assuming sequential growth throughout the year. CASM placed 394 monitors in 2014 and 379 in 2015 – so 2016 is expected to exhibit roughly flat monitor placement growth. But, most importantly the total installed base will grow – an additional 400 monitors would push the total installed base up 23% to 2,108. Again, it is growth in the total installed base that helps to drive the sensor-sales leverage effect.

We have calculated average monitor price of ~$5,100 in 2014 and ~$6,300 in 2015 – while this is an admittedly crude calculation as it does not account for differences in international versus U.S. sales, potential timing differences between shipments and revenue recognition or amount of accessories sold, we think it provides a rough gauge of future expectations. For 2016 we assume average monitor pricing remains at approximately the same level as in 2015, although this may be conservative given that U.S. sales are expected to outpace those of international territories. This results in total monitor revenue of ~$2.6M in 2016 (+8% yoy).

We have calculated that there were, on average, approximately $7,800 and $7,600 worth of sensors sold per monitor in the field in 2014 and 2015, respectively. This is also far from a perfect metric as it is also affected by timing (i.e. purchase vs. use) as well as potentially bulk purchases of sensors but, it should provide some insight into per-monitor average utilization. While we expect average value of sensors sold to grow over the long-term, particularly as monitor sales slow and customers expand use of FORE-SIGHT for more applications, we assume this averages just under $7,700 in 2016. The slight growth in sensor sales per monitor from 2015 is coming, in part, from pediatric/neonatal use. This, combined with an assumed 2,108 new monitors in the field, results in 2016 sensor sales of just over $16M (+24%).

Based on management's guidance, we model traditional monitoring revenue to remain roughly flat in 2016 from the level in 2015 (pro forma for the neonatal sensor divestiture) as the company maintains focus on growing sales of their flagships FORE-SIGHT ELITE portfolio.

2017 Outlook
We assume the trend of approximate flat growth in FORE-SIGHT monitor placements carries through to 2017 and model 420 monitors sold in that year, pushing the installed base up to just over 2.5k systems. With the pediatric/neonatal sensors on the market for just over one year through the end of 2016 and clinical data continuing to support use in both surgery and the ICU, we think demand from this segment is likely to show steeper growth in 2017. Awareness-building efforts surrounding the competitive benefits of ELITE versus competing systems have clearly already resonated with hospitals but given the long lead times (6 – 9 months or more) from initial engagement to closing a sale, much of the additional groundwork expected to be built during 2016 will show up in revenue in 2017. Next year may also further benefit from additional functionality to ELITE, including the ability to continuously measure hemoglobin.

With expected increased per-monitor utilization, we model an average of approximately $8,360 worth of sensors per installed monitor in 2017. This, combined with the forecasted 2,529 monitors in the field, results in 2017 sensor sales of over $21M (+31%) and total Tissue Oximetry sales of almost $24M (+28%).

Relative to traditional monitoring – we are estimating a 10% decline in revenue in this segment, although we believe this business may be somewhat more difficult to predict given the relative lack of metrics to guide from.

We have gross margin improving from 51.2% in 2015 to 53.1% in 2016 and 55.5% in 2017. Our GM estimates could prove conservative – as 2014 to 2015 widened bv 525 basis points (pro forma for the vital signs and neonatal sensors divestitures). This, like all of our assumptions and estimates, are subject to updating.

We expect much greater leverage in operating expenses in 2017 and think CASM can be at or near profitability sometime the following year.

Valuation
We value CASM using comparable EV/S and P/S ratios of other publicly traded companies in the tissue oximeter, patient monitoring and cardiac surgery industries including direct competitors Masimo Corporation (MASI), Hamamatsu Photonics (HPHTY) and Medtronic (MDT). As the other tissue oximetry competitors are not publicly traded, we have rounded out our comparable cohort with companies which have similar exposure to CASM's end markets including Brainsway (BRSYF), a manufacturer non-invasive brain stimulation devices and Natus Medical (BABY), which makes monitoring and detection devices for neonatal neurological disorders.

Both EV/S and P/S value CASM at approximately $4/share, indicating the market is substantially undervaluing the stock. We are initiating coverage of CASM with a $4/share price target.

	Sales Estimate (M)							
	2016	2017	EV	EV/2016	EV/2017	MC	P/S '16	P/S '17
BABY	$380	$393	$990	2.6	2.5	$1,060	2.8	2.7
MASI	$678	$721	$2,470	3.6	3.4	$2,350	3.5	3.3
BRSYF	$8	$10	$53	6.5	5.5	$59	7.1	6.1
HPHTY	$1,121	$1,234	$3,700	3.3	3.0	$4,340	3.9	3.5
MDT	$28,730	$29,640	$131,400	4.6	4.4	$112,600	3.9	3.8
Avg.				4.1	3.8		4.2	3.9

CASM Valuation Based On:						
Comparable EV/Sales				Comparable Price/Sales		
	EV	MC	Implied Share Value		MC	Implied Share Value
2016 S	$94	$96	$3.61	2016 S	$97	$3.61
2017 S	$104	$107	$3.98	2017 S	$107	$3.98
Average			$3.79	Average		$3.80

Risks
We think deft management of the balance sheet and capital structure will be critical for CASM, particularly now that the term loan is amortizing principal. While the revolver will provide some headroom and, combined with the cash

balance, should (based on our model) be sufficient to fund operations through 2017, barring refinancing of the term loan a capital raise may be necessary before the company is at a point of positive cash flow generation.

We think our financial forecasts are reasonable and attainable and believe that continued strong revenue growth and improving profitability should benefit both the near-term share price and potential pricing of a possible capital raise (if necessary). Our financial model includes debt servicing and assumptions regarding preferred-to-common conversions as well as warrant/options exercises. And while these assumptions would meaningfully increase the outstanding share count, capital raises on reasonable terms (which we think is possible based on growth assumptions) should keep the common share count at levels which afford the opportunity for generation of meaningful EPS within the next five (or less) years.

FINANCIAL MODEL

CAS Medical Systems Inc. (figures in 000s of $)

	Q1 A	Q2 E	Q3 E	Q4 E	2016 E	2017 E	2018 E
FORE-SIGHT Sensors	$3,734.0	$3,911.2	$4,134.0	$4,385.7	$16,165.0	$21,142.8	$24,953.1
yoy growth	*27.7%*	*22.3%*	*21.6%*	*25.2%*	*24.1%*	*30.8%*	*18.0%*
% of total oximetry sales	87.3%	87.0%	86.5%	84.8%	86.4%	88.6%	89.5%
FORE-SIGHT Monitors & Access.	$543.0	$582.1	$642.7	$786.4	$2,554.3	$2,733.5	$2,914.3
yoy growth	*54.3%*	*-15.6%*	*19.5%*	*-1.1%*	*7.5%*	*7.0%*	*6.6%*
% of total oximetry sales	12.7%	13.0%	13.5%	15.2%	13.6%	11.4%	10.5%
Tissue Oximetry Total Sales	**$4,277.0**	**$4,493.4**	**$4,776.8**	**$5,172.1**	**$18,719.2**	**$23,876.3**	**$27,867.4**
yoy growth	***30.6%***	***15.6%***	***21.3%***	***20.3%***	***21.6%***	***27.5%***	***16.7%***
% of total revenue	**78.4%**	**81.2%**	**83.2%**	**85.1%**	**82.1%**	**86.6%**	**89.4%**
Traditional Mntrng Total Sales	**$1,179.0**	**$1,040.0**	**$963.0**	**$907.0**	**$4,089.0**	**$3,680.1**	**$3,312.1**
yoy growth	***-5.4%***	***-45.3%***	***-9.0%***	***-11.0%***	***-34.5%***	***-10.0%***	***-10.0%***
% of total revenue	**21.6%**	**18.8%**	**16.8%**	**14.9%**	**17.9%**	**13.4%**	**10.6%**
Total Revenues	$5,455.5	$5,533.4	$5,739.8	$6,079.1	$22,807.8	$27,556.4	$31,179.5
YOY Growth	*20.7%*				*17.0%*	*20.8%*	*13.1%*
Cost of Revenues	$2,574.9	$2,622.8	$2,686.2	$2,814.6	$10,698.5	$12,262.60	$13,500.7
Gross Income	$2,880.7	$2,910.5	$3,053.6	$3,264.5	$12,109.2	$15,293.8	$17,678.8
Gross Margin	*52.8%*	*52.6%*	*53.2%*	*53.7%*	*53.1%*	*55.5%*	*56.7%*
R&D	$955.4	$1,044.0	$921.0	$864.0	$3,784.4	$3,244.0	$3,150.0
% R&D	*17.5%*	*18.9%*	*16.0%*	*14.2%*	*16.6%*	*11.8%*	*10.1%*
SG&A	$3,367.9	$3,430.7	$3,501.3	$3,556.3	$13,856.1	$15,018.2	$15,558.6
% SG&A	*61.7%*	*62.0%*	*61.0%*	*58.5%*	*60.8%*	*54.5%*	*49.9%*
Operating Income	($1,442.6)	($1,564.1)	($1,368.7)	($1,155.8)	($5,531.3)	($2,968.4)	($1,029.8)
Operating Margin	*-26.4%*	*-28.3%*	*-23.8%*	*-19.0%*	*-24.3%*	*-10.8%*	*-3.3%*
Interest Income, net	($199.2)	($193.1)	($173.7)	($151.7)	($717.8)	($536.3)	($239.5)
Other income	$4.9	$0.0	$0.0	$0.0	$4.9	$0.0	$0.0
Pre-Tax Income	($1,637.0)	($1,757.2)	($1,542.4)	($1,307.5)	($6,244.2)	($3,504.8)	($1,269.3)
Taxes	($1,091.2)	$0.0	$0.0	$0.0	($1,091.2)	$0.0	$0.0
Tax Rate	*66.7%*	*0.0%*	*0.0%*	*0.0%*	*17.5%*	*0.0%*	*0.0%*
Income (loss) from discont. ops	$2,026.6	$100.0	$65.0	$30.0	$2,221.6	$0.0	$0.0
Net Income (cont ops)	($906.8)	($2,124.7)	($1,916.3)	($1,687.9)	($6,635.7)	($5,091.8)	($1,269.3)
YOY Growth	*-53.4%*	*-7.8%*	*-4.5%*	*-19.8%*	*-36.2%*	*-23.3%*	*-75.1%*
Net Margin	-	-	-	-	-	-	-
EPS (cont ops)	($0.03)	($0.08)	($0.07)	($0.06)	($0.24)	($0.14)	($0.03)
YOY Growth	*-60.4%*	*-10.2%*	*-7.5%*	*-23.1%*	*-40.1%*	*-41.6%*	*-78.6%*
Diluted Shares O/S	26,800	27,310	27,500	27,900	27,378	36,000	42,000

Brian Marckx, CFA

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LEADERSHIP

Management

Thomas M. Patton
President and Chief Executive Officer
Thomas M. Patton joined CASMED in August 2010 as President and CEO. Previously, Mr. Patton acted as an advisor to the healthcare-focused private equity group of Ferrer Freeman & Company, LLC and as CEO of QDx, Inc., a successful start-up that developed a revolutionary platform for hematology diagnostics and was sold to Abbott Labs. Mr. Patton has previously served as the CEO of Wright Medical Group, an orthopedic device company in Memphis, Tennessee, and as President of Novametrix Medical Systems, a patient monitoring company in Wallingford, Connecticut. He graduated from The College of the Holy Cross and magna cum laude from Georgetown University Law Center.

Jeffery A. Baird
Chief Financial Officer
Jeffery A. Baird joined CASMED in January 2004 as Chief Financial Officer. He has over 25 years of extensive financial management experience in the medical products industry. Before joining CASMED, Mr. Baird was CFO of QDx, Inc., a start-up venture engaged in the development of a revolutionary platform for hematology diagnostics. Prior to his tenure at QDx, Mr. Baird held various financial positions at Novametrix Medical Systems including Controller, Treasurer, and CFO. Before joining Novametrix, Mr. Baird was employed by Philips Medical Systems.

Dr. John K. Gamelin
Vice President - Research and Development
John Gamelin joined CASMED in 2009, became the Director of Research and Development in 2010, and was appointed to Vice President of Research and Development in 2012. He has more than 20 years of experience inventing and developing optical, acoustic, and electronic instrumentation, from research concept to commercial production. Previously, as a co-founder and Vice President of Engineering for Tellium, an optical switching company, he was instrumental in driving that company from start-up to over $100 million in revenues in just four years. 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 several patent applications in biomedical imaging and medical instrumentation. 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 and was Valedictorian for his graduating undergraduate class at the University of Florida.

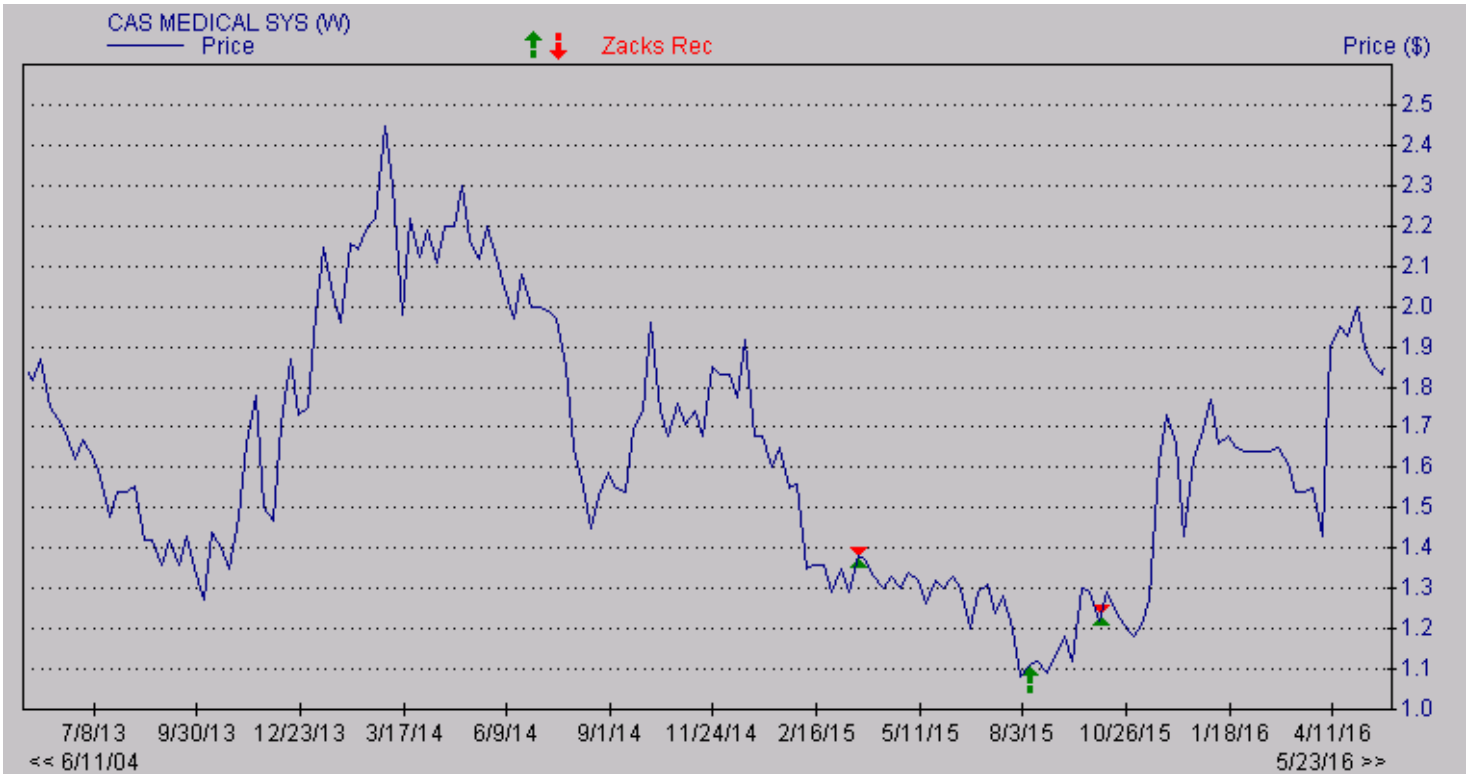
Dr. Paul B. Benni
Chief Scientific Officer
Dr. Benni joined CASMED in 1998, and in 2006 became Chief Scientific Officer. Dr. Benni is the primary inventor of the company's FORE-SIGHT® Tissue Oximeter, a near-infrared spectroscopy (NIRS) -based device to monitor the oxygen saturation of the brain and 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. Guided by Dr. Benni's continued refinement of the technology and algorithms, the performance of the FORE-SIGHT monitor continues to define the category. 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, Dr. Benni 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.

Board of Directors

- Alan W. Milinazzo - President and CEO, InspireMD, Inc.
- Paul A. Molloy - President and CEO, ClearFlow, Inc.
- Thomas M. Patton - President and CEO, CASMED
- Gregory P. Rainey - President, CCI Performance Group, LLC
- James E. Thomas - Partner, Thomas, McNerney & Partners
- Kathleen A. Tune - Partner, Thomas, McNerney & Partners
- Kenneth R. Weisshaar - Director, CenterLight Health System

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